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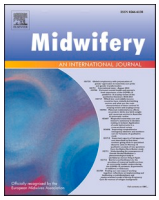

Using codesign to support the implementation of a midwifery unit in Europe

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ABSTRACT

Background: Midwifery units (MUs) have demonstrated to be a safe and cost-effective model of maternity care. Several European countries do not offer this model yet but are working towards its implementation to improve perinatal outcomes, service users' and midwives' satisfaction while making effective use of healthcare resources. Few research projects have focused on the implementation aspect. This study observed and supported the process for implementation of a new MU in Italy using participatory action research (PAR) and codesign.

Methods: A 4-stage project was conducted to codesign an implementation plan aimed at supporting the transition from the obstetrically led maternity unit to an integrated model with a MU. The study engaged maternity professionals, managers and service users via online focus groups and eSurveys.

Findings: Participants 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 intrapartum guidelines for low-risk women, appropriate risk assessment, integration hospital-community, training, effective communication and information for service users and within the team, and reflective practice. Service users supported the initiatives proposed in the implementation plan and expressed openness towards the model of care and its implementation.

Conclusions: This was the first study using codesign and PAR including maternity team, managers and service users to support the implementation of a MU. This work showed value in a collaborative codesign approach. While this work is adapted to the Italian context, the process and findings could be useful in other international contexts.

Introduction

Problem or issue	In Europe over-medicalisation of maternity care is a serious issue affecting perinatal outcomes, service users' experiences, midwives' job satisfaction and inappropriate use of healthcare resources.
What is already known	MUs are an evidence based, safe and cost-effective model of care that could help addressing this problem. However, an evidence-to-practice gap is currently notable with most European countries not offering this model.
What this paper adds	Codesign and participatory action research were valid strategies to support implementation of a MU and they were well-perceived by stakeholders. Service users were open to the implementation of the MU model.

A substantial body of evidence supports the provision of personalised, holistic, and safe care in midwife-led settings, particularly for women with uncomplicated pregnancies (Brocklehurst et al., 2011; Scarf et al., 2018; Hutton et al., 2019). Furthermore, a recent Cochrane review showed how continuity of care by a midwife reduced the caesarean section and instrumental birth rate while increasing positive experiences during pregnancy, labour and postpartum and reducing the cost for the healthcare system (Sandall et al., 2024). Modelling analyses indicate that investing in midwifery led care models could help prevent two-thirds of all maternal and newborn deaths globally (Bongaarts, 2016; Nove et al., 2021).

A midwifery unit (MU) is a setting where care is led by midwives for women with uncomplicated pregnancies, and it comes in two forms:

Abbreviations: MU, midwifery unit; OU, obstetric unit; PAR, participatory action research.

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freestanding midwifery units, which are physically separated from hospitals with obstetric unit, and alongside midwifery units, which are located within or next to the obstetric unit; unlike standard obstetric-led hospital care, midwifery units promote a bio-psycho-social model focused on supporting physiological birth with minimal medical intervention (Rocca-Ihenacho, 2017; Rocca-Ihenacho et al., 2018; Stevens and Alonso, 2020). Evidence shows that they are associated with improved perinatal outcomes, a more cost-effective use of health resources and better service users' and professionals' satisfaction (Brocklehurst et al., 2011; Brocklehurst et al., 2011; Scarf et al., 2018; Homer et al., 2019; Hutton et al., 2019; Reitsma et al., 2020).

NICE guidelines recommend midwifery units (MUs) for low-risk women, and these guidelines are widely adopted internationally (NICE, 2023). The WHO's 2024 "Transitioning to Midwife-Led Care" position paper advocates for a systemic shift towards midwifery-led continuity models as a critical strategy to achieve the Sustainable Development Goals by 2030 (WHO, 2024). Similarly, the International Confederation of Midwives (ICM) endorses Midwife-Led Birthing Centres as essential components of equitable, respectful, and effective maternity care (ICM, 2025).

