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Supporting the implementation and scaling-up of midwifery units in Europe: how can capacity in the maternity workforce be developed?

Laura Batinelli

Centre for Maternal and Child Health Research,
School of Health and Psychological Sciences
City, University of London

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Supervisors:
Professor Christine McCourt
Dr Lucia Rocca-Ihenacho
Dr Manila Bonciani

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This thesis is dedicated to the loving memory of my dad Giuseppe and my brother Matteo.

You have been with me throughout this journey and I can feel your pride and joy.

Declaration

I, Laura Batinelli, confirm that the work presented in this thesis is my own.

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Publications and dissemination

Publications as part of this PhD study

1. Batinelli, L., Thaels, E., Leister, N., McCourt, C., Bonciani, M. and Rocca-Ihenacho, L., (2022). What are the strategies for implementing primary care models in maternity? A systematic review on midwifery units. *BMC Pregnancy and Childbirth*, 22(1), pp.1-21.

2. Batinelli, L., McCourt, C., Bonciani, M. and Rocca-Ihenacho, L., (2023). Implementing midwifery units in a European country: Situational analysis of an Italian case study. *Midwifery*, 116, p.103534.

3. Batinelli, L., McCourt, C., Bonciani, M. and Rocca-Ihenacho, L., (2023). Engaging maternity team and service users to guide the implementation of primary care models in Italy: a case study using Delphi approach and participatory action research. *In submission*

Linked work to this PhD study

Project manager of the Italian Translation of the Midwifery Unit Standards for Europe (Rocca-Ihenacho *et al.*, 2018) launched in February 2020:

> Batinelli L., Gottardi M., Nespoli A., Rovelli N. e Rocca-Ihenacho, L., (2020). Standard Europei per le Midwifery Units, Traduzione Italiana del 2020 commissionata da Midwifery Unit Network e Ordine Della Professione Di Ostetrica Interprovinciale Di Bergamo Cremona Lodi Milano Monza Brianza. Available at https://www.midwiferyunitnetwork.org/mu-standards/

Conference presentations

- Oral presentation, at the 'School of Health Sciences Doctorate Conference' at City University of London, title of presentation: '*Supporting the implementation and scaling-up of midwifery units in Europe: how can capacity in the maternity workforce be developed?*' on the 17th July 2019.
- Co-presenter with a midwifery manager of the hospital where this study was conducted at the Italian national conference 'Midwifery Unit Standards – aspetti clinici assistenziali ed organizzativi del percorso nascita fisiologico a gestione ostetrica' in Milan (Italy) on the 7th of February 2020. Title of presentation: *'Implementing Midwifery Units in Tuscany'.*
- Presenter of the seminar '*What are the strategies for implementing primary care models in maternity? A systematic review on midwifery units*' for the Centre of Maternal and Child Health Research at City, University of London on the 9th November 2020**.**
- Poster presentation at the 4th Annual UK Implementation Science Research Conference at King's College London on the 15-16 July 2021. Title of presentation: "*What are the strategies for implementing primary care models in maternity? A systematic review on midwifery units*".

Abstract

Background: Midwifery units (MUs) have been demonstrated to be safe for neonates, safer for mothers, cost effective and associated with staff and user satisfaction. In some EU countries MUs and midwife-led care are more established than others. Italy has one of the highest caesarean section rates in Europe and there are currently only few alongside midwifery units (AMUs). In Tuscany, a hospital is working towards the creation of its first AMU. The transition from the default obstetrically led maternity services to an integrated model with a MU represented an ideal opportunity to examine implementation of international guidelines in national and regional context.

Methods: This PhD aimed to explore the organisational, cultural and workforce factors influencing the implementation of a new midwifery unit in a European context using Participatory Action Research (PAR). Qualitative and quantitative methods were used and professionals, managers and service users were included. Starting from a systematic review of international literature and a situational analysis of the local context, local stakeholders codesigned an implementation plan in a collaborative way using a Delphi approach. Service users were included via focus group initially and via online surveys once the Covid 19 pandemic hit.

Findings: 86 professionals and managers and 522 service users took part in this study between 2019 and 2021. Barriers and facilitators were identified during systematic review and situational analysis. The local team identified ten themes to focus the implementation work on: team vision, creation of a multidisciplinary advisory group, creation of a dedicated group of midwives, implementation of the intrapartum guidelines for low-risk women, appropriate risk assessment, integration hospital-community, midwifery and multidisciplinary training, communication and information for service users, effective communication within the maternity team and reflective practice via audit and debriefing. Service users supported the initiatives proposed in the plan and expressed openness towards the MU implementation.

Conclusion: This was the first study observing the pre-implementation process of a MU in a European context including maternity team, managers and service users. A multi-layered approach to change is required when implementing this model of care addressing structural, organisational, professional and cultural issues. This work showed value in a participatory codesign approach to facilitate change. While this work is unique for the Italian context, the findings could help similar international contexts approaching this change.

COVID-19 Impact Statement

This statement is provided for the aid and benefit of future readers to summarise the impact of the COVID-19 pandemic on the scope, methodology, and research activity associated with this thesis. The academic standards for a research degree awarded by City, University of London and for which this thesis is submitted remain the same regardless of this context.

Title of the research project: Supporting the implementation and scaling-up of midwifery units in Europe: how can capacity in the maternity workforce be developed?

1.   Summary of how the research project, scope or methodology has been revised because of COVID-19 restrictions

The research project was planned at the end of 2018. The aim was to explore the organisational, cultural and workforce factors influencing the implementation of a new midwifery unit in a European context using Participatory Action Research (PAR). The plan was to conduct a PAR cycle before and one after the implementation of the alongside midwifery unit (AMU). However, the Covid 19 pandemic significantly delayed the implementation process and by the end of the project in 2022 the AMU was yet to be opened. Therefore, only one PAR cycle before the implementation was completed including the wider maternity team, managers and service users. Although the scope of this study remained unchanged, the focus had to be on the pre-implementation work and outcomes like adoption, acceptability and appropriateness. The methodology of this implementation research project remained unchanged using PAR and critical realism as theoretical underpinning to guide the work.

2.   Summary of how research activity and/or data collection was impacted because of COVID-19 restrictions, and how any initially planned activity would have fitted within the thesis narrative

The initial proposal included regular face-to-face activities to engage the maternity team and service users in the transition to an integrated maternity service with an AMU. Conducting this work with two PAR cycles before and after the opening of an AMU would have meant observing the change for professionals and service users during the transition. This would have given a unique perspective of this type of implementation work as to date, no other study has ever observed that.

3.   Summary of actions or decisions taken to mitigate for the impact of data collection or research activity that was prevented by COVID-19

Covid restrictions limited face to face interactions with research participants and the plan to conduct engagement activities and workshops to coproduce an implementation plan had to be replaced with an online Delphi study with professionals and an online survey with local women. However, this meant that more participants from a more diverse range of services and backgrounds could take part in the study making the findings more meaningful.

As PAR researcher, I was meant to be visible and present in the maternity settings to engage and observe. Again, this was not possible due to the restrictions aimed at limiting transmission of Covid 19 but regular contacts vie email, calls and video calls allowed the work to continue. This type of communication and the burden of the pandemic on the healthcare sector meant that at times there were delays in conducting research activities (for example the launch of online surveys).

Overall, considering that all research activities were completed just few months after the expected end of this study, we consider this positive result and symbol of the commitment of the local team to conduct this work.

4.   Summary of how any planned work might have changed the thesis narrative, including new research questions that have arisen from adjusting the scope of the research project

The research question formulated for this PhD proposal in 2018 was "*How can maternity services in Europe be supported to implement midwifery units?*" and is still valid and relevant to the project that was conducted. As already mentioned, the focus of this work had to be more on the pre-implementation work with professionals and service users. A deeper analysis and understanding of the resistance and barriers that this type of model of care can encounter was possible considering the years of hesitance of the local team towards the innovation.

Therefore, to add more detail, we could say that the project used the following research questions:

-     How can maternity services in Europe be supported to implement midwifery units?
-     How can capacity in the maternity workforce be developed?
-     Why do midwifery units struggle to be implemented in European contexts like Italy?

Date of statement: 02/01/2023

Abbreviations and definitions

Acronyms

AMU = Alongside midwifery unit

CEDAP = Certificato di Assistenza al Parto

CFIR = Consolidated Framework for Implementation Research

EMA = European Associations of Midwives

FIGO = International Federation of Gynaecology and Obstetrics

FG = Focus Group

FMU = Freestanding midwifery unit

ICM = International Confederation of Midwives

LHA = Local Health Authority

MeSLab = Management and Health Laboratory, School of Advanced Studies, Pisa

MDG = Millennium Development Goal

MU = midwifery unit

NHS = National Health System (UK)

OU = Obstetric Unit, setting where secondary level of intrapartum care is provided

PAR = Participatory action research

QIF = Quality Improvement Framework

SSN = Sistema Sanitario Nazionale (Italian NHS)

SDO = Scheda Dimissione Ospedaliera (Discharge form)

TMF = Theories, models and framework

UNFPA = United Nations Fund for Population Activities

WHO = World Health Organisation

Definitions

- Women and service users

In this thesis, I used 'women' and 'service users' to refer to the population accessing maternity care services. The decision to use both terms aims to be inclusive of users who do not identify as women while still maintaining the word that most people self-identify with in maternity care.

- Guidelines and protocols

The term guidelines refers to recommendations provided by reliable national or international institutions intended to advise professionals and service users on clinical care and they are based on the best available evidence. The term protocols (often refer throughout the thesis as 'local protocols') refers to the application of guidelines by a local context to include more details on the operational level. Despite being a more prescriptive term, the local context where this study took place widely used this term and considering the different meaning from the term guidelines, I decided to keep them both. In Italy the term 'local protocol' has been used with the same meaning than 'local guideline' in England.

- Participant

Anyone who actively contributed significantly to the study data collection through interviews, focus groups, surveys, being observed or while conducting any research activities. Every participant was recruited with an informed consent.

- Stakeholder

Anyone who would have been affected by the implementation of a MU and engaged with the research during meetings, seminars, training days etc. in the local context but did not necessarily contribute actively with disclosure of information, personal views and therefore has not been recruited.

- Local and organisation level

In the context where this study took place, there was one local hospital and five community healthcare centres part of a wider Local Health Authority. The LHA level is equivalent to an NHS Trust in England. The local level included the 'local hospital' and 'community healthcare centres' whilst the organisational level referred to the wider organisation which includes the strategic leadership.

- Midwifery unit

This thesis uses the definition of the midwifery unit published in the Midwifery Unit Standards for Europe (2018) and modified from the Birthplace Study (2011). "A midwifery unit (MU) is a location offering maternity care to healthy women with straightforward pregnancies in which midwives take primary professional responsibility for care. Midwifery units may be located away from (Freestanding or FMU) or adjacent to (Alongside or AMU) an obstetric service (obstetric unit or OU)" (Rowe et al., 2011; Rocca-Ihenacho et al., 2018).

- Dual practice and intramoenia

Dual practice is the possibility to work privately while being employed by a public healthcare organisation in Italy. This option is currently available only to medical practitioners in Italy and they can practice privately within the hospital facility of top of their public role in what is called 'intramoenia' service which means private care within the hospital facility.

Introduction

This PhD project was born from a strong interdisciplinary and international collaboration. I am a midwife trained in Italy who moved to England in search of job opportunities and professional growth. During the years before this study started, I worked clinically in a midwifery unit in London, as a research assistant in a NIHR fellowship at City, University of London and I collaborated with the Midwifery Unit Network (MUNet). MUnet is a community of professionals, academics, experts and service users that want to support and promote the development and growth of midwifery units (birth centres) across Europe so they become the main care pathway for women with an uncomplicated pregnancy, providing holistic care to them and their family.

This gave me the chance to learn about the most recent evidence around place of birth and to be involved in research projects such as the development of the Midwifery Unit Standards for Europe (Rayment et al., 2020). The exposure to this research field, collaborations with MUNet and having the opportunity to work clinically in an AMU made me interested and passionate about this topic. I am also fascinated by the difficulties in implementing evidence of birthplace in practice and to transform maternity services to allow MUs to be the mainstream option for women with straightforward pregnancies. During my years in London, I have been in touch with maternity professionals from my hometown in Tuscany and on more than one occasion we had the chance to discuss recent evidence and studies on the importance of investing and promoting midwifery-led care and midwifery units.

A lead obstetrician, who was the supervisor of my MSc thesis, became very sympathetic to this cause. Since 2015, I have been collaborating with the local maternity team together in similar research projects. From then, the lead obstetrician and the team worked hard to make a case for the implementation of a new AMU in the hospital with the organisation and regional leadership and to ensure that a budget and dedicated staff were allocated to this innovative project. In October 2018, it seemed like the opening of this new AMU was due in a 12-18 months' time.

At that time, we reflected on the importance of a multi-layered change, as this type of project would imply a new service layout and way of working. Changing the way intrapartum care is delivered cannot be achieved by just opening a new physically separated midwifery-led care area. Achieving such a fundamental change required a shift not only in clinical practice but also in the organisational culture, mentality and leadership amongst clinicians, management and with the population using the service as well.

This is what led me in to write this research proposal for a three-year work project alongside the local maternity team and the Management and Health laboratory (MesLab) in School of Advanced Studies

Sant'Anna of Pisa. We envisaged that a strong collaboration between the local hospital, the MesLab (which yearly assessed the performance of the healthcare regional healthcare system in Tuscany) and City, University of London could support the implementation of evidence into practice in the real world gaining more understanding and knowledge in this field of research.

Aim of the study

The aim was to explore the organisational, cultural and workforce factors influencing the implementation of a new midwifery unit in a European context using Participatory Action Research (PAR). A PAR cycle before the implementation was completed including the wider maternity team, managers and service users.

Objectives

1.   Conduct a systematic review on midwifery units' implementation

2.   Conduct a situational analysis of the organisational, cultural and professional readiness to the opening of a new midwifery unit using the Consolidated Framework for Implementation Research

3.   Engage with local maternity team to coproduce the implementation plan using codesign and a Delphi approach

4.   Assess service users' knowledge of the MU model of care and gain feedback from them on the implementation plan produced by the maternity team

5.   Reflect on the experience of research with local stakeholders and key midwifery leaders to contextualise the findings to the Italian context

6.   Develop a model for maternity services to support the transition from the traditional layout of maternity care to an integrated model with a MU

7.   Gain a deeper understanding of the analysis of the overall research findings using a critical realist framework

Thesis structure

Using a PAR approach, different research steps allowed me to *plan, act, observe and reflect* with local stakeholders on the change required for the innovation. The chapter structure of this thesis reflects this PAR journey. Here, I present an overview of the thesis and a brief introduction to each section.

- **Chapter 1, Background** – in this chapter I introduce the background of the study, the wider relevant literature, the evidence to practice gap and I set the rationale for conducting this study in Italy.

- **Chapter 2, Methodology** – in this chapter I start from the ideas included in the initial research proposal and I present the research design, theoretical underpinning and research methods chosen for this study.

- **Chapter 3, Systematic review** – this chapter presents the systematic review of the existing international literature on implementation of MUs which helped in addressing the evidence to practice gap, learn from existing evidence on how to support this change in the real world, to inform and underpin this study. A paper was published from this chapter in 2022 and is attached in appendix 8.

- **Chapter 4, Phase One, Situational analysis** – this is the first step of the PAR cycle (the plan phase) in which I conducted a situational analysis to assess the readiness of the local context for the innovation. In this chapter, I present the findings of the first round of data collection (pre-pandemic) and analyse them with the support of the Consolidated Framework for Implementation Research (CFIR) (Damschroder *et al.*, 2009). A paper was published from this chapter in 2023 and is attached in appendix 9.

- **Chapter 5, Phase Two and Three, Codesign using a Delphi approach and service users survey** – this chapter presents the work conducted with local maternity team and service users as part of the 'act and observe' phase of the PAR cycle. I report the findings of the Delphi study and the service users' survey to codesign an implementation plan for the MU.

- **Chapter 6, Phase Four, Reflection on local and national context** – in this chapter, I reflect on the experience of this research using my research diary, the feedback gained by the local team and interviews with four key midwifery leaders with experience of implementing midwifery-led care in Italy. This phase of the cycle helped to contextualise the findings on a national level.

- **Chapter 7 Discussion** – in this chapter I draw together the findings of all chapters in light of the wider literature using a critical realist framework to analyse the different levels (real, actual and empirical) and reflect on the strengths and limitations of this work.

- **Chapter 8 Conclusions** – this chapter concludes the thesis, with a summary of the study, contribution to knowledge and implications for future research, policy, practice and education.

Chapter 1 - Background

In this chapter, I used a funnel approach for introducing the topic of this thesis going from a general introduction of the state of maternity care globally to a closer focus on the position of MUs in the Italian context.

The first section is an overview of the current state of maternity care globally. The second is more specifically related to MUs covering definition of a midwifery unit, the evidence that shows that they represent the best option for women with straightforward pregnancies and concluding with a discussion of the evidence-to-practice gap.

The rationale for describing these aspects is that prior to commencing an implementation research project, it is paramount to ensure a good quality of evidence sustains and justifies the change that is about to be promoted and implemented. This represents the foundations and the essential preamble for any implementation research work.

1.1.   Maternity care globally

The Lancet series on Right Care published in 2017 explained how two elements are undermining the possibility to reach universal health coverage: overuse and underuse of healthcare (Elshaug *et al.*, 2017). These are defined in the Lancet Series as follows (see figure 1):

- Overuse is the provision of medical services that are more likely to cause harm than good
- Underuse is the failure to use effective and affordable medical interventions

Figure 1 Glossary of terms from WHO (Elshaug et al., 2017)
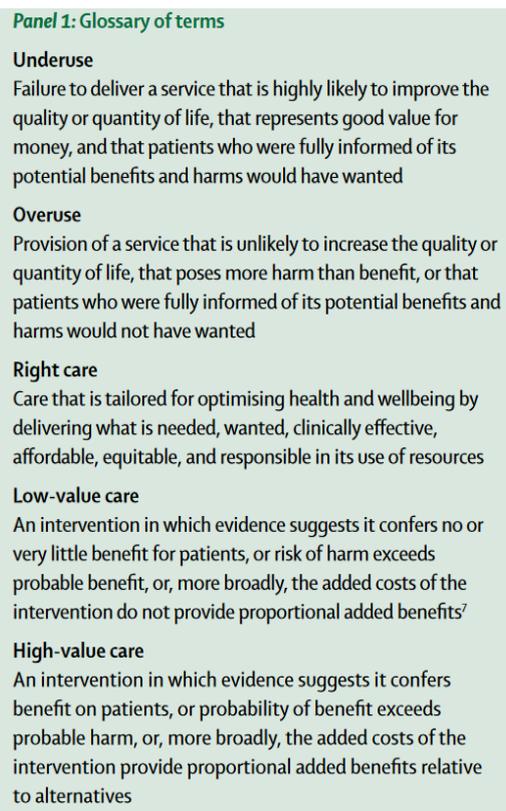
Panel 1: Glossary of terms

Underuse
Failure to deliver a service that is highly likely to improve the quality or quantity of life, that represents good value for money, and that patients who were fully informed of its potential benefits and harms would have wanted

Overuse
Provision of a service that is unlikely to increase the quality or quantity of life, that poses more harm than benefit, or that patients who were fully informed of its potential benefits and harms would not have wanted

Right care
Care that is tailored for optimising health and wellbeing by delivering what is needed, wanted, clinically effective, affordable, equitable, and responsible in its use of resources

Low-value care
An intervention in which evidence suggests it confers no or very little benefit for patients, or risk of harm exceeds probable benefit, or, more broadly, the added costs of the intervention do not provide proportional added benefits[7]

High-value care
An intervention in which evidence suggests it confers benefit on patients, or probability of benefit exceeds probable harm, or, more broadly, the added costs of the intervention provide proportional added benefits relative to alternatives

Despite being in antithesis, they represent two sides of the same phenomenon: inappropriate and ineffective use of resources. They are significantly affecting the life of millions of people globally and they are both causing harms on a physical, psychological and social level with a wasteful allocation of resources and citizens' taxes for society. Intuitively, one would think that underuse is a problem of the low- and middle-income countries while the overuse a problem mostly present in high-income countries. Instead, both exist and coexist within the same contexts, populations, health care systems and even within the same group of patients in all countries. Underuse and overuse are about failing to provide the care needed, at the right time, in an appropriate and respectful way and following the principles of healthcare as a human right and equity amongst countries and populations.

The authors of the Lancet Right Care Series conclude that "*action is possible and necessary*" to address this issue and therefore researchers, clinicians, policy makers and politicians need to be aware of this critical phenomenon and work on finding possible solutions (Elshaug *et al.*, 2017).

There is no universally accepted definition of quality of care world-wide, as it really depends upon the different perspectives and dimensions, including by health care providers, managers or patients and the health care system. The key characteristic identified by WHO for quality of care are: safety, effectiveness, timeliness, efficiency, equity and patient-centredness and the provision and experience of care (World Health Organization, 2016).

When we think about quality of care for pregnant women and their newborns, we refer more to a definition that describes "*the degree to which maternal and newborn health services (for individuals and populations) increase the likelihood of timely, appropriate care for the purpose of achieving desired outcomes that are both consistent with current professional knowledge and take into account the preferences and aspirations of individual women and their families*" (World Health Organization, 2016).

The main points and aspects of this definition are about the quality of the care that health professionals are able to provide, and the quality of care perceived by women and their families. Those two aspects are both essential to ensure not just perinatal wellbeing for mother and babies but also for safeguarding the birth experience for the family and the role this life-changing event plays in society. To highlight the importance of both these levels, WHO created a framework for maternal and newborn care (see figure 2) where there is a clear distinction of quality of care in terms of provision and experience (Renfrew *et al.*, 2014).

Figure 2 Maternal and newborn care framework Renfrew et al. 2014
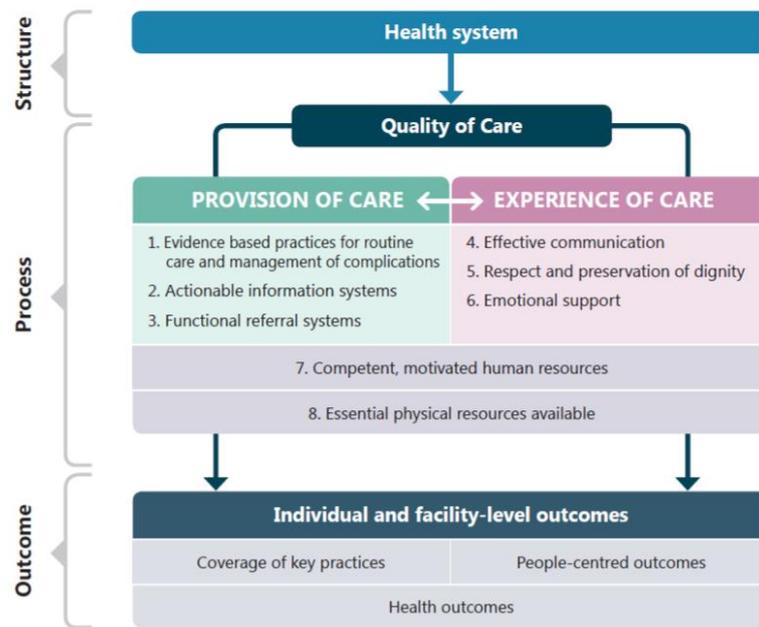
The Agenda for Sustainable Development by the United Nations (UN) provides a global blueprint for dignity, peace and prosperity for people and the planet, by 2030 through the achievement of seventeen main goals (United Nations, 2016). The third one states, *"Ensure healthy lives and promote well-being for all at all ages"* and the UN stressed the concept that ensuring healthy lives and promoting the well-being at all ages is essential to sustainable development.

The primary targets in order to achieve this are about maternal and newborn health, by reducing maternal mortality to 70 per 100,000 live births, reducing neonatal mortality to at least as low as 12 per 1,000 live births and reducing by one third premature mortality from non-communicable diseases through prevention and treatment and promoting mental health and well-being (United Nations, 2016).

Looking at the global picture, from 1990 to 2015 the maternal mortality ratio dropped by almost 50%. Unfortunately, that data alone do not give justice to the much more heterogeneous situation that maternal health is facing in different countries. In fact, only nine countries with an initial maternal mortality ratio greater than 100 per 100,000 achieved the Millennium Development Goal (MDG) target of 75% reduction, 26 countries made no progress, and in 12 countries— including the USA— maternal mortality ratios increased. Neonatal mortality has also declined at a slower rate globally and stillbirths remain high (Bongaarts, 2016).

What became clear by the analysis presented in the Lancet articles "*Quality maternity care for every woman, everywhere: a call to action*" in 2016 is the increased gap between countries with highest and

lowest mortality rate despite the increased use of maternity care (Koblinsky *et al.*, 2016). Nineteen percent of all maternal deaths happened in Nigeria, fifteen percent in India and in countries like Sierra Leone and Chad the maternal mortality risk rate is of 1 in 17 and 1 in 18 which is the highest estimated lifetime risk of maternal mortality. In high-income countries, the estimated lifetime risk of maternal mortality is 1 in 3300 while in low-income countries is 1 in 41. In emergent humanitarian settings due to conflicts or natural disasters, maternal mortality can face relevant rise due to the unstable and fragile conditions of the health systems. This shows how deeply heterogeneous the situation around the globe is (Koblinsky *et al.*, 2016).

Setting the correct targets plays a crucial role in making an impact for maternal and neonatal health around the world. If we take for example the MDGs, one of the targets requested by each country was to increase women's access to care and a sufficient number of contacts with birth attendants. Looking only at the retrospective analysis at the end of the MDG era we could say that the goal was achieved with global coverage of births occurring with skilled birth attendants increased from 57% to 74%, one or more antenatal visits from 65% to 83%, and four or more antenatal care visits from 37% to 64% (Campbell *et al.*, 2016). However, in some of these countries the maternal mortality ratio was still very high and not affected even with significant improvements in the selected indicator (e.g. the number of contacts of care). It may be that not considering the content or quality of those contacts so even if an increase coverage was noted, it did not make any impact on maternal mortality.

Data collection, auditing and performance assessment through indicators are common ways of monitoring the clinical outcomes and use of resources in healthcare systems globally but could also be the cause of unintended consequences. As Van Thiel & Leeuw highlighted in the article "*The Performance Paradox in the Public Sector*" there is often a weak correlation between the performance measured and the reality of the performance itself which is therefore defined as a paradox (Thiel and Leeuw, 2002). Some of these are due to what have been described as "performance traps". Choosing the wrong indicators might lead to an imprecise analysis of the phenomenon. Some examples of those traps are: the "goal fixation focus" (like the one described above for the MDG and percentage of antenatal visits) which focuses on obtaining good numbers but not on quality and content, the "tunnel vision trap" in which focusing just on some indicators can make the rest forgotten, or the "cream skimming or cherry picking" in which the focus goes on selecting just the patient population which is associated with the indicator of good performance and not considering enough of the rest of the population. Performance traps might lead to the "hitting the target but missing the point" anomaly in which the evaluation and assessment of a phenomenon is misread and interpreted not appropriately.

For this reason, researchers have started to look at strategies to overcome these traps and to make the performance analysis fairer, more thorough and transparent. Some of the strategies identified focus on the following pillars to build an effective performance management are: multiple dimensions agreed by different stakeholders (different kind of dimensions not just financial ones), benchmarking, openness, timeliness, assessment and voluntary.

The efforts made with the MDG in trying to improve maternity care internationally showed the impact of considering inappropriate performance indicators and how even after significant effort poor and rural women still did not get enough access of care (and when they did, they often experienced disrespect and abuse) and healthier richer and urban women often received harmful over-treatment. International critiques of MDG policy implementation reported how the strategies selected were often enacted in isolation while causes of mortality and morbidty are complex, working across many factors and levels (Kassebaum *et al.*, 2014). Unfortunately, the focus of national governments was often on institutional care rather than addressing wider causes investing resources in ineffective and even harmful technological interventions instead of for example developing midwifery. Programme were mainly top-down and externally driven lacking to focus on local cultures and communities (Kassebaum *et al.*, 2014).

In 2016, maternity care around the world was found to be facing two opposite and extreme situations: too little, too late (TLTL) and too much, too soon (TMTS) (Miller *et al.*, 2016). TLTL is often to be found in low- and middle-income countries where lack of access, infrastructures and skilled healthcare practitioners affects perinatal mortality and morbidity significantly. In high income countries, TMTS specifically describes the routine over-medicalisation of normal pregnancy and birth and includes unnecessary use of non-evidence-based interventions as well as use of interventions that can be lifesaving when used appropriately, but harmful, when applied routinely or overused. However, middle income countries suffer particularly from rapid rise in TMTS with high variation within the country relating to income/class inequality and rurality or urban living (Miller *et al.*, 2016).

The Midwifery Framework published by Lancet highlighted how Midwifery was associated with more efficient use of resources and improved outcomes when provided by well-trained midwives and well-functioning health systems (Renfrew *et al.*, 2014). The WHO, UNFPA and ICM agree that one important aspect of implementing evidence-based care in maternity is therefore extending midwifery care settings and increasing women's access to them.

The State of the World's Midwifery (SoWMy) report by UNFPA, ICM and WHO highlighted how investing in midwifery workforce and capacity could potentially help preventing two thirds of all

maternal and newborn deaths (ICM, UNFPA and WHO, 2014; UNFPA, WHO and ICM, 2021). Midwives could also deliver 87 per cent of all essential sexual, reproductive, maternal and newborn health services. Their role becomes key for family planning, fighting female genital mutilation (FGM), for women and girls' rights and for providing reproductive health services. This comprehensive professional profile makes their societal role important for promoting public health in all communities around the world.

In one of the Global Health Lancet Series in 2021, the Lives Saved Tool modelling study showed how investing and strengthening this profession could improve maternal and neonatal mortality and significantly reduce stillbirths in low- and middle- income countries (Nove *et al.*, 2021).

Therefore, midwifery becomes *the public health intervention* and *global priority* that could improve perinatal outcomes, birth experiences and cost effectiveness for the public health care systems. This is applicable for all international contexts from low, to medium- and high-income countries where the current underdevelopment and underutilisation of midwifery leads to the TLTL and TMTS phenomenon (Renfrew and Malata, 2021).

"*Midwives can optimise normal physiological processes, strengthen women's own capabilities, provide interventions for women and neonates that both prevent and treat complications and enable timely access to multidisciplinary services for those who need them. This model of care promotes continuity across community and facility settings, relationship-based care, local community knowledge and resilience, and equitable, individualised care that responds to clinical, psychological, social, and cultural needs*" (Renfrew and Malata, 2021)

The mission is therefore clear. International evidence in now focusing more on how to support the implementation of midwifery led models of care and strategies could help different international contexts in moving towards this transition. Midwifery Units (MUs) have demonstrated to be a valid midwifery led model of care and valuable option to promote midwifery led care for different contexts: from low- and middle-income countries to high income ones, both in the public and private health sectors. In the next paragraph, I will start introducing what a MU is, the available international definitions, the evidence which support the implementation of this model and the evidence to practice gap currently present in many contexts.

1.2. What is a Midwifery Unit

There are currently many names and terms used internationally to describe midwifery units and the differences are often caused by differences in the physical space, organisation of care, the level of autonomy of the midwives, cultural values around childbirth and societal perception of safety. Some

examples of names used are midwifery unit, birth or family centre, normal birth unit, midwifery-led centre, maternity homes, or birth houses.

In 2017 as part of the Nice Birthplace Action NIHR research project led by Dr Rocca-Ihenacho at City University of London, we worked on the update of Royal College of Midwives' "Birth Centres Standards" (2009) and as a team we had to decide a definition for the English context when working on identifying the standards for these unit (Rayment, Rocca-Ihenacho, *et al.*, 2020). At that time, we questioned which one would be the best term to use in order to achieve the most relevant impact. After interesting discussions with the multidisciplinary advisory group of the research project, a decision was made to opt for the term "Midwifery Unit" already adopted for the Birthplace Study in 2011. The rationale that led to a change in terms from the previous standards published by the Royal College of Midwives in 2009 was that "birth centre" reminded mainly of a birthing event and a place solely for intrapartum care (which is often the misleading perception among stakeholders) (Ackerman and Hutcherson, 2009). Instead, it was important to give the idea that these units provide also antenatal and postnatal care and should represent a hub for maternity care services in general not being limited to the childbirth event. Considering that the MU Standards document was also meant to have a European perspective, it was also very important to highlight the midwifery model of care to empower this profession even for countries in which midwives are not as autonomous practitioners yet. Hence the decision for choosing "midwifery units" and then for the name of the document Midwifery Unit Standards for Europe.

In 2018 the report was published by City, University of London, and in the document a modified version of the Birthplace definition of midwifery units by Rowe and colleagues (2011) during the Birthplace study was adopted: "*A midwifery unit (MU) is a location offering maternity care to healthy women with straightforward pregnancies in which midwives take primary professional responsibility for care. Midwifery units may be located away from (Freestanding) or adjacent to (Alongside) an obstetric service*" (Rowe *et al.*, 2011; Rocca-Ihenacho *et al.*, 2018).

This definition wants to highlight the key characteristics of these models of care is that they are staffed and managed by midwives, offering primary care for women with uncomplicated pregnancies. More details in the document explain that in a MU if a deviation from physiology occurs and medical diagnostic and treatment services, including obstetric, neonatal and anaesthetic care are needed (such as cardiotocography for example), a transfer to the obstetric unit (OU) would then be recommended and, if the woman agrees, would be facilitated. Most of the times, the transfer of care happens before a complication take place and in fact, the main aim of this primary level of care is to

identify a deviation from physiology which may need medical intervention and take preventative action where possible or transfer to a medical setting. For this reason, transfers are usually facilitated calmly via wheelchair (in case of an AMU) or via ambulance (in case of a FMU). In case of obstetric emergencies, midwives are trained to provide the appropriate care and escalation protocols are in place to seek support in the unit or facilitate the transfer more quickly. Previous work on transfer showed how in England over one in four women are usually transferred from AMUs to the OU and over one in five from FMUs to OU involving mainly first time mothers (R. Rowe *et al.*, 2012). Most of the times the transfer was elective (for example for pain relief support) and emergency ones were overall uncommon (R. Rowe *et al.*, 2012).

Recently, an important work on the international definition of midwifery centers (as the authors named them) has been conducted by Stevens and Alonso part of the Goodbirth Network in California (Stevens, Alonso, 2020). The Goodbirth network is promoting midwifery centers in low- and middle-income countries with the collaboration and support of global peers. In 2016, the authors organised a working group to draft an initial definition with representatives from low-, middle- and high-income countries and they conducted focus groups and online stakeholder meetings on the different definitions identified in the existing literature (see table 1).

Table 1 Summary of international definition of MU, modified from Stevens and Alonso 2020

UK definition (Rowe et al., 2011): "Freestanding midwifery unit (FMU): an NHS clinical location offering care to women with straightforward pregnancies during labour and birth in which midwives take primary professional responsibility for care. General Practitioners may also be involved in care. During labour and birth diagnostic and treatment medical services including obstetric, neonatal and anaesthetic care, are not immediately available but are located on a separate site should they be needed. Transfer will normally involve car or ambulance."

US definition (AABC, 2017): "The birth center is a health care facility for childbirth where care is provided in the midwifery and wellness model. The birth center is freestanding and not a hospital. Birth centers are an integrated part of the health care system and are guided by principles of prevention, sensitivity, safety, appropriate medical intervention and cost- effectiveness. While the practice of midwifery and the support of physiologic birth and newborn transition may occur in other settings, this is the exclusive model of care in a birth center. The birth center respects and facilitates a woman's right to make informed choices about her health care and her baby's health care based on her values and beliefs. The woman's family, as she defines it, is welcome to participate in the pregnancy, birth, and the postpartum period."

Australian definition (Laws et al., 2009): "A birth center is a midwifery-managed unit separate from a labour ward but with established links to a referral service - offering both antenatal care and care during birth to women at low risk of medical complications. Birth centers are characterized by a commitment to normality of pregnancy and birth, and a homelike environment."

Dutch definition (Hermus et al., 2017): "Birth centers are midwifery-managed locations that offer care to low risk women during labour and birth. They have a homelike environment and provide facilities to support physiological birth. Independent community midwives take primary professional responsibility for care. In case of referral the secondary caregiver (obstetrician or paediatrician) takes over the professional responsibility of care. Three types of birth centers were identified based on location: A freestanding birth center is located separate from a hospital with obstetric services. In case of referral the woman needs to be transferred to a hospital with obstetric services which will normally be by car or ambulance. An alongside birth center is located in a hospital with obstetric services or on such a hospital's grounds, but separate from the obstetric unit. In case of referral the woman needs to be transferred which will normally be by bed or wheelchair. An on-site birth center is located within an obstetric unit of a hospital. In case of referral the woman does not need to be transferred: the secondary caregiver (obstetrician or paediatrician) will enter the birthing room."

Final definition proposed by Stevens and Alonso, 2020

"A midwifery center is a healthcare facility offering birth and sexual and reproductive health care services, using the midwifery model of care. It specializes in care for routine birth, ensures access to basic emergency care, and is fully integrated within the healthcare system. A midwifery center is distinguished by its alignment with the midwifery philosophy of care. This human-rights-based, woman-centered approach, is expressed through a home-like shared space that encourages participation of the woman, and her community. The midwifery center aligns the level of care provided to changing needs, staying alert and responsive, to provide an optimal outcome. The care provided at a midwifery center is oriented and directed towards the woman's experience."

Three main concepts around this model of maternity care were identified: a midwifery model of care as guiding theoretical framework, risk assessment in an appropriate and timely manner and a proper integration with health care systems.

This final definition proposed by Stevens and Alonso is very similar to and aligned with the one used for the MU Standards for Europe. Key concepts are the primary care level, responsiveness in case of emergency or transfer needed (thanks to the integration with the healthcare system) and the focus/orientation towards the woman's experience and therefore towards the bio-psycho-social model of care. The main difference between the two definitions is the inclusion of the sexual and reproductive health in Stevens and Alonso's one. We could consider this as an extra layer of services that midwifery units could offer in many countries.

Based on all the above international definitions of MUs, we could now summarise the common denominator of the definition for midwifery units in the following characteristics:

- A midwifery model of care
- A unit separate from the obstetric unit
- Offers primary level of maternity care
- Ensures risk assessment and emergency care when needed
- Fully integrated within the healthcare system
- Oriented towards a bio-psycho-social model of care and women experiences

In this thesis considering that the fieldwork was conducted in a European context, we will refer to these services as MUs as per the MU Standards for Europe definition (Rocca-Ihenacho, et al., 2018).

1.3. Place of birth matters

Internationally, the impact of place of birth on safety and wellbeing has been widely discussed during the last decades. One of the main points of discussion in this debate is the safety of planned home birth versus planned hospital birth for women with straightforward pregnancies. De Vries et al. in 2013 analysed how researchers could come up with different conclusions on this issue even when discussing similar findings and how divergent maternity systems and different national and regional provision could affect the recommendations coming from meta-analysis studies or other primary RCTs (De Vries *et al.*, 2013).

In the Cochrane review conducted in 2012 by Hodnett, Downe and Walsh about alternative versus conventional institutional settings for birth, the authors concluded that giving birth in institutional birth centres was associated with fewer interventions during labour and birth, more satisfaction and no increased risk for either mothers or babies as compared with hospital obstetric-led units (Hodnett, Downe and Walsh, 2012).

The systematic review on place of birth by Scarf et al. (2018) identified 28 high quality international articles and they examined whether there was any difference in terms on clinical perinatal outcomes for planned birth in three different settings: hospital, birth centre and home (Scarf *et al.*, 2018).

Women who decided to give birth in MUs were two times more likely to experience a vaginal birth compared to women opting for hospital birth and therefore less likely to have a caesarean section or an instrumental birth (Scarf *et al.*, 2018). The authors of the review conclude that "*women who planned to give birth in a birth centre or at home had significantly lower odds for intervention and severe morbidity in labour and birth. (…) these findings have important implications for healthcare costs and services. They support the expansion of birth centres and home birth services*" (Scarf *et al.*, 2018).

Another systematic review published in 2020 compared the occurrence of birth interventions and maternal outcomes among low-risk women who begin labour intending to birth at home compared to women intending to birth in hospital (Reitsma *et al.*, 2020). The review compared hospital and out-of-hospital settings directly so split MUs into both sides – AMUs (which are uncommon beyond the UK) were calculated with hospital and FMUs with homebirths. Findings were similar to the Scarf et al.'s review but they also showed with a sub-group analysis that outcomes are better where the health system was integrated (midwifery services as part of the mainstream system not outside). This finding is particularly relevant for most European countries in which, like in Italy, there is a lack of integration between homebirth service and mainstream maternity care service. I will discuss more in detail the configuration of maternity care in Italy in the following paragraph.

In the UK, MUs have a long history and in fact, before hospital became the main birthplace option, giving birth in the community at home or in maternity homes was the norm, representing the primary care option for women with uncomplicated pregnancies and the hospital birth was only recommended for women with significant risk factors (Campbell and Macfarlane, 1987). Maternity homes were developed especially to cater for those with poor housing and complex social conditions, they were usually run by midwives in collaboration with general practitioners, who could be called in to assist women with complications. Since 1970s, despite the lack of supporting and robust research evidence and with the push to universal hospital beds under the NHS, women were encouraged to give birth in hospital settings and many of these centres were closed often due to low intrapartum numbers (Loudon, 1992). They kept on existing mainly only in rural areas where access to hospital was more difficult to facilitate. This led to what has been defined as the "*centralisation of birth*" and hospitals

started having an increased activity becoming large obstetric units (OUs). Giving birth in an OU was, and nowadays still is, perceived as the safest and only option for women.

In England, following the first review of intrapartum care by the National Institute for Health and Care Excellence and a policy push for more choice in childbirth (NICE, 2007), a large national cohort study was commissioned to address questions of safety and economic costs around different places of birth: homebirth, FMU, AMU and obstetric unit (Hollowell *et al.*, 2011).

The Birthplace in England programme was centred on a prospective cohort study to compare the safety of birth and a range of clinical outcomes by planned place of birth (home, FMU, AMU or OU) at the start of care in labour (Hollowell *et al.*, 2011).

The primary outcome was to compare for the 'low risk' women population the perinatal (intrapartum and early neonatal) serious morbidity, using a composite outcome including mortality and serious morbidity that could be associated with the birth process. Secondary outcomes were individual components of the primary outcome, other adverse perinatal outcomes, maternal outcomes, interventions during labour and birth, transfer rates and outcomes for women who transferred. The cohort included 79,774 eligible women, of which 64,538 (81%) were 'low risk'.

The findings from the study were:

- AMUs and FMUs are safe for women and babies at low risk of complication at the onset of labour (both nulliparous and multiparous) and are associated with less risk of interventions for mothers and more likelihood of breastfeeding initiation for babies;
- Homebirth is safe for multiparous women at low risk of complication at the onset of labour with benefits for both mums and babies (less interventions and more frequent initiation of breastfeeding). For nulliparous women there is a slightly increased chance of an adverse perinatal outcome with planned home birth but this risk is reported to be modest;
- Maternal morbidity outcomes were significantly lower in MUs (especially in freestanding MUs) with less risk of requiring a blood transfusion, being admitted to the intensive care unit or having an episiotomy and overall perineal injury;
- The substantially lower incidence of major interventions (including intrapartum CS) in MUs and homebirths has benefits to both women and the NHS.

(Hollowell *et al.*, 2011)

The Birthplace Collaborative group also conducted a cost-effectiveness analysis of the different costs of birth for the NHS in those four different settings for the same population of low risk (Schroeder *et*

al., 2012). The findings from this analysis found MUs to be cost-effective for both nulliparous and multiparous women and therefore associated with a better use of resources of the NHS.

This study showed how for the same population of low-risk women the decision of where to give birth can affect their clinical outcomes, their experience of childbirth and the cost for the NHS. From 2014 this has been reflected in the NICE intrapartum guidelines and in national policies like Better Births (National Institute for Care and Health Excellence, 2014; National Maternity Review, 2016). The NICE Intrapartum guidelines published after the dissemination of the Birthplace study findings changed the recommendations and highlighted how for women with uncomplicated pregnancies, we should be recommending a birth in a MU or at home (National Institute for Care and Health Excellence, 2014).

This national guideline, together with national Better Births policy published in 2016, were responsible for the changes in maternity services layout identified by Walsh and colleagues in the Birthplace place follow up study "*Mapping midwifery and obstetric units in England*" published in 2018 (Walsh *et al.*, 2018). A significant increase in the provision of MUs in England from 2010 to 2018 was noted especially in regards to AMUs, although 32 Trusts were still without a MU (see figure 3 below).

Figure 3 From "Mapping midwifery and obstetric units in England" By Walsh et al. 2018
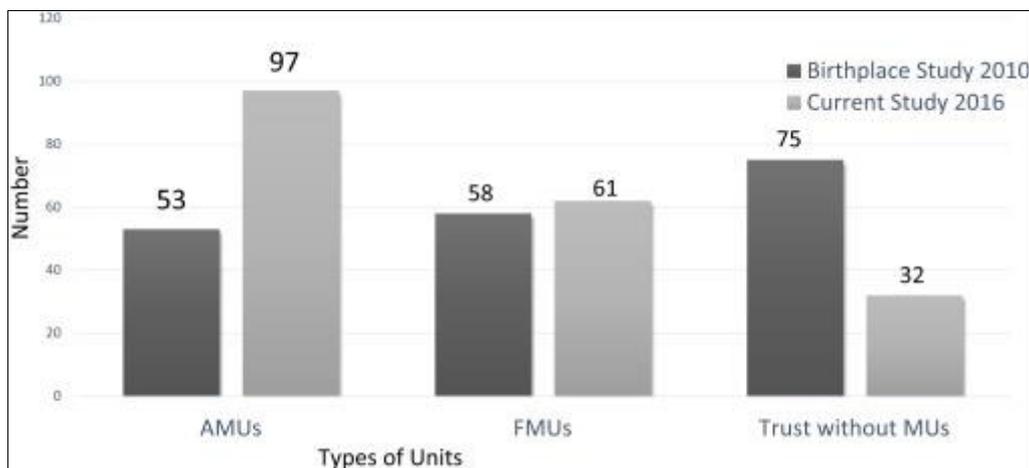
Utilisation of AMUs was also improved after the publication of the NICE guidelines with an improvement from 3% to 12% of births whilst the utilisation of FMUs remained stable at 2% of births. Considering a pragmatic calculation of the eligible population which could be using MUs, the authors reported that 36% of births should be happening in midwifery led settings. Seen that the report identified a total of 86% of births still happening in the OUs this shows a continued underutilisation of the MUs in England. The final recommendations from that study were that both availability and utilisation of MUs in England should be improved (Walsh *et al.*, 2018).

These findings show how a national guidelines and policies with clear recommendations on place of birth could significantly affect the provision of MU care but also leave an evidence-to-practice gap after more than 5 years from their publication. Therefore, it becomes crucial to investigate this gap, trying to understand and address these issues with different strategies to enable all eligible women to benefit from the positive impact of MUs care.

1.4.   Mind the gap: evidence and practice

Starting from the example of the United Kingdom in which national guidelines recommend for both first time mothers or women who have already given birth "*planning to give birth in a midwifery-led unit (freestanding or alongside) **particularly suitable** for them because the rate of interventions is lower and the outcome for the baby is no different compared with an obstetric unit*" we saw how there still is an urgent need to investigate better strategies to improve the existing MUs and to implement new ones in Trusts that do not have any yet (National Institute for Care and Health Excellence, 2014; Walsh *et al.*, 2018).

In a linked series of case studies of services with differing levels of implementation, Walsh et al. (2020) identified factors influencing the provision, utilisation, and sustainability of MUs in England (Walsh *et al.*, 2020). Analysis of the findings using the Consolidated Framework for Implementation Research identified key reasons for continuing underuse in England (Damschroder *et al.*, 2009; Walsh *et al.*, 2020). Amongst the main barriers to the implementation one important factor was found to be the perceptions of MUs for midwives, clinicians and managers based on personal belief, perceptions of the financial constraints and lack of confidence by the midwifery component due to OUs being the mainstream setting for training (Walsh *et al.*, 2020). While managers and service commissioners and a number of professionals argued that interest from women and families was low, focus groups with a diverse group of community members identified lack of information and awareness of the availability of such services, or the evidence about their safety. Opportunities for implementation in England were identified in: a transformational leadership (able to be exercised both vertically within the hierarchy and horizontally amongst different professional groups), an opt-out mechanism by which women with straightforward pregnancies are by default directed to the MUs unless they decide otherwise and provision of appropriate and evidence-based unbiased information to service users (Walsh *et al.*, 2020).

According to the GoodBirth Network, midwifery centres were identified in 56 countries in low, middle, and high-income countries (Goodbirth.net, 2018). However, this map does not take into account many

European countries due to a lack of information received via the website. Thanks to the connection and work conducted at City, University of London with the Midwifery Unit Network, we could confidently say that currently in Europe MUs have been identified at least in: United Kingdom, Italy, Spain, France, Bulgaria, Belgium, Netherlands, and Czech Republic. A study is being conducted at present by researchers at City in collaboration with the University of Paris and Euro-Peristat Network to map all MUs in Europe and to collect data on the number of births registered in them to have an initial idea of the utilisation of these models of care.

Therefore, we could say that currently more than sixty countries around the world have tried some level of implementation of these models of care. The degree to which each has been able to succeed in this implementation is unknown as no research has been conducted about this yet. Hence, the relevance of my research that will contribute to the existing body of knowledge looking more in detail at what are the effective strategies which have been found internationally to support implementation of new MUs (via my systematic review) and at how the maternity workforce could be developed in countries in which MUs are yet not well established (via the participatory research with this case study). Are there any important lessons that we could take from the English and more international context to support the change of delivering intrapartum care in European countries? The systematic review conducted as part of research project and described in chapter 3 will examine more in detail what is known about these strategies internationally.

1.5.   An Italian case study

1.5.1. Why Italy?

In some EU countries MUs and midwife-led care are more established than others (Euro Peristat and Macfarlane, 2018).

In Italy there were only five MUs (all AMUs) when this project started in 2019 and there was a growing interest in this field. A national guideline was published in 2017 to define and promote more midwife-led care for women with uncomplicated pregnancies (Comitato Percorso Nascita Nazionale, 2017).

Within the region of Tuscany, a hospital has been working towards the creation of its first AMU. As already mentioned, this transitional phase from the default obstetrically led maternity services to an integrated model with a midwifery unit represented an ideal opportunity to examine implementation of international evidence and guidelines in national and regional context. This was the first study in Italy and in Europe on this issue and it contributes to a better understanding of barriers and facilitators

to implementation of MUs in countries in which they do not currently represent an option. It will contribute to implementation theory development in maternity care.

Having the chance of studying a local context before the opening of an AMU represented rare research and learning opportunity and this is why this specific Italian context was chosen as case study.

1.5.2. The Italian Healthcare System

The national healthcare system in Italy, called Sistema Sanitario Nazionale (SSN), was created in 1978 and provides universal coverage for all health services being financed mainly through general taxation. Healthcare is provided to all citizens with the possibility to access private care too. The SSN is organized under the Ministry of Health and is administered regionally. There are 20 regions, 5 of which have what is called "*statuto speciale*" which is a higher level of autonomy due to specific linguistic, geographical and cultural differences (Paparella, 2016).

Prior to the establishment of the national healthcare service, the system was ruled by principles of selective coverage based on citizens who were insured via their employment. This meant that citizens who had an occupation which allowed them to be insured, like for example industrial occupations, were able to access healthcare services whilst citizens like the ones working for the agrarian sector could not. There were big differences and disparities between demographic groups in Center-Northern regions versus Southern regions and also between urban areas versus rural areas (Doetter and Götze, 2011).

This insurance-based system went bankrupt by the mid-1970s with a lot of dissatisfaction from the population and strong political interests in changing it. So, in the late 1970s, the left political party, who had interest in a an equal healthcare system, and the conservative political party, who had interest in reducing the financial burden of this sector, both became interested in a centralised and universalistic national healthcare system (Brown, 1984). Following the English model, this way of organising the healthcare service seemed to be for both parties the most effective, viable and cost-contained solution (Doetter and Götze, 2011). Consequently in 1978, the Servizio Sanitario Nazionale (SSN) was established under the principles of universality, equality and uniformity of services that were free at the point of delivery (France, 2006). With this important reform introducing universalism, Italy solved the problem of selective coverage and it centralised the control of expenditure of this sector. The provision of the service was organised on a three-tier structure including the national government, the twenty regions and the local health authorities (LHA) also called "Aziende Sanitarie

Locali". The government set the ceiling of expenditure, distributing the National Health Fund to the Regions based on their needs (for example favouring the poorer in the South) and it was up to the LHAs to decide how the resources will be spent based on the local needs. This model succeeded in reducing regional inequalities between 1977-1987 (Fargion, 1992).

The main difference from the English NHS was that Italian regions were not held accountable for over-expenditure and did not have to prove their success and effectiveness via monitoring of their performance. Having a system with centralised financing but decentralised spending without a robust monitoring system enabled instances of fiscal irresponsibility (France, 2006). In the 1980s this led to an unsustainable situation in which a new reform was needed to track and control the use of resources. Two main trends affected this new reform: decentralisation of the healthcare financing and the introduction of an internal market (Doetter and Götze, 2011).

Since 1990s, after the New Public Management movement, a strong decentralisation policy was adopted in many healthcare systems to shift control and increase the flexibility of the local level (Hood, 1991). The Italian regions became more autonomous in terms of jurisdiction and more responsible for their own political, administrative, fiscal and organisational level.

The past three decades of political leadership from both left and right parties continued this path of decentralisation. In 2009, the most recent reform of fiscal federalism was approved, and it meant an even greater decentralisation giving even more autonomy to regions whilst holding them accountable and responsible for better and more efficient expenditure with a more careful monitoring systems now in place.

In 2017, the OECD Country Health Profile related to Italy published by the European Observatory on Health Systems and Policies reported that "*Italy spent 9.1% of its GDP on health in 2015 and this translated to EUR 2 502 per capita (adjusted for differences in purchasing power), which was 10% below the EU average*" (OECD, 2014, 2021). After the economic crisis of 2008, the healthcare expenditure remained flat or decreased for few years and it then started to increase slowly again after 2014. In terms of sources, 76% of the total healthcare expenditure came from public sources and 24% from private mostly direct out-of-pocket payments from citizens. Private health insurance has a marginal role at present in Italy (OECD, 2014, 2021).

Italy has the oldest population in Europe with 22% of the population over 65. If we add to this data the birth rate which has been decreasing from 1980s, it explains why most of healthcare expenditure for a country with these characteristics focuses mainly on chronic diseases and elderly care (ISTAT,

2019). Having to provide healthcare services for this ageing population is often perceived as a threat to financial sustainability and therefore as a public burden (GBD 2017 Italy Collaborators, 2019).

The Italian workforce is reported to be "*a relatively high density of doctors and a low density of nurses*" (OECD, 2021). Even though the analysis from the OECD reported on a high ratio of doctors in the country there is a generational problem within the professional category. More than 50% of doctors are over 55 years old and according to the main union for doctors in the country between 2018 and 2025, 50% will retire creating a staffing shortage of at least 16.700 doctors (Paterlini, 2019; Piscitelli *et al.*, 2019). The main causes have been identified in poor planning for the specialisation grants for doctors (each year 10.000 medical degrees are awarded but only 7000 specialisation fellowship allocated) and retention in the public healthcare sector of specialised doctors (many leave for the private sector or to seek career opportunities abroad) (Paterlini, 2019). In 2019 and during the Covid pandemic, in few Italian regions a call was made for retired medical specialists to go back to work on the public sector to help dealing with the shortage in the emergency departments. Many clinicians criticised this approach as unsafe and short-sighted.

Data from the European Commission suggest that at least 1000 qualified and trained doctors a year leave Italy (the so called "brain drain" issue) and it is likely to be to go in other countries and work in more gratifying and appealing healthcare systems (Piscitelli *et al.*, 2019). Retention is therefore another important issue to tackle when considering shortage of doctors in Italy nowadays (Colla, 2019).

In the next years it is likely that we will see an increased shortage of specialised doctors in Italy due to retention issues and to a high number of doctors retiring like presented above. This problem is seeing an investment of resources and responsibilities to primary care professions like nurses and midwives and in fact in the last decade the annual numbers of graduates from nursing school has already been quadrupled (OECD, 2021). In such difficult times investing in evidence-based primary care (like MUs) could represent a viable, safe and appropriate way of investing public resources whilst maintaining high-quality level of care.

1.5.3. Maternity Care in Italy

Maternity care is included in the service provided by the SSN and is free at point of care. It represents an important event for the female Italian population and for the healthcare sector expenditure being the main reason for women's hospitalisation (Annesi Pessina *et al.*, 2013).

The demographic indicators reported 435.000 babies born in 2019 which is the lowest rate since 1918 showing a constant decline in the birth rate at national level in the past century (ISTAT, 2019).

Midwives are recognised by the law and regulated in their professional profile as lead professionals in the context of physiology of pregnancy, birth and postnatal period (D.M. 740/94, 1995). Midwives are employed by the SSN and they work mainly in hospitals with a smaller percentage of them working in the community. Only 2% of midwives practice privately and do not always facilitate and support homebirths. In 2019 birth outside the hospital was 0,1% of total births with 0.03% being referred as "other" places and were probably born-before-arrival births and only 0.07% registered as home births with notable regional variations (Lauria *et al.*, 2012; Cicero *et al.*, 2022).

Midwives in Italy are also point of reference for other areas of women's healthcare and in their scope of practice there have included contraception, menopause, pelvic floor health, cervical cancer screening and fertility (D.M. 740/94, 1995). During the past decade midwives have seen their scope of practice expanding also to areas of surgical support in the operating theatre and assistant for IVF and fertility treatments so we could say that they now cover many different specifications and facets of the professional profile.

There is a strongly hierarchical professional structure in which doctors have primary responsibility for the care and midwives are considered (and some levels are truly) under their responsibility (Colaceci *et al.*, 2022). One example of this is that midwives cannot admit for example low-risk women in labour but require the so called *'doctor's signature'*. Even if that doctor does not even see the patient but trust the midwife's judgement in assessing the correct time to admit her. This is due to a legal requirement stated in the Ministerial Decree n.740 of 1994 and in the Article 1 of Law n.42 of 1999 which defined the area of responsibility of the healthcare professionals and the professional profile of midwives in Italy. Another example of the lack of autonomy is that midwives do not have '*midwives' exemption*' on some key drugs administration like in the UK. A doctor prescription is always required even for a tablet of paracetamol. This approach to the professional autonomy of the midwifery professional might impact on the working relationship with other professional figures, in the midwives' satisfaction level and consequently even in the way service users perceive each healthcare professional role.

A recent article commissioned by European Board and College of Obstetrics and Gynaecology (EBCOG) on the provision of antenatal care in Europe showed how the lead professional providing antenatal care is a medical practitioner in 73% of cases and midwives are involved in only 27%. This data is consistent in Italy where majority of women go for antenatal care to a private obstetrician (78.5%)

and only in 11% of cases they chose the care of the community centre with the midwife (Lauria *et al.*, 2012).

Being born, raised and trained as a midwife in Italy, I experienced the public perception that "*public care is not as good as private*" and the idea that you need a named obstetrician. Obstetric-led care is the norm in Italy and even if it is not what the current evidence recommends, or in line with the current directive for midwife-led care, it has been accepted by women with the majority reported to be satisfied with quality of care received in pregnancy (Lauria *et al.*, 2012). However, is this an appropriate use of resources for the public Italian healthcare system? Are women aware of the evidence around midwifery-led care models? Does this ensure an equal and fair access to maternity care?

A national report from 2018 showed how midwives were present at birth in the 95% of cases, an obstetrician for 88% of all births and paediatricians for 68% (Istituto Nazionale di Statistica, 2020). This data seems to suggest an overuse of resources that are otherwise considered scarce. In 2018, a trans-European survey Babies Born Better (B3) was submitted to service users in different EU countries to capture the range of experiences of maternity care. In Italy, a research group has conducted quantitative and qualitative analysis of the 1000 responses received between 2010 and 2015.

Findings show that women want kind, compassionate and skilled care (which is in line with the WHO intrapartum recommendations of 2016) and that overall many women in Italy have positive

Figure 4 Findings from the Italian Babies Born Better (B3) survey - Weather forecast of women experiences of childbirth in Italy - Skoko et al. 2018

experiences even though there is high variability amongst regions and different service contexts (see figure 4).

A main source of data to analyse and monitor the maternity situation in Italy and to make comparison amongst different regions comes from the Certificato di Assistenza al Parto (CeDAP) which represents the birth certificate that each midwife has to fill at birth and from the Scheda Dimissione Ospedaliera (SDO) which is the maternity report at the moment of discharge. These are a national requirement and it represents the common denominator of data amongst all 20 regions and a reliable and high-quality source of data. Each Region or LHA can collect some additional and more specific data related but these extra indicators can vary between one region to the other.

The latest CeDAP report prior the start of this study about all births in Italy in 2016 (Rosaria *et al.*, 2019) presented some key findings to understand the state of maternity care before the pandemic:

1. The average age for mothers was 32,8 for Italian citizens and 30,2 for non-Italian mothers;
2. 74,6% of women had more than 3 scans (no evidence of improved clinical outcomes for more than 2 scans in pregnancy according to the Cochrane systematic review by Bricker Neilson and Dowswell (Bricker, Neilson & Dowswell, 2008);
3. 89,2% of births happened in public hospitals or accredited centres, 10,5% in private centres and only 0,1% in other places like home;
4. The caesarean section (CS) rate in Italy was 33,7%, one of the highest in Europe. Higher rates and significant differences have been noticed in accredited centres (50,9%) compared to 31,7% in public hospitals. Another relevant difference is that the CS rate amongst Italian mother is 35,4% whilst for non-Italian mothers is 27,8% which suggests a possible different professional approach for the two populations;
5. From the analysis of the Robson's categories, high variability in the use of CS in different regions and different LHAs not based on risk level was noted.

This data once again suggests different professional approaches and that organisational and professional improvements could and should be achieved. Some graphs from the report show differences of CS rate amongst different type of healthcare facility: public, accredited or private in figure 5 and per different region in figure 6.

Figure 5 Distribution of births in 2016 according to mode of delivery and healthcare facilities (public, accredited and private) Rosaria et al., 2019)
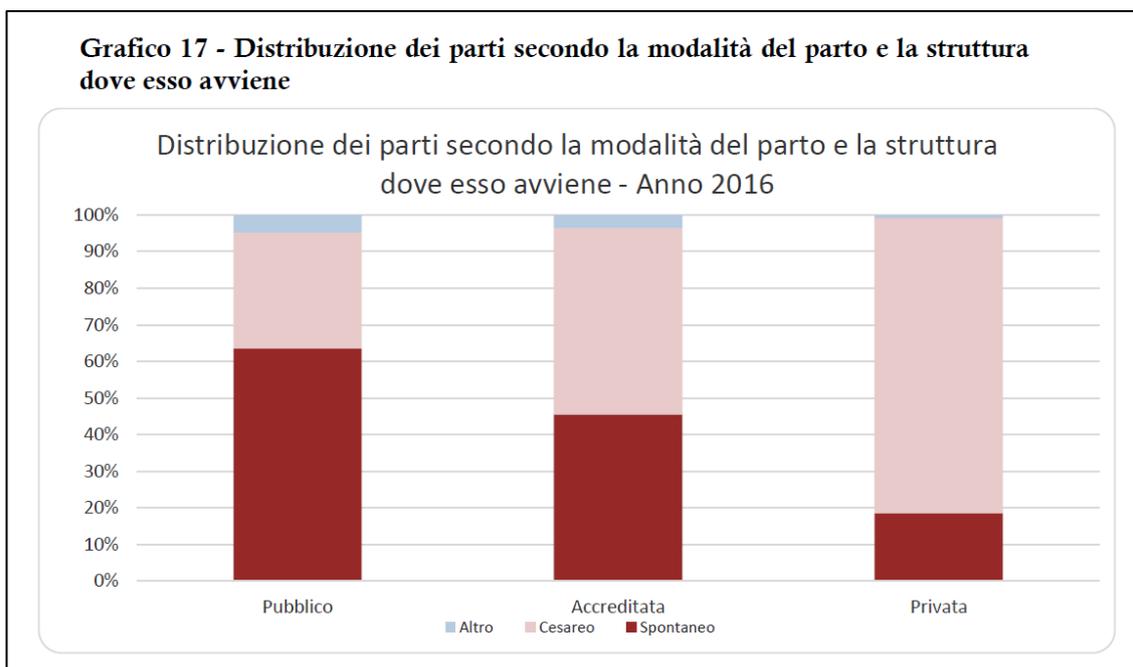
*Public is any facility part of the SSN, **accredited** is any private facility which works in collaboration with the LHA or Regional level with a reimbursement system and **private** is any autonomous and private facility in which the citizen has to pay to receive the care with no reimbursement.*

Figure 6 Regional distributions of CS rate amongst the total births. Source (Rosaria et al., 2019)
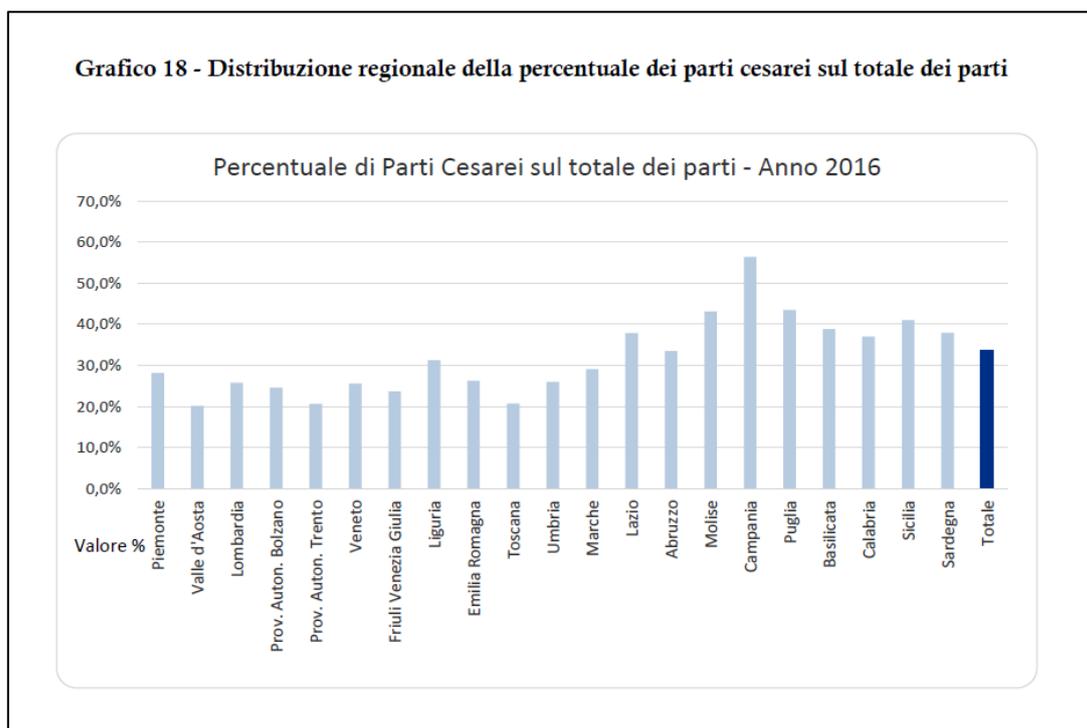
The graphs above highlight the variability of professional practices and how this could affect a clinical outcome such as the CS rate. There is no credible reason by which women who live in the south (for example in the Campania region) would require so many more CS in comparison to women in Tuscany. It is a clear signal that work needs to be done on the professional and organisational level to level up differences and variability. This also shows how this research project, with an implementation and participatory-action-research approach could give precious insights on how to facilitate positive and evidence-based change and reduce variability among the maternity team.

In 1985, the WHO position statement was that a CS rate of more than 10-15% is not justifiable. A more recent systematic review by WHO researchers and an ecological analysis concluded that a CS rate higher that 10% was not associated with better outcomes or reductions in perinatal mortality (Betran *et al.*, 2015).

A systematic review published in 2018, aimed at identifying interventions targeted for health professionals to reduce unnecessary use of CS (Kingdon, Downe and Betran, 2018). The review concluded that according to the general behavioural change theory for changing professionals and policy makers is important to work on three main levels: personal beliefs about what is right to do, what is normal in this context and what is under my control to do. To summarise their findings and implications for practice, professionals need to believe "*in physiological labour and birth as intrinsic values and that they are personally performing unnecessary CS*" (Kingdon, Downe and Betran, 2018). Inter and intra disciplinary collaboration amongst different professional groups to discuss and agree on change of local norms has been found to be effective in improving practice. Continuous professional development and education in self-reflective practice were identified as practical tool for improvement. Professional needs also to be put in the condition to address barriers about power of various groups, medico-legal concerns, monetary gain and efficiency concerns (Kingdon, Downe and Betran, 2018).

These are all findings and actions which should be taken into consideration when trying to implement safer maternity care in a medicalised country like Italy with high variability of medical practices.

1.5.4. MUs in the Italian context

As highlighted in the CEDAP report above, in Italy almost all births take place into hospitals (public, private and accredited). However, this data includes both obstetrically led and midwifery-led units as the data collected is cumulative of both.

In 2020, during a Midwifery Unit Network conference held in Milan in which the Italian translation for the Midwifery Unit Standards was launched, it was estimated that there are currently 5 AMUs working within the public nation healthcare system: Florence, Genoa, Turin, Brescia and Modena. These units are all located in North and just one in the Centre of Italy showing a more significant lack of midwifery-led care intrapartum services in the Centre and South of Italy. A freestanding MU was closed in 2017 in Rome and is currently still closed. During the years, it has been difficult to map opened MUs as they have been closed in different circumstances showing how not only implementation but even sustainability is an issue for MUs in Italy.

Fourteen private maternity homes were identified via the official website of the "Associazione Nazionale Culturale Ostetriche Parto a Domicilio e Casa Maternità" in March 2020 (www.nascereincasa.it). These maternity homes are similar in terms of philosophy of care and services that they can offer but in a home environment and they follow homebirth regulation. The main difference from the MUs is that they are not fully integrated with the system. They are run by independent midwives who work autonomously from the public maternity service. In few regions (Piemonte, Emilia Romagna, Marche, Lazio and provinces of Bolzano and Trento) women could access maternity services of independent midwives and then ask the Region for a partial reimbursement of the service (usually 50%) (Cicero *et al.*, 2022). This regulation helps to make the work of independent midwives more equitable and accessible to women with different economic background.

A national guideline was published in 2017 to define and promote midwife-led care pathways for women with uncomplicated pregnancies and highlighted for the first time the fact that women with uncomplicated pregnancies should receive midwifery led care in a *space physically separated from the obstetric unit but still within the hospital setting* (Comitato Percorso Nascita Nazionale, 2017). In the guideline the existing AMUs part of the national context were cited as example and as point of reference for the rest of Italy. This has represented a milestone for the existence and the implementation of this model of care as for the first time an Italian guideline was encouraging and recommending MU care for women with straightforward pregnancy.

As previously discussed for the international and English context, having a national guideline recommending these models of care plays an important role and represents a first step towards the implementation of the innovation. For the local context in which this research project is sited, this guideline has been an important facilitator to support professionals making the case for the innovation with the organisational and managerial level. However, seeing the interpretation of the international evidence limited to MUs located *within the hospital* already shows resistance and scepticism towards part of the evidence and a perception of safety associated mainly the hospital.

1.6. Conclusions

To summarise the key points of this chapter, maternity care is facing problems and consequences of an over-medicalisation of pregnancy and childbirth in many countries and Italy is one of the European countries in which this is most visible, with one of the highest CS rates in Europe. This has not only caused clinical and health repercussions but also a significant social impact on the population as it has changed the perception of safety among professionals but also among women and families, who are now accustomed to a more technocratic and medicalised care.

This overuse or inappropriate use of resources has relevant consequences not only to perinatal outcomes but to the services that the healthcare systems can afford and provide to the population and should therefore be addressed in the interest of all citizens. In addition to this, a shortage in the number of doctors in Italy in the next decades anticipates the need of investing in primary care and in professions like midwives and nurses. Hence, the relevance of the implementation of evidence-based primary models of care becomes key for the next years.

Literature suggests that MUs are safe, evidence-based and provide a cost-effective bio-psycho-social model of care for women with straightforward pregnancies and should therefore become a mainstream option for the healthy population. Recent policy and guideline developments in Italy provide an enabling framework for implementation and some examples of MUs exist in Italy but typically services are hospital-based and medically centred and the potential scope of midwifery care is not yet realised.

The next chapter will present the theoretical underpinning, the methodology and the research methods chosen to conduct this study.

Chapter 2 - Methodology

Introduction to the chapter

Deciding which methodology to use has been an ongoing journey and it has helped me to deepen my knowledge on different approaches, theories and methods. This chapter presents this journey: from the ideas included in the initial proposal, to the rationale for changing plans along the way due to the Covid pandemic, to finally introduce the design and research methods used for this study.

The aims of this chapter are:

- To present the theoretical underpinning that led to the choice of the research design;
- To introduce the models and frameworks adopted and the rationale for choosing them in this project;
- To give an overview of the research methods planned to be used and the ones used once the plans were adjusted due to the pandemic impact;
- To reflect on my role as researcher in this study focusing on positionality, reflexivity and ethical considerations.

2.1. Theoretical underpinning
[1]2.1.1. Critical Realism

The advent of Evidence Based Practice (EBP) changed the way healthcare was researched and practiced. The EBP movement was generated by the need to make care more consistent and evidence-based across different places and practitioners. EBP was embedded more systematically within the NHS in the nineties to make the healthcare system more modern and dependable (Department of Health, 1997). This approach diffused widely in other public healthcare systems to ensure appropriate use of resources which were tax funded.

The rapport between maternity care and EBP did not start on the right foot though. Dr Archie Cochrane, founder of the Cochrane Library, awarded obstetrics with a wooden spoon for its poor use of scientific approach with randomised controlled trials among all medicine specialities. The obstetrician Ian Chalmers took this criticism very seriously and together with Murray Enkin and Marc Keirse published in 1989 the first evidence-based edited book of obstetric practice (Crowley *et al.*, 1989). For the first time in obstetrics, a shift from opinion-based medicine to a more systematic and

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[1]

consistent approach was made (Forrester King, 2005). Meanwhile, midwifery research was starting its independent journey moving away from nursing research and social sciences. Midwifery was not considered a research-based profession and therefore needed to prove itself to be credible over time. It has developed significantly and exponentially in the past two decades becoming a rigorous branch of research now collaborating with other disciplines like obstetrics, nursing, social sciences and public health.

Those events significantly affected the way maternity care and practice has been shaped and how it looks like nowadays. The run to catch up with other disciplines and for RCT research led by a positivist paradigm in which research questions were interested in simple answers (and truths) was the foundation of maternity research in those years.

The debate around place of birth provides a classic example of contested truths within maternity care in different international contexts. Midwifery units and home birth have demonstrated to be safe and cost-effective alternatives to the now-traditional obstetric unit by strong international evidence (Hollowell *et al.*, 2015; Scarf *et al.*, 2018). However, despite guidelines and global recommendations like the Lancet's for high-, low- and middle-income countries (as discussed in chapter 1), they struggle to be implemented in contexts in which they are not mainstream options and to be sustained in contexts where they have already been implemented. Interestingly, and unlikely other type of innovations like pharmacological or technological ones, research coming from positivist epistemology demonstrated safety and benefits of these models but that reality encounters organisational, environmental and cultural barriers which affect the use of this evidence creating the so-called evidence-to-practice gap. When reflecting on the appropriate theoretical and philosophical underpinning for this thesis, it became clear the need to use a paradigm which included a multi-layered vision of the world which could address complex phenomena such as the evidence-practice gap.

Ontology is the branch of philosophy dealing with questions like: what is reality? What constitutes existence? And what can be said to exist? A critical realist approach to ontology acknowledges the complexity of the world and reality and allow a vision of the world more holistic including different perspectives (Walsh and Evans, 2014). Seminal work by Bhaskar in 1997 proposed a vision of the world through the lenses of critical realism in which ontology has three levels: the **empirical** which is what can be observed, the **actual** represented by what is known but cannot always be seen and the **real** represented by the hidden but necessary preconditions for the actual and empirical (Bhaskar, 1997).

Walsh and Evans (2014) recommended the use of this philosophical approach to midwifery research arguing that until recently most of the studies used a positivist or interpretivist approach limiting the quality of findings and answers to research questions (Walsh and Evans, 2014). Clarifying what vision of the world researchers have before approaching a complex issue is paramount to then define how knowledge will be generated and the research question to be answered. One example mentioned by Walsh and Evans (2014) was the study of labour dystocia. Approaching this issue from a positivist stand means that our view of the world has only one possible reality which is certain and generable not giving space to the complexity of the problem. Using this approach, labour is seen as a process with a cause-and-effect linearity (Downe and McCourt, 2008). But labour, especially when there is a dystocia, is much more complex and affected by many external and internal variables. On the other hand, using interpretivism to tackle it would limit the research findings as infinite possible realities are possible lacking to explain more generalisable aspects of the phenomenon.

