



City Research Online

City St George's, University of London

Citation: Rayment, J., Rocca-Ihenacho, L., Newburn, M., Thael, E., Batinelli, L. & Mcourt, C. (2020). The development of midwifery unit standards for Europe. *Midwifery*, 86, 102661. doi: 10.1016/j.midw.2020.102661

This is the published version of the paper.

This version of the publication may differ from the final published version. To cite this item please consult the publisher's version.

Permanent repository link: <https://openaccess.city.ac.uk/id/eprint/24120/>

Link to published version: <https://doi.org/10.1016/j.midw.2020.102661>

Copyright and Reuse: Copyright and Moral Rights remain with the author(s) and/or copyright holders. Copies of full items can be used for personal research or study, educational, or not-for-profit purposes without prior permission or charge, unless otherwise indicated, provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way. For full details of reuse please refer to [City Research Online policy](#).



Contents lists available at ScienceDirect

Midwifery

journal homepage: www.elsevier.com/locate/midwThe development of midwifery unit standards for Europe ^{☆,☆☆}Juliet Rayment^a, Lucia Rocca-Ihenacho^{a,*}, Mary Newburn^b, Ellen Thaela^a, Laura Batinelli^a, Christine Mcourt^a^a Centre for Maternal and Child Health Research, City, University of London, 1 Myddelton Street, London, EC1R 1UB, UK^b Independent service user researcher, London, UK

ARTICLE INFO

Article history:

Received 4 November 2019

Revised 6 February 2020

Accepted 8 February 2020

Introduction

The WHO Global Strategy for Women's, Children's and Adolescents' Health 2016–2030 emphasises the importance of maternity services in preventing illness and promoting optimal clinical outcomes (Every Woman Every Child, 2015). Midwifery has been recognised as having huge potential for transformation; worldwide, over 50 health outcomes could be improved by expanding provision and access to quality midwifery care (Renfrew et al., 2014). Midwifery care is also associated with efficient use of resources (Renfrew et al., 2014).

In Europe, where over five million women give birth each year (European Board and College of Obstetrics and Gynaecology, 2014), there is recognition that the sustainability of the midwifery workforce, staff morale and working to one's full potential are interlinked (Büscher et al., 2009). Various innovative models of midwifery-led care are recognised as having the potential to benefit women both as services users and midwives as providers of care. This includes midwife-led continuity models of care, which are associated with fewer obstetric interventions and greater satisfaction with care (Sandall et al., 2016), and midwifery-led environments for intrapartum care. As well as benefiting women (NICE, 2014), providing care in non-obstetric settings enables mid-

wives to have greater autonomy; a protective factor against occupational 'burn-out' (Yoshida and Sandall, 2013).

A recent systematic review concluded there is high-quality evidence to support the expansion of midwife-led birth centre and home birth options for women with low-risk pregnancies in high income countries, with 'no statistically significant impact on infant mortality and lower odds of maternal morbidity and obstetric intervention' (Scarf et al., 2018). The review included 26 studies and 28 articles; 15 articles were from studies conducted in six different European countries, Denmark (e.g. Overgaard et al., 2011), France (Gaudineau, et al., 2013), the Netherlands (e.g. Wiegerinck et al., 2015), Norway (e.g. Blix et al., 2012), Slovenia (Prelec et al., 2014) and the UK (e.g. Birthplace in England Collaborative Group, 2011), together with studies from Australia, Iceland, Japan, New Zealand, and the USA. The findings support the expansion of birth centres and home birth options, and 'the systems to support them, including professional guidelines and education ... and the circumstances necessary to optimise the safety and well-being of mothers and newborns' (Scarf et al., 2018). This comes at a time when there is a growing sense of an inadequate match between a need for specialist obstetric services and experience of medical procedures, with some women experiencing 'too little too late' and others 'too much too soon' as an impact of routine over-medicalisation of normal pregnancy and birth (Miller et al., 2016).

Mapping of midwifery units across Europe has not yet been carried out, so the gap between current provision and potential access has not been determined. The Euro-Peristat project reports units by size but not by type (Obstetric or Midwife-led); it reports home birth rates for England, Wales, Iceland, Scotland and the Netherlands only, and states that the numbers of women using midwifery-led units alongside, or adjacent to, an obstetric unit can rarely be disaggregated from obstetric unit statistics. The Netherlands is an exception; 11.4% of all births occurred in one of 26

* <https://twitter.com/MUStandards>.☆☆ <https://twitter.com/midwiferyunits>.

* Corresponding author at: Centre for Maternal and Child Health Research, City, University of London, 1 Myddelton Street, London, EC1R 1UB.

E-mail addresses: Juliet.rayment.1@city.ac.uk (J. Rayment), Lucia.Rocca-Ihenacho@city.ac.uk (L. Rocca-Ihenacho), marynewburn77@gmail.com (M. Newburn), EThaels@uclan.ac.uk (E. Thaela), Laura.Batinelli@city.ac.uk (L. Batinelli), Christine.McCourt@city.ac.uk (C. Mcourt).

Social media: (J. Rayment), (L. Rocca-Ihenacho), (M. Newburn), (E. Thaela), (L. Batinelli), (C. Mcourt)

(mainly alongside) midwifery units (Euro-Peristat Project, 2010). New Zealand also has rates of midwife-led birth unit use of over 10% (Scarf et al., 2018). Unlike the UK, MUs in continental Europe, for example in France, Italy and Spain, are often only available within obstetric hospital buildings (European Midwives Association, 2015). Some countries have very few public alongside MUs (e.g. Belgium and Italy) and some none at all (e.g. Greece, Portugal and Austria). In England, a 2016 mapping study found that 12% of births were in either alongside or freestanding MUs (Walsh et al., 2018), and this proportion was reported as 14.7% in the national clinical audit of births in 2016/17 (Blotkamp, 2019).

