# Organisational Readiness for Midwife-Led Units: Characteristics Linked to Successful Implementation - A Systematic Review and Meta-Synthesis.

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| **ABSTRACT** | | | |
| Abstract | 2 | See the PRISMA 2020 for Abstracts checklist. | Pg 10 |
| **INTRODUCTION** | | | |
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| **METHODS** | | | |
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| Effect measures | 12 | Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results. | N/A |
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| | 13f | Describe any sensitivity analyses conducted to assess robustness of the synthesized results. | N/A |
| Reporting bias | 14 | Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases). | N/A |

| Section and Topic | Item # | Checklist item | Location where item is reported |
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| | 24b | Indicate where the review protocol can be accessed, or state that a protocol was not prepared. | 4.8 |
| | 24c | Describe and explain any amendments to information provided at registration or in the protocol. | N/A |
| Support | 25 | Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review. | 4.7 |
| Competing interests | 26 | Declare any competing interests of review authors. | 4.9 |
| Availability of data, code and other materials | 27 | Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review. | Appendices & Supplementary |

## ABSTRACT

### Objective
To identify organisational readiness characteristics associated with the successful implementation of midwife-led units (MUs) in public maternity services, and to inform the development of a context-specific organisational readiness assessment tool.

### Design
Systematic review and qualitative thematic meta-synthesis.

### Data Sources
CINAHL, Medline, Ovid MEDLINE, Embase, Emcare, MIDIRS, and Global Health were searched using terms related to “midwife-led units,” “organisational readiness,” and “innovation.” Additional sources were identified through citation tracking, journal browsing, and expert recommendation.

### Eligibility Criteria
Peer-reviewed primary studies describing implementation of MUs in public maternity services and reporting qualitative data on organisational conditions, perceptions or experiences of change. Studies focused solely on other models of midwifery care were excluded.

### Methods
A thematic synthesis was undertaken using Thomas and Harden’s (2008) three-stage method, supported by NVivo 14. Analytical themes were mapped to the Consolidated Framework for Implementation Research (CFIR) to enhance theoretical rigour and transferability.

### Results
Nineteen articles met inclusion criteria, spanning diverse geographical contexts. Eight major themes of organisational readiness emerged: *organisational culture and climate; innovation characteristics and implementation process; midwifery autonomy and role empowerment; leadership and governance; external context and enabling conditions; evidence-inspired service; resources and infrastructure; and communication and dissemination*. High-readiness characteristics for midwife-led unit implementation included collaborative cultures, strong midwifery leadership, distributed decision-making, and alignment between institutional values and the midwifery philosophy of care. Midwife autonomy, psychological safety, and team cohesion were central enablers. Mapping to CFIR revealed partial alignment, with several relational and midwifery-specific characteristics - such as professional autonomy and values-based leadership - not fully captured by existing frameworks.

### Conclusions
Organisational readiness for midwife-led unit implementation is multifaceted, encompassing cultural, relational, and philosophical dimensions. This review examines the characteristics of organisational readiness for implementing midwife-led units in public maternity systems and highlights the limitations of generic readiness frameworks in capturing the unique dynamics of midwifery-led care particularly in this context, underscoring the need for a tailored assessment tool. Findings offer critical guidance for health leaders, policymakers, and implementation teams seeking to embed midwife-led units within public sector maternity systems.

### Keywords
Midwife-led units, organisational readiness, innovation, implementation, healthcare strategy, public health, leadership, maternity services, qualitative synthesis, midwifery autonomy

# 1. INTRODUCTION

## 1.1 Background

Midwife-led units (MUs) offer a care model rooted in physiological birth, relational continuity, and a holistic understanding of maternal health. Operating as standalone birth centres (Freestanding Midwife-led Unit - FMU) or alongside hospital settings (Alongside Midwife-led Unit - AMU), MUs are staffed and managed by midwives trained to international standards (ICM Competencies, 2024). midwife-led units can vary in their provision of women's health services across the reproductive continuum, yet always offer a midwifery-model of care that contrasts starkly with the medical paradigm of obstetric-led units (Stevens & Alonso, 2020; Lancet, 2014). Over a decade of evidence has demonstrated that midwife-led units are associated with significantly fewer interventions, higher rates of spontaneous vaginal birth, improved maternal satisfaction, and no increase in adverse neonatal outcomes, particularly in high-income countries (HICs) (Birthplace, 2011; MacFarlane et al., 2014). These findings are echoed in international research which collectively advocates for midwife-led units as a cost-effective, woman-centred option that supports both clinical safety and humanised care (Benatar et al., 2013; Edmonds et al., 2020). Emerging literature from low- and middle-income countries (LMICs) found 57 mostly freestanding midwife-led units, and reports that when supportively integrated into health systems, midwife-led units can provide high quality care to women the world over (Nove et al., 2023; Bazierete et al., 2023; Turkmani et al., 2023).

The recent launch of the UNFPA's Midwifery Accelerator outlines a seven-step path towards global investment in midwives as a proven strategy to save over 4.3 million lives by 2035 (UNFPA, 2025; SoWMy, 2021; Nove et al., 2021). The WHO's 2024 *Transitioning to Midwife-Led Care* position paper calls for a system shift toward midwifery-led continuity models to meet Sustainable Development Goals by 2030 (UN, 2015; WHO, 2024). Likewise, the International Confederation of Midwives (ICM) endorses Midwife-Led Birthing Centres [MUs] as key to equitable, respectful and effective maternity care (ICM, 2025). In Europe, the development of the *Midwifery Unit Standards* (Rayment et al., 2020) have provided operational blueprints for safe and sustainable MU provision. However, despite these endorsements, MUs remain underutilised or non-existent in many contexts. In England - where strong evidence, awareness and a history of implementation is strong - only around 14% of women give birth in MUs (Walsh et al., 2018). Globally, the picture is more varied, with slow public sector uptake in many LMICs and fragmented provision in higher-income contexts (Bazirete et al, 2023; Batinelli et al., 2022; Bączek et al., 2020).

This implementation gap persists despite growing international consensus on the value of MUs and decades of empirical research. Understanding why such a well-evidenced, policy-aligned model remains difficult to implement at scale is therefore a matter of urgent concern for health systems seeking to improve maternal and newborn outcomes, reduce unnecessary interventions, and build respectful, rights-based maternity care.

## 1.2 Problem Statement

The underutilisation of MUs cannot be explained by clinical outcomes alone, but rather reflects organisational, political, and cultural complexities inherent in maternity healthcare systems. Studies have highlighted a range of implementation challenges, including resistance

from medical hierarchies, resource constraints, and a lack of structural or cultural readiness to adopt models grounded in midwifery autonomy (Edmonds et al., 2020; Batinelli et al, 2022; Sangy et al., 2023).

In public maternity services - particularly those serving diverse or marginalised populations - these challenges intersect with broader concerns about over-medicalisation, equity and access. Failure to implement MUs risks entrenching inequalities in maternal health outcomes and brushing aside the well-documented Lancet phenomena of *'too much too soon; too little too late'* in maternity care (Miller et al, 2016). Addressing this requires not just clinical or economic arguments, but innovative strategic organisational planning that considers the specific factors required to implement, support and sustain this change.

### 1.3 Literature Gap

The literature on midwife-led units is extensive, with a focus on outcomes, cost-effectiveness, and user experiences (Birthplace, 2011; Benatar et al., 2013; Rayment et al., 2020). As global implementation of MUs and midwifery-led care models has not reflected the expected uptake of such a strong economic and positive global health preserving model, researchers have taken to implementation science to ask: '*why not?*'. An MU-specific research focus on barriers and facilitators to implementation is relatively recent but growing (Batinelli et al., 2022; Bazirete et al, 2023).