Similarly, the place of birth and models of care debates require a vision of the world that allows a holistic approach to the complexity of the problems and research questions, especially when considering implementation and improvement research. Approaching this study with interpretivist lenses would limit the work to a relative vision of the world in which any reality is provisional, partial and subjective. Certainly, this specific research will generate knowledge that would apply to this specific context. However, conducting an analysis that include deeper layers of ontology and trying to reflect on the hidden preconditions can help explaining the implementation phenomenon. As Bhaskar said, "*the best we can do is to look for tendencies, not certainties*". This analysis could be useful for similar international contexts.

When working on this research I must be opened to reflect not only on the visible empirical and actual level but also on the conditions that might have led the local context to respond, adapt and be in a certain way. As nicely presented in the tree diagram proposed by Dyson and Brian (2005), I am interested in all three ontological levels: the leaves (empirical), the tree (actual) and the roots (real).

Figure 7 Tree diagram of the ontological levels, source (Walsh and Evans, 2014)
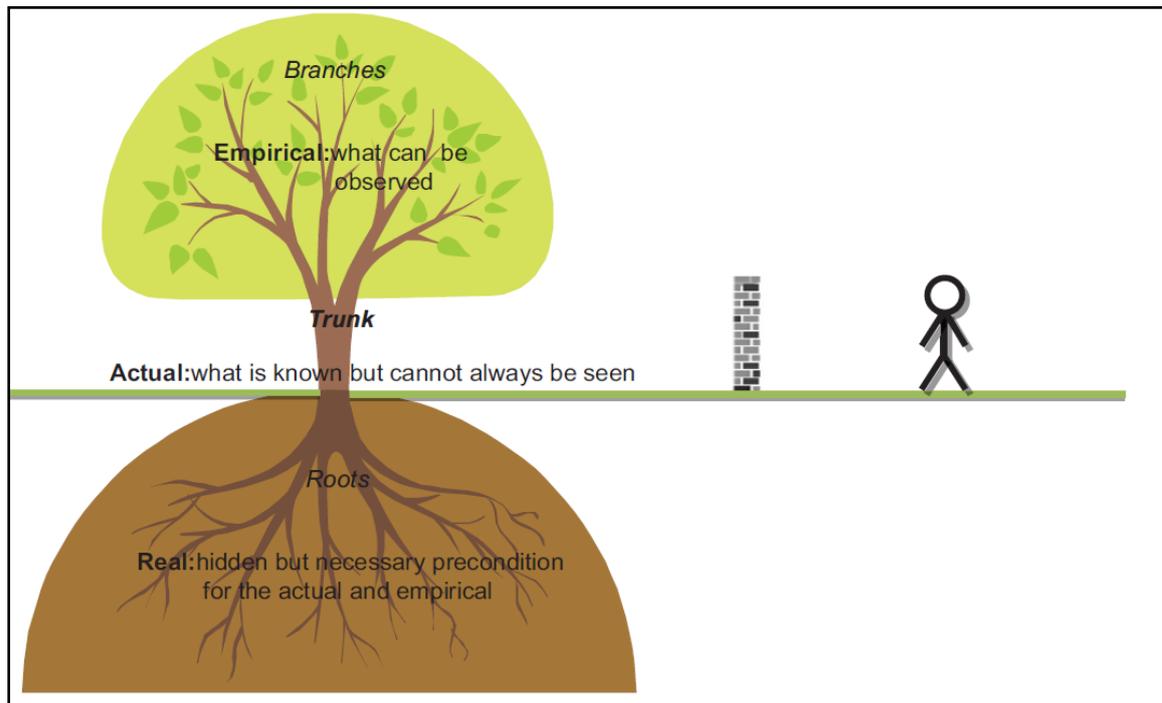
Approaching a study on maternity care, and a midwifery model of care in Italy, requires a research process that focuses also on the mechanisms that could have led the reality of limited autonomy and utilisation of midwifery care in Italy. Italy is known to be a patriarchal country. Maternity care is one of the very few health disciplines caring exclusively for women. The midwifery workforce is constituted of women for the very vast majority. Therefore, an analysis of the oppressive mechanisms will be included to explain the interplay between different levels of knowledge and reality.

Previous studies have identified action research as a particularly appropriate research method informed by critical realism as it concerns emancipatory change and the human agency needed for the social work of change (Meyer, 2003; Houston, 2010). Using critical realism, the researcher can identify how and why interventions (often called innovation in implementation science) work or don't work in specific circumstances. Action research includes the opportunity to involve stakeholders and understand why programme effectiveness can vary.

Hence, the decision to use a critical realist approach and participatory action research for a research study investigating the implementation process of a non-well-established midwifery model of care in that context and to learn lessons and 'tendencies that could be useful for similar social contexts.

2.2. Research design

2.2.1. Implementation Science

Implementation Science is a research field born during the last couple of decades as a result of increasing awareness in the health sciences of the considerable research-to-practice gap. It is estimated that an evidenced-based practice (EBP) could take on average 17 years to be incorporated into routine general practice (Bauer *et al.*, 2015). Some researchers believe that one of the main barriers to this is that different disciplines such as biomedical, social science, organisational, and managerial do not communicate to each other effectively research findings or service improvement strategies and often lack in collaborating with each other. The long time that research findings can take to be implemented in practice can lead to patients receiving substandard care and consequently suboptimal clinical outcomes. In a study conducted in the Netherlands, for example, researchers estimated that 30-35% of patients did not receive the care recommended by scientific evidence and therefore received a type of care which was not needed and potentially harmful (Grol, 2001). However, some type of interventions (including some unevaluated technologies) take a shorter amount of time to be implemented and can be established within complex healthcare system more easily (Downe and McCourt, 2008). This can be associated with underuse of beneficial interventions or models of care and overuse of those that are harmful or not beneficial (Graham *et al.*, 2006).

A review of implementation strategies by Davis et al. (2003) noted that only 10% of the studies identified provided an explicit theoretical rationale for their strategies (Davis *et al.*, 2003). Poor theoretical underpinning makes it hard to understand and explain how, when, for whom and why an implementation strategy succeeds or fails. The use of theoretical approaches offers the potential of increasing the predictability of successful implementation (Rycroft-Malone and Bucknall, 2010; Nilsen, 2015).

In 2005, Eccles and Mittman acknowledged this uneven uptake of research findings in healthcare professions, organisations and different settings and, for this reason, decided to address this issue launching a new journal called *Implementation Science* in order to promote better communication between different disciplines and with the public. Implementation research was already present in different disciplines from social sciences to healthcare but the aim of this journal was to give a specific space for interdisciplinary researchers and practitioners which focused on strategies to bridge this big gap between evidence and clinical practice in healthcare.

The definition given by the co-founders for the concept of *Implementation Science* was "*the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services and care*" (Eccles and Mittman, 2006). Hence, implementation science has been defined as the study of how evidence-based programmes can be embedded to maximise successful outcomes (Kelly and Perkins, 2012).

Before considering implementation research strategies and the adoption of an innovation in healthcare, the validity of the evidence base of that innovation should be assessed. It is paramount to move to the implementation stage solely practices, recommendations or techniques which have demonstrated to have a significant beneficial impact.

There should not be any rush in implementing innovations that have not been tested adequately or that do not yet represent evidence-based practice. The deriving risk could be to invest funding, resources and time in the implementation of ineffective innovations which would require in few years time to be de-implemented and this would automatically mean a negative impact delivering no good to service users and wasting healthcare resources. A clear example of this related to maternity care is the introduction of CTG monitoring despite the weak evidence on improving outcomes and the challenge currently faced in de-implementing a practice many professionals and patients had become comfortable with (Walsh, 2008; Alfirevic *et al.*, 2017; Wattar *et al.*, 2021).

Implementation science therefore highlights the importance of understanding when and how it is appropriate to decrease or end interventions (Ogden and Dean, 2014; Brownson *et al.*, 2015; Niven *et al.*, 2015).

This PhD study will use Implementation Science design as it aims to explore how the available good quality evidence about the safety of midwifery units could be implemented into practice in countries in which they are not well-established yet in the maternity system (like Italy) and therefore in contexts in which there is a gap between best research evidence available and everyday practice. For this project, the implementation phenomenon of interest is the scalability and spread of MUs in the European context.

As explained in the report made by the Health Foundation "The spread challenge" the definition of scaling and spread can be expressed like this:

"*Scaling, which is a subset of spread, refers to an initiative to replicate an intervention specifically through a higher-level organisation or geographical entity (such as a professional body or government*

*agency); but **spread** can also happen through horizontal connections between adopters, without the involvement of a higher-level entity.*" (Horton, Illingworth and Warburton, 2018)

In order to provide transparency on definitions of implementation outcomes in this study we will refer to them as per Proctor et al.'s taxonomy as shown in table 2 below (Proctor *et al.*, 2011).

At the beginning of this study, the plan was to focus on studying five outcomes: acceptability, adoption, appropriateness, fidelity and feasibility, leaving cost, penetration and sustainability only for some preliminary reflections. However, due to the delay in opening the MU for various reasons including the Covid pandemic and the fact that only one PAR cycle could be completed, only three pre-implementation outcomes could be included fully in the analysis: acceptability, adoption and appropriateness. Nonetheless, during data collection activities some participants shared their thoughts about fidelity, sustainability and feasibility. Therefore, some preliminary reflections on those outcomes are reported throughout the thesis even if the outcomes that were analysed and tackled more in depth in the final findings chapter (chapter 6) were only the three pre-implementation ones.

Table 2 Implementation outcomes taxonomy by Proctor et al. in 2011

Implementation Outcome	Definition
Acceptability	The perception that the intervention is agreeable, satisfactory, or confers a relative advantage
Adoption	Early uptake or intent to try
Appropriateness	Pre-adoption perception of practicability, fit, or relevance
Cost	Marginal cost, cost-effectiveness, cost-benefit
Feasibility	Whether the intervention is suitable for everyday use, practicable, or fits with provider workflow
Fidelity	Whether the core components of the intervention were implemented as intended
Penetration	Spread within an eligible population or level of institutionalization
Sustainability	The extent to which an intervention can be maintained, routinized, or institutionalized by a provider or facility

Therefore, the means to investigate the scalability of MUs in this specific case study are to: develop capability within system, organisation, professionals (maternity workforce) and investigate acceptability, adoption, and perceptions of appropriateness amongst stakeholders.

2.2.2. Theories, models and frameworks - TMFs

During the first years of implementation research, empirically driven implementation studies did not cite and explain their theoretical underpinnings, and this made it difficult to understand and explain why an implementation intervention succeeded or failed. Because of this, in the last decade, researchers in this field started acknowledging the importance of using theories, models or frameworks (also known as TMFs) and publishing many new ones. The unintended consequence of this is that there are now so many TMFs that it becomes hard to choose and identify the most appropriate one for a research project. Some TMFs were borrowed from psychology, sociology and other disciplines while others emerged from different studies of implementation science. The rationale for using theories is that being explicit, they can be questioned or examined, they can be adopted or abandoned, and they are more consistent with accumulated knowledge.

In his seminal work in 2015 "*Making sense of Implementation theories, model and frameworks*", Per Nilsen tried to clarify and explain the different kinds of TMFs, their roots and purposes in implementation research (Nilsen, 2015). He also clarified that even if theories, models and frameworks are distinct concepts, those terms are sometimes used interchangeably in implementation science (Nilsen, 2015).

So what is a **theory**? It is a tool to make certain assumptions specific and can be defined as "*a set of analytical principles or statements designed to structure our observation, understanding and explanation of the world*" (Nilsen, 2015). A good theory provides a clear explanation of how and why specific relationships lead to specific events clarifying the causal mechanism. It also tries to describe core components and active ingredients and to explain how and why events happen. The use of a good theory would help and support the development of implementation and improvement studies.

A **model** is instead a "*deliberate simplification of a phenomenon or a specific aspect of a phenomenon*" with only a descriptive purpose and so no causal mechanism explanation (Nilsen, 2015). Models and theories are often used interchangeably and sometimes the difference are not clear but the main difference between the two is that theories have an explanatory purpose in addition to the descriptive one.

Finally, a **framework** is an overview or a structure to describe the phenomenon with a different set of variables and categories and the relationship between them (Nilsen, 2015). It does not give an exhaustive explanation.

As already mentioned, in the last decade implementation researchers have focused mainly on creating explanatory theories and in fact, there are currently hundreds of them in the field. In the scoping review by Strifler and colleagues (2018), they found 596 studies reporting on the use of 159 TMFs (Strifler *et al.*, 2018). The majority of them (87%) were used in five or fewer studies, with 60% used just once. The purpose of choosing a TMF was usually to inform planning or design, implementation and evaluation activities, and occasionally used to inform dissemination and sustainability/scalability activities. In their scoping review, all TMFs were used for at least individual-level behaviour change, whereas 48% were used for organisation-level, 33% for community-level, and 17% for system-level change (Strifler *et al.*, 2018).

Given the current heterogenous profusion of literature, it becomes now difficult to select the right TMF and for this reason, researchers often do not select TMFs systematically and the criteria or rationale for the choice are often not described.

For this reason, Prof Birken and colleagues from the Dissemination and Implementation Methods Unit at the North Carolina Translational and Clinical Sciences Institute (NC TraCS) decided in 2018 to create a tool to make the decision of a certain TMF for research and implementation purposes easier and more consistent (Birken *et al.*, 2018). They published the T-CaST theory comparison and selection tool which is publicly available to help researchers and practitioners to find and adopt the right TMF for their implementation projects (Birken *et al.*, 2018; https://impsci.tracs.unc.edu/tcast).

During my first year of this PhD study, I took an Implementation Science masterclass at King's College London and I had the opportunity to take part in a workshop facilitated by Prof Birken on how to use this tool to select a TMF appropriate for my type of study. This work helped me and guided me in the selection of the TMF.

The aim of the T-Cast tool is to select the appropriate TMF to guide an implementation project, which has the potential to promote transparent reporting of the criteria used to select TMF (Birken *et al.*, 2018). Main purposes of the tool are:

- To reflect and assess which are the most relevant features of a TMF for the project;
- To compare the potential TMFs based on the needs of the project;
- To increase transparency on the decision-making process when choosing a TMF;
- To help to communicate to stakeholders the reasons why a TMF was selected.

This tool does not include an inventory of all TMFs so prior to using it, researchers need to identify potential eligible TMFs. To do so there is a publicly available online inventory of dissemination and implementation TMFs which can be found at http://www.dissemination-implementation.org.

Once the researcher has identified possible TMFs, the T-CaST tool can help to make a comparison between them and to identify which would best support the specific implementation project using a rating system. In the tool, there are four main domains which support the identification of the most appropriate TMF: usability, testability, applicability and familiarity.

T-CaST can help to understand and then justify why you should use one more than the other; for example, whether the Consolidated Framework for Implementation Research (CFIR) or the Theoretical Domains Framework (TDF) would be the best choice for a research project. CFIR covers the individual level in a more general way while TDF focuses mainly on the individual level but does not cover environment and context dynamics as much as the CFIR. When conducting a study there might be the need for different determinants at different stages so it might be appropriate to use more than one framework and to integrate them. What becomes very important, therefore, is to question the utility of the chosen TMF at all stages and use it as needed. Using the T-CaST tool it is possible to reflect whether for a certain study it is more relevant to focus on one dimension or the other and select the appropriate TMF accordingly.

For this PhD study, it was agreed with the supervisory team that two different TMFs were needed: a model for planning and guiding the steps of the implementation process with stakeholders (more focused on the 'action side' of the work) and a framework to support the stage of data analysis and theory development. In the next paragraph I present the decision-making process that led to the selection of the two TMFs.

2.2.3. The choice of TMFs for this project

When approaching the issue of searching for the appropriate TMF for the implementation process, I started by looking at the existing TMFs categories. Nilsen's work identified five them based on their aims and purposes (see figure 8):

1. **Process models** made to describe and/or guide the translating process of research into practice specifying the stages from production of evidence to implementation into practice.
2. **Determinant frameworks** aim to explain and understand which key ingredients influence final outcomes (like barriers and facilitators).

3. **Classic theories** from other fields which could be used for implementation research purposes.

4. **Implementation theories** developed by implementation research from scratch for understanding and explanation.

5. **Evaluation frameworks** made to evaluate aspects of the implementation success.

<div align="right">(Nilsen, 2015)</div>

Figure 8 Diagram on TMFs categories (from Nilsen, 2015)

Figure 1 Three aims of the use of theoretical approaches in implementation science and the five categories of theories, models and frameworks.
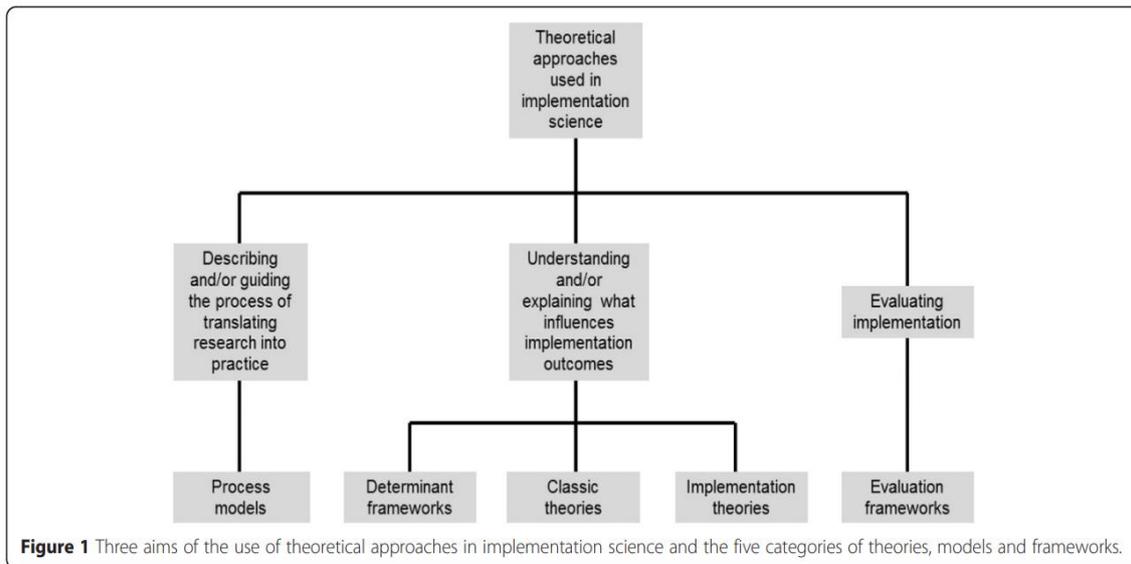
For the specific purpose of the implementation dimension of this PhD project, I thought that the most appropriate choice would be a **process model**. A model has a descriptive analysis and therefore does not aim at explaining the causality during the implementation process. Furthermore the nature of process models would help to support the description of the situational analysis and guide the translation process of evidence into practice.

While looking in the existing literature on process models in implementation research I found two models often used which have relied on both systematic reviews and experiences on the field: the Knowledge-to-Action framework (Graham *et al.*, 2006) and the Quality Improvement Framework (Meyers, Durlak and Wandersman, 2012). Both these TMFs are in fact models (even if their name stated framework) and this shows how sometimes in this discipline terms like theory, models and frameworks are used interchangeably.

As explained in the previous paragraph, the CFIR was chosen as main TMF with the purpose of supporting the implementation process and its analysis. By using the same approach and framework

as used in the wider literature in midwifery implementation studies would make comparison of findings clearer and more pertinent. CFIR is a determinant framework and therefore more focused on understanding and explaining what forces and ingredients influence the implementation. It was published in 2009 by Dr Damshroeder and colleagues in the US (Damschroder *et al.*, 2009). On their public website www.cfir.org the team describes the purpose of the framework as follows:

"*The CFIR provides a menu of constructs that can be used in a range of applications – as a practical guide for systematically assessing potential barriers and facilitators in preparation for implementing an innovation, to providing theory-based constructs for developing context-specific logic models or generalizable middle-range theories."* (Damschroder *et al.*, 2009)

This framework has had many applications in implementation research and in Nursing and Midwifery research. CFIR pays a lot of attention to context and all the forces that are part of it including micro, meso and macro levels (several existing frameworks include just the first and the latter not giving enough importance to the meso dimension). Also, it was developed based on a wide range of published theories, so it consolidates the thinking across them.

For this PhD project, in which the organisational and system dimensions are researched and assessed, supervisors and I agreed that the use of the CFIR seemed opportune **to support the stage of data analysis and theory development** (see figure 9). The CFIR was used as a theoretical framework to help guiding the analysis stage and the synthesis of how the implementation process works in that specific context and time. The aim is to then develop a model at the end of the study in this thesis which could be useful within Italy but also in other international contexts approaching similar implementation work. The CFIR framework was also used for the previous similar work in the midwifery field such as the implementation study for an AMU in Canada and another study assessing the utilisation of MUs in England (Walsh *et al.*, 2020; Darling *et al.*, 2021). Therefore, it constituted a coherent and consistent choice with the wider literature too.

Figure 9 Consolidated Framework for Implementation research by Damschroder et al., 2009
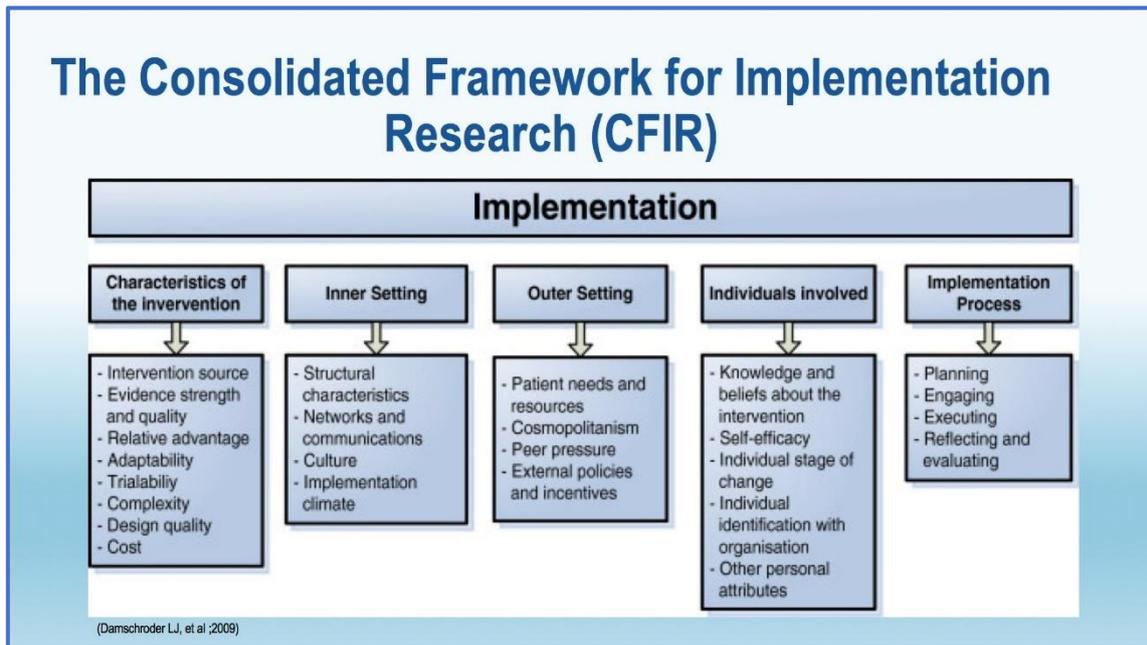
Another aspect which became clear during the planning stage of creating a research protocol is that this study required additional theoretical support to guide and frame the implementation process that the research would be facilitating in the local context.

For this reason, the choice of another TMF was required **to design, guide and frame the implementation process** for the PAR cycle. Hence the decision to use the T-CaST tool to choose between the Knowledge-to-Action framework and the Quality Improvement Framework.

Doing so, it was possible to assess both the appropriateness of the type of TMF chosen and the relevance for this specific research project.

The first TMF to be considered was the **Knowledge-to-Action framework** by Graham and colleagues, which was specifically created for health care contexts and is one of the so-called action models because it offers practical support for planning the implementation process (Graham *et al.*, 2006). Those types of models are made to "*guide or cause change*" and are often used in nursing research. Knowledge generation and the implementation of existing and new solutions is an intricate cyclical process and the authors have tried to explain those links and interconnections (figure 10 below).

Figure 10 Knowledge-to-Action framework by Graham et al., 2006
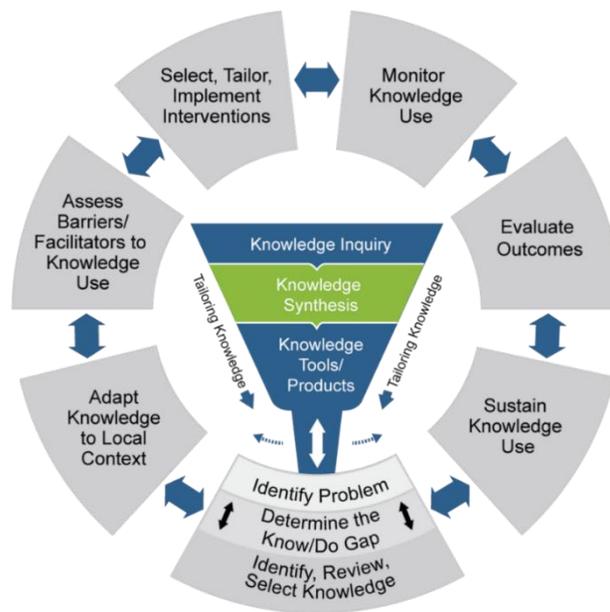
The second option was the **Quality Improvement Framework** created in 2012 with the intention to address three main goals: to synthesise the information from 25 implementation frameworks in a new one with QIS (Quality Improvement Stages), to summarise and explain the research support for future studies and to describe the practical implications for improving future implementation efforts in the world of practice (Meyers, Durlak and Wandersman, 2012). Figure 11 below shows the results of this work and the final QIF.

Figure 11 Quality Improvement Framework by (Meyers, Durlak & Wandersman, 2012)
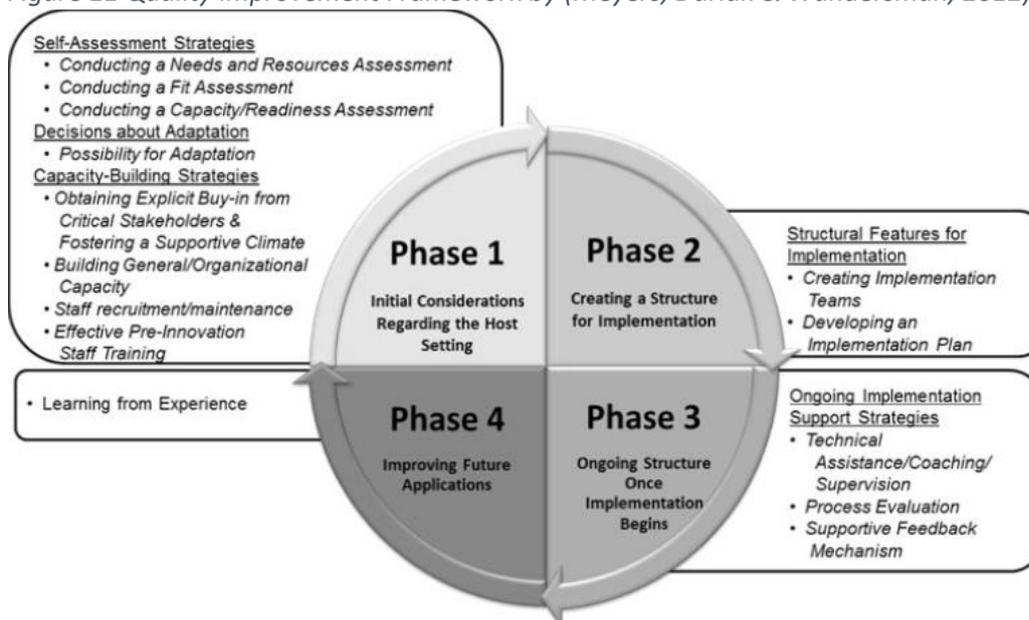
Assessment through T-Cast tool

To conduct an assessment between the Knowledge-to-Action and QIF framework, I applied the T-Cast Tool (see appendix 5 for a copy of this assessment).

The first step when using the T-Cast Tool is to select the characteristics that are relevant to the research project. On the left-hand side of the table there is a list of 16 attributes subdivided into the four categories of: usability, acceptability, testability and applicability. For the purpose of identifying the best TMF for the PhD project, I selected 10 characteristics which I believed to be important for this research project (see appendix 5). For the features which were not selected a note on the right side of the respective row has been left to explain the rationale for the exclusion from the scoring system.

The frameworks selected for assessment were plotted on at the top of the third and/or fifth columns and I then proceeded with the appraisal of the two TMFs for the selected attributes: 2 for good fit, 1 for moderate fit and 0 for poor fit. Each time a 0 or a 1 were given, notes on the right side would explain the reasons why the fit was thought to be not fully pertinent for the research project.

The Knowledge-to-Action Framework received a total score of 10. The main points in which the framework did not receive full score were: providing an explanation of how included constructs influence implementation and/or each other; having a particular research method which could be used with the TMF; addressing particular analytical level and familiarity to stakeholders.

For the QIF, the total score was 18 registering fewer points in the attributes related to the inclusion of relevant constructs and the familiarity to different stakeholders of the project. As either tool was to be used in conjunction with CFIR as an analytical framework, these limitations were less relevant.

The final decision was therefore to use QIF as a published, peer reviewed, step-by-step guidance to support the initial phase and the planning, acting and observing phases of this participatory action research project. This TMF guided and informed the implementation planning stage whilst the CFIR framework supported the analysis of the findings and the synthesis of those findings.

The combination of this model (QIF) and framework (CFIR) helped to support the description of the situational analysis, guide the translation process of evidence into practice and then analyse and synthesise the findings. The third component of TMFs – the Theory – will be considered and introduced at the analysis stage in the with the critical realist framework in chapter 7 in order to support a deeper analysis of what underlay the barriers and facilitators, implementation or lack of implementation observed in this study and to develop an explanatory model.

2.2.4. Participatory Action Research

With its roots in psychology and phenomenology, Participatory Action Research (PAR) consists of a family of research methodologies, which pursue the development of an intervention with active engagement of the co-participants (Houston, 2010). It involves situational analysis, intervention design and definition, implementation, process analysis and simultaneous evaluation of outcomes. PAR provides the opportunity "*for communities and science to work in tandem to ensure a more balanced set of political, social, economic, and cultural priorities that satisfy the demands of both scientific research and communities*" (Israel *et al.*, 2001).

PAR works in an iterative and cyclic way. Change is planned, implemented and evaluated by all stakeholders at the same time and in a cyclical way following the structure of: Plan, Act, Observe and Reflect. This is what is called a PAR cycle and like Hills and colleagues described in 2007 "*by engaging in iterative cycles of action and reflection, evidence for change is created and acted upon*" (Hills, Mullett and Carroll, 2007)*.*

PAR uses a collaborative process with the community to design and conduct an action plan that will help to integrate the new knowledge and evidence in the local context.

Due to the nature of PAR, it is necessary to start with some engagement activities in the local context to give visibility to the research project and initiatives. For this reason, in this study, there was an initial phase of stakeholders' engagement to make the research project visible. Considering that it is not uncommon to face some resistance to the change initially, this could give some time to stakeholders before agreeing to take part in the research activities.

One of the reasons that led me to choose this research approach is that, as clinical academic midwife I experienced the struggle of knowing what the best available evidence-based care is and being unable to put it in into practice due to a non-supportive system or lack of resources. I also experienced how sometimes changes (not necessarily EBM) are forced into the professionals' everyday practice just because the organisational level decided to do so without explaining the rationale, reasons or asking the opinion to the people primarily affected by those changes like service users and frontline practitioners (top-down changes).

My clinical background played a meaningful role when deciding to use PAR for this study. In fact, I strongly believe that the implementation of EBP needs to happen in a collaborative way with active engagement of the community who will be affected by it and with the support of research facilitators. This assumption defined my role as researcher in this study and it was often topic of reflections in the

research diary. This will be discussed further in the paragraph 'reflexivity and positionality in this chapter and in the Discussion chapter (chapter 7).

Structure of the PAR Cycle

For this PhD project, as previously mentioned, PAR was applied using the QIF as a model. To give a better idea of the integration of research design and TMFs I prepared a visual representation (figure 12).

Figure 12 Visual tool of research design and TMFs used for this project
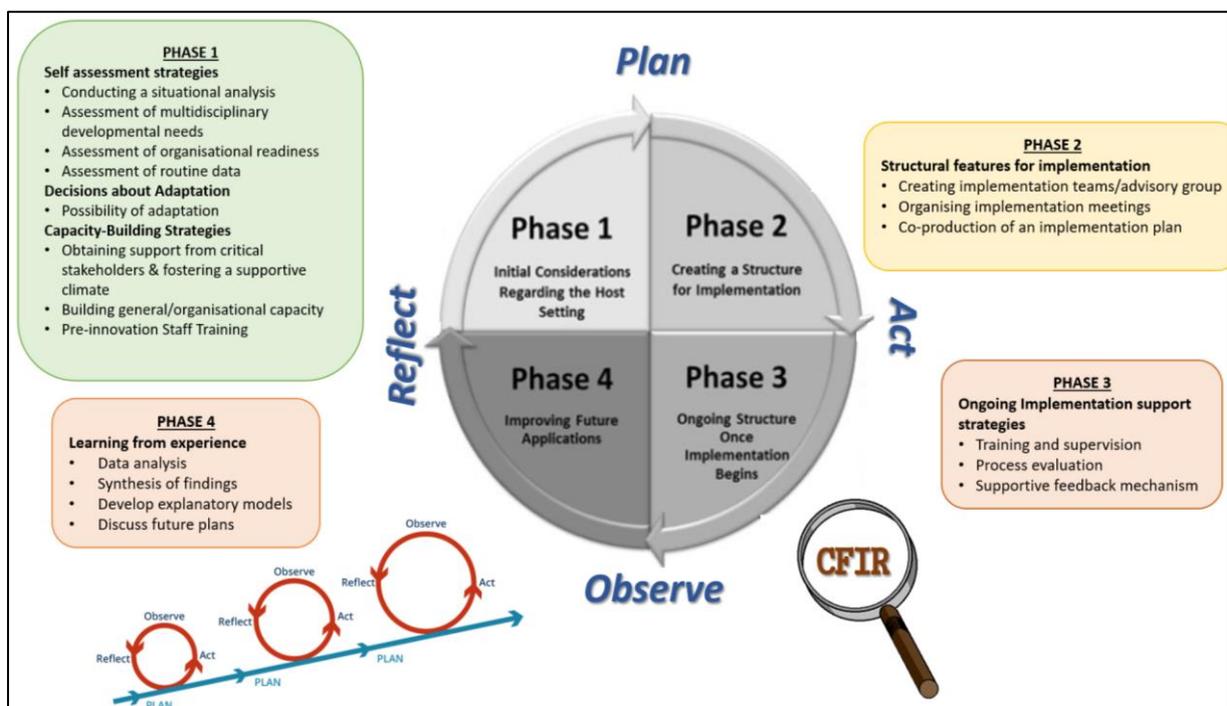
A situational analysis was conducted, the change planned with stakeholders, observed and finally reflected on by myself as an external researcher and facilitator but also by the local maternity team and leadership.

As mentioned in the Covid statement at the beginning of this thesis, the initial plan was to conduct 2 PAR cycles: one before the opening of the MU and one after (hence the representation of more cycles in the figure). However, due to the delays and the Covid pandemic, only one cycle could be completed before the opening of the MU.

The PAR cycle structure has four main phases which fit well with QIF phases. The cycle conducted as part of this research included:

A. PLAN (Phase 1 of the QIF)

1. Situational analysis of the organisational, cultural and professional readiness for the new model of care using the Consolidated Framework for Implementation Research as a guide

2. Assessment of multidisciplinary developmental needs in terms of readiness to work within and in relation to a MU

3. Assessment of routinely collected data, local audits and service user experiences as part of routine service evaluation

B. ACT and OBSERVE (Phase 2 and 3 of the QIF)

1. Stakeholder engagement

2. Coproduction of an implementation plan using a Delphi study

3. Involvement of service users in the codesign of the plan for the MU

4. Support the implementation plan developed by local stakeholders

C. REFLECT (Phase 4 of the QIF)

1. Analysis the PAR cycle, research diary notes and feedback from local stakeholders

2. Include feedback of key leaders with experience of implementing MUs in Italy

3. Reflect on organisational, professional and cultural aspects

4. Create a visual model of the main findings and research journey

The structure of this thesis mirrors these steps and the research journey giving also a chronological and cyclical idea of this experience.

2.3. Study population

For this project, I aimed to recruit as participant anyone who could be involved in the transition from the default maternity services to the new model of care with an AMU: service users, multidisciplinary maternity team, operational management and strategic stakeholders in order to understand the range of perspectives on the implementation.

One main challenge that often occurs while using PAR is the definition of what counts as participation and action for the specific study. Therefore, I am going to clarify this concept here:

A PAR **participant** is anyone who actively contributes significantly to the study data collection through interviews, focus groups, surveys, being observed or while conducting any data collection activity. Participants need to be recruited and to provide informed consent.

A PAR **stakeholder** is anyone who is affected by the change and engages with the research during meetings, seminars, training days etc. in the local context but does not contribute actively with disclosure of information, personal views or has not been observed personally.

Recruitment of participants for face-to-face data collection happened before the research activity with the use of the PIS to guide the discussion for presenting the research (appendix 4). Any questions were answered by the researcher and contact details for more queries or to request to opt out of the study were given.

The informed consent in the online surveys (for both professionals and service users) was in the first section of the online survey with the PIS attached via link and also sent via email in the invitation. Participants had a mandatory field in which they had to agree to take part in the study in order to access the online survey and answer questions. An example can be see in appendix 9 where report a copy of the service users survey.

In this thesis I use "participants" only for the group of people who have been recruited for the study and I refer to "stakeholders" as wider group which might include a mix of participants and stakeholders.

2.4. Ethical approvals

Approval to conduct this study was received by the Ethics Committee at City university of London on the 29th of April 2019 and by Ethics Committee of the Local Health Authority in Italy on the 14th of October 2019.

In the initial ethics approval, service users' involvement was envisaged via interviews, focus groups and data routinely collected by MesLab via the regional surveys presented above. However, due to the impossibility to conduct face to face data collection during the Covid pandemic and the decision to adopt online focus groups and surveys to co-create an implementation, I had to request an ethics amendment to include an online survey produced during the Delphi study with the maternity team as new method of data collection to engage service users. This amendment was approved on the 4th of November 2021 by the Maternal and Child Health Proportionate Review Committee at City, University of London.

Both approvals and the amendment are included in appendices 1 and 3 of this thesis.

2.5. Research methods

In this section, I outline the main data collection methods chosen for this project. This research incorporates qualitative and quantitative methods. First, an overview of the methods is given and then a more detailed account of each is provided.

The qualitative methods included in-depth and semi-structured interviews, focus group discussions, observation of stakeholders' events and analysis of surveys' open-ended questions and local guidelines. The choice for these methods was informed by PAR, implementation science theory as well as previous relevant research experiences in similar projects. The aim for using different methods and with diverse groups of participants is to allow different perspectives when trying to answer the research question. As this research was located in a European healthcare setting not used to the world of research, I used a flexible approach as the context was not always responsive and participants' availability was be limited for various reasons (pandemic restrictions and staff commitments included).

Analysis included also data collected during multidisciplinary implementation meetings, field notes and observations reported in the research diary.

Quantitative data was collected via surveys and data routinely collected as part of the annual performance recorded by the Management and Health Laboratory (MeS) based in the Sant'Anna School of Advanced Studies in Pisa, which was a key collaborator of this study. The analysis of existing service users' surveys gave a useful overview especially for the initial phase of situational analysis in which data collection with service users had to be suspended. However, their voice could still be included via the data collected by the maternity pathways surveys collected by MeSLab (more detail will be given in the paragraph "surveys" below in the chapter).

All data collection activities were conducted by me with occasional support of external supervisor of this study who provided key insight on how to navigate the regional and local system and dynamics. All activities were conducted in Italian. Reflexivity was embedded throughout the research process to navigate power dynamics and the influence of positionality. Notes and reflections were kept in the research diary and reflexivity and positionality were discussed in monthly meetings with supervisors. For this project, working in another country but still being known to the team and aware of many dynamics and relationships, helped facilitating stakeholders' engagement, multidisciplinary collaboration and being both an insider and an outsider to the team.

2.5.1. Interviews

To gain an in-depth view of professional and management perspectives, I planned to combine narrative interviews with semi structured interview techniques.

As the participants of this study were going to be heterogenous and from different backgrounds (from healthcare professionals to service users to managers and organisational level), these different techniques helped to explore a wide range of perspectives amongst them. Narrative technique was used more with service users whilst semi-structured interviews were used more with professionals and managers. However, another reason for choosing one technique instead of the other could be due to a time or context restriction (not enough time or interview guide not available) as per the flexible approach needed for this type of study. Based on the availability of participants, interviews varied in length from a ten minute minimum requirement to over an hour. Sometimes participants expressed their interest in contributing with an interview while they had some spare time on duty so, even if the length of the interview could not be as long as desirable, I thought it would be important to still record and document their contribution after gaining informed consent to participate.

The interview guide was prepared merging the experiences of similar projects which had a similar research focus such as the NICE Birthplace Action study (NIHR Knowledge Mobilisation) in which I worked before as research assistant. A copy of the interview guide is attached in appendix 6. External supervisor offered support in reviewing the guide based on the different stages of the project and ensuring that the questions were suitable for the research design, the context and the type of participants.

The first question would usually be an ice breaker with a word-association exercise. An example of this would be "*could you tell me which is the first word that comes to your mind if I tell you 'midwifery unit'*?". The aim for this is that being the Italian context rich in different preconceptions of these models of care, the exercise gives an interesting understanding of what the predispositions that participants might had towards them.

The following questions would then be more specific to previous experiences of working in a MUs, barriers and facilitators and strategies for the implementation of these models in the local context. The function of these questions were to guide a conversation in a non-restrictive manner so if other relevant and pertinent topics comes up the discussion could be deepened.

The final question was usually related to any additional information or contribution that the participant wants to add related to research project. It would be something like "*Is there anything else*

that you would like to add and that you think would be relevant to the research project?". Closing the interview with an open question as such allows the participants to add any other information which they believed to be missing and it helps the researcher to understand if any adjustment to the interview guide is needed.

2.5.2. Focus groups

Focus group discussions (FG) were also used since the interactions emerging in a group discussion help to generate ideas as member of the group talk and react spontaneously to one another and that represents indispensable data. It is often used for 'action' and 'feminist' research due to its collaborative and participatory nature (Kitzinger, 1994). As it well described and define in the book "*Understanding and using healthcare experiences*" by Ziebland and colleagues, we should not take for granted this nature as focus groups are not immune to power dynamics or ambiguous self-disclosure declarations and, on the contrary, they could impact the participants in a negative way if not guided appropriately (Ziebland *et al.*, 2013). Researchers conducting FG discussions need to be aware of this risk and need to prepare prior to a focus group taking this into consideration.

When facilitating a focus group discussion, I always explained to the participants my outsider/insider position (I am a midwife, I speak Italian like them but I work for an English University and I am not an employee of the hospital) and the lack of conflict of interests (which for the Italian context is always an important acknowledgement to be seen trustworthy).

The interview guide presented in the previous paragraph was used for the focus group as well to have some prompts and a structure to follow in case the group would be not responsive and talkative. If instead the participation and the flow of the conversation happened spontaneously, the questions were only used to steer and guide the conversation when the discussion was going too far. The fluid and dynamic nature of a group discussion was facilitated and explored together with participants.

For the focus groups conducted as part of the Delphi study had a different guide was codesigned with supervisor and I explain more in detail the questions covered in section 5.1.1 of this thesis.

For the focus group discussion with service users, who were not aware of what a MU was, the first minutes of the discussion was left to a brief description of the model of care and the evidence behind them, while for professionals and managers the same questions were used as in the individual interviews (see appendix 6).

Informed consent was always gained prior to starting and the discussion and the focus group was recorded with a voice recorder. An important feature of FG discussion is also that it helps to understand the power dynamics within a group. For this reason, while conducting focus groups, I wrote some comments and notes in my personal notebook to not miss out on signs, body language and behaviour which could help deepen the reflection and analysis of what was being said.

2.5.3. Observation

Observation notes were taken during meetings and events. They were recorded in the research diary and analysed in NVivo 12 with the rest of qualitative data. When a meeting or an event was conducted together with the external supervisor of this project, a reflective session was usually held after and notes about those reflections added in the research diary. This aspect of the research helped me to learn how to navigate the system even in terms of engagement strategies and local politics within different groups.

The research diary was therefore a precious source of data that helped to collate details of how dynamics and events unfolded, especially considering the resistances and the delays due to the pandemic and the hesitance to the implementation.

2.5.4. Routine data

For this PhD project three main official sources of quantitative data were used to observe and monitor the performance of the maternity pathway in the local service:

1. The online and publicly available MesLab platform collecting routine data about the maternity pathway in the project service and to make comparison with the rest of Tuscany or other Regions (https://performance.santannapisa.it/pes/start/start.php). The MesLab platfrom includes indicators calculated using the two main sources: CEDAP (certificate of birth) and the regional administrative data of community healthcare centres. The Certificato di assistenza al parto (CEDAP) is the certificate of each birth and the relative details that all hospitals need to fill, send to the Region and then to the Ministry of Health. The regional administrative data collects data related to all type of access related to antenatal and postnanal care (type of visits, participation in antenatal classes etc.).

2. Local audit and routine data collected by the local team to monitor specific aspects of care.

In the initial plan, quantitative data was going to be used to observe the trend and progress over the course of years to check whether the implementation work affected the services and the care offered to women and their family. This data however was significantly affected by the service configuration changes due to the pandemic and by the delays in implementing the MU. Therefore, it could not be included and considered at the end of this study to the reflection on the impact of this PAR work as those confounding factors would have not allowed a rigorous analysis.

2.5.5. Codesign using a Delphi approach

Following a PAR approach, in this study change was codesigned by the stakeholders with my support as researcher and PAR facilitator. A codesign method was used to lead the creation of the implementation plan that the maternity team wanted for the local hospital. To do so, a Delphi approach was used in which stakeholders were considered "experts" in leading the change and through different rounds of data collection, analysis and synthesis, it was possible to draft an implementation plan and involve the whole team and local population.

A Delphi study involves a group of experts in a discussion about a specific and often complex issue through sequential stages of data collection (also called rounds) to develop consensus among the members. Using this design, a group of individuals can communicate more effectively in an iterative and inclusive discussion (Nasa, Jain and Juneja, 2021). These interactions can be facilitated face to face or online depending on the group members location and it could be anonymised or not depending on the nature of the subject and whether there is a need to avoid bias like dominance or group conformity (Boulkedid *et al.*, 2011; Nasa, Jain and Juneja, 2021). This methodology was first used in the 1950s during the Cold War and it became popular later in other sectors like healthcare especially when there is no data tested or empirical evidence on a specific topic (Dalkey and Helmer, 1963; Nasa, Jain and Juneja, 2021). Few attempts in the past tried to define the quality parameters to conduct and evaluate Delphi studies (Boulkedid *et al.*, 2011; Diamond *et al.*, 2014; Nasa, Jain and Juneja, 2021).

Two examples of the use of Delphi methodology and approach in midwifery are the study about standards for maternity care professionals attending planned upright breech births (Walker, Scamell and Parker, 2016) or the creation of the midwifery unit standards for Europe (Rayment, *et al.*, 2020).

For this project, the choice to adopt a Delphi approach was made to support the participatory aspect of this work and reaching and engaging different stakeholders during an historical time where face to

face research activities had to be suspended due to the Covid 19 pandemic. Using this approach, it was possible to engage them all in the co-production of an implementation plan remotely.

As the rationale for choosing a Delphi approach in this research was for participatory purposes, participants were not assessed for their expertise and instead all members of the team were encouraged to take part, from different disciplines and maternity settings. Furthermore, as the aim was to engage the team in developing an implementation plan, a ranking system for the reduction of the items after each stage was not conducted as all ideas and suggestions were considered valid for discussion. The final survey included all the items ranked in a scale from 1 to 10 to support leaders mapping priorities when putting the plan into practice.

Following this, service users were also included via an online survey co-designed with professionals to engage them with the project, explore their knowledge and perceptions about the innovation and their opinion on the implementation plan drafted by the team.

Using both online focus groups and surveys, it was possible to facilitate remote interactions with stakeholders and to include different levels of detail (focus groups allowed more in-depth discussions while online surveys facilitated wider participation) ensuring anonymous rounds through surveys to avoid potential biases such as dominance or group conformity.

In chapter 5, I present more in detail the steps completed as part of the codesign using Delphi approach to create the implementation plan.

2.5.6. Surveys

Surveys are often used in healthcare research with the aim of measuring social and personal preferences and experiences in order to suggest areas of improvement, to identify gaps in the provision and to promote a transparent culture. With the arrive of EBM and the recognition that patient experience is a fundamental part of healthcare quality, surveys started to play more and more an important role in the performance management of healthcare systems.

In the initial plan for this study, the plan was to engage participants mainly via face-to-face data collection activities to follow the PAR approach and engage participants. However, due to the pandemic and the change of plans mentioned already in the Covid impact statement at the beginning, online surveys played a bigger role than initially planned and became the main research method during the last years of the project.

The Management and Health laboratory, established in 2004 at the Scuola Superiore Sant'Anna of Pisa, measures the capacity of the regional health system, of the health authorities and the district areas to be effective and efficient, in delivering appropriate services in line with the needs of the population. To do so, it regularly submits surveys to patients and professionals in Tuscany and in other 11 Italian regions to then being able to make a comparison, conduct benchmarking activities, celebrate good examples and support lower-performing services.

For this research project, I benefited from this strong collaboration with MeSLab to use some of data that they collect for the maternity pathway in my study area. MesLab collects data from women in Tuscany via surveys before and after pregnancy. Each woman accessing the maternity care services is asked during the booking appointment if she is happy to take part in the evaluation of the service. Surveys are translated in 7 different languages to promote integration and inclusivity when collecting feedback from different communities in the region. If the woman agrees she will be contacted via email and via hAPPyMamma (online App dedicated to the maternity service which every service user could download on the phone) at 8 different stages of the maternity journey unless there is a change of clinical conditions (for example miscarriage or preterm birth) or if she decides to drop out. In each survey the woman is asked to answer to 15-20 multiple choice questions about the overall health

condition and her experience of the pregnancy care (see table 3). She will also have the possibility to add free text comments for some questions.

Table 3 Systematic surveys to maternity service users in Tuscany collected by MesLab

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RILEVAZIONE SISTEMATICA DELLA SODDISFAZIONE, DELL'ESPERIENZA E DEGLI ESITI RIPORTATI DAI *PAZIENTI NELLA SANITA' TOSCANA by MeS Laboratory*

SYSTEMATIC DETECTION OF SATISFACTION, EXPERIENCE AND OUTCOMES REPORTED BY SERVICE USERS IN TUSCAN HEALTHCARE by MeS Laboratory

All service users eligible to receive a booking appointment are asked if they would like to take part in these surveys. Informed consents and surveys are in 7 different languages (the most spoken in Tuscany) to increase and ensure a high level of inclusivity. Throughout the pathway, women receive specific questionnaires based on the experience they report (for example in case of a premature birth they will receive specific surveys accordingly and the questions will be related to that experience).

There are 8 surveys in different moments of the pathway:

1. After the booking appointment (T0g)
2. In the second trimester (T2g)
3. In the third trimester (T3g)
4. Around the expected due date (in case they have not given birth yet they are asked some questions about the end of pregnancy and then asked to finish it in a week time) (T0p)
5. After a month from birth (T1p)
6. After 3 months from birth (T3p)
7. After 6 months from birth (T6p)

Service users' survey contribution was initially included via the pre-existing MesLab surveys (**secondary** source of data) and later via an online survey co-created with the maternity team to gain feedback on the implementation plan and views on the MU innovation (**primary** source of data).

The platform used to design, distribute and collect data via online survey for the Delphi and the service users survey was Qualtrics as main survey software available at City, University of London. The survey was distributed via email invitation and participants could only access the survey via the unique link included in the email. The answers were anonymised by the software who allocated an ID for each email address in the list. The survey was left open for few weeks (depending on the project timeline it was usually 3-4 weeks) and regular reminders were sent to increase participation. An estimated time of completion was given as the beginning to help participants planning the right time to complete it and it was also clearly explained (both in the email text and in the first landing page of the survey) that once the survey was initiated it could only be continued if opened in the same browser and from the same device.

2.6. Reflexivity and positionality

Since being an action researcher can present ethical challenges, a reflective diary has been used for the duration of the project to reflect my role and ensure sufficient reflexivity.

To understand better my role as researcher and my position in this project it is important to have some background information and to reflect on how this role has changed throughout the past years.

During my BSc studies at the University of Siena back in 2010-13, I had the opportunity to choose each year to spend 3 months in a different hospital of the southern part of Tuscany. This is when for the first time I worked with the local maternity team in my hometown. I was a young midwifery student doing my placement for learning about clinical practice. It was an intensive placement and I remember working full-time hours during the summer months on top of my exams. During the time there I had the chance to really build some good relationship with the team, to observe different ways of working and to collaborate with different midwives and doctors.

Following the BSc, as there were not many job opportunities, I decided to invest my time in studying more and doing a Master programme at the University of Florence and when it came to decide a location in Tuscany for a sonography placement, I chose the hospital of my hometown again. This is when I got to meet the Fetal Medicine team and the lead obstetrician Dr Colosi who the became supervisor of my MSc thesis.

After completing the Master programme, I moved to the UK to do an experience abroad and to learn more about the healthcare system and the midwifery model here. As I explained in the introduction of this thesis, I kept visiting the maternity team in my hometown during my annual leave back home and this is how this collaboration continued growing.

The transition of my role went from the stage in which I was a final-year midwifery student, to a postgraduate internee to then an ex-patriated colleague who worked in London. In the following years, I was given by Dr Colosi the possibility to present during conferences and seminars the English maternity model of care and the research that I was involved in at City, University of London. The team there started seeing me with another hat of research midwife and contacted me on few occasions asking for material and resources of the most up to date studies in the field.

Dr Colosi kept on moving forward the idea of a midwifery unit project with the organisational and regional level leading the way in a very effective and convincing way. He always referred to me as a 'colleague working in the UK' in a completely respectful and equal relationship. For the Italian context,

this was unusual as the healthcare system (and the society) tends to have very strong hierarchical power dynamics. This will be discussed further in the discussion chapter (chapter 7).

In 2017 together with Dr Lucia Rocca-Ihenacho researcher from City, University of London we ran two sessions of two-day interdisciplinary workshops with midwives, obstetricians and paediatricians in Tuscany. These workshops were perceived positively and enthusiastically by the team there and this contributed to consolidate my role as midwife and researcher with special interests in MUs with them.

This is how my position was perceived when I first started this research project with the advantages of being somehow both an **outsider** and an **insider**. Working in another country but still being known to the team and aware of many dynamics and relationships, has helped facilitating the engagement of stakeholders and the multidisciplinary collaboration.

During the past year, with the new hat of PhD student dedicated full time to this research project, more variations occurred in how my role was perceived by the local team and writing a research diary has helped to keep track of those changes and how power dynamics were involved. I discuss these changes again in chapter 6 and 7 of this thesis.

Reflections on my role, the factors affecting it and any adjustment required are always topic of the supervision's agendas and having a local supervisor helped ensuring positionality in respect to my role.

2.7. Ethical considerations

During data collection activities I anticipated the possibility to find myself in uncomfortable situations in which I could struggle for some ethical issues. My clinical background gives me a better knowledge and understanding of what the evidence-based practice is and which on the other hand are unnecessary (and sometimes harmful) intervention. The Italian maternity system unfortunately is not immune to this unnecessary and inappropriate use of interventions in clinical practice.

Experiencing or witnessing the use of non-evidence-based practice could put my role as researcher in the uncomfortable position in which I would have to reflect and decide whether it would be fair and correct to speak out and confront the local team of professionals or not. Which would be the best thing to do when experiencing something like that? Being coherent and honest with the professional midwife in me, which tells me to confront them and address the problem, or sticking with the researcher role and being the "*eyes and ears*", which only need to observe and study the phenomenon? This topic has been discussed thoroughly and in frequent occasions with supervisors

who have been very helpful in showing me how all my background facets could be valuable when conducting this type of projects and attempting to research and read an implementation phenomenon. As this is participatory research, the collaborative nature of it cannot be neglected or taken for granted. If by confronting professionals or managers, there is the risk to undermine the research role and my position as researcher and facilitator, then this should be avoided and saved for the analysis and dissemination of the findings.

When preparing the research protocol, supervisors and I also reflected on the possibility that some participants during interviews and FGs could accuse or blame other colleagues or that some service users could complain about previous personal experiences. In the past, when conducting FGs with professionals, I had the opportunity to see how sometimes they become eager to discuss topics like personal experiences, non-evidence-based practices, mistakes and other topics not strictly pertinent or relevant for the research project.

The resulting decision was that if participants disclosed information about malpractice, mistakes or problems within the team, this would be reported to the local leadership in an anonymous fashion in order to address and to deal with the issue internally. PAR and implementation research may expose the researcher to this information, but the management of the problem should always be left to the local team to avoid interference in my role of *outsider*.

2.8. Data management

All data collected were anonymised and each participant given a secure code for identification which is used for all subsequent data activity including details like type of stakeholders (service users, manager or professional) and type of profession (midwife, obstetrician, neonatologist or other).

Only supervisors and I had access to identifiable information and the excel file with the demographic details and the secure code for each participant is safely saved on a OneDrive connected to the password-protected City email address. Backup of the folder were carried out monthly. A second copy is saved in a password protected folder on the researcher's encrypted hard disk. During travels to and back from Italy, the hard drive was left safely in London and I was able to access data and files via the online OneDrive platform. This reduced the risk to lose any important file or confidential data collected.

Interviews and focus group data were digitally recorded always after having gained informed consent by participants. Files are labelled according to data and type of research activity. A separate excel document was kept recording all research activities and the participants involved in those using the secure code assigned.

2.9. Data analysis

As mentioned in the previous chapter, the TMF used to guide the analysis was the CFIR framework (Damschroder *et al.*, 2009). A CFIR NVivo project template for implementation studies has been requested to the Official CFIR website (https://cfirguidetemp.blog) and has been downloaded on the PhD Nvivo project. This template has all the constructs of the CFIR framework and helps for coding the data collected. As the template was very detailed, some parts were used more than others based on the type of data and on the stage of the research project. The plan was in fact to use the CFIR as a guide in a flexible way and not as the only lens to read the data; it is important to maintain a reflective and critical approach to integrate new themes or categories which could become more emergent or predominant in this research.

As already anticipated, different research methods were used at each stage of this study. Each chapter reporting the study findings begins with a more detailed paragraph on the data collection and analysis method used, a presentation of findings and a discussion section. Finally, the integration of the analysis from different data sources will be presented in chapter 7 during the overall discussion of findings using the critical realist framework.

Data triangulation was used in this study to increase completeness of data and validity of findings (Robson, 2011). The choice of using different research methods was made in line with PAR approach and with the intent to gather data from different sources and in different forms. This helps to avoid findings being influenced by the way they were collected or interpreted. Furthermore, having different stakeholders included in this study from clinicians to managers to service users, helped to increase the validity of some findings when there was agreement across them.

2.10. Conclusions

After a long time spent reading previous similar and relevant work to the research question identified for this study, I made key decisions which shaped the way I approached and studied this research topic.

Critical realism seemed the most appropriate theory to study a multi-layered change process like the one identified for this study. Its layered vision of the world including the reflection of pre-existing and hidden dynamics suited this case study and helped to gain a deeper understanding of the process.

The decision to use two TMFs to guide the codesign work and the analysis of findings helped to receive different support from existing validated tools. The T-Cast tool allowed me to make a rigorous decision across different TMFs options that I had.

The inclusion of different research methods was perceived as the best way to guide the participatory research and to help with validity of findings. Some adjustment had to be made along the study due to the pandemic, but all methods were coherent with a PAR approach.

In the next chapter, I will present the first step of this research journey which helped to synthetise existing work and lessons from the wider literature: the systematic review.

Chapter 3 – Systematic review

Introduction to the chapter

As discussed in the first chapter, MUs have a demonstrated association with good perinatal (maternal and infant) outcomes, service users' and professionals' satisfaction and cost-effectiveness but they do not represent the mainstream option of maternity care in many countries internationally (Hollowell *et al.*, 2011). Understanding which are the effective strategies when trying to integrate this model of care into obstetrically led services could support and inform the implementation process that many countries still need to approach and face.

The main focus of this review was to research and synthesize the existing knowledge on how to support the implementation of new MUs internationally. The aims of the review were to contribute to addressing the evidence to practice gap and to learn from existing evidence on how to support this change in the real world, to inform and underpin the participatory-action-research process in this research study and to inform the analysis of the empirical study findings.

This review has two main features: one is its specificity in discussing aspects relevant just for MUs model of care and second is that it aims to cover just characteristics and features of an implementation nature and so not related to clinical outcomes but to strategies relevant for the adoption, sustainability and scalability of these primary care centres internationally.

When first started this review, I was not expecting to find many papers and primary research which could answer the review's research question and that it may be necessary to "dig out" knowledge from studies which have different primary aims but cover aspects related to implementation outcomes. The challenges in systematic searching and screening for a review of this type, and the solutions identified will be described in this chapter. First, the formulation of the research question is outlined. The following section describes the scoping search conducted prior starting the systematic review to inform the research strategy and to refine the inclusion and exclusion criteria. Finally, the systematic review process and findings are set out.

Considering that this work was conducted with the support of a research team made of more senior supervisors and other international researchers, I will often use the pronoun "we" when describing the decision-making process as it was a team decision and not my only work, even though I took the lead role in conducting the review.

3.1.   Research question

One of the biggest challenges about conducting this review was trying to find the precise focus for the research question.

There was a clear understanding amongst the research team and supervisors that implementation research is relatively under-developed and under-used in midwifery and obstetrics to support change in clinical practice. Research is often focused on validating existing or new practices or models of care more than understanding how to promote the already validated evidence in current maternity services internationally.

The process that led to the current research question felt somehow like trying to adjust the zoom of a camera (and not a digital one). Together with supervisors, we identified a phenomenon of interest in the real world which needed to be studied in order to synthesise the existing knowledge and, like with a camera, attempted to adapt the focus and zoom in the best way in the attempt to take a clear picture of the state of the art at present.

A scoping search was conducted initially, to gain an insight of the existing studies conducted on this specific topic. It helped to identify the primary research articles and the research gaps in the existing literature and to guide the formulation of the eventual search strategy.

The research question for the scoping search was:

Which are the effective strategies for implementing midwifery units?

3.2.   The scoping search

The reasons for conducting a scoping search were the following:

- To check whether there was any previous literature review on this topic that supervisors and I were not aware of and, in case there were, whether it would be possible to update them with most recent research;
- To establish whether there was enough literature available on this topic to justify a systematic review and meta-synthesis or whether the research question needed to be broader or narrower;
- To understand what kind of search strategies and search terms had been used so far for this topic or for similar ones.

Two main concepts were identified to prepare a research strategy and appropriate search terms: one for midwifery units and one for implementation aspects.

Since that there are many different names used to refer to midwifery units internationally, we started by using terms identified from a previous literature review conducted by the team in 2018 to underpin development of Midwifery Unit Standards for Europe (Rayment, *et al.*, 2020) with the intention to add any others which were found via the scoping search, to use in our subsequent systematic search.

At this stage, considering that we were not expecting to find many papers on implementation of MUs specifically, we decided to broaden the search strategy to include any relevant study about implementation of midwifery-led models of care. Therefore, the search terms identified were not just limited to MUs but included terms like "midwifery care" and "midwifery". Our aim was to identify any relevant implementation research studies in the field of midwifery which could had supported the creation of a research protocol and validating the search terms to be used for this systematic review.

For the terms related to implementation we searched into previous literature reviews on implementation outcomes (Proctor *et al.*, 2011; Lewis *et al.*, 2015).

The resulting search strings were:

Table 4 Scoping search terms

Search terms:	Search string
Midwifery units	midwifery-led or midwifery units or midwifery or midwifery care or midwif* or "birth centre" or midwife-managed or birthplace or "birth place" or "birth setting" or "place of birth"
Implementation	Implementation or "implementation science" or "service improvement" or "organisational readiness" or organisation or development or "scale-up" or "scale up" or uptake or provision or acceptability or adoption or feasibility or sustainability or fidelity or facilitators or barriers or "influencing factors" or "factors influencing" or "knowledge translation" or "knowledge transfer" or "research translation" or "research transfer" or "knowledge broker" or "evidence based implementation"

We searched the following databases: Ebsco (Medline, Cinahl, SocINDEX), Ovid (Embase, Midirs, Global health) and Scopus. In April 2019 the search was run with the following results:

- Ebsco Medline (159)
- Ebsco Cinahl (231)
- SocINDEX (12)
- Ovid- Embase, Midirs, Global health (469)

A total of 871 papers were identified and imported into ProQuest Refworks. After de-duplication, only 745 were left and imported to EppiReviewer to conduct the screening by title. Based on screening by title, the 745 articles were divided in three folders: relevant (75), not relevant (554) and maybe relevant but needing a full-text screening prior to decision (116). The papers were then reviewed with supervisors to agree on a final search strategy for the systematic review.

3.2.1. Reflections from the scoping search

After this initial scoping search, we were able to address some key considerations for the systematic review protocol and search strategy. As it is a very specific and niche field of research, questions regarding inclusion and exclusion criteria were discussed collaboratively and regularly in supervision meetings with more expert members of the team. Firstly, using search terms such as "midwifery", "midwifery care" and "midwifery-led" we found many studies not relevant to the research question as they were related to any aspect of the discipline, such as implementation of smoking cessation clinical programmes, VBAC (vaginal birth after caesarean section) pathways of care, educational programmes for student midwives, implementation of continuity of care models. For this reason and because we found more papers than expected, it was agreed to narrow the search down to include just search terms related to implementation of MUs. When conducting the screening via full text of the articles we encountered some difficulties trying to set up the right level of specificity. As mentioned above, this process has been like adjusting a zoom in a camera to observe the phenomenon of interest with the right level of focus. We initially thought to include any article which would have some relevant information about what is seems to be an enabler or a barrier when implementing new MUs or improving the performance of existing ones. We then realised that this would have meant adjusting the search strategy in order to include any element, key ingredient or quality standard about well performing MUs and we concluded that this work had already been covered on a certain level by the previous work on the Midwifery Unit Standards (Rocca-Ihenacho *et al.*, 2018). This review wanted to be more specific on the strategies that allow stakeholders internationally to open new MUs and not on describing any element associated with a good (or bad) standard of care in the MU.

At this point, it was evident that there were two layers of interest: one more focused on the process and strategies adopted to support the process of opening new MU and other more focused on supporting the uptake of existing MUs. Consequently, we defined these in terms of two different levels of action: **implementation** and **improvement** and maintained a focus on implementation. If we look in the British dictionary the two terms are defined as follows:

Implementation = the act of making something that has been officially decided start to happen or be used

Improvement = the act of making something better; the process of something becoming better

(Oxford University Press website, 2020)

Although these terms are often used interchangeably in implementation research, it may be important to distinguish between starting or adopting something new and the act of making something that already exists better performing, which may involve a more iterative process like an augmentation of a process which is already ongoing.

In previous implementation research, reports such as "The spread challenge" by Tim Horton and colleagues (2018) the difference between innovation and improvement have been explained in this way: "*Improvement, including formal quality improvement (QI) using a structured method, is often used to describe incremental change within an existing service model, whereas innovation can be used to mean disruptive change that creates a new service model*" (Horton, Illingworth and Warburton, 2018)*.*

For the purpose of this PhD study, we agreed to keep the focus on the process of implementation rather than improvement: adopting an innovation like MU care model as this was most relevant to the focus of the planned empirical study. In addition, some relevant aspects which could help and support the improvement of existing MUs were investigated for the development of the Midwifery Unit Standards and the research team therefore considered that the research gap which needed more attention was that related to establishing new MUs (Rocca-Ihenacho *et al.*, 2018).

Finally, although contexts are likely to vary, we considered that potentially lessons about implementation could be drawn from a range of different backgrounds and therefore we agreed not to exclude papers just on the base of the country where the research was conducted.

3.3.   The new research question

The research question was refined in view of the findings of the scoping search and the reflections set out in the previous paragraph. We aimed to develop a comprehensive overview and synthesis of organisational, professional and cultural factors and strategies which have been found to influence positively or negatively the process of establishing new MUs in any international context.

To structure the search process, a modified version of PICo for non-interventional and qualitative systematic research was used: 'P' represents the phenomenon, 'I' the field of interest and 'Co' the context (The Joanna Briggs Institute, 2014). In those guidelines, the authors do not recommend stating a specific outcome statement for qualitative 'meta-aggregation', as the outcome is represented by the expression of the phenomenon of interest.

So, the research question agreed and refined after the scoping search and the quality assessment of the primary studies was:

> *"What are the strategies used for implementing new midwifery units internationally?"*

3.4.   Methods

This review was registered on the International Prospective Register of Systematic Reviews (PROSPERO) on the 18th of October of 2019 with registration number: CRD42019141443. Some amendments (based on the edits made after the scoping search) were submitted in March 2020 and accepted on the 17th of April 2020.

To conduct the search and screening, the PRISMA guidelines (Preferred Reporting Items for Systematic reviews and Meta-Analyses) were used (Moher *et al.*, 2009). These guidelines were established to improve the reporting of systematic reviews and meta-analyses.

In order to decide what type of methodology to use for the analysis systematic review, the "*Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex interventions*" was used (Booth *et al.*, 2016). This helped taking into consideration the following points for each type of methodology: type of review question, epistemology, timeframe, resources and team expertise. A decision was made to use the thematic synthesis method by Thomas & Harden (2008) as found to be most suitable for this specific review project (Thomas and Harden, 2008).

After the scoping search the research team and supervisors agreed on the following inclusion and exclusion criteria (table 5).

Table 5 Inclusion and exclusion criteria

	Inclusion	*Exclusion*
Participants	All stakeholders involved in implementing midwifery units: maternity teams, health institutions, professionals, service users	Models of care not specific to midwifery, birth settings managed or led by obstetricians or other healthcare professionals other than midwives, home births
Phenomenon of interest	The process of implementation of a new MU which could be successful or not. For successful implementation we mean the establishment of a new MU after a process of change in the maternity care setting.	Focus on improvements of existing MUs Focus just on clinical outcomes or technical quality of care. Focus on specific issue (e.g. smoking cessation, vaginal birth after caesarean - VBAC).
Outcomes	Implementation outcomes like acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability.	No focus or substantial data on questions relating to implementation, sustaining and uptake or scaling up.
Study design	All designs including action research, grounded theory, ethnography, mixed methods studies that include qualitative data collection and analysis.	No restrictions on the types of study design were applied.
Study focus	Studies will need to cover aspects related to implementation outcomes in the data collection and analysis with particular attention to any relevant aspect or strategy related to the establishment of a new MU.	Clinical or technical quality of care. Focus on specific health issue (e.g. smoking cessation, VBAC).
Setting	Both alongside (AMU) and freestanding (FMU) midwifery units. Birthing rooms physically/organisationally separated by the main OU. Maternity systems willing to/in the process of implementing a new MU. Private and public services All countries	None
Time period	No time restriction	
Language	English, Italian, Dutch, Portuguese, Spanish, French	Other languages that the team would not be able to translate adequately.
Publication type	Peer reviewed articles Dissertation and theses Research reports	Any piece of research which cannot be peer reviewed by the research team (books, opinion pieces, commentaries, diaries etc.)

Systematic search and screening

The systematic search was conducted between December 2020 and April 2021. Databases used for this review were: Ebsco Databases (Medline, CINAHL, SocINDEX), Ovid databases (Embase, Global Health, Maternity and Infant Care MIDIRS, Ovid Nursing, Ovid Emcare), Scopus and NICE database. Grey literature was searched via OpenGrey, Google Scholar and ProQuest Dissertation and Theses.

The search strategy was adjusted in view of the findings and reflections of the scoping search. The final strategy applied to each database is reported in table 6.

Table 6 Search strategy modified the terms to narrow the search

Search terms:	Order	Search strings
Implementation	1	Mesh terms for implementation
	2	Keyword search: implementation OR implement* OR "knowledge translation" OR innovation OR utili#ation OR "scale up" OR feasab* OR sustainab* OR "service improvement" OR barrier* OR facilitator* OR enabler* OR adopt* OR diffusion OR establish* OR open* OR transition OR provision OR embed* OR integrat* OR planning OR preparation OR "implement* strategy*" OR promot*
	3	1 OR 2
Midwifery units	4	Mesh terms for midwifery units
	5	Keyword search: "midwifery unit" OR "midwi* led birth* cent*" OR "birth* unit" OR "birth* cent*" OR "birth setting" OR "low risk birth* cent*" or "midwi* unit" OR "midwi* led unit" OR "low-risk birth* room*" or "midwife-led room*" OR "midwi* cent*" OR "low-risk birth* cent*" OR "homely birthplace" OR "homely birth place" OR "homely birth* room*" OR "normal birth* unit"
	6	4 OR 5
Full search	7	3 AND 6

Screening process

After the systematic search in the above-mentioned databases, a total of 1037 articles were identified through database searching. Some key relevant articles identified by both the research team and supervisors prior to the search were added to the database and citation track referencing was conducted to identify any possible additional relevant papers (see PRISMA flowchart in figure 14 next page). All the articles were imported into ProQuest Refworks to delete all duplicates s. After de-

duplication a total of 691 papers were saved and divided in three sub-folders so that the researchers could run a screening by title and abstract for relevance and against pre-determined inclusion and exclusion criteria. Support from two co-researchers was sought to help the screening process. Each researcher screened 230 articles and allocated them into relevant, non-relevant, maybe relevant folders. The team met twice to discuss the "maybe relevant" folders and to reach an agreement. Any cases where agreement could not be reached were discussed with the first supervisor of this PhD project. This process was then replicated by reading full texts of all articles selected as potentially relevant. The research team used a screening form with all inclusion and exclusion criteria to ensure consistency for the screening process. A record in an Excel document was kept of decisions made about the inclusion or exclusion and the selection process was reported using PRISMA (Moher *et al.*, 2009) and a flow chart was made to show the study selection process (figure 14).

Figure 13 Screening process using PRISMA flowchart
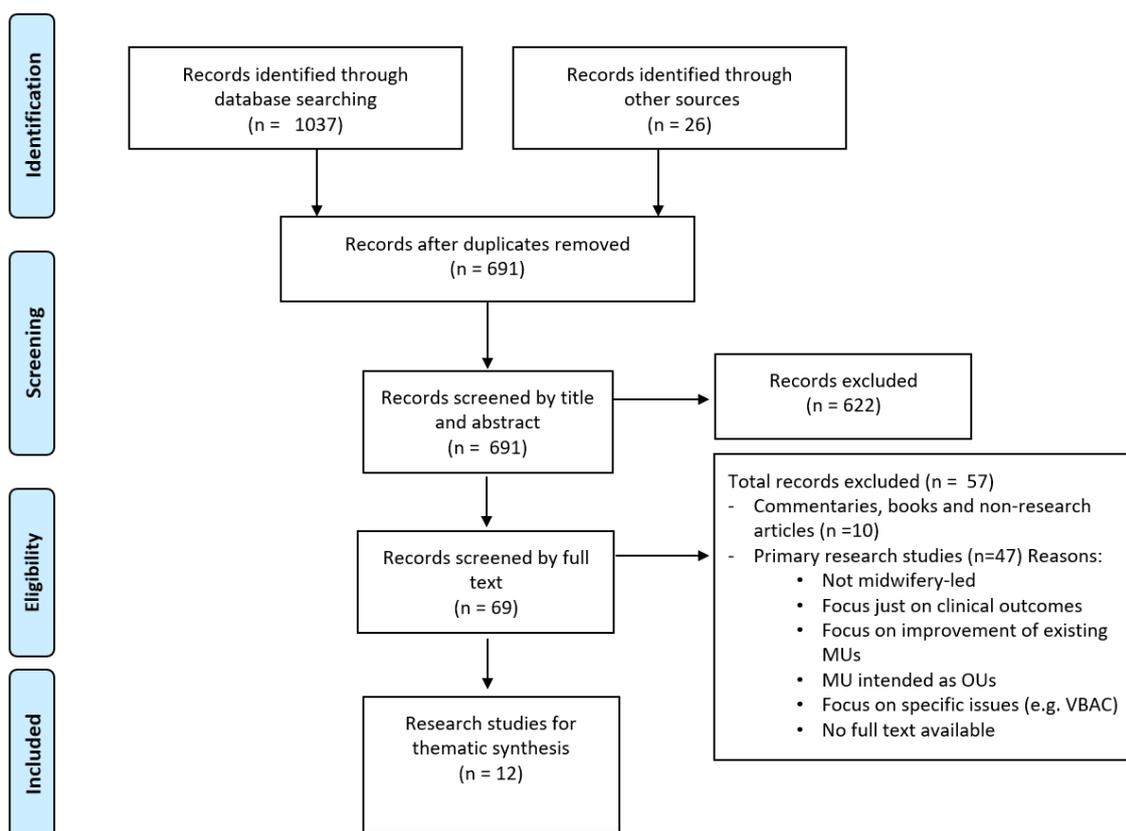
Quality Appraisal

A summary table with details for each study was created in Microsoft Excel including authors, publication year, location, design, sample, methods described and key findings.

The research team used the CASP Critical Appraisal Skills Programme tool to ensure that all studies were critically appraised in a standardized way (Moher *et al.*, 2009).