From a staffing perspective, the WHO European Region report on nursing and midwifery recommends role expansion for both groups of predominantly female workers, together with appropriate recognition and reward. The report identifies structural obstacles, including medically dominated health care systems, lack of financial resources and gender issues as preventing midwives and nurses from working to their full potential (Büscher et al., 2009). Thus, there is wide variation in provision of midwife-led care and midwifery units and there appears to be a need to address practical barriers preventing scale-up (Rayment et al., 2019; Walsh et al., 2020). In order to implement recent recommendations to expand access to midwifery units in Europe (Scarf et al., 2018; NICE, 2014), updated practical guidance on appropriate ways to develop, staff and run midwifery units is considered necessary.

Developing standards

Standards are described as 'specifications for products, services and systems, to ensure quality, safety and efficiency' (The International Organization for Standardization (<http://www.iso.org/iso/home/standards.htm>)). Statements developed for this purpose provide 'guidance to ensure consistency' (The International Organization for Standardization (<http://www.iso.org/iso/home/standards.htm>)). Within healthcare, standards provide benchmarks against which to measure the performance of services. They offer guidance on what makes a quality service. Services are expected to be safe, effective, timely, efficient, equitable and people-centred (Every Woman, Every Child, 2015). High level standards are usually accompanied by more specific indicators for audit (World Health Organisation, 2016). There is no single approach to developing health and social care service standards. The crucial components are needs assessment, systematic review of relevant evidence, and comprehensive stakeholder involvement, peer review, field testing and further consolidation (World Health Organization, 2018, 2016; National Institute For Health And Care Excellence, 2016).

Developing the midwifery unit standards

The new Midwifery Unit Standards were developed to bring together the best available evidence related to service delivery. They identify key indicators which address dynamic factors influencing organisational culture and implementation of change. We examined barriers and facilitators of well-functioning midwifery units. The Standards had the following objectives:

- To offer a framework for the implementation or improvement of MUs.
- To educate stakeholders on the key characteristics which define MUs.
- To help Maternity Services to create a vision for service improvement.

The definitions used in this work are as follows:

A midwifery unit (MU) is a location offering maternity care to healthy women with straightforward pregnancies in which midwives take primary professional responsibility for care. Midwifery units may be located away from (Freestanding) or adjacent to (Alongside) an obstetric service.

Alongside midwifery unit (AMU) - during labour and birth, medical diagnostic and treatment services, including obstetric, neonatal and anaesthetic care are available to women in a different part of the same building, or in a separate building on the same site from an obstetric unit. This may include access to interventions that can be carried out by midwives, for example electronic fetal heart monitoring. To access such services, women will need to transfer to the obstetric unit, which will normally be by trolley, bed or wheelchair.

Freestanding midwifery unit (FMU) - medical diagnostic and treatment services and interventions are not available in the same building or on the same site as an obstetric unit. Access is available as part of an integrated service, but transfer will normally involve a journey by ambulance or car.

Modified from: Rowe, R. and the Birthplace in England Collaborative group, 2011.

Midwifery units have been closely associated with a biopsychosocial model of care (McCourt et al., 2018; Rocca-Ihenacho et al., 2018). This type of care aims to be clinically safe by ensuring that the birth environment and staff support the women's and baby's physiological needs in all stages of labour and early postnatal care, as well as attending to the woman's and her family's physical, psychological and social needs, ensuring that interventions are offered only when clinically necessary (Walsh and Newburn, 2002; Renfrew et al., 2014). It promotes equality between women and their carers through women's bodily autonomy and informed decision-making (Coyle et al., 2001; Dahlen et al., 2011; Macfarlane et al., 2014; McCourt et al., 2012, 2016; Overgaard et al., 2012, 2014; Rocca-Ihenacho, 2017; Vedam et al., 2019). Midwifery units often use the name 'birth centre' reflecting the philosophy of care that was first developed explicitly within the birth centre movement (American Association of Birth Centres, 2017).

A search was carried out to identify relevant 'midwifery unit' and 'birth centre' standards. Standards for midwife-led 'birth centres' had been operational in England since 2009 (Ackerman et al., 2009). No other directly relevant standards were found. In the United States birth centre standards were created in 1985, but US birth centres are not all midwife-led (American Association of Birth Centres, 2017). New Zealand had over-arching maternity standards (Ministry of Health, 2001) and a service specification for 'primary maternity facilities' which may be 'stand-alone' or within a level 1 or 2 general hospital (Ministry of Health, 2013). The Royal College of Midwives had also developed Standards for Midwifery Services in the UK (Royal College of Midwives, 2016). As the only MU standards in Europe available in English were those developed by the RCM (Ackerman et al., 2009), these formed the starting point for the development of the standards for Europe.

The Standards were developed for use by those responsible for the organisation of national, regional and local health services, those allocating maternity resources; professionals providing support to a midwifery unit, such as ambulance services, obstetric unit clinicians and service managers and providers of midwifery unit care. They enable stakeholders, including maternity organisations and birth activists, to self-assess local provision against key quality criteria and to plan service improvements. They focus on philosophy of care and organisation of services and are intended to be used alongside clinical guidelines.

Method

The method used to develop the Standards aimed to be both robust and inclusive. It drew on established principles from The World Health Organisation (2016) and National Institute for Health and Care Excellence (2016). It is published so that our approach is clear and transparent and may offer a guide for others developing similar standards.