Previous studies have shown how MUs exist in at least 24 low and middle-income countries and others are currently being implemented, although the global scale remains limited (Nove et al., 2021). Bazirete et al. (2023) looked at what is required for successful implementation of MUs in these countries and highlighted the importance of having an effective financing model, supportive and enabling leadership and governance, midwifery care being recognised in the community, having interdisciplinary support, co-ordination and integration across healthcare services and functional referral systems (Bazirete et al., 2023).

In high-income countries, despite the strong evidence available to support this model and international guidelines recommending them for healthy women, MUs struggle to be implemented and to survive (Rocca-Ihenacho et al., 2018, 2022; Rayment et al., 2020; Walsh et al., 2020; Palau-Costafreda et al., 2023). Studies on the implementation aspect of this model of care highlight multi-factorial problems that impede establishment of MUs as the main place of birth for healthy women (McCourt et al., 2018; Walsh et al., 2020; Darling et al., 2021; Batinelli et al., 2022, 2023; Rocca-Ihenacho et al., 2022; Schantz et al., 2023). Structural problems like gendered power dynamics, hierarchy in the health system and the hegemonic production logic in healthcare were reported as well as organisational and professional barriers like discontinued and unsupportive leadership, shortage of staff and funding and an unclear role and scope of practice for midwives (McCourt et al., 2018; Walsh et al., 2020; Darling et al., 2021; Batinelli et al., 2022, 2023; Rocca-Ihenacho et al., 2022; Schantz et al., 2023). In recent years, changes in the demographics of pregnant people also affected the establishment of MUs and women access to them (Rayment et al., 2019; Walsh et al., 2020).

Across Europe, a striking variation in provision of maternity care is notable and MUs have only recently started to be implemented. In Italy, before the Covid-19 pandemic, there were only four alongside MUs (separated from the obstetric unit but still within the hospital setting) integrated within the healthcare system (Comitato Percorso Nascita Nazionale, 2017; Cicero et al., 2022). In Italy the definition of MU aligns with the Midwifery Unit Standards published in 2018 (and translated in Italian in 2020) but the national guidelines only recommends the implementation of the alongside ones (within the hospital setting) (Comitato Percorso Nascita Nazionale, 2017; Batinelli et al., 2020). In 2025, to the authors knowledge, only two alongside MUs remain open and functioning within the healthcare system in Italy.

Methods

This study was part of a PhD project aimed to support and observe the implementation process of a new alongside MU in an Italian hospital. Using Participatory Action Research (PAR) and codesign, this project engaged the multidisciplinary maternity team, leadership, managers and service users in developing an implementation plan. A PAR "plan-act-observe-reflect" cycle was conducted during the four years of the PhD to codesign the change required by the local context. During the "plan" phase, a systematic review and situational analysis was conducted to assess the readiness of the local context and useful lessons from existing international case studies (Batinelli et al., 2022, 2023). Those findings were used as a baseline to start the codesign and "act" phase of the PAR cycle (plan, act, observe and reflect) (Kelly, 2005; Koch et al., 2005). This paper focuses on "act" phase of the PAR cycle.

Codesign describes the process of active collaboration of different stakeholders to find solutions to a certain problem or support the successful implementation of an innovation (Vargas et al., 2022). PAR is a collaborative approach in which the researcher takes a more active role facilitating the engagement of stakeholders to support the research process (Kelly, 2005; Koch et al., 2005). Using PAR and co-design, this part of the study aimed to collaboratively develop an implementation plan for the opening of the new midwifery unit by actively involving the multidisciplinary maternity team, managers, and service users, with the researcher supporting the process as a PAR facilitator.

The four steps of the codesign process are summarised in Fig. 1 below:

Data collection and analysis

Ethics approval was received by the Ethics Committee at City, University of London on the 29th of April 2019 (reference number ETH1819–1265) and by Ethics Committee of the Local Health Authority in Italy on the 14th of October 2019.

Data collection took place via Zoom platform (focus groups) and via Qualtrics platform (eSurveys).