This appraisal was carried out by two independent reviewers and any differences at any stage were discussed with a third party (supervisor). A simple scoring system was added to this process to assist in summarising quality level. Each study was rated zero or one for each item of the CASP question if it was fulfilling the requirement or not (1=yes, 0=no). Every time that the score was "0" the reason for that score was reported. The sum of all CASP questions constitutes the quality score of the study (1 to 10).

After having conducted a scoping search, the research team decided not to exclude studies just because they scored lower than others while using the Critical Appraisal Skills Programme (CASP) tool, but to review and assess any piece of research with the potential to answer the research question or to add any relevant findings of insights to this review (Critical Appraisal Skills Programme, 2014). In order to give the right importance and relevance to different types or research, a qualitative sensitivity analysis was also performed to clarify the contribution of lower or higher quality studies to the synthesis (Thomas and Harden, 2008).

Data extraction and synthesis

As stated above, the research team anticipated heterogeneity in the types of studies which were retrieved during the search, and their quality. For this reason, thematic synthesis as described by Thomas and Harden in 2008 was chosen as the most appropriate method to analyse the findings of this search (Thomas and Harden, 2008). This method was developed to address review questions which were more focused on need, acceptability and appropriateness of intervention, which suits well the aims and nature of the review question of this research (Thomas and Harden, 2008; Ring, Jepson and Ritchie, 2011).

Articles were imported into NVivo 12 software for data analysis. Data synthesis was conducted of the abstract, findings and discussion sections using Thomas and Harden's (2008) approach in three stages as follows:

- Findings of the studies were coded line-by-line according to content and meaning

- Free codes were organised into descriptive themes still remaining close to the initial findings

- Analytical themes were then developed to answer the review questions

The team used standards described in the PRISMA statement on reporting of systematic reviews to write this structured report (Moher *et al.*, 2009). The aim of the report will be to critically explore all relevant aspects found through the synthesis to address the research question and to develop a comprehensive overview and synthesis of organisational, professional and cultural factors that have been found to influence the implementation of midwifery units.

Search results

The studies selected were conducted in England, Brazil, China, Canada, Iran and United States (US). Seven studies were published between 2010 and 2020 when more substantial evidence on outcomes of MUs was available, five studies took place between 1991 and 2010. Healthcare systems in different contexts and time varied quite significantly amongst the studies. A public system with universal coverage was present in countries like England and Canada whilst a mixed system with public governmental system, private sector, and NGOs was present in Brazil and China, Iran, and US.

Some studies were not purely focused on the implementation process of a new MU but had wider aims such as mapping MUs nationally or investigating how AMUs were organised (McCourt *et al.*, 2014; Moudi *et al.*, 2014; McCourt *et al.*, 2018b; Walsh *et al.*, 2018). However, the team could identify interesting and relevant aspects related to implementation of new MUs in these studies and therefore included these aspects in the analysis. Considering that a thematic synthesis of findings was conducted, studies with less content related to the implementation of MUs ended up having less codes than the ones more focused on implementation aspect (e.g. Walsh et al. 2020). This meant a smaller but still relevant contribution to the analysis.

This review aimed to analyse quantitative and qualitative data; however only three studies included a quantitative component in their research design (Walton, Yiannousiz and Gatsby, 2005; Moudi *et al.*, 2014; Walsh *et al.*, 2018). Two of them (Walton, Yiannousiz and Gatsby, 2005; Moudi *et al.*, 2014) used

quantitative data to describe the use of the MU after implementation (i.e. number of births per year) and not the implementation process therefore they were not relevant to the aim of this review. The last one, by Walsh et al. (2018), described the change of the maternity service configuration after the Birthplace study in England and the impact that this had in the adoption of MUs there. Since 2011 and the publication of the NICE guideline 2014 which were recommending for the first time the option of giving birth in a MU to all women with an uncomplicated pregnancy, the number of AMUs increased from 53 to 97 and the FMUs from 58 to 61. The number of Trusts (organisational units within the English National Health Service) without a MU significantly decreased from 75 to 32.

Midwifery was less regulated and less autonomous in countries like China, US and partially in Brazil with higher level of autonomy reported in England and Canada. No information on the status of midwifery was available in the Iranian study (Moudi *et al.*, 2014).

There was variability of the MU model of care between different countries. The common characteristics across all sites were: an intrapartum unit (within the OU, alongside or freestanding but always physically separated from the main OU rooms) staffed by midwives (hospital or community midwives) who worked autonomously providing a midwife-led primary level of care and referring service users to the secondary level of care (in situ or via transfer) when needed.

In most of the studies, participants were mainly professionals, managers and commissioners. Service users were included just in four studies and three of these were based in England.

Table 7 presents the characteristics of the selected studies.

Table 7 Characteristics of included studies

N	AUTHOR, YEAR	COUNTRY	STUDY AIMS	DESIGN	PARTICIPANTS	SETTING AND DATA COLLECTED	FINDINGS	QUALITY
1A	Cheung NF et al. 2009	China	To describe the preparations for setting up a midwife-led normal birth unit which was based on literature and practice review	Action research with a five steps cycle plus a literature review	8 midwifery team leaders 5 researchers	A highly medicalised maternity department in a Chinese hospital with annual birth rate of over a 3000. The MU was allocated two birthing rooms. The researchers analysed data from meetings, field notes and midwifery training course.	The findings are divided into seven sections: definition, negotiations, accommodation, specific practices, the philosophy of the homely birthplace, policy development, and developing local solutions for local aspirations.	8
1B	Mander R et al. 2009	China	To explore issues arising during preliminary stages of the action research project to consider the feasibility and the effects of a MU on midwives and women.	Action research using a qualitative descriptive approach	Non-defined number of stakeholders including midwifery staff, managers, university staff and researchers.	(*same setting as above*) Data were collected at meetings, by non-participant observation and by face-to-face semi-structured interviews.	MU care may be feasible after the analysis of the early stages of implementation.	8
2	Mackey MC et al. 1991	US	To report on how the idea of nurse-midwife managed? birthing rooms was initiated by nurses and the 8 strategies that led to the implementation of it.	Structured interviews	4 registered nurses with Master's degree	Four private hospitals located in the Chicago area. One-hour in-depth interviews.	Eight strategies to be used jointly to open new birthing rooms by nurses' midwives	7
3	Moudi Z et al. 2013	Iran	To assess 10 years of experience of the first Safe Delivery Posts (SDPs) established in Zahedan, Iran and to examine the reasons why women chose to give birth there. The SDPs were run by midwives.	A mixed-methods research	19 service users in the postnatal period	The two SDPs in Zahedan, the most populous city in the province. Women were selected from two Safe Delivery Posts in Zahedan city in southeast Iran.	Implementing a model of midwifery care that offers the benefits of modern medical care and meets the needs of the local population is feasible and sustainable. This model of care reduces the cost of giving birth and ensures equitable access to care among vulnerable groups in Zahedan.	9
4A	Pereira AL and Moura MA 2009	Brazil	To identify the determinants of the process of implementing the Birth Center and analyse the influence that hegemonic and counter-hegemonic groups have on that process	Dialectic qualitative research	4 commissioners 11 technical administrative professionals	Casa de Parto in Rio de Janeiro. Individual semi-structured interviews.	During the establishment process, conservative and transformative forces of the hegemonic childbirth care model clashed in the governmental and civil spheres. Legal and political dispute in the	7

						establishment process of the Casa de Parto highlighted the importance of organized social movements, especially the women's movement.	
4B	Progianti JM et al. 2013	Brazil	To discuss how the Brazilian nurse midwives trained in the Japanese birthing centres helped to implement the FMU in Brazil.	Socio-historical study with qualitative approach	1 Director of nursing 1 Nurse midwife 1 Physician 1 Former nursing director	Casa de Parto in Rio De Janeiro. Written and oral documents. Semi-structured interviews and report of the exchange experience. Data triangulation with policy and background documents.	The exchange programme enabled the Brazilian midwives to implement the first MU in Rio de Janeiro and added a larger volume of capital to their professional habitus.	9
5	Reszel J et al. 2018	Canada	To obtain the perspectives of health care providers and managerial staff about the integration of the new FMUs one year after implementation	Qualitative descriptive approach	24 amongst professionals (18) and managerial staff (6)	Ontario where homebirth and birth in OU were the only two birth settings for women prior the implementation of the two FMUs. Data was collected via 4 focus groups and 1 interview.	The collaborative approach for the planning and implementation of the MUs was a key factor in the successful integration and the positive experience of service users.	10
6	Walton et al. 2005	England	To explore organisational factors, midwives role, barriers and facilitators of the change process and training needs for midwives	Action research	Non-defined number of stakeholders including midwives, managers and medical staff.	Inner London teaching hospital that take care of over 4400 women a year. Data from meetings, educational workshops, feedback forms and audit of the 2 birthing rooms	The lack of support from medical staff, the conflicting priorities and the dominance of the medical model of care made the project not feasible and the team abandoned the idea of the MU after this pilot.	6
7A	McCourt et al. 2014	England	To investigate how AMUs are organised, staffed and managed, the experiences of women, and maternity staff including those who work in AMUs and in adjacent obstetric units. Some MUs were already established, other just recently being implemented.	Organisational ethnography approach	35 managers and key stakeholders 54 professionals 47 service users	Case studies of 4 AMUs in England, selected for maximum variation based on geographical context, length of establishment, size of unit, leadership and physical design. Observations, semi-structured interviews and documentary review were conducted.	Development of AMUs was often opportunistic. Key potential challenges included: boundary work and management; professional issues; developing appropriate staffing models and relationships; midwives' skills and confidence; and information and access for women.	10
7B	McCourt et al. 2018	England	(same as above)	(same as above)	(same as above)	(same as above)	Same as 7A but with a different level of detail and useful discussion years after the original study.	10

8	Walsh et al. 2018	England	To describe the configuration of midwifery units, both alongside & freestanding, and obstetric units in England	National survey	Heads of Midwifery in English Maternity Services	National Health Service (NHS) in England. Descriptive statistics of AMUs, FMUs and OUs and their annual births/year in English Maternity Services	Number of MUs and births in MUs in England increased after the publication of NICE guidelines (mostly AMUs). Significant difference in terms of utilisation of the MU and this suggest that some are underutilised.	10
9	Walsh et al. 2020	England	To identify factors influencing the provision, utilisation and sustainability of MUs in England	Qualitative study	57 Obstetric, midwifery and neonatal clinical leaders, managers, service user representatives and commissioners 60 midwives 52 service users	Setting England. Data collected: first, MU access and utilisation across England was mapped; second, local media coverage of the closure of free-standing midwifery units (FMUs) were analysed; third, case studies were undertaken in six sites to explore the barriers and facilitators that have an impact on the development of MUs; and fourth, by convening a stakeholder workshop.	Most managers and clinicians did not regard their MU provision as being as important as their OU. The analysis illuminates how implementation of complex interventions in health services is influenced by a range of factors including the medicalisation of childbirth, perceived financial constraints, lack of leadership and institutional norms protecting the status quo.	10

3.5.   Synthesis findings

The coding in the descriptive analysis highlighted a predominance of data regarding the organisational level followed by the professional level and relatively little on the cultural level. Nodes deriving from the contributions of service users were only a minor part. This first visual finding mirrored the participants' distribution. In fact, having the service users' perspective just in four studies out of twelve meant this data mainly focused on aspects related to the organisational and professional levels. Similarly, few studies focused explicitly on macro-level influences such as wider culture and social influences, policies or healthcare systems structures. This finding suggests that service-users were often not actively involved in the implementation of these units and so were not actively included in the studies or at the centre of the implementation work.

The discussion of the synthesis is presented as follows:

- **Drivers to open the MU**, main reasons that motivated stakeholders to approach the change;
- **Readiness**, elements found to be important in the local context at the beginning of the implementation process at cultural, organisational and professional levels;
- **Strategies**, main actions and key points identified in the case studies selected which covers common strategies, barriers and facilitators to the change.

In figure 14, a synthesis of the emerging themes is presented in a logic model to give a temporal and visual idea of the different role that these themes have during an implementation process. From the initial idea of opening a new MU to the actual adoption of the model a multi-layered change needs to take place.

Figure 14 Systematic review logic model
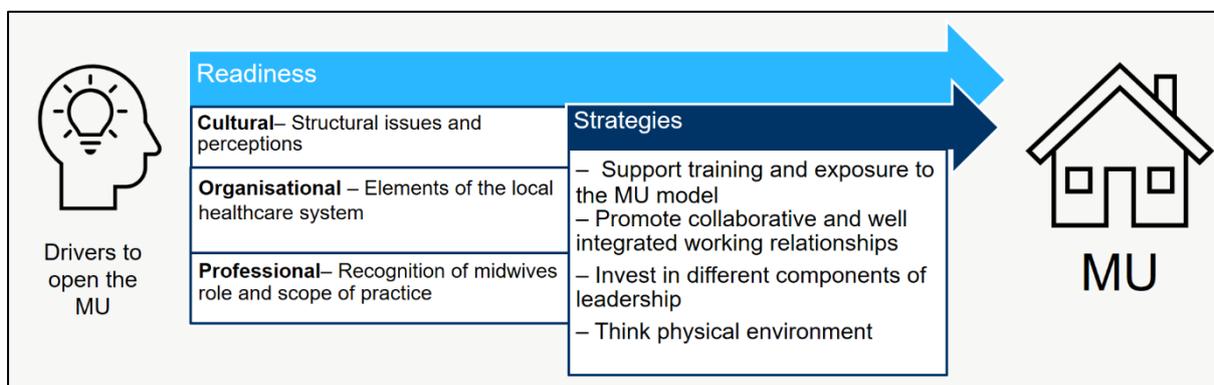
Furthermore, in table 8, I present a synthesis of the papers selected for the review summarising where (context), when (year), who (who initiated/led the implementation), why (drivers to open a MU) and how (the strategy used).

Table 8 Overview on the different strategies used to implement the MUs

N	COUNTRY	YEAR	WHO INITIATED/LED THE IMPLEMENTATION	DRIVERS TO OPEN THE MU (WHY?)	STRATEGY (HOW?)
1A	China (A)	2009	Researchers	Promote more humanised care to reduce intrapartum interventions and medicalisation	Engagement with leadership and training for midwives. A five-stage action research project was used to: define the plans, assess midwives' confidence and ability, outline policies, procedures and standards of practice, review and tackle the obstacles found in the previous steps.
1B	China (B)	2009	Researchers	(See 1A)	A follow up from study 1A with the same strategies and adding the involvement of a wider range of stakeholders (including midwifery staff managers and researchers) to assess feasibility of the MU.
2	US	1991	Nurse-midwives in four different institutions	Negotiating a middle-ground service between homebirths and the medicalised OU	Eight strategies were used, described as: going it alone, compromising, getting others involved, capitalising on consumer pressure, promoting the idea of "*it's not different*", playing the waiting game and overcoming government regulation.
3	Iran	2013	UNFPA and the Health Centre of Sistan and Balochestan Province	Increasing accessibility to perinatal care in areas with poor access to care	Response to a local situation in which vulnerable women lacked access to appropriate care and a high birth rate to increase accessibility of facilities and reduce perinatal mortality. UNFPA supervised the first three years of operation.
4A	Brazil	2009	Brazilian Ministry of Health	Promoting more humanised care to reduce intrapartum interventions and medicalisation	Normal Childbirth Centers or Childbirth Houses were implemented as consequence of a strategic governmental initiative to reduce medicalization in childbirth in Brazil.
4B	Brazil	2013	Brazilian Ministry of Health (MoH)	(see 4A)	The MoH invested in nurse-midwives' professional profile by sending them for an international exchange in a country where MUs

					were established. This was considered to give them greater symbolic power to fight for the implementation of the MU.
5	Canada	2018	The Ontario Ministry of Health and Long Term Care	Implementing evidence into practice	The availability of evidence was the reason why the MoH decided to invest in this model of care. They used interprofessional approach for planning the change, develop appropriate policies, protocols and to enhance teamwork. They also gave attention to the midwives' privileges at the moment of transfer and to the continuous service evaluation.
6	England	2005	Consultant midwife	Opportunistic or pragmatic reasons such as reconfiguration of the service, including centralisation	The refurbishment of the maternity setting became the opportunity to promote the inclusion of a MU. Consultant midwife doing a postgraduate thesis initiated an action research study, which included different stakeholders (including managers midwives and medical staff) and established a group to promote normal birth.
7A 7B	England	2014 and 2018	Midwifery managers	Opportunistic or pragmatic reasons such as reconfiguration of the service, including centralisation	Key drivers for development of AMUs in all the services studied had been a combination of pragmatic, even opportunistic, decisions. Lead midwives had often seized an incidental chance to develop the service responding also to financial constraints or existing plans for service redesign or improvement, including merging of different OUs within a single service organisation.
8	England	2018	Local managers (not specified)	Implementing evidence into practice	After the publication of the Birthplace study in 2011 the NICE Intrapartum guidelines published in 2014 recommended all 4 options of birthplace. This guideline had a significant impact and was used by stakeholders as main facilitator to make the case and open new MUs nationally.
9	England	2020	Midwifery managers	Implementing evidence into practice	Key factors for successful implementation were: leadership (and continuity of it), active promotion of the MU as part of the local policy, clear clinical pathway from the beginning of pregnancy until the onset of labour and appropriate information for women.

3.5.1. DRIVERS to open the MU

In the included studies, there were a range of reasons for deciding to open a new MU, but some main drivers were identified as:

- Promoting more humanised care to reduce intrapartum interventions and medicalisation (China and Brasil) (Cheung *et al.*, 2009; Pereira and Moura, 2009; Mander *et al.*, 2010; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013)
- Negotiating a middle-ground service between homebirths and the medicalised OU (US) (Mackey, 1991)
- Increasing accessibility to perinatal care in areas with poor access to care (Iran) (Moudi *et al.*, 2014)
- Implementing evidence into practice (Canada, England) (Reszel *et al.*, 2018; Walsh *et al.*, 2018, 2020)
- Opportunistic or pragmatic reasons such as reconfiguration of the service, including centralisation (England) (Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b)

In the case of the opportunistic drivers, while the motivator might be service-improvement or implementing evidence in practice to support quality of care and support for physiological birth, the trigger or driver of change was often related to a wider service reconfiguration plan which opened up an opportunity for change. An example of this was contexts in which small OUs were closed to centralise the service into a single large OU in the area: this represented an opportunity to keep a local service running by implementing a midwife-led unit (McCourt *et al.*, 2014). This was only noted in the English context, in which midwifery-led care in obstetric or midwifery settings had already been established and promoted by national guidelines, and in which centralisation of services was also in process, but it illustrates the complexity of influences and highlights that policies and guidelines in themselves may not be sufficient to overcome other barriers, as discussed below.

3.5.2. READINESS - Cultural level - Structural issues and perceptions
3.5.2.1. Structural issues

Codes related to culture and perceptions were ubiquitous across the different articles showing that all participants discussed on some level aspects related to society, the local culture and how this affected the implementation of MUs. Although these studies took place across seven countries and

four different continents with differing healthcare systems and periods of time when the implementation was attempted a number of consistencies were found.

On a macro-societal level, some structural issues were identified as barriers were related to gendered power dynamics, hierarchy in the health system and the hegemonic production logic in healthcare (Pereira and Moura, 2009; McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2020). For example, in the study by McCourt et al. (2014) professionals described an unbalanced gendered dynamic as a barrier to implementation and to the existence of AMUs (McCourt *et al.*, 2014). Amongst the different countries, women have different levels of autonomy, respect and rights when it comes to childbirth. The case studies from Brazil, China and Iran discussed the issue of women's rights in childbirth and obstetric violence acknowledging its presence in the respective countries (Cheung *et al.*, 2009; Pereira and Moura, 2009; Mander *et al.*, 2010; Moudi *et al.*, 2014) reflecting both the motivation to implement MUs and the challenges in doing so.

"*They wanted to examine me (vaginal examination), and I didn't let them. They told me, 'Keep your hand away'.*" Service user, (Moudi *et al.*, 2014)*, page 1077*

Opening new MUs was seen as an opportunity, to tackle this issue and the following quotes from the Iranian and Chinese studies show how the MU was perceived by service users as valid alternative to avoid such mistreatments:

"*Since my husband could be with me in this Wenxinchanfang (MU), I thought I could give it a try. I used it and it has worked for me…. If my husband was not there with me, I could certainly have requested caesarean section long time ago.*" Service user, (Mander *et al.*, 2010)*, page 523*

"*I have insurance. If I had gone to hospital, it would have been free of charge for me, but I didn't. They annoy us in hospital; they examine too much. It's more comfortable here; it's better.*" Service user, (Moudi *et al.*, 2014), page 1078

In terms of choice of birth setting, the information provided to women about choice of place of birth was often not complete and the decision-making process rigid. An example of this was asking them to decide where to give birth at the very first booking appointment (McCourt *et al.*, 2018b). This rigidity was mentioned both in English and Chinese studies (Cheung *et al.*, 2009; Mander *et al.*, 2010; McCourt *et al.*, 2014, 2018b) whilst the Iranian study (Moudi *et al.*, 2014) highlighted how one of the main reasons why women would opt for MU was the economic inaccessibility to the OU. It represented for them the best compromise between the expensive OU and a homebirth with no qualified practitioners (Moudi *et al.*, 2014).

The medicalised and industrialised model of care was cited in the English and in the Brazilian studies as a structural problem that can become the key obstacle to implementation (Walton, Yiannousiz and Gatsby, 2005; Pereira and Moura, 2009; McCourt *et al.*, 2018b; Walsh *et al.*, 2020). These studies identified that in a system that functions with a hierarchical structure and in terms of efficiency and productivity, the division between the Industrial/Medical model of care of the OU and the Bio-Psycho-Social model of care of the MU (Rocca-Ihenacho *et al.*, 2018; Rayment, Rocca-Ihenacho, *et al.*, 2020) could lead to polarisation, with an imbalanced power dynamic.

"*A normatively medical outlook persisted, that located midwifery units as marginal rather than as a core maternity service.*" Authors, (McCourt *et al.*, 2018b) page 18

In this scenario the OU represented the priority of the service and the MU an alternative which could be closed if need be.

3.5.2.2. Norms and perception of safety

A significant proportion of participants' comments were about perceptions of safety and how opening a new MU would affect it. A brief overview of these perceptions is here reported to give an idea of the culture in those places at the time of the implementation. This shows some preconceptions and ideas that different stakeholders had about MUs prior planning future implementation.

The perception of safety was mentioned in the English and Iranian case studies. The English case studies highlighted that the MU being co-located in the same building was perceived as safer than freestanding MUs (McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2018, 2020). This was often mentioned by participants even though it is not supported by existing literature that shows that FMUs are instead associated with better clinical outcomes than AMUs (Hollowell *et al.*, 2015; Scarf *et al.*, 2018).

"*Given that many professionals and service users see the proximity of alongside midwifery units to obstetric units as making them safer (…)*" *Authors,* (McCourt *et al.*, 2018b)*, page 21*

"*I think majority of women and all my friends will opt for an alongside MU, because most women do want the option of midwifery led but if anything goes wrong they just want to go down that corridor, through that door.*" *Midwifery Manager,* (Walsh *et al.*, 2020)*, page 5*

Some professionals also mentioned the idea of feeling safer by having all women in the same place and therefore having greater monitoring (and control) than having them in different locations. This preconception was clearly stated in this quote by an English consultant obstetrician:

"(…) if I were to design a unit I wouldn't split my shop in two different places on the high street. It just doesn't make sense to me. If you have everybody all in one place you don't have those problems. You've got greater monitoring of everything that's going on; you've got greater use of your resources, [it's] more efficient" Consultant obstetrician, (McCourt *et al.*, 2014)*, page 22*

On the other hand, when professionals were educated and had knowledge on the evidence and the impact that a MU might have, there was better integration and working relationships. This illuminated the importance of information and education of best available and up to date evidence to make stakeholders aware of the impact of MU on social and clinical outcomes and cost-effectiveness.

In the Iranian case study, choice was often about compromising on what was affordable (Moudi *et al.*, 2014). It was noted that women often reported perceiving the OU to be safer than the MU because of the availability of medicines and devices. However, they would opt for the MU to access a good level of care by experienced professionals at an affordable price.

"I thought, childbirth is just childbirth, no matter which place I go to. Why should I go to hospital, where the costs are very high? I didn't have health insurance, and I had to pay all that money in cash (out of pocket). Therefore, I decided to go to the nearest SDP (MU)" Service user, (Moudi *et al.*, 2014)*, page 1078*

The MU constituted the best compromise for that population to gain physical and psychological safety. However, the MU represented also the birthplace option that would allow them to avoid unnecessary medicalisation of childbirth:

"I love my daughter-in-law very much. Her childbirth was a hard time for me. In hospital, they told me she needed a caesarean, so I took her to the Post (MU). I didn't tell the ladies here (midwives) what I had been told in hospital. And thank God she had a natural delivery." Service user, (Moudi *et al.*, 2014)*, page 1079*

3.5.3. READINESS- Professional Level- Recognition of midwives' role and scope of practice

Most studies discussed the importance of a midwifery identity and the role that this profession had in those contexts. Midwifery and midwifery-led care was established with different levels of autonomy across the study countries. England and Canada had midwives that could practice autonomously in these units (Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018; Walsh *et al.*, 2018, 2020); Brazilian midwives went to Japan to gain more exposure of the midwifery model of care as they were not used to working with that autonomy (Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013), whilst China, US and Iran (Mackey, 1991; Cheung *et al.*, 2009; Mander *et*

al., 2010; Moudi *et al.*, 2014) reported not having a well-established and autonomous midwifery workforce in the healthcare system at that time.

Contexts in which midwifery was not established as an autonomous profession seem to struggle more, especially in the first phase of the implementation when the idea needed to be accepted by other stakeholders (Mackey, 1991; Cheung *et al.*, 2009; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013). In the Chinese case study, the opportunity of implementing a MU was reported to be the means to achieve a proper and recognised professional status (Cheung *et al.*, 2009).

The need of having obstetricians to promote a midwifery led model seemed important in all contexts but particularly so where midwifery was more marginalised in the decision making of the service configuration. However, it could have a 'boomerang' effect in which once the MU is implemented, the obstetric component could claim the leadership. In the American study, for example, marginalisation of the midwifery profession became apparent when nurse midwives who promoted and initiated the project of MUs had to fight with the obstetric component for the recognition and the credit of their actions:

"Although nurses were the initiators of the birthing room (MU) concept and nurses did most of the work towards implementing the concept, there is evidence that physicians are pre-empting the credit. One nurse said, -It's interesting that now the doctors think it's their idea-. Another nurse was concerned that nurses never received credit for changes they had made in her hospital and tried to avoid a repeat of that situation." Authors and nurse midwife quote, (Mackey, 1991)*, page 266*

The recognition of midwives' role and scope of practice was needed not just within the organisation and amongst professionals but on a more societal level too. This was not limited to countries where midwives are less autonomous but also to countries like Canada, where professional establishment was relatively autonomous but still recent and small-scale. In this case, the MU became a facilitator for this process of recognition of the midwifery scope of practice and therefore promotion of its role in society:

"Many participants perceived that the birth centers (MUs) have increased the respect and legitimacy of midwifery, both to the public and to other health care professionals, allowing these groups to learn more about midwifery and ultimately increase visibility and credibility of their education and practice. One paramedic stated, 'It elevated the [midwifery] profession for sure . . . I think just having the facility speaks volumes to the interest, the buy-in, the respect, and the credibility of midwifery'." Authors and paramedic's quote, (Reszel *et al.*, 2018), page 5462

3.5.4. READINESS - Organisational level - Elements of the local healthcare system
3.5.4.1. Cost and financing systems

Study authors reported that the cost effectiveness associated with MUs was not always clear to commissioners, managers and professionals (McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2020).

The concept of MU being "cost-saving" was often mentioned together with the status of financial constraint and the urgent need for healthcare organisations to save money (Mackey, 1991; Cheung *et al.*, 2009; Pereira and Moura, 2009; Mander *et al.*, 2010; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013; McCourt *et al.*, 2014; Moudi *et al.*, 2014; McCourt *et al.*, 2018b; Walsh *et al.*, 2020). This situation in which commissioners and managers are always required to save money in the short-term to help the financial constrain was reported to be a main barrier to the implementation of MUs even though they have been shown to be cost effective in the long-term:

"*Financial constraints within Trusts were often seen as limiting the development of MUs. While economic evaluations suggest the overall economic outcomes of increasing births in MUs is positive, the start-up costs were seen as a barrier, and the longer-term savings from lower morbidity in the target population that accrue across the health system were not recognised. In a climate of scarcity, new ways of structuring care must demonstrably save money, or at least, be perceived to, in the short term.*" Authors, (Walsh *et al.*, 2020), page 7

Studies identified two threads of opinions: one perceived MUs as expensive and unaffordable luxuries, or small and therefore inefficient (McCourt *et al.*, 2014; Walsh *et al.*, 2020) and so an antithesis to the need of save money of the organisation; the other recognised the cost-saving attribute but perceived it negatively as if this would necessarily mean a lower quality of care. In Brazil for example, this argument was used by the organisations which were against the promotion of MUs and in favour of a more medicalised approach; they referred to the MU model as "*poor care for the poor*" (Pereira and Moura, 2009).

Managers, commissioners and professionals' perceptions and willingness to implement the MU was also dependent on the type of healthcare system and commissioning environment of the local context. Where there was a 'payment by results' tariff in which the organisations were paid for the interventions provided, normal births were often seen as a "*loss making activity*" by commissioners and obstetricians (Cheung *et al.*, 2009; McCourt *et al.*, 2014, 2018b). In the US, where hospitals were paid by number of births, the strategy used by nurse midwives to convince physicians and commissioners that the MU would attract more women to their service was considered one of the most effective approaches (Mackey, 1991). In China, where midwives were asked to take more

responsibility working in a MU without an economic incentive, they were tempted to prefer working in the OU where for the same salary they had less responsibility (Cheung *et al.*, 2009). In Iran, where service users had to pay depending on the place of birth they chose (MU or OU attended by professionals or homebirth attended by SBA), the MU offered services which were more affordable to them while also ensuring good quality of care.

A financial system that was perceived working better in promoting midwife led provision and normal births was the one based more on assessment of risk level and service users' needs at booking (McCourt *et al.*, 2014, 2018b):

"Although the commissioning environment and payment tariffs had been described as making normal birth a 'loss-making' activity, managers and commissioners hoped that the development of a tariff centred more on assessment of women's care needs would help to remove such perverse incentives." Authors,(McCourt *et al.*, 2014)*, page 42*

3.5.4.2. National guidelines

In all the case study contexts, giving birth in an institutionalised unit even if outside the main traditional OU was legal and this represented a vital first step towards the readiness for the change.

The Iranian case study gives a good example of how regulation could affect service users' choice around place of birth. In this quote we can see how women would dislike homebirth due to the fact that a birth outside an institution would mean not accessing certificates to allow parents to register the child' birth and therefore, under a recent legislation, access to social benefits:

"(…) another important reason that the participants disliked home birth was related to legal issues, including the fact that TBAs (traditional birth attendants) cannot issue ID papers for the neonates. Under the new Iranian rules, birth certificates and ID cards are required to receive social benefits in the country (e.g., insurance, cash subsidies)." Authors, (Moudi *et al.*, 2014)*, page 1076*

National guidelines have a central role in defining the provision and configuration of maternity services and therefore to promote the implementation of MUs. A clear example of this impact, as reported in one English study, were the NICE Intrapartum guidelines published in 2014 that were promoting MUs and the possibility for each woman to choose between four places of birth based on the findings of the Birthplace Study (Hollowell *et al.*, 2011; National Institute for Care and Health Excellence, 2014).

Similarly, even in the case studies of Canada and Brazil, the new national guideline which was promoting the MU model of care was the main reason why an implementation process towards a MUs was commenced (Pereira and Moura, 2009; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013; Reszel *et al.*, 2018). The role of legislation and regulation is therefore central for implementing this evidence-based change of model of care in countries in which this does not represent an option yet. Guidelines also played an important role in professionals' perception of safety and for the collaborative work of the multidisciplinary team (McCourt *et al.*, 2014, 2018b).

"It was apparent that obstetricians were more comfortable with midwife-led care away from the obstetric unit if they felt that there was a comprehensive set of guidelines supporting that care that had been agreed across the service. This gave them more confidence that women would be appropriately referred to them for review if medical attention were necessary." Authors, (McCourt *et al.*, 2018b)*, page 18*

However, guidelines have the role of guiding the decision making and cannot cover all possible cases or substitute a personalisation of the care, as this extract illustrates:

"Most managers and midwives stated that guidelines needed to be strictly adhered to for such reasons [referring to confidence in the service], but that in practice there were many grey areas and discussions around individual cases." Authors, (McCourt *et al.*, 2018b)*, page 19*

Having a national direction in guidelines that is supportive of MUs is a first step and a key facilitator for the implementation of these contexts to allow local stakeholders starting a conversation around the adoption of the model.

3.5.4.3. Local policies

The opportunity to improve the current practice came often from the idea of revising or creating a new local protocol for physiological labour and birth. The role of a local guideline for physiological birth is not just to give clinical direction to the midwives but also to clarify the care provided in the MU for the whole maternity team. This promoted integration, as this example from an English study highlighted:

"Managers and midwives saw the local guidelines for admissions to and transfers from the midwifery unit as protecting a space for physiological birth, as well as a guide and framework for safe practice." Authors, (McCourt et al., 2018), page 18

On the other hand, attempting an implementation without such guidelines could jeopardise the whole process leaving space to interpretation, no clear distinction in pathways of care and contamination of practices (as will be further discussed in section 3.5.5.3. of this review).

"Midwifery units and midwives, as well as the women themselves, were perceived to be vulnerable without such guidelines" Authors, (McCourt *et al.*, 2014)*, page 25*

When preparing a local protocol for the management and practice in the MU, a key topic which needed to be faced and addressed was the admission criteria to the MU (definition of who is eligible for primary care). When defining who should be the eligible population, it should be assumed that this means also discussing and agreeing on transfer criteria from the MU to the OU in case that a deviation from physiology occurs.

"Prior to the opening of the birth center, we managed collaboratively with our key stakeholders, so we managed with the nurse manager but also some of the physicians, the obstetricians, about developing our current [tranfer] protocol . . . But it [was] something that we, from scratch, met together collectively, collaboratively to get everyone's approval for the current protocol that we have." Midwife, (Reszel *et al.*, 2018)*, page 545*

The multidisciplinary exchange in the production of these criteria became an opportunity for collaborative practice and a facilitator to the MUs implementation.

3.5.5. STRATEGIES
3.5.5.1. Support, training and exposure to the MU model

All studies identified that an appropriate set of knowledge, skills and training was required for midwives to work autonomously, even though midwifery regulations and background of midwives had significant differences from one context to another. Even studies located in countries were midwives worked more autonomously (England and Canada) reported a lack of confidence in physiological birth among midwives often due to a more predominant obstetric-led practice in the last decades:

"Because everyone has worked in such a high-risk environment, you become deskilled to an extent, and feel a bit apprehensive about normal birth… you know, trusting that women can have babies low risk." Focus Group Midwife, (Walsh *et al.*, 2020)*, page 6*

A good level of knowledge, up to date training and appropriate skills of the midwifery workforce were identified as an important facilitator to develop professionals' confidence in the MU model and for being able to promote it and spread it.

3.5.5.2. Training

A strategy identified in all studies was supporting staff with training initiatives as an enabler of the change. In some cases, midwives identified their own educational needs prior the implementation of the MU model of care and this helped engaging them in the project and create sense of ownership (Walton, Yiannousiz and Gatsby, 2005; Cheung *et al.*, 2009; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013; Reszel *et al.*, 2018). The autonomy and skills gained via the training helped increasing not just the clinical confidence but also the confidence in the midwifery scope of practice, the vision of the MU and its implementation (Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013; Reszel *et al.*, 2018).

Ad hoc and pre-implementation training for midwives was promoted, but also the concept of regular training, the so-called continuous practice development (CPD), was addressed in several studies (McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018; Walsh *et al.*, 2020). Studies highlighted not only its importance to keep professionals' skills up to date but also the need of covering more midwifery topics and move away from the concept that only training on obstetric emergencies needed regular updating:

"(…) a number of midwife respondents felt that practicing within them required different skills and a level of confidence, which they were not well prepared for. (…) Midwifery managers and midwives in our study recommended mandatory training in normal birth skills to address this concern." Authors, (Walsh *et al.*, 2020)*, page 5 and 6*

"Every year at our mandatory training, for three days (…) we have skills drills of obstetric emergencies and haemorrhage and eclamptic fits and stuck babies and breech babies and all of that, and I always, and in the feedback I always write, 'Where's our midwifery skills training? You assume everybody is up to speed with physiological third stage and augmenting labour naturally and advice on post-dates pregnancy etcetera … and it's not given much value by the midwives themselves or by the people who train us or by the obstetricians." Midwife, (McCourt *et al.*, 2018b)*, page 15*

Several studies described what they termed as *"skills hierarchy"* when planning training for maternity professionals with more attention given to the so called "*high risk skills*" and not as much attention given to the skills for physiological birth (Cheung *et al.*, 2009; McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2020).

3.5.5.3. Exposure to MU model

In some studies, the importance of exposure to the MU model of care for professionals before the opening of a new MU was also discussed (Cheung *et al.*, 2009; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013; McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018).

"The practical part of the course was held in several institutions. (…) To begin practicing at these Birthing Centers (MUs), the required care for nurse internship at these facilities was addressed. During the internship, it was possible to learn the philosophy and administration of each of the centers. The situations experienced by the nurses reflect the different systems of care in this field that would ultimately influence the professional practice of each one of them upon returning to Brazil." Authors, (Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013)*, page 197*

The aspect of the exposure to midwifery models was not limited to midwives but could be promoted to other maternity professionals and students too. In some contexts, where MUs were not established yet, home birth represented another option to experience midwifery led care (Reszel *et al.*, 2018). This was important not just for witnessing the model of care but also to gain an insight in each other's role and promote integration amongst the team.

"Physician exposure to home birth is associated with more positive attitudes toward home births, highlighting the importance of increased exposure through interprofessional training opportunities in education and practice" Authors, (Reszel *et al.*, 2018)*, page 547*

In countries where MUs were already established, AMUs were represented as a middle ground to increase exposure to physiological birth among the maternity team and to consolidate autonomous midwifery care for midwives.

"Lack of confidence in working with physiological birth was also reported by some hospital-based midwives, and the alongside midwifery unit was seen as a steppingstone to all midwives developing their skills and confidence in midwife-led care" Authors, (McCourt *et al.*, 2018b)*, page 17*

The concept of "*contamination of practice*" was also mentioned in three studies in which rotations of staff or an international exchange were applied hoping to bring back in the OU some MU philosophy of care (Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013; McCourt *et al.*, 2014, 2018b).

3.5.5.4. Promote collaborative and well-integrated working relationships

In all studies, the planning and opening of the MU involved communication, negotiation and coordination between different stakeholders within the same organisation or part of different ones.

This highlights the importance of a collaborative approach to the change. When the importance of interdisciplinary work is acknowledged, included in the in-service training and constitutes part of the team vision, this aspect was found to be a significant enabler of the change (Mackey, 1991; Walton, Yiannousiz and Gatsby, 2005; Cheung *et al.*, 2009; Pereira and Moura, 2009; McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018; Walsh *et al.*, 2018). Conversely, the lack of an interprofessional approach could make the MU service isolated and lead to a lack of confidence and trust amongst professionals of the same team (McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2018, 2020).

"*Participants from all 4 hospitals described interprofessional meetings very early in the planning process, ensuring that all voices were considered in the birth center (MU) development.*" Authors, (Reszel *et al.*, 2018), page 544

Establishing a vision amongst the whole maternity team in which the MU is part of the care pathway for uncomplicated pregnancies and all professionals are on board with that seemed to be a key facilitator. Having opportunities to spend time together during training days was highlighted:

"*Participants gave several examples of interprofessional training opportunities resulting from the opening of the birth centers, including hospital drills, mock EMS (emergency medical service) dispatch calls and transports from the birth centers (MUs), welcoming students from different professions to the centers, and including center tours as part of EMS personnel orientation. These opportunities increased understanding of each other's knowledge, training, and roles, and improved participants' ability to communicate with one another.*" Authors, (Reszel *et al.*, 2018), page 546

This also helped the strategic planning during meetings held to gain support of the managers and organisational leadership.

In more than one occasion the need of "*compromising*" and "*negotiating*" was mentioned when discussing the change (Mackey, 1991; Walton, Yiannousiz and Gatsby, 2005). This was, however, most of the times endured by the midwifery component and not by the medical staff:

"*It appeared that only the nurses gave up some of their plans. Physicians were either for or against a birthing room (MU) in general*." Authors, (Mackey, 1991), page 264

This illuminated an imbalanced power relationship when it comes to planning a change, even towards a model that is midwifery-led.

3.5.5.5. Professional relationships

The opening of a new midwifery led setting may create a separation amongst midwives and polarisation of the work. This could lead to the scenario in which midwives might be 'othering' colleagues for working in the other setting or for being either too medicalised or too pro-physiology. This nourished the "*them and us*" culture and constituted a main barrier to the integration of the maternity team.

"Tensions identified among staff were mostly between midwives working in different areas, particularly alongside midwifery units and obstetric units, rather than between obstetricians and midwives." Authors, (McCourt *et al.*, 2018b)*, page 26*

These tensions were noted and voiced not just by midwives but by managers and service users too who perceived these as potentially detrimental to the care provided (Mackey, 1991; McCourt *et al.*, 2018b).

Rapport with obstetricians varied across the different case studies and it seemed to be related to how well midwifery led models of care were already established in the respective context. In the more recent English studies, obstetricians were overall in favour of the idea of a new MU (McCourt *et al.*, 2014), whereas in the Brazilian study a great deal of tension was reported with the medical corporation, which actively opposed the initiative of the new MU (Pereira and Moura, 2009).

Across the studies, support from the obstetric component (whether active or passive) was found to be an important, and even fundamental, facilitator to the implementation of new MUs.

"In fact, unless chief obstetricians positively sanctioned the idea, success would have been impossible. The involvement of the chiefs ranges from strong support for the idea to passivity that allowed nurses to make the idea reality." Authors, (Mackey, 1991)*, page 263*

"In the light of apparent tensions between midwives and doctors voiced in the NBSG (Normal Birth Strategy Group) and because communication with doctors was proving difficult a new attempt was made to gain some insight into the views and opinions of doctors. Initially doctors had not been considered primary stakeholders in midwifery-led care but as the project progressed it became clear that their cooperation in moving the project forward was fundamental." Authors, (Walton, Yiannousiz and Gatsby, 2005)*, page 754*

This seemed to be because midwives often need medical support to be enabled to apply changes and improvements to the service. As mentioned in theme one, gendered dynamics and the hierarchical configuration of the healthcare system play a significant part in this.

3.5.5.6. Integration within the service

On a similar note, when discussing the importance of a multi-layered change, the concept of integration was described as an essential feature, referring to the collaboration on an organisational level between different departments of the maternity service and on a professional level between different team members and professional groups.

Sometimes, the change towards a MU model of care became a useful opportunity to reflect and improve integration in the maternity services:

"Participants described the planning, implementation, and monitoring of the birth centers as a motivating force that improved interprofessional practice between different stakeholders, including nurses, physicians, midwives, paramedics, administrators, and the regional health network." Authors, (Reszel *et al.*, 2018)*, page 546*

When planning the implementation of a new MU, there should be awareness that adding a new branch of the service to the current maternity configuration may create, especially in the first phase, disjuncture and tensions amongst the professional team (McCourt *et al.*, 2018b). Some initiatives to overcome this barrier were mentioned: planned rotations of staff, mentoring for midwives who are less confident and promotion of case-loading models (McCourt *et al.*, 2014, 2018b).

Another key topic that could play the role of either a barrier or a facilitator was the staffing level. Shortage of staff experienced was due to either a permanent lack of appropriate recruitment of midwives for the MU team, or occasional due to the "*pulling away*" of staff during shifts who were meant to work in the MU but had to cover shortage of staff in other departments like the OU (Cheung *et al.*, 2009; McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2018, 2020). The staff shortage had implications even in the service users' perception of the service.

Factors that could help in developing and planning a functional staffing model were identified in having a core team that would allow continuity of philosophy or care and consistent management of the MU even in case of emergencies and rotation of a part of the staff to allow exposure to this model of care of other midwives (McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018; Walsh *et al.*, 2020).

"Some initiatives for increasing integration of care were identified which could potentially mitigate the effects of creating new boundaries or discontinuities in the service. These could also support quality and safety of care, and the well-being of professionals as well as service users. They included a planned system of rotation for staff, with mentoring for midwives who are less experienced and skilled in caring for normal physiological birth and more integrated community-hospital models in which midwives

based in the community attend the women on their caseload giving birth at home or in the FMU or AMU and transfer with them if required." Authors, (McCourt *et al.*, 2014) *, page 546*

3.5.5.7. Communication

Effective, respectful and appropriate communication, both verbal and non-verbal, was identified as having a central facilitator role in positive stakeholders' relationships. In some cases, educational activities were used to solve some communication issues and this helped to pre-empt or overcome tensions amongst the team. For example:

"We've identified gaps in terminology between the people talking on the phone, so we've been able to provide education. Yeah, it's been very, very helpful. Had we not done that, I could see that we could have had conflicts simply because we didn't understand each other and why we were doing things a certain way and I think we've been able to completely avoid that or interrupt it if it was going to start because we've been able to go, 'Oh, why'd they do that?'" Paramedic, (Reszel *et al.*, 2018)*, page 546*

The opportunity of a regular dialogue and exchange of opinions and ideas to review and debrief practice was also mentioned as important factor to improve communication between the different professional parties (Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018).

Appropriate information about the MU to the service users and the definition of a clear pathway of care outlined was reported to be a key facilitator for the successful implementation:

"Successful implementation was also dependent on a clear clinical pathway from the beginning of pregnancy until the onset of labour." Authors, (Walsh *et al.*, 2020)*, page 6*

Lack in providing such information and the options to the service users (both during the implementation process and later once the MU was established) was reported to have a significant impact on the implementation outcomes of accessibility and sustainability. (McCourt *et al.*, 2018b; Walsh *et al.*, 2020).

However, communication with service users was not mentioned much in the studies, suggesting a lack of attention to this issue. In the Chinese and Iranian case studies, the MU was perceived as a good alternative to receive better verbal and non-verbal communication and avoid mistreatment (Cheung *et al.*, 2009; Moudi *et al.*, 2014). The Brazilian case study reported how an organised civil society movement for birth rights was successful in influencing the governmental spheres (Pereira and Moura, 2009).

3.5.5.8. Invest in different components of leadership

As shown in table 8 in section 3.5, those who moved forward the idea of the implementation of MU were often midwives, nurse midwives or midwifery managers highlighting the importance of the midwifery component in leadership for this type of change. Senior midwifery support was often mentioned and in the English studies this was identified in the figure of the consultant midwives (Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2020).

Good leadership was sometimes showed in group or by a single professional who could either be a senior midwife or an obstetrician depending on the context. The role of one charismatic and motivated leader was often mentioned as key ingredient to start a conversation and to initiate the adoption process.

"-it's crucial to have an inspirational leader. If you don't have somebody at the very top who is passionate about it (MUs) happening, it won't happen. And they must cascade, get everybody onboard. – (Midwives Focus Group)

-a charismatic leader to kind of bring it together… unless you've got that then I think it's quite hard to bring it to fruition.- (Manager)" Midwife and manager, (Walsh *et al.*, 2020)*, page 6*

The figure of one charismatic and motivated leader was reported to be essential especially at the early stages and later, during the planning process, this leader needed to be combined with a group of stakeholders and interdisciplinary members of which the obstetric component is essential. This layer of leadership was described to be necessary for the integration of the service and for promoting a culture of inclusion of different figures (including service users) in the development of a service change:

"Management respondents emphasised the importance of senior midwifery, obstetric and general managers working together to support and sustain the development." Authors, (McCourt *et al.*, 2014)*, page 24*

Overall, the studies in this review identified the key functions of leadership to support the implementation of a new MU as to:

- Inspire and start a conversation about the change and promote a vision
- Advocate for the team and for the service users
- Promote participation of different figures for planning and developing the change
- Ensure integration within the service

- Negotiate and move strategically with inside knowledge
- Support training and establish a learning culture

3.5.5.9. Think physical environment

All studies discussed of concept of the MU as a distinct built or designed environment separate from the OU as a prerequisite of an effective implementation plan. In some cases, the refurbishment of the physical environment or a reconfiguration became the means to promote a change in clinical practice and in the birth culture of the local context (Mackey, 1991; Walton, Yiannousiz and Gatsby, 2005; Pereira and Moura, 2009; Mander *et al.*, 2010; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013; McCourt *et al.*, 2014, 2018b). The new physical layout was the most visible feature of the wider change that was being promoted and implemented:

"The accounts of professionals and service users suggest that these different aspects of the care environment cannot simply be unpicked as they are closely inter-related. Although some respondents regarded the design aspects of the environment, such as domestic touches, as superficial in relation to actual care processes, our study findings overall suggest that attempts to alter either processes or environment of care in isolation are less likely to be effective." Authors, (McCourt *et al.*, 2014), page 26

The literature reported that an appropriate use of the physical environment has the potential to be an important strategy for the new MU, especially at the beginning of the negotiations when involving different stakeholders (Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2020).

On the other hand, if the planning of the change does not consider all the different layers implied, including the shift in culture, practice and integration required, then there is the risk that the physical layout case alone could become a trap in which energy and resources could be wasted. Focusing just on the MU physical layout and not on the MU model of care was reported as a potential barrier to effective implementation (Mackey, 1991; Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b):

"I'm afraid we could end up with a room that's just decorated differently; that's about all that would be different" Midwife, (Mackey, 1991), page 265

The clear physical separation from the OUs was also mentioned as facilitator for the implementation of the new MU:

"*We thought it would be easier to do it outside the hospital due to institutional resistance.*" Manage, (Pereira and Moura, 2009), page 872

And when it was not, it became an obstacle to the MU model of care:

"As there was no physical barrier between these rooms and the rest of the labour ward, it was too easy to use them for other purposes when demand was high." Authors, (Walton, Yiannousiz and Gatsby, 2005)*, page 754*

3.5. Discussion

The twelve studies included in this review were heterogeneous in their aims, methodology and local contexts but it was interesting to find agreement and coherence of many of the findings. Themes and sub-themes identified in single studies were coherent with those looking across a wider range of services (McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2018, 2020).

Key drivers that led to the implementation of new MUs were: desire to reduce interventions and to promote humanised care (Cheung *et al.*, 2009; Pereira and Moura, 2009; Mander *et al.*, 2010; Progianti, Bastos Porfirio and de Figueiredo Pereira, 2013), need to negotiate a middle-ground service between homebirth and OU (Mackey, 1991), desire to increase access to care (Moudi *et al.*, 2014), commitment to implement recent scientific evidence (Reszel *et al.*, 2018; Walsh *et al.*, 2018, 2020) or opportunistic reasons such as refurbishment of the unit or reconfiguration of the service (Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b).

Few studies focused explicitly on macro-level influences such as wider culture and social influences, policies or healthcare systems structures suggesting mainly institution-centred approach to implementation. The systemic issues mentioned concerned the role of barriers posed by gendered power dynamics, hierarchy in the healthcare system and an industrialised approach in healthcare (Pereira and Moura, 2009; McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2020) but only a few studies included a focus on the role of service user or public activism in implementation or examined levels of public awareness and information (Pereira and Moura, 2009; McCourt *et al.*, 2014, 2018b). This seems to suggest that women's groups could be big drivers in facilitating change in maternity (Reiger, 2006; McIntyre, Francis and Chapman, 2011) but lack of their inclusion in the data collections of the selected studies shows how this aspect has not been researched sufficiently.

In spite of differences in midwifery autonomy across the contexts of this review, most studies discussed the importance of a midwifery identity and the role that this profession has in the respective society prior implementing a MU (Mackey, 1991; Cheung *et al.*, 2009; Pereira and Moura, 2009; McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018; Walsh *et al.*, 2020). The ICM Standards for Midwifery Education (revised in 2021) aim to address local differences and promote a skilled professional midwifery workforce internationally to facilitate the implementation of midwifery led care models (Barger *et al.*, 2019).

Walsh et al. (2020) noted lack of awareness of the economic evidence that MUs are cost-effective even when working at 30% of their capacity (Schroeder *et al.*, 2012, 2017; Walsh *et al.*, 2020). Different contexts showed how different commissioning systems could affect the adoption of the MU model. Most studies reported the need to adopt a cost-saving model to support a climate of financial constraint. This situation in which commissioners and managers are required to save money in the short-term was reported to be a main barrier to the implementation of MUs. Promoting the concept of cost-effectiveness among stakeholders and allowing longer-term goals to be reflected in the healthcare financing system were reported to be potential facilitators for this type of change (McCourt *et al.*, 2014, 2018b; Walsh *et al.*, 2020).

National guidelines and local protocols were mentioned as key enablers of the change and found to play an important role in terms of "readiness" of the local context. For participants it was equally needed to have some reference at a national level (via guidelines) and on a local level (via organisational protocols). This helped the perception of safety, protection for midwives' work, midwives' autonomy and the sense of integration amongst professionals in the organisation. Furthermore, the quantitative results from Walsh et al. (2018) described the impact that Research and policy can have in affecting the configuration of maternity services and therefore support the implementation of MUs.

Training midwives (sometimes with the multidisciplinary team) was a common strategy to facilitate the implementation. Another element reported to be relevant for promoting trust in the MU model and integration within the team was the exposure to the MU model. AMUs were seen as the appropriate middle ground to facilitate this exposure (McCourt *et al.*, 2014; Rocca-Ihenacho, 2017; McCourt *et al.*, 2018b; Walsh *et al.*, 2018).

All cases mentioned the importance of a collaborative approach to the change. This is coherent with work previously conducted in research about patient safety which identified lack of these components as threats to patient centred care and safety (West, 2000; Dixon-Woods, 2010; Liberati *et al.*, 2020).

The professional tensions mentioned showed a clear majority of intra-professional issues more than inter-professional ones. This is coherent with feminist work on midwifery arguing that midwives could be at the same time be the "oppressed" and "oppressors" (Yuill, 2012). This is consistent with previous findings that identified lack of understanding and trust between midwives working in AMUs or in OUs (Rayment, 2011; Rocca-Ihenacho, Yuill and McCourt, 2021). Such negative relationships have been identified as a significant cause of midwives' stress, emotional labour and reduction in practice confidence (Hunter, 2004; Bedwell, McGowan and Lavender, 2015; Fontein-Kuipers *et al.*, 2018; Hunter *et al.*, 2019). Across the studies, support from the obstetric component (whether active or passive) was found to be an important facilitator to the implementation of new MUs.

This study was coherent with previous work that identified leadership as important enabler for the promotion and adoption of new MUs (McCourt *et al.*, 2018b; Rocca-Ihenacho *et al.*, 2018; Walsh *et al.*, 2020). A necessary feature was the senior midwifery component, although support from and collaboration with obstetric leaders was also found to be a key enabling factor. The studies reported the relevance of both single leaders who often initiated the conversation and were key for the engagement and a group of stakeholders for moving the projects forward at later stage.

A good level of integration within the organisation was found to be a crucial facilitator. The shift from the existing maternity configuration to the inclusion of a MU could either destabilise the existing structure or reinforce the rapports within the organisation (McCourt *et al.*, 2014, 2018b; Reszel *et al.*, 2018).

Previous studies have shown that the physical environment in the healthcare sector, and specifically in midwifery, has the potential to affect staff wellbeing (or burnout) and therefore the care that is provided to service users (Ulrich *et al.*, 2008; McCourt *et al.*, 2016; Hammond, Homer and Foureur, 2017; Hunter *et al.*, 2019; Joyce, 2020; Rocca-Ihenacho, Yuill and McCourt, 2021). Stakeholders tend to have the greater perception of safety towards AMUs in contrast to FMUs. However, participants reported the need to be physically separated and independent to facilitate the implementation and future sustainability (Walton, Yiannousiz and Gatsby, 2005; McCourt *et al.*, 2014, 2018b). The cases studies where normal birthing rooms were attempted and had closer proximity to the OU reported

more effort and difficulty in doing so (Mackey, 1991; Walton, Yiannousiz and Gatsby, 2005). Other authors have previously explained this concept using Fahy's theory of Birth Territory in which AMUs were an intermediate space with more complex power dynamics and jurisdictions due to the closeness to the OU (Fahy, Foureur and Hastie, 2008; Dahlen *et al.*, 2020).

3.6.1. Strengths and limitations

The strengths of this review lie in the robust research approach, systematic search and critical selection of studies to meet the inclusion criteria. This review was also the first ever conducted on the very specific phenomenon of interest of "implementation of new MUs". We decided to exclude confounding factors which could be related to the improvement aspect and the uptake of existing ones, although in practice this was challenging to achieve as authors often described factors as also important to quality and sustainability of care after implementation. While there was considerable heterogeneity of contexts in which implementation took place, the analysis found consistencies amongst the studies. This adds value to the findings of the review, but more studies are needed in other contexts, including low-income countries. One limitation identified was that amongst the twelve studies only four had contributions from service users denoting a lack of involvement of their perspective when conducting this type of study.

3.6. Conclusions

This review examined what kind of strategies have been used so far when attempting to implement new MUs in different international context. It identified which are the drivers that move leaders to attempt the implementation and factors that could become enablers or barriers or the process of change. Conducting this review as first step in this study helped to contextualise the research topic within a wider international context identifying the multi-layered change required for the implementation of MUs and the importance of including stakeholders during the change.

This review added value and evidence base to the decision of the participatory approach including different stakeholders and particularly service users in this study. Furthermore, it helped to map the levels (cultural, organisational and professional) and the factors (barriers and enablers) that required attention when attempting a similar implementation in Italy.

The analysis and logic model derived from this review were presented and included in the implementation work with professionals during the "Act" phase of the PAR cycle with the Delphi study to inform participants of previous implementation experiences and what we could learn from them. It constituted a baseline for reflections when starting to think at the implementation work required by the local hospital.

In the next chapter, a situational analysis conducted prior to the implementation phase of the cycle will be presented and I will refer to these review findings in assessing the implementation readiness of the local context.

Chapter 4 – Phase One - Situational analysis

Introduction to the chapter

In this chapter, I describe the local context's readiness and the results of the first rounds of data collection as part of this situational analysis. The first section provides a more detailed account of the relevant data collection methods following the overview in chapter 2 (methodology) and sets out the sample from which the analysis is drawn. Prior to going through the constructs of the CFIR framework as lens to read the situational analysis, I present three paragraphs to set the scene of the research study. First will be an overview of the local territory and population, then an excursus of the professional workforce and healthcare system layout and finally a brief description of the previous and current experiences of similar models of care in Tuscany and the local service studied. The themes emerging from the analysis are then reported using the structured approach of the CFIR framework, to support the synthesis of different sources of data and to give a more fluent description of the state of things at the beginning of this study (Damschroder *et al.*, 2009).

In chapter 2 (methodology), I explained the approach used for this research study. The cyclical nature of the change was represented via the QIF circle and is reflected in the different phases of PAR: plan, act, observe and reflect. This chapter therefore reports on the first phase. When conducting a situational analysis at the beginning of an implementation research project, the data collected constitute the baseline to analyse the readiness of the local context on different levels and, for this specific study, on the cultural, organisational and professional ones.

4.1 Data collection and analysis

Mixed methods with diverse groups of participants were used to incorporate different perspectives in this situational analysis and follow a PAR approach. A detailed account of each method used is provided in chapter 2, methodology.

For the stage of the situational analysis, qualitative methods included focus group discussions, in-depth and semi-structured interviews, open-ended questions from surveys, analysis of local guidelines and observation of stakeholder events. Quantitative data included surveys, routine data and

maternity indicators collected by MeSLab, including data from women collected via online surveys before and after pregnancy.

Data collection activities were planned with the hospital leadership in a flexible way around the work of the team and the needs of the research in terms of different stakeholders' representation. For example, if the opportunity of a meeting with hospital and community staff arose, after checking that it was appropriate for me to do so, I offered participants to stay a bit longer after the meeting for a focus group as part of this study. Furthermore, by keeping an up-to-date record of the recruitment and the research activities conducted, I had an overview of which stakeholders needed more representation than others and I could address the research activities around that.

Transcribed focus groups, interviews and the research diary (where observation notes were reported) and qualitative data from the open-ended questions of MeS surveys were uploaded into NVivo 12 software for data management and analysis. Quantitative data from the surveys and the hospital performance data were analysed by MeSLab as part of the yearly performance monitoring of the regional health service and included in the analysis where relevant as supporting material.

As described ed in chapter 2, the Consolidated Framework for Implementation Research (CFIR) was used to guide the analysis (Damschroder *et al.*, 2009). The analysis was initiated with a descriptive coding using NVivo to gather an initial idea and feel of the data that was collected. After that, the use of the CFIR framework helped to map the categories at analytical level across to the different aspects of the implementation within the innovation level, outer setting, inner setting, individual characteristics and process level. This helped identify areas of better or worse readiness. I used the CFIR NVivo project template and the online CFIR codebook with the detailed description of each construct which can be found at https://cfirguide.org/constructs-old/). This helped me to better understand the different aspects of the framework and avoid confusion or misinterpretation between them. The analysis was discussed and reviewed by supervisors.

Some of the constructs of the original study were not relevant for this specific innovation (for example 'Design Quality & Packaging') and were therefore not included a priori in the analysis. Other constructs were not represented in the descriptive level of the analysis and therefore ended up not being included in the final synthesis of findings. As previously mentioned, the CFIR framework was used as a guide to map the descriptive codes and makes sense of the different levels but not all construct ended up being relevant for this context and innovation.

For this situational analysis a total of 48 participants amongst professionals (midwives, obstetricians and neonatologists) and organisational level (midwifery leaders and medical directors) were recruited by the end of January 2021. Unfortunately, due to the Covid pandemic only one face to face focus group was conducted with seven service users. However, service users' contribution and feedback about the local maternity service was included thanks to the MeSLab surveys. Between 2018-2019, 347 service users who gave birth in the local hospital completed the online survey after birth and more than a thousand open ended comments were left and analysed. Table 9 below summarises the data collected for the situational analysis from November 2019 to January 2021. Three colours represent the three stakeholders' levels: blue for professionals, yellow for organisational leadership and orange for service users.

Table 9 Primary data collection for the situational analysis.

When	Data collection events	Time (Min)	Participants number	Type of data
November 2019	1 FG community midwives	25	15	Primary
	1 FG lead midwives	75	5	Primary
	In-depth interview lead midwife 1	23	1	Primary
	1 FG hospital midwives	61	12	Primary
	In-depth interview hospital midwives	51	2	Primary
	Brief Interview hospital midwife	6	11	Primary
December 2019	Strategic multidisciplinary meeting	76	7	Primary
	In-depth interview lead midwife 2	58	1	Primary
January 2020	1 FG hospital and community midwives	30	8	Primary
	1 FG with service users	55	7	Primary
February 2020	Strategic interview with regional lead midwife	80	1	Primary
	1 FG with obstetricians	48	5	Primary
September 2020	Multidisciplinary meeting	59	8	Primary
January 2021	3 multidisciplinary FGs	69 65 32	14	Primary
2018-2019	MeS surveys related to intrapartum experience in the local hospital (both quantitative and qualitative data)	2018-2019	347	Secondary

4.2 Setting the scene of the local context
4.2.1 Territory and population using maternity services

The province where the local hospital is located occupies more than 4,500 square kilometres in the south of Tuscany. It is the most extensive in the Tuscan region and one of the least dense in population in Italy with a population of 220, 025 residents (Istituto Nazionale di Statistica, 2019).

As previously illustrated in chapter 1, demographic indicators in Italy are showing the lowest level of birth rate since 1918 after the First World War (Rosaria *et al.*, 2020). In Tuscany between 2010 and 2018 there was a reduction of births of 23,6% (Puglia, Voller and Dubini, 2019). The local hospital witnessed a constant decline of the birth rate in the past 10 years when from roughly 1400 births in 2012 (when I was working there as student midwife), the hospital assisted only 1187 births in 2018 and 1105 in 2021. This phenomenon was present even though in the last decade some of the peripheral small hospitals which were points of reference for intrapartum care for the rural population were closed or reconverted into community healthcare centres. A guidelines in 2010 recommended that only hospitals registering over 1000 births should remain open to guarantee a higher level of safety (Comitato Percorso Nascita Nazionale, 2010). Therefore, from five centres where women could give birth in the province only one was left in the main town. If the local hospital used to serve mainly the high-risk cases of the province, now all women living in the province had to go there to give birth regardless of their risk, as it is now the only hospital with intrapartum services.

The ARS "*Agenzia Regionale di sanità in Toscana*" is a regional institution that monitors healthcare statistics and indicators in Tuscany around pregnancy and birth every year. The report from 2018 showed that the average age of women at birth was 32,1 (higher than the national one of 31,9) with more than 36% of service users being over 35 at birth and 9,8% being 40 or more (Puglia, Voller and Dubini, 2019). The vast majority of the population that access the maternity services and give birth in Tuscany (72,1%) had a level of education which is medium-high which is higher than the average of the whole regional population suggesting that for women planning to have a family their personal and social realisation is important. This is confirmed by the fact that 61% parents had a working situation in which both work at the time of birth and only 3,5% are both unemployed (Puglia, Voller and Dubini, 2019). Couples with at least one foreign parent are 30,1% of the whole population using maternity services and 65% of them are both from another country. Almost all of them are people coming from low- and middle-income countries with strong migration pressure (96,3%) and only 3,7% from a high

income country. Countries more represented are Albania (19,7%), Romania (15,1%), China (11,9%) and Morocco (10,2%) (Puglia, Voller and Dubini, 2019).

Community healthcare services are being used for antenatal care mainly by women that are young (18-24 years), unemployed, low level of education, are Italian or coming from countries with high pressure of migration. Women that have a higher level of education, are over 30 and are Italian or from high-income countries usually choose a private obstetrician for the pregnancy care even if this percentage shifted from 68% in 2004 to 48,5% in 2018 (Puglia, Voller and Dubini, 2019). This shows as improvement in the use of primary care services provided mainly by midwives in the past decades.

In terms of birth settings, in Tuscany almost all users gave birth in hospital with only 15 births registered as home births and 10 happened on their way to the hospital in 2018 (Puglia, Voller and Dubini, 2019).

Some data suggested a level of medicalisation that, even though lower than the Italian average, is still present in Tuscany. The regional caesarean section rate in 2018 was 27,1% which is lower than the national average of 32,3% in 2018 (48% elective, 23% emergency and 27% in labour). Induced labours were 20,1% of the total of births. The Kristeller manoeuvre use (which is not evidence based as explained in chapter 1) was significantly reduced in the past 15 years (from 20% to 3,8%) but it is still being performed, especially during operative births for first time mothers.

4.2.2 Professional workforce and healthcare system

The local hospital is one of three main hospitals in the Local Health Authority. As previously mentioned, the province has now only one hospital for intrapartum care and five community centres that provide antenatal and postnatal care spread across the territory. These centres are called community healthcare centres and they are run by a multidisciplinary team composed mainly by midwives, a psychologist and obstetricians that move from the hospital to the community for appointments on set days a week, based on the workload. In 2018 a total of 1500 booking appointments were carried out in the whole province with more than 400 done in the local community centre and each peripheric one did between 70 and 220 appointments (*local data disclosed by community coordinator during interview on the 3/1/2020*).

The midwifery workforce is divided into hospital midwives working in the hospital and community midwives working across the five community healthcare centres.

The hospital team was composed at the beginning of this research project in January 2019 of 36 midwives. Two years later in January 2021 the number of midwives working FTE in the hospital had increased to 47. The recruitment of new midwives was due to a change in services layout and midwives were now requested to work in wards in which they did not work previously. For example, until the end of 2019, some nurses were working in the postnatal ward looking after babies and assisting neonatologists during births whilst midwives were only doing intrapartum care or postnatal care just to women. Nowadays antenatal, intrapartum and postnatal wards are staffed by midwives and nurses have been re-allocated and rotated into other departments of the hospital. As already anticipated in chapter one, midwives in Italy are required to have knowledge and skills to work also in the operating theatre and other departments. In 2019, the LHA leadership promoted and started a project to integrate and later substitute the nurses with midwives in the operating theatre for both obstetric and gynaecological procedures. This was an organisational objective to improve the use of resources and make the most of the professional profiles in each department.

This significant increase of team members affected the team spirit and the working climate. Some members reported feeling the team less united. Another issue affecting the midwifery workforce in the hospital is the retention of midwives. The employment process has changed in the last decade from being at local level to being via a big regional recruitment process with thousands of candidates applying for positions across the whole region. What happened consequently was that many midwives started the preceptorship in one hospital and then, once the permanent contract is confirmed, they requested to be moved to other regional hospital that they preferred. This meant for the local team a big initial investment of energies to train newly qualified or new midwives who were likely move to a different hospital and this caused of frustration and fatigue.

"We've seen an absurd turnover of staff over the last few years...from a group of about 30 people to having almost 50...not considering that like 20 have been trained and might have left for other hospitals...so much energy has been invested by the whole team as well. We're all a little tired right now from all the different changes." Midwife coordinator, 27/11/2019

The community healthcare centres' midwives are composed of very small teams. They do not meet regularly and they reported not being much connected with one another. The care provided can sometimes differ significantly from one place to the other.

"It's a shame that we never see each other and that we don't know how our colleagues in other areas work. I, for example, have no idea how they work in [name of local community healthcare centre], just

as I don't think many of our colleagues in [name of local hospital] know what we do in [name of other local community healthcare centre]" Community midwife, 19/11/2019

There are two midwifery coordinators, one for the community teams and one for the hospital team. There is an operational manager midwifery position and two midwifery managers who are in charge of the continuous practice development and skill mix of all midwives in the province.

The obstetric team is mainly located in the hospital where most of the diagnostics and specialist services are carried out. They also rotate regularly in the different healthcare centres to run clinics. All secondary level services of the pregnancy pathway are conducted at the hospital. The obstetric team is divided in two sub-groups. One group is composed by 15 obstetricians working mainly in the acute areas of gynaecology ward, antenatal and postnatal ward, labour ward and operating theatres (both obstetric and gynaecological). The other one is composed of 5 obstetricians who are fetal medicine specialists and experts in IVF.

The managerial levels could be divided into a local hospital manager who is responsible for activities and events of the hospital and a wider organisational manager who is more in charge of strategic decisions that will affect all hospitals and healthcare centres belonging to the LHA.

4.2.3 Regional and local experiences of low-risk care

In Tuscany there is one alongside midwifery unit in Florence. It was opened in 2007 after many years of negotiations and planning between hospital directors and maternity team thanks to a big push from the regional political component in Florence (*information given during interview with former lead of the AMU in Florence which will be discussed more in detail in chapter 6*). Women can request MU intrapartum care at the 36 weeks appointment if the pregnancy has been uncomplicated and there are no risk factors. The first years of existence of this MU registered an increasing number of births (roughly 500 which was 20% of all births in the hospital) and the MU became very popular amongst service users of the local contexts and professionals nationally. After some changes in the leadership and in the structure of the midwifery team, numbers started to drop and nowadays the AMU registers less than 200 birth per year (information disclosed by former leader of the regional AMU during interview for this study, more details in section 6.2). However, looking at the feedback registered in the online survey by MeS, the AMU was always mentioned in relation to positive comments and experiences.

The following comment is an example of the 25 similar comments left that mentioned the AMU: *"I am at my third birth and therefore third stay in [name of regional AMU]! Fully satisfied, the*

opportunity to stay here with my other sons has meant that for everyone had a positive experience, without detachment and without having the perception of being hospitalised but feeling welcomed in a birth house! Thanks to all the staff!" Service user 245, survey Regional MeS survey

Other previous experiences of midwifery led care practice were often mentioned by senior midwives who had previously worked in small hospitals of the province before the national policy encouraged and required the closure of intrapartum centres who registered less than 1000 birth per year (Comitato Percorso Nascita Nazionale, 2010). These centres were converted into community health centres and were left to provide only antenatal and postpartum primary level of care. Before this they also offered intrapartum care to women with uncomplicated pregnancies and the care was mainly provided by midwives. Doctors (obstetricians and anaesthetists) were only called in if there was a problem identified by midwives, so some similarities with the MU model can be noted.

A similar model of care was provided by the so called "*stanze del parto naturale*" (rooms for natural birth) which were intrapartum settings dedicated to uncomplicated pregnancies. In the local hospital, one such room was opened in the 1990s and it was called "*stanza rosa*" (the pink room). The previous experience of working in such environment was mentioned during data collection by both midwives and obstetricians who were working there at that time.

"Facilitator: What kind of opinion do you have with respect to that type of care model (MU)?

Obstetrician: 'in complete honesty I am not very supportive. (...) I'm saying this because I worked in a place where there was the pink room and so on... And when there was an emergency it was a real problem." FG obstetricians, 26/2/2020

"Community midwife: (…) when I came here in the early 1990s, we had the Pink Room. We opened the Pink Room overnight, no one prepared us, remember?! (...) We started all of a sudden one day.

Facilitator: And how was that experience?

Community midwife: Beautiful, I would go back and do it again a thousand times…Even with a lot of anxiety because it is logical…

Facilitator: Anxiety given to the sudden autonomy in practice?

Community midwife: No, unlike today, you didn't have anyone behind you who supported it, you had everyone against it.

Facilitator: So, there was some resistance?

Community midwife: There was total resistance apart from a couple of doctors who were there for you on this journey and who gave you the peace of mind to say -Look if you need anything I am just behind that door-... So it was more almost like an act of rebellion right? A revenge in order to say -Look, we can do it-. So if we managed to made it happen in a context like that…

Facilitator: You mean today with a different support network?

Community Midwife: Yeah exactly. I mean the same situation as 30 years ago but in a much more supportive environment so of course it's [the plan to open an MU] scary… but all changes are scary"
Focus group hospital and community midwives 11/1/2021

Overall, these different memories of previous midwifery led care experiences represent the history of the local context told by the local professionals who have lived and worked there in the past decades. It is an important starting point when trying to understand their attitudes, preconceptions and values when attempting to implement an innovation such as a MU.

4.3 Findings

The conditions that determined the readiness of the local context and potentially affecting the implementation of the MU which were identified during this situation analysis are reported below using the CFIR constructs. Illustrative quotes are added in each section to present the findings with the participants' own words. Quotes and citations were translated in English for the benefit of the reader. Translation was always reviewed by the two supervisors of the thesis who spoke both Italian and English.

4.3.1 Innovation - Innovation source

When discussing the MU model of care with stakeholders from different backgrounds, professionals often reported the idea that the innovation was being imported "*from the outside*" and specifically from a different type of healthcare systems like the English one. There was a general perception that the local leadership had decided to follow the example of this country with the aim of bringing innovation to the local maternity services. Only few participants mentioned the national Italian guidelines that promoted such innovation in Italy too and they were all midwives or midwifery managers. Medical managers, doctors and service users did not seem to have knowledge of other Italian contexts and the national guidelines that promote these models of care.

This idea that the innovation source was external and that an effort was required to import it in the local context was often associated with examples of resistance towards the project and as a justification for its inapplicability.

"I feel like this model of care can work in a different healthcare system and with different type of midwives. I don't see this applicable in this context" Obstetrician, FG 26/2/2020

Certainly, my influence as a researcher of an English University and as a midwife practicing in a London AMU influenced this view. This was notable when, during some data collection activities, participants referred to me asking specific and practical questions about the model of care. I recorded this aspect in my research diary and reflected on it using reflexivity and positionality. In these circumstances, I observed my position as a research midwife and how this impacted participants' views of the innovation. In my role of facilitator and PAR researcher, I tried to remind participants of other national and regional examples of MUs and referring to Italian guidelines in the attempt to help them move from the "externally developed" to the "internally developed" perception of the source of the innovation and promote a sense of ownership about it.

4.3.2   Innovation - Evidence strength and quality

At the beginning of the project, participants' perception of the evidence around MUs was not uniform.

Midwives had more knowledge and awareness about this model of care and seemed to trust the evidence. Some of them reported having seen the benefits of this evidence in practice in previous attempts of similar models of care in Tuscany or when working in other hospitals in Italy where similar models existed. The importance of the exposure to the model of care that was frequently mentioned by professionals. Having seen or practiced in such contexts made them feel more confident about the evidence and seemed to influence their trust in MUs.

Midwifery managers stressed the importance of having an Italian guidelines about this model of care to make a case with commissioners and directors that would otherwise not trust international evidence thinking that it only refers to different type of healthcare systems. Interestingly, some professionals believed that international guidelines like the WHO ones were mainly valid for low- and middle-income countries and believed the Italian context to be too different. This tendency to trust and rely more national guidelines and recommendations was notable amongst professionals and managers.

In the group of obstetricians, the knowledge of evidence on the midwifery model of care and their approach to its quality and validity seem to differ according to generation. This was evident in a focus group conducted with five obstetricians, all working in the intrapartum area. Doctors from the previous generation felt that a MU was not a good idea and that the previous experience of a low-risk birthing room demonstrated its inapplicability regardless of what international guidelines

recommended. On the other hand, younger doctors showed more knowledge and a positive perception of the quality and validity of the evidence. Two of them had previous exposure in international contexts (England and Belgium) and reported these experiences as eye-opening as they did not see that model during the medical school or in previous work experiences in Italy.