Wider healthcare research is beginning to explore the concept of *organisational readiness for change* as a means of assessing and addressing an organisation's potential barriers to change and strategizing to overcome these prior to implementing complex system innovations (Jacobs et al., 2015; Storkholm et al., 2018; Harrison et al., 2022). Exploring characteristics such as shared beliefs, motivation, commitment and resources, Organizational Readiness for Change (ORC) theory was initially conceptualized in 2009 by Weiner as: *"an organisational members' change commitment and self-efficacy"*. This was further developed by Holt et al. (2010), who in collaboration with Weiner created four constructs to help define organisational readiness for change: Individual Psychological, Individual Structural, Organisational Psychological and Organisational Structural. Rafferty et al. (2013) then built upon this to emphasise that organisational readiness for change must be considered as a multilevel construct; spanning the individual, team and institutional levels. A *"gold standard"* definition of organisational readiness remains elusive (Miake-Lye et al, 2020). However, the general theory posits that successful implementation of a change, such as midwife-led units, is contingent upon both individual and collective motivation, as well as perceived capability for change. This review will take a multilevel consideration of organisational readiness for change, with emphasis on the meso- or "team" level as pertaining to maternity settings.

A variety of instruments have been created to measure organisational readiness (Weiner, 2009; Holt et al., 2007), yet these frameworks have not yet been widely applied in maternity care (Crowe et al., 2019; Dadich et al., 2021). Where readiness tools have begun to be tested in midwifery, they have so far focused on practice change rather than MU implementation (Bayes et al., 2015; Adelson et al., 2021; Davis et al., 2022).

A rapid scoping review conducted at the outset of this project found no organisational readiness for change assessment tool suitable for the unique conditions of MU

implementation. Studies by van de Water et al. (2024), Kuipers et al. (2024), and de Leo et al. (2025) begin to explore related questions on readiness to provide respectful maternity care or midwives' readiness for midwife-led care. Moreover, reviews of readiness assessment tools have concluded that most are highly context-specific and often necessitate creation de novo or adaptation for use in other settings (Miake-Lye et al., 2020; Timmings et al., 2016).

To date, no systematic synthesis exists that identifies which organisational readiness characteristics are associated with successful MU implementation across different contexts. This gap hinders the development of targeted readiness assessment or change management strategies and leaves change leaders without clear and potentially crucial guidance for pre-implementation planning.

### 1.4 Rationale

As interest in MUs grows globally, there is an urgent need to understand the conditions that enable or constrain their adoption within public maternity systems.

By identifying organisational characteristics associated with MU implementation readiness, this review aims to bridge the gap between advocacy and practical implementation. This systematic review aligns with broader calls in global health to strengthen the evidence base for systems change, particularly in maternal and newborn care (Lancet, 2014; WHO, 2016). This review does not restrict inclusion to HICs, theorising that organisational readiness is shaped by contextual factors that may transcend developmental and economic conditions. Midwife-led units are being explored and implemented across diverse settings, and valuable insights into enablers and barriers may arise from both LMICs and HICs. Beginning with this inclusive approach supports the later development of context-sensitive readiness tools that can be adapted to various policy environments and resource levels.

The findings of the review are intended to inform a subsequent phase of tool development, co-produced with stakeholders, that will support strategic readiness assessment at the pre-conceptualisation stage of MU implementation.

Implementation science frameworks, particularly the Consolidated Framework for Implementation Research (CFIR) (Damschroder et al., 2022), offer well-studied tools to analyse how innovations are adopted and sustained in complex systems. CFIR highlights the importance of inner and outer setting factors, intervention characteristics, and implementation processes - many of which overlap with what is known anecdotally or qualitatively about successful MU implementation. Mapping the findings of this review to the CFIR framework could assist in identifying gaps in previous implementation strategies where characteristics specific to MUs may not have been considered, as well as aiding in the generalisability and wider dissemination of the research.

### 1.5 Aim, Objectives, and Review Question

The aim of this review is to identify and synthesise organisational readiness characteristics associated with the successful implementation of midwife-led units in public maternity services. The findings will inform the development of a context-specific organisational readiness assessment tool for change leaders in maternity care.

### 1.6 Objectives:

1. To synthesise existing qualitative evidence describing the organisational readiness characteristics that enabled MU implementation.
2. To identify gaps in organisational readiness for change that could be addressed prior to implementation.

## 2. METHODS

A systematic review methodology was chosen to comprehensively identify, appraise, and synthesise existing qualitative evidence on the implementation of midwifery-led units. This approach ensures transparency, reproducibility, and rigour when exploring complex interventions across diverse settings (Gough et al., 2017). Given the qualitative nature of the review, a thematic analysis was chosen to code and categorise key patterns across texts, allowing for comparison while preserving contextual meaning (Thomas & Harden, 2008). To elevate the synthesis beyond mere aggregation, a meta-synthesis - drawing on the interpretive methodology of Noblit and Hare (1988) and later refined by Thomas and Harden (2008) - was undertaken. This enabled the development of new conceptual understandings around organisational readiness and relational models of care, grounded in primary study findings. Together, these methods offered a robust, theory-informed approach suitable for informing policy and practice within maternity care systems.

### 2.2 Question Development

Prior to commencing the review, an initial scoping search of available literature around organisational readiness was undertaken to develop an understanding of the concept, available organisational readiness tools and current application in practice. The search confirmed that no existing organisational readiness tool could fully be applied to the context of assessing MU implementation readiness, which underscored the need for the development and operationalisation of a bespoke tool (Timmings et al, 2016). A further scope of the literature showed no available evidence directly addressing organisational readiness to implement midwife-led units, with some studies discussing the wider context of readiness in other healthcare settings, and limited emerging research focusing on midwifery-led care and maternity settings (Bayes et al, 2019; Esan et al, 2022). Though a young field of study, articles exploring barriers and facilitators to implementation of midwife-led units in public heath settings were found to be more readily available. This guided the development of the research question and methodology towards a strategy of harnessing inductive analysis to generate themes from a broader range of relevant literature that may not appear initially specific to organisational readiness for MUs. The decision to focus on publicly funded settings reflects the equity imperative of MU implementation within universal health coverage systems, making the potential findings of the review more relevant to policy development.

The research aimed to identify key characteristics of organisational readiness rather than comparing specific interventions or outcomes. The SPIDER Framework was therefore used to formulate the research question, as this was appropriate for exploring perceptions,

experiences, or contextual factors in qualitative research (City St Georges, UoL, 2025). This can be seen in Table 1.

| SPIDER | Definition | Question Development |
|---|---|---|
| **Sample** | Group focusing on | Maternity services or healthcare professionals involved in the implementation of midwife-led units |
| **Phenomenon of Interest** | Behaviour/experience being examined | Organizational readiness for implementing midwife-led units. |
| **Design** | How was the research carried out | Studies that examine OR in maternity context (qual/quant/mixed). |
| **Evaluation** | Which outcome is being measured | Key characteristics for assessing organisational readiness specific to context. |
| **Research type** | Qual/quant/mixed? | All available. |

***Table 1 Question Formulation Framework***

### 2.3 Theoretical Framework

This systematic review is underpinned by Organizational Readiness for Change (ORC) theory, as conceptualized by Weiner (2009), Holt (2010) and Rafferty (2013).