The Royal College of Midwives Standards (Ackerman et al., 2009), used as the starting point for the Standards for Europe, had been developed by an expert panel but had not included a systematic review of the evidence. Our method involved reassessing and expanding these for a new, broad group of countries. There was input from midwives and others from seven European countries throughout the process, and a total of 13 European countries, plus USA, New Zealand and Australia, contributed during at least one stage. Representatives with knowledge and expertise from relevant countries were identified via the Midwifery Unit Network, a community of practice (Rocca-Ihenacho et al., 2017), academic publications, and the European Midwifery Association (<http://www.europeanmidwives.com/home>). A list of 122 relevant European and international experts on midwifery units was developed, from 18 countries. The European countries that contributed were: Bulgaria, Czech Republic, England, France, Germany, Italy, the Netherlands, Northern Ireland, Portugal, Scotland, Spain, Switzerland and Wales. European countries which have MUs but were not successfully reached were: Estonia, Iceland and Norway.

We used the following steps:

- 1) A systematic search was carried out of the qualitative evidence on the function and organisation of midwifery units (as opposed to clinical outcomes), and a synthesis made of their findings (January and October 2017).
- 2) The findings from this review of the evidence were integrated into a Delphi study, using clear expertise criteria, which involved two online surveys. The first Delphi survey was launched in May 2017 and the second in February 2018.
- 3) A series of stakeholder meetings to review the initial items and contribute to the Standards document at each key stage of development. The first stakeholder meeting was held in London in early June 2017, the second at the International Confederation of Midwives in Toronto in late June 2017 and the third in London in December 2017.
- 4) An initial synthesis was developed by combining findings from the literature, the first Delphi survey and the stakeholder workshops. This continued to be refined throughout the rest of the process.
- 5) Semi-structured interviews were carried out with three midwifery unit leaders in services in England that already met similar organisational standards.
- 6) Peer review by twelve interdisciplinary European stakeholders.

Identifying and reviewing qualitative research evidence

The Standards aimed to incorporate learning from published evidence on the processes, practices and experiences of staff and service users in emerging or established MU services in high income countries, to include evidence most relevant for European countries. The Standards do not address clinical practices or outcomes.

A systematic search of the literature was carried out using keywords to cover all synonyms for both alongside and freestanding midwife-led units.² The review question was “What are the key

barriers and facilitators of well-functioning midwifery units?”. The inclusion and exclusion criteria and PRISMA table can be found in Supplementary Tables 1 and 2. The search found 24 papers and three PhD theses that met the criteria for inclusion. Negative cases were as important as papers that reported on high achieving MUs. For example, reports of the impact of poor leadership could lead to conclusions about the importance of good leadership.

Each journal paper was reviewed for quality by two independent reviewers using a modified version of Walsh and Downe's criteria (2005). PhD theses were considered to have reached an acceptable standard through the examination process. Papers were scored for each of six assessment categories, up to a total possible score of 42 and attributed as ‘High’ ($n=8$), ‘Intermediate’ ($n=8$), ‘Moderate’ ($n=7$) or ‘Poor’ ($n=0$) quality. Full details of the assessment process can be found in Supplementary Table 3 and the quality scores for each paper can be found in Supplementary Table 4. No papers were found to be ‘Poor’ and so none were excluded on the grounds of quality. The papers scored as moderate quality included data that were consistent with that found in higher-quality papers and they were considered useful for the synthesis.

All reported findings (not including author analysis and discussion sections) were coded thematically, using Nvivo 11, using codes generated inductively through the coding process. One team member carried out an initial pilot coding of two papers chosen at random: Annandale (1988) and Walsh (2007), and the codes were checked by a second member of the team. Following this pilot, the rest of the papers and theses were coded, generating 45 open thematic codes (see Supplementary Table 5). This coding process and the subsequent synthesis was designed to fulfil the aim of identifying key themes relating to the function of MUs to be considered for inclusion in the new Standards. These themes were then considered for inclusion through a process described below.

The next steps involved filtering the evidence through real-life expertise. As much of the published literature originated in the UK, USA and Australia, it needed to be assessed for applicability in mainland Europe.

The Delphi process

A Delphi approach offers a structured method for consulting a large number of stakeholders through “a group communication process” (Linstone and Turoff, 2002), with the aim of developing a consensus. It has been widely used in healthcare including in development of quality standards, particularly where the published evidence benefits from supplementation by the clinical experience of healthcare professionals (Boulkedid et al., 2011). Delphi allows a large number of individuals in different locations and with different expertise to participate, avoiding the dominance of individual voices (Jairath and Weinstein, 1994).

We invited 122 midwifery unit experts from across Europe and with at least two years' experience in developing, managing, working, evaluating or supporting midwifery units, to participate in two online Delphi surveys supplemented by stakeholder meetings (See Supplementary Table 6 for a list of meeting participants) and interviews with managers of high-performing services.³ Participants came from seven different European countries. The surveys aimed to construct a consensus from the expert group as to which standards should be included or excluded in the new Standards for Europe.

birth cent*; alongside birth cent*; alongside midwifery unit; alongside midwifery-led unit; co-located birth cent*; co-located midwifery unit; co-located midwifery-led unit.

³ Recipients of the Midwifery Unit Network ‘Beacon Sites’ awards. Information about the Beacon Sites programme can be found here: <http://www.midwiferyunitnetwork.org/beacon-sites>.

