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Implementing midwifery units in a European country: situational analysis of an Italian case study

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Ethics approval and consent to participate

All research reported received ethical approval.

Availability of data and materials

All data and materials reported in this study are available from the corresponding author.

Competing interests

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 and conducted the data collection and analysis. 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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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 AMU 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.

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 service 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 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 (Istituto Nazionale di Statistica, 2020). 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).

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.

Table 1. Primary data collection for the situational analysis. 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 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 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 reversible. 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 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 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.

Figure 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.

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
	Exclusive 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

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.

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 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 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 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. 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

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