"XXX (medical director) also mentioned the fact that in the latest regional report, birth rate is going to reduce more in the next 10 years and all women will be around 40 years old so all high risk. Therefore, there is no point to do a birth centre or invest in this in their view. Everyone in the room nodded and agreed with this. (…) The local dimension for them is essential. They are not going to implement a change if the local numbers or guidelines suggest so. They feel 'different'; 'we are not like UK', 'we are not like rest of Europe', 'WHO guidelines don't apply to this type of context'" Research diary, 2019

The perspective of professionals and managers of the quality and validity of the evidence arose during a strategic regional meeting when I presented the research project to the regional leadership as part of the engagement activities. The audience was constituted mainly of obstetricians, neonatologists and medical directors. They showed concerns about the quality and validity of the evidence and openly expressed hesitation about the success of this model of care in Tuscany due to what was perceived as the unsustainable existing model of the regional MU in Florence. However, this nourished their interest in an implementation research project like this one to find out more about the adaptability and sustainability necessary to implement this model regionally and nationally.

4.3.3   Innovation - Relative advantage

Stakeholders' perception of the relative advantage of a MU were heterogenous amongst different participants' categories and even within the same professional group. Participants did not have a clear stance and it seemed that at the beginning of the project there was an even distribution of who saw the advantage of a MU and who instead would have opted for an alternative investment. Some believed that the advantage of a MU would be minimal (or even a loss) for the organisation and would have preferred that same money to be spent in a training programme for midwives or in refurbishment of the existing intrapartum setting. This was believed to be better use of resources in the long term especially considering the decrease of birth rate registered at national and regional level.

"They (service users) are ready to point the finger at us and I find a great immaturity among women compared to the past with regards to pregnancy and their birth experience that they delegate to others

whether is a midwife or a doctor. (…) I do not see all this great awareness in women, and not seeing it, I consider the idea of the birth centre (MU) an outline absolutely superfluous" Obstetrician, FG 26/2/20

Another group, on the contrary, found that MU would have been a good opportunity to improve clinical outcomes and also to attract more service users interested in a more natural approach to give birth. Some obstetricians were aware that for a low-risk pregnancy being cared by an obstetrician instead of a midwife could have a negative impact:

"I am convinced that if a woman is really low risk, the least we do (as obstetricians) the best outcomes she will have" Obstetrician, FG 26/2/2020

However, there was a unanimous position amongst managers, different professionals and even service users that an AMU (rather than a freestanding unit) would be the safest option; being inside the hospital was seen as an essential prerequisite. They all saw the relative advantage of an AMU as a steppingstone to move towards a less medicalised approach while maintaining a good level of safety. A freestanding MU or even the homebirth option were considered unsafe by all neonatologists and obstetricians interviewed and by some midwives too. During the focus group with service users all women reported being open to the option of an MU but stressed their need to be in hospital to feel safe.

4.3.4 Innovation - Adaptability and complexity

Adaptability and the need to make the innovation appropriate for the local needs and population was often mentioned by managers. Especially considering that most of the stakeholders saw the innovation as something that belonged to a different healthcare system, it became clear their need to adapt it in order to accept it. This concept was often mentioned and stressed during meetings and research activities.

A big role in this was played by the sudden change of leadership which happened during the first year of this research project. The change of main actors and the lack of leadership continuity threatened the project's success and significantly affected the implementation timeline. The new leadership expressed a need to adapt the project to be able to promote it and moving it forward. Professionals and managers often discussed the need to adapt the project to the local needs and felt pressurised by a perception that this type of innovation was not reversable.

Two midwifery managers often reported this aspect as something that caused stress and burden especially in a historical moment already full of big changes for the maternity team. Having just implemented two new teams of midwives in settings such as the operating theatre and the postnatal ward took time, drained most of the team energies and affected the team spirit. Therefore, they looked at the MU project as another cause of emotional and professional labour.

"It's all a change. As you begin to consolidate something, you dismantle it and immediately there is another new thing to do" Midwifery manager, FG 20/11/2019

Another midwifery manager with an extensive experience of the midwifery model of care in one of the small hospitals that was closed ten years before, for low number of births per year, reported frustration and the sensation of being "*back to square one*". She felt like in the past two decades the model like the one where she used to work was dismantled in favour of a more medicalised and technocratic one and now, with the MU project, the team was attempting to implement a model that was very similar to the one where she used to work in. All the midwifery knowledge and confidence that she saw and experienced was lost and now the organisation was attempting to bring it back, promoting a multi-layered and complex change. She saw this as an ineffective use of resources and a cause of frustration for midwives like her who was now just looking forward to retirement.

Overall participants were aware of complexity of the MU innovation and felt that it would require a long time to be implemented in a public healthcare system. Italian bureaucracy was mentioned as a barrier to any implementation in this system.

4.3.5   Innovation - Cost

The plan was to reorganise the maternity department using extra space which became available in the floor above after the renovation works in the hospital. Therefore, costs associated with the intervention were mainly related to the architectural changes, extra midwifery staff and training programme to prepare the dedicated staff who would work in the MU. A budget for this was allocated in 2019 by the organisational leadership. However, discontinuity of leaders and the Covid 19 pandemic led to a suspension of the expenditure of the allocated budget.

"Oh well, many things were left on hold, because of Covid certainly and also for other reasons... It must be that this thing (MU project) does not have a linear development. But that's the way it is. Maybe there is an update (...) it is that the budget has now been allocated." Midwifery manager, multidisciplinary meeting

4.3.6   Outer setting - External policies

Two main documents in Italy define the pathways of care for uncomplicated pregnancies and midwives' autonomy in being the lead healthcare professionals for primary care. The main antenatal care guideline for uncomplicated pregnancies, "*Linee Guida Gravidanza Fisiologica*", was published in 2011 and updated in 2013   (Istituto Superiore di Sanità, 2011). It summarises the available evidence and gives recommendations for practice. Interestingly, in this guideline, the paragraph about the healthcare professionals mentioned the evidence about the importance of continuity of midwifery led care and case loading models. The following is the closing recommendation:

Italian text:

"*Alle donne con gravidanza fisiologica* **deve essere offerto** [my emphasis] *il modello assistenziale basato sulla presa in carico da parte dell'ostetrica/o. In collaborazione con l'ostetrica/o, il medico di medicina generale, i consultori e le altre strutture territoriali costituiscono la rete di assistenza integrata alla donna in gravidanza. Questo modello prevede, in presenza di complicazioni, il coinvolgimento di medici specializzati in ostetricia e di altri specialisti.*" (Istituto Superiore di Sanità, 2011)

English translation:

"*Women with physiological pregnancies* **must be offered** [my emphasis] *a care model based on the assumption of responsibility by the midwife. In collaboration with the midwife, the general practitioner, the community centres and other facilities constitute the network of integrated care for the pregnant woman. This model provides, in the presence of complications, the involvement of physicians specialized in obstetrics and other specialists*."

It is worth noticing the use of the word "deve" in the first sentence which is an imperative verb in Italian which could be translated as "must" in English. The guideline is therefore not only encouraging but highly recommending midwifery led care for low-risk pregnancies. Considering that it was published five years before the evidence like Cochrane review by Sandall et al. (2016) and how medicalised the Italian context is, this represents an important point of reference for midwives or stakeholders interested in implementing midwifery led models of care in Italy. The importance of this document was notable even during FGs with healthcare professionals as they all mentioned it.

The second, "*Linee di indirizzo per la definizione e l'organizzazione dell'assistenza in autonomia da parte delle ostetriche alle gravidanze a basso rischio ostetrico (BRO)*" (Guidelines for the definition and care planning for low-risk pregnancies by midwives in autonomy), was published in 2017 (Comitato Percorso Nascita Nazionale, 2017). Just looking at the titles of the two documents, we can notice how the different choice of words and the shift from using "gravidanza fisiologica" (physiological

pregnancy) in the 2011 one to the "low risk pregnancy" in 2017. This language shift seems to highlight a more risk-oriented approach of the policy makers who worked on the latter guidelines. The word "rischio" (risk) is mentioned 36 times across the 8 pages document.

In fact, the acronym BRO "basso rischio ostetrico" (low obstetric risk) which was repeatedly used in the 2017 guideline soon started to being used on a national level to refer to uncomplicated pregnancies. Interestingly, during data collection activities many managers and healthcare professionals would refer to these service users as "BRO" whilst service users during the FG used the words "gravidanza fisiologica" (physiological pregnancy) to refer to their uncomplicated pregnancy.

"Very interesting to see how important the decision around the name for the MU in Italian is. People want to call them "unita gestionale a basso rischio ostetrico" (unit for low obstetric risk) which is really not service users friendly. It's a technical name. Italian guidelines and operational documents really have a formal, difficult and techy language. I understand however that if you call them this way hospitals and professionals will be more inclined to listen and apply the change because it's their own national guideline telling them to do so." Research diary, 10/12/2019

"I had a physiological pregnancy, luckily everything went well" FG Service users 10/1/2020

Stakeholders showed the need to have a national guideline before attempting any MU implementation and often stood back from international guidelines and evidence even when they were based on rigorous studies such as Birthplace in England (Hollowell *et al.*, 2011). They frequently expressed doubts and concerns about the validity of international evidence for the Italian context, explaining that "*le donne italiane sono diverse*" (Italian women are different) and highlighting how the population, the local culture and the healthcare system could not be comparable.

"but it's not that. It's more that they are two populations too different and so it's hard to even look at NICE guidelines because they don't do to represent the reality that you live...." Obstetrician, FG 26/2/2020

During the past decades, the local context implemented big changes such as new first trimester screening tests and intrapartum monitoring with less resistance than this project encountered for an innovation like an AMU. Midwife respondents raised this issue and identified the primary reason as a patriarchal and doctor-centred approach to pregnancy and childbirth in Italy. They saw this as the result of decades in which the obstetrics and gynaecological profession was mainly led by men and argued that this also affected the service users' mentality and ideology about birth. For over five decades, service users have referred to obstetricians as the lead healthcare professional for pregnancy and birth paying them for private visits hoping to be looked after by them during birth in the public hospital. They felt that dismantling this would require a long time and is likely to encounter resistance

from both the medical side (for taking away some profitable private workload from them) and from the service users who are now associating the concept of "safety" with the medical profession and do not know much about the midwifery profession.

Furthermore, some midwives mentioned how even the midwifery educational system was led by the medical component. If lecturers and professors of a midwifery course are mainly male doctors then the education would reflect a medicalised mentality and approach to the professions on the new generation of midwives too. They identified this problem as a national issue, not limited to the local context:

"...In fact even in all the training (that we have done) over the years there is a highly medicalised culture. But not only in XXX, but in Italy as a whole. In my opinion this is a big obstacle. And women are immersed in this culture." FG with hospital and community midwives, hospital midwife, 9/1/2020

"training about pregnancy is predominantly based on a medical culture. Even at the university, the people teaching you are doctors. The problem starts there already." FG with hospital and community midwives, community midwife, 9/1/2020

During the past ten years, the organisational leadership actively promoted the implementation of programmes to empower the role of the midwives within the organisation. Furthermore, the LHA included in the improvement plan for the upcoming years some key areas such as community-hospital integration, continuity of carer in the community and implementation of protocols for midwife led intrapartum care. All these objectives aligned perfectly with the MU project and therefore played a significant role in supporting the MU project.

4.3.7 Outer setting - Cosmopolitanism and peer pressure

If the lack of networking and collaborative work was notable at the organisation level, it became more apparent at regional and national levels, where the guidelines and the maternity service configurations could differ significantly. What seemed to be lacking was the possibility to spend time together to get to know colleagues of the same LHA and the projects happening in neighbouring hospitals or communities.

"It's a missed opportunity that we don't know each other or that we've never done courses together even though we're part of the same organisation. By doing courses like this one, you really get to spend time together and realise what kind of services are being offered in other parts of the organisation... It's a shame there are no regular opportunities for this" FG after training days with community midwives, community midwife, 19/11/2019

Across the different regional LHAs protocols and the maternity service layout sometimes could differ significantly. If between LHAs the contacts and occasion to exchange opinions and collaborate were rare, they were almost inexistent between different Italian Regions. This suggests a low level of cosmopolitanism and a barrier to implementation.

A clear sense of pride to belong to the Tuscany Regional healthcare model arose during data collection activities. A good reputation of the Tuscany model nationally was also mentioned by a midwifery manager who joined this model after having worked in different regions.

"Yes, from this point of view, Tuscany is certainly well developed, both in its organisational models and in its professional resources, I mean, for example, the midwifery-led care model (...). There is not this level of development in other regions." Midwifery Director, Interview 28/4/2020

Having already a MU in Tuscany had a paradoxical role of being both a facilitator and barrier at the beginning of this research. Initially, when there was the need to initiate a conversation and to convince the organisational leadership of the feasibility of the AMU project, having a regional point of reference was positively decisive. It nourished the leaders' need to rely on national and local examples more than international ones. It reduced the sense of fear of the unknown that stakeholders had when imagining the innovation as imported into Tuscany from a different country. During the first months of this research, mentioning the regional AMU during engagement activities really became an effective strategy to "open the gate" and to stimulate interest towards the project. However, after a while, I noted a shift in the approach towards the regional MU. That model was seen as unstainable and sometimes associated with the expression of like "failed attempt". One influencing factor was that a new organisational leader, who arrived in the local hospital in summer 2019, had previously worked in Florence (where the MU is) and had a negative experience of that model of care. The perception was that the number of births annually was not high enough to make it sustainable and that the two teams (OU and MU ones) were having unbalanced workload.

"Well yeah of course, but we could not accept that some midwives would do 400 births per year in comparison to others who do 2000, this is not fair and acceptable. Midwives should not be 'mono-professional' and out of practice for high risk intrapartum care. We had to rotate them." New Hospital Director, multidisciplinary meeting 23/12/2019

This change of leadership and previous negative experience seemed to affect local managers and professionals' attitude towards the regional MU and therefore to the MU model in general. However, as this new leader left the autonomy to the maternity team to decide for their own improvement plan for the following five years, the project was not completely abandoned. This was considered a

'positive' example of leadership from the team, as promoting ownership of the change amongst the maternity team allowed the midwifery manager to continue with the MU project.

4.3.8   Outer setting - Service users' needs

The involvement of service users in strategic decisions for the maternity configuration was not well-established. Service users are not regularly involved in advisory groups or organisational meetings related to the planning of innovations in maternity services. At the beginning of this research project, there were no regular occasions to meet, discuss and exchange opinions between organisational leaders, professionals and service users' representatives.

When a MU advisory group was established by the lead obstetrician in 2018, two representatives of a non-profit local organisation of mothers were invited to be part of the group and they enthusiastically accepted. This group continued to meet twice yearly in the following years but did not invite these representatives after the first meeting. When leaders were interviewed, they explained that the reason for this exclusion was that at that stage of the project the meetings topics were too technical and specific and therefore there was no point to include non-professional stakeholders. Throughout the first year and a half of this project, I did not identify any form of involvement of service users in the planning activities. When I organised an event to conduct a focus group with service users and the local NGO, one of the midwifery managers suggested "*being cautious*" as it was not clear whether this NGO had some personal interest behind the collaboration. This showed a local culture to approach the change which seemed to be mainly organisation-centred than patient-centred and a lack of familiarity or comfort with public involvement.

"You also have to see what population you are referring to, the mentality of the women you work with ... here they are all obese. Willingness to give birth seems to me that they have very little or almost zero. Also, they request a caesarean section at the second contraction ... women are not motivated, you often struggle to try to make them physiological" Obstetrician, FG 26/2/2020

A report of the findings from the MeS surveys completed by service users in 2018-19 was prepared for the maternity team including quantitative indicators (as shown in table 10), thematic analysis of qualitative data and word clouds. As part of the preparation of that report, I conducted a thematic analysis of the open-ended questions related to the birth experience of service users in Tuscany in those years. This represents a rich source of data that can help set out the main points and needs that women discuss about the experience of the regional maternity pathway. A total of 4494 participants across Tuscany took part in the surveys and 375 of them gave birth in the local hospital left open-

ended comments that were analysed. As the questions asked were about any positive or negative comments that the users felt the need to add to the close questions, the approach used for the analysis included an initial coding based on the main sentiment: positive, negative or suggestion. For example:

"I really liked the human approach that everyone has towards you, they make you feel like at home" *Service user – Regional MeS survey 2019-20*

"I felt a lot of disorganisation as well as little cohesion among the staff, everyone had their own idea of how the birth should have gone and I felt confused, not safe" Service user – Regional MeS survey 2019-20

"I have always had conflicting advice, differing opinions and a lack of communication especially during the shift change." Service user – Regional MeS survey 2019-20

A more thematic coding was then conducted and the emerging themes about what was reported to be important to users were mapped. The following items were the themes most discussed:

- Rapport with professionals – specifically the importance of appropriate communication, language and ability to listen
- The importance of always providing clear, understandable and coherent information, even to women who already had previous babies
- Having felt lonely in labour on some occasions
- The importance of having different pain relief options
- Not being listened to when requesting an epidural
- Having felt supported by professionals in a homely environment
- The postnatal time spent on the ward as crucial for a good start with breast feeding and as a mother
- The postnatal ward as being too crowded during visitors' time
- Having always a partner during the postnatal stay as essential especially for users who had a caesarean section
- Being happy to have the baby in the room with them but not when there were too many visitors or when they were left by themselves (especially after CS surgery)
- Suggesting refurbishment for the maternity wards
- A suboptimal standard of cleanliness on the ward
- Having felt lonely during the pandemic months when there was no partner and no visitor policy – here some extra support by the professionals felt needed

Looking at the quantitative data from MesLab surveys of the birth experiences in the local hospital between 2018-19, some areas for improvement could be identified in the following indicators: continuity of care in labour, pain relief options, skin-to-skin contact after birth, teamwork, cleanliness of the environment and quality of care. Good scores were registered in the breastfeeding and willingness to recommend the hospital indicators.

Performance assessment by MesLab include a benchmark activity to map good examples present in Tuscany to promote a culture of positive competition and learning from each other to improve the care provided in the region. Benchmark of different indicators follows where available WHO standards and where no obvious standard existed, the regional average was used with adjustments where necessary for different risks between health authorities (Nuti *et al.*, 2009, 2017).

In the table 10, the different colours indicate different level of performance of the local hospital as analysed by MesLab on the experiences of service users (green – best performance; light green – good performance; yellow – average performance; orange: poor performance; red: worst performance). The boxes in white are data available but not measured for the performance due to the impact of the Covid 19 pandemic. The indicators concerning pregnancy and first year refer to the two districts of the local area (therefore two numbers for each indicator). N.D. = data not available for this indicator in that timeline.

Table 10 MeS indicators of maternity care pathway users' experience 2018-2020 in the local hospital (first column) and regional context (second column)

Indicator	2018		2019		2020	
	Local area	Region	Local area	Region	Local area	Region
Pregnancy						
Quality of booking appointment (score 0-100)	82,6 82,8	79.7	86,4 86,5	83.4	86,4 83,9	85
Experience with midwife during booking appointment (score 0-100)	69,7 71,6	65.9	77,3 74,7	73.7	76,9 72,7	74.8
Benefit of the antenatal care classes (score 0-100)	56,3 60,4	57.4	N.D.	N.D.	56,5 60,4	54.3
Willingness to recommend community centre (score 0-100)	91,8 86,2	88	N.D.	N.D.	92,2 82,4	86.9
Birth						
Autonomy in labour and at birth (score 0-100)	75.5	76	71.5	73.4	72.1	69.9
Respect and dignity from professionals during labour and birth (score 0-100)	89.6	90.2	88.6	86.3	89.4	87.4
Continuity of care in labour and at birth (score 0-100)	81.1	84.9	82.5	80.5	85.5	83.1
Pain relief in labour and at birth (score 0-100)	68.7	75.9	72.1	71.7	72.1	71.7
Skin to skin contact (%)	38.3	62.7	N.D.	N.D.	49.5	59.3
Esclusive breastfeeding when discharged from hospital (%)	83.8	76.7	N.D.	N.D.	76.6	75.2
Team work (score 0-100)	81.2	86.5	76.2	80.3	81.4	80.8
Coherence of information received (score 0-100)	71	76.7	65	73.4	72.5	73.3
Clarity of information when discharged (score 0-100)	79.9	79.9	68.6	73.1	70.1	70.9
Quality of care in the birth setting (score 0-100)	82.7	87.7	79.9	82.6	82.8	82.4
Willingness to recommend the birth setting(score 0-100)	90.7	93.5	84.4	89	88.5	89.3
First year						
Women invited to a postpartum visit by the birth setting or community setting (%)	60,3 55,6	69.4	N.D.	N.D.	57 65,4	64.2
Experience with professionals in the community centre (score 0-100)	67,8 63,9	69.2	N.D.	N.D.	60.1 59,2	63
Willingness to recommend the community centre (score 0-100)	82,9 81,7	85.5	N.D.	N.D.	77,4 76,7	78.6
Exclusive breastfeeding at 3 months of life (%)	65,7 50,7	63.3	N.D.	N.D.	64,4 62,2	61.5
Exclusive breastfeeding at 6 months of life (%)	15,5 5,7	15.5	N.D.	N.D.	9,7 0	14.7

Managers did not seem to know the research activity conducted yearly by MeS Laboratory well and asked questions like when the users are asked to fill these surveys, who was recruiting them and what kind of population completes them. Considering that the recruitment happens during each booking appointment and that previous years' results had been previously presented to them during the annual performance meeting with MeS, this lack of knowledge and confidence with the data seemed to suggest that they do not refer to this source regularly.

The themes arising from these surveys were coherent with the ones emerging from the face-to-face focus group I conducted during the breakfast with service users in January 2020. The main topic stressed in that discussion was the importance of appropriate communication and body language not only in labour but also in the postnatal ward when supporting women to best start with breastfeeding. Infant feeding consultants (who work in the postnatal ward) were mentioned as gold standard examples in this sense.

4.3.9   Outer setting - Networks and communications

The quality of the communication within the organisation was often topic of discussion during interviews and focus groups. Professionals mentioned the rigidity of the communication system.

Midwifery leaders seemed to play the role of "filters" of the communication between the organisational and medical leadership and the rest of professionals in both directions, influencing the "what" and "how" information was reported to each end. This meant that were seen as the hub of the communications by the team, who sometimes did not take ownership of their practice or activities and delegated the responsibility back to them. In more than one occasion for example, professionals who did not attend research activities replying "*but they didn't tell me!*" or "*I wasn't told that I had to do it by …*". This shows the downside of a hierarchical structure with strong power and control dynamics in which team members often act passively and expect to be told what to do instead of developing ownership and sense of autonomy and accountability for their work.

Lack of communication between the community teams and the hospital team were often mentioned by participants. They reported not being aware of "*the other side of the medal*" and being willing to know more about that. What was identified as facilitator to help the integration of the service were the study days.

"We only see each other during study days and sometimes not even during them. I think it would help to have more opportunities to spend time together and get to know how other people work. We have been talking about rotating in the community for quite some time now…" Hospital midwife, Interview 27/11/2020

4.3.10 Inner setting - Culture

The analysis indicates a context in which norms, values and basic assumptions tend to be based on a medicalised vision of childbirth. In more than one occasion stakeholders mentioned "*a birth is normal and physiological just retrospectively*".

"I kind of say it's just because of the insidiousness of this job that I don't feel it's safe to have that kind of situation (MU)... Because a woman has not given birth well until proven otherwise. That's it. You can talk about physiology but you have to see the baby out first. Very often in these cases... let's say from 5 centimetres to the birth or postpartum, it's a time that is absolutely unpredictable and therefore, because of what I've been experiencing over the years, sometimes things happen and I say 'thank goodness we were here'. So, I am happy to work here because there are always three midwives available, a delivery room, I always have an anaesthetist or a neonatologist available. And despite this, there still some problems sometimes. You could say to me the contrary that they happen because of that. Maybe they would but anyway..." Obstetrician, FG 26/2/2020

The expression "*natural birth*" was sometimes associated with fear or a sense of irresponsibility. On the other hand, technology was often associated with positive attitudes and with the idea of working with an innovative and up to date portfolio. Professionals identified the regulatory system in Italy as a significant contributor to this medicalised philosophy of care. They mentioned that the responsibility for a negative or adverse outcome is placed more on each individual healthcare professional than the organisation, as opposed to other international healthcare systems. This implies a certain level of awareness of their medicalised approach and its limitations but also perhaps a misconception of other healthcare systems.

A great deal of attention was often given to a binary concept of low risk versus high risk. Professionals seemed to have a vision of the risk factors in pregnancy and during birth as static and non-specific. Instead of continuous assessment, doctors and midwives would often keep the "high risk" label "*just in case*".

In 2020, however, a new further division was promoted by the organisation leadership: the inclusion of the "medium risk" concept. Those pregnancies would be followed jointly by a doctor and a midwife antenatally and will have doctor led care intrapartum. The aim for this change was to ensure that whoever belongs to the low-risk category is actually low risk of anything and that appropriate

screening is done in pregnancy. Professionals had ambivalent opinion about this approach. A part of the team felt reassured that in this way the low-risk women looked after by midwives would be "really low risk" and another part of the team believed that this would be an attempt in medicalising pregnancy and birth as very few women would now fit in the "low risk category". A contributory factor for this change in approach might be found in the 2017 national guidelines in which the concept of risk was central (see External policies paragraph 4.3.6 for details).

The service users' rapport with healthcare professionals looked very unbalanced with most of the decision-making power laying in the professionals' hands leaving to the users the possibility to agree or not with the plan of care. Women's autonomy is not always recognised and respected justifying, once again, this approach with the fact that the "*responsibility for this birth and any negative outcomes relies on me as healthcare professional on a legal point of view*" (FG 26/2/2020). Out of guidelines birth plans or the possibility to opt out from clinicians' recommendations were not something that professionals experienced or would happily support. However, it was evident that even amongst service users there was no tendency to ask for out of guidelines care or to show autonomy in the decision-making process about their care. A tendency of not being actively involved in the care but instead tending to delegate the decisions to the healthcare professionals was noted. The cause for this interaction and power dynamic might be found, as already anticipated in the chapter 1, in the previous decades of male-obstetrician dominance in the gynaecological and obstetric care.

"The problem is that culturally they (service users) know that when they are pregnant they go to the obstetrician. No one has ever told them that BRO (low risk) pregnancy are looked after by midwives. (...) Basically it's always been the prevailing male figure who has obviously always done the wrong thing with this. And in addition, midwives tend to be nice and understanding while the obstetrician discredits midwives easily as soon as there is something wrong. He immediately discredits the figure of the midwife and this impacts the woman's opinion. The woman perceives that the obstetrician is capable and the midwife is not." Community midwife, FG 19/1/2020

"Once a woman has been followed in the high-risk outpatient clinic how can you tell her 'okay ma'am you are low risk as of today'? And especially with some of the intermediate situations it's hard for them to make them return to low risk...by then she's being looked after by the doctor." Obstetrician, FG 26/2/2020

4.3.11 Inner setting - Implementation climate

The local hospital was seen within the LHA as one of most receptive to innovations. The team felt they had good skills in terms of adaptation and absorptive capacity even if continuous changes were sometimes tiring and demanding.

The learning climate however was not always positive and constructive. Some episodes were observed in which the medical leadership did not appreciate the work of some team members and instead of giving constructive feedback, attacked aggressively and negatively the work done (in their own free time) by some midwifery colleagues.

A low tendency for reflective practice became also evident in terms of difficult rapport with MeS Laboratory as institution which conducted the performance analysis each year and it seemed like the team was doubting the validity of the data reported annually by MeS.

"She (lead midwife) referred to MeS and the evaluation of the performance as 'Big Brother's Eye'"
9/1/20 research diary

Professionals seemed to feel the pressure of the performance analysis. The performance evaluation aims at measuring the capacity of the regional health system, of the LHAs and communities to be effective and efficient, in delivering appropriate services for the population. No penalty is expected even in case of a low performance. However, professionals struggle with the idea of being judged and, on several occasions, they expressed concerns about the indicators selected for the evaluation not being reliable.

There were three types of professionals' attitudes towards the MU innovation:

- A small group who openly expressed support to the MU project
- A small group who openly expressed disagreement and not being supportive
- A larger number who did not openly disclose being in favour or against

In each of these groups there was representation of midwives, obstetricians, neonatologists and managers, indicating that this did not fall along professional group lines. This quote from a supportive neonatologist shows how the team was aware of the resistance towards the project but also how some of them had changed throughout time.

"(...) over the years the percentage of people who are ready for something like this (MU) is increasing... we have to work on maybe those resistances as well. Some things we will be able to do, some other things will remain resistant. But we all have to move forward with the project, a project belonging to everyone. (…) Because if you understand the model you believe in it. You need to have the possibility to understand it. You have to understand that it's safe. That's the key thing." Neonatologist, FG 11/1/2021

4.3.12 Inner setting - Readiness for implementation

Key elements of readiness to implement MU were found in the receptive context to innovations and motivation of some professionals and managers. However, leadership engagement towards the implementation of the MU changed periodically. Key reasons for this were: change and discontinuities in organisational leadership, previous negative experiences of new leaders and change in the budget available for the innovation (also due to the pandemic).

The importance of leadership continuity during the first stage of promotion and planning of the change became clear after the loss of the former lead obstetrician who had championed the project initially. Unfortunately, he passed away in early 2019 and the team was significantly affected by this sudden event. Not having been able hand over the project to new team members or to involve any other leaders to push this project forward made it hard the following months to realise where the project was left.

This engagement seemed to require constant and regular effort from the researcher as a facilitator and sometimes it felt like the passive approach to change could become synonym of lack of ownership and therefore a key barrier to the feasibility of the implementation.

Sometimes the uncertainty experienced by the leaders regarding the MU was reflected in the blurred vision that the maternity team had.

"I believe that as of today, and correct me if I'm wrong, nobody knows what we want to do, if we still want to do it and if this new management wants to do it. " Lead midwife, FG 20/11/2019

"Facilitator: In your opinion, when we think about the implementation of these realities in today's reality, what are the main barriers? (…)

Group: Cultural

Midwife 1: Although today things have certainly changed. Before birth, labour, and pregnancy were delegated so much to the doctor. Medical care equals wellbeing: wellbeing for the woman and well-being for the newborn. Today we are certainly going back to less medicalization by re-evaluating other figures and also re-evaluating other models of care that are certainly alternatives to the hospital, however, there is still a long way to go ..." FG with hospital and community midwives, 19/1/2020

However, by the end of the first year of research activities I noted an increase in the leadership proactivity towards the MU project. The midwifery operation manager took greater ownership and promoted the MU model in front of the whole team asserting that "*si va avanti*" (we are moving forward). She also identified a group of motivated and dedicated midwives to ask them to give feedback to the plans that the architects had prepared (3 possible drafts). This was received positively

by the team and promoted enthusiasm about the project. The invitation for me to participate as researcher and facilitator during that meeting also signalled a growing engagement with the research project.

After a long period of uncertainties in terms of funding available and dedicated to the MU project a key trigger for release of resources was the Covid pandemic in 2020. During the state of emergency, the national government released a significant amount of funding for the healthcare sector after years of constant cuts to the national and regional budgets. This allowed the team to opt for a bigger and more complete refurbishment plan, dropping the idea of only modernising the intrapartum ward. It was notable also how a deadline to submit a project to the Tuscan Region in order to get funding was a positive force to push the project forward.

Stakeholders' access to knowledge and information about the MU was overall good thanks to the networking activities of the previous years and also the participation of members of the team to the Midwifery Unit Network Italian conference in Milan in February 2020. In this occasion the team from local hospital (two midwifery leaders and three clinical midwives) were exposed to other national settings which were attempting similar changes and gained more inside knowledge on the adaptability and adoption required for Italian contexts. They also received the Italian translation of the Midwifery Unit Standards as guideline to be used when planning the change (Batinelli *et al.*, 2020).

4.3.13 Individual knowledge and beliefs about the intervention

This PhD project was discussed and planned together with the former lead obstetrician in 2018 as a consequence of previous years of collaborations and research projects. Since 2015 when I started working in the English NHS as midwife, I was invited once or twice a year for conferences or seminars to present the maternity care system and specifically about the MUs model. Therefore, at the beginning of the study there was a baseline of knowledge amongst professionals about what the MU model was and existing experiences in the Italian context.

Managers and directors with a medical background, by contrast, seemed to have a general knowledge on the topic but not a detailed insight of the standards for the MUs model of care and its functionality.

"Obstetrician: why, sorry, could you not start an oxytocin drip for augmentation in a MU?
Senior midwife: Absolutely not!
Obstetrician: No I mean I don't know....

Midwife 3: Are you kidding?

Facilitator: If you need an oxytocin drip, you have to transfer otherwise there is contamination of the practice. (…)

Obstetrician: No, I don't know I am asking... but don't they use oxytocin in XXX (small hospital within organisation)?

Facilitator: XXX is not a MU. No, it's a hospital that works a lot with that kind of practice and philosophy, but it's not a midwifery led unit." FG, 11/1/2021

As part of this situational analysis, even service users were asked about their knowledge about the MU model of care during the only face to face focus group conducted in January 2020. In the group of seven pregnant and postnatal women, only three of them heard about MUs models and their understanding of the model seemed vague. However, there was a good level of knowledge of the midwifery role as experts of physiology and an overall sense of trust amongst the whole group towards this profession was noted.

"Facilitator: So, would you see an alongside midwifery-led birth centre inside the hospital in [local hospital] as a good fit?

Group: yes! yes!

SU5: It would be a dream!" Service users, FG 10/1/2020

4.3.14 Individual self-efficacy

In this situational analysis, the self-efficacy theme emerged mainly in the category of professionals and managers. During the first year of this research project, professionals' attitudes towards the innovation and their belief in the capability of applying the change to the local context fluctuated.

An overall good level of confidence was, however, noted in relation to other type of midwifery innovation such as the replacement of the nursing staff with midwives in the operating theatre and in the postnatal ward or the implementation of continuity of carer in all the communities of the LHAs. These changes were reported to add "professionalism" to the midwifery component. Even though these projects were reported as having drained much of the energies and motivation in the team, midwives seemed to fully believe in their abilities to cover these roles and felt more valued within the maternity organisation. A higher level of confidence was noted in comparison to other areas of the LHAs and this was acknowledged also by the Lead Midwifery manager of the LHA.

"Every time I come here it seems like breathing a fresher air, air of renewal and change... for you [local team] it might seem that nothing ever changes but in comparison to other realities (even within the LHA) here in XXX the change arrives earlier" Midwifery manager, multidisciplinary meeting 23/12/2019

"Also, because I really believe in it, I have to tell the truth: this group has a lot of facets (...) I have to say that we have shown very high professional maturity in welcoming and taking on new projects on over the years." Midwife coordinator, FG 27/11/2019

4.3.15 Individual state of change

Support from the organisational leadership towards the MU project was observed as variable and sometimes passive - not a manifested or apparent opposition but an immobility and lack of proactivity.

However, when a significant financial budget was released, organisational leaders became more committed to carry out the project. In this climate, midwifery leaders felt backed up by the organisation and started actively moving the project forward with the rest of the team.

The released budget was not only important on a practical level, but it showed high-level institutional support, which increased confidence amongst professionals. Having the organisational leadership support allowed clinical leaders to actively promote the change with the rest of the team. This seemed to have a cascade effect within the team and made it possible to move from a contemplation to the preparation stage of individual change just before the implementation events planned for the PAR cycle ('Act phase' in chapter 5).

4.3.16 Individual identification with the organisation

"We are all people who work well and also work with a certain type of motivation. Certainly, at this moment in my opinion, motivation is missing, in some moments even the change of the new staff has also led us to have moments of lack of communication, perhaps even with the medical staff, the neonatology staff, so we need to find some circularity from now on. But, for example, even neonatologists are on our side and even some obstetricians. In my opinion, we have good potential" Midwife coordinator, FG 27/11/2019

A sense of pride for belonging to the Tuscany healthcare system and sometimes even more specifically to the LHA was noted amongst professionals and leaders. In this quote from a community midwife this aspect arises clearly and it is interesting to notice how grateful she sounds even in respect to one of the latest regional changes that allowed midwives to sign autonomously the pregnancy booklet when booking a woman. Before this was something that needed to be signed by either an obstetrician or a general practitioner as doctors even if the whole one hour booking appointment was carried out

by the midwife. This recognition of their role and their autonomy was positively accepted by the midwifery component.

"In the end we are lucky to work in Tuscany... in many parts of Italy there is not this same structure of maternity care, the pregnancy booklet that we as midwives can now sign directly." Community midwife, FG 19/11/2019

This pride is an important facilitator that help individuals trust the organisational vision and therefore is an important feature in terms of readiness for the change.

Nonetheless, some negative episodes of not having felt valued, appreciated, or supported by the organisational leadership of the LHA as institution were reported by some professionals and most of them were midwives. This was also notable when talking to another lead midwife who stepped down as coordinator after one year of covering that role because she felt overwhelmed and by the fact that the organisation leadership promised to hire another coordinator so that she could share the workload but never actually did. These episodes highlight how the sense of fairness and organisational justice was not always good especially amongst midwives who had been working a long time within the LHA.

4.3.17 Process - Planning and engaging

At the beginning of the project, a long phase of engagement via conferences, seminars and multidisciplinary training organised by the local hospital and facilitated by researchers allowed the project to be visible to the team. Midwifery leaders and medical directors were used to engaging and planning changes collaboratively but this often did not include the wider team or the involvement of service users. However, the intention to improve this aspect was clear and the interest in interfacing more especially with the service users was unanimous. The PAR approach of this project was particularly appreciated by managers for the principle of engaging the whole team in reconfiguring maternity services. Codesigning the change to make it specific to the local population's needs became a key requirement for them while trying to implement the MU model.

4.3.18 Process - Opinion Leaders

The hierarchical set-up of the organisation meant that the engagement and support by the organisational leadership was decisive in moving the project forward. On a more local level, the medical director and lead obstetrician seemed to significantly influence the attitudes of the rest of the maternity team towards the innovation. However, some informal leaders were also noted and identified by professionals and they were midwives, obstetricians and neonatologists, some of whom were supporters of the MU and others were opposed to the idea. They had the ability to informally influence the attitudes and beliefs of those who did not have a clear opinion about the project.

4.4 Discussion

This situational analysis was coherent with previous studies that showed how AMUs are often seen as steppingstone and perceived as safer by professionals even though the evidence on FMUs is stronger (McCourt *et al.*, 2018a; Walsh *et al.*, 2020; Batinelli *et al.*, 2022). Both professionals and service users in the local context saw the AMU model as feasible option for the local context whilst maintaining resistance towards the idea of FMUs or homebirths. This shows how understanding of evidence quality and validity can be influenced by the local content culture and perceptions of safety. Participants were sceptical to trust international recommendations as applicable to the local context and often needed to refer to the regional or national dimension to trust the guidelines. This was an important finding that helped me to understand how to approach the MU evidence conversation in the following stages of the project when during the introduction I always made sure to include a citation to the regional guidelines.

Therefore a key facilitator for the MU project was having national and regional guidelines pushing in this direction (Comitato Percorso Nascita Nazionale, 2017; Regional Act DD10214, 2021). Medical, but especially, midwifery managers felt supported by these guidelines in promoting the change. It was interesting to notice the relatively quick shift in language among professionals associated with this (from "physiological pregnancy" to "BRO = low obstetric risk") considering that the guideline was published in 2017. This language change was not noted among service users who still referred to "physiological pregnancy".

Previous implementation research has demonstrated how organisations which are open to outside with networking, communication and peer pressure with other organisations are more likely to adopt

innovations and new changes (Greenhalgh *et al.*, 2004; Damschroder *et al.*, 2009). In this case study, lack of cosmopolitanism and regular communication with other contexts was noted as a barrier to the innovation. There is also strong evidence that if competitors or colleagues in other organisations or in other parts of the same organisation are all using an innovation, people may feel compelled to do so as well (Greenhalgh *et al.*, 2004). This phenomenon is called "*mimetic pressure*" and it was notable at the beginning of this research project where stakeholders referred to the regional example of AMU and wanted to be the first within their organisation to adopt it. Reading this dynamic was useful and became a successful strategy when I approached managers and leaders in the consequent stages of the research.

In the Italian context, public and private maternity service coexist and whilst the first is more midwifery led in the community centres the latter is mainly doctor led in the hospital. This configuration has been in place for decades, significantly affecting the way generations of women and service users see and use the maternity care. Midwives raised this issue and identified a patriarchal and male doctor-centred approach to pregnancy and childbirth in Italy as a barrier to implementation. This showed a level of awareness within the midwifery component about the gendered dynamic which were also identified in the systematic review in the Brazilian case study (Pereira and Moura, 2009). Midwives felt that dismantling this would require a long time and is likely to encounter resistance from both the medical side (for taking away some profitable private workload from them) and from the service users who are now associating the concept of "safety" with this model. However, most service users showed a good understanding of the midwifery profession and scope of practice, which is an important factor in terms of readiness of the local contexts for this type of innovations as shown by the systematic review of this thesis.

Having an allocated budget played a key facilitating role in saving the project even when the leadership felt insecure and doubtful of its applicability. It functioned as an *anchor* when other variables and influences were pushing the vision of the team towards other ideas. This showed how funding allocation can help but also how important working on the readiness for the innovation among stakeholders is for the adoption of change as the budget was there but was not being spent.

The importance of being exposed to physiology and midwifery-led care models to increase their trust in them was acknowledged both by midwives and doctors. Some midwifery managers mentioned this concept in relation to the erosion of midwifery skills in the new generation of practitioners. This is

coherent with a recent systematic review which showed this to be a barrier for promoting physiological approach to birth (Darling et al., 2021).

Main argument of the opposers to the model was the low numbers of women who would have accessed this service and the concern that this would make the innovation unsustainable. One internal audit conducted by the local team in 2019 showed that roughly 300 women out of the 1300 that give birth annually could be eligible for low-risk care. This meant that without actioning an implementation plan and any work to promote the unit there was a baseline of 300 potential women who could access the service. However, when this data was shown to managers there was reluctance in trusting these numbers. It was interesting to notice how this were considered low numbers for a maternity service considering that 23% of the population could have benefit from this model of care prior any implementation work from the maternity team. It also raises the question of what percentage of the population would be high enough to implement the model? Other innovations that would affect less women were implemented more easily in the local context previously (e.g., DNA test to integrate the combined test and Covid protocols) and sometimes with no evidence in support of it (e.g., the medium risk classification). This goes back to the concept of valuing different knowledge and evidence different and how often more medical-technological innovation are better and more easily trusted by healthcare professionals (Downe and McCourt, 2008).

This argument of numbers in relation to sustainability was mentioned in other research on AMUs in England (McCourt *et al.*, 2014; Walsh *et al.*, 2018, 2020). It seems like MUs need to justify their existence in terms of number of births and not in terms of long-term public health outcomes for having reduced interventions and medicalisation. This approach threatens the existence of MUs. A similar approach was noted during the covid pandemic in which the centralisation of the service was perceived safer even if not solving the shortage of staff issue (Grollman *et al.*, 2022; van den Berg *et al.*, 2022). Identifying key indicators for maternity services that include a salutogenic and long-term approach is key for the existence of these models. Existing research in Europe and in Italy is starting to address this issue for maternity care and low risk women in general (Escuriet *et al.*, 2015; Maga *et al.*, 2022).

During this stage of the project, development was not a linear process but more of an explorative path in which sometimes stakeholders walked away or ended up back where they started. The transtheoretical model by Prochaska and Velicer (1997) defined different stages an individual may be in while implementing a change as: pre-contemplation, contemplation, preparation, action and

maintenance (Prochaska and Velicer, 1997). Greenhalgh et al. (2004) describe how initially "*innovation is discussed, contested and reframed*". In this stage of the study, the researcher noted how stakeholders spent most of the time in the contemplation phase of the change: discussing, contesting and reframing. Doubts were also sometimes noted amongst the hospital leadership. Again, this is coherent with previous work by Darling et al. (2021) in Canada who described a long period of incubation of the idea prior the implementation of a new MU in a context not used to this model of care.

4.5 Conclusions

Thanks to this situational analysis, I examined the perspectives of different stakeholders towards the MU project and generated a baseline understanding of readiness of the local context. Application of the Consolidated Framework for Implementation Research offered the opportunity to deepen the analysis on all levels: micro, meso and macro (Damschroder *et al.*, 2009). This analysis allowed professionals to reflect on their readiness before drafting an implementation plan. One of the main barriers identified was the power imbalance between medical professionals, midwives and the women using the maternity services which led to autonomy issues both for service users and midwives. The importance of guidelines, protocols and training opportunities to increase confidence was acknowledged by professionals. They also saw the opportunity of having exposure to the MU model as facilitator even if the lack of similar models of care in the local and regional context made this extremely challenging. Thanks to the collaboration with MeSLab, it was possible to include the service users' perspective by analysing their experience of maternity care in the local hospital and starting to map the feedback and needs that they reported before and during the pandemic. Closure towards the idea of an out-of-hospital MU or homebirth was evident among most stakeholders including midwives in this context.

These findings helped to assess the local readiness using different sources of data and including different stakeholders. A certain level of readiness was noted within the local context which allowed this project to move forward and to start reflecting on strategies which could have supported the implementation work. Findings from this chapter and the systematic review helped to guide the following stage of the PAR cycle which will be presented in the next chapter, the "act and observe" phase, in which stakeholders codesigned the implementation plan for the local hospital.

Chapter 5 - Phases Two and Three – Participatory creation of the implementation plan

Introduction to the chapter

In this chapter, I describe the steps made towards the creation of a co-produced implementation plan for the opening of the AMU in the local context. This represents the action phase of the implementation cycle in which stakeholders collaborated in the creation of a plan to move towards the change.

After having conducted a first round of data collection for the situational analysis, the Covid 19 pandemic hit and data collection activities had to be suspended for months. The initial intention for the following phase was to conduct multidisciplinary and stakeholders' meetings to facilitate group discussions and work groups that will lead to the co-production of an implementation plan. However, in December 2020, after having unsuccessfully attempted several times to resume face to face data collection activities, it became clear that a new approach was needed to allow online data collection and comply with new Covid 19 regulations.

Therefore, a decision was made to integrate codesign using a Delphi approach with online focus groups and online surveys to involve the multidisciplinary team in the co-creation of the implementation plan.

A 3-stage project with the maternity team to codesign an implementation plan using a Delphi approach, followed by a survey to the local population to gain feedback on the plan and the innovation constitute the 4 steps of this PAR cycle. This process is reflected in the structure of this chapter, with four main sections (one for each step) and a discussion at the end relating to the overall findings of the 'Act and Observe' phase. Each step has a paragraph called "Process" in which data collection activities and analysis for that stage are presented and a "Findings" section.

Below I give an overview of the whole process prior to diving into more detail of each step.

Codesign using a Delphi approach

The rationale for choosing this methodology for the 'Act and Observe' phase of the cycle was presented in the Methodology chapter section 2.5.6.

Here, I present an overview of the steps that led to the creation of a co-produced plan and the rationale for each one:

1. **Multidisciplinary online focus groups** *(January 2021).* To start an open discussion about possible steps needed by the maternity team towards the implementation of the MU. This stage was more creative and allowed the team to discuss any aspects they considered relevant for the implementation.

2. **First Delphi survey** *(March-April 2021).* To share ideas discussed during focus groups with the wider team and allow everyone to feedback and contribute with other ideas. Multiple choice, ranking and open-ended questions were included at this stage. This allowed the team to contribute in various way and still adding any missing points that were not covered during the focus groups.

3. **Second Delphi survey** *(June 2021).* After having analysed and included the contributions of the first survey, professionals were sent a survey with a list of statements for the implementation plan and asked to rate each point. This allowed them to rank importance and set priorities when considering how to put the plan into practice.

4. **Service user's survey** *(January 2022).* An online survey with questions about the innovation proposed (MU) and the implementation plan drafted by professionals was open to all women who gave birth in the local hospital in the past 2 years to receive feedback on the future configuration of maternity services.

In keeping with the PAR approach of the overall study, after each step, results were presented in a report which was shared with the whole maternity team to ensure transparency and give the opportunity to the whole team to engage with and discuss ideas arising from the project.

In figure 16, a flowchart represents a summary of samples included at each step, type of data collection and response rate at each stage to help the readers gaining an understanding of the overall process.

Figure 16 Summary of codesign steps

Step 1 – Multidisciplinary focus groups
- Invitation open to the whole maternity team (hospital and community centers) – 108 professionals
- 14 multidisciplinary professionals volunteered to take part
- 3 online focus groups completed (157 minutes)

Step 2 – Delphi survey 1
- Invitation open to the whole maternity team (hospital and community centers) – 108 professionals
- 48 questions (closed and open-ended) prepared from the thematic analysis of the FG transcripts
- 57 started the survey, 52 completed it (48% response rate and 91% completion rate)
- Sample included all professional categories

Step 3 – Delphi survey 2
- Invitation open to the whole maternity team (hospital and community centers) – 108 professionals
- 40 statements for the implementation plan to be ranked in a scale of importance from 1 to 10 by the team
- 46 started the survey, 44 completed it (43% response rate and 98% completion rate)
- Sample included all professional categories

Service users' survey
- Open to all service users' who gave birth in local hospital in the past 2 years and agreed to be contacted for research purposes (data linkage of 2 lists)
- Survey co-created by researcher and multidisciplinary group from implementation plan and questions related to knowledge and attitudes towards MU
- 28 questions – estimated time for completion 10 minutes
- 654 started the survey, 102 completed partially and 515 completed it all (45% response rate and 78% completion rate)

Findings of this project are not generalisable as these surveys were specifically co-created for this local context in a very unique historical time. The findings are mainly descriptive to allow a reflection for the maternity team to build on when putting in practice the implementation plan but findings are not supposed to be generalisable. This is line with PAR principles.

5.1. Step 1 - Multidisciplinary focus groups

After the situational analysis and systematic review of the literature, a baseline of local needs and previous strategies used in different international contexts was identified. This constituted the main source of knowledge and information to guide the discussion about plans and objectives to work towards the implementation of the MU. I presented those findings to professionals in multidisciplinary meetings and disseminated them in a report attached to the invitation email of the Delphi project. The main aim was to share baseline knowledge on the innovation and to include all different perspectives involved in the situational analysis (professionals, managers and service users) to inform the beginning of the discussion about the implementation plan. The first step of the Delphi project was to conduct focus groups with the maternity team.

5.1.1. Process

An effort was made by midwifery leaders to ensure that all different professional categories were included in this research activity and that the participants' sample was representative of the wider maternity team. My role at this stage was only to remind leaders of the initiative and timeline but the overall engagement work was led by the midwifery leaders. This was part of PAR strategy to promote more local ownership of the change and innovation. This showed good level of engagement and motivation by the them towards the creation of a co-produced plan.

In January 2021, three multidisciplinary focus groups were organised and facilitated online using Microsoft Teams and Skype. Considering the participants and my own prior experience of conducting focus groups online, having two possible platforms helped in anticipating IT issues and possible need to switch platforms in case the first did not work (which happened during the 3rd online focus group).

The midwifery leaders put out a call to volunteer to take part and some professionals stepped forward. A list was then made by the midwifery leaders to ensure that during each FG there was representation of different disciplines. The list of attendance was cross referenced with the recruitment database and participants who had not been recruited before during the situational analysis received an informed consent via email prior the focus group.

As mentioned in the previous paragraph, participants were sent a report few days before the focus group covering: background and description of the research project, updates on the progress so far, main findings from the situational analysis and the questions they will be asked during the focus group.

The focus group guide was prepared with supervisors and included:

- Round of introductions/ice breaker
- First part with open questions to start a group discussion "*What do you think is needed to implement an AMU in [name of local service]?*", "H*ow do you think we can start working towards that?*"
- Second part more reflective and aiming to come up with SMART (simple, measurable, achievable, realistic and time defined) objectives
- Closure asking for suggestions and feedback about the research project

The focus groups were recorded and transcribed using NVivo Transcription software which helped optimising time and moving more quickly into the analysis to create a second survey.

5.1.2. Findings

Three focus groups were facilitated, and they lasted respectively 60, 65 and 32 minutes. A total of 14 participants took part :

- midwifery managers (3)
- medical director (1)
- obstetricians (3)
- neonatologists (3)
- hospital and community midwives (4)

After a first round of descriptive coding of the transcripts a Word document with main suggestions from each group about the implementation plan was created. Ten main themes emerged from the transcripts (some of which were coherent with the ones arising from the systematic review and the Midwifery Unit standards, see table 11) and they became the main sections of the first survey.

Table 11 Themes comparison

Themes comparison		
MU Standards (Rocca-Ihenacho *et al.*, 2018)	**Systematic review** (Chapter 2)	**Codesign with Delphi approach** (Chapter 5)
1. Biopsychosocial model of care 2. Clinical Governance 3. Autonomy and accountability 4. Staffing, recruitment and workload 5. Knowledge, skills and training 6. Working across boundaries 7. Leadership 8. Equality, diversity and social inclusion 9. Pathways of care 10. Environment and facilities	1. Culture and perceptions 2. National guidelines and local protocols 3. Midwives' identity and role 4. Knowledge, skills and training 5. Leadership 6. Collaborative practice and relationships 7. Integration 8. Model of care 9. Environment	1. Team vision 2. Implementation of the intrapartum protocol for low-risk women 3. Appropriate risk assessment 4. Midwifery and multidisciplinary training 5. Creation of a multidisciplinary advisory group which will support the MU 6. Creation of a dedicated group of midwives who will work in the MU 7. Integration hospital-community 8. Communication and information for service users 9. Effective communication within the maternity team 10. Reflective clinical practice via audit and debriefing

Here, I present the ten theme and the analysis arising from the analysis of the focus groups which then led to the formulation of the sections and questions in the first survey.

1. Team vision

The team identified the need to share a common vision for the new configuration of the maternity service and how the different settings would work with each other in the future. After months of changes of plan and ideas (which felt like going back and forth), the team expressed the need to

finalise the decision about the implementation of the AMU. The need to avoid past lack of communication among the different teams (hospital/community, hospital/fetal medicine, maternity/neonatal teams) was highlighted.

2.   Creation of a multidisciplinary advisory group which will support the MU

The team stressed the importance of having all different professional figures involved in the planning and implementation of the MU project. This was seen as particularly relevant in the formulation of specific local protocols and procedures (e.g. transfer from the MU to the OU or newborn care at birth in the MU) and to avoid lack of support once the MU was opened. They all agreed that support, especially from the medical component (both obstetricians and neonatologists), was key at this stage both in terms of advocacy of the MU and to facilitate a shared vision and practice within the team from the beginning.

3.   Creation of a dedicated group of midwives who will work in the MU

The team agreed that a group of dedicated midwives should be identified for the MU and that this group needed to be highly motivated, with significant experience in midwifery led care and the right philosophy of care. However, the group was not homogeneous on what specific characteristics these midwives should have and mentioned various features (like teamwork approach, empathy, patience, extra training in specific skills). Another important aspect raised was whether the midwives would work regular shifts or on call or in an integrated model with both. This point seemed to be relevant to define who would be eligible to be in the dedicated group but there was not agreement on which would be the best option.

4.   Implementation of the intrapartum protocol for low-risk women

A protocol for intrapartum care of low-risk women was already in place. However, midwives perceived that not all team members were aware of it and that it was not being followed consistently. Professionals also mentioned the possibility to network with other existing Italian and regional services to share knowledge and compare current protocols for the MU.

5.   Appropriate risk assessment

The importance of a thorough risk assessment throughout pregnancy was one the main topics of discussion. It was often not clear amongst the team who should be the professional in charge of this assessment and most believed it was a shared responsibility between midwives and obstetricians. The current practice identifies three main risk categories of women: low, medium

and high risk. Grey areas between these categories were observed by the team in everyday practice and a common perception that this assessment was often "*professional dependent*" was mentioned. Furthermore, professionals were hesitant in moving women from high/medium risk to low risk when the clinical situation improved (e.g., risk of preterm birth which disappears after 37 weeks) but not the other way round from low risk to medium/high. Therefore, the need to make the practice more consistent was identified as a priority.

6.   Integration hospital-community

Professionals shared an overall understanding that pregnancy and birth are a continuum and that in order to facilitate the best care in labour there needs to be proper antenatal care and education. Therefore, it was clear that the implementation of the MU needed to involve community teams as well as the hospital one. Ideas to improve communication between the teams were put forward (e.g. regular meetings and staff rotation). This aspect was also mentioned by managers as in line with the objectives that the team already set for the upcoming year (2021).

7.   Midwifery and multidisciplinary training

Suggestions on mandatory training for staff who will be working in the MU were made. Furthermore, the team mentioned the importance of having multidisciplinary training to share vision and practice of the care of low-risk women in labour and in case of emergencies in the MU. The idea to nominate champions on specific topics who would then share and cascade the learning to the rest of the team was also made.

8.   Communication and information for service users

Correct and appropriate communication and information for service users was identified as main aspects to promote and encourage trust in the MU model of care among the local population. The groups discussed the need to reach women and engage them in the planning of the MU.

9.   Effective communication within the maternity team

There was a shared view that communication between professionals and service users could be improved in current practice. However, the team was not clear on how to achieve this. Difficult communication among the team was often mentioned with main barriers being between managers, medical and midwifery component but also between hospital and community staff.

10.   Reflective clinical practice via audit and debriefing

The groups often mentioned lack of opportunities to discuss and reflect on clinical cases and on the overall performance of the team. Time constraints and lack of dedicated staff to organise this were identified as main barriers. Some members mentioned the importance to do this in a safe environment for staff and avoiding a blaming culture that could have the counter-productive result of fragmenting the team.

5.2.   Step 2 - Delphi survey 1 – Including the wider team

5.2.1. Process

After the more creative phase during the multidisciplinary focus group, a first survey was developed using the findings and supported by Qualtrics software. The aim of this survey was to open the discussion about the implementation plan to the wider team hence, the choice for it to be anonymous and to combine closed, ranking and open-ended questions to allow participants to feel free in their answers. This is coherent with previous Delphi studies that used more open-ended questions for the initial stages (Hasson and Keeney, 2011).

The survey was divided into ten sections matching the ten themes identified during the focus groups. The questions were formulated by the PAR researcher from the transcripts of the focus groups. Maintaining open ended questions for each theme during the first survey allowed participants to add comments or suggestions in case they did not agree with the way the questions were formulated or wanted to add more. Each section had a minimum of 2 and a maximum of 7 questions, giving a total of 48 questions. The estimated time for completion was 10-20 minutes.

Data analysis was conducted using Qualtrics and Microsoft Excel for descriptive statistics and NVivo 12 software for the qualitative responses.

Invitation to the survey was sent via email list from Qualtrics so only participants who received the email could take part in the study. Responses were anonymised and Qualtrics automatically generate IDs for each email address. Demographic information such as age, gender, job title, years of experience and place of work was also collected. These questions were not mandatory but helped to gain a baseline of the respondents' profile.

Before dissemination to the wider team, two drafts were reviewed by supervisors and three local managers and amendments made. The survey was distributed via secure email invitation (unique URL generated for each participant).

To promote engagement, a short explanatory video was added via a private YouTube link at the beginning of the survey. In this video, I briefly introduced the research project and the structure of the survey to prepare participants on what to expect. A copy of the PIS and a request of informed consent was also sent via invitation email and added in the first webpage before proceeding to the survey. Participants had to agree to take part in the study in order to move on to the survey.

In line with a PAR approach, the first survey was open to all 108 multidisciplinary professionals of the maternity team on the 15th of April 2021 for a month. Two reminders were sent a week and 48 hours before closing the survey and they helped increasing the survey response. Verbal reminders were also given by midwifery managers on shifts.

5.2.2. Findings

A total of 57 participants started the survey and 52 completed it (48% response rate and 91% completion rate among respondents). This showed overall a good level of engagement by the maternity team considering that it was a non-mandatory research activity.

Participants were from different professional backgrounds as presented below in table 12. Among them there were midwifery managers and medical directors. Minimum age was 26 and maximum 65 with a SD of 11. Ten participants were from the community health centres, five from fetal medicine unit, five from obstetric and gynae theatre and the rest from the maternity wards (antenatal, postnatal, triage and OU).

Table 12 First Delphi survey, participants' professional background

Profession	N Sample	% Sample	N Invited	% Invited
Midwife	31	65%	60	55%
Obstetrician	4	8%	24	22%
Neonatologist	2	4%	5	5%
Nurse	1	2%	2	2%
Healthcare assistant	10	21%	17	16%

Considering that a range of question types were included in the survey, the presentation of findings in the below section will alternate tables and graphs sometimes colour coded to help the analysis of the findings. In few occasions, the Net Promoter Score® graph generated by Qualtrics was reported to give a better understanding of which options were more appreciated by stakeholders. The Net Promoter Score® (NPS) is a survey metric developed by Fred Reichheld with Bain and Company to present the "promoters", "passives", and "detractors" of an option. Using a 1-10 scale and assuming that promoters usually respond with 9 and 10, passives with 7 and 8 and detractors with less than 7 calculating the NPS requires to subtract the percentage of detractors from percentage of promoters. The NPS score can be anywhere between -100 and +100 and sometimes its visual representation gives a better idea of how much the idea suggested was supported or not than just the mean, SD and variance. Hence, why I decided to include it on few occasions, especially where the means and SD were very similar among the options proposed and NPT helped to understand which option was more or less promoted by the group. The only purpose of using NPS was to offer a better visual idea of those items and was not used for including or excluding them.

Whenever there was an open-ended question, illustrative quotes have been added to present the synthesis of data and most common answers.

Overall, there was agreement of most point suggested during the focus groups so to give an idea of the different shades of support for each item I colour coded the table of findings. The use of colours (green for highest scores, yellow for middle scores and red for lower scores) is not based on a fixed scoring system but instead used to facilitate the reader in understanding which ideas were more supported than others. For example, for items that are coloured in red did not receive a high rating but this did not mean that they were excluded from the second survey.

5.2.3. Overall themes

The first question for each section aimed to gain the perceptions of the wider team on the themes identified during the focus groups and to check whether the extended team felt they were relevant and appropriate when preparing an implementation plan for an AMU. As shown in table 13, all themes were valued by participants highly with high means over 8.6/10 and relatively small SDs.

Table 13 Delphi 1 Themes

How important do you find the following themes suggested by the theme on a scale from 1 (not important at all) to 10 (extremely important)?	Mean	SD	Variance
1. Shared vision of the innovation	9.05	1.66	2.74
2. Creation of a dedicated multidisciplinary team that will support the MU	8.88	1.81	3.27
3. Creation of a dedicated group of midwives that will work in the MU	8.6	2.1	4.43
4. Creation of a local protocol for the MU	9.33	1.58	2.5
5. Appropriate risk assessment	9.3	1.53	2.35
6. Hospital-community team integration	9.16	1.63	2.65
7a. Midwifery training	9.4	1.56	2.43
7b. Multidisciplinary training	9.09	1.63	2.64
8. Information and education to service users	9.02	1.53	2.35
9. Effective communication among the maternity team and with service users	9.24	1.57	2.47
10. Reflective practice with audit and debriefing	9.09	1.57	2.46

Theme 1 - Shared vision of the innovation

Participants were asked which stakeholders should be sharing the collective vision for the implementation of the MU and their answers are reported in table 14. Participants could select multiple options.

Table 14 Delphi 1 – T1D1

Answer	Count	%
Hospital Obstetric team (midwives and obstetricians)	42	23%
All community healthcare centres in province	35	19%
Neonatal Team	34	19%
Hospital Directors	19	10%
Service users	17	9%
Organisational Directors	15	8%
Fetal Medicine Unit	11	6%
Community healthcare centre (local)	10	6%

Interestingly, three options like the hospital directors, FMU and the local community health centre were selected by less than 10% of participants. The latter might be explained by the fact that there was a more inclusive option which referred to all healthcare centres of the province. However, the fact that Fetal Medicine Unit and organisational directors were not seen by the group as key stakeholders who should share the collective vision could be in line with the fragmented team approach that professionals reported during the situational analysis or by the fact that they did not want a top-down approach to change.

When asked what their opinion was about implementing an AMU in their maternity service, participants were overall very supportive of the initiative (see figure 17).

Figure 17 Delphi 1 - T1D2

Personally, what do you think of the idea of implementing a AMU near the OU in the [name of service]?
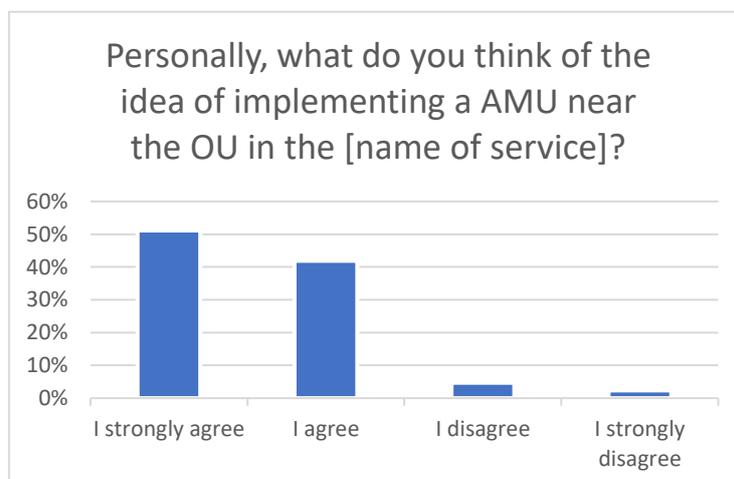
This is coherent with the findings of the situational analysis and shows the local willingness to move towards the model of care. However, it is relevant to notice that few people disagreed or strongly disagreed with the idea and this is valuable for this Delphi study because means that there was some representation of the "opposers" in the sample who completed the survey.

When asked to explain their previous answers with an open-ended response, participants often mentioned the importance to promote physiology and reduce medicalisation while being in a safe environment near the OU. They mentioned a "*gradual change, compatible for a first stage*". Disagreement was associated with the fact the number of women using this type of service would be relatively low and that the amount of work needed for this innovation was considered to be too big and that money could be invested elsewhere.

"Because based on the data collected, BRO (low risk) users are currently bare-bones. There is no (such) culture and I'm sure there will be great resistance from obstetricians because they follow 90% of pregnancies to refer women to low risk care. Plus we're not trained" Participant 5, Hospital Midwife

"It represents the possibility of creating a more welcoming and less hospitable place where it is possible to assist low-risk pregnancies with the right times and interventions without excess or lack of, with the convenience and then the guarantee of medical intervention if needed, because still close to the obstetric unit. I believe that this could be a first step towards a midwifery management of this type, still unknown in Italy that needs to be introduced into our system with caution to be better appreciated and understood" Participant 22, Community midwife

Theme 2 - Creation of a dedicated multidisciplinary team that will support the MU

During the focus groups, the respondents discussed the composition of a dedicated multidisciplinary group to support the AMU, whether it could be open or closed, representative of all disciplines and the number of people that should be included. In the survey, the vast majority of respondents (84%) opted for the open model in which people could volunteer to take part but with also a core number of participants representative of all different disciplines.

When discussing the inclusion of service users in this group, there was heterogeneity among the group: 32% thought that it was "important and doable", 25% thought it was "important but not doable", 35% thought it was "not necessarily important for this type of project" and three suggested in open ended box that it was "important but for a later stage of the project".

This suggests that the team is not used to involve service users in the codesign of maternity services and believes that professionals should be main stakeholders.

The frequency of meetings suggested for the dedicated group was monthly (58.1%) or at least every two-three months (39.5%).

Theme 3 - Creation of a dedicated group of midwives that will work in the MU

When discussing the working models for the MU, professionals mentioned the possibility of having midwives on shift, on call or both in an integrated model (shifts cover Monday-Friday during the day and on calls at night and holidays). In the survey, 61% of participants voted for the shifts model, 37% for the integrated model and 2% voted for the on-call model.

Views on the required skills to work in the MU are presented in table 15 (red indicates a mean lower than 5 and green over 5).

Table 15 Delphi 1 - T3D3

Skills midwifery team	Mean	SD	Variance
Right philosophy of care	2.7	1.25	1.56
Relevant experience in midwifery led care models	2.6	1.32	1.74
Effective communication skills with the team	3.69	1.02	1.03
Motivation	2.13	1.57	2.46
Master/Postgraduate degree	6.15	1.75	3.05
Years of work	5.62	1.08	1.16
Leadership	5.41	1.21	1.47
Others… *(added by participants)* - Teamwork approach - Empathy - Patience - Extra training in pain relief techniques, hydrotherapy obstetric emergencies and suturing	7.79	0.72	0.52

Interestingly, the skills most valued by the team as requirement to work there were a postgraduate degree, seniority, leadership and other skills suggested such as empathy, patience and an extra professional training. Skills like motivation, effective communication, right philosophy of care and relevant experience in midwifery led model received a very low score. These findings seem to suggest a perception among the team that to work in an AMU there needs to be extra training from the one received during the midwifery degree. Valuing seniority and postgraduate degree is also coherent with the highly hierarchical organisational structure that was identified during the situational analysis.

When asked, if they thought it was feasible to identify a dedicated midwifery team in the next 3/6 months, the majority (50%) said maybe and the rest was almost divided in half with 27% thinking "yes" and 23% "no". Main reasons for this answer were shortage of staff, Covid pandemic and not enough time (suggesting at least one year).

Theme 4 - Creation of a local protocol for the MU

At the time of the survey, there was a local protocol for intrapartum care of low-risk women already in place in the hospital. In the survey, the majority of the team (60%) found this would be a "useful" document and 25% considered it "very useful". Only 15% answered "not very useful". When asked what could be improved in the current protocol, participants mentioned deeper level of detail, better clarity, the addition of inclusion/exclusion criteria for midwifery led care, addition of transfer criteria and a wider dissemination to the team.

For the creation of the new protocols for the MU, participants agreed that all disciplines should be included (midwives, obstetricians, neonatologists) and from different settings (community and OU).

The team highly valued the possibility to network and have meetings with the existing Italian MUs (especially the regional one) to get to know their own local protocols.

Theme 5 - Appropriate risk assessment

Four tools were identified to promote more consistent care across the team and scored a mean of over 8.5: protocol for low-risk pregnancy, protocol for intrapartum and postpartum care for low-risk women, flowchart with pathways and criteria for low, medium and high-risk care and personalisation of care around women's needs. Some open comments suggested adding a checklist with the criteria

for low-risk care to be shared at organisational level and to develop risk self-assessment forms for women.

When asked who they thought was the professional responsible for the risk assessment in low-risk women 59% of participants answered "midwife" while 41% answered "obstetrician and midwife". This is in line with findings in the situational analysis and shows how even though there is a regulation in place to make the midwife primary healthcare professional for uncomplicated pregnancy care, in reality the culture is still very much doctor centred.

In figure 16, shows responses to a multiple-choice question on what initiatives would be feasible to promote midwifery led care.

Table 16 Delphi 1 - T5D4
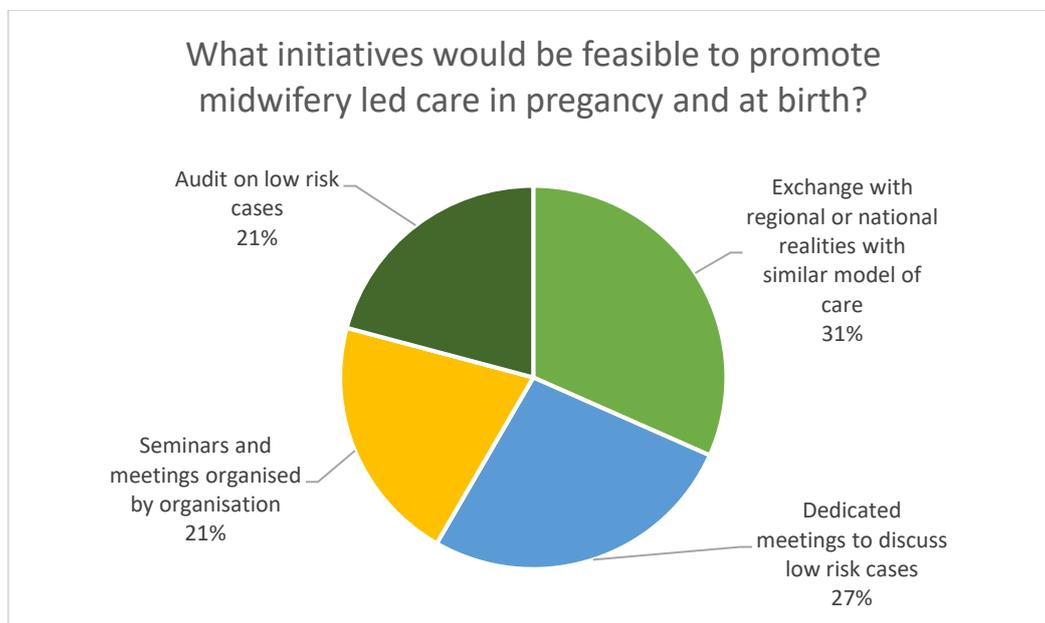
Overall, the team finds the labels low, medium and high risk for women's pathways of care appropriate and comprehensible. However, 34% of participants found the wording not entirely appropriate and comprehensible especially for service users. They explained in the open question that users from different nationalities could struggle with that, that the focus on the "risk" concept could create anxiety and that especially the "medium risk" concept was difficult to explain to service users.

When asked what they thought of the idea of calling pathways with names of flowers to move the focus away from the risk concept (as suggested during the focus groups), the majority supported the idea (51.2%) while the rest was divided between disagreeing (21.9%) and neither agreeing nor

disagreeing (26.8%). Some professionals were more in favour of the risk terminology as they found it more honest to service users. They expressed doubts about the flowers terminology as that could confound women more. They highlighted that clear and honest communication about risks is important for care. On the other hand, those in favour saw the flower names as an opportunity to have a positive language to reduce medicalisation and anxiety about pregnancy and birth.

Theme 6 - Hospital-community team integration

Overall, the team agreed with the suggestions made during the focus group about initiatives to promote better hospital-community integration (see table 17). However, the high SD and variance shows there were a wide range of differences in the view about some initiatives like rotations and updates via email.

Table 17 Delphi 1 - T6D1

Suggestion	Mean	SD	Variance
Regular meetings hospital-community staff	8.54	1.62	2.64
Having hospital staff during AN education and community staff doing tours in hospital (exchange)	7.93	1.85	3.43
Regular updates via email	6.95	2.14	4.58
Short staff rotations hospital-community (supernumerary)	6.97	2.35	5.52
Longer rotations of staff for selected professionals non supernumerary	6.78	2.67	7.14

In figure 18 using the Net promoter Score representation it is clearer which ones were promoted/retracted by the team.

Figure 18 - T6D1 Net Promoter Score
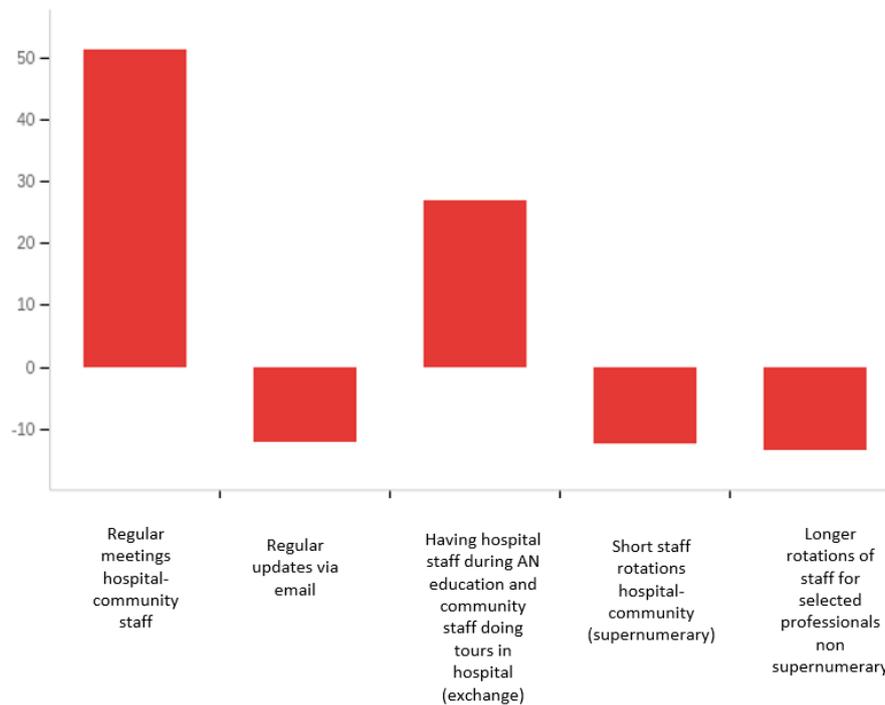
The team suggested regular hospital-community meetings every month (49%) or at least every 3 months (39%), just a small minority voted for every 2 or 6 months (5% and 7%). The vast majority opted for a hybrid mode of face-to-face and online meetings (59%) while 41% voted just the face-to-face option. These findings need to be contextualised to the historical moment of Covid pandemic. Professionals learnt alternative ways to meet and conduct meetings but might have also felt the need of face-to-face interactions after a year of recurrent lockdowns in Italy.

When asked how they thought the continuity and the integration hospital-community could be improved, most participants mentioned investing in better communication and information sharing.

Theme 7 – Midwifery and multidisciplinary training

Among the team there was a good level of agreement on additional training that the midwifery group would need to work in the AMU. As presented in table 18, all suggestions had a very high mean and a relatively small SD and variance.