During the first codesign step, three focus groups with members of the multidisciplinary team using a semi-structured guide were conducted to start an open discussion about possible steps needed by the maternity team towards the implementation of the MU. This stage was intentionally more creative and allowed the team to discuss any aspects they considered relevant for the implementation. In each focus group there was representation of each discipline (obstetric, midwifery, neonatology and leadership). Focus group data were audio-recorded, transcribed verbatim, and analysed by the first author using an inductive thematic approach. Initial descriptive coding was used to organise the data, followed by grouping similar codes into categories and overarching themes (Thomas and Harden, 2008). Ten themes emerged and they became main sections of the codesign eSurvey 1 which was opened to the extended maternity team with a mix of multiple choice, ranking and open-ended questions to allow the wider team to give feedback and add any missing points.

Subsequently, the first author analysed all responses from the survey and with the local leaders drafted a second survey with a list of statements for the implementation plan arising from those findings. The maternity team was then asked to rate each statement during step 3 with only ranking questions; this allowed them to rank importance and set priorities when considering how to put the plan into practice. This stage served as a prioritisation exercise, and responses were analysed quantitatively by calculating mean and median rankings to establish the order of priority for implementation actions. This constituted the draft of the implementation plan with ranks of importance from the wider maternity team.

Finally, service users were involved during the codesign step 4. They were asked for feedback about the innovation (MU) and about the implementation plan prepared by the maternity team. This eSurvey was created by the researcher in collaboration with the multidisciplinary team (following PAR principles of participation, collaboration and co-creation of knowledge) and included a mix of multiple choice, ranking and open-ended questions and was open to all women who gave birth in the local hospital in the previous 2 years (Winter and Munn-Giddings,