### 2.4 Eligibility Criteria

The PICOS Framework (Population, Interventions, Context, Outcomes and Study designs) was used to define inclusion and exclusion criteria then adapted to meet PROSPERO structure requirements. This can be seen outlined in Table 2. Studies published in English and other languages spoken by the primary researcher were included.

***Table 2 Inclusion/Exclusion Criteria***

| Criteria | Inclusion | Exclusion |
|---|---|---|
| **Participants** | Public maternity services, staff, service users and all stakeholders involved in the implementation of a midwife-led unit or in the assessment of the organisational readiness of any public maternity services planning to implement or having already implemented a midwife-led unit. | Private midwife-led units. Other healthcare services. |
| **Phenomenon of Interest** | Implementation of midwife-led unit specific organisational readiness characteristics. | Implementation strategies or improvement strategies not mentioning characteristics of organizational readiness. Midwife-led models of care not specific to midwife-led units. |
| **Outcomes** | Common characteristics for assessing organisational readiness in maternity settings preparing for or having already implemented a midwife-led unit. | Implementation strategies not concerning midwife-led units. |
| **Study Design** | Qualitative and mixed-methods with qualitative component. | Other systematic reviews. |
| **Study Focus** | Studies concerning the organisational readiness of maternity services to implement midwife-led units. | Studies examining nursing or other healthcare sectors. Studies concerned with other midwifery models of care. |
| **Setting** | Maternity services considering the implementation of, currently implementing or which have already implemented midwife-led units. | Studies not in maternity services or studies about other midwife-led models of care. |
| **Time period** | No restriction. | |
| **Language** | English, Spanish, Polish, French. | Other languages. |
| **Publication Type** | Peer reviewed. | Non-peer reviewed research or reports. |

## 2.5 Search Strategy

To maximise the data available to answer the research question, a broad systematic review was conducted using a qualitative thematic meta-synthesis approach and reported following Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines (Page et al, 2021). The focus on qualitative research was grounded in the development of the review question, which aimed to explore contextual and experiential dimensions of organisational readiness in wider MU implementation research.

An inductive approach to thematic analysis was further justified to ensure unconstrained identification of themes, which could later be mapped to an existing implementation framework to test for coverage and comparison (Thomas & Harden, 2008).

A full search strategy was developed for each database using MESH terms where available, and search terms related to “midwife-led units”, “birth centres”, “organisational readiness”, “innovation”, and “organisational culture”. An example search strategy for Ovid MEDLINE is provided in Figure 1.

| Set | Search Statement | Annotations | Insert | Edit | Delete |
|---|---|---|---|---|---|
| 1. | organization/ or organizational culture/ or organizational development/ or organizational theory/ | | | | |
| 2. | health care planning/ or strategic planning/ or planning/ | | | | |
| 3. | 1 and 2 | | | | |
| 4. | ((organi?ation* or service* or system or team or unit or context or change) adj5 (readiness or preparedness or culture or innovation or capacity or willingness or assessment)).af. | | | | |
| 5. | 3 or 4 | | | | |
| 6. | (midwi* unit or midwi*-led unit or birth* unit or birth* cent* or birth* house or matern* unit or matern* care unit or obstetric* unit).af. | | | | |
| 7. | midwife/ | | | | |
| 8. | obstetrics/ | | | | |
| 9. | maternal care/ or maternal health service/ | | | | |
| 10. | 6 or 7 or 8 or 9 | | | | |
| 11. | 5 and 10 | | | | |

***Figure 1 Search Strategy for OVID Medline***

A protocol for this review was developed in advance of data extraction. The review protocol was registered on PROSPERO on 16th March 2025: Registration No. CRD420251009197. The review focused on identifying organisational readiness characteristics associated with the successful implementation of MUs in public maternity services.

A systematic review of the literature was conducted between October 2024 and November 2024, then repeated in March 2025 to ensure inclusion of any newly published and relevant studies. Searches were conducted across the following databases: CINAHL, Medline, Ovid MEDLINE, Embase, Emcare, MIDIRS and Global Health. Other pertinent peer-reviewed studies were sourced from Google Scholar (limited to first 50 'hits'), journal browsing, citation tracking and following expert recommendation.

### 2.6 Study Selection

Titles and abstracts were screened for relevance by two independent reviewers MC and EB via a shared folder, with a third senior reviewer available for supervisory support (LR-I). Discrepancies at any stage were resolved through meetings, and with the involvement of the third reviewer when necessary. Screening was managed using RefWorks and an Excel spreadsheet.

Since concerns around a paucity of available literature had instigated a broad search strategy with search terms that could ultimately include other midwife-led models of care, studies were carefully screened for their discussion of midwife-led units only, excluding work addressing other midwifery-led models of care. A PRISMA Flowchart of the study selection process can be seen in Figure 2