Table 18 Delphi 1 – T7D1

Topic	Mean	SD	Variance
Non-pharmacological pain relief techniques	9.07	1.77	3.12
Autonomous midwifery care in labour and birth	9.25	1.89	3.59
Promotion of optimal fetal positioning techniques	9.43	1.39	1.94
Natural techniques to solve prolonged labour	9.23	1.48	2.18
Care of the healthy newborn	9.45	1.32	1.75
Obstetric emergencies in MU	9.55	1.34	1.8
How to facilitate transfers from the MU to the OU	9.38	1.48	2.18
Case scenarios of deviation from physiology	9.45	1.36	1.85
Intermittent Intelligent Auscultation	8.82	1.6	2.54
Perineal Suturing	9.2	1.52	2.31

Other suggestions were about communication skills, neonatal emergencies and non-pharmacological induction of labour. These suggestions reflect a professional profile that currently feels less confident in terms of neonatal care, since nurses were caring for newborns until recently.

A similar scenario was applicable to the multidisciplinary training suggestions, with a high level of agreement (see table 19). Again, communication skills was suggested in the open-ended question.

Table 19 Delphi 1- T7D3

Topic	Mean	SD	Variance
Care for low-risk pregnancies	9.43	1.38	1.89
Care for low-risk labour and birth	9.55	1.22	1.5
Obstetric emergencies in MU	9.5	1.32	1.75
How to facilitate transfers from the MU to the OU	9.47	1.28	1.65
Case studies on deviation from physiology	9.32	1.37	1.87

The team was particularly interested in practical sessions led by team member experts on specific topics (42%), training organised by the service (25%) and only partly in private courses (13%) or regular theoretical seminars (20%). They really valued the suggestion to nominate an expert in a specific area who would then become point of reference for that specific issue for the team (76% voted for this).

Lastly, the opportunity to do a placement experience in an existing Italian MU was mentioned in the open suggestions.

Theme 8 – Information and education to service users

Of the suggested initiatives on how to promote better communication and information with service users, the extended team agreed overall, with some options (e.g., booklet and more information provided during AN classes) scoring more than others (e.g., involving service users in projects and meetings with the team).

Table 20 Delphi 1 – T8D1

Suggestion	Mean	SD	Variance
Informative booklet about the maternity pathway and midwifery led care	8.95	1.61	2.6
Further information on midwifery led care during AN classes	9.25	1.46	2.14
Simple and informative poster about maternity pathway (pregnancy and birth) in the hospital and community clinics	7.92	2.03	4.12
Engaging and involving service users in projects and meetings	7.33	2.1	4.42
Engaging GPs and private obstetricians in the MU project to make them promote the service	8.45	2.19	4.8

In this Net Promoter Score View (figure 19 in next page), we can see again how engaging service in projects and meetings was the options on which professionals were less keen. This is consistent across the whole the whole survey showing hesitancy in codesign and collaboration with service users.

In the open-ended question, participants also suggested a video for the waiting rooms in which the midwifery led model was presented to service users and other informative channels (like local TV and radio).

Figure 19 Delphi 1 – T8D1 Net Promoter Score
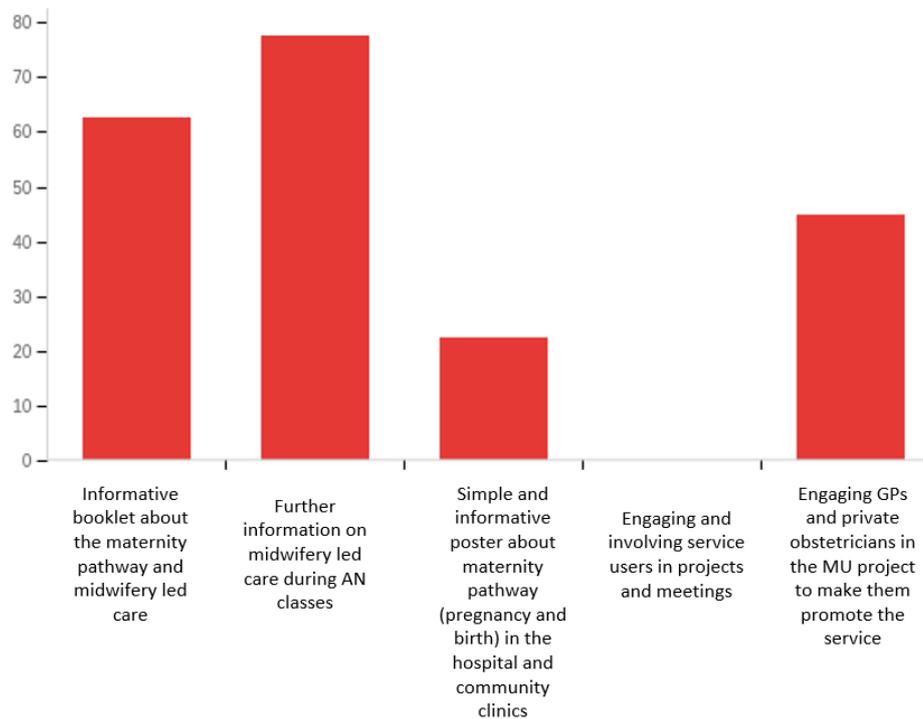
9. Effective communication among the maternity team and with service users

This section had open ended questions as no clear suggestions were made during the focus groups on how communication among the team and with service users could be improved. Main suggestions were regular meetings, seminars, training together, reflective practice and an open, respectful and non-competitive/judgemental communication. Some of the quotes highlighted issues the team was facing in this regard:

"With shared protocols and procedures, with regular briefings and discussion meetings, but above all with courses and practical simulations on a regular basis to better standardize the work of the team" Participant 22, Midwifery manager

"Through meetings even online to make sure that problems identified in the team are resolved" Participant 25, Hospital midwife

"It would be good to have a super partes moderator. The meetings in themselves are emblematic of the impossibility of communication between midwives and obstetricians. But also among obstetricians and obstetricians." Participant 5, Hospital midwife

In terms of ideas which could support a better communication with the local population, some suggestions were made and they were coherent with the ones discussed in Theme 8.

10. Reflective practice with audit and debriefing

There was a high level of agreement with the focus group proposals promoting reflective practice among the team focus group (see table 21).

Table 21 Delphi 1 – T10D1

Suggestion	Mean	SD	Variance
Keeping the multidisciplinary debriefing meeting in the morning as dedicated and protected time	9	1.69	2.85
Identifying some team members to conduct audit (for example on low risk cases) and present them to the team	8.7	1.93	3.71
Promote a follow up of practice assessment at 3/6/12 months	8.6	2	3.99
Reflect on data collected and present findings to the team (both hospital and community)	8.5	1.84	3.4

When asked which the most useful and effective way was to present data and reports to the team, the majority voted for both emails and meetings (73%) while the rest opted for only the meetings (27%).

Name of the MU

At the end of the survey, a final question was asked about an appropriate name for the AMU. The figure below presents the findings of these answers:

The preferred option seemed to be a non-clinical/technical name like for example a flower. Interestingly, the option that scored less was the one with the low obstetric risk definition that uses the vocabulary of the national guideline and the MU English version was not considered at all showing again preference to detach from international context. Key reasons for these choices were the need to keep a clear simple name, to avoid clinical words and to promote sense of belonging among the group who would choose the name:

Figure 20 Delphi 1 – Name for the local AMU
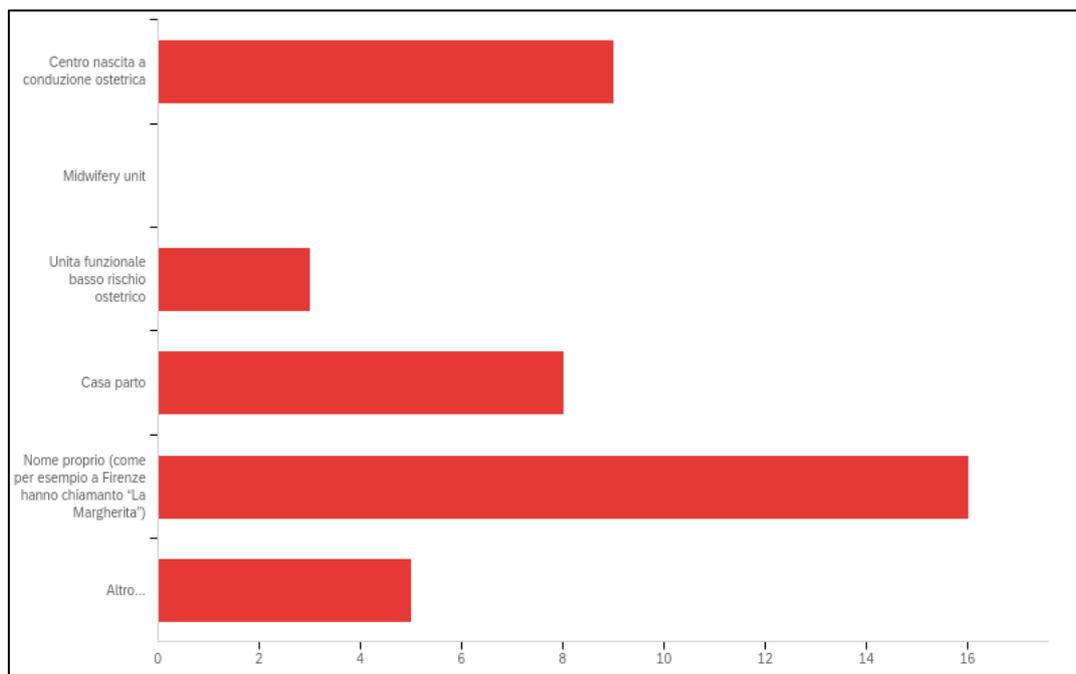
"Because the name is not needed by the operators but as a business card for the users. The proposed names are very useful and representative for the technical model but less so for the woman who has to give birth there" Participant 12, Neonatologist

"The proper name chosen by the group seems to me more a choice of personalization and belonging" Participant 17, Midwifery manager

5.3. Step 3 – Delphi survey 2 – Reaching consensus

5.3.1. Process

After the first Delphi survey, data were analysed and synthesised to include the comments and suggestions made by the extended team and prepare the first draft of the implementation plan. A decision was made not to use a specific score for including/excluding the items voted by the team as the average was high for most of them. However, when there was a remarkable difference and variations among the options the ones with lowest score were excluded. When I was unsure whether to include or exclude an item due to the scores being similar, I always kept the item in this second survey to allow the second round of Delphi to clarify the agreement about it. The comments left in the open-ended questions helped to refine the wording, merge similar items or add new items that could be voted in the second Delphi round. From the initial 48 questions in the first round, this survey had 40 statements to be rated in a scale of importance from 1 to 10 from the team.

This draft of implementation plan was then used to prepare the second survey, which was structured differently from the previous one. If in the first Delphi survey there was a range of questions type to allow participants to contribute more actively to the implementation plan (open ended, multiple choice and rating scales), questions were now formulated as consensus statements that participants would rate on scale of importance from 0 (not important at all) to 10 (extremely important) using a slider. This is in line with the rationale for use of a Delphi approach described in chapter 2 section 2.5.6.

A total of 28 items divided in the 10 theme sections was created and some were subdivided if there were different components of the suggestion to be rated. For example, if one topic had four initiatives suggested, this was represented with one question and four items. An open-ended question at the end of each theme section was left in case participants wanted to add comments.

Time estimated for completion was 10 minutes and invitation was sent via mailing list using Qualtrics maintaining anonymity. The whole maternity team was invited again regardless of their previous participation to first survey or not. This decision was made in the attempt to give to all members the opportunity to contribute and engage with the research project at any stage. Also, a report with findings from the first round was circulated on the 13th of May to the whole team to make findings available and accessible as per PAR approach.

The second Delphi survey was opened on the 1st of June 2021 for 2 weeks with reminders sent by the researcher a week and 48 hours before closing it. A shorter timeline was agreed after the previous

experience with survey 1 and because a multidisciplinary meeting was planned for the 21st of June 2021 and the researcher wanted to have this data available for discussion in that occasion.

5.3.2. Findings

Out of the 108 professionals invited, 46 started the survey and 44 completed it, giving a response rate of 43% and a completion rate among respondents of 95%. Overall, this was again a positive sign of engagement from the team and indicated that the survey was a feasible tool. The demographic questions were not mandatory and were answered by 41 participants. All participants were female, age between 26 and 65, (mean 45, SD 11). Years of work experienced ranged from 1 to 38, (mean 17, SD 11). This shows the sample was varied and representative of different generations of practitioners.

Overall, there was a similar representation of the different disciplines from the first survey with majority of participants being midwives (see table 22). Positive note was that there was representation of professionals from all different maternity settings including different hospital wards and all the community healthcare centres in the province (see figure 21).

Table 22 Delphi 2 - Participants profession

Profession	N Sample	% Sample	N Invited	% Invited
Midwife	25	60%	60	55%
Obstetrician	6	14%	24	22%
Neonatologist	4	10%	5	5%
Nurse	1	2%	2	2%
Healthcare assistant	6	14%	17	16%

Figure 21 Delphi 2 – Participants' work setting
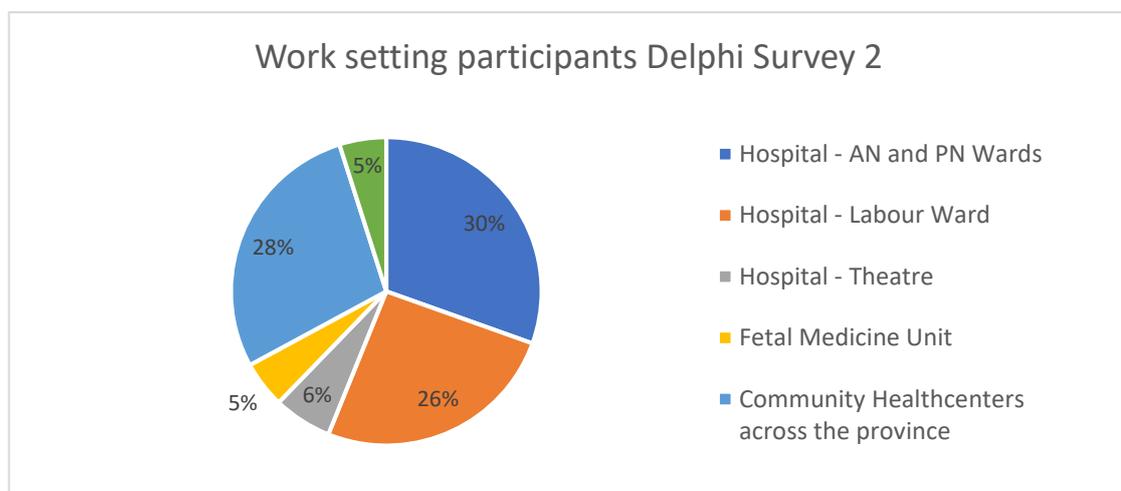
Overall, there was as strong consensus on the items of the implementation plan suggested during the first two stages of the Delphi study with an average always above 6.

Table 23 Consensus statements results from Delphi survey 2

Theme	Field	Mean	SD
1	The collective vision for the integration of an AMU in [name of service] has to be shared among obstetric team, neonatal team, all community healthcare centers, organisational leadership, service users, hospital leadership and FMU.	9.27	1.16
1	In the upcoming months, the team will work on promoting a collective vision of the innovation via multidisciplinary meetings, training events and seminars.	9.25	1.57
1	The whole team will strengthen the multidisciplinary collaboration working on sharing concepts on midwifery led care and risk factors (referring to the concept that risk is specific and dynamic in pregnancy).	9.30	1.32
2	For the creation of the multidisciplinary group dedicated to the AMU, the team agreed to have an open group with volunteers and a fixed group representative of all professional disciplines and service users.	9.14	1.23
2	The inclusion of service users during the operational meetings to plan the AMU is important.	6.35	2.76
2	In the upcoming months, the team will work on the feasibility (mode and timing) to include service users in the implementation of the AMU.	7.14	2.49
2	The dedicated multidisciplinary group that will support the AMU will meet monthly, and in case not possible, not later than three-monthly.	7.23	2.44
3	The dedicated group of midwives who will work in the AMU will use either a shifts model or an integrated model shifts and on-calls for night and holidays.	8.33	2.03
3	In the upcoming months (depending on the Covid pandemic), the team will work to identify a dedicated group of midwives for the AMU.	8.91	1.70
3	The current protocol for low-risk intrapartum care is useful/very useful to the team.	8.02	2.02
4	In the upcoming months, the team will work to improve the following aspects:		
	a. Define criteria for low-risk care	9.38	0.88
	b. Define transfer criteria for deviation from physiology	9.64	0.74
	c. Add further detail to the protocol (vaginal examinations, bladder care, external signs of progress etc.)	9.40	0.98
	d. Share the current protocol with all doctors and midwives	9.73	0.61
4	For the creation of new protocols on the management of transfers or emergencies in the AMU, the team that will work on this will include: - One dedicated obstetrician - One dedicated neonatologist - A senior hospital midwife - A senior community midwife - A midwife of the selected team of midwives for the AMU - A midwife from the nursery ward	9.16	1.21
4	In the upcoming months, there will be meetings (possibly online) with similar contexts (like the regional one [name of service]) to network, share and get to know more their operational protocols.	9.29	1.05
5	In the upcoming months, there will be work done to identify in detail how to promote midwives' autonomy in conducting risk assessment during each contact with low-risk women.	9.38	1.25

5	To promote autonomous midwifery care in pregnancy and at birth for low-risk women, there will be: - Training - Dedicated meetings to discuss low risk cases - Audit on low-risk care - Exchange with regional and national contexts with similar models already implemented	9.38	1.14
5	The differentiation between low, medium and high risk is appropriate and comprehensible to service users to explain the pathways of care offered.	7.82	2.13
5	In the upcoming months, there will be an operational multidisciplinary meeting (possibly including service users) to reflect on the proposal of some colleagues to call pathways of care with non-clinical names (E.g., like flowers) to avoid focusing the attention on risk.	7.71	2.48
6	In the upcoming months, the hospital-community meetings will be organised every 1-3 months (both online and face to face).	8.69	1.15
6	In the upcoming months, the team will promote the presence of the hospital team during AN classes in the community and the community staff during tours in the hospital.	8.53	1.45
7	In the next 12-18 months, before the opening of the AMU, midwives will be supported to train on the following topics: - Non-pharmacological pain relief techniques - Autonomous midwifery care in labour and birth - Promotion of optimal fetal positioning techniques - Natural techniques to solve prolonged labour - Care for the healthy newborn - Obstetric emergencies in the MU - How to facilitate transfers from the MU - Case scenarios of deviation from physiology - Intermittent Intelligent Auscultation - Perineal Suturing	9.55	0.89
7	In the next 12-18 months, before the opening of the AMU, the multidisciplinary team will be supported to train on the following topics: - Care for low-risk pregnancies - Care for low-risk labour and birth - Obstetric emergencies in MU - How to facilitate transfers from the MU to the OU - Clinical cases of deviation from physiology	9.45	1.03
7	The training will be organised via: mandatory training, regular theoretical seminars of 1-2 hours, regular practice sessions offered by expert in the team to improve the exposure to the whole team.	9.36	1.11
8	In the upcoming months, service users will be engaged, informed and trained about the midwifery led care model via the following initiatives:		
	a. Update the informative booklet about the maternity pathway and midwifery led care	8.70	1.71
	b. Provide further information on midwifery led care during AN classes	8.93	1.40
	c. Engaging and approach GPs and private obstetricians in the MU project to make them promote the service	9.07	1.63
	d. Organise informative video and meetings for service users	8.61	1.96
9	To promote the communication among the team, the following activities will be promoted:		
	a. Regular meetings with the team with an open and respectful discussion for all professionals	8.88	1.57

			Mean	SD
	b.	Skills and drills on emergencies	9.56	1.13
	c.	Training opportunities on effective communication	9.28	1.47
	d.	Small groups to discuss clinical cases	9.30	0.95
9	To improve a good communication with service users, the following initiatives will be promoted:			
	a.	"Open day" of hospital and community whenever possible	8.58	1.98
	b.	Present all professional figures during AN classes	8.72	1.73
	c.	Meetings aimed to present the midwifery model near the time of the AMU opening	9.07	1.47
10	To promote reflective practice and debriefing, the following initiatives will be promoted:			
	a.	Keeping the multidisciplinary debriefing meeting in the morning as dedicated and protected time	9.26	1.04
	b.	Identifying some team members to conduct audit (for example on low risk cases) and present them to the team	9.07	1.55
	c.	Reflect on data collected and restitution of findings to the team (both hospital and community)	9.12	1.32
	d.	Promote a follow up of practice assessment at 3/6/12 months	9.14	1.44

Once again, it was interesting to notice that the items that scored less where the ones about the involvement of service users in the MU project.

When asked about the name for the AMU, participants agreed on the idea of having a proper noun like for the regional MU. However, the suggestions made previously by the team scored really low (see table 24 below).

Table 24 Delphi 2 – Name for the AMU

Question	Mean	SD
Based on what has been discussed about the name for the AMU, the idea is to choose a proper noun (like for example the regional one [name of service]).	8.00	2.11
What do you think of the following suggestions made by the team in the previous survey?		
a. Low obstetric risk unit a. Unità percorso nascita BRO	5.94	3.02
b. A mum is born b. Nasce una mamma	4.00	3.48
c.Pollicino's nest c. Il nido di Pollicino	3.09	3.01
d.Sweet Birth d. La dolce nascita	5.14	3.17
e. The happy stork e. La cicogna felice	4.09	3.50

5.4.   Step 4 - Service users' survey – Engaging the local population

Engaging and involving the local population in the work conducted by the team to prepare an implementation plan aligns with the participatory approach chosen for this research to investigate the local culture on this specific topic and represent the first research in Italy on MUs conducted engaging service users.

The collaboration with MeS Laboratory allowed me to access a precious database of women who gave birth in the health district in the past two years and gave permission to be contacted for research activities related to maternity services. This collaboration enabled this research to reach a wide group of users, optimise timing and receive a high number of responses.

5.4.1. Process

After a multidisciplinary meeting in June 2021 in which I presented the findings of the second Delphi survey, the maternity team supported the idea to involve the local population via online survey, using the implementation plan as a baseline of questions and adding more specific questions to explore knowledge of and attitudes towards the AMU model. Therefore, I initially worked on making the second Delphi survey more accessible for lay audience and after that a multidisciplinary focus group was organised by the lead hospital midwife to discuss the questions that the team found relevant to ask to the local population. This online focus group was well attended with 7 professionals including midwifery managers (both hospital and community), an obstetrician, a neonatologist and three midwives. After transcription and analysis, I synthesised the contributions and added them to a draft version of the online survey. This version was then opened to two service users who were recruited in the initial stage of this research asking them to complete it to check the usability, language and clarity. Their feedback was used to improve the draft.

Initially, the team welcomed my suggestion to add a short introductory video (like the one I made for them in the first Delphi survey) to present the project to the local population. Having the team presenting the AMU project idea to the local population was seen as a good way to engage them and increase the response ratio. The midwifery manager in the hospital supported this and made a video with 5 hospital midwives talking in turn to present the idea of the AMU and the survey showing a sense of ownership of the project. However, unfortunately, during the final stages of approval with the organisational leadership, a director did not support this initiative and asked for this video to be

removed. The survey was therefore circulated without it. Instead, a short introductory text co-produced by the local team was approved by the organisational leadership.

As described in chapter 2, the list of contacts used was the one that MeS Laboratory had from the hAPPy Mamma database (women who used the regional application on their phone as pregnancy booklet). This database was available from March 2019 until the end of 2021.

These women agreed during the booking appointment to be contacted via email for research activities related to maternity services. However, a data linkage with another database of the women who gave birth at term in the local hospital was needed to avoid contacting women who lost their pregnancy. This dataset was obtained from the organisational office by the lead midwife, showing good level of engagement and proactivity in this part of the research. This database also included demographic details and birth outcomes data so these questions were not needed in the survey. No sample calculation was needed as the invitation was directed at all women who gave birth at term in the last 2 years in the local hospital and could give feedback and contribution on the implementation plan and innovation.

After data linkage, a database with 1444 contacts was obtained. As there were different nationalities included in the database, a decision was made with supervisors to include English and French translations to increase accessibility and inclusivity for local.

The survey included 28 questions divided into 8 blocks which matched some of the themes of the Delphi survey plus other relevant points identified by the team during the focus group. Most of the questions were multiple choice and some were open ended to give participants the possibility to articulate their answer.

After a long approval phase, the survey was open on the 11th of January 2022 and remained open for a month until 14th of February 2022. Three reminders were sent a week, two days and a day before closing to increase the response rate.

5.4.2. Findings

One of the findings that came up even before starting data collection (via research diary) was how difficult it was to promote the implementation of the AMU and sense of ownership of the innovation due to the highly hierarchical structure of the service. It was fascinating to notice with the example of the introductory video to the survey, that even though the team was cohesive and motivated in promoting the AMU and the survey in front of the population, one director had the ability to stop the initiative based on his own judgement. He explained that being all local midwives, it would have looked like a hospital initiative and instead of an organisational one. However, instead of suggesting new way to make it look like a wider level initiative, he preferred to switch to an introductory text, which was written and signed by the hospital team anyway. To some local stakeholders, it seemed like the organisational leadership was still unsure about the AMU project and preferred not to actively promote it.

A total of 654 service users started the survey (45% response rate) with 102 who completed it partially and 515 who completed it all (78% completion rate). This overall is a positive result showing that the online survey was a feasible tool especially considering it was aimed to a lay audience. Maternity survey in England had a response rate of 46.5% in 2022 showing similar response rate but with different research infrastructure and resources in comparison to this study (Care Quality Commission, 2022).

Demographic data is available for the 617 participants who gave consent and started the survey.

Table 25 Service Users Survey - Demographic data

	Mean	SD	**Demographic - Service users' survey**		
	Mean	*SD*			
Age	32.95	5.21			
	Number	*Percentage*		*Number*	*Percentage*
Gender			**Type of pregnancy**		
Female	617	100%	Physiological	397	64.34%
Year of birth			Pathological	220	35.66%
2019	72	11.67%	**Type of birth**		
2020	350	56.73%	SVB	387	62.72%
2021	195	31.60%	ELCS	110	17.83%
Nationality			EMCS (not in labour)	64	10.37%
Italy	550	89.14%	EMCS (in labour)	38	6.16%
Romania	25	4.05%	Instrumental birth	18	2.92%
Albania	13	2.11%	**Weeks of gestation**		
Unknown	4	0.65%	Less than 37 weeks	34	5.60%
Poland	4	0.65%	37- 40 weeks	459	74.40%
Russia	2	0.32%	40-42 weeks	83	13.40%
Moldavia	2	0.32%	Unknown	41	6.60%
Bangladesh	2	0.32%	**Parity**		
Morocco	2	0.32%	Nullipara	228	36.95%
Brazil	2	0.32%	Multipara	389	63.05%
Bulgaria	1	0.16%	**Education**		
Germany	1	0.16%	Secondary School	68	11.02%
Ukraine	1	0.16%	High School Diploma	313	50.73%
North Macedonia	1	0.16%	Postgraduate diploma	66	10.70%
Philippines	1	0.16%	University degree	153	24.80%
Jordan	1	0.16%	Unknown	17	2.76%
Egypt	1	0.16%			
Senegal	1	0.16%			
Somalia	1	0.16%			
Tunisia	1	0.16%			
USA	1	0.16%			

Figure 22 Type of birth participants of the service users survey
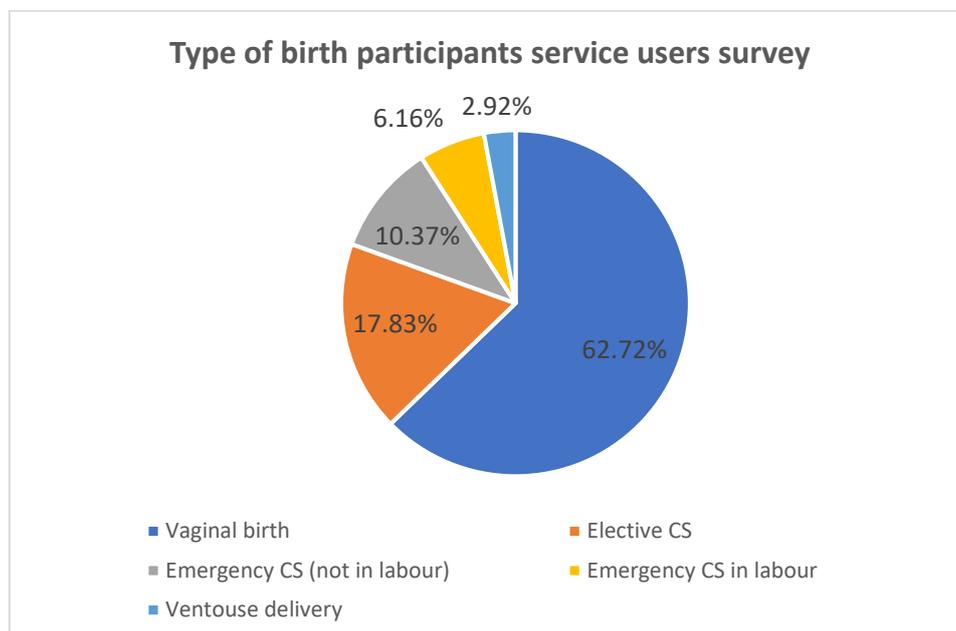
As presented in figure 22, this sample seemed representative of the Italian situation with a CS average around 33% here in comparison to the local context (33,6% in 2021) and the Italian one (31,2% in 2021). As discussed in chapter 1 the CS rate high but typical for the Italian context.

The majority of participants (88%) gave birth between the 37 and 42 weeks of gestation and most of them were multipara (63%). The remaining 11% from 27 to 37 week of gestation. The decision to not exclude preterm, CS or high-risk pregnancies was made on the assumption that this survey was investigating knowledge, perceptions and opinions of the general maternity population without limiting it to only low risk women eligible for MU care.

Here I present the analysis from the survey divided by following areas:

- General questions
- Knowledge and attitude towards the MU
- Risk Assessment
- A new model of care
- Service users' role
- Name for the AMU

General questions

The main reasons given for choosing the local hospital to give birth are presented in figure 23. Participants could select more than one option.

Figure 23 Service Users' survey D1

What made you choose to give birth in [name of service]?

- To be looked after my obstetrician/midwife
- It was suggested by family/friends
- It was suggested by my obstetrician/midwife
- I trust the maternity team
- I found it appropriate to handle complex situations
- My labour started while I was in that area
- I had previous positive experiences
- It was the only alternative in the province
- Other…

Most women (50%) chose to have both the public care offered by the SSN and some private visits with a local obstetrician (who often are also employed publicly and work in the hospital), while 42% chose to only have the public pathway of care and only 8% choosing just private. The decision to add private visits with a local doctor seems to be due to the need of having continuity of carer. This finding is present in different questions across the survey (even in the previous one in which women chose the birth setting to find the same practitioner who followed them in pregnancy).

In this sample, most women were looked after antenatally by the hospital and privately (see figure 24). However, it was positive to see that there was representation from people who received care in all the community healthcare centres in the province too.

Figure 24 Service Users' survey D3
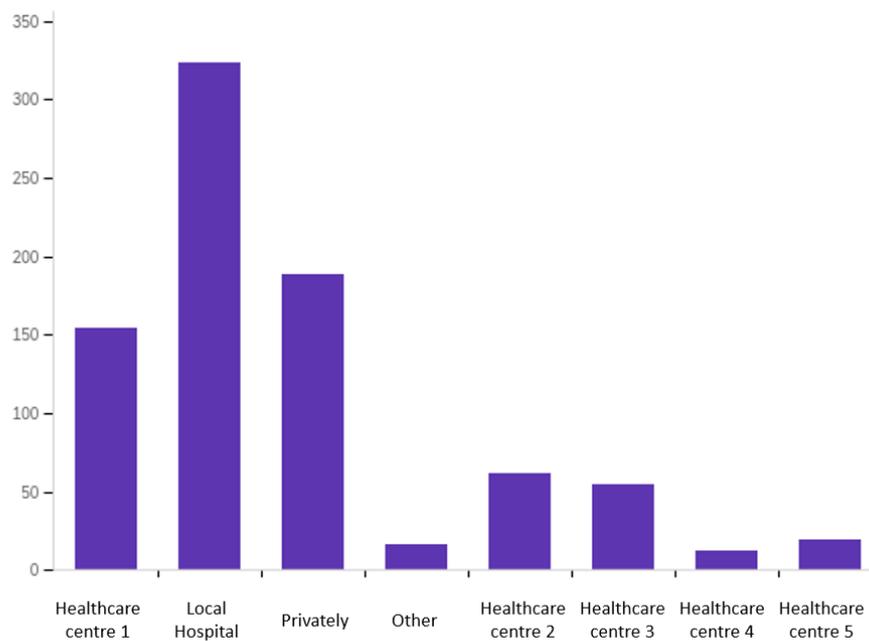
When asked about the level of satisfaction for the type of care that they received before, during and after birth, service users had overall good scores with antenatal care having an average of 7.95/10, intrapartum care 7.87/10 and postpartum 6.7/10. This finding was coherent with the data used for the situational analysis in which women were more negative about the postpartum care (both in hospital during the first few days and in the community when going back home) and consistent with wider literature (e.g. the maternity survey in England (Care Quality Commission, 2022).

Knowledge and attitude towards the MU

In terms of knowledge about the model of care, most women (65%) answered that they did not know or never heard about the MU model. Only 18% answered "yes" and 17% answering "maybe" to this question. When asked "*what would you think of integrating such model in [name of service] inside the hospital and on the same floor of the OU?*", women seemed to be in favour of the innovation with only small percentage not interested at all and 59% interested in the proposal. Considering that the overall knowledge about the model was low, many women opted for "I don't know" option (see figure 25). This was reinforced by the following question about the interest of giving birth in such model in case of a future physiological pregnancy in which 47% answered "yes", 40% "maybe" and 13% "no".

This seems to suggest a positive attitude of the local population towards the innovation but also the need to inform them more in detail about the model.
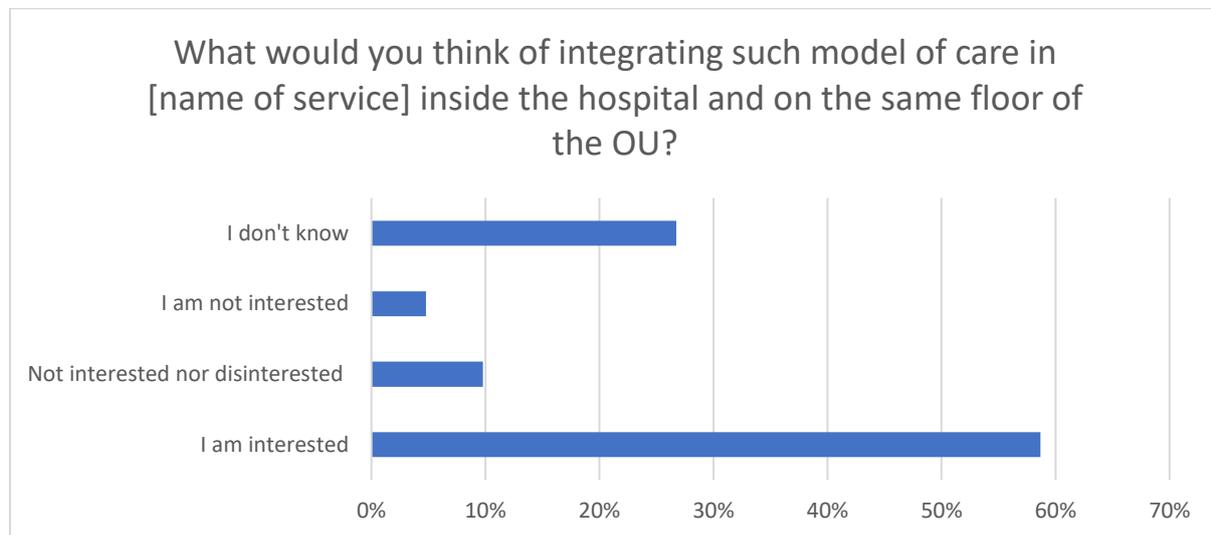
In the open-ended question asking to explain the previous answer, participants often mentioned the need to know more about the model, reassurance of it being inside the hospital to access medical care if needed and the possibility to reduce medicalisation of birth this way. Overall, the midwifery-led aspect of the model was seen positively and associated with trust towards the profession. Also mentioned as valuable aspects were the possibility to choose a model of care and to have continuity of carer.

"My birth was completely physiological and I was assisted by midwives, I imagine that a midwife-only centre is interesting, but I would only try it if I was sure it was inside the hospital and close to the obstetric unit" Participant 67, service user

"It could be interesting, natural and not dangerous because it is still inside the hospital" Participant 437, service user

"Because childbirth is too medicalised, I was lucky on both sides to find midwives similar to me in the desire to experience childbirth as a natural thing, but this is not the case for all women." Participant 149, service user

Risk Assessment

Interestingly, when asked the question about who they thought is the professional responsible for risk assessment for women with uncomplicated pregnancies, service users had similar answers than professionals with 54% answering "obstetrician and midwife" (most voted answer among

professionals too), 27% opting for "obstetrician" and 19% for "midwife". This finding seems to highlight again the doctor-centred philosophy that is present in the local context.

Participants found the labels of low, medium and high risk for the different pathways of care offered appropriate and comprehensible. However, they also agreed with the idea of calling them with proper nouns like flowers (like suggested by some professionals during the Delphi) to avoid focusing on the concept of risk (Figure 26).

Figure 26 Service users' survey D12
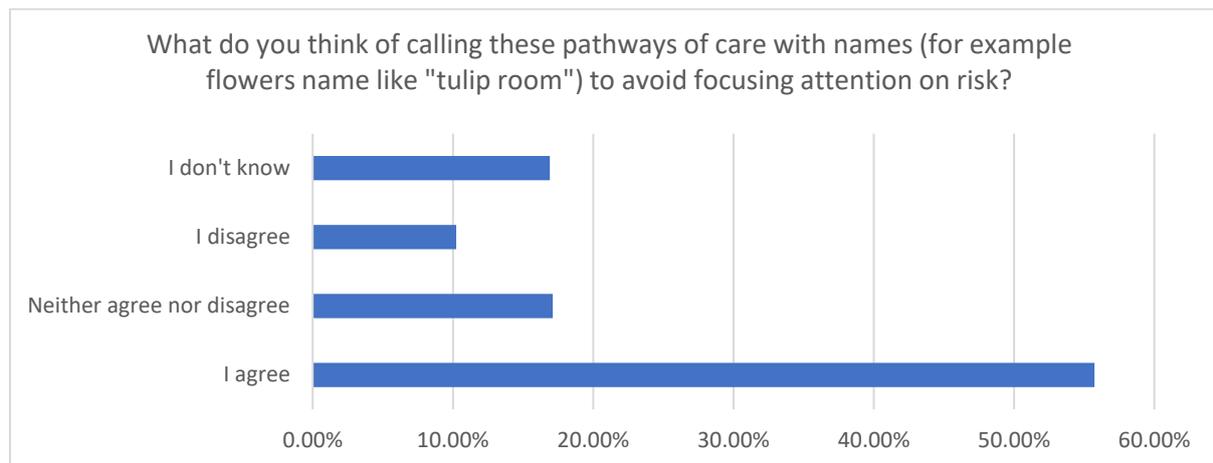
In the open-ended question, when they asked to explain the reason of their answer, majority of women agreed with idea of using flower names to reduce stress, anxiety and fear related to the concept of risk. The ones who disagreed highlighted that an honest and clear communication was paramount to send a realistic message and suggested avoiding new terminology which could confuse users.

"A mother who knows she has a risky pregnancy, I think she hardly pays attention to the name of the path. But I agree because the last few months we have been followed by 'pathology' to monitor growth, and the name scared me a bit." Participant 207, service user

"During pregnancy I was diagnosed with gestational diabetes and have been followed up in the 'tulip room' throughout. It makes you feel less 'sick'" Participant 362, service user

"Changing the name does not shift the focus. The woman must be accompanied along this path with dialogue, establishing tranquillity and awareness without omitting or lightening reality." Participant 415, service user

A New model of care

Service users showed a good level of interest in the idea of having continuity of carer from the same midwife antenatally who would come for the birth too (see figure 27).

Figure 27 Service users' survey D14
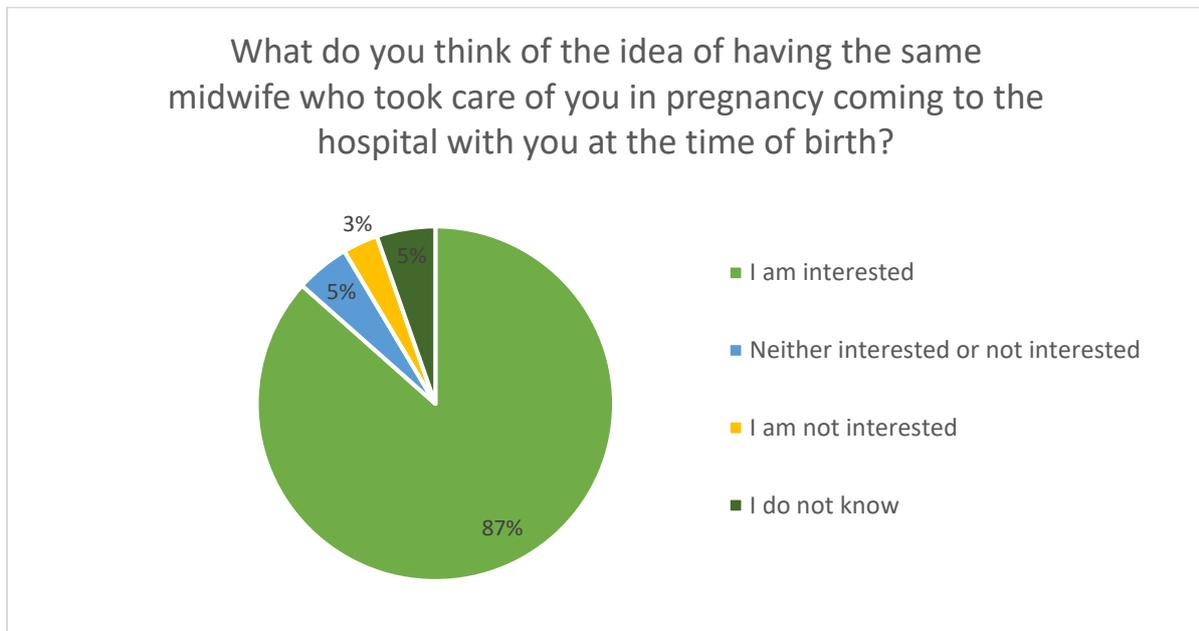
Similar responses were left about the suggestion of integrating a telephone triage to assess women on early stages of labour at home before coming to the hospital; 83% answered "I am interested", 7% "I do not know", 5% "I am not interested" and 5% "neither interested nor not interested".

During the Delphi stage, professionals agreed on a list of training for the dedicated team of midwives of the AMU and among these were training about new pain relief techniques to offer to women. In this survey, a question was about what they thought about the suggested new pain relief options. Women were overall in agreement with the suggestions with means always above 6/10 (see table 26). However, the only option which seemed to be welcomed more enthusiastically with a mean over 8/10 was water immersion in labour. Interestingly, this is an option that has been offered to some women in the past in the local hospital as there is a birthing pool in one of the labour rooms. However, most professionals reported not feeling confident enough in using it and in facilitating births there especially due to the resistance from neonatologists and the concerns about the room temperature.

Table 26 Service users' survey D15

Suggestion	Mean	SD	Variance
Aromatherapy	6.2	3.16	10
Acupressure	6.84	2.94	8.64
Gas and air (nitrous oxide)	6.09	3.18	10.11
TENS machine (electro stimulator to be applied to the lumbar part of the back)	6.53	2.89	8.34
Rebozo (Mexican massage technique with a cloth)	6.77	2.82	7.97
Water immersion (birthing pool for labour and/or birth)	8.08	2.44	5.93

When asked what they thought of the idea of having a birthing partner that would stay with them for the whole duration of labour, birth and postpartum in a homely environment, 94% of women answered to be interested. Only 4% said "I do not know" and less than 2% were not interested nor disinterested. Similarly, the question about having the possibility of having children or other family members in the room during the postpartum period received positive responses by the women (see figure 28).

Figure 28 Service users' survey D18

What would you think of the idea of being able to have other children/family members in the room with you during the postpartum period?

- ■ I am interested
- ■ I am not interested
- ■ I do not know
- ■ Neither interested nor not interested
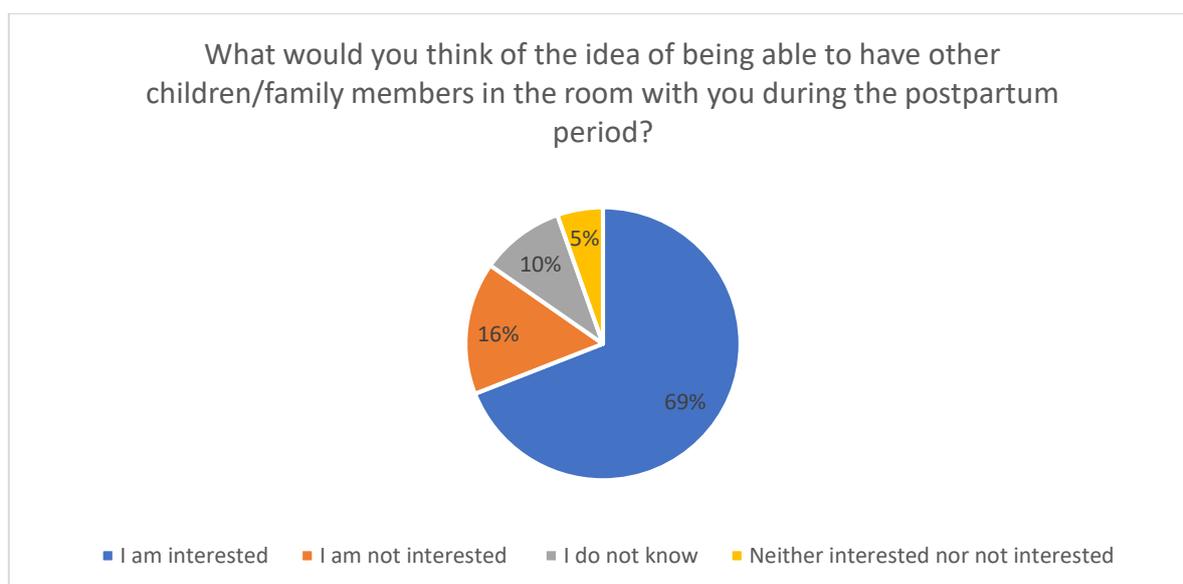
Women were also very much in favour (90% answered "I am interested") of the idea of having the neonatologist visit to the baby not at birth but within 24 hours in the room if no other needs. This was one of the points that professionals struggle the most with (especially neonatologists) as seeing it far from their current practice and because they believed women would not agree with that. Therefore, seeing a positive response from service users was not expected.

The following question was about what type of midwifery care they believed most appropriate for the postpartum period after being discharged from the hospital. Professionals suggested different options like home visits, free access or planned visits to the community healthcare. The response to the survey shows an interest in a mix of these options (see figure 29). Women were also interested in having a professional coming to their home in the post-partum period (79% answered to be interested).

Figure 29 Service users' survey D20
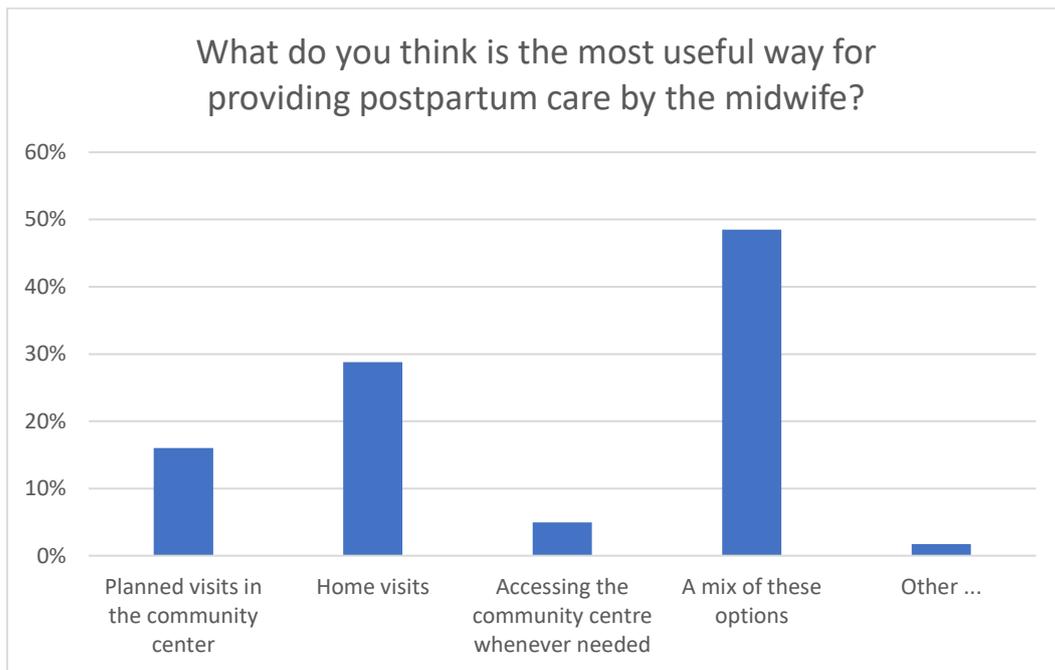
Regarding the question about the possibility of being discharged home earlier than the usual 72 hours, women showed positive interest even though 23% were "neither interested nor disinterested" or did not know and 11% were not interested in this option (see figure 30).

Figure 30 Service users' survey D21

What would you think of the possibility of being discharged home earlier (before 72 hours) provided the right level of care and home support was given from the midwife in the community?

- I am interested — 66%
- Neither interested nor not interested — 10%
- I am not interested — 11%
- I do not know — 13%
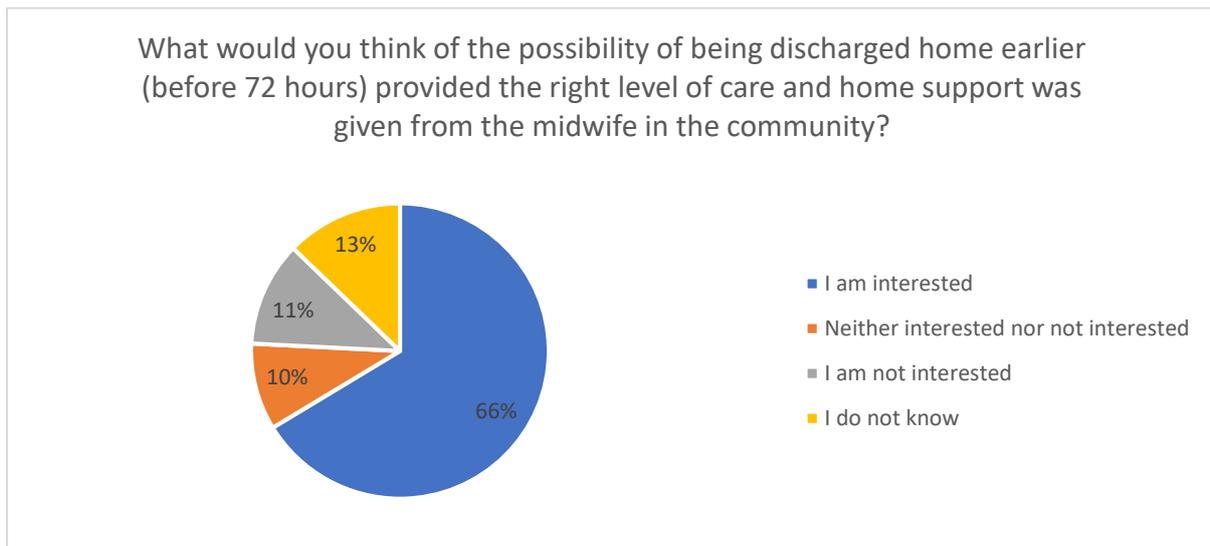
Service users' role

When asked what they thought of the idea of including service users' representatives in the multidisciplinary meeting to plan the AMU, 58% of women answered to be interested, only 6% said 'not interested' and the rest were either 'not interested nor disinterested' or 'did not know' (see figure 31).

Figure 31 Service users' survey D23

What do you think of the idea of including some women representatives of the local population during multidisciplinary meetings with the maternity team for planning the midwifery unit led by midwives?

- I am interested — 58%
- Neither interested nor not interested — 16%
- I am not interested — 6%
- I do not know — 20%
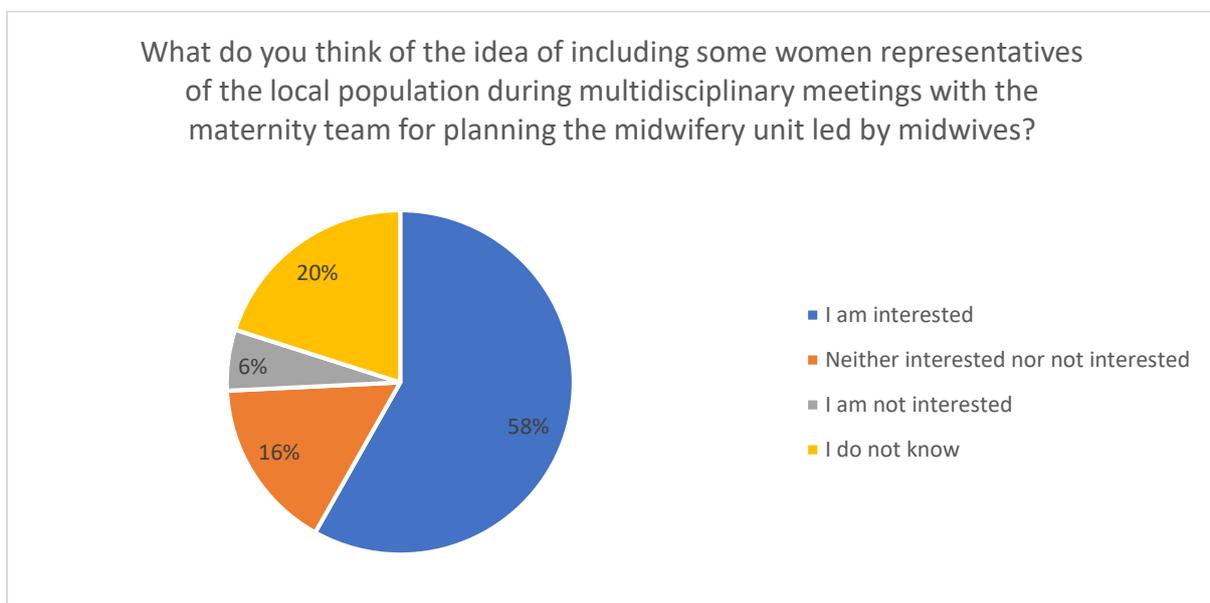
This is consistent with the answers given by professionals considering that almost half of the sample did not vote for "I am interested". This highlights again, even from this perspective, a culture in which

service users tend not to be included in the service configuration of maternity service and so are unfamiliar with this idea.

During the Delphi, the maternity team proposed ideas to engage, inform and educate service users about the AMU model. Women ranked these ideas in scale of importance and the results are reported in table 27 below, showing a high level of support, particularly for direct information from health professionals.

Table 27 Service users' survey D24

Field	Mean	SD	Variance
Informative booklet about midwifery led care	8.17	1.93	3.72
Further information on midwifery led care during antenatal classes	8.04	1.98	3.9
Engage general practitioners, obstetricians and paediatricians regarding the birth centre initiative to ensure that they promote it to women	8.3	1.8	3.23
Posters and videos shown in the community and in the hospital	7.28	2.35	5.52
Social media	7.41	2.53	6.42
Newsletter/emails/regular communications on the progress of the project	6.96	2.64	6.97

In the open-ended question about "*how do you think the communication aspect between the maternity team and service users can be improved*?", women left many comments and the thematic analysis showed their preference for a 24/7 accessible phone line. Other suggestions were made about chats, webpages and mobile apps showing a strong inclination for technology to support direct communication. Majority of comments highlighted the need for more contacts with maternity team to receive more detailed information about the maternity pathway. The need for more empathy from the maternity team when communicating with service users was also often mentioned. They referred to the community health care centres as main places to access information and meet the team. Furthermore, it was very positive to see many comments in agreement and enthusiastic about the suggestions made by the professionals in the previous question.

"Activate a telephone line for a period to get all the information, or enhance the community services to do this, or create an ad hoc website." Participant 203, service user

"By explaining everything we are going to deal with in a simpler way and greater availability by those who assess you in clarifying any doubts. It would take more dialogue and more meetings so that a good relationship is established on both sides. First of all, trust and a greater possibility for women to have explanations." Participant 145, service user

"In these options there are all the channels that I think are really useful for communication, if they really were implemented it would be great." Participant 388, service user

Name for the AMU

As with the Delphi surveys, the final questions focused on what name they found to be most appropriate for the AMU among the options supported by the team and management. Similarly, to the Delphi results, women did not tend to like the options with more clinical or technical names (Option 1 and 2 in the table 28 below) but preferred the idea of a proper name like the regional AMU has.

Table 28 Service users' survey – Name for the AMU

Field	Mean	SD	Variance
Unità funzionale per il basso rischio ostetrico (BRO) (Unit for low risk pregnancies)	4.27	2.75	7.58
Centro nascita a conduzione ostetrica (Birth centre midwifery-led)	6.83	2.73	7.46
Casa parto (Birth house)	7.00	2.96	8.76
Un nome proprio come un fiore (proper noun like a flower)	7.35	2.88	8.30

The last open-ended question asked women to suggest specific names for the AMU. The word cloud in figure 32 shows the most popular suggestions made like "birth home", "birth centre", "stork", "life", "nest", "sunflower", "sun", "together" or "tree".

Figure 32 Word cloud for the AMU name

A report from this survey was made and presented to the team in the final event of this research project. A copy was also shared via email with the wider maternity team to show them the findings of the service users' survey.

5.5.   Discussion

The Delphi approach was agreed during the Covid pandemic to keep the project ongoing in a moment in which face to face meetings and workshops could not be facilitated. However, even if this was not the initial plan, it became a successful strategy to include staff members working in different settings across the province. The engagement was facilitated via online communication and with support from the midwifery leaders. Both focus groups and survey registered good attendance and completion rate. This was positive especially for the survey considering that it was an anonymous research activity to be completed on a voluntary basis without getting anything in return. The co-design aspect of the research was particularly appreciated by stakeholders and fed the professionals needs to adapt the innovation to the local context based on theirs and service users' needs. This positively affected the approach towards the innovation, helped to prepare an implementation plan and had an impact on professionals openly supporting the project (this will be discussed more in chapter 6). A positive finding was also the good level of engagement from service users to complete the survey (45% response rate) and the inclusion of fifteen different nationalities among respondents (see table 25). This suggested that including English and French translation helped inclusivity and showed service

users' willingness to take part in codesigning the maternity service. The sample seemed representative of the local population in terms of demographics and perinatal outcomes of the pregnancy and birth. However, most women (56%) gave birth in 2020 which was in the middle of the pandemic. Furthermore, they were mainly multiparas (63%) who had a physiological pregnancy (64%) showing that most of them had previous exposure to maternity service and midwifery.

Generally, women were satisfied with the experience of maternity care in the local hospital. The weak spot across the service was the postnatal care which score lower than the others. This is consistent with wider literature and maternity care in general (Care Quality Commission, 2022).

One of the main findings was seeing that local women had a strong interest in the MU project but not enough knowledge of the model yet. They frequently asked for more information in the qualitative comments. Therefore, an educational and informative intervention seems necessary for the local context to increase the acceptability and appropriateness among them.

Continuity of carer by a midwife is the gold standard model for all women and the significant impact on women's and babies health is now known (Sandall *et al.*, 2016). It was interesting to notice from the service users' survey, how the Italian context even when the system does not provide this model of care users seek it by accessing private care of clinicians who work in the public hospital. A trusting relationship with the professional who could be present during birth was very important for them influencing significantly the decision about what type of care to have in pregnancy and where to give birth. However, this is currently possible only via integration of private care on top of the public one with a local obstetrician. This also presents some inequity aspects making an evidence-based intervention not affordable for some women and unfairness towards the midwifery category who cannot offer a similar service on top of their public work like doctors can.

The main themes arising from the Delphi project were well supported by the extended team. They were interestingly similar to the ones arising from the systematic review of this thesis and the ones of the MU Standards giving even more relevance to those areas for the implementation work (Rocca-Ihenacho *et al.*, 2018; Batinelli *et al.*, 2022).

Although there was a high level of support expressed from service providers and users for the development of a midwifery-unit, a unanimous finding, for both professionals and service users, was that the MU needed to be alongside and near the OU to align with the perception of safety that stakeholders had. The majority did not perceive an FMU as safe. This is a significant finding for this

local and national context. It shows some level of readiness in Italy for AMUs but not yet for FMUs or homebirths integrated within public maternity services. This is reflected in the national guidelines that only recommends low risk units within the hospital (Comitato Percorso Nascita Nazionale, 2017) and in the rate of homebirth currently taking place in Italy is around 0.07% via private service (Cicero *et al.*, 2022).

The positive response to the Delphi showed how having a shared vision of the innovation was important for professionals and unanimous agreement was reported about having all disciplines represented in the advisory group. However, when deciding who should be sharing that vision it became clear that some stakeholders were perceived to be less important than others like fetal medicine team, organisational directors and service users. This showed an idea of the innovation mainly dedicated to the intrapartum team and is reflective of a fragmented approach to maternity services. Furthermore, an approach mainly institution-centred considering that service users were not perceived as key stakeholders in the design of the AMU.

However, this attitude was notable even from the service users' perspective. In the survey completed by local women, a high percentage of them (42%) were reluctant to be involved in designing the new service. This shows a cultural aspect in which the community is unfamiliar with the concept of codesign and community engagement in healthcare. However, a recent Cochrane review and extensive literature highlights how the involvement of service users is a key facilitator when planning implementation of person-centred care innovations (Merner *et al.*, 2019). In Italy, even if national legislation recommends involvement of service users and community groups representatives and the use of surveys for the assessment of healthcare services (Decrees Nos. 502/1992 and 517/1993), only a few regions have given a systematic approach to this (Paparella, 2016). Contributing to this aspect is the federalism previously mentioned in chapter 1. Although, Tuscany is one of the regions to systematically assess and monitor service users' experience via surveys that evaluate the performance of all hospitals, service users are not systematically involved in advisory boards, committees or meetings.

Overall, local service users have shown trust in the midwifery profession. Although, some women reported negative experience, the vast majority had positive experiences with midwives and trust the professional category. This is relevant in terms of readiness of the local context especially considering the findings of the systematic review that highlighted how in different context this was a prerequisite to the implementation (Batinelli *et al.*, 2022).

Creating a group of dedicated midwives for the MU seemed a challenging task for the team. However, this aspect was influenced by the ongoing pandemic and different priority in the hospital. It was interesting to notice that the staffing model more supported was the shift-based or a combination of shifts and on call during weekend and nights. The on-call model was not seen as a feasible option. Staffing models in the MUs vary depending of the local context, the services provided and the numbers of population accessing them (Rocca-Ihenacho *et al.*, 2018; Stevens and Alonso, 2020; Murray-Davis *et al.*, 2022).

Addressing midwives' training needs to develop autonomy and being ready to work in the AMU was a key aspect of the implementation plan created by professionals. This seems to suggest that midwifery education, CPD and current practice model are currently not preparing the midwifery workforce for working in autonomy. Other international studies have identified a lack of training to support physiology; for example in Australia (Carolan-Olah, Kruger and Garvey-Graham, 2015), Cyprus (Hadjigeorgiou and Coxon, 2014), Ireland (Healy, Humphreys and Kennedy, 2017) and England (Darling, McCourt and Cartwright, 2021). However, this is not just a training issue but it also concerns the fact that midwives need to be enabled to practice in autonomy by the context in which they are working, including feeling supported by obstetric colleagues. Healy et al. (2017) in Ireland identified this as one of the main reasons to explain how midwifery has assumed a peripheral position in favour of a more risk focused provision of maternity care.

In the Delphi, professionals agreed unanimously on the training needs, both for midwives and the multidisciplinary team. This shows collective awareness on the areas they were currently lacking in. Big attention was given to newborn care and neonatal resus as this was not currently part of their job profile. This is probably relevant for most of the Italian contexts as this skill set is covered by nurses in most maternity services. These training needs were aligned with the ones suggested by the 'Midwifery Unit Standards for Europe' (Rocca-Ihenacho *et al.*, 2018) and in the 'Open a Midwifery Center manual' (Alonso, 2019). Therefore, this showed to be useful and valid guidelines for services approaching a similar transition even in this type of context.

An interesting finding was seeing that for both professionals and service users the professional responsible for the assessment of low-risk women should be "midwife and obstetrician". This shows how in principle midwives are recognised as autonomous practitioner by guidelines but, in reality, obstetric control over the midwifery decision making is still perceived as needed both from

professionals and women's perspectives. This represents a strong cultural barrier to overcome when attempting to implement midwifery led care models.

Both professionals and users agreed with the suggested labels of low, medium and high risk but women also agreed with the suggestions of giving them proper nouns to move the focus away from the concept of risk which is something that professionals were not much in favour of. Most women recognised a negative impact causing more fear and anxiety using frequently the "risk" word. Nonetheless, clarity and consistency of the information were more important to them than the labels and this was aligned with professional views. A recent systematic review by Nickel et al. (2017) showed how the use of more medicalised terms can significantly impact both the professional's management of the care and the psychological outcomes in patients (Nickel *et al.*, 2017). Therefore, knowing that words matter, changing terminology to support decision making could be a strategy to address patients' preferences.

Managers and professionals considered the use of a flowcharts or checklists as essential to ensure patient safety (e.g., the criteria for low, medium and high risk). However, the concept of personalisation of care and partnership in decision making was rarely mentioned. Supporting women with 'out of guidelines' choice was not common practice in this context. Previous studies have shown how shared decision making is not well-established practice in the Italian healthcare system and identified an evidence to practice gap when it comes to person-centred care (Goss *et al.*, 2007; Meier, Carter and De Maria, 2021).

The regional guideline published in 2021 with specific recommendations for intrapartum care for low-risk women (Regional Act DD10214, 2021) was valued by professionals and was perceived as a key facilitator for implementing the MU. A local guideline on low-risk intrapartum care was also already in place in the local context. It was interesting to use the prescriptive word "protocol" as reference for this guideline. Instead of being a set of recommendations that would allow personalisation of care, the local participants were more used to a set of rules to follow (like a protocol) than to the concept of guideline to support women's choices. However, information provision, listening and respect were identified as key aspects of shared decision making from the women's point of view in the service users' survey.

Integration between different parts of the service was recognised as weak among the team. It was one of the objectives agree to work on in 2020 but left aside in the middle of the pandemic. In the

Delphi survey, this aspect was recognised to be important when implementing innovations like the MU. The most valued approach to increase integration was having regular hybrid meetings that staff could join from home even when not working. Furthermore, a strategy suggested by the team during the focus groups to improve integration among midwives was a gentle rotation of some community and hospital professionals as way to "contaminate" and improve the working relationships. This aspect came up in a study about AMUs conducted in England where managers suggested either caseloading or planned midwives' rotation to ensure experience and understanding across areas (McCourt *et al.*, 2014). The study respondents highlighted that this intervention needed care to avoid just disrupting people's work or reducing continuity rather than enhancing it. Midwives observed that some colleagues were not keen to move between areas as used to working in one way, but also suggested that it might be more beneficial for relationships between different professional groups. Therefore, this is an aspect requiring caution when implemented to avoid staff dissatisfaction. This was consistent with the Delphi findings in which gentle rotations did not score high and were the detractors' options within the Net Promoter Score.

Challenges in communication were identified by both professionals and women as a barrier to positive birth experiences and working relationships. From the professionals' perspective, as already noted in the situational analysis (chapter 4), the problem lay mainly in how they were communicating as a team and the conflictual, judgmental and competitive approach that some members seemed to have. This was made worse by the frequent change in leadership (and often leadership gaps in between) and the Covid pandemic that added workload pressure and shortage of staff. From the women's perspective, communication needed to improve to feel more supported, less judged and more informed about the care they were receiving.

Both professionals and service-users agreed on the need to provide more information to women about MU model and the evidence around it as facilitator for the implementation. Some of the channels of communication suggested by professionals were supported by users too. They also frequently mentioned the use of social media to support information provision. They suggested a WhatsApp chat and social media pages to facilitate communication between the two parts. Mobile health interventions are now spreading in healthcare in the attempt to accommodate those needs ensuring correct and appropriate information (Chen *et al.*, 2018). The local context recently started to have a mobile app called hAPPyMamma to facilitate this showing again good readiness for some technological innovations (Bonciani, De Rosis and Vainieri, 2021).

Professionals and managers agreed that a reflective approach to practice was key to improvement and to learn from both positive and negative experiences. If conveyed by appropriate communication, this was also seen as an opportunity to promote team cohesion. This is consistent with previous work to promote a more collaborative culture in maternity care (Downe, Finlayson and Fleming, 2010).

5.6. Conclusions

The pandemic forced this project to change the planned approach to reach stakeholders and to continue a participatory work to create an implementation plan. The use of a Delphi approach to co-design and service-users' online survey were found to be good engagement strategies that allowed the project to continue even during a global pandemic. The good participation from both professionals and service users to the surveys, despite the context of a pandemic which limited capacity to conduct face-to-face engagement prior to the surveys showed how this aspect of the research was highly valued by stakeholders and confirms that participatory action research is appropriate for this type of study. Similar work on improvement of existing MUs in six European countries found the same support by stakeholders to the codesign aspect of change (Yuill *et al.*, 2023). The suggestions made by professionals for the creation of the implementation plan were overall positively supported by service users showing some alignment in the vision for the implementation (for example 83% strongly agreed with the idea of receiving continuity of care intrapartum from the same midwife and 83% strongly agreed on the idea of having a phone triage to improve support and communication while at home). This good level of engagement in the codesign of the innovation constitutes a key step forward for the local context.

The implementation plan created as part of this stage is the output codesigned by the local team to support the transition from the obstetrically led traditional OU to an integrated model with an AMU and an OU.

In the next chapter, I present the findings arising from 'reflect' phase in which I stopped and reflected on the experience of this PAR cycle with the maternity team, using my research diary and involving key Italian stakeholders who had previous experience of implementation of MUs in that national context.

Chapter 6 - Phase four – Reflections on local and national level

Introduction to the chapter

In this chapter, I present the findings and analysis arising from the last stage of the implementation cycle: the "reflect" phase. A reflective approach has been used throughout the whole project as per Participatory Action Research (Koch *et al.*, 2005) but this last phase is particularly focused on reflection, to draw out lessons from this research experience. "*The aim of collaborative inquiry is to construct meaningful, practical knowledge from the experiences of the participants*" and the collaborative, reflective discussions had with participants and stakeholders in this project were helpful in generating deeper insights and understandings about the research enquiry (Koch *et al.*, 2005).

The main source of data for this analysis was the research diary and transcripts from the final stage of the research after the creation of the implementation plan. A final event was held with participants (managers and professionals) at the end of the project to gain a better understanding of how the experience of the co-creation was perceived. Furthermore, in-depth interviews with four key midwifery leaders with experience of implementing and leading MUs in the regional and national context were carried out. This helped to contextualise the findings arising from the local context in the wider Italian context.

This chapter is therefore divided in two main sections. The first is about the reflections on the implementation project with local participants where I discuss what it meant to do this study during a pandemic, I reflect on the three implementation outcomes observed (adoption, acceptability and appropriateness) and I report the experience of research from the participants' perspectives and my own perspective. In the second section, I present the reflections from the interviews with the four key midwifery leaders in order to contextualise the findings on the wider regional and Italian context.

6.1. 'Reflect' local

In this section, findings arising from the analysis of the research diary and the transcripts of the final stage of the project are presented. Reflections on this part of the analysis are here presented in three paragraphs: one on the impact of the covid pandemic (the good and the bad), one on the

implementation outcomes that could be analysed and observed during this research project prior to the implementation of the AMU (acceptability, appropriateness and adoption) and the last one on the experience of research (from researcher and participants' perspectives).

6.1.1. Research during a pandemic

One year after the beginning of this research, the Covid pandemic hit and significantly affected the events of the following years. All projects were suspended, especially research ones. Time and energies were focused on coping with the healthcare crisis. This involved things like redesigning the maternity service to reduce the spread of Covid in the hospital and in the community centres, training staff on new infection control protocols and coping with shortage of staff due to sickness. Priority was given to Covid initiatives and the other innovations like the MU were set aside.

"The pandemic has not helped the MU project in [name of local service]. All projects have been put on hold by the directors. The focus is on pathways of care for covid women. They had just one birth from a [Covid-19] positive patient so far (…) They moved wards and pathways hundred time, reports XXX (lead midwife)." Research diary, July 2020

Significant efforts by managers and professionals during those months were dedicated to the creation of new guidelines and procedures to reduce transmission as much as possible among patients and staff. This meant redesigning the service and creating dedicated pathways of care. However, due to the changing situation that was proceeding in waves of lockdowns and new openings those readjustments needed continuous reviews. This led to a "Covid fatigue" that was often reported by managers when approached to discuss the research project.

"Today was the first day of new regulations in place in the hospital. The team had to move all the activities online and started new covid protocols. Everyone seemed overwhelmed and tired." Research diary, October 2020

Consequently, due to this fatigue and the different priorities of the healthcare system, any research activity was not welcomed like before and in more than one occasion the team postponed data collection events.

"She reports a climate in the hospital a bit tense because of all the different things that they need to do with the new wave of Covid. It's a busy moment that needs to calm down before doing anything else." Research diary 2021

Collateral effect also reported by professionals was an increased medicalisation of the care. On one occasion, a hospital midwife collected data and presented the audit findings to the local team showing

a higher use of induction of labour and consequent caesarean section increase. Doctors trivialised the data collection and the work presented by her exposing herself in front of the team in the attempt to promote a reflection on how to improve practice. Midwifery leaders did not support this colleague even though MeS regional data also confirmed this increased medicalisation in the local hospital. Overall, this created more tensions between the obstetric and midwifery team.

This is consistent with the national context in which, due to the Covid pandemic, only one AMU out of four within the SSN was left open at the beginning of 2022. On the other hand, the private birth houses (small FMU in private houses regulated by home birth guidelines and procedures) registered an increased request of service from the population (Cicero *et al.*, 2022).

One positive consequence of the pandemic was the release of significant national budget in healthcare, especially for primary care. The MU being a primary care model helped to save the initial budget allocated to this initiative in 2019 not to be reinvested in other initiatives. Therefore, even without much proactivity and effort by the team to keep pushing for this innovation, the project was saved (although delayed) and still relevant to the national agenda. Later in 2021, the energies required to cope with the pandemic reduced and this made space to reopen the conversation about the MU project and how to actively push it forward by local stakeholders.

"XXX (architect) also suggested to apply for funding as nowadays a lot of funding opportunities has been given to the healthcare sector. The problem here is that there is none good enough in terms of motivation, energies and skills who could move this forward from the inside." Research diary 2020

"XX (midwifery leader) shared that with the pandemic it was not easy to move this type of project forward but that now it's the right time to keep moving. We need to get the organisational directors on our side now." Research diary 2022

Furthermore, an opportunity that came along with the pandemic was that intrapartum care had to be split in three areas for non-covid women, covid women and women waiting for the results of the test (grey area). This latter area was in the wing in which the MU was initially planned to be (physically separated by the main ward and with direct access through triage). Therefore, women who were labouring and waiting for their Covid test result were looked after by midwives in this area away from the labour ward and sometimes women ended up giving birth here with the midwife. This represented the most similar practice to a MU that the local context experienced in recent years. Neonatologists and obstetricians did not have to be present at birth anymore and were only called in case of need and midwives got to experience more autonomy intrapartum. The quote below from the research

diary presents my experience of being present as birth companion for a family member during that time and how different it was when I did the same support in 2019.

"Being in the 'grey area' (query covid positive) allowed us to have a similar experience to a midwifery unit. Total respect from other professionals who waited outside of the door, doctors (obstetricians and neonatologists) included which was unusual. We had intermittent auscultation and [name of midwife] managed the whole care in autonomy including perineal assessment and suturing after birth. Baby had 2 hours on undisturbed skin to skin and partner was always with her. This experience was completely different to the one in 2019." Research diary 2021

Therefore, if the pandemic had negative impact on some aspects of the project like collaborative face to face workshops and change of organisation priorities it also became a good opportunity for others like autonomous midwifery led care intrapartum and long-term investments from the SSN.

6.1.2. Acceptability, appropriateness and adoption

This project was conducted before the opening of the MU meaning that when analysing the implementation outcomes for this innovation only three can be considered for discussion: adoption, acceptability and appropriateness.

"*Adoption is defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice*" (Proctor *et al.*, 2011)

The initial decision to implement the MU was championed by the lead obstetrician in 2018/2019. He promoted the innovation from the inside, presenting it to organisational leadership and starting the negotiations that led to the allocation of the initial budget. The following years adoption was affected by leadership dynamics and changes and was often reframed or reconsidered. However, by the end of the research project in July 2022, the MU project was still ongoing and the intention to adopt the model stronger than the beginning among the wider local team.

For this context, the adoption of the MU needed to be supported by the medical component and organisational leadership. Midwifery leadership support was key in keeping the conversation going but this innovation had to be backed up by the lead obstetrician and directors as prerequisite.

This became clear in 2021 when a medical director of the wider LHA (not much involved with the project) showed how one senior individual who do not trust the model can significantly obstruct the

implementation. Again, this showed a strong hierarchical system led mainly by doctors even when it concerns midwifery led innovations.