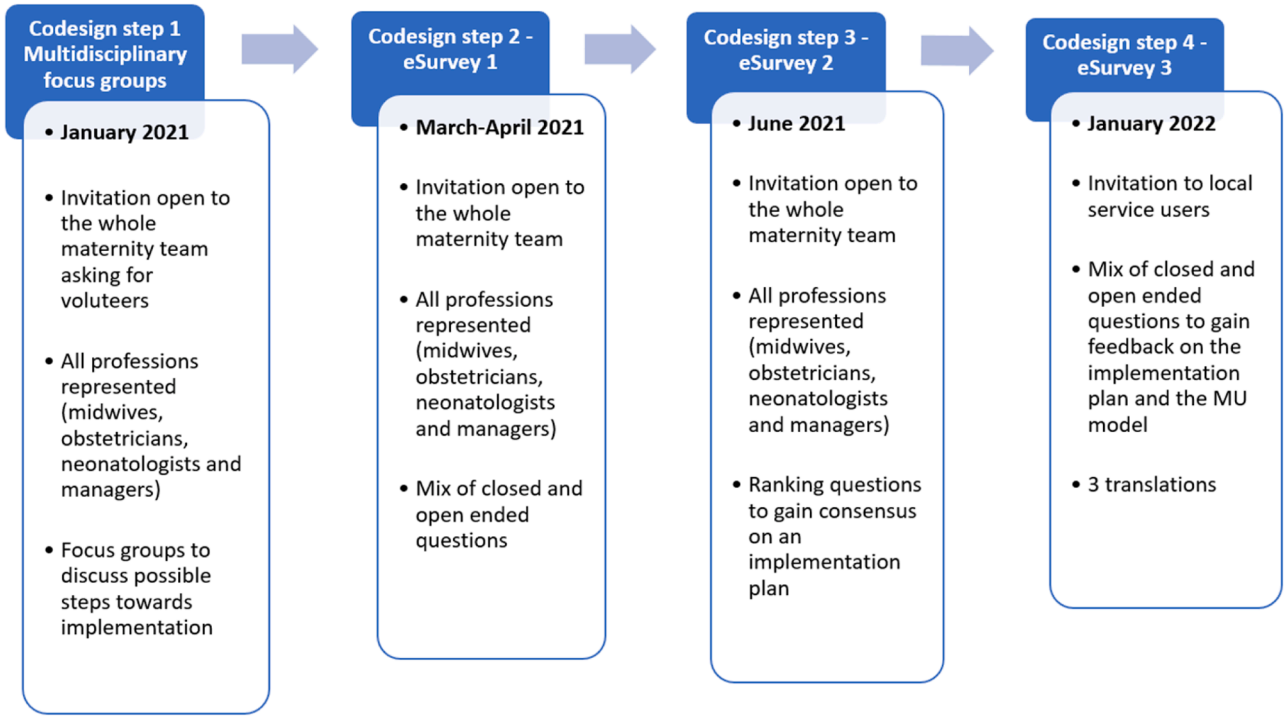

Fig. 1. Codesign steps.

2001). Quantitative data from this survey were analysed descriptively, while open-text responses were thematically coded to identify additional considerations and ensure that the plan was responsive to service users' views.

Recruitment

During step 1, a call for volunteers was circulated via email to all professionals working in the hospital or community settings. Once representation of all professions was reached, three focus groups organised.

All eSurveys were anonymous and only a few demographic details were asked at the beginning. For the eSurveys with professionals, all maternity professionals were invited by email. For the service users eSurvey, a list of contacts was retrieved from the hAPPy Mamma database (the regional application used by local women as pregnancy booklet) of users who agreed to be contacted for research activities. No sample calculation was required as the invitation was directed at all women who gave birth in their third trimester (from 28 weeks) 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, English and French translations were also made to increase accessibility and inclusivity.

The participant information sheet (PIS) was sent prior any data collection activity and informed consent was given prior to participation in the online focus groups or eSurveys.

All data collection activities were conducted by the first author (doctoral fellow at the time) who had been a previous student in the local hospital and was working as a clinical and academic midwife in the UK when conducting this study. Working in another country but being known to the team and aware of many dynamics and relationships helped facilitating stakeholders' engagement, multidisciplinary collaboration, being both an *insider* and an *outsider* to the team. This dual positioning as someone external to the local health system but with established relationships and contextual knowledge offered a good balance of familiarity and objectivity.

Reflexivity was embedded throughout the project to navigate power dynamics and the influence of positionality. A research diary was maintained to document observations, methodological decisions, and reflective notes. These reflections were regularly discussed during monthly supervisory meetings, creating a structured space to address and mitigate any biases or assumptions that could influence the study design, data collection, or interpretation of findings.

The datasets used and analysed during this study are available from the corresponding author on reasonable request and with permission of the local health authority.

Findings

Step 1

During the first step, three focus groups were facilitated with 14 multidisciplinary participants who volunteered to take part: midwifery managers (3), medical director (1), obstetricians (3), neonatologists (3), hospital and community midwives (4). A total of 157 min of data was transcribed verbatim and analysed thematically.

Thematic analysis

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 hesitancy (due to changes in leadership) the team expressed the need to finalise the decision about the MU. They highlighted the need to avoid past lack of communication among the different teams (hospital/community, hospital/fetal medicine, maternity/neonatal teams).
2. **Creation of a multidisciplinary advisory group which will support the MU**
   All different professions needed to be involved in the planning of the MU project. This was seen as particularly relevant in the formulation of specific local guidelines and to avoid lack of support once the MU was opened. Support from the medical component

(both obstetricians and neonatologists) was seen as key at this stage both in terms of advocacy for the MU and to facilitate a shared vision and practices 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 skills they should have. Questions on whether midwives would work regular shifts or on call or in an integrated model were raised. This point seemed to be relevant to define who would be eligible to be in the dedicated group, but no agreement was reached.

4. **Implementation of the intrapartum guidelines for low-risk women**

   Intrapartum guidelines for low-risk women were already in place. However, midwives perceived that not all team members were aware of them and that they were not being followed consistently. Professionals also mentioned the possibility to network with other existing Italian MUs to share knowledge and compare current guidelines.

5. **Appropriate risk assessment**

   Appropriate risk assessment 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 identified 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. Therefore, the need to make practice more consistent was identified as priority.