² Midwifery-led unit; free-standing birth cent*; free-standing midwifery unit; freestanding midwifery unit; stand-alone birth cent*; standalone birth cent*; stand-alone midwifery unit; midwife-led unit; home-like birth cent*; home-to-home;

In the first survey (Delphi 1), participants were invited to score each of the original Royal College of Midwives' Standards⁴ (2009) plus further relevant points from the [Royal College of Midwives Standards for Midwifery services \(2016\)](#), on a five-point scale from 'Extremely important' to 'Not important at all'. A consensus was defined by a threshold of 75% or more of participants scoring it the highest two points (most important). Participants were invited to suggest new standards or add open text responses on any aspect of the document. Ninety-eight participants started the first Delphi survey, 64 respondents completed it. Not all respondents answered all questions; with a mean of approximately 46 responses to each question.

Following the first survey, seven standards were discarded⁵ as they fell below the threshold, five of these from the section on Public Health. This left a total of 54 standards grouped under the seven themes (Royal College of Midwives, 2009):

- Safety and clinical governance ($n=7$)
- Staffing ($n=7$)
- Organisation ($n=11$)
- Family focus ($n=7$)
- Public health ($n=5$)
- Communication ($n=8$)
- Environment & facilities ($n=9$)

Stakeholder meetings

The themes of leadership, organisational culture, models of care and women's autonomy arose frequently in the free-text comments but were underrepresented in the previous standards (Royal College of Midwives, 2009; 2016). Issues around women's autonomy and models of care were also referred to extensively in the literature (See Supplementary Table 5). In early June 2017, members of the expert Delphi panel were invited to a face-to-face meeting in London with the aim of generating new Standards to encompass these themes. Twenty-nine attendees plus four members of the research team formed three small groups, each of which engaged in detailed discussion on one or two topics. Discussions were recorded, with permission, through written notes and audio recording.

A second stakeholder group held during the International Confederation of Midwives (ICM) Triennial Conference in Toronto on 21st June 2017, canvassed wider expert views to complement the Delphi panel. Fifty conference delegates with an interest in midwifery unit provision participated in facilitated small group discussion on their responses to the existing Royal College of Midwives Standards (2009, 2016). This event generated a further four topics that participants deemed important, but that had not been addressed by the previous Standards: 'user representation in management'; 'marketing, PR and community relationships'; 'ownership and leadership'; and 'service development through continuous audit and monitoring of service user and staff experiences'. Detailed

notes and recordings from the group discussions were used to refine and flesh out the Standards covering these eight themes.⁶

The research team included native speakers of Spanish, Italian, French, Portuguese and Flemish. Researchers met with mixed groups of midwives and families in Spain, Italy and Belgium where the emerging standards were presented and discussed to ensure their relevance in different European countries and cultural settings.

Developing a synthesis

The literature search, Delphi 1 survey and the workshops resulted in a large number of draft standards and themes. At two project meetings in summer 2017 these were combined and synthesised into the smallest number of standards that could accommodate all themes. The aim at this stage was to draft a revised set of standards ready for an assessment by the second Delphi panel.

This synthesis process was as follows:

- A Each standard, theme or thematic code was written on a sticky note and duplications and overlapping notes were removed or consolidated.
- B The authors attempted to group each item under one of the original seven themes from the Royal College of Midwives Standards (2009).
- C It became clear that this framework was no longer sufficient to encompass them all. The team repeatedly revised the groupings, recording and resolving specific problems as they arose.
- D A third meeting was held with an additional researcher to bring 'fresh eyes' to the process.
- E The topics were eventually satisfactorily re-grouped within ten new categories:
 - 1 Biopsychosocial model of care
 - 2 Environment and facilities
 - 3 Pathways of care
 - 4 Staffing, recruitment and workload
 - 5 Leadership
 - 6 Autonomy and accountability
 - 7 Knowledge, skills and training
 - 8 Equality, diversity and social inclusion
 - 9 Clinical Governance
 - 10 Working across boundaries
- F Those topics that had not previously been represented, were drafted as standards.

A third (final) stakeholder meeting was held in London on 6th December 2017 (18 participants) to 'member check' the new structure.

Interviews with experienced managers

We also interviewed managers of three high-performing services to discuss their expertise on the underdeveloped themes of 'leadership', 'community relationships' and 'working across boundaries'. These themes had arisen repeatedly in the literature, stakeholder discussions and free text comments in the Delphi sur-

⁴ The Royal College of Midwives Standards 2009 are structured as seven 'Standards' with 63 sub sections. These correspond to the new Standards' Themes and Standards. We use the term 'Standards' throughout this paper to describe the smallest unit, as per our new document.

⁵ Discarded standards Survey 1: 2.3 (a) Focus on organisational culture (71.7%); 2.3 (c) Environmental Health and Safety (68.1%); 5.2 (c) Benchmarking against Public service agreements (63.8%); 5.2 (d) Reporting policies and outcomes to the local Director of Public Health's Annual Report (60.9%); 5.2 (e) A structure that respects the minors' rights and works in partnership with the local child welfare network (72.3%); 5.2 (f) Audited systematic programmes which meet the requirements of a national service framework, up to date evidence including national plans (72.3%); 6.3 (b) Standardised documentation (63.8%).