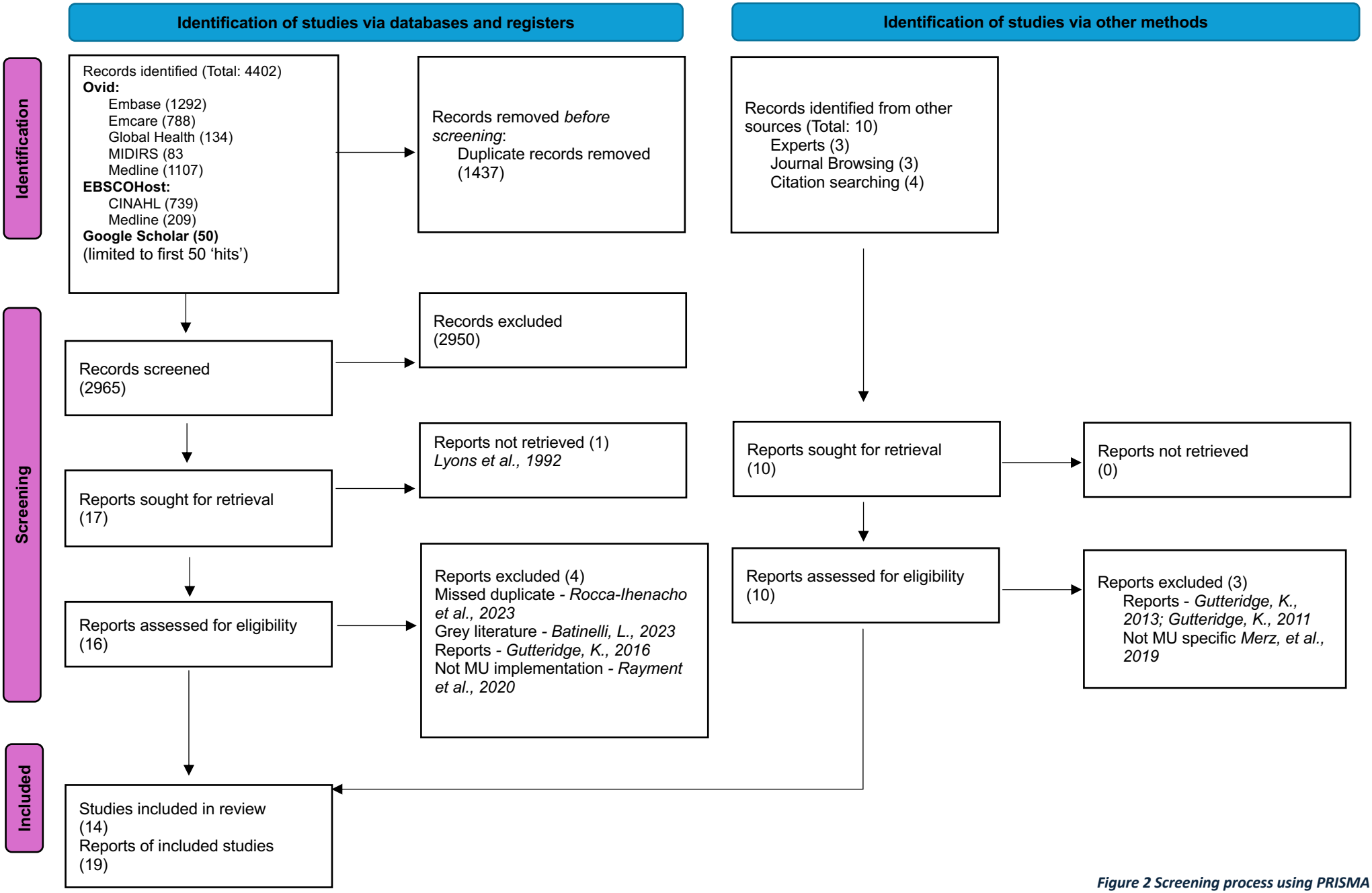


*Figure 2 Screening process using PRISMA*

### 2.7 Quality Appraisal

The methodological quality of included studies was appraised using an independent quality assessment tool, developed by Rocca-Ihenacho and Yuill for qualitative systematic reviews (2020 & 2021), and chosen for its increased sensitivity to validity. A copy of this tool can be found in Appendix I. The studies were divided between reviewers, screened independently against the assessment tool, and then cross-checked. The tool is comprised of 33 questions assessing the rationale, design, interpretation, discussion, reflexivity and ethical dimensions of each study. Scoring each question between 0 (low quality) and 2 (high quality) per stated criteria to a maximum score of 66. All 19 studies scored 50/66 or above indicating high quality, therefore none of the studies were excluded. The scores can be seen in the Key Data Characteristics Table in Table 3.

### 2.8 Data Extraction & Synthesis

A bespoke Excel spreadsheet was developed to capture the extracted key characteristics of each paper. This can be seen in Table 3.

Data were then synthesised using Thomas and Harden's (2008) three stages of thematic synthesis:

- 1. line-by-line inductive coding of relevant findings from the results sections of each study;
- 2. organisation of codes into descriptive themes representing recurrent patterns across the literature; and,
- 3. development of analytical themes that interpret and extend beyond the original data to generate new insights.

Initial line-by-line coding was carried out on paper for all articles by the primary reviewer to generate themes and subthemes, following which, PDFs of the articles were uploaded to NVivo 14 and coding to themes was conducted within the software.

Thematic meta-synthesis was selected due to its appropriateness for synthesising conceptually rich qualitative literature, and for its capacity to generate new interpretations and understandings that are actionable for practice.

Following synthesis, analytical themes were mapped to the latest Consolidated Framework for Implementation Research (CFIR) as a secondary interpretive framework (Damschroder et al, 2022). A copy of the CFIR coding guide can be found in Appendix II. This enabled examination of how the identified characteristics of organisational readiness in this context aligned with established constructs in implementation science, supporting the potential development of a readiness assessment tool for MU implementation.

**Table 3 Key Data Characteristics**

| Study No. | Author, Year | Country | Study aims | Study Design | Sample size | Implementation Phase | Setting & Data collected | Key findings | Quality Assessment Score |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Walsh, 2006 | United Kingdom | To explore the culture, beliefs, values, customs, and practices around the birth process within a free-standing birth centre (FSBC). | Qualitative (Ethnography) | 30 women, 10 midwives, 5 MCAs | Post-implementation | An FMU with a small district hospital in the UK; included participant observation and interviews. | FMUs provide greater flexibility in labour care, emphasize relational care. The absence of a 'processing mentality' supports a more individualized birth experience. | 56 |
| 2 | Walsh, 2007 | United Kingdom | To explore the culture, beliefs, values, customs, and practices around the birth process within a free-standing birth centre. | Qualitative (Ethnography) | 30 women, 10 midwives, 5 MCAs | Post-implementation | An FMU with a small district hospital in the UK; included observations and interviews with participants. | The study revealed resistance to dominant biomedical and professional care discourses. Women and staff engaged in alternative childbirth narratives, emphasizing autonomy and flexibility. | 50 |
| 3a | Rocca-Ihenacho et al., 2021 | United Kingdom | To explore relationships and trust as fundamental components of a well-functioning Freestanding Midwifery Unit (FMU) and their impact on service users, midwives, and maternity care outcomes. | Qualitative (Ethnography) | 82 participants, including midwives, maternity care assistants, hospital midwives, consultants, commissioners, and service users. | Post-implementation | An FMU in East London; included participant observation, semi-structured interviews and document analysis. | Relationships and trust were the foundation of a well-functioning FMU. The study highlighted the significance of ownership, autonomy, continuous learning, and power balance within the FMU. | 64 |
| 3b | Rocca-Ihenacho, 2023 | United Kingdom | To explore the philosophy, organizational culture, and practices within an FMU model of care, highlighting key characteristics of well-functioning FMUs. | Qualitative (Post-Critical Feminist Ethnography) | *As above.* | *As above.* | *As above (FMU).* | The study identified key factors that contribute to a well-functioning FMU, including ownership, team spirit, accountability, and partnership with service users. It emphasized the importance of resisting hierarchical and biomedical constraints while promoting woman-centred care. | *64* |

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|---|---|---|---|---|---|---|---|---|---|
| 3c | Rocca-Ihenacho, 2023 | United Kingdom | To explore staff perspectives on working within a Freestanding Midwifery Unit (FMU) and understand the organizational culture that enables best practices and a positive team spirit. | Qualitative (Ethnography) | *As above.* | *As above.* | *As above (FMU).* | Staff at the FMU reported high job satisfaction due to autonomy, team spirit, and a shared commitment to the Bio-Psycho-Social model of care. The study also highlighted challenges such as staffing constraints and external pressures from the obstetric unit. | *64* |
| 3d | Rocca-Ihenacho, 2023 | United Kingdom | To explore service users' perspectives and experiences within a Freestanding Midwifery Unit (FMU) and what they perceive as important for feeling safe and in control during childbirth. | Qualitative (Ethnography) | *As above.* | *As above.* | *As above (FMU).* | Service users valued the strong rapport and trust built with midwives, even without continuity of care. The FMU environment, which emphasized one-to-one care and non-interventionist support, contributed to positive birth experiences. | *64* |
| 3e | Rocca-Ihenacho, 2023 | United Kingdom | To explore the organisational perspectives of a Freestanding Midwifery Unit (FMU), focusing on team dynamics, leadership models, workload balance, integration with the community, and sustainability. | Qualitative (Ethnography) | *As above.* | *As above.* | *As above (FMU).* | A well-functioning FMU relies on shared leadership, a positive team culture, balanced workload distribution, and strong integration with the local community. The study identified 11 core values guiding FMU operations. A lack of investment in leadership and training led to staff retention issues and a decline in FMU performance. | *64* |
| 4 | Batinelli et al., 2023 | Italy | To conduct a situational analysis of the implementation of a midwifery unit in Italy, identifying barriers and facilitators in a context where midwifery-led care is not well established. | Mixed-methods (Situational Analysis & Participatory Action Research) (CFIR) | 48 professionals (midwives, obstetricians, neonatologists, and medical directors) and secondary data from 347 service users via regional surveys. | Pre-implementation | A hospital in the Tuscany region transitioning towards an AMU; included qualitative interviews, stakeholder meetings, document analysis, and survey results from service users and professionals. | National guidelines and funding facilitated implementation, but hierarchical structures, a predominant medical model, and lack of trust in midwifery-led care created barriers. Professionals were skeptical of international recommendations and emphasized local adaptability. Leadership stability and long-term stakeholder engagement were identified as crucial factors for success. | 64 |