6. **Integration hospital-community**

   There was common understanding 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 or staff rotation).

7. **Midwifery and multidisciplinary training**

   Suggestions on mandatory training for staff who will be working in the MU were made. The importance of having multidisciplinary training to share vision and practice in case of emergencies in the MU was mentioned. A suggestion 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 important to promote and encourage trust in the MU model of care among the local population, to reach women and engage them in planning for the MU.

9. **Effective communication within the maternity team**

   There was a shared view that communication between professionals and service users could be improved but no clarity on how to achieve this. Difficult communication among the team was often mentioned with main barriers being between managers, medical and midwifery components but also between hospital and community staff.

10. **Reflective clinical practice via audit and debriefing**

    The group 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 for 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.

Step 2

From the thematic analysis of the focus groups, forty-eight questions (closed and open-ended) were prepared and became eSurvey 1 for which invitation was sent to the whole maternity team (108 professionals) to widen participation. In eSurvey 1, questions aimed to explore participants' views on the themes identified during the focus groups. Each theme was accompanied by a mix of open- and closed-ended questions designed to assess their agreement with the concepts discussed, while also allowing space for additional input and suggestions.

Fifty-seven professionals started the survey (48 % response rate) and 52 completed it (91 % completion rate). Sample included different levels of seniority and leadership roles with midwives (31), obstetricians (4), neonatologists (2), nurse (1) and healthcare assistants (10).

During the first eSurvey, there was agreement of most points suggested during the focus groups. When asked their opinion about implementing an MU, participants were overall very supportive: 51 % strongly agreed and 41 % agreed with the initiative. However, a few people disagreed (6 %) or strongly disagreed with the idea (2 %) which provided reassurance that professionals who were opposed to the development did engage in the research process. In the open-ended questions, participants often mentioned the importance to promote physiology and reduce medicalisation while being in a safe environment near the OU. Disagreement was associated with the perception that the number of women eligible for the MU would be relatively low. Some felt that the amount of work needed for this innovation was too great and that money could be invested elsewhere:

> *"Because based on the data collected, low risk women are currently bare bones. There is no (such) culture and I'm sure there will be great resistance from obstetricians to refer women to low-risk care because they follow 90 % of pregnancies. Plus, we're not trained" Participant 5, Hospital Midwife*

Consistent with focus group findings, all agreed that support from medical staff (obstetricians and neonatologists) was necessary. When asked about inclusion of service users in the advisory group, there was heterogeneity of responses: 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 comments that it was "important but for a later stage of the project". This may be related to lack of experience of involvement of service users and a belief that professionals should be the main stakeholders in these projects.

Respondents agreed that a group of dedicated midwives should work in the MU. The skills most valued as requirement to work in a MU were a postgraduate degree, seniority, leadership, empathy, patience and additional professional training (mean scores between 6.15 and 7.79). Skills like motivation, effective communication, right philosophy of care and relevant experience in midwifery led model received a very low score (mean scores between 2.6 and 3.6 out of 10). These findings highlight perceived needs for additional training to that received during the midwifery degree, and specific training needs were proposed (reported more in detail in survey 2). There was particular interest in practical sessions led by nominated team member experts on specific topics 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. Valuing seniority and postgraduate degree is also coherent with highly hierarchical organisational structures.

When asked about working models, 60 % of participants selected the shifts model, 38 % integrated model shifts (cover Monday-Friday during the day and on calls at night and holidays) and 2 % the on-call model.

Midwives perceived that not all team members were aware of the guidelines for low-risk care and that it was not being followed consistently. Majority (60 %) found this would be a "useful" document and 25 % considered it "very useful". Participants mentioned need for 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 to improve the guidelines. For the creation of specific guidelines for the MU, participants agreed that all disciplines from different parts of the service should be involved.

When asked who they thought was the professional responsible for the risk assessment for uncomplicated pregnancies 59 % of participants answered "midwife" while 41 % answered "obstetrician and midwife". This suggests that although there is a regulation in place to promote midwifery care, the culture is still very much doctor centred.