⁶ Examples of these new Standards include: **Leadership**: "5.1.1 A clinical lead for the MU. This is a strategic role responsible for making decisions about resources and policies and acting as an advocate for the midwifery unit. This person is: visible on the birth centre, retains involvement in 'every day' clinical practice, able to support staff through hands on clinical practice and share experience (including plans for out of guidelines, on calls etc.);"; **Women's autonomy**: "8.2.3 A clear statement acknowledging and encouraging women's autonomy in decision-making, including a statement that women are able to access the MU 'outside of guidelines' with a personalised care plan" and **Ownership**: "10.1.2 Promote ownership among maternity staff inviting them to unit meetings (governance meetings, incident report meetings, guidelines meetings) and facilitate their role in decision-making."

veys but had not yet been developed into standards and in addition, although they were highlighted as important in the literature, articles lacked detail on the qualities of leadership required. City, University of London Ethics Committee granted ethical approval (reference MCH/PR/Staff/16-17/08) and the interviews were audio recorded with permission and transcribed. Their content was checked against the draft to identify any further themes that could be incorporated into new standards.

Semi-structured interviews were carried out with three midwifery unit leaders in services in England which already met similar organisational standards. These were units identified as 'Beacon Sites' using eight criteria set by Midwifery Unit Network (<http://www.midwiferyunitnetwork.org/beacon-sites/>). The interviews were used to gain lived-experience perspectives and insights to expand on selected themes that arose from the literature but were scarce in detail. This was necessary if the themes were to be worked up into standards and indicators. None of the participating advisers, Delphi participants or peer reviewers knew of a similar initiative to identify MUs meeting specific quality criteria in other countries. The draft standards were refined accordingly.

Next, the revised standards, including the new draft standards was circulated to the original expert panel (plus some additional colleagues from continental Europe), in February 2018 for a period of one month (the Delphi 2 survey). Participants were asked to respond to each item in the same way as Survey 1. Four draft standards were discarded for being under the cut-off threshold for inclusion.⁷

For the second survey, 44 participants came from seven EU countries and six from outside the EU (Australia, New Zealand and the USA). Half the participants had over 20 years' experience and half less than 20 years, with the majority ($n=29/49$) between 11 and 30 years. Twenty-five participants were in clinical midwifery roles, with others working in education, other medical roles (Obstetrics and Neonatology), service user involvement, policy or commissioning. The majority were educated to postgraduate level.

Peer review

The penultimate draft of the Standards document with specific quality indicators was peer reviewed by 12 interdisciplinary European expert reviewers. The reviewer group was selected to include British and mainland-European midwives, obstetricians, service user representatives, campaigners, service improvement professionals and commissioners and was independent of the Delphi panel. Feedback from their reviews was incorporated into the final, published version of the Standards, a 31-page document, available to download for free from: www.midwiferyunitnetwork.org/mu-standards.

Discussion: quality standards as a motivator for change

This paper has set out the methodology used to produce MU Standards for Europe, based on a systematic review of evidence and a synthesis of the findings with expert knowledge. This has

been achieved, involving a significant number of relevant stakeholders from numerous European countries, through a complex, iterative, participative process. A key aim of these Standards is to provide a tool and benchmark by which services with MUs can assess their performance, and also encourage and guide the development and implementation of new MUs in settings where no MUs have been established in recent times.

It was the first time that the qualitative evidence on the processes, practices and experiences of staff and service users (as opposed to clinical care and their outcomes) had been brought together in one place. Previous standards (e.g. Ackerman et al., 2009; Royal College of Midwives, 2016) were developed with expert input but did not include a systematic search or evaluation of the published evidence. The strength of the new Midwifery Unit Standards comes from the combination of systematic search, synthesis and expert consultation. Our Delphi process tested the applicability of the evidence base in real life clinical practice for Europe, beyond the countries in which it had been generated, from the viewpoint of those with expertise in the field. Clear description and transparency of the method will enable future replication in Europe or elsewhere.

It is a strength that the Standards have already been translated into Spanish and Italian and are in the process of being translated into Czech, French, Portuguese, Flemish and Catalan, indicating support from midwives in several European countries. In addition, Brazil and Saudi Arabia, are developing MU Standards based on the Standards for Europe, with support from the European authors. In October 2019 the Midwifery Unit Standards received endorsement from the National Institute for Health and Care Excellence (NICE).

While there are therefore many strengths, a limitation of the approach has been that the available evidence was limited and mostly carried out in the UK, the USA and Australia. The wide variation in provision of MUs in Europe posed a challenge. We aimed to devise a document that is general enough to facilitate the setting up of MUs where provision is new and be sufficiently precise to be useful to those with an established network of MUs, where provision can be further refined and better embedded in good practice. Thus, some of the standards may be aspirational in some settings. The Standards were envisaged to be implemented flexibly in order for them to be useful in all European countries, from those with no provision (e.g. Greece, Portugal and Austria) to those with established midwifery units, such as the Netherlands (Euro-Peristat Project, 2010) and Denmark (Overgaard et al., 2011, 2012). Providers will be able to benchmark their current position in relation to the standards, identify further objectives and develop improvement plans. The Standards will need to be reviewed at intervals as new evidence and expertise is developed. Some of the authors are following up this work with a project to map MUs in Europe. This will involve engagement with MU contacts and expertise in countries missing from this project and involve them in an update of the standards planned for 2021.