"He also expressed not being sure about the evidence about MUs as it's coming from countries in which the maternal and infant mortality is higher than Italy. This is the main knot, I think. He does not trust the evidence and uses the power coming from being a medical doctor and covering his position to hinder the application of national guidelines and regional recommendations." Research diary 2021

This shows that even when there is intention among the team to adopt the innovation and the public shows interest in it, in a hierarchical system such as this one the stakeholders at the top of the pyramid have a final say.

"they went to have a meeting with hospital leadership and it looked like XX (lead obstetrician) and XX (one of medical directors) were in agreement on what needed to be done and they were saying things like 'there is no point in doing a MU', 'I do not have midwives for the MU'. XX (Lead midwife) arrived at that meeting completely unaware of the change of plans. She said that it really did not look like a team decision because he (lead obstetrician) went there saying those things before consulting her or the rest of the team." Research diary 2021

However, after two years of PAR work, during the Delphi study and the service users' survey, the majority of professionals (93%) showed support on the adoption of the model and a good percentage of women (59%) reported being interested in implementing the model locally. Therefore, the participatory approach of this project seemed to affect the local stakeholders' attitude the innovation positively.

"Acceptability is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory" (Proctor *et al.*, 2011)

At the beginning of this project, many participants reported doubts about the acceptability of the innovation. This was discussed in the situational analysis when professionals and managers doubted the validity of evidence and its applicability to the local context. Seeing the innovation as something brought from another international context made them question the model initially. However, by the end of the project the innovation seemed to be more acceptable among different professional categories such as midwives, doctors, managers and service users. However, doubts were still noted both among professionals and service users.

"I think it's a titanic job, not only to change service users' minds, but also the professionals' ones. Lots of money that could be saved and used in other ways" Delphi survey 1, open comment T1D3

One facilitating factor that helped professionals trust the model more and to view it as acceptable was seeing the results of the service users' survey of this project. This reassured them that there was trust

in the midwifery profession among the local population and that there was a good interest towards this innovation.

As discussed in previous chapters, a key facilitator among professionals in terms of acceptability were the national guidelines published in 2017 and the wider international evidence recommending a more appropriate use of resources to reduce medicalisation of birth and improve outcomes (WHO, 2016, 2018; Comitato Percorso Nascita Nazionale, 2017).

The MU model was perceived as more acceptable, and its validity recognised, among stakeholders who had previous exposure of the model. This shows again how exposure to midwifery led care models facilitates professionals in trusting the model.

However, the complexity of the innovation was often mentioned with the need to adapt it to the local needs and context. This is related to the professionals' perceptions of the appropriateness of the innovation.

"Appropriateness is the perceived fit, relevance, or compatibility of the innovation or evidence-based practice for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem. (…) We preserve a distinction because a given treatment may be perceived as appropriate but not acceptable and vice versa" (Proctor *et al.*, 2011)

This seemed to be the case for the MU model, which was perceived by many professionals as acceptable in principle but not necessarily appropriate for the local context. Appropriateness was the weaker implementation outcome among professionals and managers even at the end of this project. There were several pushbacks due to local context (not enough births a year and not enough low risk women were often cited), historical moment (Covid pandemic), professionals' perceptions of service users' needs ("*our women want doctor led care*"), lack of training in midwifery-led care and lack of exposure to this model during education.

Adapting to the local needs was mentioned many times and the "how to" seemed to be the bigger obstacle of the implementation. An example of the hesitance related to this project is the architectural plans that the project went through during the four years of the research: if in march 2019 a whole wing was to be dedicated to the MU, in 2020 the idea changed in having 2 low-risk birthing rooms within the same intrapartum setting and later on was changed again in another area (half wing) with independent access and 2+1 rooms (2 main intrapartum plus one for triage that could be used as birthing room in need). Figure 33 gives a visual overview of this.

Figure 33 Planimetry of hospital maternity wards showing how the idea of the dedicated space for the MU changed in time
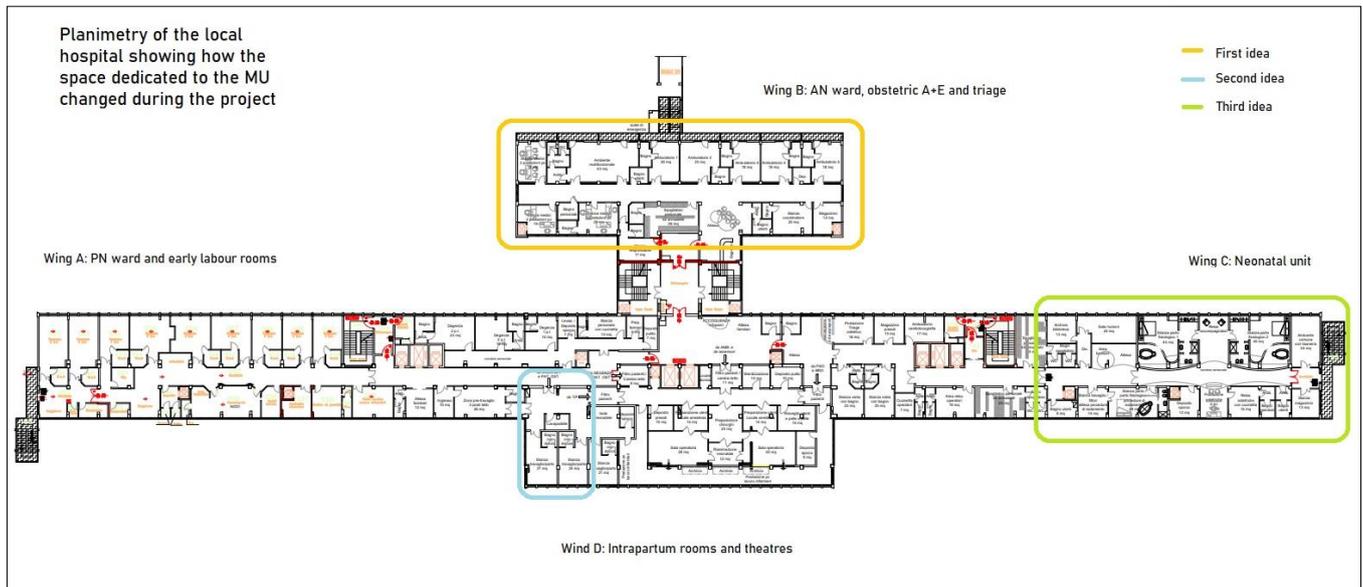
The need to adapt to local needs was perceived as crucial for the adoption of the model. However, this also required discussions around the fidelity of the innovation. Especially, when the project shifted to the idea of just dedicating two intra partum rooms to low-risk care, conversations around the risk of creating a hybrid version of a MU had to be facilitated by myself with the midwifery leaders. If at the beginning there was resistance towards this, with time this became clearer and the lead midwife started advocating for an independent space. A key enabler at this point was the MU Standards document which was just being published in Italian. The MU standards, based on evidence review and an expert Delphi survey, reinforced the concept and value of a specific space (Rocca-Ihenacho *et al.*, 2018; Batinelli *et al.*, 2020). Again, having that document endorsed by Italian institutions made them trust the recommendations more.

6.1.3. Engagement and experience of research

One of the biggest challenges during this research project was the engagement of the local team and organisational leadership towards the project and the innovation. As anticipated in the situational analysis chapter, a lot of energies and time were dedicated in the initial stage to 'open the gate' of interest. Initially this was championed by the local leader who promoted the initiative from the inside. However, when sadly that support was not available anymore due to the sudden loss of this leader,

this became more the role of the researcher and local supervisor. If opening the gate took several months of engagements activities attending meetings and introducing the research to different levels of leadership, keeping the gate open throughout the years became very hard also due to the Covid pandemic.

"Interesting to see how being away for a while makes people more distant and more reluctant towards me or the project. Importance of 'strike the iron while is hot' as people need to be kept interested." Research diary, January 2020

Main barriers to this were noted again in the hierarchical system which required to work on different leadership levels (local/regional, organisation/hospital, obstetric/midwifery/neonatology), a rigid communication system within the healthcare sector and frequent changes in leadership at hospital, organisational and regional level. Interestingly, the engagement often needed to happen one leader at the time to increase the chances of gaining support since the conversation around the MU model of care seemed to be divisive in the local context. By engaging one leader at the time, we could notice a cascade effect among the group who felt that they were going in the direction of the innovation. Furthermore, once the lead obstetrician agreed to support the project, midwifery leaders felt more confident in presenting the project to the team and make it more visible. In fact, the lead obstetrician held the leadership role with a final say about the local maternity service configuration. Having had four different lead obstetricians in four years meant that after each change the researcher had to re-engage and ask for support for continuing the project. The same cascade pattern was noted every time and this is typical to hierarchical systems.

As mentioned in chapter 4, during the situational analysis there was a fear of the unknown about the MU model and the energies that would require for it to be implemented. However, the exploratory and participatory nature of this research project was used by midwifery leaders as a cautious pretext to keep the project moving forward. Doing research to investigate readiness, barriers and facilitators made them feel less pressurised and somehow supported in the transition.

"she (midwifery manager) gave updates on the MU project to everyone in the room and told them that a proposal was being written for the Directors. She also showed the numbers from the work in 2018 (number of women receiving low risk care intrapartum) and the fact the numbers are good. Midwives looked interested and had many questions for them." Research diary, January 2020

During the "Act" phase of this project, the team showed good engagement and the response rate to the surveys opened to the whole maternity team is a proof of that. Positive feedback was received by different professionals about the collaborative nature of the project and having participants'

representative of different disciplines present during the implementation FGs, surveys and the final event showed interdisciplinary support to it in the local team. Furthermore, it was positive to see that participants worked in the different settings of the service: from fetal medicine unit to hospital wards and five different community healthcare centres. This showed that the strategy of using online surveys, hybrid meetings and regular email communication on project's progress to the whole team worked well to maintain engagement and increase professionals' representativeness within the sample.

"Interestingly some people already replied to the invitation email enthusiastically about the (Delphi) FG: one obstetrician, two paediatricians, one community midwife and one hospital midwife." Research diary, 2021

Key collaborations that helped to keep the engagement up and approached this innovation from different angles were the ones with the MeSLab in Pisa and the architects from a regional university. An architect from the University of Florence worked as part of her PhD on the MU project and made planimetries for the new layout of maternity and neonatal wards within the local hospital. Again, having research support and academic partners helped the conversation around the innovation giving it a high profile and showing that it was part of the bigger interdisciplinary agenda.

The final event to present research findings of the overall project, was appreciated as twenty multidisciplinary participants took part in it from different settings of the hospital. Doing a hybrid meeting for that event was challenging in terms of preparation of the online platform as there were significant IT issues in the hospital to facilitate that. This meant that the meeting start was delayed by 15 minutes and we potentially lost online participants in that timeframe. However, twenty took part and contributed to the final reflective discussion. During this event, a slide with key questions deriving from the "Reflect" phase of the QIF framework were left on the screen to guide the conversation. However, participants struggled to keep the focus on those questions and generalised the conversation more on the state of the maternity and service users' needs in the local context. In a busy moment for maternity and healthcare in general, discussing the practical side and actions to move the innovation forward seemed hard and the same feeling of pressure and hesitance were noted.

The role of the researcher, and even more so of the PAR researcher, was not always clear to the maternity team and had to be clarified on few occasions. The leadership team initially wanted full control over this and struggled for example with the idea that data arising from interviews and FGs

with the team would be anonymised and not available to them. This shows a local context in which professionals were not used to work side by side an external researcher. However, this was then adjusted with time and led to a positive working relationship in which participants were proactive in sharing data and took part in research activities planned even during a difficult pandemic moment.

"XXX (midwifery leader) stepped in and said how valuable the research had been to reflect on current practice and start a wider multi layered reflection taking into account different aspects. She said sometimes it was not easy to hear critical comments on our own work but that this type of approach is the foundation for the future." Research diary 2022

One of the barriers that the team struggled with was being open to the feedback about their service and their work that was coming from the data on different levels. This was notable for example after the first presentation of the service users feedback report in 2020 when professionals struggled to 'trust' the data and instead preferred to rely on the more positive comments left in a box in the postnatal ward by service users than the data coming from the MeS survey (more rigorous and bigger sample). However, even if sometimes receiving feedback was not easy for them, professionals kept on engaging and took more and more ownership of the research activities for example contributing to shape the questions of the service users' survey after the Delphi study.

The overall feedback about the experience of research with this PAR project was positive from the different categories of participants. The quotes below show this.

"… We must also strengthen in the female population (the concept of) what is appropriateness of care. This is what we are talking about, we are not talking about how good the midwives are in comparison to others. We know that for certain aspects pathways of care must be applied according to what are the most appropriate and best level care. (…) This is a research project that was aimed at an operational planning about where we want to go. (…) This is a safe base that has been offered to this territory, let's remember it. And it can be acted and will also be able to give an idea on how to guide similar implementations in the Tuscan landscape… Therefore, we really thank Laura for this work" **Organisational director**, *Final event, July 2022*

"it is also true what XXX (director) says that numbers (of low risk births) are low but the issue is so important that even if for few women we have to do it. Those numbers are low but to ensure that they do not become less and less, we have to work in parallel (and if it is true that the national funding are to be invested on the on the community) (…) You have to come from afar to increase the numbers and not to impoverish our patrimony more and more. In fact, we have the awareness that it is so important to keep it going even if it was for only 100 women a year" **Lead midwife**, *Final event, July 202*

"I have a reflection that has also come to me during the last few months after seeing how we are working and the data that come out is unfortunately not very optimistic... I have a reflection as big sponsor of a birth centre run by midwives because in my opinion it would be really beautiful. However, at least personally since I have been working here (five years) I have seen this population change and

*there are very few truly physiological pregnancies and births. And this is also because of us (as medical category). It's true and I put a hand on my conscience and do a 'mea culpa'. We have said so many times, 'too many inductions' etc. And we know that. But here we are looking for a way to work on the general population even before they become pregnant so that when the twenty-five-year-old who is well and becomes pregnant we try to educate her to the fact that pregnancy is not an illness and that if she is well she can then access to a type of birth that will certainly be a beautiful birth with the husband next to her etc. Here, this is my reflection however regarding the project you have certainly done a great job and in difficult years because covid stopped the research at the beginning and still you managed to get some excellent results. So, good. Well done." **Obstetrician**, Final event, July 2022*

*"For the project I have always expressed my reservations, but over time I have appreciated your work and I think that your great commitment has paid off. I think it is positive and important to have an idea of the expectations of women especially women of childbearing age who will be able to see their expectations realised, even on solutions that culturally do not belong to us. I also appreciate the participation of many doctors and paediatricians, perhaps they are starting to understand that we work together. I believe that this experience (PhD project), the results of your work and ours, even if sometimes lacking a bit in collaboration, can be reproduced in other contexts by taking our experience as a small example. So yes to 'The birth house', strongly yes." **Community Midwifery leader**, written feedback after final event July 2022.*

6.1.4. Reflexivity

In chapter 2 section 2.6, I presented my reflexivity stance and positionality at the beginning of this journey. While conducting this study, I continued to work clinically in a MU and I started my journey as midwifery lecturer in London while regularly travelling to Italy to conduct field activities.

As anticipated in chapter 2, I was an both an insider and an outsider for the local team. I grew up in that town, I spoke Italian, I was known to them from previous collaborations and for having been a student there during my BSc and MSc placements. I had been around in different forms for the past years. However, I was also not living there anymore, and I was working in an international context where I was trying to purse a clinical academic career doing both research and clinical shifts which is not the norm in Italy.

Being a clinical midwife working specifically in an AMU in London while trying to implement a similar model of care in Italy has affected the way in which this study was shaped. Having the opportunity to continuously reflect on this aspect and wearing both hats of the practitioner and the researcher was beneficial for me professionally and personally. I actively challenged my preconceptions and my attitudes towards both systems, the English one and the Italian one, and I learnt to observe and

become more aware of hidden structures that affect the way they work (which will be discussed more in depth in chapter 7 during the Discussion using a critical realist framework).

I firmly believe that being a clinical midwife working in this model of care while trying to facilitate the MU implementation in Italy added value to this research to gain a deeper understanding of the phenomenon. The same research project conducted by someone else who did not have the same insight in the clinical practice and significant exposure to both maternity systems would have probably led a to more superficial analysis of the phenomenon.

6.2. 'Reflect' national

As part of this research project, four in-depth interviews with key midwifery leaders in the national context were conducted. These leaders had relevant experience in implementing midwifery led care services in the region or working and leading in current MUs (one public and one private). They were all midwives with different range of experiences: one led the opening of a public AMU and led it for ten years, one led the conversion of a small maternity unit into a midwifery-led centre, one was only recently been appointed as director of an AMU (one year) and the last one worked several years as independent midwife in a private birth house (like a FMU but regulated like home birth) and recently did a postgraduate thesis on private birth houses in Italy.

I conducted these interviews between 2020-2021 together with the external supervisor of this research project who had insider knowledge of the regional context and identified these people as useful contributors for their career and midwifery work. We approached these people via email inviting them to take part in this research and they all happily agreed to be interviewed which was a positive sign of engagement.

The interviews were semi-structured and co-led by the external supervisor and myself. The questions asked were similar to the ones used for the situational analysis but with a wider perspective on the regional and national context (see Interview guide in appendix 9). Furthermore, the interview started with a question about their own personal experience of implementing midwifery led care and continued with what they thought about the barriers, facilitators and strategies to implement MUs.

Below I present the thematic analysis of those interviews and the main findings which could help a final reflection on this Italian case study. After reading and re-reading the transcripts, open coding was

used to identify possible categories which were then mapped on an analytical level into 6 key themes. This is line with the principles of thematic analysis (Braun and Clarke, 2006).

Findings from key midwifery leaders' interviews
6.2.1. Heterogeneity of Italian context

One of the first reflections arising from all those interviews was the heterogeneity of the Italian situation due to the regional federalism of the healthcare systems. This meant that some contexts were perceived to be readier for implementing these models than others. Some regions had guidelines and tools to support the provision of midwifery led care services (for example the pregnancy booklet in Tuscany and Piemonte regions) while others could only refer to national ones (all regions in the South).

Sometimes different regional legislation meant that women could access reimbursement (often only partial) from their region to access private maternity care services by independent midwives (including homebirth service). This is however possible in few regions in Italy (Piemonte, Emilia Romagna, Marche, Lazio and provinces of Bolzano and Trento) all located in the Northern part of the country. This seems to lead to inequality of care across the country and seems also to be aligned in the different perinatal outcomes reported in chapter one (north vs south of Italy, Italian vs non-Italian mothers).

The wider cultural aspect of maternity care and services in Italy was also mentioned as a big obstacle to overcome when attempting this implementation.

"*But even now, if women say 'I am under the care of the midwife' that already questions how the pregnancy is being followed. We are still at these levels that the obstetrician is best. So the road (towards change) is still long. I mean we welcome a conversation on places for birth other than the traditional obstetric unit. But in my opinion the road is even longer.*" Midwifery leader 4, May 2020

6.2.2. Inter and intra professional resistance

Tensions and resistance in those case studies were often coming from the midwifery groups. Stakeholders reported struggling to get midwives on board with the idea of midwifery led care models as often the trade-off of more responsibility and autonomy for the same salary and professional profile was not appealing to them. This was usually not the entire midwifery component and there was always a motivated group to work with in the initial phase of the project. However, sometimes a group of

midwives (even a minority) would exercise resistance even when working within the same hospital but in different settings to oppose the model.

"Leader 1: 'the group of midwives at the XXX (hospital) absolutely opposed the possibility of developing a path in physiology'

Researcher: 'So the resistance came from colleagues?'

Leader 1: 'Only from midwives. (…)'

Researcher: 'And the fears or resistance that came from these colleagues, what was it dictated by? Was there the fear of being autonomous in managing this journey?'

Leader 1: 'At the time it was mainly about defensive medicine and a defensive attitude. Another point was for what they give us (midwifery salary) I won't expose myself'" Midwifery leader 1 Interview, February 2020

Inter-professional tensions were also mentioned coming usually from neonatologists but sometimes also from the obstetric or nursing component.

"(…) So it was with the midwives then (…) from the point of view of the obstetricians there was no resistance. If there was resistance to the low risk path, it was more from paediatricians" Midwifery leaders 1, February 2020

A common theme reported by those leaders was how hard it was to push for these implementations and to be a midwifery leader for those projects. They felt unable to "fight the fight alone" and even when the support was found and the project ongoing there could be resistance on different levels which could threaten the project. It was interesting to note how all of them refer to this resilience aspect of the role as "resisting the resistance".

"I had these inter-professional conflicts on my skin... I know what they are and I resisted. I resisted because I had a 'vis a tergo' represented by those regional choices (political support) etc. That had inflated the sails so much that I arrived, let's say, without big problems until around 2013 ... Then the big problems started and I left in 2014 when I resigned." Midwifery leader 3, February 2021

6.2.3. Powerful allies

Powerful allies (either medical or political) seemed to be essential to make the change happen. In the experiences reported by these key midwifery leaders, this support was found in a regional politician or medical directors with a background of obstetrics or neonatology. Those allies often had the role of "granting for safety" with management and protecting these facilities from the threat of closure.

One example was that when one of those projects was ongoing registering good outcomes (even if low number of births) a campaign was started by a politician (who was candidate mayor of that town) saying that the maternity in that hospital was not safe anymore because neonatal unit was closed due to low numbers. This put a lot of pressure from the public and the maternity unit was closed not long after.

"And then the local people ruined it because they made a big controversy about the neonatal unit. Because the maternity unit was converted into this project while the neonatal unit did not have the numbers to remain open anymore. They wanted a neonatal unit, neonatal intensive care and the mayor made the crusades and his electoral campaign out of this" Midwifery leader 1, February 2020

However, when support on all levels was given and midwifery leadership supported, the project could not only be implemented but flourish in a supportive system and births started going up to the point that more staff was needed.

"When asked which of the doctors will be the AMU lead, the director's response was 'the AMU director will be a midwife' and therefore everyone was a bit like... they weren't very happy. Especially some (of them) were really not happy and I can understand why. But it is a way to remove, let's say, the conflict from the group of doctors. (...) This thing (AMU) grew very quickly, the calls were so many and so we had to start a shift with two midwives. We recruited other people. When I arrived there, I had to mediate with the doctors, write the project, recruit the staff and let's say to create paths with the community. In short, it was a huge work. But it quickly paid off. Very quickly!" Midwifery Leader 3, February 2021

6.2.4. Personal and emotional burden

What came out strongly by those interviews was the emotional and personal burden that those leaders had to put into the projects as if this was somehow a necessary ingredient for the implementation of these models. And even after all that, variables within the context like a change in medical or political leadership could threaten all the work and investment put into the project. This point was often cause of frustration and for one of them also cause of resignation after a decade of outstanding work for the local service. It seems like this work had a personal and professional cost for the midwifery leaders when moving these projects forward.

A multifaceted professional midwifery role seemed also to be a barrier to being autonomous skilled practitioners for pregnancy and birth. Midwives could work in a wide variety of settings from maternity pathway to gynaecology, to IVF, to pelvic floor rehab, menopause, surgical scrub assistant (both obstetric and gynae), managerial roles, clinical roles and lately also director roles (only in few

regions). However, those key midwifery leaders felt that their autonomy in any of those roles was perceived as minimal with often a more assistant-to-the-doctor role. Hence, the difficulty in pushing for more autonomy in maternity care in which often they are not trained to work autonomously.

"However, I want to acknowledge one thing. In my opinion all these obstacles are surmountable. The big problem I see (however) is the training of midwives. So at least in Italy we have focused everything on the managerial role and on the professional role we have nothing. We only have these Professionalizing Masters managed mainly by medical personnel who do not teach the midwifery profession. So, the midwife who comes out of a university degree course, and in university hospitals it is known that you give birth in the most traditional and medicalized way possible. Either they have a midwifery belief of their own or otherwise they don't see it" Midwifery Leader 1, February 2020

6.2.5. Service users' interest

When talking to the midwife working in the independent birth house, she highlighted how there is a part of the population accessing maternity services who is interested in a birth outside the current system. This explains how the number of private birth houses has increased significantly in the last decade and more midwives practice independently from the SSN to provide that type of care (Cicero *et al.*, 2022). As shown also by the service users' survey of chapter 5, there clearly is interest among women on these models of care and this is what allowed the existing regional AMU to be successfully implemented in 2006.

"There was like a proper need! That's it. I went in a situation very facilitated by the need and the need was first of all the need of the midwives who created facilitation to the emerging need of women." Midwifery Leader 3, February 2020

6.5.6. Supportive network

All key midwifery leaders highlighted the importance of a supportive network to allow the AMU or birth house not to be isolated to provide good and safe care to service users even in case of transfer to the secondary level of care. This was for example an ongoing communication by the lead with different part of the maternity service to make the AMU visible and help its promotion to service users antenatally. Or the effort in communication that private midwives make with the public hospital to allow good transfer of care when needed.

"it was a facilitation. I personally went to speak with the midwives of the community centres to bring them brochures, I sent them all the data of how many women of their case load had given birth with

us (in the AMU). I was always in contact with them, all the time. I was always popping in the community centres and I think that without this you don't get the numbers that give the possibility to keep such a structure standing." Midwifery Leader 3, February 2021

"we (birth house) can exist only if there are hospitals. (…) We already knew it but now we have studies that confirm that out of hospital birth is safe for low-risk pregnancies if you have the possibility of a network with a hospital. Because otherwise if you have no connections, you are afraid to transfer because they treat you badly making up things, or you know that if you bring the woman in they will not accept her ... this is a serious problem that no longer makes an extra-hospital birth safe so for us it is essential that there is a good relationship with the hospital" Midwifery Leader 4, May 2020

When comparing the reflections arisen with these key midwifery leaders it was interesting to notice different set up and needs that public maternity systems and private midwifery services had when attempting to implement models like a MU or a birth house. A summary of this is reported in table 29 to give an overview of the different situations.

Table 29 Comparison between public and private HC sectors for implementing midwifery led care

What does the **public HC sector have**?	What does the **private HC sector have**?
• Multidisciplinary team • Big teams • Hierarchical structure • All levels of care • Majority of population accessing the service • Fragmented care • High level of medicalisation • Midwives used to work in team and with a wide range of skills • Institutional support • Slow system of implementation • General population (default option) • High demand • Possibility to access public funding • Affected by political influences/changes • Aims for public health and effective use of public resources	• Teams of midwives • Small teams • Flat structure • Only primary level of care • Low numbers of users accessing the service • Continuity of carer • Low transfer to secondary care • Autonomous, motivated and trained midwives • NGO support • Agile system of implementation • Motivated users looking for this service • Low demand • Independent from political changes • Aims to provide a good service to keep the service financially sustainable
What does the **public HC sector need?**	What does the **private HC sector need?**
• Reduce medicalisation of birth • Autonomous and motivated midwifery leadership • Exposure to midwifery led care • Training and mentoring for midwives • Reconfiguration of services • More time • More continuity of care and carer	• Multidisciplinary support • Better integration with hospitals • Data monitoring • To be recognised nationally on all regional regulations • Regional reimbursement for service users who access their service • Scaling up of service • Possibility to access public funding to provide basic primary care

Looking at the table above, a reflection arises on how different, sometimes even diametrically different, those two systems are. However, it is also interesting to notice how some of the things needed reported by key midwifery leaders could be found in the other side of the table. For example, the private service has skilled midwives used to work autonomously and the public one needs more exposure and training for their midwives on autonomy. The private needs more multidisciplinary support in the hospital (especially in case of transfer) and the public is used to work as a multidisciplinary team. The public often struggles with high demand and numbers whilst the private sector does not have a regular case load. The public is accessed by all population whilst the private has a big issue of access for women who cannot afford but would like the care offered.

This leads to a reflection on whether these two worlds could collaborate to facilitate the implementation of midwifery led care for women who want it. However, if the independent midwife seemed open to this opportunity and acknowledged the importance of both systems and the opportunity to collaborate between them, during the research a closure towards independent midwives was often mentioned by professionals. It seems like there is a lack of trust towards the independent midwives and not openness to collaborations.

Collaborations between public and private in healthcare are not uncommon in maternity care in Italy (this aspect will be discussed more in detail in chapter 7, section 7.1). However, this is currently more accessible to the medical component and almost impossible for primary care professionals and it raises potential inequity of access for service users. Hence, the need to address a fairer collaboration between public and private for maternity services seems an important one to address.

6.3. Discussion

Global maternal and fetal outcomes have worsened during the COVID-19 pandemic, with an increase in maternal deaths, stillbirth, ruptured ectopic pregnancies, and maternal depression (Chmielewska *et al.*, 2021). Furthermore, we have seen how maternity services reconfiguration in response to the pandemic often did not value primary care models like MUs but instead more centralisation of care and staffing (Rayment, McCourt, *et al.*, 2020; Yuill, 2020). This often led to the closure of MUs and homebirth services and low risk women having to go to the hospitals where the risk of infection transmission was higher.

In the local context, the implementation of the AMU was postponed and delayed because of the pandemic. However, it also saved the project when the healthcare funds were released on a national level to invest in primary care and created the opportunity to experience a similar model to the MU for midwives and the wider team. It allowed the team to move some births out of the traditional OU and trust midwives to work in autonomy.

In Italy, the pandemic also meant an increased in out-of-hospital birth interest among service users (Cicero *et al.*, 2022). Internationally, other authors have commented on how the pandemic allowed rapid implementation of innovations in maternity like telehealth, digital communication, early discharge and staff wellbeing initiatives to help professionals with exhaustion (van den Berg *et al.*, 2022; Ladds *et al.*, 2023). This shows how a crisis can become a useful window of opportunity to

implement valuable new approaches to healthcare in a dynamic and creative way. However, as Van De Berg and colleagues add, those innovations were not tested or evaluated before implementation for their use in the long term. For example, we saw the positive impact that telehealth had during the pandemic to allow service users to access care without the risk or Covid 19 exposure and transmission. However, is telehealth the best way to provide care in a non-pandemic context? Attention should be given to study the actual benefit and equity of those interventions before embedding them permanently in the system (van den Berg *et al.*, 2022). This is particularly relevant when considering that we now know that de-implementation of inappropriate practices can be more challenging than the implementation (Wang *et al.*, 2018). De-implementation can require much time and resources and this issue is particularly relevant in public funded healthcare systems.

The local context was open to the idea of co-production of an implementation plan and supported it from day one. On the contrary, conversations about de-implementation of outmoded or disproven practices were not easy to have for the researcher and it triggered a defensive attitude. It is known that the problem with learning something new in healthcare is the need to unlearn old practices (Bonchek, 2016). Literature showed that implementation and de-implementation require different strategies and both need to be considered when attempting to improve practice (Wang *et al.*, 2018). This aspect has not yet been studied much in maternity care but could help addressing the inappropriate use of resources, the persistence of practices and models not supported by evidence and the challenge to introduce evidence-based practices which are complex and person-centred. More research should focus on both implementation and de-implementation strategies.

The analysis of adoption, acceptability and appropriateness showed similar findings to the ones reported by a similar recent case study in Canada in which the "long gestation" period of the AMU took ten years before its opening. Using a collaborative approach for the design phase "*allowed the relative advantage to become apparent*" (Darling *et al.*, 2021). Similarly, our findings showed how the participatory aspect became a successful strategy to improve support among the maternity team. This is where the local team got stuck and delayed during the years of this project when medical leaders showed hesitance about the appropriateness. This finding reinforces the concept that even though leadership is key to move the idea of the innovation forward, support from the wider multidisciplinary team and openness from service users is a prerequisite for the implementation and its sustainability.

Involving service users in designing the maternity service design is not something that the local context was used to initially. However, there was openness in involving them via surveys. Engaging them in

meetings was however difficult and even though the researcher offered to include them on a few occasions there was always closure towards this idea (even before the pandemic). More work needs to be done by the local (but even the regional and national) context to include service users regularly and systematically in healthcare configuration (Paparella, 2016).

The interviews with key midwifery leaders who had experience of managing, leading and working in this model of care in different parts of Italy showed again a fragmented approach to this innovation and also to maternity care. Considering the strong international evidence and the clear national guidelines promoting this model of care, it is interesting to notice how the evidence to practice gap in Italy happens mainly on the regional and local level leading to disparity and different access to care across the country (Alba *et al.*, 2019; Cicero *et al.*, 2022). Interventions and strategies to reduce this gap should therefore be aimed at this level to create a more consistent approach to maternity care nationally.

In their own experience of implementation of MU models, key midwifery leaders witnessed both intra and inter professional tensions and this is consistent with previous similar studies (McCourt *et al.*, 2014; Walsh *et al.*, 2020). The need of allies when attempting this change, especially in contexts not used to the model, was seen as paramount. Powerful allies were found in doctors (obstetricians or neonatologists) or strategic/political people visible in the local context. However, a group of strong, motivated and enthusiastic midwives was also essential for the success of the implementation. Identifying both these two levels of support could help future contexts approaching this change.

The personal and professional burden at stake for those leaders was unfortunately another common theme showing an unfair system for midwives and midwifery leaders in this country. Key barriers identified by them included the multi-faceted role of midwifery profession which "dilutes" the autonomy in the specific field of maternity care. Furthermore, the salary and the societal status made it not worth the fight for some midwives who only see this model as 'more responsibility for the same salary' issue.

Key midwifery leaders also agreed that in Italy midwifery leadership is a key issue. Leadership position involve most of the times managerial and administrative work and rarely senior clinical position to support staff. Therefore, even strong clinical leaders who get a promotion end up covering managerial and administrative roles and so are unable to support junior staff in clinical practice. This aspect has been observed in other international contexts like Ireland (Healy, Humphreys and Kennedy, 2017),

England (Warwick, 2015) and Australia (Adcock, Sidebotham and Gamble, 2022) showing that is not only an issue of creating a midwifery leadership workforce but also enable them to fulfil their role especially on a clinical level.

Currently, private and public care co-exist in maternity services in Italy. The medical component is better placed to conduct both public and private work while midwives (and other primary healthcare professions) do not have same opportunities. Homebirth, on the other hand, is only accessible via private service. When discussing the public/private aspect with key midwifery leaders, it seemed like there could be room and opportunities for collaborations to support both sides (as illustrated in Table 29 in section 6.5.6.). However, if independent midwives seem to be open to the idea and clearly see the importance of reciprocal trust, this does not seem to apply for most public professionals (both midwives and doctors) who do not seem to trust their independent midwifery colleagues or the concept of homebirth itself. Previous studies have discussed the importance of integration among services to promote positive service users experience, especially in case of transfer (Rowe *et al.*, 2012; Darling *et al.*, 2021; Rocca-Ihenacho, Yuill and McCourt, 2021). Therefore, more work to promote reciprocal trust and collaborations seem to be needed in this context. Professional councils could have a key role to address this issue.

6.4. Conclusion

This final findings' chapter helped to contextualise this project more on anational level through a reflective analysis which drew on of the research diary conducted throughout, the final event in which the main findings of this work were presented to the local team and four in-depth interviews with midwifery leaders with experience of managing, leading or working in this model of care in Italy.

The pandemic significantly affected this work and made amendments to the initial plan necessary. However, useful and important lessons were learnt and this research experience was overall positive and allowed the analysis of aspects never researched before in Italy.

Pre-implementation participatory work became a useful exercise to reflect on aspects that need strategies specifically addressed at promoting the acceptability and appropriateness of the innovation to then allow the adoption of the model.

The participatory nature of this project, my role as researcher with features of both insider and outsider and being able to dedicate time and energies (together with the senior external supervisor) to conduct the "invisible" engagement work made the biggest impact in the local context confirming wider evidence that codesign is necessary for making change more sustainable.

Finally, the interviews with key midwifery leaders confirmed and reinforced some of the findings arising from this analysis making them more valuable and adding useful insight to the work. These findings could be used in future while continuing the implementation of this model both in the local context but also in other regions in Italy.

Chapter 7 – Discussion

Introduction to the chapter

The overarching aim of this thesis was to assess the organisational, cultural and professional readiness for the implementation of a new midwifery unit in a European context like Italy and to observe and support the implementation process. Chapter 4, 5 and 6 presented the findings of the PAR cycle that led to the creation of the implementation plan for the maternity team to move in the direction of the opening of the AMU.

Using an hourglass approach, this research journey started by looking at the existing examples in the literature with a systematic review, moved into the detail of the local context with the PAR cycle to conduct a situational analysis, engage in development activities and finally reflect on both local and wider national context before leading to the discussion of this chapter. This approach that started from general to the specific case study to the general again is simplified in picture 34 below.

Figure 34 Hourglass approach of the thesis
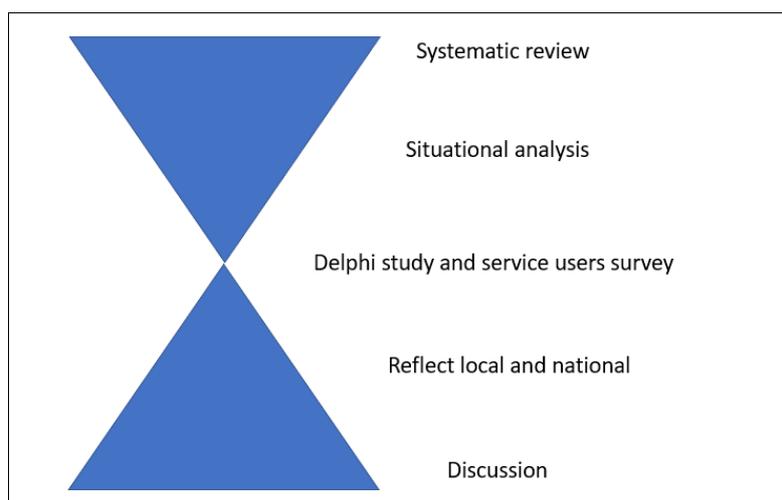
In this chapter, therefore, I discuss the key findings of this project, in the light of wider relevant literature to draw out the meanings and wider implications of this research. Furthermore, I will address strengths and limitations encountered during this journey, I will relate them to other existing studies.

A critical realist framework will be used in this chapter for the synthesis of findings according to the three levels identified in critical realist theory: the real (hidden preconditions that had an impact), the actual (what is known but cannot always be seen) and the empirical (what could be observed with

this work) (see account of critical realism in chapter 2) (Bhaskar, 1997). To provide a visual overview, I will then present a model in which I have synthesised the main steps of this iterative and participatory work and the main barriers and facilitators to the implementation arising from the different steps of the project.

7.1. Real level – What you cannot see but has an impact

This research project did not see the opening of the MU but offered a useful perspective on the years pre-implementation and the resistance that this type of innovation can encounter. Spending years working with the maternity team towards the implementation of this model allowed me to observe some dynamics and reflect on the hidden preconditions that caused them.

High-income countries like Italy often face problems caused by modern healthcare systems valuing technology rather than salutogenesis. While technology can have benefits for health, this approach led in the past to an unnecessary medicalisation and over-use of technology in maternity care (Teijlingen *et al.*, 2004; Miller *et al.*, 2016). The current paradigm in these contexts focuses more on risk-aversion than health-promotion. A risk-centred philosophy of care was one of the preconditions that affected participants in this project.

The concept of risk was constantly mentioned throughout the project mainly by managers and professionals but also by some service users. This is coherent with a vision of the world similar to the one formulated by Ulrich Beck in his book "Risk Society: towards a new modernity" in which risk preoccupations are a product of modern society and institutions like industry, science and government (Beck, 1992). Risk is seen as an objective phenomenon that can be predicted and controlled via knowledge, expertise and use of technology (Lupton, 1999). Hence, the illusion to control the unpredictability of childbirth via risk management and clinical governance that have been embedded in maternity care in the past decades, despite its effectiveness not being based on evidence (Scamell and Alaszewski, 2012; Chadwick and Foster, 2014).

In a technocratic model of birth, technology is seen as a tool to control uncertainty and adversity (Davis-Floyd, 1994). This approach was also notable in this local context and shows how mental models of professionals and service users were affected by this pre-existing notion. One example in the local context was the common use of CTG even for low-risk women which gave professionals a feeling of more control over the baby's wellbeing even though the scientific evidence identifies more harms

than benefits of routine use (Alfirevic *et al.*, 2017). Another example is the easier implementation of technological innovations such as the first trimester tests like the Combined or DNA test, or the telehealth app hAPPy Mamma. This shows how in the view of local stakeholders, technology is sign of progress and modern healthcare while the investment in a model of care complex and costly.

In the local context, risk was often perceived as static and non-specific instead of a vision of risk which is specific and dynamic throughout pregnancy, birth and postnatally. There seemed to be a lack of trust in the biological and physiological processes of childbirth. Checklists and technology were used *'to find physiology'* instead of identifying pathology or deviation from normal processes. This shows a biomedical position that all births are potentially pathological instead of potentially physiological. It also shows a lack of trust in those processes and an attitude to care mainly defensive and risk aversive. Risk management regimes give the illusion of control over the unpredictability of birth process. This approach has been identified in other similar western contexts like the UK labour ward (Scamell and Stewart, 2014).

The way in which risk management has been shaped in maternity care focusing mainly on short term outcomes and mainly an avoidance of adverse events made lose sight of the bigger picture and public health and social impact that birth has in society. This shows how the choice of goals and indicators to monitor healthcare performance can affect the way in which culture can be shaped. Research is now focusing more on trying to identify core outcomes which are more significant in a salutogenic approach to maternity care (Perez-Botella *et al.*, 2015). A recent study by Maga et al. (2022) addressed this issue in the Italian context proposing a tool of core midwifery outcomes which could help reducing medicalisation and making midwifery care more spread and consistent.

The assumption that risk can be identified and managed objectively ignores the risks that are hidden because of the ways in which our cultural and social structure shape mental models and what can perceive as risky or not (Scamell and Alaszewski, 2012; Gentner and Stevens, 2014). So, for example, objectively, MU care reduces the 'real' but hidden risks of CS, instrumental birth and birth trauma. The risks to the mother of over-medicalised care are not seen. The risks to health service limited resources are not seen. Douglas' theory showed how risk is shaped by the social and cultural context affecting significantly what risk we choose to see or not (Douglas, 2013).

 In this project, both professionals and service users agreed with communicating the different pathways of care based on the gravity of the risk (low, medium and high) and found this nomenclature to be clear and appropriate. However, women also expressed the impact that the using the word "risk"

in the labels could cause more stress and anxiety in relation to pregnancy and birth. Therefore, their openness to renaming these pathways, without obscuring information should be considered. Wider literature have shown the importance of word choice in healthcare management and patient psychology so this should be taken into account especially in maternity where at the center of the care there is a biological event and not an illness (Nickel *et al.*, 2017).

A marked gendered power dynamic was notable in this study. Italy is a country with a strong history of patriarchal power and control over women's reproductive rights and within healthcare professions. In the second half of twentieth century, a process called "feminisation of medical profession" started in many high-income countries. Even if proceeding at a slower pace than other European countries like Finland, Portugal, Spain and UK, Italy too started this process and in 2014 Organisation for Economic Co-operation and Development (OECD) registered a 40% female component within the medical profession (Denekens, 2002; Scheele *et al.*, 2014). However, most of the leadership position are still covered by men and a significant gender pay gap is still present (Gaiaschi, 2019). The feminisation is still in progress and considering that majority of doctors who are retiring are men and majority of newly qualified doctors are women, the situation could improve in the future. The question on whether this new generation of female doctors (who were trained in a patriarchal and medicalised context) would still have values and philosophy of care however remains.

Interestingly, during this project, although the medical component had a good representation of both genders, all appointed lead obstetricians throughout the years were male. Even at organisational level, most senior and strategic roles were covered by men. A gendered power dynamic was notable especially if we consider that all midwives were women and even the ones in leadership and at director level were still 'under' the male medical lead obstetrician. This power dynamic was entrenched with gender and professional status: male doctors and female midwives. Midwives seemed to be aware of this and openly reported it during data collection, whilst doctors and managers seemed to keep it more implicit and accepted. Discrimination can be direct (for example openly limiting training or career progression opportunities) or indirect (like inappropriate working conditions or undermining of someone's authority or scope of practice and expertise). The examples reported by midwives when explaining this seems to be an example of indirect discrimination. This could be due to gender unconscious biases or the hegemonic masculine culture within healthcare and organisations, not just in Italy but globally (Gherardi, 1998; Gaiaschi, 2019).

One clear example derived by the entrenched gender and professional power dynamic was the possibility for doctors employed by the public hospital of working privately, the so-called dual practice. This privilege allows doctors to earn extra money while using public clinical and infrastructure out of hours. The aim for establishing this service this was to help reducing public waiting lists and create a source of income for the hospital who would receive a small percentage of the doctors' earnings (De Pietro, 2006). However, this is only possible for doctors (mainly men) and not for primary healthcare professionals like midwives, nurses, physiotherapists (mainly women). In the specific case of obstetrics, doctors offer private visits to women who are looked after by the public pathway regardless of their risk factors offering continuity of carer to women who can afford it. Midwives, on the other hand, cannot offer the same service to women with uncomplicated pregnancies in autonomy but can only take part of that service as doctor's assistant and earn some extra money. This configuration has been in place for decades meaning that generations of local women have been used to choose a doctor (often male) to have continuity and see midwives as an assistant and not as autonomous practitioner.

If the category who makes decision for the healthcare system is mainly constituted by the medical component, which is mainly male dominated, the consequence is likely to be a system made around doctors' needs. This type of privileged rules not only fuel interprofessional tensions but also lead to inequality within healthcare (Cioffi, 2021). The issue is complex and shows a system that favours doctors and secondary rather than primary healthcare professionals and therefore secondary/acute care over primary care can also lead to an inappropriate use of public resources.

However, if gender and professional status intensify the interprofessional tensions and, an inappropriate use of resources and inequality within maternity care, a horizontal power dynamic within the midwifery category was also notable during this project.

Previous feminist works have identified the position of midwives as being both an oppressed group working and advocating for an oppressed category (women) (Yuill, 2012). However, it is not uncommon within oppressed groups for some members to become oppressors and exercise horizontal violence towards those with less power than themselves, or through passive resistance to change, even when positive (Leap, 1997; Stapleton *et al.*, 2002). Similarly, the midwifery category in this research project showed some aspects of this both towards other colleagues who were trying to promote change and even towards the researcher (see examples mentioned in chapter 6). This was notable especially at managerial level when midwifery managers needed to conform to the biomedical

domination and therefore needed to act in accordance with doctors' interests. Colleagues who were challenging the status quo and inappropriate practices were shut down and marginalised instead of being supported. One example (previously presented in chapter 6) was the presentation of an audit that showed increased inductions and medicalisation during the first Covid wave. Doctors trivialised the data collection collected by a midwife who presented the work exposing herself in front of the team in the attempt to promote a reflection on how to improve practice, and midwifery leaders did not support this colleague.

7.2. Actual level – What is known but cannot always be seen

In high income countries, litigation in obstetrics has risen in the past decades affecting significantly the ways healthcare practitioners provide care (Symon, 2000; Gualniera *et al.*, 2020). Fear of litigation led to the phenomenon of defensive clinical practice in which professionals tend to practice following the principle of risk avoidance and risk reduction (Symon, 2000). This has been described as "litigation based practice" as risks are managed through protocols and procedure to reduce exposure to medico-legal action (Dahlen and Homer, 2013).

Theory of Regret Regulation explains how anticipating regret when facing a decision can affect which decisions people make (Zeelenberg and Pieters, 2007). Some initial studies are starting to show the impact that regret has on healthcare professionals can affect the care they provide (Hozo and Djulbegovic, 2008; Ziarnowski, Brewer and Weber, 2009; Courvoisier *et al.*, 2011).

In this project, professionals openly disclosed how this fear of litigation and anticipated regret affected their everyday practice and shaped their rapport with service users. This shows some awareness around this issue from the professionals' perspective. The quote from a female obstetrician in the situational analysis' chapter saying how women have changed "*and they are now not open to give birth naturally as they want everything perfect and no effort"* shows the detachment in this rapport. This is particularly notable in the light of the women's surveys locally and in this study, which did not support this view. Therefore, even though this context was not used to service users' involvement and were defensive about receiving feedback from them some senior professionals believed that the responsibility for the increased medicalisation was theirs for "not wanting to birth naturally". A similar example to this was when at the beginning of 2000s, professionals and media reports blamed women for being "*too posh to push*" and blaming them for the increase of CS rate when evidence showed that

consumer demand contributed only in small part and that main causes lay within the system configuration and professional practice (Gamble and Creedy, 2000; McCourt *et al.*, 2007).

This study showed a highly hierarchical organisational structure and the impact that this had on professionals' attitudes towards the innovation. Decision making power lay mainly in the hands of the lead obstetrician at the top of the pyramid. Each time that there was a change in leadership convincing the new leader was paramount to have the cascade effect of consensus on the rest of the team. This was reflected in different level of consensus on the AMU project in different stages depending on the leader's opinion. The bottom-up and codesign approach to the innovation using PAR was unusual for the local context and although there was general motivation and openness to work with this on some occasions singular medical leaders stopped collective work on the basis of personal views and opinions.

The hierarchical structure observed in the organisation and more widely at healthcare system level, inevitably affected the leadership approach that professionals had. In a hierarchical system, a single focal leader tends to focus more on compliance, control and leading through power (Komives and Dugan, 2010). This type of leadership that could be observed in this context consistently throughout the project. However, post-industrial theories on leadership have shown how effective leadership should be based on reciprocal relationships in which the team is actively contributing in the work and not passively completing tasks (Komives and Dugan, 2010). In this case, focal leaders "*adopt more inclusive practices recognize the need for leadership that goes beyond linear problem-solving and hierarchical decision-making towards an approach that focuses on mobilizing employee intelligence*" (Komives and Dugan, 2010; O'Donovan *et al.*, 2021). Transformational leadership focuses on motivating and coaching the team using emotional intelligence (Lega, Prenestini and Rosso, 2017). Studies have shown how this type of leadership have positive impact on increasing quality of care, team learning and performance and ultimately also patient satisfaction (Komives and Dugan, 2010; Lega, Prenestini and Rosso, 2017; Anselmann and Mulder, 2020). Interestingly, in this study, the only leader that showed similar characteristics and a transformational approach was a midwifery coordinator who decided to resign after 1-2 years of covering the role because she was not recognised as leader by the team. This showed how the system structure and a historical hierarchical approach to leadership can impact whether transformational leaders can succeed or not. As discussed in chapter 6, key midwifery leaders needed the support from a more powerful and strategic ally to allow the implementation to take place even when they were recognised as transformational leaders by the

team. This reinforces the concept that hierarchy in the current organisation and healthcare system can stop midwifery leaders to successfully implement evidence-based innovations. The impact of the pyramidal structure could also explain the burden that those leaders reported as a "personal and professional cost" to believe and actively promote the MU model.

The International Confederations of Midwives (ICM) recognised this aspect and in a policy brief in 2021 recommended building enabling environments for midwives (ICM, 2021). An enabling environment should "*support the infrastructure, professional and system level integration needed for midwives to effectively practise their full scope of work*" (ICM, 2021). Midwives, even in high income countries where they are regulated, need to be enabled to lead implementation of midwifery led care, be recognised in their scope of work and societal role to deliver care that is more equitable, accessible and high-quality. A recent study by Stevens et al. (2022) showed how enabling midwifery in MUs in India had a positive impact on women's experience of respect and trust compared to other models, even during the Covid 19 pandemic (Stevens *et al.*, 2022).

A barrier to this identified by local midwives was the medicalised education that they received in university where most of the lecturers and professors are from a medical or obstetric background. They thought that this aspect was a major contributor to the medicalisation of the profession in Italy in the past years. University hospitals where both midwives and obstetricians trained were perceived to be more medicalised than smaller hospitals. Exposure to this might have contributed to an education of generations of practitioners more pro-interventions and less used to physiology. Midwifery and medical education institutions as well as regulatory bodies and associations need to play an active role in trying to address this issue (Mattison *et al.*, 2021).

As anticipated in chapter 5, the local context showed some readiness to the idea of an alongside MU but was clearly closed towards the idea of a freestanding MU or homebirth. This is an important finding showing a strong cultural component affecting perception of safety among professionals and service users. However, data arising from the service users' surveys also showed that a proportion of the population (even if small) might be interested in out of hospital birth. This has also been registered with a significant increase of private birth houses and home birth services registered on the national website www.nascereacasa.it in the past ten years.

A general resistance to the concept of homebirth is not uncommon in other similar European countries like Spain and France (Leon-Larios *et al.*, 2019; Sestito, 2022). In France however, pressure from women and midwives after the launch of an observatory on obstetric violence responsible for

denouncing interventions that violate the physical integrity of women made the French Ministry of Health authorising the opening of nine birth centres on a trial basis (Sestito, 2022). This shows how service users allied with midwives could make an impact in the implementation of those models (Pereira and Moura, 2009; McCourt *et al.*, 2018b; Batinelli *et al.*, 2020).

In Italy, despite the evidence of midwifery led care for low-risk women and homebirths, the Italian Society of Neonatology (SIN) states on its website "*For the society, hospital is the safest place to give birth*" and "*in occasion of the intentional day of homebirth, SIN confirms its position against homebirth*" without addition to references or international guidelines to support such statements (Societa Italiana Neonatologia, 2020). What is the impact of this public, rigid and non-evidence-based position on such platform easily accessible to service users? Ground-breaking research in Italy is trying to challenge the discourse around homebirth in Italy also by showing its cost-effectiveness for the Italian healthcare system (Cicero *et al.*, 2022).

Service users in this study expressed how important respect for their choices and a good effective communication with professionals are for them. It is now known that ineffective communication, poor rapport and supportive care are considered a type of mistreatment of women during pregnancy and birth (Bohren *et al.*, 2015). Respect for their choices was also reported as key factor the national survey assessing women's experience of birth in Italy (Skoko *et al.*, 2018)

During the Erasmus exchange that I did in MesLab in the School of Advanced Studies in Pisa as part of this PhD (3 months), I had the opportunity to take part in a seminar by Prof Paul Battaglio. Together with colleagues from the MesLab he conducted an interesting study on behavioural science applied to public administration and gave an overview on how concepts like bounded rationality, cognitive biases and nudging could be used to tackle administration, management and policy issued (Battaglio *et al.*, 2019). They started from the work of Nobel Laureates Herbert Simon, Daniel Kahneman and Richard Thaler. Simon's theory claimed that as humans we make decision that are guided not only by rationality but also emotions, values and feelings making our rationality "bounded". What limits our rationality are cognitive biases like loss aversion, overconfidence or framing effect. This means, as Thaler and Sustein presented in their "Nudge Theory", that the way we frame options and choices to citizens (or service users in the example of healthcare) can affect the way in which they choose. They called this "*choice architecture*" which makes the people with the responsibility to offer the options (like practitioners) "c*hoice architects*". The authors argue that a neutral design is impossible and people are always *nudged* in a direction or another whether consciously or unconsciously. Therefore,

choice architects have the role to present those choice in a way that should benefit the evidence based or beneficial one. One example in the default enrolment that all citizens can have in pension schemes or organ donor schemes. People can opt out in case they do not want to but the choice architect (in this case the government) have *nudged* them towards the option that could help them in the long term. This concept was particularly fascinating to me and made me reflect on the impact that such theory and approach applied to midwifery led care models like MUs could make. A study about to place of birth by Coxon et al. (2014) showed how the professional narrative and discourse of birth as risky influence women's choice on place of birth (Coxon, Sandall and Fulop, 2014). So why not using a default option to promote the evidence-based option? Like for example enrolling by default low risk women to receive MU care or homebirth depending on their preferences. Women would still be able to opt out in case they plan to have an epidural or OU care but the system would nudge them towards the option that would allow them to reduce risk of cascade of interventions. Other studies have already shown how in reality utilisation of MUs is limited and affected by practitioners' perception of safety and resistance to trust the model or to provide full unbiased information to women (McCourt *et al.*, 2014; Walsh *et al.*, 2020).

7.3. Empirical level – What can be observed

To present what was observed at the empirical level of this research, I created a visual model which syntheses the different steps during the PAR cycle and the main findings which arose from different sources of data (see figure 35 in next page). This model might help other contexts approaching a similar transition to reflect on the ingredients that could affect the implementation process and optimising time and resources.
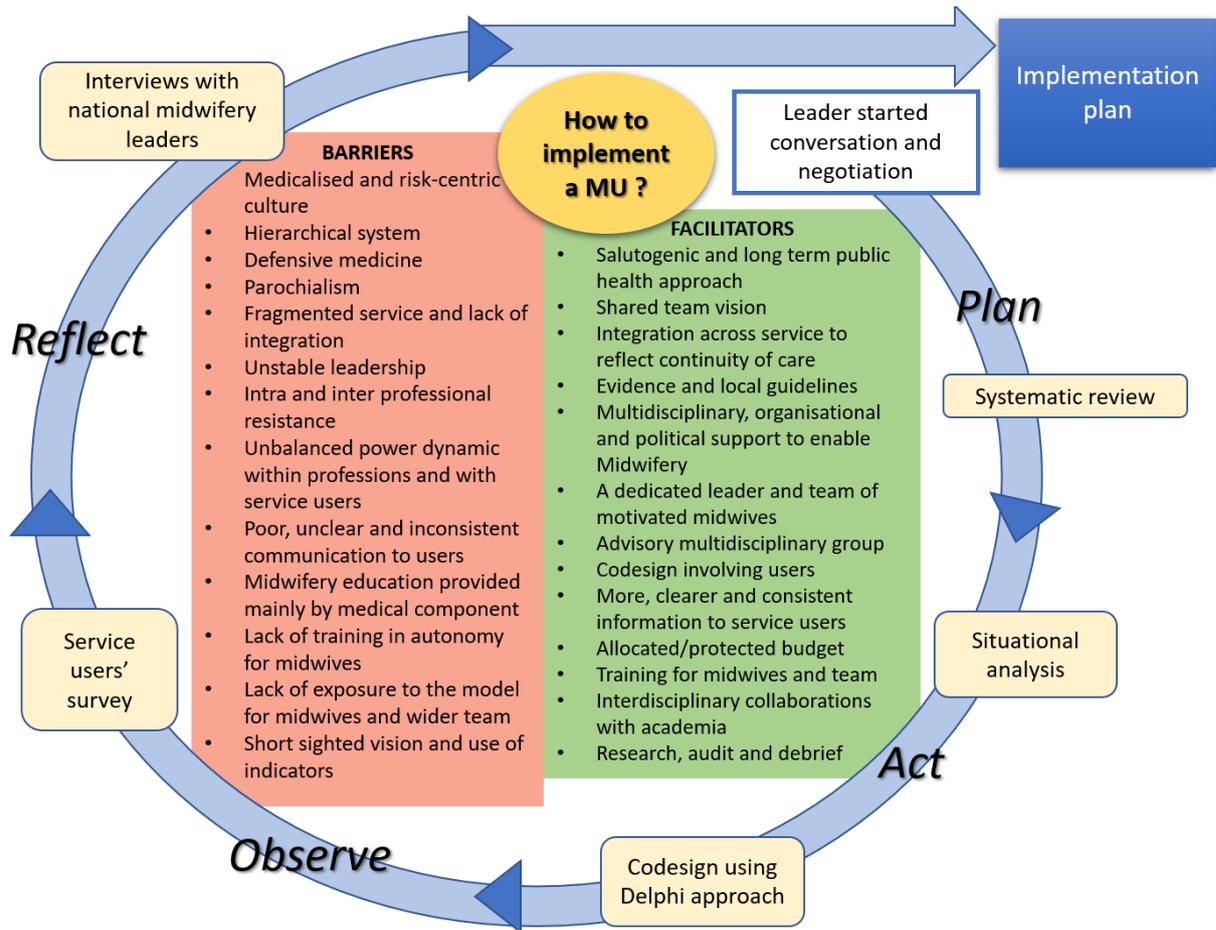
Figure 35 Visual model synthesising research steps and main findings

This project started with an international collaboration and a local leader starting a conversation and negotiation with organisational leadership to implement this idea. It then took a bumpy road of engagement and a PAR project to facilitate the transition. Due to the pandemic, research methods had to be refined but fidelity in the PAR approach allowed to codesign with the maternity team and consulting the local users an implementation plan. This plan has objectives for the local team to work on while waiting for the physical MU to be in place. During each step of the way the analysis showed different ingredients that were playing the role of barriers and facilitators and are reported in the middle of the circle as were derived from an overall reflection of all the steps in the PAR process.

Some of the aspects in the middle of the circle have already been discussed at sections 7.1 and 7.2 of this chapter, as they are more hidden and not always visible, or if visible not always seen since risk perceptions are shaped by existing mental models, norms and practices. Relations of these findings

with the wider literature were discussed in the discussion section of the previous chapters. Here I present the synthesis of the main findings that led to the creation of this model.

The impact of a medicalised culture and the challenges in trying to change it within a strongly hierarchical structure were discussed earlier. Another inhibiting factor was the "parochialism" noted within different hospitals, organisations and even regions. Each component tended to be closed to the outside. Previous implementation research has identified such lack of cosmopolitanism as an obstacle to change. However, I also noted how the prospect of being one of first in Italy to implement this model of care was a motivating argument when trying to convince new leaders to embrace the project stimulating a sense of innovation and competition with other contexts.

The idea of the MU encountered resistance from different professional categories but also within the midwifery profession. This aspect was not category or generation dependent meaning that supporters (or opposers) to the model could be midwives, obstetricians, neonatologists and being young or older.

A facilitator to professional support was the previous exposure that some members had of similar models of care. Professionals who had the opportunity to work in this model of care (even for a short exchange programme) or a similar midwifery led model tend to trust the model. Vedam et al. (2014) also suggests that exposure is a key element to improved midwifery led care (Vedam *et al.*, 2014). Therefore, even if ad-hoc training was found to be important for both midwives and the wider maternity team, the opportunity to experience the model directly seemed to be meaningful too.

Service users were open to the idea of the MU and were willing to know more about the model showing a need for an educational intervention around the evidence of midwifery led care for uncomplicated pregnancies.

Leaders and managers throughout this project demonstrated hesitance to change. This vision was anchored and kept alive by a significant budget released by the regional healthcare system and allocated to this project in the early stages and re-confirmed during the pandemic. This showed the importance that policy, guidelines and funding, can make, even if the gap to become routine practice still takes a long time.

In similar contexts, for the MU model to be trusted by the public and the healthcare organisation, doctors needed to support the cause. Their support should be ongoing via an advisory group to protect the MU. Lack of such support by those in more influential positions threatens the existence of these models.

Unstable medical leadership was one of the biggest barriers that impeded the implementation of the MU. It is worth noting that midwifery leadership even with the continuity of the same people throughout the project was not strong enough to overcome this. As discussed earlier, midwifery leaders need to be supported by the medical component to be able to succeed and the fragility of decisions in relation to changes of leadership reflects a style of management which is hierarchical rather than distributed, as discussed in the *real level* of this chapter.

This leads to another barrier which was the lack of integration within the maternity team. Midwives, obstetricians, neonatologists and the wider team should have a shared vision based on the best evidence available to promote the optimal care for service users. Instead, the fragmented approach to maternity care, lack of communication within the wider team and lack of exchange opportunities led to a 'silos' culture in the local context.

The codesign aspect of this research helped the team to start a dialogue and reflective work on what is needed for them to move towards the integration of the MU. Stakeholders valued this reflective and collaborative work and understood its relevance to make the change suited to the local context and more likely to be sustainable. The involvement of the service users via the survey made this project more relevant to them. Especially in a hesitant context, the supportive voice of women saying that they were interested in the model was a facilitator and source of reassurance for the team.

This work was possible thanks to the collaborations of the hospital with academia. Healthcare would struggle to find resources for a similar approach internally so the opportunity of having academic institutions supporting this work with their resources (both for this PhD and for the architect PhD) made this a facilitator of the implementation process.

7.4. Strengths and weaknesses of this study

This was the first study to observe the implementation process required by a medicalised context like Italy to implement MUs *before* the change happened. This allowed particular focus on barriers and facilitators and issues related to adoption, acceptability and appropriateness outcomes. No other studies, to our knowledge, have had this specific focus allowing a unique perspective on needs, barriers and facilitators when moving towards the transition from the traditional maternity layout to the integrated model with a MU. Furthermore, no other European studies have focused on the implementation aspects of this model (only English studies). This transition is still required by many

European and international countries so findings and knowledge generated with this research could be valuable to some of these contexts.

Previous MU implementation study conducted in Ontario by Darling et al. (2021) and the ones included during the systematic review used different research designs in different times and contexts but still identified factors that influenced the implementation process which are consistent with the ones arising from this study. This makes the findings of this project even more robust and useful for stakeholders and policy makers interested in this change internationally.

Another strength of this study was the richness of data collected using different qualitative and quantitative methods with diverse stakeholders. This ranged from directors and managers to professionals from different disciplines, service users and key midwifery leaders with experience of implementing MUs in Italy. This facilitated inclusion of different perspectives in action research, in the co-creation of the implementation plan and in the analysis of the Italian context. As shown in my systematic review, this type of research has rarely included representation of all stakeholders (especially service users), which makes this project more rigorous and the findings more relevant. Thanks to the collaboration with MeSLab, we could include service users' data already collected to evaluate maternity service and could use this to guide the discourse with professionals and managers even during the pandemic. This made the codesign of the implementation plan possible.

Considerable time was dedicated to engagement with professionals and managers at the beginning and throughout the project, and with the external supervisor and this made a positive impact on the participatory aspect of this research. Good engagement of professionals and service users made the data collection more diverse and therefore the value of the data more significant, but it also in itself formed an important part of the PAR process.

Another strength of this research was a rigorous research approach which allowed the possibility to include dissemination of research findings along the way with stakeholder. For example, the systematic review and situational analysis findings were used to guide the implementation plan codesign. Those findings were circulated to the team before the Act Phase and included in the presentations before multidisciplinary meetings and events and formed a basis for discussion of views and of next steps in the process.

One challenge encountered during this project, which is inherent in such a multi-method and stage approach was about synthesising different sources of data. This is not unusual in implementation and action research projects. However, a rigorous reflexivity analysis, regular supervision meeting and

having both internal and external supervisors helped by ensuring the decisions and the analysis were discussed and shared. In addition, the PAR process of sharing ongoing analyses with the maternity teams provided an additional layer of reflection. It was important, as an insider-outsider researcher to examine my own role in facilitating the PAR process, how to balance the desire to achieve outcomes with the need to maintain a codesign approach and awareness of the need for sustainability of the work following my own contribution. I had to learn to be a facilitator available to the team engaging them in the idea and research activities without taking over any aspect of the actual work so that they could develop ownership of the project. Sometimes it was not easy to hide instinctive emotional responses and frustration but having a supervision team available to me to discuss things through and reflecting on events helped me to transform those responses in research diary entries which helped the analysis in the 'reflect' phase.

However, this study also had some limitations. The first is the considerable change of research plan (and protocol) due to the impact of Covid pandemic on the timeline of this research and in the implementation of the innovation. If the initial plan was to conduct two cycles of PAR before and after the opening of the MU, this was not possible for the simple fact that the MU was not opened during the years of this project. Nevertheless, meaningful work and useful findings could still be drawn through the amended research plan. As mentioned in chapter 6, if the pandemic was a big limitation in terms of face-to-face research plans, it also became an inadvertent opportunity for the maternity team to move some births away from the traditional OU and for midwives to practice more autonomously. It also had the positive impact of securing funding for primary care that allowed this project to still exist.

Furthermore, service users were mainly involved by surveys and only one focus group was completed before the pandemic hit and Covid regulations limited the research. However, the use of different type of questions within the survey and the possibility of including open ended comments helped add more depth to the analysis. The invitations sent to take part in research activities were all on online platforms (via email for the survey or social media for the focus group). This means that we might have missed women who do not have or use these communication platforms. Before the pandemic, together with the PhD student in Architecture, there was a plan in place to recruit service users during antenatal classes in the community centres to engage different populations. We received the permission to go ahead from the directors but this could never be completed due to the Covid regulations.

Lastly, using different languages for the data collection (Italian) and for the synthesis of findings (English) might have led to missing out on shades of detail. This type of issues were sometimes discussed with the other two supervisors of this project who both spoke Italian and English and addressed as a team.

Chapter 8 – Conclusions

8.1 Summary of this study

This participatory action research has facilitated the process and elicited the experience of attempting to implement a midwifery unit in a European context where this model of care is not yet well-established.

A total of 86 professionals and managers and 522 service users took part in this study between 2019 and 2021 at different stages of the PAR cycle (situational analysis, Delphi study and service users survey). This was the first ever study conducted on the implementation of a MU before its opening and including such a wide representation of stakeholders makes its contribution to knowledge notable.

At the beginning of this journey, a supportive transformational leader with authority to bring about change was pushing for the implementation from the inside with external support from international researchers. However, the situation changed rapidly and continuously throughout the four years of the project when different obstacles were encountered including changes of leadership and a global pandemic. Nevertheless, despite these challenges the MU project was maintained and progressed in this time. A main contributor to this resilience was the codesign aspect of this work which increased support and trust in the international evidence and ensured engagement of staff at different levels and from different professions.

The aim of this study was to observe and support the implementation process of a MU in the Italian context. The study findings have demonstrated achievement of this goal even though the implementation itself is still in process.

8.2. Contribution to knowledge

This study has contributed to understanding the process and challenges of implementing MUs in the local context, Italy and in comparable contexts. Here, I summarise the key contributions, following the chapters' structure.

Starting from the examination of the previous international implementation work with a systematic review, it became clear how this type of innovation struggles to be embedded as a mainstream option

in maternity systems. The review analysis suggested that this is due multiple factors on different levels: from the structural issues like gendered dynamics, industrialised and hierarchical approach to healthcare; to organisational factors like local protocols, leadership physical environment and service integration; to the professional level that included recognition of midwives' identity, scope of practice and training support for the wider team. The logic model created from this review, presented in chapter 7, aims to simplify those levels and stages. No papers were found related to the implementation of MUs in European countries other than England and this reinforces the need for this type of study in different European contexts and the contribution to knowledge that this study made. Furthermore, considering that the studies included in the literature review were all conducted after the MU was implemented, it highlighted the need to observe the process before implementation to explore in more depth issues like acceptability, appropriateness and adoption of the model. Lastly, the review showed how service users were often not involved in the configuration of the change when implementing the MU model and how in settings where they could push for the innovation, this became a facilitator of change. The review findings confirmed the value of my planned project design as PAR study, commencing pre-implementation, and the relevance of a plan which included service users throughout.

The next step was a situational analysis, which examined the perspectives of different stakeholders towards the MU project and generated a baseline understanding of readiness of the local context. This analysis allowed professionals to reflect on their readiness before drafting an implementation plan. Main barriers identified were the divergence between the level of autonomy that medical component and midwives had, the power imbalance and medicalisation of childbirth that this created and a discontinuous and hesitant leadership. Support for and resistance to the AMU was not influenced by professional category, meaning that in both supportive and resistant groups there was multidisciplinary representation showing that this aspect is mostly affected by individuals' beliefs, values and experiences. The importance of guidelines, local protocols, an allocated budget and training opportunities to increase confidence was acknowledged by professionals and they saw the opportunity of having exposure to the MU model as facilitator even if the lack of similar models of care in the local and regional context made this extremely challenging. Closure towards the idea of an out-of-hospital MU or homebirth was evident among most stakeholders including midwives in this context and they all saw the AMU as the best option for the local context. Professionals and managers demonstrated a lack of knowledge of service users' needs and preferences for maternity care and

showed that the team (and the organisation in general) has not prioritised their involvement in service configuration so far.

During the "act and observe" phase, the Delphi study with professionals and the service users' survey showed how PAR was a successful engagement strategy that allowed the inclusion of a large and diverse sample and that the codesign aspect of the research was valued by stakeholders. The implementation plan that was coproduced by the maternity team and supported by the local women during the surveys included ten areas to facilitate the change to an integrated model with an AMU. The ten areas covered aspects related to: team vision, implementation in practice of the local protocol for low-risk intrapartum care, appropriate risk assessment, midwifery and multidisciplinary training, creation of a multidisciplinary advisory group and a team of dedicated midwives for the AMU, integration of the hospital and community services, effective communication within the team and with service users and a reflecting approach to practice using audit and debriefing regularly.

This was the first study that involved Italian service users in discussing the implementation of a MU and they showed interest towards the model, support towards the initiatives proposed by the maternity team in the implementation plan but also expressed the need to receive more information and education about the evidence and nature of the model of care.

During the last phase of the PAR cycle, I reflected on the findings of the study with local participants, key midwifery leaders and with my own reflexivity stance. The pandemic played a role in this study and became a barrier (for delaying the project) but also an opportunity (for securing funding and promoting more autonomy for midwives in practice). Stakeholders were supportive to the adoption of the model and even though they seemed to find the MU an acceptable innovation they showed hesitance and sometimes struggled to find it appropriate for the local context and expressed the need to adapt it, raising issues of fidelity to the evidence-based model.

The implementation work often required a personal and professional cost from the midwifery leaders who pushed the innovation. The main barriers identified by them where the heterogeneity of the Italian healthcare context, intra and interprofessional resistance, midwifery education being manly medicalised and not focused on promotion of physiology and a multifaced professional profile for midwives in Italy. Facilitators were found in service users' interest for out of hospital birth in the Italian population (noted in the private sector), powerful allies (often from a medical or political background) and the opportunity to establish a supportive network between private and public sector to support each other's need.

The main **outputs** from this work that benefit the local reality were the coproduced implementation plan and all the reports arising from the different research stages, which were shared with the team and allowed a *reflective approach to the change*. For the wider international level, the outputs are represented by the first systematic review specific on this topic, the publications and a visual model (presented in chapter 7) which summarises the PAR journey and the main findings of this work which could be relevant to countries attempting similar implementation work.

8.3. Unanswered questions and future research

The main question that remains unanswered from this study is whether the MU will eventually be opened or not. Throughout the project it was clear that the dedication and motivation towards pursuing this change fluctuated for various reasons including a hesitant leadership or professional resistance. It also became clear that a high level of motivation and focus was required to achieve a change of this type. My role as external facilitator with sensitivity to the local context was crucial. In keeping with a PAR approach, I aimed to reduce the level of my involvement as facilitator over time, encouraging local service leads to take more ownership. If the MU is implemented, it would be interesting to conduct an *after* phase of the study, in line with initial planning for this project and observe the changes. Such a longer-term impact assessment or evaluation could not have been the aim of this PhD project which could have otherwise lasted many years with the potential scenario of never seeing the opening of the MU anyway.

Another question that could not be answered fully, therefore, was whether the implementation plan was useful and effective in developing capacity and guiding the team towards the change. The reflection phase identified that the approach helped to increase the level of acceptance of the innovation through engaging different stakeholders with the process and the evidence but a more formal evaluation of this impact would have required a longer '*observe*' phase and the evaluation of key indicators before and after the plan, which was not feasible for the local context during the pandemic years when primary organisational goals and priorities were to cope with the emergency.

One point that future research should look more in detail into is why homebirth and freestanding midwifery unit are not an option for the Italian context. Why are these models of care for low-risk women that are supported by the international evidence not seen as a viable option in the Italian context? This study noted how the idea of being inside the hospital was associated with a strong perception of safety in the local context but could not dive deeply in investigating 'why'. This work

could help to create strategies for addressing the evidence-to-practice gap noted around this topic in the Italian maternity care system.

MUs often need to prove their worth by making the institution save money or resources. However, the concept of *cost-effectiveness* being an appropriate use of the resources in the long term and not necessarily *cost-saving* did not always seem clear to stakeholders. This aspect arose both in the systematic review and during the PAR cycle. This is an important point that should be considered for future research and when attempting similar future implementation work to set the correct expectations (especially from managers and organisations) towards the innovation. Previous studies reported how MUs are still cheaper than the OUs even when working at 30% of their capacity (Schroeder *et al.*, 2017; Walsh *et al.*, 2020). Using a salutogenic approach, it is important to state that MUs are **safer** than the OUs for women with uncomplicated pregnancies reducing the use of interventions (and therefore potential costs). Although economic analyses have found them to be cost-saving, *they are not intended to be a money-saving intervention but a health-promotion one.*

The need to justify a financial benefit was used as a successful strategy to open the gate and raise interest of leadership at the beginning of this project and it worked in starting a conversation. However, when the existing regional MU started registering low number of births the unit started to be seen as a loss-making activity and was perceived as an unfair system where midwives worked less than in the OU creating tensions within the team and risk of closure. This is because the tendency is to judge those units only on the intrapartum care service (number of births per year) and not by all the other care that they can provide, or in terms of savings which can be invested in staffing, which could release burden from the main service. Savings through achieving appropriate intervention rates and enhanced maternal health outcomes decrease burden to the service overall in terms of hospital bed days used, theatre use and pressure on materials and anaesthetic staffing costs. MUs can also provide wider services such as antenatal classes, triage in early labour, phone triage, postnatal care, breastfeeding support, infant health clinics and reproductive health services, depending on the local context and population.

It is important, therefore, to look at those units as community hubs offering a wider range of services as promoted in the Better Births and Best Start policies in the UK and not just as a unit with rooms to give birth in a homely-like environment (National Maternity Review, 2016; Maternity Transformation Programme, 2020). Future research should address the issue of MU sustainability in relation to services provided, costs for the healthcare system and long-term public health effect. This is especially

considering that this is the reason and argument that often threatens the closure of the MUs or even, as in this case study, the opening of a facility (McCourt *et al.*, 2018b; Rocca-Ihenacho *et al.*, 2018; Walsh *et al.*, 2020).