Overall, participants found the labels low, medium and high risk for women's pathways of care appropriate and comprehensible. However, 34 % 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.

Overall, respondents agreed with the suggestions made during the focus groups about initiatives to promote better hospital-community integration. Most mentioned investing in better communication and information sharing to facilitate integration.

Some issues in terms of communication among the team were also reported:

> *"It would be good to have a super partes moderator. Team meetings are emblematic of the impossibility of communication between midwives and obstetricians. But also, among obstetricians and neonatologists." Participant 5, Hospital midwife*

Main suggestions to improve this aspect were regular meetings, seminars, training together, reflective practice and an open, respectful and non-competitive/judgemental communication. There was a high level of agreement with the focus group proposals promoting reflective practice among the team focus groups.

The team agreed that information provision to service users needed to improve and they suggested the following initiatives: more sessions of antenatal classes, informative booklet and posters of maternity pathway and engaging general practitioners and private obstetricians to promote the service.

Step 3

After eSurvey 1, data were analysed and synthesised to include the comments and suggestions made by the wider team and prepare a draft of the implementation plan. Questions were formulated as consensus statements that participants would rate on scale of importance from 0 (not important at all) to 10 (extremely important).

Of the 108 professionals invited, 46 started the survey (response rate 43 %) and 44 completed it (completion rate 95 %). A similar representation of the different disciplines from the first survey with majority of participants being midwives was noted: midwives (25), obstetricians (6), neonatologists (4), nurse (1) and healthcare assistants (6). Again, there was similar representation of different levels of seniority and leadership roles.

The results from the second eSurvey are reported in Table 1. This also represents the implementation plan drafted by the maternity team after steps 1, 2 and 3, ranked in terms of priority perceived by the team (in scale 1 to 10).

The resulting plan provided a clear and actionable framework for the team to advance the implementation of the MU. These findings were shared with the wider maternity team and leadership during a hybrid engagement event, in line with Participatory Action Research (PAR) principles of co-creation and closing the feedback loop ensuring participants saw how their input from the survey had been used. The team endorsed the proposed actions and began working on those considered most urgent and feasible.

Table 1
Consensus statements results from eSurvey 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 centres, 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 transfer 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	7.71	2.48

(*continued on next page*)

Table 1 (*continued*)

Theme	Field	Mean	SD
	call pathways of care with non-clinical names (E.g., like flowers) to avoid focusing the attention on risk.		
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 h, 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
	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

Step 4

During the final step, service users were invited to give feedback to the implementation plan above and the idea of the MU for the local context. Questions aimed to explore their knowledge and perceptions about the innovation (MU), how the model of care would look like in their local context and their opinion on the implementation plan drafted by the team. A total of 617 service users started the survey (45 % response rate) with 102 completing it partially and 515 fully (78 % completion rate). Demographic data is available for the participants who gave consent and started the survey (see Table 2).

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. Participants seemed to be in favour of the innovation with only small percentage not interested at all and 59 % interested in the proposal; 13 % answered "I don't know". The interest of giving birth in such model in case of a future uncomplicated pregnancy was positive for 47 %, 40 % answered "maybe" and 13 % said "no".

In the open-ended question, 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 with it. 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.

Table 2
Demographics of service users.