A significant number of participants invited to take part in the Delphi surveys did not participate at both stages. The response rate for the surveys was probably influenced by the length as they requested assessment of around 57 draft standards each. However, this is a typical response rate for professional surveys, which often fall well below 50%. In addition, the survey process was supplemented by a series of stakeholder meetings. Importantly service user activists and advocates have been integrally involved in the NICE Birthplace Action Study of which development of these standards has formed at key part. Three were on the advisory group which has helped to shape all aspects of the research from the initial design and funding application stage, through to and including writing up and taking a lead on acquiring the endorsement from NICE. The researchers also met with community women and mixed groups of midwives and families in London, Spain, Italy and

⁷ Discarded standards, Survey 2: 1.1.2 Services are focused on 'mothering the mother' for example by providing support for physical recovery, help to develop practical baby care skills for the mother and her partner, and promotion of emotional wellbeing (74.5%); 2.3.2 MU ideally includes: A common area where service users and staff can socialize and a common kitchen open to service users. Ideally these two areas should be in the same space or nearby (72.6%) 2.2.4 Women should be allocated the same room for labour, birth and the postnatal stay (72.6%); 2.2.5 Access to external green space encourages women to walk about in natural environments during labour (60.8%); 7.1.4 The MU has links with local community leaders (religious leaders etc.) and proactively engages with them and the community (60.0%).

Belgium, and a researcher from Northern Ireland was a key stakeholder taking part in the Delphi study and attending all stakeholder meetings.

The success and utility of the Standards document will be assessed by their use in practice for impact evaluations. Work is currently underway to develop a set of indicators for each of the Standards and a self-assessment tool, with which Maternity Services will be able to evaluate their own service or readiness to develop a Midwifery Unit. We expect that this will eventually form an accreditation process for midwifery units, similar to the model of the UNICEF Baby Friendly Initiative.⁸ Other researchers may wish to appraise the methodology or the outcome of our practical tool.

Conclusions and implications for practice

Midwifery units are associated with excellent clinical outcomes for women and babies (Scarf et al., 2018; Birthplace in England Collaborative Group, 2011; Sutcliffe et al., 2012; Overgaard et al., 2011) and women's experiences of care are also consistently positive when they were cared for in midwifery unit settings (Overgaard et al., 2012; Macfarlane et al., 2014), but these types of services are little-known in many parts of Europe with wide variation in women's access to the model of care. The authors aimed to identify a robust set of Midwifery Unit Standards addressing barriers and facilitators of well-functioning midwifery units in high-income countries, including processes, practices and experiences of staff and service users, in order that these can be widely disseminated across Europe. Based on a systematic review of evidence combined with input from clinical midwives, and other healthcare professionals and maternity advocates at multiple stages in their development, the standards can be used to implement best practice in new and established MUs; to educate professionals during their training and as part of continuing professional development; and to direct strategic development of services by commissioners, service managers, finance directors and other stakeholders.

A substantial amount of new evidence has been published since 2009 when the Royal College of Midwives standards were published (Ackerman et al., 2009) and these new standards for Europe are substantially different in content and structure. We intend that the standards will support the development of new units, improve the function and sustainability of existing ones and make women's access to this model of care more equitable across Europe. Not all standards will currently be achievable or entirely relevant in all countries, but we hope they will stimulate reflection and debate about improving service provision for women and families and developing opportunities for midwifery care.

In developing the Standards, we did not distinguish between 'alongside' and 'freestanding' midwifery units, although some domains will be more relevant to freestanding units, which could be developed as Community Hubs (NHS England, 2016). Particularly in the light of the economic pressures on existing FMUs (Walsh et al., 2018), and the clear evidence (Birthplace in England, 2011, Vedam et al., 2019) that freestanding MUs are likely to be 'different' from alongside MUs in important ways, despite their similarity in being midwife-led and sharing recommended clinical 'eligibility' criteria (Healy and Gillen, 2016; RQJA, 2016), it is important that these Standards are used to support development and sustainability of freestanding midwifery units. This is in line with the National Perinatal and Maternity Audit clinical report recommendation for England that "Maternity service providers and local service users should work together to understand the barriers to birth without intervention in their service" (R8) as a priority in

strategic planning, implementation, and in birth place options offered to women (Blotkamp, 2019; p xv).

The literature review conducted as part of this project suggests that, despite an increase in recent research publications, the evidence-base on the development, management and sustainability of MUs, and literature on what constitutes good quality of care in MUs, remains very limited. Further work is needed to gain a fuller understanding of how the positive outcomes of care and staff and families' experiences in MUs are achieved.

Ethical approval

Ethical approval was granted by City, University of London Ethics Committee (reference MCH/PR/Staff/16-17/08)

Funding sources

This work was supported by: Dr Rocca-Ihenacho NIHR Knowledge Mobilisation Fellowship KMRF-2015-04-001. City, University of London Impact Funding £10,000 (approximately).

Royal College of Midwives £3000 contribution towards Dr Rayment's time to conduct the literature review.

Declaration of Competing Interests

All authors are or have been affiliated with the Midwifery Unit Network.

Acknowledgements

We would like to thank the NIHR, City, University of London, The Royal College of Midwives for their financial support. We also want to acknowledge all the experts who participated in the Delphi study and in the stakeholder events, the peer-reviewers and the service leaders from the MUNet Beacon sites for their contribution. Additionally, we would like to acknowledge Claire Biros, Shujana Keraudren and Deidre Munro who took part in the early part of the project.

The authors would like to thank all participants of the stakeholder engagement meetings and the Delphi survey respondents. Thank you too to Dr Kirstie Coxon for her helpful comments on an earlier draft of this paper.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.midw.2020.102661.