A key area related to this was also the staffing model for the unit. Various examples of staffing models have been reported in literature including a shift-based model, on-call, continuity teams or hybrid models (for example by integrating community midwifery teams with core MU staffing) depending on the local area and healthcare system (Rocca-Ihenacho *et al.*, 2018; Walsh *et al.*, 2020; Darling, McCourt and Cartwright, 2021). However, an analysis of the benefits of each option from a professional, managerial and service users' perspective has not yet been conducted. This could help supporting new contexts approaching this change with a better idea of the options available and choosing the one more suited for their needs. Some interesting work related to the staffing models to provide continuity of carer has been published and could guide a similar discussion on the MUs model as well (McCourt *et al.*, 2006; Newton *et al.*, 2016; Sandall *et al.*, 2016; Rayment-Jones *et al.*, 2020; Dharni *et al.*, 2021)

Finally, future research should investigate the phenomenon of MUs closures (temporary and definitive ones) which worsened during the pandemic (Rocca-Ihenacho and Alonso, 2020; Yuill, 2020; Grollman *et al.*, 2022). This was observable in Italy where the number of open MUs integrated within the healthcare system dropped from five to only one while new private birth houses were opening to meet the needs of the population. Moreover, in England reports showed how MUs were often closed due to an acute shortage of staff and the perceived need to centralise the service for safety reasons. A media analysis study of the closure of FMUs, showed a range of factors driving closures including manager beliefs that they are more expensive and that women were not interested while services users reported often not being aware of, nor being involved in the service configuration (Rayment, *et al.*, 2020). Research should look at the possible impact that this could have had on perinatal outcomes, women's choice and satisfaction and cost for the maternity services.

8.3.1. Implications for clinicians

One the key implication of this study is that it is clear now that local women are currently not being offered the best evidence-based care due to the way in which the maternity system is structured and functioning. Italy, like many other international contexts, need to acknowledge this and should focus on addressing this gap as a salutogenic, public health priority.

If having clinical guidelines on a more national and regional level is a facilitator to push for this change, the strongly hierarchical team structure creates obstacles and difficulties to put clinical guidelines into practice. Similar realities approaching this transition should consider targeted activities to support the team in improving clinical practice.

In the Italian context, professionals felt the need to improve their practice in caring fo low-risk women in labour and suggested focusing and investing in training support. However, they also acknowledged that to change practice a training day does not suffice and that the opportunity of having exposure, on-the-job support from clinical leaders and teamwork is also needed to promote change. Therefore, more work on a leadership level to facilitate and enable those conditions is needed to improve the confidence and the trust in the MU model among the team.

Awareness of the medicalisation of maternity care in this context should also help in developing strategies aimed at standardisation of some practice based on the evidence, not leaving it up to the clinician's discretion. Shared practices and better integration across the service on an organisational, regional and national level is needed to avoid the inappropriate use of public resources currently present in Italy. A clear example mentioned in the background chapter is the CS rate that changes significantly from different regions (with wider difference between North and South) and for different populations like Italian and non-Italian mothers, as well as between different European countries. These differences are clearly being affected by the different approaches to maternity care across different organisations and clinicians and this cannot be acceptable. Federalism has widened disparities for service users in Italy and this should be addressed to ensure all women receive comparable care across the country (Nante *et al.*, 2021).

As noted during this study, implementation of evidence-based innovations requires '*simultaneous de-implementation of the outdated and non-evidence-based ones'* (Wang *et al.*, 2018). This requires an ongoing reflective and open approach to clinical practice within the maternity team and moving away from the 'we have always done it this way' approach that often affects not only maternity but healthcare in general. Examples of improvement in clinical practice in Tuscany are the use of fundal pressure in second stage (3.7% in 2021 against 10.5% in 2010) and episiotomy (7% in 2021 against 22% in 2010) (ARS, 2022). However, considering that fundal pressure is a non-evidence-based practice, 3.7% is still a high number after ten years of work especially if we consider that in that happens mainly in first time mothers and during instrumental births (ARS, 2022). Is this acceptable after ten years with

extensive literature not supporting this practice (Hofmeyr *et al.*, 2017) and reports on obstetric violence mentioning the impact of those practices on women (Skoko *et al.*, 2018).

More work should be done on *how to* support clinicians in de-implementing inappropriate practices and to implement evidence-based ones *more rapidly* to ensure that service users receive the best available care.

8.3.2. Implications for managers, policymakers

It is evident from the findings that the development of a MU is only possible if those at the top of the organisation are supportive. However, their support in often affected by their personal views and beliefs more than the evidence available. Discontinuous and at times unsupportive leadership significantly affected the development of the MU project. Hence, the need for a stable, supportive, evidence-based and transformational leadership becomes pivotal for the success of the MUs implementation. Midwives need to be **recognised, supported and enabled** in their leadership roles by the medical component in the interest of the public (better outcomes and appropriate use of resources). The 2021 State of World's Midwifery report recommended focus on four key areas of investment for strengthening the state of global midwifery: health workforce, education and training, midwifery led services and midwifery led governance and leadership (UNFPA, WHO and ICM, 2021). Managers and directors of healthcare organisations and maternity service in Italy should actively and openly support this.

Furthermore, policy makers should not only push for the evidence-based guidelines that we have seen can positively affect the conversation on MUs but should also recognise and acknowledge more the power dynamic currently existing in this area (maternity care) and in this context (Italy and similar countries). The impact that gender and professional category power dynamics had in the development of configuration of maternity service in the past decades, the strong hierarchical structure embedded in the healthcare organisations and the lack of regular involvement/engagement of service users in the service configuration should be addressed on a policy level.

8.3.3. Implications for education

In the local context of this research, participants expressed concerns about midwifery education being mainly delivered by obstetricians and the wider medical category. This could be one of the factors

having affected the medicalisation of birth and the reduced midwifery autonomy in Italy in the past decades and it should be considered by education providers and midwifery councils when supporting the development of the new generations of midwives.

A more diluted role of midwifery due to being involved in many healthcare services like gynaecology, IVF, surgery etc. seems to be affecting the midwifery identity in Italy. Some saw this as a growth opportunity to step out of the old conception of midwives *'only doing pregnancy and birth';* others saw this just as a way to increase the facets of the profession but always in a support/assistant of the doctor role and never increasing the autonomy as practitioners. On a national level, education providers and midwifery councils should ensure that midwifery role and scope of practice is clear and uniform so that this could impact on the societal role that midwives have as well as the way they are perceived by service users.

It was clear how there was a need amongst midwives and the wider multidisciplinary team to learn how to support physiology by experiencing this model in practice. This is difficult or almost impossible in contexts where this model is not established. Therefore, educational providers should work on creating this opportunity of exposure with collaborations outside the system such as private midwifery practices or exchanges with other countries. This could help working relationships across sector and creating a new generation of practitioners that are more open towards physiological birth.

Finally, after the experience of conducting this study, I now believe that education for healthcare professionals (like midwives and obstetricians) should include more implementation research and focus on the evidence to practice gap problem from the undergraduate level. This could help making professionals more aware of the idea of continuous improvement that clinical practice requires and the available knowledge on strategies that could help reducing this gap. This topic was not tackled at all during my studies in Italy (BSc and MSc) and it is only partly mentioned and covered in the new NMC standards for midwifery proficiency in the UK (NMC, 2019).

8.4. Closing remarks

This thesis represents my growth journey as researcher, midwife, academic and more generally as a person. Throughout this journey, I observed and supported the attempt of implementing a healthcare innovation in my native country while living and working in the UK. Many events have happened in these four years on a research level but also on a global and personal level.

I learnt to embrace unpredictability and being comfortable with '*not knowing'* andthe importance of sharing an idea and a vision for the sustainability of the cause in the long term. I now know how much energy is needed to engage people in an idea, but also how essential it is for a change to be shared, codesigned and participated. Furthermore, it is also now clear to me that a multi-layered innovation like this to promote an evidence-based model of care requires changes in the existing power structure to support the professional group currently lower down in the hierarchal system. Acknowledgement and awareness of such power dynamics is the first step to start tackling this issue and enabling the midwifery profession as recommended by international evidence.

The use of a diverse range of research methods, theoretical underpinning and implementation frameworks taught me the complexity of research and of the world we live in and how important it is to always try to use the best lenses to observe and try to explain a phenomenon. The commitment of the local reality to continue this research journey together, even during an extremely difficult time, was very inspiring to me and a testimony of the incredible hard work that healthcare professionals have in improving and providing the best care to women and the local population they serve. However, it was also clear, that without the external facilitation and my role as PAR researcher, the maternity team would have not felt supported and able to keep this level of commitment going. Therefore, my contribution played a significant and positive difference in maintaining the work towards the innovation going forward.

Although I had ongoing support from my supervisors and two external researchers contributed to the systematic review, I conducted all this doctoral work autonomously and independently achieving a lot in only four (pandemic) years.

I believe that this work makes a significant contribution to midwifery and offers precious insights for implementing MUs more widely around the world. For many countries this conversation still needs to start but extensive literature and strong evidence has shown the importance of this cause and how the first step is often the hardest to take.

Appendices

Appendix 1. Ethics approval gained from City University of London

Ethics ETH1819-1265: Laura Batinelli (External approval)

Date	28 Apr 2019
Researcher	Laura Batinelli
Project	Supporting the implementation and scaling-up of midwifery units in Europe: how can capacity in the maternity workforce be developed?
School	School of Health Sciences
Department	Division of Nursing

Ethics application

Project details

EP1) Project title
Supporting the implementation and scaling-up of midwifery units in Europe: how can capacity in the maternity workforce be developed?

EP2) Principal Applicant
Laura Batinelli

EP3) Co-Applicant(s) (City)

EP4) External Co-Applicant(s)

EP5) Supervisor(s)
Prof Christine McCourt

EP6) Project start date
01 Jul 2019

EP7) Estimated project end date
31 Jan 2021

EP8) Is City acting as the Sponsor, i.e. responsible for managing this project?
Yes

EP8.1) Name of the person signing off on behalf of City as the Sponsor.
Prof Christine McCourt

Ethics

EE1) Please give a brief lay summary of the project (max 500 words).
(a)
The primary aim is to assess the organisational, cultural and professional readiness of a new midwifery unit (MU) in a European context and evaluate the implementation process. The secondary

aim will be to enhance understanding of how to implement evidence-based service organisation and delivery changes for wider application nationally, internationally and to other areas of healthcare.

(b)

MUs have been found to be safe for neonates, safer for mothers, cost effective and associated with staff and user satisfaction. In some EU countries, MUs and midwife-led care are more established than others. In Italy there are currently just three MUs and there is a growing interest in this field. In Tuscany, the hospital Misericordia in Grosseto is working towards the creation of its first MU.

The transition from the default obstetrically-led maternity services to an integrated model with a midwifery unit represents an ideal opportunity to examine implementation of international guidelines in national and regional context.

(c)

Design: This study will use Participatory Action Research (PAR), informed by implementation science.. Change will be co-planned, implemented and evaluated in a cyclical way following the nature of a PAR-cycle: plan, act, observe and reflect.

The Midwifery Unit Support for Excellence (MUSE)-Pathway is a guide for research and service improvement developed at City. This will be used along with the Consolidated Framework for Implementation Research (CFIR) to support the implementation process and its analysis.

Collaborations: The study will receive additional academic support by the Management and Health Laboratory (MeS) based in the University St Anna of Pisa and partner of the Regional Health Department which monitors the performance of the Tuscany Regional Health System annually.

Participants: All stakeholders involved in the transition from the default maternity services to the new model of care with an AMU: service users, multidisciplinary maternity team, operational management, architects and strategic level stakeholders.

Methods: Both qualitative and quantitative methods will be included within the plan of work: focus groups, in-depth interviews, analysis of local documents and guidelines, observation of practice and data collected while using implementation tools and strategic planning techniques. Qualitative data will be analysed using thematic analysis guided by the CFIR framework. Quantitative data gathered as part of existing service audits and surveys will be analysed pre and post-implementation.

(d)

We do not expect to encounter any specific ethical issues but since being a researcher as well as a change facilitator can present ethical challenges, a reflective diary will be used to reflect on power dynamics within the field and my role will be discussed with supervisors to ensure sufficient reflexivity.

(e) The project will be undertaken in at the Hospital Misericordia in Grosseto (Tuscany, Italy).

(f) Participants will include:

- Users of the maternity service (pregnant women and their families)

- Professionals (midwives, doctors, or any member of the maternity and neonatal team)

- Organisational leadership (operational and strategic managers at regional and local level)

Sampling will be purposive and sample sizes will be estimates based on available personnel and guided by data saturation.

EE2) Please provide the name and contact details of the external research ethics committee.
Name
Sandra Bianchini

Contact details
email: sandra.bianchini@uslsudest.toscana.it

Telephone:+39 0575 254650

EE3) Does the research involve any of the following:
Specifically recruiting pregnant women or women in labour
Research being conducted with participants outside the UK (This includes Skype interviews but excludes online/postal surveys/experiments/questionnaires)

Outcome

Outcome

OL1) Application reference number.
ETH1819-1265

OL2) Was your application approved?
Yes

OL3) Please upload the outcome letter.

Attached files

PARERE Comitato etico Oct2019.pdf

COMITATO LOCALE DI BIOETICA CLINICA
Azienda USL Toscana Sud Est
(Delibera del DG N.1275 del 06/12/2018)

Prot/Staff 2019/000372 CLdBC   Arezzo, 14/10/2019

Egr. Dr. Antonio D'Urso
Direttore Generale

Egr. Dr.ssa Marzia Sandroni

Egr. Dott. ssa Laura Batinelli

OGGETTO: "SUPPORTARE L'IMPLEMENTAZIONE E LO SVILUPPO DI CENTRI DI NASCITA A CONDUZIONE OSTETRICA IN EUROPA: COME SI PUO' SVILUPPARE CAPACITA' ALL'INTERNO DEI SISTEMI SANITARI?".

Promosso: Dott.ssa Laura Batinelli – Ricercatore c/o City University of London

Assume la funzione di segretario verbalizzante la Dott.ssa Sandra Bianchini, Resp. dell'Ufficio Ricerca Clinica e Profili Etico-giuridici, che constata la presenza del numero legale di 12 su 23 componenti aventi diritto al voto. L'Avv. Carlo Valle e il Dott. Giovanni Mandriani si collegano alla stanza virtuale; il Dott. Becattini, l'Avv. Luca Fanfani, il Dott. Luca Mencaglia, il Dott. Roberto Monaco e il Dott. Rossano Santori si esprimono telematicamente.

I nominativi dei componenti con le rispettive qualifiche e afferenze, distinti fra presenti e assenti, risultano dal foglio ufficiale delle firme come sopra riportato

	NOMINATIVO		QUALIFICHE	
1.	Dr. Marco Becattini	Interno	Direttore dell'Unità Funzionale di Medicina della Farmaco tossicodipendenze	Presente telematicamente
2.	Dr. Fabrizio Boldrini	Interno	Responsabile di Zona Distretto Area Grossetana	Assente giustificato
3.	Dr. Pier Giorgio D'Ascola	Esterno	Pediatra	Presente
4.	Dr. Lorenzo Droandi	Esterno	Ordine dei Medici Chirurghi e Odontoiatri Sede Operativa di Arezzo	Assente giustificato
5.	Avv.to Luca Fanfani	Esterno	Avv. Foro di Arezzo	Presente telematicamente
6.	Dr.ssa Patrizia Funghi	Esterno	Bioeticista Università di Siena	Assente giustificato
7.	Dr. Evaristo Giglio	Interno	Responsabile di Zona Distretto Aretina	Assente non giustificato
8.	Prof.ssa Maura Lodovici	Esterno	Farmacologa Università di Firenze	Assente giustificato
9.	Prof. Pasquale Giuseppe Macrì	Interno	Medico Legale Dir. UOC Medicina Legale Sede Operativa di Arezzo	Presente
10.	Dr. Roberto Madonna	Esterno	Ordine dei Medici Chirurghi e Odontoiatri – Sede Operativa di Grosseto	Assente non giustificato
11.	Dr. Giovanni	Interno	Medico Legale Dir. UOC Medicina	Presente

Azienda USL Toscana sud est

Coordinatore Comitao Locale di Bioetica e Profili Etici Giuridici :
Prof. Pasquale Giuseppe Macrì
Tel: 0575/254998 – 4996
Email:
pasqualegiuseppemacri@uslsudest.toscana.it

Responsabile Segreteria:
Dr. Sandra Bianchini
Tel: 0575/254650
Email:
sandra.bianchini@uslsudest.toscana.it

Azienda USL
Toscana Sud Est Arezzo
Via Curtatone, 54
52100 Arezzo
Tel. 0575.2551
P.I. e C.F. 01458450515

www.uslsudest.toscana.it
E.mail:
urp@uslsudest.toscana.it

COMITATO LOCALE DI BIOETICA CLINICA
Azienda USL Toscana Sud Est
(Delibera del DG N.1275 del 06/12/2018)

	NOMINATIVO		QUALIFICHE	
	Mandriani		Legale Sede Operativa di Siena	telematicamente
12.	Dr.ssa Ilaria Martini	Interno	Referente Tutela dei sogetti fragili e amministrazione di sostegno – Medicina Legale Sede Operativa di Arezzo	Presente
13.	Dr.ssa Sara Mazzoli	Interno	Infermiere – Medicina Legale Sede Operativa di Arezzo	Presente
14.	Dr. Luca Mencaglia	Interno	Ginecologo Direttore del Centro di Procreazione Medicalmente Assistita Cortona (AR)	Presente telematicamente
15.	Dr. Stefano Milano	Interno	Direttore Dipartimento Salute Mentale	Assente non giustificato
16.	Dr. Roberto Monaco	Esterno	Ordine dei Medici Chirurghi e Odontoiatri – Sede Operativa di Siena	Presente telematicamente
17.	Dr. Marco Picciolini	Interno	Responsabile di Zona Distretto Senese	Assente giustificato
18.	Stefania Polvani	Interno	Sociologo	Assente giustificato
19.	Avv.to Massimo Rossi	Esterno	Avv. Foro di Siena	Assente non giustificato
20.	Dr. Rossano Santori	Interno	Medico Legale Dir. UOC Medicina Legale Sede Operativa di Grosseto	Presente telematicamente
21.	Valerio Signorini	Esterno	Rappresentante del Volontariato	Assente giustificato
22.	Avv.to Carlo Valle	Esterno	Avv. Foro di Grosseto	Presente telematicamente
23.	Dr. Dino Vanni	Esterno	Clinico Medinica Interna	Presente

ESTRATTO VERBALE n.5 del 01 Ottobre 2019

Esaminata la seguente documentazione:

- Scheda progetto;
- Modulo informativo e consenso partecipante ver. del 01.09.2019;
- Application 2018 Laura Batinelli;

Preso atto che:

- il progetto, della durata di 3 anni, si svolgerà c/o l'Ospedale Misericordia di Grosseto e coinvolgerà i professionisti del materno infantile (tra cui ostetriche, medici, infermieri, OSS ecc); gli utenti del servizio (donne, partners e le loro famiglie); la direzione e personale strategico all'interno dell'Azienda USL Toscana Sud Est e del comitato del percorso nascita regionale;
- l'intento è studiare il processo di implementazione necessario da un punto di vista organizzativo, professionale e culturale per la creazione di un centro nascita a conduzione ostetrica (*Birth Centre*) in un contesto Europeo come quello italiano attraverso un modo innovativo quale la *Participatory Action Research*, in cui i ricercatori diventano facilitatori del processo di diffusione, conoscenza e attuazione delle evidenze scientifiche, favorendo il cambiamento e la comunicazione tra tutti gli *stakeholders*;

Azienda USL Toscana sud est

Servizio Sanitario della Toscana

Coordinatore Comitao Locale di Bioetica e Profili Etici Giuridici :
Prof. Pasquale Giuseppe Macrì
Tel: 0575/254998 – 4996
Email:
pasqualegiuseppemacri@uslsudest.toscana.it

Responsabile Segreteria:
Dr. Sandra Bianchini
Tel: 0575/254650
Email:
sandra.bianchini@uslsudest.toscana.it

- non sono previsti costi a carico del SSR e SSN;

Dato Atto che il Comitato ha valutato gli aspetti etici e fattuali del progetto e nello specifico:
- congruità dell'attività da realizzare rispetto agli obbiettivi da raggiungere e non riconducibilità della stessa alla programmazione ordinaria;
- tutela della salute e dignità dei pazienti nonché rispetto dei soggetti per quanto concerne le informazioni e modalità per garantire la protezione dei dati personali;
- conformità delle procedure previste per la proprietà dei dati e l'utilizzo dei risultati nonché della loro comunicazione;
- insussistenza di situazioni di conflitto di interesse di tipo diretto o indiretto tra l'Azienda USL Toscana Sud Est e l'University of London;

Il COMITATO LOCALE DI BIOETICA CLINICA, in merito al progetto "Supportare l'implementazione e lo sviluppo di centri di nascita a conduzione ostetrica in Europa: come si può sviluppare capacità all'interno dei sistemi sanitari?" che si effettuerà presso il P.O. Misericordia di Grosseto, esprime parere favorevole.

Il Coordinatore del Comitato Locale di Bioetica
(Prof. Pasquale Giuseppe Macrì)

Ethics ETH2122-0358: Miss Laura Batinelli (Low risk)

Date Created	26 Oct 2021
Date Submitted	26 Oct 2021
Date forwarded to committee	27 Oct 2021
Academic Staff	Miss Laura Batinelli
Student ID	180031072
Category	Doctoral Researcher
Supervisor	Prof Christine McCourt
Project	Supporting the implementation and scaling up of midwifery units in Europe: how can capacity in the maternity workforce be developed?
School	School of Health & Psychological Sciences
Department	Nursing
Current status	Approved

Ethics application

Amendments

SA1) Types of modification/s

Change the design and/or methodology of the project, including changing or adding a new research method and/or research instrument

SA2) Details of modification

I would like to add a survey to service users as method of this study. I will share a survey on Qualtrics to all women who have had a baby in the past two years in the local hospital where this project is based.

This is to include them in the implementation plan produced by professionals in the past months. They will receive a survey with multiple choice and open ended questions about the implementation plan drafted by the professionals to open a midwifery unit in the local hospital. This will help investigating their knowledge, perceptions and preferences about the midwifery unit model of care.

SA3) Justify why the amendment is needed

In the ethics application we stated that we would use existing survey collected as routine data collection. This survey is new and recently created with the contribution of the multidisciplinary team hence why we are requesting this amendment.

This change will allow to reach a bigger and more representative sample of service users considering that all the face to face interactions with service users have been suspended since the beginning of the pandemic.

SA4) Other information

SA5) Please upload all relevant documentation with highlighted changes

Project amendments

P1) Project title

Supporting the implementation and scaling up of midwifery units in Europe: how can capacity in the maternity workforce be developed?

P2) Principal Applicant

Name

Miss Laura Batinelli

P3) Co-Applicant(s) at City

P4) External Co-Applicant(s)

P5) Supervisor(s)

Prof Christine McCourt

Dr Lucia Rocca-Ihenacho

Attached files

Workflow English Translation.txt

Dear Laura

Reference: ETH2122-0358

Project title: Supporting the implementation and scaling up of midwifery units in Europe: how can capacity in the maternity workforce be developed?

I am writing to you to confirm that the research proposal detailed above has been granted formal approval from the Maternal and Child Health Proportionate Review Committee. The Committee's response is based on the protocol described in the application form and supporting documentation. Approval has been given for the submitted application only and the research must be conducted accordingly. You are now free to start recruitment.

The approval was given with the following conditions:

- ...Please see comments attached to the amendment

Please ensure that you are familiar with City's Framework for Good Practice in Research and any appropriate Departmental/School guidelines, as well as applicable external relevant policies.

Please note the following:

Project amendments/extension

You will need to submit an amendment or request an extension if you wish to make any of the following changes to your research project:

- Change or add a new category of participants;
- Change or add researchers involved in the project, including PI and supervisor;
- Change to the sponsorship/collaboration;
- Add a new or change a territory for international projects;
- Change the procedures undertaken by participants, including any change relating to the safety or physical or mental integrity of research participants, or to the risk/benefit assessment for the project or collecting additional types of data from research participants;
- Change the design and/or methodology of the study, including changing or adding a new research method and/or research instrument;
- Change project documentation such as protocol, participant information sheets, consent forms, questionnaires, letters of invitation, information sheets for relatives or carers;
- Change to the insurance or indemnity arrangements for the project;
- Change the end date of the project.

Adverse events or untoward incidents

You will need to submit an Adverse Events or Untoward Incidents report in the event of any of the following:

a) Adverse events

b) Breaches of confidentiality

c) Safeguarding issues relating to children or vulnerable adults

d) Incidents that affect the personal safety of a participant or researcher

Issues a) and b) should be reported as soon as possible and no later than five days after the event. Issues c) and d) should be reported immediately. Where appropriate, the researcher should also report adverse events to other relevant institutions, such as the police or social services.

Should you have any further queries relating to this matter, please do not hesitate to contact me. On behalf of the Maternal and Child Health Proportionate Review Committee, I do hope that the project meets with success.

Kind regards

Rose Coates

Maternal and Child Health Proportionate Review Committee

City, University of London

INFORMAZIONI SCRITTE per il partecipante al progetto di ricerca
Versione del 24/2/2019

Titolo del progetto di ricerca: Supportare l'implementazione e lo sviluppo di centri nascita a conduzione ostetrica in Europa: come si può sviluppare capacità all'interno dei sistemi sanitari?
Promotore della ricerca: City, University of London
Collaboratore della ricerca: Laboratorio Management e Sanità (MeS), Scuola Superiore Sant'Anna, Pisa
Ricercatore Principale: Dottoranda Laura Batinelli

Gentile Signora / Signore,

Le è stato chiesto di partecipare ad un progetto di ricerca e questo documento ha lo scopo di informarLa sulla natura, sul fine che esso si propone, su ciò che comporterà per Lei una tale partecipazione, sui suoi diritti e le sue responsabilità. La prego di leggere attentamente queste informazioni scritte prima di prendere una decisione in merito ad una eventuale Sua partecipazione al progetto. Lei avrà a disposizione tutto il tempo necessario per decidere se partecipare o meno.

Potrà, inoltre, porre liberamente qualsiasi domanda di chiarimento e riproporre ogni quesito che non abbia ricevuto una risposta chiara ed esauriente.

Nel caso in cui, dopo aver letto e compreso tutte le informazioni ivi fornite, decidesse di voler partecipare al progetto, Le chiederò di voler firmare e personalmente datare il modulo di Consenso Informato allegato a questo documento.

Che cosa si propone il progetto
Il progetto ha come obiettivo quello di studiare il processo di implementazione necessario da un punto di vista organizzativo, professionale e culturale per la creazione di un centro nascita a conduzione ostetrica (anche detto Birth Centre) in un contesto Europeo come quello italiano.

Quali sono le caratteristiche di questo progetto
Si tratta di una ricerca per andare ad indagare tra utenza, professionisti sanitari e management come poter supportare la creazione di un centro nascita a conduzione ostetrica nell'Ospedale di Grosseto. Questo tipo di ricerca è un'**indagine esplorativa** e di **implementazione del servizio** con professionisti sanitari e utenza senza il coinvolgimento di farmaci. Verranno utilizzate diverse metodologie di ricerca come interviste, questionari, focus groups, raccolta dati e indicatori di routine del materno infantile, osservazione della pratica clinica e dei protocolli locali. La partecipazione alla ricerca avrà una durata di circa **tre anni** e saranno arruolati partecipanti presso l'Ospedale di Grosseto e l'Azienda USL Toscana Sud Est.

Cosa comporta la sua partecipazione
La partecipazione a questo progetto di ricerca è *volontaria*. Nel caso in cui Lei decidesse di partecipare alla ricerca, La informiamo che, dopo aver valutato la possibilità di poterLa includere nel progetto di ricerca. prevede la sua partecipazione tramite interviste, focus group, survey o osservazione della pratica clinica. Non è previsto alcun tipo di trattamento medico.

Nel caso in cui Lei decidesse di partecipare al progetto, non le verrà richiesto di effettuare alcun tipo di indagini o visite. La partecipazione non avrà alcun tipo di impatto sulla sua vita in quanto le verrà richiesto solo di contribuire riportando pareri, idee ed eventuale partecipazione ad incontri.

Quali sono i benefici che potrà ricevere partecipando il progetto
Non vi è alcun beneficio diretto derivante dalla partecipazione al progetto, ma le conclusioni che ne deriveranno contribuiranno a implementare e portare innovazione alla realta' locale dell'Ospedale di Grosseto.

Quali sono i rischi derivanti dalla partecipazione il progetto
La partecipazione non comporta inconvenienti e rischi poiché si tratta di una raccolta analisi di dati raccolti. Per questo non è prevista una copertura assicurativa.

Modulo informativo e consenso partecipante
Versione 24/2/2020
Ricerca: Supportare l'implementazione e lo sviluppo di centri nascita a conduzione ostetrica in Europa

1

Possibili alternative
L'unica alternativa possibile è la *non partecipazione* alla ricerca in oggetto e quindi il rifiuto di conferire il consenso al trattamento dei Suoi dati personali.

Cosa succede se decide di non partecipare al progetto
La partecipazione al progetto è del tutto volontaria: Lei è libero/a di non partecipare oppure, se decide di partecipare, avrà il diritto di ritirarsi in qualsiasi momento e senza l'obbligo di fornire spiegazioni, dandone tuttavia comunicazione alla ricercatrice Laura Batinelli (Laura.Batinelli.2@city.ac.uk). In tal caso non saranno raccolti ulteriori dati che La riguardano e potrà chiedere la cancellazione di quelli già raccolti. Il suo percorso assistenziale attuale e futuro presso l'Ospedale di Grosseto non sarà compromesso dalla Sua decisione.
Se lei lo richiederà, alla fine dello studio potranno esserle comunicati i risultati generali dello studio.

INFORMAZIONI IN MERITO AL TRATTAMENTO DEI DATI PERSONALI:

Titolari del trattamento e relative finalità
L'ospedale di Grosseto e la City University of London hanno commissionato lo Studio che Le è stato descritto, ciascuno per gli ambiti di propria competenza e in accordo alle responsabilità previste dalle norme di Buona Pratica Clinica (D.L. 211/2003), dal D. Lgs. 30 giugno 2003, n. 196, dal Regolamento UE 2016/679 del Parlamento e del Consiglio Europeo relativo alla protezione delle persone fisiche con riguardo al trattamento dei dati personali, nonché alla libera circolazione di tali dati (di seguito GDPR), dal D.Lgs. 10 agosto 2018, n. 101 recante disposizioni di adeguamento della normativa nazionale al Regolamento UE 679/2016, norme denominate congiuntamente anche "Normativa privacy", tratteranno i suoi dati personali, soltanto nella misura in cui sono indispensabili in relazione all'obiettivo dello Studio e per le finalità di seguito indicate.
Il ricercatore principale sarà qualificato come il Responsabile per la parte del Trattamento dei dati di cui il Promotore sarà Titolare. A tal fine i dati indicati saranno raccolti dal Centro di sperimentazione e trasmessi al Promotore. La informiamo che i Titolari, ai sensi dell'articolo 37 del GDPR EU 2016/679, hanno proceduto ad individuare e nominare il Responsabile della Protezione dei dati (anche "*Data Protection Officer*" o "DPO"):

DPO dell'Ospedale Misericordia di Grosseto: privacy@uslsudest.toscana.it
DPO della City university of London: Laura.Batinelli.2@city.ac.uk

Categorie di dati oggetto del trattamento
Il presente trattamento avrà ad oggetto i Suoi dati personali, di seguito meglio specificati: dati identificativi (nome e cognome), dati clinici atti a rivelare lo stato di salute e dati raccolti e da Lei rilasciati durante il corso di questo progetto. Il trattamento dei dati personali è indispensabile allo svolgimento del progetto: il rifiuto di conferirli non Le consentirà di parteciparvi.

Finalità del trattamento
I dati sopra descritti verranno trattati per consentire lo svolgimento della ricerca in parola e di tutte le relative operazioni ed attività connesse.

Base giuridica del trattamento
Il consenso informato costituisce la base giuridica per il trattamento dei Suoi dati per gli scopi descritti nella scheda informativa. In assenza di consenso firmato non potremo utilizzare i Suoi dati per la conduzione e le analisi del progetto. Potrà interrompere la Sua partecipazione in qualsiasi momento senza fornire alcuna motivazione; in tal caso, i dati a Lei correlati verranno trattati come descritto nella scheda informativa del progetto. Non saranno inoltre raccolti ulteriori informazioni che La riguardano, ferma restando l'utilizzazione di quelli eventualmente già raccolti per determinare, senza alterarli, i risultati della ricerca.

Modalità di Trattamento dei dati
Le finalità sopra indicate prevedono lo svolgimento del trattamento dei dati personali mediante strumenti manuali ed informatici con logiche strettamente correlate alle finalità stesse e, comunque, in modo da garantire la sicurezza e la riservatezza dei dati stessi. I dati raccolti per i fini del progetto di ricerca verranno gestiti in forma codificata e anonimizzata e restituiti in forma aggregata. I dati che La riguardano ad eccezione del Suo nominativo, saranno trasmessi alla City University of London e dalla stessa struttura registrati, elaborati e conservati.

Modulo informativo e consenso partecipante
Versione 24/2/2020
Ricerca: Supportare l'implementazione e lo sviluppo di centri nascita a conduzione ostetrica in Europa

2

Ambito di comunicazione dei dati

La diffusione dei dati scientifici risultanti dalle analisi dei dati della ricerca, potrà avvenire solo in forma anonima e per sole finalità scientifiche. In pratica, i risultati delle ricerche scientifiche potranno essere presentati in forma aggregata nell'ambito di Convegni o pubblicati su riviste specializzate senza mai permettere la precisa identificazione dei pazienti.

Politica in materia di conservazione dei dati personali

I dati personali raccolti nell'ambito di questo progetto di ricerca verranno conservati presso l'Ospedale di Grosseto, la City University of London e le strutture coinvolte nello Studio, per un periodo minimo di 7 anni dopo la conclusione della ricerca o per un periodo più lungo, se necessario, in base ad ulteriori requisiti di legge.

Diritti dell'Interessato
- *Diritto di accesso ai dati*
- *Diritto di rettifica ai dati*
- *Diritto di portabilità dei dati*
- *Diritto di cancellazione dei dati*
- *Diritto di reclamo*

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Il progetto di ricerca che Le è stato proposto è stato approvato dal Comitato Locale di Bioetica Clinica in data 14/10/2019. Il Comitato Etico ha tra le altre cose verificato la conformità dello studio alle Norme di Buona Pratica Clinica della Unione Europea ed ai principi etici espressi nelle Dichiarazione di Helsinki. Lei potrà segnalare qualsiasi fatto ritenga opportuno evidenziare, relativamente alla ricerca che La riguarda, al Comitato Etico e/o alla Direzione Sanitaria di questa struttura ospedaliera.

Ricercatrice	Laura Batinelli
Email	Laura.Batinelli.2@city.ac.uk

Nome per esteso del ricercatore   Data   Ora   Firma
che ha consegnato l'informativa

Laura Batinelli

Modulo informativo e consenso partecipante
Versione 24/2/2020
Ricerca: Supportare l'implementazione e lo sviluppo di centri nascita a conduzione ostetrica in Europa

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MODULO DI CONSENSO INFORMATO
Versione del 1/9/2019

Titolo del progetto di ricerca: Supportare l'implementazione e lo sviluppo di centri nascita a conduzione ostetrica in Europa: come si può sviluppare capacità all'interno dei sistemi sanitari?
Promotore della ricerca: City, University of London
Ricercatore Principale: Dottoranda Laura Batinelli

Io sottoscritto/a _____

nato/a il ___/___/_____ a _____ residente a _____

Recapito telefonico: _____ Recapito email: _____

DICHIARO

- di aver ricevuto dal ricercatore esaurienti spiegazioni in merito alla richiesta di partecipazione alla ricerca in oggetto, secondo quanto riportato nella scheda informativa, facente parte di questo consenso, della quale mi è stata consegnata una copia in data …………………………………………
- che mi sono stati chiaramente spiegati e di aver compreso la natura, le finalità, le procedure e le alternative del progetto;
- di aver avuto l'opportunità di porre domande chiarificatrici e di aver avuto risposte soddisfacenti;
- di aver avuto tutto il tempo necessario prima di decidere se partecipare o meno;
- di non aver avuto alcuna coercizione indebita nella richiesta del Consenso;
- che mi è stato chiaramente spiegato di poter decidere liberamente di non prendere parte al progetto o di uscirne in qualsiasi momento senza fornire giustificazione, e che tali decisioni non modificheranno in alcun modo i rapporti con i medici curanti e con la struttura presso la quale sono in cura;

DICHIARO pertanto di voler partecipare al progetto di ricerca

Nome per esteso del partecipante	Data	Ora	Firma
_____	_____	_____	_____

Io sottoscritta Laura Batinelli

Dichiaro che il Partecipante ha firmato spontaneamente la sua partecipazione allo studio
Dichiaro inoltre di:
- aver fornito al Partecipante esaurienti spiegazioni in merito alle finalità della ricerca, alle procedure, ai possibili rischi e benefici e alle sue possibili alternative;
- aver verificato che il Partecipante abbia sufficientemente compreso le informazioni fornitegli
- aver lasciato al Partecipante il tempo necessario e la possibilità di fare domande in merito alla ricerca
- non aver esercitato alcuna coercizione od influenza indebita nella richiesta del Consenso

__ _____ _____
Data   Ora   Firma

NOTA BENE una copia del presente modulo, firmato e datato, allegato alle "Informazioni scritte per il Paziente" dovrà essere consegnata al Partecipante stesso

Modulo informativo e consenso partecipante
Versione 24/2/2020
Ricerca: Supportare l'implementazione e lo sviluppo di centri nascita a conduzione ostetrica in Europa

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Dati demografici del partecipante – Scheda Professionisti

Titolo del progetto di ricerca: Supportare l'implementazione e lo sviluppo di centri nascita a conduzione ostetrica in Europa: come si può sviluppare capacità all'interno dei sistemi sanitari?

ID Participante: ……………………………….

Eta':		Sesso:		F M Other	
Nazionalita':					
Titolo di studio: (diploma, laurea, laurea, master, magistrale ecc.)					
Lavoro attuale:		**Anni di pratica nel corrente ruolo:**		**Anni di pratica in generale:**	
Luogo di lavoro: (fare croce a aggiungere dettagli se indicato)	**Sala parto** (specificare dove)	**Reparto** (specificare quale)	**Territorio** (specificare quale)	**Fisiopatologia della riproduzione**	**Altro** (specificare dove)

Theory, Model, and Framework Comparison and Selection Tool (T-CaST) for Implementation Researchers

See _final page_ for additional information, including the _purpose of the tool_, _how the tool was developed_, and _where you can find theories/models/frameworks_ to use with this tool.****

Instructions:

1. Complete Table 1 with information about your implementation project
2. Complete Table 2 to evaluate the fit of one or more theory/model/framework (TMF) to your project. The tool can be used to evaluate, assess gaps, and/or identify opportunities to combine TMFs.
   - Step 1: In column 1, select the characteristics that are relevant to your project.
   - Step 2: Note potential TMF(s) at the top of the third and/or fifth columns
   - Step 3: For each selected characteristic, rate the fit of the potential TMF to your project, and include notes that explain your score.
     - 0 = Poor fit (TMF does not fit project along this characteristic)
     - 1 = Moderate fit (TMF somewhat fits project along this characteristic)
     - 2 = Good fit (TMF fits project well along this characteristic)
   - Step 4 (Optional): Calculate average score in final row, and use to assess fit of theory to particular project. If multiple team members are completing the tool, consider averaging scores across team members.
   - Step 5: Repeat as needed with alternative TMFs.
   - Step 6: In the action section, describe how you will apply the information from the completed tool to your project.

Table 1: Project information

Project Title:	
Supporting the implementation and scaling-up of MUs in Europe: how can capacity in the maternity workforce be developed?	
Research Questions:	**Aims:**
How can we assess and implement the organisational, cultural and professional readiness of a new midwifery unit in a European context?	The primary aim of the research project will be to assess and implement the organisational, cultural and professional readiness of a new midwifery unit in a European context. This part will include developing an assessment tool for
Study Design: Mix-methods study	**Constructs:**

Theory, Model, and Framework Comparison and Selection Tool (T-CaST) for Implementation Researchers

Data Collection: Qualitative (surveys, focus groups, observation, and interviews) Quantitative (routine data collection of maternity setting)	Analysis Plan:

Table 2: Theory Evaluation

Select to Include	Theory / Model / Framework (TMF) Characteristic	TMF 1: Knowledge-to-Action		TMF 2: Quality Improvement Framework	
		Score (0,1,2)	Notes	Score (0,1,2)	Notes
	1. Usability				
✔	a. TMF includes relevant constructs (e.g., self-efficacy; climate)	1	No explicit constructs but stages of the implementation process	1	No explicit constructs but stages of the implementation process
✔	b. Key stakeholders (e.g., researchers; clinicians; funders) are able to understand, apply, and operationalize TMF.	2		2	
✔	c. TMF has a clear and useful figure depicting included constructs and relationships among them.	2		2	
✔	d. TMF provides a step-by-step approach for applying it.	1	A more fluid and dynamic approach suggested (not step by step)	2	
✔	e. TMF provides methods for promoting implementation in practice.	2		2	
✔	f. TMF provides an explanation of how included constructs influence implementation and/or each other.	0	no explanation	2	
	2. Testability				
	a. TMF proposes testable hypotheses.				Not necessary for this project as this is a niche field in midwifery
	b. TMF includes meaningful, face-valid explanations of proposed relationships.				Same as per point 2a.
✔	c. TMF contributes to an evidence base and/or theory development because it has been used in empirical studies.	2	Based on a review of 31 planned action theories	2	Based on a review of 25 implementation frameworks
	3. Applicability				
	a. TMF focuses on a relevant implementation outcome (e.g., fidelity; acceptability).				Not needed for this project to focus on just one impl outcome.

2

Select to Include	Theory / Model / Framework (TMF) Characteristic	TMF 1: Score (0,1,2)	TMF 1: Notes	TMF 2: Score (0,1,2)	TMF 2: Notes
✔	b. A particular method (e.g., interviews; surveys; focus groups; chart review) can be used with TMF.	0	Not explicitly stated	2	TMF questions could be used for interviews, FG and other methods
✔	c. TMF addresses a relevant analytic level (e.g., individual; organizational; community).	0	No distinction of different analytic level	2	Questions specific for different analytical level
	d. TMF has been used in a relevant population (e.g., children; adults with serious mental illness) and/or conditions (e.g., attention deficit hyperactivity disorder; cancer).				Not known previous use of these TMFs for the same population of this study
	e. TMF is generalizable to other disciplines (e.g., education; health services; social work), settings (e.g., schools; hospitals; community-based organizations), and/or populations (e.g., children; adults with serious mental illness).				TMF use will be very specific for this project (maternity and midwifery units)
	4. Acceptability				
✔	a. TMF is familiar to key stakeholders (e.g., researchers; scholars; clinicians; funders).	0	Not familiar to stakeholders in healthcare	1	Familiar to scholars, commissioners and funders
	b. TMF comes from a particular discipline (e.g., education; health services; social work).				Not needed.
Scoring (Optional)	Total Score:	10		18	
	Number of Characteristics:				
	Average Score (Total Score / Number of Characteristics):				
	Average Score Among Team:				
Action	**How will you apply the information from this tool?** *(e.g., Which TMF(s) did you select? What is your rationale for selecting the TMF(s)? If applicable, how will you combine multiple TMFs?)* Rationale for selection of KTA framework and QIF framework explained in the thesis chapter. From the assessment with this tool, It seems more appropriate to use the QIF framework for the purpose of this research project. The QIF framework will be used alongside the CFIR framework. The former will guide and inform the implementation process and stages whilst the latter will provide evidence-based support during data analysis.				

3

Additional Information

What is the purpose of this tool?

Implementation researchers can use this tool to assess the utilization of one or more theory, model, or framework (TMF) in a particular project. More specifically, the tool can be used for:

- Considering the characteristics of TMFs most important for the project
- Presenting characteristics to stakeholders to identify their priorities
- Evaluating the ways in which one or more TMF meets the needs of the project
- Comparing potential TMFs to select the best fit for the project
- Identifying ways in which multiple TMFs can complement one another to address all important criteria
- Communicating to various stakeholders reasons why a TMF was selected
- Increasing transparency related to TMF selection and use in reporting (manuscripts, grants, etc.)

How was this tool developed?

This tool was developed by the Dissemination and Implementation Methods Unit at the North Carolina Translational and Clinical Sciences Institute (NC TraCS) at the University of North Carolina at Chapel Hill under the leadership of Principal Investigator Sarah A. Birken. You can read more about the process for criteria selection and tool development at https://rdcu.be/bbTLQ.

Where can I find TMFs to use with this tool?

An inventory of D&I TMFs can be found at http://www.dissemination-implementation.org.

Please note that this resource is likely not inclusive of all TMFs that can be used in implementation research and practice. For example, Strifler et al. (2018) identified 159 TMFs used in implementation studies.

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Appendix 6. Interview and focus group guide

1. Could you tell me which is the first word that comes to your mind if I tell you 'midwifery unit'?

   • PROMPT Can you explain me why?

2. Could you tell me what do you think a midwifery unit is?

3. Do you know if there are midwifery units in Italy?

   • PROMPT Do you know where they are in Italy?

   • PROMPT Do you know any other international context where they are established?

4. Do you know the evidence of any guidelines related to MUs? If so, can you name them?

   • PROMPT Do you think they help the implementation of midwifery led care?

5. Have you ever had experiences of working in a midwifery unit or in a similar model?

   • PROMPT If so, how was your experience?

   • PROMPT if not, are you aware of any similar context in Tuscany/Italy?

6. Do you think that this model of care is implementable in [local hospital]?

   • PROMPT Can you explain me why?

7. What are the main barriers of this implementation in your opinion?

   • PROMPT Can you explain me why?

8. What are the main facilitators of this implementation in your opinion?

   • PROMPT Can you explain me why?

9. What do you feel would help to facilitate the transition from the way the maternity unit currently is and works to an integrated model with a MU?

10. Is there anything else that you would like to add and that you think would be relevant to the research project?

Service Users' Survey

Qualtrics Extract of English Translation

Intro

The [Name of the local hospital] part of the Azienda USL Toscana Sud Est
and City, University of London are delighted to present you this survey which was prepared to
collect the opinion of the local population about the project of opening a midwifery unit for
physiological birth in [Name of local town].

A midwifery unit is a location offering maternity care to healthy women with straightforward
pregnancies in which midwives take primary professional responsibility for the care. Even if you
have not had the experience of physiological pregnancy or birth, *we would like to hear from
you about this service reconfiguration*.

The questions will **only take 10 minutes,** you will have a month to fill it out and you can
continue later as long as you use the same device (computer or mobile) and browser (Chrome,
Explorer, Modzilla etc.). Responses will be treated **confidentially and anonymised**.

Page Break

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CNSNS

A copy of the information sheet to take part in this study was sent in the invitation email and can be found at this link as a reference Informativa progetto ricerca utenza15nov2021

Proceeding in the survey, you are agreeing to take part in the research project explained in the information sheet provided. Participation is voluntary and can be withdrawn by contacting the researcher (laura.batinelli@city.ac.uk). The data will be managed in accordance with EU Regulation 2016/679 of the European Parliament and Council concerning the protection of individuals with regard to the data management of personal data and the Privacy Policy.

○ I confirm that I want to participate in this research project

End of Block: Intro

Start of Block: Blocco 1

D1 1.   Why did you choose to give birth in [Name of local hospital]? Please select all relevant options.

☐   I trust the maternity team

☐   I had positive experiences in the past

☐   It was the only option in the area

☐   It was suggested to me by family/friends

☐   I find it appropriate to handle complex cases

☐   To be cared by my obstetrician/midwife

☐   It was suggested by my obstetrician/midwife

☐   The labour started while I was in the area

☐   Other ... (8) _____

D2 2. What pathway of care did you choose <u>in pregnancy</u>?

○ Public healthcare

○ Private service

○ Both public and private services

○ None

D3 3. Where did you have your antenatal appointments <u>in pregnancy</u>?

☐ Hospital of [Name of local hospital]

☐ Community services in [Name of local town]

☐ Community healthcare service in the province 1

☐ Community healthcare service in the province 2

☐ Community healthcare service in the province 3

☐ Community healthcare service in the province 4

☐ Privately

☐ Other ... _____

D4 4.   How satisfied overall are you of the maternity services for pregnancy, birth and the postnatal period in [Name of local hospital] during your last maternity experience?
Move the slider to the degree of satisfaction (from 1 to 10) that you deem appropriate for each moment.

	0 1 2 3 4 5 6 7 8 9 10
Pregnancy ()	▬▬▬▬▬█▬▬▬
Birth ()	▬▬▬▬▬█▬▬▬
Postpartum ()	▬▬▬▬▬█▬▬▬

D5 5.   Could you briefly explain the reason for selecting a number below 6?

_____

End of Block: Blocco 1

Start of Block: Blocco 2

D6 6. Do you know or have you ever heard of a midwifery unit for physiological /natural birth?

○ Yes

○ No

○ Maybe, I am not sure

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D7 7. What do you personally think of the idea of integrating this model of care in [Name of local hospital] inside the hospital and on the same floor as the general obstetric unit?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D8 8. In case of a future low risk pregnancy, would you be interested in giving birth in a midwifery unit for physiological birth inside the hospital and near the obstetric unit at [Name of local hospital]?

○ Yes

○ Maybe

○ No

D9 9. Could you briefly explain the reason to your previous answer?

_____

End of Block: Blocco 2

Start of Block: Blocco 3

D10 10. Based on your knowledge, in case of a pregnancy without medical complications or risks, who is the professional responsible for risk assessment at each visit?

○ Obstetrician

○ Midwife

○ Obstetrician and midwife jointly

D11 11. In your opinion, the terms "low, medium and high risk" are appropriate and understandable to explain the different maternity care pathways offered? Please add the reason in case you choose "No" or "Not entirely".

○ Yes

○ No because... _____

○ Not entirely because... _____

D12 12. What do you think of calling these pathways of care with names (for example flowers name like "la sala tulipano") to avoid focusing attention on risk?

○ I agree

○ Neither agree nor disagree

○ I disagree

○ I do not know

D13 13. Could you briefly explain the reason to your previous answer?

_____

End of Block: Blocco 3

Start of Block: Blocco 4

D14 14. What do you think of the idea of having the **same midwife** who took care of you in pregnancy coming to the hospital with you at the time of birth?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D15 15. What do you think of the idea of providing women with a telephone number to ring to the maternity services in order to be able speak to a professional in case of early labour, spontaneous rupture of membranes (waters break), need of support etc. instead of having to go to the hospital?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D16 16. What do you think of the following ideas for **pain relief options** in the birth centre for physiological birth? Please express your interest of the following options from 0 (not interested at all) to 10 (totally interested). You can not answer if you do not know the technique mentioned.

0 1 2 3 4 5 6 7 8 9 10

Aromatherapy ()	
Acupressure ()	
Water immersion (delivery tub for labor and / or delivery) ()	
Gas (nitrous oxide) ()	
TENS machine (electrostimulation to be applied in the lumbar part of the back) ()	
Rebozo (mexican massage technique with a cloth) ()	
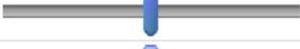
D17 17.In a midwifery unit led by midwives there is the possibility that a partner or a family member can remain with you and stay overnight with you if you wish, with a double bed provided in a home-like environment. What would you think of the possibility of having this person in the room with you at all stages of labour, birth and postpartum?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D18 18. What would you think of the idea of being able to have other children /family members in the room with you during the postpartum period?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D19 19. In this model of care, the visit of the neonatologist is scheduled within 24 hours directly in your room to guarantee continuity of contact between mother and newborn, unless there are other needs. What would you think of this option?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

End of Block: Blocco 5

Start of Block: Blocco 6

D20 20. What would you think of the idea of having a home visit by a professional postnatally?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D21 21. What would you think of the possibility of being discharged home earlier (before 72 hours) provided the right level of care and home support was given from the midwife in the community?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D22 22. What do you think is the most useful way for providing postpartum care by the midwife?

○ Planned visits in the community centre

○ Accessing the community centre whenever needed

○ Home visits

○ A mix of these options

○ Other ... _____

End of Block: Blocco 6

Start of Block: Blocco 7

D23 23. What do you think of the idea of including some women representatives of the local population during multidisciplinary meetings with the maternity team for planning the midwifery unit led by midwives?

○ I am interested

○ Neither interested nor not interested

○ I am not interested

○ I do not know

D24 24. The maternity team proposed the following ideas to engage, inform and train service users about the midwifery unit. How useful do you think the following ideas are? Select the degree of usefulness for each option and if you have other ideas add them in the "other" box.

	0 1 2 3 4 5 6 7 8 9 10
Informative booklet about midwifery led care ()	
Further information on midwifery led care during antenatal classes ()	
Posters and videos shown in the community and in the hospital ()	
Engage general practitioners, obstetricians and paediatricians regarding the birth centre initiative to ensure that they promote it to women ()	
Newsletter/emails/regular communications on the progress of the project ()	
Social media ()	
Other ... ()	
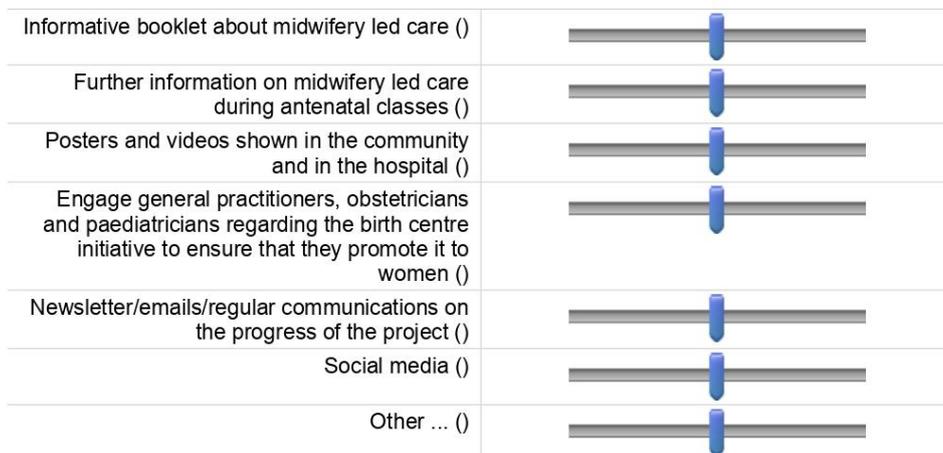
D25 25. How do you think the communication aspect between the maternity team and service users can be improved?

_____

Final
Now the last two questions about the name to be identified for this midwifery unit.

D27 27. What name do you find most suitable for a midwifery unit led by midwives in [Name of local hospital]? Rate each of the following options from 1 to 10.

	0	1	2	3	4	5	6	7	8	9	10
Centro nascita a conduzione ostetrica (Birth centre midwifery-led)											
Unita funzionale per il basso rischio ostetrico (BRO) (Unit for low risk pregnancies)											
Birth house											
A proper noun (like for example [name of regional MU])											

D28 Final Can you think of any another proper name that might be suitable? If so please add it here.

_____

End of Block: Final question

RESEARCH   **Open Access**

What are the strategies for implementing primary care models in maternity? A systematic review on midwifery units

Laura Batinelli[1*], Ellen Thaels[2], Nathalie Leister[1], Christine McCourt[1], Manila Bonciani[3] and
Lucia Rocca-Ihenacho[1]

Abstract

Background: Midwifery Units (MUs) are associated with optimal perinatal outcomes, improved service users' and professionals' satisfaction as well as being the most cost-effective option. However, they still do not represent the mainstream option of maternity care in many countries. Understanding effective strategies to integrate this model of care into maternity services could support and inform the MU implementation process that many countries and regions still need to approach.

Methods: A systematic search and screening of qualitative and quantitative research about implementation of new MUs was conducted (Prospero protocol reference: CRD42019141443) using PRISMA guidelines. Included articles were appraised using the CASP checklist. A meta-synthesis approach to analysis was used. No exclusion criteria for time or context were applied to ensure inclusion of different implementation attempts even under different historical and social circumstances. A sensitivity analysis was conducted to reflect the major contribution of higher quality studies.

Results: From 1037 initial citations, twelve studies were identified for inclusion in this review after a screening process. The synthesis highlighted two broad categories: implementation readiness and strategies used. The first included aspects related to cultural, organisational and professional levels of the local context whilst the latter synthe-sised the main actions and key points identified in the included studies when implementing MUs. A logic model was created to synthesise and visually present the findings.

Conclusions: The studies selected were from a range of settings and time periods and used varying strategies. Nonetheless, consistencies were found across different implementation processes. These findings can be used in the systematic scaling up of MUs and can help in addressing barriers at system, service and individual levels. All three levels need to be addressed when implementing this model of care.

Keywords: Midwifery units, Midwifery led care, Birth centres, Midwifery centres, Primary care models, Implementation, Innovation, Adoption, Metasynthesis, Qualitative research

Background

A growing body of evidence has identified the impact and cost-effectiveness of midwifery models of care in improving maternal and newborn health [1, 2]. The Lancet series on Midwifery highlighted the central role of midwifery care models in preventing the "too much too soon and too little too late" phenomenon that is affecting maternal

*Correspondence: laura.batinelli@city.ac.uk
[1] Centre for Maternal and Child Health Research, School of Health Sciences, City, University of London, 1 Myddelton Street, London EC1R 1UW, UK
Full list of author information is available at the end of the article

and newborn health worldwide, both in low- and middle-income countries (LMIC) and in high income countries (HIC) [3, 4].

International studies have demonstrated that for healthy women with uncomplicated pregnancies, midwifery units (MUs) are associated with better maternal and similar perinatal outcomes compared to obstetric units (OUs) while being cost-effective and associated with high satisfaction amongst service users and midwives [5–7]. MUs were mapped in over 56 LMIC and HIC countries on the Goodbirth.net platform [8]. The Midwifery Unit Standards for Europe (2018) and the commentary by Stevens and Alonso (2020) helped in reaching consensus of the definition and the standards for MUs in different international contexts [9, 10]. The MU standards for Europe defined a midwifery unit as "*a location offering maternity care to healthy women with straightforward pregnancies in which midwives take primary professional responsibility for care. Midwifery units may be located away from (Freestanding) or adjacent to (Alongside) an obstetric service*" [9]. Stevens and Alonso (2020) expanded this definition for LMIC to also include sexual and reproductive health as part of the main midwifery centre activities [10].

Walsh et al. (2020) recently published a study about which factors affect the implementation and improvement of MUs in England and highlighted an underutilisation of this model of care even in a country with a long history of policy and guidelines supporting MUs [11]. However, there is still little international literature on how to implement MUs in contexts in which the OUs represent the main form of care provision.

The main aim of this review is to identify and synthesise existing knowledge on how to support the implementation of new MUs internationally, to fill the evidence to practice gap and to learn from existing evidence on how to support this change of the maternity care provision in the real world. The research question chosen for this review informed by a scoping search was: "*What are the strategies used for implementing new midwifery units internationally?*". This review is the first of its kind.

Methods

The "*Guidance on choosing qualitative evidence synthesis methods for use in health technology assessments of complex interventions*" informed our methodology decision [12]. The following points for each type of methodology were considered to decide which type of review to conduct: type of review question, epistemology, timeframe, resources and team expertise. The thematic synthesis method by Thomas & Harden (2008) was selected [13]. This method was developed to address review questions focused on need, acceptability and appropriateness of

intervention which suits well the aims and nature of the review question of this review [13, 14].

This review was not focused on clinical outcomes of MUs. Instead it aimed to understand implementation related outcomes like acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability, as defined by the taxonomy of Proctor et al. (2011) [15].

This review was registered on the International Prospective Register of Systematic Reviews (PROSPERO) on the 18th of October of 2019 with registration number: CRD42019141443.

To conduct the search and screening, the PRISMA guidelines (Preferred Reporting Items for Systematic reviews and Meta-Analyses) were used [16] and the following inclusion and exclusion criteria were agreed (see Table 1).

Systematic search and screening process

The systematic search was conducted between December 2020 and April 2021. Databases searched for this review were: Ebsco Databases (Medline, CINAHL, SocINDEX), Ovid databases (Embase, Global Health, Maternity and Infant Care MIDIRS, Ovid Nursing, Ovid Emcare), Scopus and NICE database. Grey literature was searched via OpenGrey, Google Scholar and ProQuest Dissertation and Theses.

The final strategy applied to each database is reported in Table 2.

The research team added some key relevant articles to the search on the databases and conducted a citation track referencing. After de-duplication, the papers identified were saved and divided in three sub-folders so that LB, ET and NL could run a screening by title and abstract for relevance and against pre-determined inclusion and exclusion criteria. The team met regularly to discuss papers and reach agreement in the screening. Any cases where agreement could not be reached were discussed with CMcC (author and senior researcher). This process was then replicated by reading full texts of articles selected as potentially relevant.

Search results

After a systematic search, a total of 1037 articles were identified and 26 papers were added after citation track referencing, ending up with the identification of 1063 articles. After de-duplication, 691 papers were screened as shown in Fig. 1.

Of the sixty-nine studies selected for full text screening, only twelve studies were primary research and eligible for the aims for this review. One good quality study (10/10) about AMUs in England was included

Table 1 Inclusion and exclusion criteria

	Inclusion	Exclusion
Participants	All stakeholders involved in implementing midwifery units: maternity teams, health institutions, professionals, service users	Models of care not specific to midwifery, birth settings managed or led by obstetricians or other healthcare professionals other than midwives, home births
Phenomenon of interest	The process of implementation of a new MU which could be successful or not. For successful implementation we mean the establishment of a new MU after a process of change in the maternity care setting.	Focus on improvements of existing MUs Focus just on clinical outcomes or technical quality of care. Focus on specific issue (e.g. smoking cessation, vaginal birth after caesarean - VBAC).
Outcomes	Implementation outcomes like acceptability, adoption, appropriateness, costs, feasibility, fidelity, penetration and sustainability.	No focus or substantial data on questions relating to implementation, sustaining and uptake or scaling up.
Study design	All designs including action research, grounded theory, ethnography, mixed methods studies that include qualitative data collection and analysis.	No restrictions on the types of study design were applied.
Study focus	Studies will need to cover aspects related to implementation outcomes in the data collection and analysis with particular attention to any relevant aspect or strategy related to the establishment of a new MU.	Clinical or technical quality of care. Focus on specific health issue (e.g. smoking cessation, VBAC).
Setting	Both alongside (AMU) and freestanding (FMU) midwifery units. Birthing rooms physically/organisationally separated from the main OU. Maternity systems willing to/in the process of implementing a new MU. Private and public services All countries	None
Time period	No time restriction	
Language	English, Italian, Dutch, Portuguese, Spanish, French	Other languages that the team would not be able to translate adequately.
Publication type	Peer reviewed articles Dissertation and theses Research reports	Any piece of research which cannot be peer reviewed by the research team (books, opinion pieces, commentaries, diaries etc.)

**Table 2** Search strategy modified the terms

Search terms:	Order	Search strings
Implementation	1	Mesh terms for implementation
	2	Keyword search: implementation OR implement* OR "knowledge translation" OR innovation OR utili#ation OR "scale up" OR feasab* OR sustainab* OR "service improvement" OR barrier* OR facilitator* OR enabler* OR adopt* OR diffusion OR establish* OR open* OR transition OR provision OR embed* OR integrat* OR planning OR preparation OR "implement* strategy*" OR promot*
	3	1 OR 2
Midwifery units	4	Mesh terms for midwifery units
	5	Keyword search: "midwifery unit" OR "midwi* led birth* cent*" OR "birth* unit" OR "birth* cent*" OR "birth setting" OR "low risk birth* cent*" or "midwi* unit "OR "midwi* led unit" OR "low-risk birth* room*" or "midwife-led room* "OR "midwi* cent* OR "low-risk birth* cent*" OR "homely birthplace" OR "homely birth place" OR "homely birth* room*" OR "normal birth* unit"
	6	4 OR 5
Full search	7	3 AND 6

twice [17, 18] comprising a peer-reviewed journal article and a more in-depth report rich in useful data. In Table 3, they are listed as 9A and 9B to clarify this. The Chinese and the Brazilian case studies had two papers each related to different aspects of the implementation process. Therefore, we listed them as 1A/1B for the Chinese and 4A/4B for the Brazilian (see Table 3). The quality of the studies identified was overall good with scores above 6/10 and five studies scored 10.

Quality appraisal

Two independent reviewers (LB and ET) carried out critical appraisal using the CASP Critical Appraisal Skills Programme Qualitative Research Checklist (CASP) [26] and any differences at any stage were discussed with a more senior team member (CMcC). A simple scoring system was added to this process to assist in summarising quality level. Each study was rated zero or one for each item of the CASP question if it was fulfilling the requirement or not (1 = yes, 0 = no). Every time that the score was "0" the reason for that score was reported. The sum of all CASP questions

Fig. 1 Screening process using PRISMA flowchart
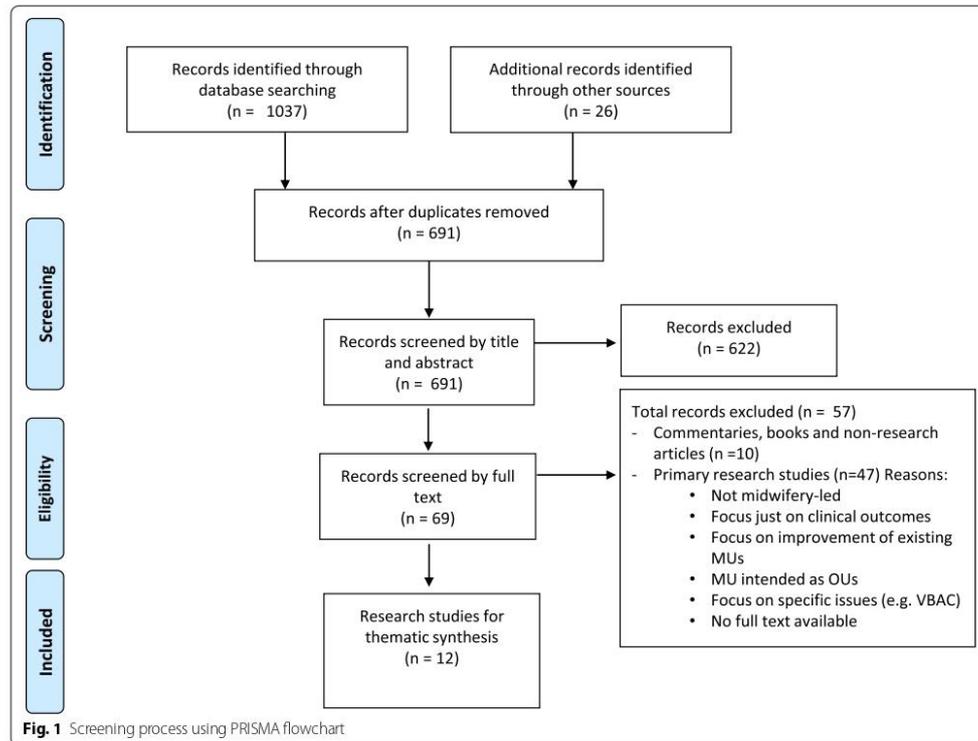
constitutes the quality score of the study (1 to 10). During the writing of the synthesis, the team used a sensitivity analysis and more importance was given to the higher quality articles.

Data analysis and synthesis

The articles selected for the analysis were imported into NVivo 12 software for data analysis. Data in the abstract, findings and discussion sections were analysed thematically using a three-stage process approach: coded line-by-line, organised into categories to capture descriptive themes and analytical themes were then developed to answer the review questions [13].

Descriptive findings

The studies selected were conducted in England, Brazil, China, Canada, Iran and United States (US). Seven studies were published between 2010 and 2020 when more substantial evidence on outcomes of MUs was available,

five studies took place between 1991 and 2010. Healthcare systems in different contexts and time varied quite significantly amongst the studies. A public system with universal coverage was present in countries like England and Canada whilst a mixed system with public governmental system, private sector, and NGOs was present in Brazil and China, Iran, and US.

Some studies were not purely focused on the implementation process of a new MU [11, 17, 18, 25, 27], but had wider aims such as mapping MUs nationally or investigating how AMUs were organised. However, the team could identify interesting and relevant aspects related to implementation of new MUs in these studies and therefore included them in the analysis.

This study aimed to analyse quantitative and qualitative data however only three studies included a quantitative component in their research design [24, 25, 27]. Two of them [24, 27] used quantitative data to describe the use of the MU after implementation (i.e. number of births per year) and not the implementation process therefore

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Table 3 Characteristics of included studies

N	Author, Year	Country	Study aims	Design	Participants	Setting and data collected	Findings	Quality
1a	Cheung NF et al. 2009 [19]	China	To describe the preparations for setting up a midwife-led normal birth unit which was based on literature and practice review	Action research with a five steps cycle plus a literature review	8 midwifery team leaders 5 researchers	A highly medicalised maternity department in a Chinese hospital with annual birth rate of over a 3000. The MU was allocated two birthing rooms. The researchers analysed data from meetings, field notes and midwifery training course.	The findings are divided into seven sections: definition, negotiations, accommodation, specific practices, the philosophy of the homely birthplace, policy development, and developing local solutions for local aspirations.	8
1b	Mander R et al. 2009	China	To explore issues arising during preliminary stages of the action research project to consider the feasibility and the effects of a MU on midwives and women.	Action research using a qualitative descriptive approach	Non-defined number of stakeholders including midwifery staff, managers, university staff and researchers.	(*same setting as above*) Data were collected at meetings, by non-participant observation and by face-to-face semi-structured interviews.	MU care may be feasible after the analysis of the early stages of implementation.	8
2	Mackey MC et al.1991 [20]	US	To report on how the idea of birthing room was initiated by nurses and the 8 strategies that led to the implementation of it.	Structured interviews	4 registered nurses with Master's degree	Four private hospitals located in the Chicago area. One-hour in-depth interviews.	Eight strategies to be used jointly to open new birthing rooms by nurses' midwives	7
3	Moudi Z et al. 2013	Iran	To assess 10 years of experience of the first Safe Delivery Posts (SDPs) established in Zahedan, Iran and to examine the reasons why women chose to give birth there.	A mixed-methods research	19 service users in the postnatal period	The two SDPs in Zahedan, the most populous city in the province. Women were selected from two Safe Delivery Posts in Zahedan city in southeast Iran.	Implementing a model of midwifery care that offers the benefits of modern medical care and meets the needs of the local population is feasible and sustainable. This model of care reduces the cost of giving birth and ensures equitable access to care among vulnerable groups in Zahedan.	9

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Table 3 (continued)

N	Author, Year	Country	Study aims	Design	Participants	Setting and data collected	Findings	Quality
4a	Pereira AL and Moura MA 2009 [21]	Brazil	To identify the determinants of the process of implementing the Birth Center and analyse the influence that hegemonic and counter-hegemonic groups have on that process	Dialectic qualitative research	4 commissioners 11 technical administrative professionals	Casa de Parto in Rio de Janeiro. Individual semi-structured interviews.	During the establishment process, conservative and transformative forces of the hegemonic childbirth care model clashed in the governmental and civil spheres. Legal and political dispute in the establishment process of the Casa de Parto highlighted the importance of organized social movements, especially the women's movement.	7
4b	Progianti JM et al. 2013 [22]	Brazil	To discuss how the Brazilian nurse midwives trained in the Japanese birthing centres helped to implement the FMU in Brazil.	Socio-historical study with qualitative approach	1 Director of nursing 1 Nurse midwife 1 Physician 1 Former nursing director	Casa de Parto in Rio De Janeiro. Written and oral documents. Semi-structured interviews and report of the exchange experience. Data triangulation with policy and background documents.	The exchange programme enabled the Brazilian midwives to implement the first MU in Rio de Janeiro and added a larger volume of capital to their professional habitus.	9
5	Reszel J et al. 2018 [23]	Canada	To obtain the perspectives of health care providers and managerial staff about the integration of the new FMUs one year after implementation	Qualitative descriptive approach	24 amongst professionals (18) and managerial staff (6)	Ontario where homebirth and birth in OU were the only two birth settings for women prior the implementation of the two FMUs. Data was collected via 4 focus groups and 1 interview.	The collaborative approach for the planning and implementation of the MUs was a key factor in the successful integration and the positive experience of service users.	10
6	Walton et al. 2005 [24]	England	To explore organisational factors, midwives role, barriers and facilitators of the change process and training needs for midwives	Action research	Non-defined number of stakeholders including midwives, managers and medical staff.	Inner London teaching hospital that take care of over 4400 women a year. Data from meetings, educational workshops, feedback forms and audit of the 2 birthing rooms	The lack of support from medical staff, the conflicting priorities and the dominance of the medical model of care made the project not feasible and the team abandoned the idea of the MU after this pilot.	6

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Table 3 (continued)

N	Author, Year	Country	Study aims	Design	Participants	Setting and data collected	Findings	Quality
7	Walsh et al. 2018 [25]	England	To describe the configuration of midwifery units, both alongside & freestanding, and obstetric units in England	National survey	Heads of Midwifery in English Maternity Services	National Health Service (NHS) in England. Descriptive statistics of AMUs, FMUs and OUs and their annual births/year in English Maternity Services	Number of MUs and births in MUs in England increased after the publication of NICE guidelines (mostly AMUs). Significant difference in terms of utilisation of the MU and this suggest that some are underutilised.	10
8	Walsh et al. 2020 [14]	England	To identify factors influencing the provision, utilisation and sustainability of MUs in England	Qualitative study	57 Obstetric, midwifery and neonatal clinical leaders; managers; service user representatives and commissioners 60 midwives 52 service users	Setting England. Data collected: first, MU access and utilisation across England was mapped; second, local media coverage of the closure of the free-standing midwifery units (FMUs) were analysed; third, case studies were undertaken in six sites to explore the barriers and facilitators that have an impact on the development of MUs; and fourth, by convening a stakeholder workshop.	Most managers and clinicians did not regard their MU provision as being as important as their OU. The analysis illuminates how implementation of complex interventions in health services is influenced by a range of factors including the medicalisation of childbirth, perceived financial constraints, lack of leadership and institutional norms protecting the status quo.	10
9a	McCourt et al. 2018 [26]	England	To investigate how AMUs are organised, staffed and managed, the experiences of women, and maternity staff including those who work in AMUs and in adjacent obstetric units. Some MUs were already established, other just recently being implemented.	Organisational ethnography approach	35 managers and key stakeholders 54 professionals 47 service users	Case studies of 4 AMUs in England, selected for maximum variation based on geographical context, length of establishment, size of unit, leadership and physical design. Observations, semi-structured interviews and documentary review were conducted.	Development of AMUs was often opportunistic. Key potential challenges included: boundary work and management; professional issues; developing appropriate staffing models and relationships; midwives' skills and confidence; and information and access for women.	10
9b	McCourt et al. 2014 [18]	England	(same as above)	(same as above)	(same as above)	(same as above)	Same as 9A but explored more in detail.	10

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they were not relevant to the aim of this review. The last one, by Walsh et al. (2018), described the change of the maternity service configuration after the Birthplace study in England and the impact that this had in the adoption of MUs there. Since 2011 and the publication of the NICE guideline 2014 which were recommending for the first time the option of giving birth in a MU to all women with an uncomplicated pregnancy, the number of AMUs increased from 53 to 97 and the FMUs from 58 to 61. The number of Trusts (organisational units within the English National Health Service) without a MU significantly decreased from 75 to 32.

Midwifery was less regulated and less autonomous in countries like China, US and partially in Brazil with higher level of autonomy reported in England and Canada. No information on the status of midwifery was available in the Iranian study [27].

There was variability with the MU model of care within different countries. The common characteristics across all sites were: an intrapartum unit (within the OU, alongside or freestanding but always physically separated from the main OU rooms) staffed by midwives (hospital or community midwives) who worked autonomously providing a midwife-led primary level of care and referring service users to the secondary level of care (in situ or via transfer) when needed.

In most of the studies, participants were mainly professionals, managers and commissioners. Service users were included just in four studies and three of them were based in England.

Synthesis findings

The discussion of the synthesis is presented under two broad categories: readiness (elements found to be important in the local context at the beginning of the implementation process) and strategies (main actions and key points identified in the case studies selected). The first

category is divided into cultural, organisational and professional levels whilst the latter includes four key themes, each of which covers common strategies, barriers and facilitators to the change.

In Fig. 2, a synthesis of the emerging themes are presented in a logic model composed of two main categories: readiness and strategies. This model was created to give a temporal and visual idea of the different role that these themes have during an implementation process. From the initial idea of opening a new MU to the actual adoption of the model a multi-layered change needs to take place.

Readiness
Cultural level - structural issues and perceptions
Structural issues
Codes related to culture and perceptions were ubiquitous across the different articles showing that all participants discussed on some level aspects related to society, the local culture and how this affected the implementation process. Studies took place across seven countries with differing healthcare systems and periods of time when the implementation was attempted, however some consistencies were found.