Demographics - Service users' survey					
	Mean	*SD*		*Number*	*Percentage*
Age	32.95	5.21	**Type of pregnancy**		
	Number	*Percentage*	Physiological	397	64.34 %
Gender			Pathological	220	35.66 %
Female	617	100 %	**Type of birth**		
Year of birth			SVB	387	62.72 %
2019	72	11.67 %	ELCS	110	17.83 %
2020	350	56.73 %	EMCS (not in labour)	64	10.37 %
2021	195	31.60 %	EMCS (in labour)	38	6.16 %
Nationality			Instrumental birth	18	2.92 %
Italy	550	89.14 %	**Weeks of gestation**		
Romania	25	4.05 %	<37 weeks	34	5.60 %
Albania	13	2.11 %	37- 40 weeks	459	74.40 %
Unknown	4	0.65 %	40–42 weeks	83	13.40 %
Poland	4	0.65 %	Unknown	41	6.60 %
Russia	2	0.32 %	**Parity**		
Moldavia	2	0.32 %	Nullipara	228	36.95 %
Bangladesh	2	0.32 %	Multipara	389	63.05 %
Morocco	2	0.32 %	**Education**		
Brazil	2	0.32 %	Secondary School	68	11.02 %
Bulgaria	1	0.16 %	High School Diploma	313	50.73 %
Germany	1	0.16 %	Postgraduate diploma	66	10.70 %
Ukraine	1	0.16 %	University degree	153	24.80 %
North Macedonia	1	0.16 %	Unknown	17	2.76 %
Philippines	1	0.16 %			
Jordan	1	0.16 %			
Egypt	1	0.16 %			
Senegal	1	0.16 %			
Somalia	1	0.16 %			
Tunisia	1	0.16 %			
USA	1	0.16 %			

"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

"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 physiological event, but this is not the case for all women." Participant 149, service user

Interestingly, when asked about who they thought is the professional responsible for risk assessment for uncomplicated pregnancies, service users had similar answers than professionals with 54 % answering "obstetrician and midwife", 27 % opting for "obstetrician" and 19 % for "midwife". This finding seems to highlight again a doctor-centred philosophy 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 previous steps) to avoid over-focusing on the concept of risk.

"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

Service users showed a high level of interest in the idea of having continuity of carer from the same midwife antenatally who would come for the birth too (87 % were interested).

Similar responses were left about the suggestion of integrating a telephone triage to assess women in early stages of labour at home before coming to the hospital (83 % interested).

Participants were overall in agreement with the suggestions about the training needs for midwives for new pain relief techniques, with means always above 6/10. 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. However, most professionals reported not feeling confident enough in using it and in facilitating births there especially due to the resistance from neonatologists and concerns about the room temperature.

Most women (94 %) responded positively about having the possibility of having partner and other children or family members in the room during the postpartum (69 % interested). Participants were also very much in favour (90 %) of the idea of having the neonatologist visit to the baby not at birth but within 24 h in the room. This was one of the points that professionals struggled most with (especially neonatologists) as seeing it far from their current practice and because they believed women would not agree with that.

When asked what they thought of the idea of including service users' representatives in the multidisciplinary meeting to plan the MU, 58 % answered to be interested, only 6 % said 'not interested' and the rest were either 'not interested nor disinterested' or 'did not know'. This is consistent with professionals' answers and highlights again a local culture in which service users tend not to be engaged in service configuration but nonetheless indicates that over half of women would be interested in such involvement. Service users also showed a high level of support of the ideas.

To improve communication between the maternity team and service users, women 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 the maternity team during the maternity pathway. They referred to the community health care centres as main places to access information and meet the team. Furthermore, it was positive to see many comments in agreement about the suggestions made by the professionals in the previous question.

"In this (implementation plan) there are all the channels that I think are really useful for communication, if they really were implemented would be great." Participant 388, service user

Discussion

One key finding was seeing that local women had a strong interest in the MU project but not enough knowledge of this model of care yet. Therefore, an educational and informative intervention seems necessary for the local context to increase the acceptability and appropriateness of the intervention.

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 a freestanding MU as safe regardless of the strong evidence available (Brocklehurst et al., 2011; Scarf et al., 2018). This is a significant finding for this local and national context showing some level of readiness in Italy for alongside MUs but not yet for freestanding or homebirth 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 at around 0.07 % via private service (Cicero et al., 2022). Following a long period of advocacy of hospital birth as safer and a lack of experience of any kind of midwifery unit for professionals and public, this was not a surprising finding. In the UK, despite robust evidence of safe and optimal outcomes in freestanding MUs, many professionals and public perceptions continued to expect that alongside units would be safer (Brocklehurst et al., 2011; Walsh et al., 2020).