References

- Ackerman, B., Cooke, P., Hutcherson, A., 2009. Standards for Birth Centres in England: A Standards Document. RCM, London.
- American Association of Birth Centres, 2017. Birth Center Standards [online] Available at: <https://www.birthcenters.org/page/Standards> (Accessed 1 June 2018).
- Annandale, E.C., 1988. How midwives accomplish natural birth: managing risk and balancing expectations. *Soc. Probl.* 35 (2), 95–110.
- Birthplace in England Collaborative Group, 2011. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the birthplace in England national prospective cohort study. *BMJ* 343 (d7400).
- Blotkamp, A. for the NMPA Project Team, 2019. National Maternity and Perinatal Audit: Organisational Report 2019. RCOG, London 2019.
- Boulkedid, R., Abdoul, H., Loustau, M., Sibony, O., Alberti, C., 2011. Using and reporting the delphi method for selecting healthcare quality indicators: a systematic review. *PLoS ONE* 6 (6), e20476. doi:10.1371/journal.pone.0020476.
- Büscher, A., Sivertsen, B., White, J., 2009. Nurses and Midwives: A Force for Health Survey on the Situation of Nursing and Midwifery in the Member States of the European Region of the World Health Organisation Available at: www.euro.who.int/_data/assets/pdf_file/0019/114157/E93980.pdf. (Accessed 17.06.19).

⁸ <https://www.unicef.org/programme/breastfeeding/baby.htm>.