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| 5 | Darling et al., 2021 | Canada | To examine how the conditions at Markham Stouffville Hospital (MSH) made it possible to create Canada's first alongside midwifery unit (AMU) and to identify lessons that could inform the spread of this model. | Qualitative (Explanatory Study) (CFIR & Greenhalgh et al.'s theory of diffusion of innovations) | 15 key informant interviews + 13 documentary sources, including news articles, government records, and hospital reports. | Pre-implementation | Canada's first AMU opened in 2018; included interviews and document analysis. | Successful implementation was facilitated by strong midwifery leadership, stakeholder involvement, change management strategies, and organizational support. Challenges included scepticism from medical professionals, policy barriers, and cultural resistance to midwifery-led care. The AMU model demonstrated cost savings, increased service user satisfaction, and potential for national adoption. | 66 |
| 6 | McCourt et al., 2018 | United Kingdom | To investigate how alongside midwifery units (AMUs) are organised, staffed, and managed, as well as the experiences of women and maternity staff, including those working in AMUs and adjacent obstetric units. | Qualitative (Organisational Ethnography) | 136 interviews (47 women/partners, 54 clinical staff, 35 managers and stakeholders), plus 20 observations. | Post-implementation | Four AMUs across England; case studies. | Four key areas were identified as crucial for sustainable AMU care: finance and management support, staffing, training, and appropriate guidelines. Challenges included boundary management, professional tensions, staffing models, midwives' skills and confidence, and accessibility for women. Integrated care models, leadership development, and well-defined guidelines were key to addressing these challenges. | 65 |
| 7 | Miah & Adamson, 2015 | United Kingdom | To investigate how midwives and midwifery managers aimed to provide choice for women through the creation of a distinct care culture within a new alongside midwifery unit (AMU). | Qualitative (Interview-Based Study) | 15 midwives and midwifery managers purposively sampled. | Post-implementation | An AMU in a diverse, high-birth-rate inner-city area of Northern England; included semi-structured interviews before opening. | The AMU was designed to provide a distinct environment of 'safe normality' for low-risk women. Staff aimed to create a midwifery-led culture, distinct from the obstetric unit, through careful selection of staff, the design of the birth environment, and a focus on woman-centered care. Challenges included the risk of boundary blurring between the AMU and OU, staffing constraints, and the integration of AMU services within an obstetric-led hospital system. | 54 |

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| 8 | Tracy et al., 2005 | Australia | To explore the introduction of caseload midwifery and the implementation of the first midwifery-led unit in New South Wales (NSW) within an integrated service network. | Qualitative (Case Study) | Multiple stakeholders including service managers, midwives, hospital administrators, and secondary data from service users. | Pre- AND Post-implementation | FMU at Ryde Hospital; included stakeholder engagement, qualitative interviews, and policy analysis. | Barriers included resistance from medical staff, concerns about risk management, and staffing constraints. Facilitators included strong consumer demand, midwifery leadership, and structured referral pathways for complications. The model demonstrated improved outcomes, cost-effectiveness, and better satisfaction rates among women receiving care. | 51 |
| 9 | Maillefer et al., 2015 | Switzerland | To explore the perceptions of women and healthcare providers regarding the implementation of a Midwife-Led Unit (MLU) in a Swiss university hospital. | Qualitative (Descriptive Study) | 63 participants (14 pregnant women, 30 postnatal women, 10 midwives, 9 obstetricians). | Pre-implementation | AMU at University Hospital of the Canton of Vaud; included focus grouos, one-to-one interviews, telephone interviews. | The study found strong support among women and healthcare providers for the implementation of an MU to promote physiological birth. Barriers included limited awareness of midwives' full scope of practice among women and concerns about interprofessional collaboration from midwives and obstetricians. The study emphasized the importance of clear guidelines, training, and teamwork for the successful implementation of an MU. | 55 |
| 10 | Murray-Davis et al., 2025 | Canada | To explore and describe the experiences of midwives working in Canada's first Alongside Midwifery Unit (AMU) and assess its impact on midwifery practice. | Qualitative (Grounded Theory Approach) | 14 participants (11 individual interviews and 1 focus group with 3 midwives). | Post-implementation | Canada's first AMU opened in 2018; included semi-structured interviews and a focus group. | Midwives reported positive impacts of the AMU, including improved interprofessional relationships, greater autonomy, stronger continuity of care, and an ability to uphold midwifery philosophies such as physiological birth. | 66 |
| 11 | Walsh et al, 2020 | United Kingdom | To identify factors influencing the provision, utilisation, and sustainability of midwifery units (MUs) in England, including both free-standing (FMUs) and alongside midwifery units (AMUs). | Qualitative (Comparative Case Study) | 57 individual interviews, 26 focus groups (60 midwives, 52 service users). | Pre- AND Post-implementation | Six AMU & FMUs in NHS Trusts across England; interviews and focus groups. | Barriers to MU uptake included historical obstetric-led care models, lack of awareness about midwifery-led care among decision-makers, and financial constraints. Many Trusts failed to prioritize MUs as core maternity services, leading to underutilization. Leadership engagement, interprofessional | 62 |

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| | | | | | | | collaboration, and effective promotion of MU services were key facilitators for increasing use. | |
| 12a | Mander et al, 2009 | China | To explore the feasibility of establishing a Midwife-Led Normal Birthing Unit (MNBU) in mainland China and identify key challenges and opportunities in its implementation. | Qualitative (Action Research) | Not explicitly stated; involved midwives, maternity professionals, and two interviewed service users. | Pre-implementation | AMU located within a large general hospital in Hangzhou, China, serving a population of 7.5 million; included non-participant observation, face-to-face semi-structured interviews, and meeting discussions. | Challenges included staff shortages, the dominance of medicalized childbirth, legal uncertainties, and the low confidence of midwives in non-interventive care. Midwives faced cultural barriers and concerns about practicing without routine interventions like episiotomies and oxytocin use. Hospital administration showed interest in sustaining the MU if the model proved viable. | 63 |
| 12b | Cheung et al., 2009 | China | To describe the preparations for establishing a midwife-led normal birth unit (MNBU) within a hospital setting in China to promote physiological birth and improve women's birthing experiences. | Qualitative (Action Research) | Not explicitly stated; involved midwifery professionals, hospital staff, and training course participants. | Pre-implementation | AMU located within a large general hospital in Hangzhou, China; included interviews, discussions, collaborative meetings, and training sessions | The introduction of an MU was groundbreaking in China, where midwifery had been largely replaced by obstetric-led care. The project required new policies and procedures to support midwifery autonomy and normal birth approaches. | 54 |
| 13 | Reszel et al, 2018 | Canada | To qualitatively investigate the integration of Ontario's first two freestanding, midwifery-led birth centres into the local preexisting maternal-newborn services. | Qualitative (Descriptive Study) | 24 healthcare providers and managerial staff from four hospitals. | Post-implementation | Two FMUs in Ontario; included focus groups and interviews. | Successful integration of FMUs was attributed to extensive pre-opening collaboration, training, and clear transport protocols. Challenges included administrative issues with hospital records and unfamiliarity with policies among some hospital staff. The birth centres enhanced interprofessional collaboration and strengthened midwifery legitimacy within the healthcare system. | 63 |