Overall, local service users have shown trust in the midwifery profession. 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; Bazirete et al., 2023).

Addressing midwives' training needs to develop autonomy and being ready to work in the MU was a key aspect. Other international studies have identified a lack of training to support physiology (Hadjigeorgiou and Coxon, 2014; Carolan-Olah et al., 2015; Larkin, Begley and Devane, 2017; Darling, McCourt and Cartwright, 2021). However, this is not just a training issue as midwives need to be "*enabled to practice in autonomy*" by the context in which they are working, including feeling supported by obstetric colleagues (ICM, 2021). Healy et al. (2017) in Ireland identified this as a key factor in midwifery having assumed a peripheral position in favour of a more risk-focused approach.

Both professionals and service users believed "midwife and obstetrician" should be responsible for the assessment of low-risk women. This shows how obstetric control over midwifery decision-making is still perceived as needed. 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 using proper nouns to move the focus away from preoccupation with risk, something that professionals were not much in favour of. A 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 (Nickel et al., 2017).

Professionals and managers agreed that a reflective approach to practice was key to improve 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).

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. It was interesting to note the use of the prescriptive word "protocol" as reference for this guideline. Instead of being a set of recommendations that would allow personalisation of care, participants were more used to a set rule 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 in the service users' survey.

The use of codesign with focus groups and online surveys were found to be good engagement strategies that allowed the project to continue even during a global pandemic. The active participation from both professionals and service users 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 European countries found the same support by stakeholders to the codesign aspect of change (Yuill et al., 2023).

The good level of engagement from service users (45 % response rate) and the inclusion of fifteen different nationalities among respondents suggests that including English and French translation helped inclusivity and showed service users' willingness to take part in codesigning the maternity service.

Although codesign would require service users' involvement from the beginning, this was not achievable for the local context which used to only engage professionals in healthcare service configuration. There was however significant progression from usual practice by involving local population in the last step of codesign. 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).

Strengths and limitations

To the authors' knowledge, this is the first study to use a codesign approach to explore the implementation of a MU in a European context. A key strength was the richness of data gathered from a wide range of stakeholders including directors, managers, and multidisciplinary professionals which supported inclusive, participatory action research. Thanks to the collaboration with MeSLab in Pisa, we could reach service users even during a global pandemic.

While the Covid 19 pandemic limited in-person engagement, it unexpectedly enabled wider participation through eSurveys. Due to time constraints, statistical analysis of parts of the service user survey was not conducted; instead, descriptive findings were used to guide the co-produced implementation plan. Finally, conducting data collection in Italian and synthesising findings in English may have led to some loss of nuance, though these issues were actively discussed and addressed in supervision meetings with bilingual supervisors.

Conclusion

An implementation plan was codesigned by the local team with service users feedback to support the transition from the obstetrically led OU only to an integrated model with an alongside MU and an OU. Professionals' suggestions were overall positively supported by service users showing some alignment in the vision for the implementation. Codesign including more virtual forms of engagement was planned because of Covid-19 restrictions but became a successful strategy to include staff members working in different settings across the province. This type of the research was particularly appreciated by stakeholders and fed the professionals' expressed needs to adapt the innovation to the local context based on theirs and service users' needs.

This good level of engagement in the codesign of the innovation constitutes a key step forward for the Italian context but also for similar European contexts in which service users are not often involved in health service design. Further research will be needed to consider whether and how the implementation plan formed through this participatory approach is used in practice and to monitor impact.

CRediT authorship contribution statement

Laura Batinelli: Writing – review & editing, Writing – original draft, Software, Resources, Project administration, Methodology, Investigation, Funding acquisition, Formal analysis, Data curation, Conceptualization. **Christine McCourt:** Writing – original draft, Supervision, Methodology. **Manila Bonciani:** Writing – review & editing, Supervision, Methodology, Conceptualization. **Lucia Rocca-Ihenacho:** Writing – review & editing, Supervision, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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