- Coyle, K.L., Hauck, Y., Percival, P., et al., 2001. Ongoing relationships with a personal focus: mothers' perceptions of birth centre versus hospital care. *Midwifery* 17 (3), 171–181.
- Dahlen, H., Jackson, M., Schmied, V., Tracy, S., Priddis, H., 2011. Birth centres and the national maternity services review: response to consumer demand or compromise? *Women Birth* 24, 165–172.
- European Board and College of Obstetrics and Gynaecology, 2014. Standards of Care for Women's Health in Europe Available at: www.uems.eu/_data/assets/pdf_file/0020/8750/Item-5.3.8-EBCOG-Standards-of-Care-for-Gynaecology-PDF-FEB-11-2014-FINAL-DRAFT.pdf. (Accessed: 1 June 2018).
- European Midwives Association, 2015. State of Midwifery in France in 2016 Available at: www.europeanmidwives.com/upload/filemanager/content-galleries/members-map/France_EMA_MIDWIFERY_MAPPING_2016.pdf. (Accessed 27.02.19).
- Euro-Perinat Project, 2010. European Perinatal Health Report. Health and Care of Pregnant Women and Babies in Europe in 2010 Available at: www.europeristat.com.
- Every Woman, Every Child, 2015. Global Strategy for Women's, Children's and Adolescents' Health 2016–2030. WHO, Geneva.
- Gaudineau, A., Sauleau, E.A., Nisand, I., Langer, B., 2013. Obstetric and neonatal outcomes in a home-like birth centre: a case control study. *Archives of gynecology and obstetrics* 287 (2), 211–216.
- International Organization for Standardization. Geneva (<http://www.iso.org/iso/home/standards.htm> (accessed 03.02.2020)).
- Jairath, N., Weinstein, J., 1994. The Delphi methodology (Part one): a useful administrative approach. *Can. J. Nurs. Adm.* 7 (3), 29–42.
- Healy, M., Gillen, P., 2016. Planning birth in and admission to a midwife-led unit: development of a GAIN evidence-based guideline. *Evidence Based Midwifery* 14 (3), 82–86.
- Linstone, H.A., Turoff, M., 2002. Introduction. In: Linstone, Turoff (Eds.), *The Delphi Method: Techniques and Applications*. Addison-Wesley Publishing Company, Advanced Book Program, Reading MA.
- Macfarlane, A.J., Rocca-Ihenacho, L., Turner, L.R., Roth, C., 2014. Survey of women's experiences of care in a new freestanding midwifery unit in an inner city area of London, England – 1: methods and women's overall ratings of care. *Midwifery* 30 (9), 998–1008.
- McCourt, C., Rayment, J., Rance, S., Sandall, J., 2012. Organisational strategies and midwives' readiness to provide care for out of hospital births: an analysis from the birthplace organisational case studies. *Midwifery* 28 (5), 636–645.
- McCourt, C., Rayment, J., Rance, S., Sandall, J., 2014. An ethnographic organisational study of alongside midwifery units: a follow-on study from the birthplace in England programme. *Health Serv. Deliv. Res.* 2 (7).
- McCourt, C., Rayment, J., Rance, S., Sandall, J., 2016. Place of birth and concepts of wellbeing: an analysis from two ethnographic studies of midwifery units in England. *Anthropol. Action* 23 (3), 17–29.
- McCourt, C., Rance, S., Rayment, J., Sandall, J., 2018. Organising safe and sustainable care in alongside midwifery units: findings from an organisational ethnographic study. *Midwifery* 65, 26–34.
- Miller, S., Abalos, E., Chamillard, M., Ciapponi, A., Colaci, D., Comandé, D., Diaz, V., Geller, S., Hanson, C., Langer, A., Manuelli, V., Millar, K., Morhason-Bello, I., Castro, C.P., Pileggi, V.N., Robinson, N., Skaer, M., Souza, J.P., Vogel, J.P., Althabe, F., 2016. Beyond too little, too late and too much, too soon: a pathway towards evidence-based, respectful maternity care worldwide. *Lancet* 388 (10056), 2176–2192.
- National Institute for Health and Care Excellence, 2014. Intrapartum Care For Healthy Women and Babies (Clinical guideline CG190). Available at: www.nice.org.uk/guidance/cg190.
- National Institute for Health and Care Excellence, 2016. Health and Social Care Directorate Quality Standards Process Guide <https://www.nice.org.uk/Media/Default/Standards-and-indicators/Quality-standards/quality-standards-process-guide.pdf>.
- NHS England, 2016. Better Births: Improving Outcomes of Maternity Services in England. National Maternity Review. NHS, England <https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf>.
- Overgaard, C., Fenger-Grøn, M., Sandall, J., 2012. The impact of birthplace on women's birth experiences and perceptions of care. *Soc. Sci. Med.* 74 (7), 973–981.
- Overgaard, C., Møller, A.M., Fenger-Grøn, M., Knudsen, L.B., Sandall, J., 2011. Free-standing midwifery unit versus obstetric unit: a matched cohort study of outcomes in low-risk women. *BMJ* 1 (2), e000262 open, 1.
- Rayment, J., Rance, S., McCourt, C., Sandall, J., 2019. Barriers to women's access to alongside midwifery units in England. *Midwifery* 77, 78–85.
- Renfrew, M.J., McFadden, A., Bastos, M.H., Campbell, J., et al., 2014. 'Midwifery and quality care: findings from a new evidence informed framework for maternal and newborn care. *Lancet* 384, 1129–1145. doi:10.1016/S0140-6736(14)60789-3.
- Rocca-Ihenacho, L., 2017. An Ethnographic Study of the Philosophy, Culture and Practice in an Urban Freestanding Midwifery Unit Unpublished PhD thesis. City. University of London, London.
- Rocca-Ihenacho, L., Batinelli, L., Thael, E., Rayment, J., Newburn, M., McCourt, C., 2018. *Midwifery Unit Standards*. City, University of London, London.
- Rowe, R. Birthplace in England Collaborative Group, 2011. Birthplace Terms and Definitions: Consensus Process. Birthplace in England Research Programme. Final Report Part 2. NIHR Service Delivery and Organisation programme Available at: <https://www.npeu.ox.ac.uk/birthplace>.
- Royal College of Midwives, 2016. The RCM Standards for Midwifery Services in the UK. Royal College of Midwives, London.
- RQIA, 2016. GAIN Guideline for Admission to Midwife-Led Units in Northern Ireland '046 Northern Ireland Normal Labour '046 Birth Care Pathway. RQIA, Belfast.
- Sandall, J., Soltani, H., Gates, S., Shennan, A., Devane, D., 2016. Midwife-led continuity models versus other models of care for childbearing women'. *Cochrane Database Syst. Rev.* doi:10.1002/14651858.CD004667.pub5.
- Scarff, V., Rossiter, C., Vedam, S., Dahlen, H.G., Ellwood, D., Forster, D., Foureur, M.J., McLachlan, H., Oats, J., Sibbritt, D., Thornton, C., Homer, C.S.E., 2018. Maternal and perinatal outcomes by planned place of birth among women with low-risk pregnancies in high-income countries: a systematic review and meta-analysis. *Midwifery* 62, 240–255.
- Sutcliffe, K., Caird, J., Kavanagh, J., Rees, R., Oliver, K., Dickson, K., Woodman, J., Barnett-Paige, E., Thomas, J., 2012. Comparing midwife-led and doctor-led maternity care: a systematic review of reviews. *J. Adv. Nurs.* 68, 2376–2386. doi:10.1111/j.1365-2648.2012.05998.x.
- Vedam, S., Stoll, K., Taiwo, T., Rubashkin, N., Cheyney, M., Strauss, N., Mclemore, M., Cadena, M., Nethery, E., Rushton, E., Schummers, I., Declercq, E. the GYTM-US Steering Council, 2019. The giving voice to mothers study: inequity and mistreatment during pregnancy and childbirth in the United States. *MBMC Reprod. Health* 16.
- Walsh, D., Downe, S., 2005. Meta-synthesis method for qualitative research: a literature review. *J. Adv. Nurs.* 50 (2), 204–211.
- Walsh, D., Newburn, M., 2002. Towards a social model of childbirth. *Br. J. Midwifery* 10 (9), 540–544.
- Walsh, D., Spiby, H., Grigg, C.P., Dodwell, M., McCourt, C., Culley, L., Bishop, S., Wilkinson, J., Coleby, D., Pacanowski, L., Thornton, J., 2018. Mapping midwifery and obstetric units in England. *Midwifery* 56, 9–16.
- Walsh, D.J., 2007. A birth centre's encounters with discourses of childbirth: how resistance led to innovation. *Sociol. Health Illness* 29 (2), 216–232.
- Wiegerinck, M.M., van der Goes, B.Y., Ravelli, A.C., et al., 2015. Intrapartum and neonatal mortality in primary midwife-led and secondary obstetrician-led care in the Amsterdam region of the Netherlands: A retrospective cohort study. *Midwifery* 31 (12), 1168–1176.
- Walsh, D., Spiby, H., McCourt, C., Grigg, C., Coleby, D., Bishop, S., Scanlon, M., Culley, L., Wilkinson, J., Pacanowski, L., Thornton, J., 2020. Factors influencing the utilisation of free-standing and alongside midwifery units in England: a qualitative research study. *BMJ open* 10 (2).
- World Health Organisation, 2018. WHO Recommendations: Intrapartum Care for a Positive Childbirth Experience. WHO, Geneva Available at: <https://www.who.int/reproductivehealth/publications/intrapartum-care-guidelines/en/>. (Accessed 18.06.19).
- World Health Organization, 2016. Standards For Improving Quality of Maternal and Newborn Care in Health Facilities. WHO, Geneva http://www.searo.who.int/docs/default-source/mca-documents/advisory-groups/quality-of-care/standards-for-improving-quality-of-maternal-and-newborn-care-in-health-facilities.pdf?sfvrsn=3b364d8_2.