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| 14 | Bogren et al., 2023 | India | To explore contextual factors influencing the implementation of midwifery-led care units (MLCUs) across India and identify key enablers and barriers for their successful establishment. | Qualitative Study (Focus Group Discussions and Content Analysis) | 16 participants from six organizations involved in India's midwifery policy implementation. | Pre-implementation | India’s public healthcare system, focusing on Government Medical College and district hospitals with over 600 births per year (AMUs & FMUs); included focus group interviews. | Challenges included limited recognition of midwives’ roles, resistance from the medical community, and a lack of awareness among women about midwifery care. Other barriers include the dominance of the obstetric-led medical model, lack of legal frameworks, and insufficient training opportunities. Success factors include strong midwifery leadership, clear policies for midwife autonomy, and community engagement to build trust in midwifery services. Effective implementation requires interdisciplinary collaboration and policy-level support. | 63 |

## 3. RESULTS

All 3404 articles were loaded to Refworks, then de-duplicated, leaving 2965 records for screening. After excluding 2941 records, the full texts of 27 potentially eligible records were retrieved and assessed against the inclusion criteria. Three papers were found to be non-primary research in the form of reports; one paper was found to focus on midwife-led care rather than a midwife-led unit; one paper discussed the development of MU standards rather than experience of their application; one was not peer-reviewed; one duplicate was discovered; and one paper was not retrievable - with no response from a request for access to the author. All were excluded, leaving the full texts of 19 records to be appraised for their quality.

All 19 articles were included in the review. Five papers were found to stem from one original study, with one of the papers dedicated entirely to the methodology of the study. Since this paper was required for quality appraisal, a discussion with supervisor LR-I and a senior librarian concluded that all papers should be included and labelled 3a-3e, with the methodology paper (3b - Rocca-Ihenacho, 2023) not subsequently featuring in the data synthesis. Similarly, two further articles stemmed from one study, though both incorporated their respective methodologies, and so were divided into 12a and 12b.

### 3.1 Country and setting

The studies included in this review span diverse geographical contexts, with the majority conducted in high-income countries. Of the 14 studies, six were from the United Kingdom, three from Canada, and one each from Australia, Switzerland, Italy, India, and China. While several studies focused on urban or peri-urban settings - including London, Ontario, and Sydney - others explored implementation across varied regions such as India and multiple NHS Trusts in England. Settings included five freestanding midwifery units (FMUs), seven alongside midwifery units (AMUs), situated within hospitals or as geographically separate units, with two final studies examining both. Among the studies five evaluated a pre-implementation context, seven reported on post-implementation and two discussed both phases.

### 3.2 Study participants and methods

Studies gathered data from a broad spectrum of participants, including midwives, obstetricians, hospital managers, service users, commissioners, and other maternity stakeholders. While participant numbers varied - from small samples of 15 to over 130 individuals - data collection methods were consistently qualitative in nature. Methodologies included ethnography, grounded theory, case studies, and action research, with common techniques being interviews, focus groups, and participant observation.

### 3.3 Review findings

Findings highlighted key organisational readiness characteristics of successful midwife-led unit implementation: collaborative team dynamics, midwifery autonomy, relational care values,

and midwifery leadership. Barriers to readiness for change included entrenched biomedical models, staffing issues, a lack of self-efficacy, and hierarchical systems that limited midwifery-led innovation. Eight themes were most prominent across the reviewed literature, with 26 related subthemes, a table of which can be found in Table 4.

***Table 4 Themes & Subthemes***

| Theme | No. of Papers | Subtheme |
|---|---|---|
| Organisational Culture & Climate | 18 | Collaborative & Respectful Work Environment |
| | | Improvement-Oriented Culture |
| | | Service User Involvement |
| | | Trust & Psychological Safety |
| Innovation Characteristics & Implementation Process | 17 | Bio-Psycho-Social |
| | | Entrepreneurial thinking, ownership & empowered creativity |
| | | Innovation Alignment & Fit |
| | | Process of Implementation |
| Midwifery Autonomy & Role Empowerment | 16 | Expanded & protected roles |
| | | Professional Autonomy |
| | | Training & Skills Development |
| Leadership & Governance | 15 | Change Management Theory Use |
| | | Distributed & De-centralised Leadership |
| | | Flexible Bureaucracy |
| | | Supportive Leadership Culture |
| External Context & Enabling Conditions | 13 | Catalytic or Unique Conditions |
| | | Policy & Political Support |
| | | Wider Cultural Readiness |
| Evidence-Inspired Service | 12 | Awareness of evidence |
| | | Clear & Supportive Guidelines |
| | | Internal data collection |
| Resources & Infrastructure | 12 | Dedicated Funding & Infrastructure |
| | | Other Human Resources |
| Communication & Dissemination of Change | 6 | Communication with other MLUs or Implementation Sites |
| | | Targeted benefits sharing with medical team |
| | | Transparent & multi-modal updates & knowledge sharing |

### 3.3.1 Organisational Culture and Climate

***Subthemes: Collaborative & Respectful Work Environment, Improvement-Oriented Culture, Service User Involvement, Trust & Psychological Safety***

Organisational culture emerged as a defining readiness characteristic for the successful implementation of midwife-led units, with 18 of the 19 included studies highlighting its influence. Readiness was consistently facilitated by respectful, collaborative environments where shared values, psychological safety, and improvement-focused behaviours were embedded across teams.

A dominant subtheme was the presence of respectful inter- and intra-professional relationships. Studies described how midwifery units thrived when staff, including non-clinical

personnel, engaged in positive, inclusive interactions: "*positivity was evident in daily interactions between all staff members, including administrative, security, and hospitality staff"* (Rocca-Ihenacho et al., 2021). In Canadian settings, the implementation of an MU even appeared to generate interprofessional curiosity: *"Now there's this kind of approval… tell me more about how you do what you do"* (Murray-Davis et al., 2025). Conversely, where relationships were characterised by disrespect or professional silos, implementation was hindered. Midwives recounted being met with hostility during transfers to obstetric units: *"I've been greeted with 'oh, here comes another failure from FMU'"* (Walsh et al., 2020), a reflection of persistent 'othering' that undermined readiness (McCourt et al., 2018).

Shared values and team spirit further enabled readiness for change. Several studies described how team cultures were intentionally cultivated through socialisation, peer support, and values-based recruitment (Rocca-Ihenacho, 2023; Miah et al., 2015). A strong sense of personal commitment and team identity was common: *"staff interviews repeatedly raised the topic of the changes that had been achieved… very proud of the homey ambience they had created"* (Walsh, 2006). In some settings, this commitment was reinforced by institutional loyalty: *"There was a sense of pride in belonging to the regional healthcare system"* (Batinelli et al., 2023).

Intentional investment in team building - both formal and informal - was inspirational. Shared spaces and opportunities to connect across disciplines were reported to foster trust and cohesion: *"the AMU became a home base… facilitating more opportunities to interact and build relationships"* (Murray-Davis et al., 2025). In China, a stakeholder meeting held in a restaurant was used to celebrate progress and *"foster a more congenial"* atmosphere (Mander et al., 2009). In contrast, the absence of team development activities due to workload pressures was described as a barrier (Rocca-Ihenacho, 2023).

Staff wellbeing and psychological safety were core to sustaining MU implementation. Midwives working in supportive environments described feeling "*less stressed, more relaxed and more welcoming"* (Rocca-Ihenacho, 2023). These conditions allowed for reflective practice, one-to-one care, and emotional engagement. Conversely, excessive workloads, redeployments, or service integration challenges led to burnout and disengagement.