On a macro-societal level, structural issues highlighted as barriers were related to gendered power dynamics, hierarchy in the health system and the hegemonic production logic in healthcare [11, 17, 18, 21]. For example, in the study by McCourt et al. 2014, professionals described an unbalanced gendered dynamic as a barrier to implementation and to the existence of AMUs [17]. Amongst the different countries, women have different levels of autonomy, respect and rights when it comes to childbirth. The case studies from Brazil, China and Iran discussed the issue of women's rights in childbirth and obstetric violence acknowledging its presence in the respective countries [19, 21,


Fig. 2 Logic model

Readiness

Cultural– Structural issues and perceptions

Organisational – Elements of the local healthcare system

Professional– Recognition of midwives role and scope of practice

Drivers to open the MU

Strategies

– Support training and exposure to the MU model
– Promote collaborative and well integrated working relationships
– Invest in different components of leadership
– Think physical environment

MU

27, 28]. Opening new MUs became an opportunity to tackle this issue and the following quotes from the Iranian study shows how the MU was perceived by service users as valid alternative to avoid such mistreatments:

> "I have insurance. If I had gone to hospital, it would have been free of charge for me, but I didn't. They annoy us in hospital; they examine too much. It's more comfortable here; it's better." Service user, [27], page 1078

The information provided to women about choice of place of birth played a key role in the decision-making process that was often found to be rigid. An example of this was asking service users to decide where to give birth at the very first booking appointment [17, 18] with not many occasions to reconsider their choice. This rigidity was also mentioned in the Chinese studies [19, 28].

The medicalised and industrialised model of care was cited in the English and in the Brazilian studies as a structural problem that can become the key obstacle to implementation [11, 18, 21, 24]. These studies identified that in a system that functions with a hierarchical structure and in terms of efficiency and productivity, the division between the Industrial/Medical model of care of the OU and the Bio-Psycho-Social model of care of the MU [9, 29] could lead to polarisation, with an imbalanced power dynamic.

> "A normatively medical outlook persisted, that located midwifery units as marginal rather than as a core maternity service." Authors, [18] page 18

In this scenario the OU represented the priority of the service and the MU an alternative which could be closed if need be.

Norms and perception of safety

A significant part of participants' quotes was about perceptions of safety. The English studies identified that the MU being co-located in the same building was perceived to be safer than FMUs [11, 17, 18, 25]. This was often mentioned by participants (both professionals and service users) even though it is not supported by existing literature that shows that FMUs are instead associated with better clinical outcomes than AMUs [6, 30].

> "I think majority of women and all my friends will opt for an alongside MU, because most women do want the option of midwifery led but if anything goes wrong they just want to go down that corridor, through that door." Midwifery Manager, [11], page 5

Some professionals also mentioned the idea of feeling safer by having all women in the same place and therefore having greater monitoring (and control) than having them in different locations. This preconception was illustrated in this quote by an English consultant obstetrician:

> "(...) if I were to design a unit I wouldn't split my shop in two different places on the high street. It just doesn't make sense to me. If you have everybody all in one place you don't have those problems. You've got greater monitoring of everything that's going on; you've got greater use of your resources, [it's] more efficient" Consultant obstetrician, [17], page 22

On the other hand, when professionals were educated and had knowledge on the evidence and the impact that a MU might have, there was better integration and working relationships. This seemed to show the importance of information and education of best available and up to date evidence to make stakeholders aware of the impact of MUs on social and clinical outcomes and cost-effectiveness.

In the Iranian case study, choice was often about compromising on what was affordable [27]. It was noted that women often reported perceiving the OU to be safer than the MU because of the availability of medicines and devices. However, they would opt for the MU to access a good level of care by experienced professionals at an affordable price.

> "I thought, childbirth is just childbirth, no matter which place I go to. Why should I go to hospital, where the costs are very high? I didn't have health insurance, and I had to pay all that money in cash (out of pocket). Therefore, I decided to go to the nearest SDP (MU)" Service user, [27], page 1078

The MU constituted the best compromise for that population to gain physical and psychological safety. However, the MU represented also the birthplace option that would allow them to avoid unnecessary medicalisation of childbirth:

> "I love my daughter-in-law very much. Her childbirth was a hard time for me. In hospital, they told me she needed a caesarean, so I took her to the Post (MU). I didn't tell the ladies here (midwives) what I had been told in hospital. And thank God she had a natural delivery." Service user, [27], page 1079

Professional level - recognition of midwives' role and scope of practice

Most studies discussed the importance of a midwifery identity and the role that this profession had in those contexts. Midwifery and midwifery-led care was established with different level of autonomy. England and Canada

had midwives that could practice autonomously in these units [11, 17, 18, 23–25]; Brazilian midwives went to Japan to gain more exposure of the midwifery model of care as they were not used to work with that autonomy [22], whilst China, US and Iran [19, 20, 27, 28] reported not having a well-established and autonomous midwifery workforce in the healthcare system at that time.

Contexts in which midwifery was not established as an autonomous profession seem to struggle more, especially in the first phase of the implementation when the idea needed to be accepted by other stakeholders [19, 20, 22]. In the Chinese case study, the opportunity of implementing a MU was reported to be the means to achieve a proper and recognised professional status [19].

The need of having obstetricians to promote a midwifery led model seemed important in all contexts but particularly so where midwifery was more marginalised in the decision making of the service configuration. However, it could have a 'boomerang' effect in which once the MU is implemented, the obstetric component could claim the leadership. In the American study, for example, marginalisation of the midwifery profession became apparent when nurse midwives who promoted and initiated the project of MUs had to fight with the obstetric component for the recognition and the credit of their actions:

"Although nurses were the initiators of the birthing room (MU) concept and nurses did most of the work towards implementing the concept, there is evidence that physicians are pre-empting the credit. One nurse said, -It's interesting that now the doctors think it's their idea-. Another nurse was concerned that nurses never received credit for changes they had made in her hospital and tried to avoid a repeat of that situation." Authors and nurse midwife quote, [20], page 266

The recognition of midwives' role and scope of practice was needed not just within the organisation and amongst professionals but on a more societal level too. This was not limited to countries where midwives are less autonomous but also to countries like Canada, where professional establishment was relatively autonomous but still recent and small-scale. In this case, the MU became a facilitator for this process of recognition of the midwifery scope of practice and therefore promotion of its role in society:

"Many participants perceived that the birth centers (MUs) have increased the respect and legitimacy of midwifery, both to the public and to other health care professionals, allowing these groups to learn

more about midwifery and ultimately increase visibility and credibility of their education and practice. One paramedic stated, 'It elevated the [midwifery] profession for sure . . . I think just having the facility speaks volumes to the interest, the buy-in, the respect, and the credibility of midwifery." Authors and paramedic's quote, [23], page 5462

Organisational level - elements of the local healthcare system
Cost and financing systems
Study authors reported that the concept of cost effectiveness associated with MUs was not always clear to commissioners, managers and professionals [11, 17, 18]. The concept of MU being "cost-saving" was often mentioned together with the status of financial constraint and the urgent need for healthcare organisations to save money [11, 17–22, 27, 28]:

"Financial constraints within Trusts were often seen as limiting the development of MUs. While economic evaluations suggest the overall economic outcomes of increasing births in MUs is positive, the start- up costs were seen as a barrier, and the longer term savings from lower morbidity in the target population that accrue across the health system were not recognised. In a climate of scarcity, new ways of structuring care must demonstrably save money, or at least, be perceived to, in the short term." Authors, [11], page 7

Studies identified two threads of opinions: one perceived MUs as expensive and unaffordable luxuries, or small and so inefficient [11, 17] and therefore an antithesis to the need of save money of the organisation; the other perceived the cost-saving attribute negatively as if this would necessarily mean a lower quality of care. In Brazil for example, this argument was used by the organisations which were against the promotion of MUs and in favour of a more medicalised approach; they referred to the MU model as "*poor care for the poor*" [21].

Managers, commissioners and professionals' perceptions and willingness to implement the MU was also dependent on the type of healthcare system and commissioning environment of the local context. Where there was a 'payment by results' tariff in which the organisations were paid for the interventions provided, normal births were often seen as a "*loss making activity*" by commissioners and obstetricians [17–19]. In the US, where hospitals were paid by number of births, the strategy used by nurse midwives to convince physicians and commissioners that the MU would attract more women

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to their service was considered one of the most effective approaches [20]. In China, midwives were asked to take more responsibility working in a MU without an economic incentive, they were tempted to prefer working in the OU where for the same salary they had less responsibility [19]. In Iran, where service users had to pay depending on the place of birth they chose (MU or OU attended by professionals or homebirth attended by SBA), the MU offered services which were more affordable to them while ensuring good quality of care.

A financial system that was perceived working better in promoting midwife led provision and normal births was the one based more on assessment of risk level and service users' needs at booking [17, 18]:

> *"Although the commissioning environment and payment tariffs had been described as making normal birth a 'loss-making' (manager XXX) activity, managers and commissioners hoped that the development of a tariff centred more on assessment of women's care needs would help to remove such perverse incentives." Authors [17], page 42*

National guidelines
In all the case studies contexts, giving birth in an institutionalised unit even if outside the main traditional OU was legal and this represented an important first step towards readiness for the change. A clear example of positive impact, as reported in one English study, were the NICE Intrapartum guidelines published in 2014 that were promoting MUs and the possibility for each woman to choose between 4 places of births based on the findings of the Birthplace Study [5, 11, 25, 31].

Similarly, in Canada and Brazil, the new national guideline promoting the MU model of care was reported as a key trigger for an implementation process towards MUs [21–23].

Guidelines also played an important role in professionals' perception of safety and for the collaborative work of the multidisciplinary team [17, 18].

> *"In XXX, for example, managers emphasised the need for obstetric support for normal birth and midwife-led care and saw guidelines as helping to sustain obstetricians' confidence in the alongside unit. It was apparent that obstetricians were more comfortable with midwife-led care away from the obstetric unit if they felt that there was a comprehensive set of guidelines supporting that care that had been agreed across the service. This gave them more confidence that women would be appropriately referred to them for review if medical attention were necessary." Authors, [18], page 18*

Having a national guideline is a first step and a key facilitator for the implementation of these realities to allow local stakeholders starting a conversation around the adoption of the different model.

Local policies
The opportunity for a MU came often from the idea of revising or creating a new local protocol for physiological labour and birth. This promoted integration, as this example from an English study highlights:

> *"Managers and midwives saw the local guidelines for admissions to and transfers from the midwifery unit as protecting a space for physiological birth, as well as a guide and framework for safe practice." Authors, [18], page 18*

On the other hand, attempting an implementation without such local guidelines could jeopardise the whole process leaving space to interpretation, no clear distinction in pathways of care and contamination of practices (as will be further discussed in point 4.2 of this review).

> *"Midwifery units and midwives, as well as the women themselves, were perceived to be vulnerable without such guidelines, which also helped to create and protect a space for supporting physiological birth." Authors, [17], page 25*

When preparing a local protocol for the management and practice in the MU, key topics that needed facing and addressing were the access criteria of the MU and transfer criteria from the MU to the OU.

> *"Prior to the opening of the birth center, we managed collaboratively with our key stakeholders, so we managed with the nurse manager but also some of the physicians, the obstetricians, about developing our current [transport] protocol . . . But it [was] something that we, from scratch, met together collectively, collaboratively to get everyone's approval for the current protocol that we have." Midwife, [23], page 545*

The multidisciplinary exchange in the production of these criteria became an opportunity for collaborative practice and a facilitator to the MU's implementation.

Strategies
Support, training and exposure to the MU model
All studies identified that an appropriate set of knowledge, skills and training was required for midwives to work autonomously, even though midwifery regulations and background of midwives had significant differences from one context to another. Even studies located in

countries where midwives worked more autonomously (England and Canada) reported a lack of confidence in physiological birth among midwives often due to a more predominant obstetric-led practice in the last decades:

> *"Because everyone has worked in such a high-risk environment, you become deskilled to an extent, and feel a bit apprehensive about normal birth... you know, trusting that women can have babies low risk." Focus Group Midwife, [11], page 6*

A good level of knowledge, up to date training and appropriate skills of the midwifery workforce were identified as an important facilitator to develop professionals' confidence in the MU model and for being able to promote it and spread it.

Training
A strategy identified in all studies was supporting staff with training initiatives as an enabler of the change. In some cases, midwives identified their own educational needs prior the implementation of the MU model of care and this helped engaging them in the project and create sense of ownership [19, 22–24]. The autonomy and skills gained via the training helped increasing not just the clinical confidence but also the confidence in the midwifery scope of practice, the vision of the MU and its implementation [22, 23].

Ad hoc and pre-implementation training for midwives was promoted, but also the concept of regular training, the so-called continuous practice development (CPD), was addressed in several studies [11, 17, 18, 23]. Studies highlighted not only its importance to keep professionals' skills up to date but also the need of covering more midwifery topics and move away from the concept that only training on obstetric emergencies needed regular updating:

> *"(...) a number of midwife respondents felt that practicing within them required different skills and a level of confidence, which they were not well prepared for. (...) Midwifery managers and midwives in our study recommended mandatory training in normal birth skills to address this concern." Authors, [11], page 5 and 6*

> *"Every year at our mandatory training, for three days (...) we have skills drills of obstetric emergencies and haemorrhage and eclamptic fits and stuck babies and breech babies and all of that, and I always, and in the feedback I always write, 'Where's our midwifery skills training? You assume everybody is up to speed with physiological third stage and augmenting labour naturally and advice on post-*

dates pregnancy etcetera ... and it's not given much value by the midwives themselves or by the people who train us or by the obstetricians." Midwife, [18], page 15

Several studies described what they termed as *"skills hierarchy"* when planning training for maternity professionals with more attention given to the so called *"high risk skills"* and not on the skill for physiological birth. Instead, the kind of skills reported as prerequisite of working in a MU were often the ones more related to physiological birth and autonomy in decision making [11, 17–19].

Exposure to MU model
In some studies, the importance of exposure to the MU model of care for professionals before the opening of a new MU was also discussed [17–19, 22, 23].

> *"The practical part of the course was held in several institutions. (...) To begin practicing at these Birthing Centers (MUs), the required care for nurse internship at these facilities was addressed. During the internship, it was possible to learn the philosophy and administration of each of the centers. The situations experienced by the nurses reflect the different systems of care in this field that would ultimately influence the professional practice of each one of them upon returning to Brazil." Authors, [22], page 197*

The aspect of the exposure to midwifery models was not limited to other midwives but could be promoted to other maternity professionals and students too. In some contexts, where MUs were not established yet, home birth represented another option to experience midwifery led care [23]. This was important not just for witnessing the model of care but also to gain an insight in each other's role and promote integration amongst the team.

> *"Physician exposure to home birth is associated with more positive attitudes toward home births, highlighting the importance of increased exposure through interprofessional training opportunities in education and practice" Authors, [23], page 547*

In countries where MUs were already established, AMU represented the middle ground to increase exposure to physiological birth to the maternity team and to consolidate autonomous midwifery care for midwives.

> *"Lack of confidence in working with physiological birth was also reported by some hospital-based midwives, and the alongside midwifery unit was seen as a steppingstone to all midwives developing their skills and confidence in midwife-led care" Authors, [18], page 17*

The concept of "*contamination of practice*" was also mentioned in three studies in which rotations of staff or an international exchange were applied hoping to bring back into the OU some of the MU philosophy of care [17, 18, 22].

Promote collaborative and well integrated working relationships

In all case studies, the planning and opening of the MU involved communication, negotiation and coordination between different stakeholders within the same organisation or part of different ones. This highlights the importance of a collaborative approach to the change. When the importance of interdisciplinary work is acknowledged, included in the in-service training and constitutes part of the team vision, this aspect was found to be a significant enabler of the change [17–21, 23–25]. Conversely, the lack of an interprofessional approach could make the MU service isolated and lead to a lack of confidence and trust amongst professionals of the same team [11, 17, 18, 25].

> "*Participants from all 4 hospitals described interprofessional meetings very early in the planning process, ensuring that all voices were considered in the birth center (MU) development.*" Authors, [23], page 544

Establishing a vision amongst the whole maternity team in which the MU is part of the care pathway for uncomplicated pregnancies and all professionals are on board with that seemed to be a key facilitator. Having opportunities to spend time together during training days was highlighted:

> "*Participants gave several examples of interprofessional training opportunities resulting from the opening of the birth centers, including hospital drills, mock EMS (emergency medical service) dispatch calls and transports from the birth centers (MUs), welcoming students from different professions to the centers, and including center tours as part of EMS personnel orientation. These opportunities increased understanding of each other's knowledge, training, and roles, and improved participants' ability to communicate with one another.*" Authors, [23], page 546

This also helped the strategic planning during meetings held to gain support of the managers and organisational leadership.

In more than one occasion the need of "*compromising*" and "*negotiating*" was mentioned when discussing the change [20, 24]. This was, however, most of the times endured by the midwifery component and not by the medical staff:

> "*It appeared that only the nurses gave up some of their plans. Physicians were either for or against a birthing room (MU) in general.*" Authors, [20], page 264

This illuminated an imbalanced power relationship when it comes to planning a change, even towards a model that is midwifery-led.

Professional relationships

The opening of a new midwifery led setting may create a separation amongst midwives and polarisation of the work. This could lead to the scenario in which midwives might be 'othering' colleagues for working in the other setting or for being either too medicalised or too pro-physiology. This nourished the "*them and us*" culture and constituted a main barrier to the integration of the maternity team.

> "*Tensions identified among staff were mostly between midwives working in different areas, particularly alongside midwifery units and obstetric units, rather than between obstetricians and midwives.*" Authors, [18], page 26

These tensions were noted and voiced not just by midwives but by managers and service users too who perceived these as potentially detrimental to the care provided [18, 20].

Rapport with obstetricians varied across the different case studies and it seemed to be related to how well midwifery led models of care were already established in the respective context. In the more recent English studies, obstetricians were overall in favour of the idea of a new MU [17], whereas in the Brazilian study a great deal of tension was reported with the medical corporation, which actively opposed the initiative of the new MU [21].

Across the studies, support from the obstetric component (whether active or passive) was found to be an important, and even fundamental, facilitator to the implementation of new MUs.

> "*In fact, unless chief obstetricians positively sanctioned the idea, success would have been impossible. The involvement of the chiefs ranges from strong support for the idea to passivity that allowed nurses to make the idea reality.*" Authors, [20], page 263

> "*In the light of apparent tensions between midwives and doctors voiced in the NBSG (Normal Birth Strategy Group) and because communication with doctors was proving difficult a new attempt was*

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made to gain some insight into the views and opinions of doctors. Initially doctors had not been considered primary stakeholders in midwifery-led care but as the project progressed it became clear that their cooperation in moving the project forward was fundamental." Authors, [24], page 754

This seemed to be because midwives often need medical support to be enabled to apply changes and improvements to the service. As mentioned in theme one, gendered dynamics and the hierarchical configuration of the healthcare system play a significant part in this.

Integration within the service

On a similar note, when discussing the importance of a multi-layered change, the concept of integration was described as an essential feature. With the term *"integration"* studies referred to the collaboration on an organisational level between different departments of the maternity service and on a professional level between different team members.

Sometimes, the change towards a MU model of care became a useful opportunity to reflect and improve integration in the maternity services:

> *"Participants described the planning, implementation, and monitoring of the birth centers as a motivating force that improved interprofessional practice between different stakeholders, including nurses, physicians, midwives, paramedics, administrators, and the regional health network." Authors, [23], page 546*

When planning the implementation of a new MU, there should be awareness that adding a new branch of the service to the current maternity layout may create, especially in the first phase, disjuncture and tensions amongst the professional team [18]. Some initiatives to overcome this barrier were mentioned: planned rotations of staff, mentoring for midwives who are less confident and promotion of case-loading models [17, 18].

Another key topic that could play the role of a barrier was the staffing level. Shortage of staff experienced was due to either a permanent lack of appropriate recruitment of midwives for the MU team, or occasional due to the *"pulling away"* of staff during shifts who were meant to work in the MU but had to cover shortage of staff in other departments like the OU [11, 17–19, 25]. The staff shortage had implications even in the service users' perception of the service:

> *"A problem highlighted during the data collection relates to a perceived shortage of staff. This has particularly serious implications for women likely to give birth at night." Authors, [28], page 525*

Factors that could help developing and planning a functional staffing model were identified in having a core team that would allow continuity of philosophy or care and consistent management of the MU even in case of emergencies and rotation of a part of the staff to allow exposure to this model of care of other midwives [11, 17, 18, 23].

> *"Some initiatives for increasing integration of care were identified which could potentially mitigate the effects of creating new boundaries or discontinuities in the service. These could also support quality and safety of care, and the well-being of professionals as well as service users. They included a planned system of rotation for staff, with mentoring for midwives who are less experienced and skilled in caring for normal physiological birth and more integrated community-hospital models in which midwives based in the community attend the women on their caseload giving birth at home or in the FMU or AMU and transfer with them if required." Authors, [17] , page 546*

Communication

Effective, respectful and appropriate communication, both verbal and non-verbal, was identified as having a central facilitator role in positive stakeholders' relationships. In some cases, educational activities were used to solve some communication issues and this helped to pre-empt or overcome tensions amongst the team. For example:

> *"We've identified gaps in terminology between the people talking on the phone, so we've been able to provide education. Yeah, it's been very, very helpful. Had we not done that, I could see that we could have had conflicts simply because we didn't understand each other and why we were doing things a certain way and I think we've been able to completely avoid that or interrupt it if it was going to start because we've been able to go, 'Oh, why'd they do that?'" Paramedic, [23], page 546*

The opportunity of a regular dialogue and exchange of opinions and ideas to review and debrief practice was also mentioned as important factor to improve communication between the different professional parties [17, 18, 23, 24].

Appropriate information about the MU to the service users and the definition of a clear pathway of care outlined was reported to be a key facilitator for the successful implementation:

"Successful implementation was also dependent on a clear clinical pathway from the beginning of pregnancy until the onset of labour." Authors, *[11], page 6*

Lack in providing such information and the options to the service users (both during the implementation process and later once the MU was established) was reported to have a significant impact on the implementation outcomes of accessibility and sustainability [11, 18].

However, communication with service users was not mentioned much in the studies, suggesting a lack of attention to this issue. In the Chinese and Iranian case studies, the MU was perceived as a good alternative to receive better verbal and non-verbal communication and avoid mistreatment [19, 27]. The Brazilian case study reported how an organised civilian movement for birth rights was successful in influencing the governmental spheres [21].

Invest in different components of leadership

As shown in Table 4, those who moved forward the idea of the implementation of MU were often midwives, nurse midwives or midwifery managers highlighting the importance of the midwifery component in leadership for this type of change. Senior midwifery support was often mentioned and in the English studies this was identified in the figure of the consultant midwives [11, 17, 18, 24].

Good leadership was sometimes shown in groups or by a single professional who could either be a senior midwife or an obstetrician depending on the context. The role of one charismatic and motivated leader was often mentioned as key ingredient to start a conversation and to initiate the adoption process.

"-it's crucial to have an inspirational leader. If you don't have somebody at the very top who is passionate about it (MUs) happening, it won't happen. And they must cascade, get everybody onboard. – (Midwives Focus Group)

-a charismatic leader to kind of bring it together... unless you've got that then I think it's quite hard to bring it to fruition.- (Manager)" Midwife and manager, *[11], page 6*

The figure of one charismatic and motivated leader was reported to be essential especially at the early stages and later, during the planning process, this leader needed to be combined with a group of stakeholders and interdisciplinary members of which the obstetric component is essential. This layer of leadership was described to be necessary for the integration of the service and for promoting a culture of inclusion of different figures

(including service users) in the development of a service change:

"Management respondents emphasised the importance of senior midwifery, obstetric and general managers working together to support and sustain the development." Authors, *[17], page 24*

Overall, the studies in this review identified the key functions of leadership to support the implementation of a new MU:

- Inspire and start a conversation about the change and promote a vision
- Advocate for the team and for the service users
- Promote participation of different figures for planning and developing the change
- Ensure integration within the service
- Negotiate and move strategically with inside knowledge
- Support training and establish a learning culture

Think physical environment

All studies discussed of concept of the MU as a distinct built environment separate from the OU as a prerequisite of an effective implementation plan. In some cases, the refurbishment of the physical environment or a reconfiguration became the means to promote a change in clinical practice and in the birth culture of the local context [17, 18, 20–22, 24, 28]. The new physical layout was the most visible feature of the wider change that was being promoted and implemented:

"The accounts of professionals and service users suggest that these different aspects of the care environment cannot simply be unpicked as they are closely inter-related. Although some respondents regarded the design aspects of the environment, such as domestic touches, as superficial in relation to actual care processes, our study findings overall suggest that attempts to alter either processes or environment of care in isolation are less likely to be effective." Authors, *[17], page 26*

The literature reported that an appropriate use of the physical environment has the potential to be an important strategy for the new MU, especially at the beginning of the negotiations when involving different stakeholders [11, 17, 18, 24].

On the other hand, if the planning of the change does not consider all the different layers implied, including the shift in culture, practice and integration required, then

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Table 4 Overview of different strategies used to implement the MUs

N	Country	Year	Who initiated/led the implementation	Drivers to open the MU (WHY?)	Strategy (HOW?)
1A	China (A)	2009	Researchers	Promote more humanised care to reduce intrapartum interventions and medicalisation	Engagement with leadership and training for midwives. A five-stage action research project was used to: define the plans, assess midwives' confidence and ability, outline policies, procedures and standards of practice, review and tackle the obstacles found in the previous steps.
1B	China (B)	2009	Researchers	(See 1A)	A follow up from study 1A with the same strategies and adding the involvement of a wider range of stakeholders (including midwifery staff managers and researchers) to assess feasibility of the MU.
2	US	1991	Nurse-midwives in four different institutions	Negotiating a middle-ground service between home-births and the medicalised OU	Eight strategies were used, described as: going it alone, compromising, getting others involved, capitalising on consumer pressure, promoting the idea of 'it's not different', playing the waiting game and overcoming government regulation.
3	Iran	2013	UNFPA and the Health Centre of Sistan and Balochestan Province	Increasing accessibility to perinatal care in areas with poor access to care	Response to a local situation in which vulnerable women lacked access to appropriate care and a high birth rate to increase accessibility of facilities and reduce perinatal mortality. UNFPA supervised the first three years of operation.
4A	Brazil	2009	Brazilian Ministry of Health	Promoting more humanised care to reduce intrapartum interventions and medicalisation	Normal Childbirth Centers or Childbirth Houses were implemented as consequence of a strategic governmental initiative to reduce medicalization in childbirth in Brazil.
4B	Brazil	2013	Brazilian Ministry of Health (MoH)	(see 4A)	The MoH invested in nurse-midwives' professional profile by sending them for an international exchange in a country where MUs were established. This was considered to give them greater symbolic power to fight for the implementation of the MU.
5	Canada	2018	The Ontario Ministry of Health and Long Term Care	Implementing evidence into practice	The availability of evidence was the reason why the MoH decided to invest in this model of care. They used interprofessional approach for planning the change, develop appropriate policies, protocols and to enhance teamwork. They also gave attention to the midwives' admission privileges at the moment of transfer and to the continuous service evaluation.
6	England	2005	Consultant midwife	Opportunistic or pragmatic reasons such as reconfiguration of the service, including centralisation	The refurbishment of the maternity setting became the opportunity to promote the inclusion of a MU. Consultant midwife doing a postgraduate thesis initiated an action research study, which included different stakeholders (including managers midwives and medical staff) and established a group to promote normal birth.

Table 4 (continued)

N	Country	Year	Who initiated/led the implementation	Drivers to open the MU (WHY?)	Strategy (HOW?)
7	England	2018	Local managers (not specified)	Implementing evidence into practice	After the publication of the Birthplace study in 2011 the NICE Intrapartum guidelines published in 2014 recommended all 4 options of birthplace. This guideline had a significant impact and was used by stakeholders as main facilitator to make the case and open new MUs nationally.
8	England	2020	Midwifery managers	Implementing evidence into practice	Key factors for successful implementation were: leadership (and continuity of it), active promotion of the MU as part of the local policy, clear clinical pathway from the beginning of pregnancy until the onset of labour and appropriate information for women.
9A 9B	England	2014 and 2018	Midwifery managers	Opportunistic or pragmatic reasons such as reconfiguration of the service, including centralisation	Key drivers for development of AMUs in all the services studied had been a combination of pragmatic, even opportunistic, decisions. Lead midwives had often seized an incidental chance to develop the service responding also to financial constraints or existing plans for service redesign or improvement, including merging of different OUs within a single service organisation.

there is the risk that the physical layout case alone could become a trap in which energy and resources could be wasted. Focusing just on the MU physical layout and not on the MU model of care was reported as a potential barrier to effective implementation [17, 18, 20, 24]:

> *"I'm afraid we could end up with a room that's just decorated differently; that's about all that would be different" Midwife, [20], page 265*

The clear physical separation from the OUs was also mentioned as facilitator for the implementation of the new MU:

> *"We thought it would be easier to do it outside the hospital due to institutional resistance." Manager, [21], page 872*

And when it was not, it became an obstacle to the MU model of care:

> *"As there was no physical barrier between these rooms and the rest of the labour ward, it was too easy to use them for other purposes when demand was high." Authors, [24], page 754*

Discussion

The twelve studies included in this review were heterogeneous in their aims, methodology and local contexts but it was interesting to find agreement and coherence of many of the findings. Themes and sub-themes identified in single studies were coherent with those looking across a wider range of services [11, 17, 18, 25].

Key drivers that led to the implementation of new MUs were: desire to reduce interventions and to promote humanised care [19, 21, 22, 28], need to negotiate a middle-ground service between homebirth and OU [20], desire to increase access to care [27], commitment to implement recent scientific evidence [11, 23, 25] or opportunistic reasons such as refurbishment of the unit or reconfiguration of the service [17, 18, 24].

Few studies focused explicitly on macro-level influences such as wider culture and social influences, policies or healthcare systems structures suggesting an approach of mainly institution-centred. The systemic issues mentioned concerned the role of barriers that gendered power dynamics, hierarchy in the healthcare system and an industrialised approach in healthcare can play [11, 17, 18, 21] but only a few studies included a focus on the role of service user or public activism in implementation or examined levels of public awareness and information [17, 18, 21]. This seems to suggest that women's groups could be big drivers in facilitating change in maternity [32, 33] but lack of their

inclusion in the data collections of the selected studies shows how this aspect has not been researched enough yet on this review's topic. We recommend that future research should involve more focus on the service users' perspective.

In spite of differences in midwifery autonomy across the contexts of this review, most studies discussed the importance of a midwifery identity and the role that this profession has in the respective society prior to implementing a MU [11, 17–21, 23]. The ICM Standards for Midwifery Education (revised in 2021) aim to address local differences and promote a skilled professional midwifery workforce internationally to facilitate the implementation of midwifery led care models [34].

Walsh et al. (2020) noted lack of awareness of the economic evidence that MUs are cost-effective even when working at 30% of their capacity [11, 35, 36]. Different contexts showed how different commissioning systems could affect the adoption of the MU model. Most studies reported the need to adopt a cost-saving model to support a climate of financial constraint. This situation in which commissioners and managers are required to save money in the short-term was reported to be a main barrier to the implementation of MUs. Promoting the concept of cost-effectiveness among stakeholders and allowing longer-term goals to be reflected in the healthcare financing system were reported to be facilitators for this type of change [11, 17, 18].

National guidelines and local protocols were mentioned as key enablers of the change and found to play an important role in terms of "readiness" of the local context. For participants it was equally needed to have some reference at a national level (via guidelines) and on a local level (via organisational protocols). This helped the perception of safety, protection for midwives' work, midwives' autonomy and the sense of integration amongst professionals in the organisation. Furthermore, the quantitative results from Walsh et al. (2018) described the impact that Research and policy can have in affecting the configuration of maternity services and therefore support the implementation of MUs.

Training midwives (sometimes with the multidisciplinary team) was a common strategy to facilitate the implementation across all studies. One element reported to be relevant for promoting trust in the MU model and integration within the team was the exposure to the MU model. AMUs were seen as the appropriate middle ground to facilitate this exposure [17, 18, 25, 37]. The theme of exposure to midwifery-led care models was also mentioned in relation to midwifery students learning experience in Rawnson's work (2010) which showed a better learning experience and the application of theory to practice when they were exposed to caseloading models [38].

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All cases mentioned the importance of a collaborative approach to the change. This is coherent with work previously conducted in research about patient safety which identified lack of these components as threats to patient centred care and safety [39–41].

The professional tensions mentioned showed a clear majority of intra-professional issues more than inter-professional ones. This is coherent with feminist work on midwifery arguing that midwives could be at the same time be the "oppressed" and "oppressors" [42]. This is consistent with previous findings that identified lack of understanding and trust between midwives working in AMUs or in OUs [43, 44]. Such negative relationships have been identified as a significant cause of midwives' stress, emotional labour and reduction in practice confidence [45–47]. Across the studies, support from the obstetric component (whether active or passive) was found to be an important facilitator to the implementation of new MUs.

This study was coherent with previous work that identified leadership as important enabler for the promotion and adoption of new MUs [9, 11, 18]. A necessary feature was the senior midwifery component, although support from and collaboration with obstetric leaders was also found to be a key enabling factor. The studies reported the relevance of both single leaders who often initiated the conversation and were key for the engagement and a group of stakeholders for moving the projects forward at later stage.

A good level of integration within the organisation was found to be a crucial facilitator. The shift from the existing maternity configuration to the inclusion of a MU could in fact either destabilise the existing structure or reinforce the rapports within the organisation [17, 18, 23].

Previous studies have shown that the physical environment in the healthcare sector, and specifically in midwifery, has the potential to affect staff wellbeing (or burnout) and therefore the care that is provided to service users [44, 47–51]. Stakeholders tend to have the greater perception of safety towards AMUs in contrast to FMUs. However, participants reported the need to be physically separated and independent to facilitate the implementation and future sustainability [17, 18, 24]. The case studies where normal birthing rooms were attempted and had closer proximity to the OU reported more effort and difficulty in doing so [20, 24]. Other authors have previously explained this concept using the theory of Birth Territory by Fahy (2008) in which AMUs were an intermediate space with more complex power dynamics and jurisdictions due to the closeness to the OU [52, 53].

Strengths and limitations

The strengths of this review lie in the robust research approach, systematic search and critical selection of studies to meet the inclusion criteria. This review is also very specific to the phenomenon of interest of the "implementation" of new MUs, excluding confounding factors which could be related to the improvement aspect and the uptake of existing ones, although in practice this was challenging to achieve as authors often described factors as important to quality and sustainability of care after implementation. While there was considerable heterogeneity of contexts in which implementation took place, the analysis found consistencies amongst the studies. This adds value to the findings of the review, but more studies are needed in other contexts, including low-income countries. One limitation identified was that amongst the twelve studies only four had contributions from service users denoting a lack of involvement of their perspective when conducting this type of study.

Implications for policy and practice

Our review synthesised the strategies used in different international context when attempting to implement an innovation such a midwifery unit. This synthesis helps to identify what are the drivers that usually make the MU implementation happen, the elements that could become barriers or facilitators and which strategies had been reported in the existing literature when opening new MUs. Those elements should be considered by stakeholders to optimise time and resources in future attempts to open new MUs and when preparing an implementation strategy.

This review also identifies a gap in evidence to practice around active involvement of service-users input in maternity service reorganization. Future international policies on MUs should address this gap.

Conclusions

MUs are a valid and evidence based model of care and their implementation has been recommended by many international guidelines and studies [3, 4, 31, 54, 55]. This is the first review that examines what kind of strategies have been used when implementing new MUs in different national contexts to identify what factors should be considered when adopting such innovation. This review examines experiences of implementing MUs, analysing the strategies used so far in different national contexts. Key drivers were found to be: desire to reduce interventions and to promote humanised care, need to negotiate a middle-ground service between homebirth and OU, desire to increase access to care, commitment to implement recent scientific evidence

or opportunistic reasons such as refurbishment of the unit or reconfiguration of the service. Three key themes were found to be important for the readiness of the local context and four key themes were identified in the analysis of implementation strategies.

Changing the mainstream maternity service requires time and a multi-layered change in which cultural, organisation and professional factors should be taken into consideration and addressed to promote readiness in the local context.

Abbreviations
AMU: Alongside midwifery unit; FMU: Freestanding midwifery unit; HIC: High income countries; LMIC: Low and middle income countries; MU: Midwifery unit; MUs: Midwifery units; OU: Obstetric unit; US: United States of America; UNFPA: United Nations Population Fund; MoH: Ministry of Health.

Declarations

Ethics approval and consent to participate
All research reported received ethical approval.

Consent for publication
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Competing interests
The authors declare that they have no competing interests.

Author details
[1]Centre for Maternal and Child Health Research, School of Health Sciences, City, University of London, 1 Myddelton Street, London EC1R 1UW, UK. [2]Faculty of Health & Wellbeing, School of Community Health and Midwifery, University of Central Lancashire, UCLAN, Brook Building, Victoria Street, Preston PR17QT, UK. [3]Laboratorio Management e Sanità, Institute of Management, Scuola Superiore Sant'Anna, Piazza Martiri della Libertà, 33, CAP 56127 Pisa, Italy.

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Publisher's Note

Appendix 9. Situational analysis paper published

Implementing midwifery units in a European country: Situational analysis of an Italian case study

Laura Batinelli [a,*], Christine McCourt [a], Manila Bonciani [b], Lucia Rocca-Ihenacho [a]

[a] Centre for Maternal and Child Health Research, School of Health and Psychological Sciences, City, University of London, 1 Myddelton Street, London EC1R 1UW, UK
[b] Laboratorio Management e Sanità, Institute of Management, Scuola Superiore Sant'Anna, Piazza Martiri della Libertà, 33, CAP 56127 Pisa, Italy

ABSTRACT

Introduction: Strong evidence recommends midwifery-led care for women with uncomplicated pregnancies. International research is now focusing on how to implement midwifery models of care in countries where they are not well established. In Europe, many countries like Italy are promoting midwifery-led care in national guidelines but often struggle to apply this change in practice.
Methods: This study collected data on professional, organisational and service users' levels to conduct a situational analysis of an Italian service which is approaching the implementation of a midwifery unit. Participatory Action Research was used together with the support of the Consolidated Framework for Implementation Research to conduct data collection and analysis.
Results: Forty-eight participants amongst professionals (midwives, obstetricians and neonatologists) and at organisational level (midwifery leaders and medical directors) were recruited; secondary data on service users' views was analysed via regional online surveys. Barriers and facilitators to the implementation were identified to assess the readiness of the local context.
Conclusions: This study is the first to include professionals, managers and service users in a European context such as Italy. Facilitators to the implementation of the alongside midwifery unit were found in national guidelines, allocated funding, collaborative engagement and medical support. Hierarchical structures, a prevalent medical model and lack of trust and awareness of the evidence of safety of midwifery-led models were main barriers.

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Background

Midwifery-led care is an evidence-based strategy to improve maternity care globally (Miller et al., 2016; Renfrew et al., 2014). International evidence and guidelines recommend midwife-led care for women with uncomplicated pregnancies and continuity of midwifery care for all women (Renfrew et al., 2014; Sandall et al., 2016; World Health Organization, 2018). In the past decade, studies conducted internationally also demonstrated the benefit that midwife-led birth settings have for maternal and neonatal outcomes for healthy women (Brocklehurst et al., 2011; Hollowell et al., 2011; Homer et al., 2019; Scarf et al., 2018). Those studies indicated how midwifery units (MUs) represent the gold standard model of care for women with uncomplicated pregnancies as they are associated with improved clinical perinatal outcomes, cost effectiveness for the healthcare systems and better ser-

vice users and professionals' satisfaction (Macfarlane et al., 2014; McCourt et al., 2018; Overgaard et al., 2012; Scarf et al., 2018; Schroeder et al., 2012; Walsh and Devane, 2012).

MUs have been defined as primary healthcare centres, led and managed by midwives, providing maternity and reproductive care for healthy women (Hermus et al., 2017; Laws et al., 2009; Rocca-Ihenacho et al., 2018; Stevens and Alonso, 2020). They can vary in the type of sexual and reproductive health services they provide (e.g., preconception, ante, intra and postpartum or only intrapartum), location (freestanding or alongside a hospital with obstetric services) or their level of integration with the healthcare system (public, integrated or private). Despite the evidence, they are still not well established in many countries (Rayment et al., 2020); therefore, research is now focusing on influences and strategies to support the spread and scaling up of this model of care internationally (Batinelli et al., 2022; Darling et al., 2021; Rocca-Ihenacho et al., 2022; Tracy et al., 2005; Walsh et al., 2020). A systematic review of influences on implementation, which included studies from China, US, England, Canada, Brazil and Iran, identified that this type of complex innovation requires a multi-layered

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approach that address cultural, organisational and professional elements (Batinelli et al., 2022).

In Europe, there is a striking variation in terms of maternity care outcomes and provision (Euro Peristat and Macfarlane, 2018). Similarly, the MU model of care is more established in some countries whilst in others is not present at all (Rocca-Ihenacho et al., 2018).

Italy has one of the highest caesarean section (CS) rates in Europe with significant differences noted across different regions (some of them with over 40% CS rate and others around 20%), different populations (e.g. Italian mothers and non-Italian mothers) and different type of health care (e.g. public sector and private sector) (Rosaria et al., 2019). This heterogeneity highlights the variability of professional practices and the impact that this could have on perinatal outcomes.

In Italy there are currently only a few MUs in the public healthcare system (all alongside the hospital obstetric unit) and there is a growing interest in implementing this model of care to reduce medicalisation (Comitato Percorso Nascita Nazionale, 2017; Sistema nazionale linee guida dell'Istituto Superiore di Sanità, 2011). National and regional guidelines now define and promote midwife-led care pathways for women with uncomplicated pregnancies and encourage the implementation of MUs within the public healthcare system (Comitato Percorso Nascita Nazionale, 2017; Sistema nazionale linee guida dell'Istituto Superiore di Sanità, 2011).

Using the case study of an Italian maternity service, this research focuses on the implementation process from the default obstetrically led maternity services (also called obstetric unit, OU) to an integrated model with a midwifery unit. This represents an ideal opportunity to observe and investigate in depth the transition still required by many maternity services internationally. As part of this work, we conducted a situational analysis to identify the service readiness and any facilitators or barriers within the local or surrounding context in order to inform an implementation strategy and this paper presents this work.

Methods

Study design and aim

This situational analysis (SA) is located within a wider study still ongoing (2019-2022) which aims at observing and supporting the implementation process using implementation and participatory action research (PAR). PAR works in an iterative, co-productive and cyclic manner. Change is planned, implemented and evaluated by all stakeholders at the same time and in a cyclical way following the structure of: Plan, Act, Observe and Reflect. PAR uses a collaborative process with the community to design and conduct an action plan that will help to integrate the new knowledge and evidence in the local context (Hills et al., 2007; Kelly, 2005). When conducting a SA data collected at the beginning of the implementation study constitute the baseline to analyse the readiness of the local context and it aims to inform and support stakeholders in the creation of an implementation plan.

Local setting

The healthcare system in Italy (SSN) is publicly funded and provides universal coverage for all health services, being financed mainly through general taxation. Italy has the oldest mean age of population in Europe and a birth rate which has been decreasing since the 1980s (Report). Maternity care is included in the service provided by the SSN and is free at point of delivery. Midwives are recognised by the law and regulated in their professional profile as lead professionals in the context of physiology of pregnancy,

birth and postnatal period. Midwives are employed by the SSN and they work mainly in hospitals with a smaller percentage working in community settings. Only 2% of midwives practice privately and they do not always facilitate and support homebirths which are currently only 0.1% of births (Lauria et al., 2012).

The hospital where this research project is conducted is in Tuscany region where there is currently only one alongside midwifery unit (AMU) established within the SSN, but midwifery-led care is more established than other regions in Italy and there are guidelines that promote this model of care for women with uncomplicated pregnancy (Regional Act DD10214, 2021). Midwives have autonomy in prescribing and booking antenatal tests for these women and refer to the medical team when there is a need for further investigations. Almost all women in Tuscany give birth in a hospital; in 2018, there were only 25 out-of-hospital births out of 25,386 total births in the whole region (Puglia et al., 2019). Some data suggest a level of medicalisation that, even though lower than the Italian average, is still present. In 2018, the regional CS rate was 27.1% (which is lower than the national average of 32.3%), induced labours were 20.1% and the Kristeller manoeuvre (fundal pressure in second stage of labour) was 3.8% which is significantly reduced from the 20% 15 years ago, but still performed, especially during operative births for first time mothers, even though demonstrated to be not evidence based (Hofmeyr et al., 2017; Puglia et al., 2019).

The hospital where this project is based is part of a wider Local health Authority (LHA) and it is the only hospital offering intrapartum care in this part of the region. It works collaboratively with community centres which offer antenatal and postnatal care to women who live more remotely. Average births a year is around 1300.

This project started as part of an international and multidisciplinary collaboration. In 2015, the local team started collaborating with the Midwifery Unit Network (MUNet) and City, University of London via research projects, seminars, conferences and multidisciplinary training events. An opportunity came along when a budget for refurbishment and renovation of the hospital infrastructure became available. A local obstetrician started promoting the idea to integrate an AMU within the hospital in the new layout of the maternity services. After some strategic stakeholder engagement, the organisational leadership allocated funds for refurbishment of the maternity ward and the integration of an AMU including funding for extra midwifery staff. Unfortunately, due to a sudden change of leadership and the Covid-19 pandemic, the project was left on hold for a while. This situational analysis was conducted during this time of uncertainty and leadership changes.

Theoretical framework

This project used a PAR approach using research to support change processes and actively engaging participants in developing the change they want to see in their local context. The Consolidated Framework for Implementation Research (CFIR) was used to guide the analysis in understanding readiness, barriers and facilitators to the implementation of a new MU in the Italian local context focusing on outer setting, inner setting, individual and process dimensions (Damschroder et al., 2009). CFIR is a determinant framework focused on understanding and explaining what forces and ingredients influence the implementation process. It pays attention to context and all the forces that are part of it including micro, meso and macro levels of influence. It was developed based on a wide range of published theories, to consolidate the thinking across them. For this project, in which the organisational and system dimensions are researched and assessed, CFIR seemed opportune to support the stage of data analysis. This is also consistent with previous research in the field about implementation of MUs such as Walsh et al. (2020) and Darling et al. (2021).

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Data collection

Mixed-methods with diverse groups of participants were used to incorporate different perspectives. Due to the nature of PAR, prior to collecting data it is necessary to start with some engagement activities. Therefore, there was an initial phase of stakeholders' engagement to make the research project visible and accepted.

Qualitative methods included focus group discussions, in-depth and semi-structured interviews, open-ended questions from surveys, analysis of local guidelines and observation of stakeholder events. The project benefited from a strong collaboration with the Management and Health Laboratory (MeSLab) at the St Anna School of Advanced Studies in Pisa and monitors every year the performance of the Regional Health System. Quantitative data include surveys, routine data and maternity indicators collected by MeSLab, including data from women collected via eight surveys before and after pregnancy. Surveys are translated in seven different languages to promote inclusivity and feedback from different communities in the region.

Participants were professionals (midwives, obstetricians and neonatologists), organisational managers (midwifery leaders and medical directors) and service users (antenatal and postnatal women). Recruitment took place face to face or online depending on the different stage of the study (and the impact of Covid 19 regulations). Participants were asked to give written consent in the study after being provided with a participant information sheet.

The first author conducted all data collection activities. She was known to the local stakeholders as former student midwife from the region and currently working as midwife and researcher in England. Reflexivity was embedded throughout the research process to navigate power dynamics and the influence of positionality. Notes and reflections were kept in the research diary and reflexivity and positionality were discussed in monthly meetings with supervisors. These dynamics are common in PAR where "*in contrast to the more traditional role of researcher as observer and community members as the subjects of research, the sharing of responsibility and power in PAR research establishes a bond between researcher and the community that creates long-term relationships, knowledge, and social change*" (Kelly, 2005, p. 66). For this project, working in another country but still being known to the team and aware of many dynamics and relationships, helped facilitating stakeholders' engagement, multidisciplinary collaboration and being both an insider and an outsider to the team.

This study was approved by the Research Committee at City, University of London (reference number ETH1819-1265) and by the Local Health Authority Research Committee on the 1st of October 2019.

Data analysis

Transcribed focus groups, interviews and the research diary (where observation notes were reported) and qualitative data from the open-ended questions of MeS surveys were uploaded into NVivo 12 software for data management and analysis. Quantitative data from the surveys and the hospital performance data were analysed by MeSLab as part of the yearly performance monitoring of the regional health service and included in the analysis where relevant as supporting material.

Qualitative data analysis was conducted by first author starting with open and descriptive coding and then mapping codes and themes using the CFIR framework to synthesise at the analytical level. This helped identify areas of more or less readiness within the outer setting, inner setting, individual, innovation and process levels. The analysis was discussed and reviewed by the second, third and fourth authors who acted as supervisors of this project.

Findings

A total of 48 participants amongst professionals (midwives, obstetricians and neonatologists) and organisational level (midwifery leaders and medical directors) were recruited by the end of January 2021. Unfortunately, due to the Covid pandemic only one face to face focus group was conducted with seven service users. However, service users' contribution and feedback about the local maternity service was included thanks to the MeSLab surveys. Between 2018-2019, 347 service users who gave birth in the local hospital completed the online survey after birth and more than a thousand open ended comments were left and analysed by the first author.

Table 1 below summarises the data collected for the situational analysis from November 2019 to January 2021.

The conditions that determined the readiness of the local context and are affecting the implementation process are reported below using the CFIR framework to present the findings of the analysis (more details on the description of each construct can be found at https://cfirguide.org/constructs/).

Illustrative quotes for each of the CFIR construct in this analysis are presented in Table 2.

Innovation characteristics

Innovation source

Professionals often saw the innovation as being imported "*from the outside*" and specifically from a different type of healthcare system such as the English one, which the local leadership had decided to follow with the aim of bringing innovation. Only few participants mentioned national Italian guidelines that promoted such innovation in Italy too and all were midwives or midwifery managers.

This idea that the innovation source was external was often associated with resistance towards the project and as a justification for its inapplicability.

Evidence strength and quality

Participants' awareness and perceptions of the evidence around MUs was not uniform. Midwives had more knowledge about this model of care and seemed to trust the evidence. Obstetricians' knowledge of the evidence and understanding of its quality and validity seemed to differ depending to their generation. Professionals who had previous exposure to the model in international contexts reported more confidence and this showed the importance of the exposure to the model of care. Interestingly, some professionals believed that international guidelines like those of the World Health Organization were mainly valid for low- and middle-income countries and believed the Italian context to be too different. This tendency to trust and rely more national or local guidelines and recommendations was particularly notable among managers.

Relative advantage

Some professionals believed that the advantage of a MU would be minimal (or even a loss) for the organisation and preferred investing funds into training, or refurbishment of the existing OU. This was believed to be a better long-term use of resources considering the decrease of birth rate registered nationally. Others, on the contrary, saw the MU as good opportunity to improve clinical outcomes and to attract more service users interested in a more physiological approach to birth.

There was a unanimous position amongst managers, different professionals and even service users that being inside the hospital was an essential prerequisite. They all saw the AMU as a steppingstone towards a less medicalised approach while maintaining a good level of safety. A freestanding midwifery units (FMU) out of

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Table 1
Data collection for the situational analysis (primary and secondary). Three colours represent the three stakeholders' levels: blue for professionals, yellow for organisational leadership and orange for service users.

When	Data collection events	Time (Min)	Participants number	Type of data
November 2019	1 FG community midwives	25	15	Primary
	1 FG lead midwives	75	5	Primary
	In-depth interview lead midwife 1	23	1	Primary
	1 FG hospital midwives	61	12	Primary
	In-depth interview hospital midwives	51	2	Primary
	Brief interview hospital midwife	6	11	Primary
December 2019	Strategic multidisciplinary meeting	76	7	Primary
	In-depth interview lead midwife 2	58	1	Primary
January 2020	1 FG hospital and community midwives	30	8	Primary
	1 FG with service users	55	7	Primary
February 2020	Strategic interview with regional lead midwife	80	1	Primary
	1 FG with obstetricians	48	5	Primary
September 2020	Multidisciplinary meeting	59	8	Primary
January 2021	3 multidisciplinary FGs to draft an implementation plan	69 65 32	14	Primary
2018-2019	MeS surveys related to intrapartum experience in the local hospital (both quantitative and qualitative data)	2018-2019	347	Secondary

the hospital or even the homebirth option was considered unsafe by all neonatologists and obstetricians and by some midwives too.

Adaptability and complexity

Professionals and managers often discussed the need to adapt the project to the local needs and felt pressurised by a perception that this type of innovation was not reversable. Midwifery managers often reported this aspect as something that caused stress and burden especially in a historical moment already full of changes for the team. They also reported frustration and the sensation of being "*back to square one*" since in the past two decades a midwifery model was dismantled in favour of a more technocratic one and now team was attempting to implement again a midwifery model similar to the one they used to work in. Midwifery leaders felt that key knowledge and confidence were lost and now attempted to bring it back.

Cost

The plan was to reorganise the maternity department using extra space which became available in the floor above after the renovation works in the hospital. Therefore, costs associated with the intervention were mainly related to the architectural changes, extra midwifery staff and training programme to prepare the dedicated staff who would work in the MU. A budget for this was allocated in 2019 by the organisational leadership. However, discontinuity of leaders and the Covid 19 pandemic led to a suspension of the expenditure of the allocated budget.

Outer setting

External policies

Two main documents in Italy define the pathways of care for uncomplicated pregnancies and midwives' autonomy in being the lead healthcare professionals for primary care. The main guideline, which cited evidence about the importance of continuity of midwifery-led care and caseloading models was published in 2011 and updated in 2013 (Sistema nazionale linee guida dell'Istituto Superiore di Sanità, 2011). Further guidelines were published in 2017 (Comitato Percorso Nascita Nazionale, 2017). The two different titles show a clear difference in word choice and the shift from using "*gravidanza fisiologica*" (physiological pregnancy) in 2011 to "*Basso Rischio Ostetrico or BRO*" (low obstetric risk) in 2017. This language shift seems to highlight a more risk-oriented approach. The latter had the word risk mentioned 36 times in 8 pages. The BRO acronym was often used during data collection activities by managers and healthcare professionals.

Cosmopolitanism and peer pressure

If the lack of networking and collaborative work was notable at the organisation level, it became more apparent at regional and national levels, where the guidelines and the maternity service configurations could differ significantly.

Having an existing regional AMU had the conflicting role of being both a facilitator and barrier. Initially, when there was the need to initiate a conversation and to engage the organisational leadership, it was positively decisive. It nourished the leaders' need to rely on national and local examples and the sense of

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Table 2
Illustrative quotations from participants

	CFIR domains	Illustrative quotations
INNOVATION	Innovation source	"I feel like this model of care can work in a different healthcare system and with different type of midwives. I don't see this applicable in this context" Obstetrician, FG 26/2/2020
	Evidence strength and quality	"XXX (medical director) also mentioned the fact that in the latest regional report, birth rate is going to reduce more in the next 10 years and all women will be around 40 years old so all high risk. Therefore, there is no point to do a birth centre (MU) or invest in this in their view. Everyone in the room nodded and agreed with this. (…) The local dimension for them is essential. They are not going to implement a change if the local numbers or guidelines suggest so. They feel 'different'; 'we are not like UK', 'we are not like rest of Europe', 'WHO guidelines don't apply to this type of context'" Research diary, 2019
	Relative advantage	"(While presenting the research project to the regional committee) The first question the doctors asked was 'Are you talking about an AMU or a FMU?' As if this was a preliminary question to decide if listening or not to the presentation. There is palpable closure towards FMU and homebirths amongst professionals of the public system." Research diary, 2019
		"They (service users) are ready to point the finger at us and I find a great immaturity among women compared to the past with regards to pregnancy and their birth experience that they delegate to others whether is a midwife or a doctor. (…) I do not see a great awareness in women, and not seeing it, I consider the idea of the birth centre (MU) an outline absolutely superfluous" Obstetrician, FG 26/2/20
	Adaptability and complexity	"It's all a change. As you begin to consolidate something, you dismantle it and immediately there is another new thing to do" Midwifery manager, FG 20/11/2019
	Cost	Lead midwife 1: "The medical director asked for a re-styling, a renovation of the OU but I don't think he asked for a massive change…"
		Lead midwife 2: "You see? The wind has changed direction, so the certainties that we might have had before, I don't think we have them now" Lead midwives, FG 20/11/2019
		"Oh well, many things were left on hold, because of Covid certainly and also for other reasons… It must be that this thing (MU project) does not have a linear development. But that's the way it is. Maybe there is an update (…) it is that the budget has now been allocated." Midwifery manager, multidisciplinary meeting
OUTER SETTING	External policies	"Women with physiological pregnancies must be offered a care model based on the assumption of responsibility by the midwife." Italian guidelines, (Ministero della Salute, 2011)
		"Although the birth event falls in the majority of cases in physiology, in the main industrialized countries in recent decades a clinical/organizational model has been launched based mainly monitoring risk factors and using a technological approach to obstetric pathology" Italian guidelines, (Comitato Percorso Nascita Nazionale, 2017)
	Cosmopolitanism and peer pressure	"Yes, from this point of view, Tuscany is certainly well developed, both in its organizational models and in its professional resources, I mean, for example, the midwifery-led care model (…). There is not this level of development in other regions." Midwifery Director, Interview 28/4/2020
	Service users' needs	"You also have to see what population you are referring to, the mentality of the women you work with … here they are all obese. Willingness to give birth seems to me that they have very little or almost zero. Also, they request a caesarean section at the second contraction … women are not motivated, you often struggle to try to make them physiological" Obstetrician, FG 26/2/2020
		"I really liked the human approach that everyone has towards you, they make you feel like at home" Service user – Regional MeS survey 2019-20
		"I felt a lot of disorganisation as well as little cohesion among the staff, everyone had their own idea of how the birth should have gone and I felt confused, not safe" Service user – Regional MeS survey 2019-20
		"I have always had conflicting advice, differing opinions and a lack of communication especially during the shift change." Service user – Regional MeS survey 2019-20
INNER SETTING	Networks and communications	"We only see each other during study days and sometimes not even during them. I think it would help to have more opportunities to spend time together and get to know how other people work. We have been talking about rotating in the community for quite some time now…" Hospital midwife, Interview 27/11/2020
		"It's a shame that we never see each other and that we don't know how our colleagues in other areas work. I, for example, have no idea how they work in [community centre 1], just as I don't think many of our colleagues in [local hospital 2] know what we do in [local community 2] …" Community midwife, FG 19/11/2019
	Culture	"The problem is that culturally they (service users) know that when they are pregnant they go to the obstetrician. No one has ever told them that BRO (low risk) pregnancy are looked after by midwives. (…) Basically it's always been the prevailing male figure who has obviously always done the wrong thing with this. And in addition, midwives tend to be nice and understanding while the obstetrician discredits midwives easily as soon as there is something wrong. He immediately discredits the figure of the midwife and this impacts the woman's opinion. The woman perceives that the obstetrician is capable and the midwife is not." Community midwife, FG 19/1/2020
		"…In fact, even in all the training (that we have done) over the years there is a highly medicalized culture. But not only here, but in Italy as a whole. In my opinion this is a big obstacle. And women are immersed in this culture." Lead midwife, FG 19/1/2020
		"Once a woman has been followed in the high-risk outpatient clinic how can you tell her 'okay ma'am you are low risk as of today'? And especially with some of the intermediate situations it's hard for them to make them return to low risk…by then she's being looked after by the doctor." Obstetrician, FG 26/2/2020
	Implementation climate	"I kind of say it's just because of the insidiousness of this job that I don't feel it's safe to have that kind of situation (MU)… Because a woman has not given birth well until proven otherwise. That's it. You can talk about physiology but you have to see the baby outside first. Very often in these cases… let's say from 5 centimetres to the birth or postpartum, it's a time that is absolutely unpredictable and therefore, because of what I've been experiencing over the years, sometimes things happen and we say 'thank goodness we were here'. So, I am happy to work here because there are always three midwives available, a delivery room, I have always an anaesthetist or a neonatologist available. And despite this, there are still problems sometimes. You could say to me the contrary that they happen because of that. Maybe they would but anyway…" Obstetrician, FG 26/2/2020
		"(…) over the years the percentage of people who are ready for something like this (MU) is increasing… we have to work on maybe those resistances as well. Some things we will be able to improve, some other things will remain resistant. But we all have to move forward with the project, a project belonging to everyone. (…) Because if you understand the model you believe in it. You need to have the possibility to understand it. You have to understand that it's safe. That's the key thing." Neonatologist, FG 11/1/2021

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Table 2 (*continued*)

	CFIR domains	Illustrative quotations
	Readiness for implementation	"I believe that as of today, and correct me if I'm wrong, nobody knows what we want to do, if we still want to do it and if this new management wants to do it. " Lead midwife, FG 20/11/2019 "Facilitator: In your opinion, when we think about the implementation of these realities in today's reality, what are the main barriers? (…) Group: Cultural Midwife 1: Although today things have certainly changed. Before birth, labour, and pregnancy were delegated so much to the doctor. Medical care equals wellbeing: wellbeing for the woman and well-being for the newborn. Today we are certainly going back to less medicalization by re-evaluating other figures and also re-evaluating other models of care that are certainly alternatives to the hospital, however, there is still a long way to go …" FG 19/1/2020
INDIVIDUAL CHARACTERISTICS	Knowledge and belief about the intervention	"I worked in places where there were projects of low obstetric risk, (…) the patient could be followed only by the midwife thanks to continuity of care and assessment, and in case a risk arose, the obstetrician was called and the risk assessment was changed. I have not had any problems with that type of experience. (…) It was in Brussels." Obstetrician, FG 26/2/2020 "Facilitator: So, would you see an alongside midwifery-led birth centre inside a hospital as a good fit? Group: yes! yes! Service User 5: It would be a dream!" FG 10/1/2020
	Self-efficacy	"Every time I come here it seems like breathing fresher air, air of renewal and change… for you it will seem that nothing ever changes but in comparison to other realities (even within the LHA) here in XXX the change arrives earlier" Midwifery manager, multidisciplinary meeting 23/12/2019 "Also, because I really believe in it, I have to tell the truth: this group has a lot of facets (…) I have to say that we have shown very high professional maturity in welcoming and taking on new projects on over the years." Midwife coordinator, FG 27/11/2019
	Individual state of change	"she (midwifery manager) gave updates on the MU project to everyone in the room and she told them that a formal proposal was being written for the hospital Directors. She also showed the numbers from the work in 2018 and the fact the numbers for low risk women look good. Midwives looked interested and had many questions." Research diary, 2020 "We are all people who work well and also work with a certain type of motivation. Certainly, at this moment in my opinion, motivation is missing, in some moments even the change of new staff has also led us to have moments of lack of communication, perhaps even with the medical staff, the neonatology staff, so we need to find some clarity from now on. But, for example, even paediatricians from this point of view are on our side. Midwife coordinator, FG 27/11/2019
	Individual identification with organisation	"In the end we are lucky to work in Tuscany… in many parts of Italy there is not this same structure of maternity care, for example the pregnancy booklet that we as midwives can now sign autonomously." Community midwife, FG 19/11/2019

competition to be leading innovation. However, that model was sometimes seen as unsustainable. The managers' perception was that the number of births that the existing regional AMU was annually attending was not high enough to make it sustainable and that the two teams (OU and AMU) were having unbalanced workload.

Service users' needs

Service users were not regularly involved in advisory groups or organisational meetings related to the planning of innovations in maternity services.

Based on both professionals' and women's data, service users' relationships with healthcare professionals appeared unbalanced with most of the decision-making power lying in the professionals' side. Women's autonomy was not always recognised by professionals justifying this approach with: "*on a legal point of view the responsibility for this birth and any negative outcomes relies on me as healthcare professional*" (FG 26/2/2020).

Service users often mentioned this power imbalance with professionals and the communication theme was dominant in the qualitative analysis. They frequently reported the need of clear and consistent information provided in a calm and non-judgemental way. When this type of rapport and communication took place, it was a vehicle for positive experiences.

The below table (Figure 1) summarises the key indicators calculated from data collected via online surveys by MeS Laboratory in 2018-2020 and it gives an overview of the experience of maternity care pathway users in the local area in comparison to the regional context. Fig. 1.

Inner setting

Networks and communications

Professionals mentioned the rigidity of the communication system. Midwifery leaders seemed to play the role of "filters" of the communication between the organisational and medical leadership and the rest of professionals in both directions. This meant they were seen as the hub of the communications by the team who sometimes did not take ownership of their practice or activities and delegated the responsibility back to them.

Lack of communication between teams (hospital, fetal medicine and community) was also often mentioned.

Culture

The analysis indicates a context in which norms, values and basic assumptions tend to be based on a medicalised vision of childbirth. In more than one occasion stakeholders mentioned "*a birth is normal and physiological just retrospectively*". The expression "*natural birth*" was sometimes associated with fear or a sense of irresponsibility. On the other hand, technology was often associated with positive attitudes and with the idea of working with an innovative and up to date portfolio.

Professionals identified the regulatory system in Italy as a significant contributor to this medicalised philosophy of care. They mentioned that the responsibility for a negative or adverse outcome is placed more on each individual healthcare professional than the organisation, as opposed to other international healthcare systems. This implies a certain level of awareness of their medicalised approach and its limitations but also perhaps a misconception of other healthcare systems.

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Indicator		2018		2019		2020	
		Local area	Region	Local area	Region	Local area	Region
Pregnancy	Quality of booking appointment (score 0-100)	82,6 / 82,8	79.7	86,4 / 86,5	83.4	86,4 / 83,9	85
	Experience with midwife during booking appointment (score 0-100)	69,7 / 71,6	65.9	77,3 / 74,7	73.7	76,9 / 72,7	74.8
	Benefit of the antenatal care classes (score 0-100)	56,3 / 60,4	57.4	N.D.	N.D.	56,5 / 60,4	54.3
	Willingness to recommend community centre (score 0-100)	91,8 / 86,2	88	N.D.	N.D.	92,2 / 82,4	86.9
Birth	Autonomy in labour and at birth (score 0-100)	75.5	76	71.5	73.4	72.1	69.9
	Respect and dignity from professionals during labour and birth (score 0-100)	89.6	90.2	88.6	86.3	89.4	87.4
	Continuity of care in labour and at birth (score 0-100)	81.1	84.9	82.5	80.5	85.5	83.1
	Pain relief in labour and at birth (score 0-100)	68.7	75.9	72.1	71.7	72.1	71.7
	Skin to skin contact (%)	38.3	62.7	N.D.	N.D.	49.5	59.3
	Esclusive breastfeeding when discharged from hospital (%)	83.8	76.7	N.D.	N.D.	76.6	75.2
	Team work (score 0-100)	81.2	86.5	76.2	80.3	81.4	80.8
	Coherence of information received (score 0-100)	71	76.7	65	73.4	72.5	73.3
	Clarity of information when discharged (score 0-100)	79.9	79.9	68.6	73.1	70.1	70.9
	Quality of care in the birth setting (score 0-100)	82.7	87.7	79.9	82.6	82.8	82.4
	Willingness to recommend the birth setting (score 0-100)	90.7	93.5	84.4	89	88.5	89.3
First year	Women invited to a postpartum visit by the birth setting or community setting (%)	60,3 / 55,6	69.4	N.D.	N.D.	57 / 65,4	64.2
	Experience with professionals in the community centre (score 0-100)	67,8 / 63,9	69.2	N.D.	N.D.	60,1 / 59,2	63
	Willingness to recommend the community centre (score 0-100)	82,9 / 81,7	85.5	N.D.	N.D.	77,4 / 76,7	78.6
	Exclusive breastfeeding at 3 months of life (%)	65,7 / 50,7	63.3	N.D.	N.D.	64,4 / 62,2	61.5
	Exclusive breastfeeding at 6 months of life (%)	15,5 / 5,7	15.5	N.D.	N.D.	9,7 / 0	14.7

Fig. 1. MeS indicators of maternity care pathway users' experience 2018-2020 in the local (first column) and regional context (second column). The different colours indicate different level of performance (green – best performance; light green – good performance; yellow – average performance; orange: poor performance; red: worst performance). The boxes in white are data available but not measured for the performance due to the impact of the Covid 19 pandemic. The indicators concerning pregnancy and first year refer to the two districts of the local area (therefore two numbers for each indicator). N.D. = data not available for this indicator in that timeline.

Attention was often given to a binary concept of low risk and high risk, with a vision of the risk factors in pregnancy and during birth as static and non-specific. However, they would often keep a high-risk label just in case.

In 2020, the organisation leadership promoted the inclusion of the category "medium risk". The aim was to ensure that whoever belongs to the low-risk category was screened appropriately in pregnancy. A part of the team felt reassured that in this way the low-risk women looked after by midwives would be *really low risk*" and another part believed that this would be an attempt in medicalising pregnancy and birth as very few women would now fit in the low-risk category.

Implementation climate

The local hospital was seen as one of most receptive contexts to innovations within the LHA. The team felt they had good skills

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in terms of adaptation and absorptive capacity even if continuous changes were sometimes tiring and demanding.

There were three types of professionals' attitudes towards the MU innovation:

- A small group who openly expressed support to the MU project
- A small group who openly expressed disagreement and not being supportive
- A larger number who did not openly disclose being in favour or against

In each of these groups there was representation of midwives, obstetricians, neonatologists and managers, indicating that this did not fall along professional group lines. The quote from a supportive neonatologist shows how the team was aware of the resistance towards the project but also how some of them had changed throughout the time of this study (see Table 2).

Readiness for implementation

Key elements of readiness to implement MU were found in the receptive context to innovations and motivation of some professionals and managers. However, leadership engagement towards the implementation of the MU changed periodically. Key reasons for this were: change and discontinuities in organisational leadership, previous negative experiences of new leaders and change in the budget available for the innovation (also due to the pandemic).

The importance of leadership continuity during the first stage of promotion and planning of the change became clear after the loss of the former lead obstetrician who had championed the project initially. Not having been able to hand over the project to new team members or to involve any other leaders to push this project forward made it hard the following months to realise where the project was left.

However, positive attitude and proactivity by the midwifery leadership was noted in the last stage of data collection and was key to keep the project ongoing.

Individual characteristics

Knowledge and beliefs about the intervention

Managers and directors with a medical background seemed to have a general knowledge on the topic but not a detailed insight of the standards for the MUs model of care and its functionality. Midwifery managers, on the other hand, had a better knowledge of the model. They considered the midwifery educational system nationally led by the medical component as an obstacle to implementation. They highlighted that if most midwifery education is led by doctors, then this would be reflected in a medicalised mentality and approach of the new generation of midwives.

Few service user respondents had heard about MUs and their understanding of the model seemed vague. However, there was a good level of knowledge of the midwifery role as experts of physiology and an overall sense of trust towards the profession.

Self-efficacy

An overall good level of confidence was noted in the team ability to adapt to changes especially in relation to other previous midwifery innovation. A higher level of confidence was also noted in the local hospital in comparison to the others in the LHA.

However, the fact that professionals were asked to implement a model of care in which they had never practiced and to which many did not have any previous exposure made them sometimes doubt their capability to implement the innovation.

Individual state of change

Support from the organisational leadership towards the MU project was observed as variable and sometimes passive - not a

manifested or apparent opposition but an immobility and lack of proactivity.

However, when a significant financial budget was released, organisational leaders became committed to carry out the project. In this climate, midwifery leaders felt backed up by the organisation and started actively moving the project forward with the rest of the team.

The released budget was not only important on a practical level, but it showed high-level institutional support, which increased confidence amongst professionals. Having the organisational leadership support allowed clinical leaders to actively promote the change with the rest of the team. This seemed to have a cascade effect within the team and made it possible to move from a contemplation to the preparation stage of individual change just before the implementation events planned for the PAR cycle.

Individual identification with the organisation

A sense of pride in belonging to their regional healthcare system and sometimes even more specifically to the LHA was noted amongst professionals and leaders.

This pride seemed an important facilitator that helped individuals trust the organisational vision and therefore is an important feature in terms of readiness for the change.

Nonetheless, some negative episodes of not having felt valued, appreciated, or supported by the organisational leadership of the LHA as institution were reported by some professionals and most of these were midwives.

Process

Planning and engaging

At the beginning of the project, a long phase of engagement via conferences, seminars and multidisciplinary training organised by the local hospital and facilitated by researchers allowed the project to be visible to the team. Midwifery leaders and medical directors were used to engaging and planning changes collaboratively but this often did not include the wider team or the involvement of service users. However, the intention to improve this aspect was clear and the interest in interfacing more especially with the service users was unanimous. The PAR approach of this project was particularly appreciated by managers for the principle of engaging the whole team in reconfiguring maternity services. Co-designing the change to make it specific to the local population's needs became a key requirement for them while trying to implement the MU model.

Opinion leaders

The hierarchical set-up of the organisation meant that the engagement and support by the organisational leadership was decisive in moving the project forward. On a more local level, the medical director and lead obstetrician seemed to significantly influence the attitudes of the rest of the maternity team towards the innovation. However, some informal leaders were also noted and identified by professionals and they were midwives, obstetricians and neonatologists, some of whom were supporters of the MU and others were opposed to the idea. They had the ability to informally influence the attitudes and beliefs of the those who did not have a clear opinion about the project.

Discussion

This situational analysis was coherent with previous studies that showed how AMUs are often seen as steppingstone and perceived as safer by professionals even though the evidence on FMUs

is stronger (Batinelli et al., 2022; McCourt et al., 2018; Walsh et al., 2020). Both professionals and service users in the local context saw the AMU model as feasible option for the local context whilst had resistance towards the idea of FMUs or homebirths. This shows how understanding of evidence quality and validity can be influenced by the local content culture and perceptions of safety. Participants were sceptical to trust international recommendations as applicable to the local context.

A key facilitator for the MU project was having national guidelines pushing in this direction (Comitato Percorso Nascita Nazionale, 2017). Medical, but especially, midwifery managers felt supported by these guidelines in promoting the change and it was interesting to notice the shift in language among professionals associated with this (from "physiological pregnancy" to "BRO = low obstetric risk"). This language change was not noted among service users who still referred to "physiological pregnancy".

Previous implementation research has demonstrated how organisations which are open to outside with networking, communication and peer pressure with other organisations are more likely to adopt innovations and new changes (Damschroder et al., 2009; Greenhalgh et al., 2004). In this case study, lack of cosmopolitanism and regular communication with other realities was noted as a barrier to the innovation.

In the Italian context public and private maternity service coexist and whilst the first in more midwifery led in the community centres the latter is mainly doctor led in the hospital. This configuration has been in place for decades, significantly affecting the way generations of women and service users see and use the maternity care. Midwives raised this issue and identified a patriarchal and male doctor-centred approach to pregnancy and childbirth in Italy as a barrier to implementation. They felt that dismantling this would require a long time and is likely to encounter resistance from both the medical side (for taking away some profitable private workload from them) and from the service users who are now associating the concept of "safety" with this model. However, most service users showed a good understanding of the midwifery profession and scope of practice, which is an important factor in terms of readiness of the local contexts for this type of innovations (Batinelli et al., 2022).

Having an allocated budget played a key facilitating role in saving the project even when the leadership felt insecure and doubtful of its applicability. It functioned as an anchor when other variables and influences were pushing the vision of the team towards other ideas.

The importance of being exposed to midwifery-led care models was acknowledged both by midwives and doctors. Some midwifery managers mentioned this concept in relation to the erosion of midwifery skills in the new generation of practitioners. This is coherent with a recent systematic review which showed this to be a barrier for promoting physiological approach to birth (Darling et al., 2021).

During this project, development was not a linear process but more of an explorative path in which sometimes stakeholders walked away or ended up back where they started. The transtheoretical model by Prochaska and Velicer (1997) defined different stages an individual may be in while implementing a change as: pre-contemplation, contemplation, preparation, action and maintenance (Prochaska and Velicer, 1997). Greenhalgh et al. (2004) describe how initially "*innovation is discussed, contested and reframed*". In this case study, the researcher noted how stakeholders spent most of the time in the contemplation phase of the change: discussing, contesting and reframing. Doubts were sometimes noted amongst the hospital leadership. Again, this is coherent with previous work by Darling et al. (2021) who described a long period of incubation of the idea prior the implementation of a new MU in a context not used to this model of care.

Conclusions

As evidence around MUs is now strong and internationally uniform, research is now focusing more on the "how to" implement and integrate these models within the existing services (Batinelli et al., 2022; E. K. Darling et al., 2021; Walsh et al., 2020). The Covid-19 pandemic has highlighted the importance of primary care and many countries like Italy have started investing to strengthen this healthcare sector.

This research was the first of its kind to include a big and varied sample of participants including managers, professionals and service users in understanding the readiness of a local context with a situational analysis. It is also the first to research the implementation process *before* the change is implemented offering a unique perspective in this research field. Our findings could help countries that are planning to approach similar transition from a more medicalised maternity setting into an integrated model with a MU.

List of abbreviations

AMU = alongside midwifery unit
FMU = freestanding midwifery unit
MU = midwifery unit
OU = obstetric unit
LHA = local health authority
BRO = basso rischio ostetrico (low obstetric risk)
FG = focus group

Declarations

Authors' information

1 1 Centre for Maternal and Child Health Research, School of Health and Psychological Sciences, City, University of London, 1 Myddelton Street, London EC1R 1UW, UK.
2 Laboratorio Management e Sanità, Institute of Management, Scuola Superiore Sant'Anna, Piazza Martiri della Libertà, 33, CAP 56127, Pisa, Italy

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All data and materials reported in this study are available from the corresponding author.

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The authors declare that they have no competing interests.

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Authors' contributions

All authors have read and approved the manuscript. LB wrote the research protocol, conducted the data collection and analysis and wrote the main body of the article. MB contributed to data analysis, writing of the manuscript and supervision during research activities in the local context. CMcC was external supervisor, contributed to the creation of the research protocol, data analysis and writing the manuscript. LRI was external supervisor and contributed to the manuscript.

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