A culture of continuous learning and improvement was a hallmark of ready for change organisations. Mechanisms such as peer review meetings, joint case analysis, and transparent feedback systems were commonly reported (Murray-Davis et al., 2025; Reszel et al., 2018). Staff were encouraged to *"own their own work… that's what keeps you going and makes you better as a midwife"* (Rocca-Ihenacho et al., 2021). These learning practices were grounded in non-blaming cultures, where staff could raise concerns or admit uncertainty without fear: *"asking for a second opinion… disregarded organisational hierarchy"* (Rocca-Ihenacho et al., 2021). In contrast, settings characterised by litigation fear or hierarchical blame saw reduced collaboration and trust (Walsh, 2007; Walsh et al., 2020).

Finally, tension for change and a track record of innovation reinforced cultural readiness. Organisations with a history of successful transformation - *"a long history of being a trailblazer"* (Darling et al., 2021) – and a clear desire to improve women-centred care were more likely to successfully initiate and sustain MUs.

### 3.3.2 Innovation Characteristics & Implementation Process

***Subthemes: Bio-Psycho-Social Philosophy, Entrepreneurial Thinking, Ownership & Empowered Creativity, Innovation Alignment & Fit, Process of Implementation***

Across 17 studies, the implementation of midwife-led units was found to be significantly shaped by how the model itself - its philosophical underpinnings, structure, and perceived benefits - aligned with organisational values and practice norms. The bio-psycho-social philosophy of care emerged as a defining innovation characteristic of MUs. This relational, holistic approach to maternity care - rooted in presence, autonomy, and supporting physiology - stood in marked contrast to technocratic, fragmented obstetric-led systems (Walsh, 2006; Walsh, 2007; Miah et al., 2015). As one midwife described, "*Midwifery if you look at the meaning is 'with woman', not with CTG, not with monitors…"* (Rocca-Ihenacho, 2023). Where this model aligned with existing staff values and organisational aims, readiness was strengthened through professional motivation and organisational identity.

A key enabler of readiness was the embeddedness of learning and innovation within the MU model itself. Teams described MUs as dynamic, reflective spaces where physiological birth could be re-learned and re-valued. *"Many of the midwives who arrived… had not witnessed or participated in physiological labour and birth before… this was transformational for them"* (Rocca-Ihenacho, 2023). Informal mentorship, flattened hierarchies, and psychological safety allowed for embedded learning and empowered practice, thus supporting Weiner's (2009) assertion that collective efficacy enhances readiness for change.

In rejecting the standardised, industrial logic of consultant-led services, MUs enacted a deliberate shift towards flexibility, individualised care, and shared decision-making. This non-process-oriented philosophy - described by staff as *"freedom to use common sense"* and *"to be care, not do care"* (Walsh, 2006) - allowed care to be responsive rather than task-driven. Such cultural and procedural alignment supported readiness by enabling teams to practise midwifery in ways that felt authentic, meaningful and sustainable. The inherent flexibility of the model appeared ideal for the adaptability that lies at the core of change readiness.

Crucially, placing women at the centre of care was not merely aspirational but operationalised through shared decision-making, design choices, and inclusive policies. In some sites, midwives and leaders described a shift towards *"women- and family-led"* care (Miah et al., 2015), while in others, hierarchical dynamics and medico-legal concerns undermined women's autonomy (Batinelli et al., 2023). As such, relational and rights-based approaches were not peripheral to readiness - they were foundational.

The fit between the MU model and organisational priorities was also instrumental. In settings where MUs could be positioned as cost-effective, evidence-based, and aligned with quality goals, implementation was smoother (Darling et al., 2021). Prior exposure to the model further enhanced readiness by reducing job-replacement or litigation fears and normalising midwifery leadership (Batinelli et al., 2023; Darling et al., 2021).

Notably, entrepreneurial thinking and empowered creativity emerged as novel readiness characteristics. In high-readiness environments, staff exercised agency to transform spaces, raise funds, and design new roles: *"I just thought, why don't we have a Complementary Therapies room… six hours later we had a master plan and three days later it was painted and*

*done"* (Walsh, 2006). These grassroots innovations were enabled by flattened hierarchies and post-bureaucratic cultures.

Finally, the process of implementation itself mattered. Readiness was supported by iterative, paced, and inclusive change processes. Extended 'incubation' periods, stakeholder engagement, and gradual refinement allowed the model to become culturally embedded (Darling et al., 2021; Tracy et al., 2005). Conversely, change fatigue, top-down rollouts, or ambiguous leadership reduced momentum (Batinelli et al., 2023).

### 3.3.3 Midwifery Autonomy & Role Empowerment

***Subthemes: Expanded & Protected Roles, Professional Autonomy, Training & Skills Development***

Professional autonomy and the protection of midwifery roles were central to organisational readiness across 16 studies. Environments that enabled midwives to practise to the full scope of their training, enact clinical leadership, and feel respected within interprofessional teams were more likely to successfully implement and sustain MUs.

Expanded and protected roles were repeatedly cited as enabling conditions for readiness. Midwives described the transition to MU care as both liberating and professionally restorative. One midwife reflected, *"For the first time I felt that I was truly being a midwife… I was going through a transition from being an obstetric nurse to becoming a midwife"* (Rocca-Ihenacho, 2023*)*. In China, participating in an MU was seen as "*enhancing their role and clinical practice"* (Mander et al., 2009), while in Switzerland, midwives described becoming *"guardians of physiology"* (Maillefer et al., 2015*)*. However, when core MU staff were frequently rotated into obstetric units, this disrupted continuity and diluted the midwifery model (McCourt et al., 2018). Where ring-fencing of MU midwifery staff existed, such as in Australia's Midwifery Group Practice model, it fostered ownership, autonomy, and sustainability through self-nomination and team-led rostering (Tracy et al., 2005).

Readiness was highest where midwives were visibly valued, respected as professionals, and encouraged to lead. In Ontario, opening a birth centre was seen as "*a symbolic and practical endorsement of midwifery"* (Reszel et al., 2018). Conversely, hierarchical resistance - particularly from obstetric staff - was linked to midwife marginalisation and reduced MU viability. One Italian midwife reported, *"The obstetrician discredits midwives easily… this impacts the woman's opinion"* (Batinelli et al., 2023).

Empowered clinical autonomy was a strong predictor of readiness. Midwives described feeling *"confident, optimistic and passionate"* when able to shape care environments and make decisions independently (Walsh, 2006). This sense of ownership - of *"owning your own work"* (Rocca-Ihenacho et al., 2021) - was consistently linked to job satisfaction and improved care quality.

Targeted training and skill-building were also fundamental. Many midwives, having long worked in high-risk settings, felt *"deskilled"* or *"apprehensive about normal birth*" (Walsh et al., 2020). Organisational responses included mentorship, simulation-based training, and values-based learning (Darling et al., 2021; Tracy et al., 2005; Cheung et al., 2009). In China and Canada, investment in interdisciplinary training and reflective practice fostered midwifery

confidence and team cohesion (Murray-Davis et al., 2025; Cheung et al., 2009). Where training was deprioritised, such as in one London MU, readiness and retention declined: *"Many midwives eventually left and the number of births declined rather than increasing*" (Rocca-Ihenacho, 2023).

### 3.3.4 Leadership & Governance

***Subthemes: Change Management Theory Use, Distributed & De-centralised Leadership, Flexible Bureaucracy, Supportive Leadership Culture***

Leadership was a defining characteristic of organisational readiness for MU implementation across 15 studies. Rather than relying on hierarchical authority, effective leadership was distributed, transformational, and embedded in supportive structures that enabled collaboration, autonomy, and innovation.

The deliberate use of change management theory was underutilised but powerful where applied. In one Canadian study, a transformational leader successfully balanced institutional constraints with visionary change: *"This leader was also a maverick with a creative vision… supported by an organisational buffer who ensured rules were followed without hampering creativity"* (Darling et al., 2021). The application of structured frameworks, including champion identification and phased planning, was shown to reduce resistance and support continuous engagement (Darling et al., 2021).

Distributed and decentralised leadership was key to readiness. Participatory governance structures - such as working groups and steering committees - were central to co-creating the MU model and devolving decision-making. One UK team described *"putting women before the system"* by embracing flexible procedures and flattening hierarchies (Rocca-Ihenacho, 2023). In Canada, decision-making devolved to frontline teams using tools like mock scenarios and feedback boards (Darling et al., 2021). Midwives reported increased ownership and responsiveness: *"We're midwives and we make decisions together*" (Rocca-Ihenacho et al., 2021).

Flexible bureaucracy further supported innovation. In several settings, staff were able to bypass rigid hospital processes to enact timely, pragmatic changes: *"Management were very good… but I have to say we were a little bit naughty as well"* (Walsh, 2006). Such adaptive governance reflected a *"liberal bureaucracy"* that enabled grassroots problem-solving while maintaining accountability through structures like peer review councils (Murray-Davis et al., 2025).

Supportive leadership cultures were essential. Charismatic or visionary figures played catalytic roles: *"It's crucial to have an inspirational leader. If you don't have somebody at the very top who is passionate about it… it won't happen*" (Walsh et al., 2020). However, overreliance on individuals was also identified as a risk - leadership turnover often coincided with declining MU usage (Batinelli et al., 2023; Walsh et al., 2020). Crucially, leadership influence extended beyond formal roles: informal leaders were reported in midwives, obstetricians, and neonatologists who championed the model, helping build trust and driving organisational readiness (Batinelli et al., 2023).

Midwifery leadership, in particular, was strongly associated with readiness. Midwives in formal leadership roles ensured visibility, resource allocation, and role protection: *"Only strong midwifery leaders can challenge the status quo"* (Bogren et al., 2023). One hospital described as *"unique"* had a midwife in a senior hospital management position - inherently exhibiting trust in midwives, credibility and strategic influence (Darling et al., 2021).

### 3.3.5 External Context & Enabling Conditions

***Subtheme: Catalytic or Unique Conditions, Policy & Political Support, Wider Cultural Awareness***

External contextual factors played a critical role in shaping organisational readiness for MU implementation. Across 13 studies, macro-level catalysts - ranging from policy mandates to public perception - either enabled or constrained readiness. Organisational agility to respond to these conditions was crucial to successful implementation.

Catalytic or unique events, such as policy shifts, mergers, or spatial opportunities, frequently served as turning points. One UK study reported how changes in NHS Trust payment models *"were seen as an opportunity to consolidate recent developments in midwife-led service provision"* (McCourt et al., 2018), while in Canada, physical proximity to the obstetric unit was both a practical enabler and an unexpected opportunity: *"space was available on the floor above after renovations"* (Batinelli et al., 2023*)*. Population growth also created strategic justification: *"an opportunity for the hospital to increase the number of midwife-attended births"* (Darling et al., 2021).

Policy and political support emerged as key enablers. In Ontario, the Ministry of Health's support for cost-efficient midwifery models provided crucial momentum: *"The Ontario Midwifery Program… was eager to support a new model"* (Darling et al., 2021*)*. Similarly, national frameworks such as Maternity Matters in the UK acted as a *"major driver"* for implementation (Miah et al., 2015). In India, the *"India Midwifery Initiative"* marked a paradigm shift positioning midwives as central to normal birth (Bogren et al., 2023). Conversely, risk discourse and litigation concerns created policy barriers, with some MUs described as *"a lesser priority and an optional extra"* (Walsh et al., 2020).

Wider cultural readiness was equally critical. In Italy, midwives reflected on systemic medicalisation: *"there is a highly medicalized culture… women are immersed in this culture"* (Batinelli et al., 2023). A common view reported by an Italian midwife was that *"no one has ever told them that low-risk pregnancies are looked after by midwives"* (Batinelli et al., 2023) or that MUs even existed (Walsh et al., 2020). Some MU users described learning about their options only through proactive GPs or promotional efforts: *"She [GP] told me that there is the FMU"* (Rocca-Ihenacho, 2023); although in other studies service users reported GPs actively advising against MU use: "they kind of scare you" (Walsh, 2007). Yet in some contexts, growing public trust signalled shifting readiness: *"the percentage of people who are ready for something like this is increasing"* (Batinelli et al., 2023). In India and Switzerland, women's trust in midwives was growing, but often contingent on assurances of transfer pathways and continuity of care (Maillefer et al., 2015).

### 3.3.6 Evidence-Inspired Service

***Subthemes: Awareness of Evidence, Clear & Supportive Guidelines, Internal Data Collection***

Organisational readiness to implement midwife-led units was closely associated with alignment to evidence-informed practice. Across 12 studies, services that actively engaged with research, creation of clinical guidelines, and collection of internal data reported stronger legitimacy, safety, and professional trust - key enablers of implementation success.

Awareness of the evidence underpinning MUs was not universal. Several studies described *"little awareness of the evidence on cost-effectiveness of MU facilities"* (Walsh et al., 2020). Variability across professional groups was common, with midwives generally more familiar with the literature than their medical colleagues, and generational differences among obstetricians noted: *"participants' awareness and perceptions… was not uniform"* (Batinelli et al., 2023). In some cases, international guidance was dismissed as inapplicable, highlighting both a lack of perspective understanding and the importance of local relevance (Batinelli et al., 2023).

Where research capacity was integrated, evidence use was stronger. Canada's AMU project *"engaged with midwifery research leaders… to ensure a robust evaluation"* (Darling et al., 2021), while an Australian team used three RCTs to advocate for implementation (Tracy et al., 2005). In China and India, the use of local indicators and clinical checklists aimed to legitimise MUs within the national context (Cheung et al., 2009; Bogren et al., 2023). However, as Indian participants pointed out, *"There will have to be guidance… saying that this has been established"* (Bogren et al., 2023).

The presence of clear, contextually tailored guidelines was critical. Protocols for admission, transfer, and collaborative care reassured staff and supported safety. In Ontario, *"urgent and nonurgent transports… facilitated improved interprofessional practice and teamwork"* (Reszel et al., 2018), while co-developed policies enhanced ownership and autonomy (Murray-Davis et al., 2025; Rocca-Ihenacho et al., 2021). National policy alignment was also instrumental; for example, Italy's guidance that *"women with physiological pregnancies must be offered a care model… by the midwife"* (Batinelli et al., 2023).

Internal outcome tracking further strengthened implementation readiness. Some sites collected and used internal service data (e.g. audits, outcomes tracking) to support continuous improvement, justify the MU model, and monitor achievement of goals. For example, a Canadian AMU used case-costing and birth outcome monitoring to demonstrate cost-savings (Darling et al., 2021), while the midwifery group in Australia prepared a "report card" of the first 100 bookings to showcase low intervention rates and highlight adherence to safety standards (Tracy et al., 2005).

### 3.3.7 Resources & Infrastructure

***Subthemes: Dedicated Funding & Infrastructure, Other Human Resources***

Organisational readiness to implement midwife-led units was consistently associated with the availability and strategic use of resources across 12 studies. Dedicated funding, purpose-built infrastructure, and human resource planning were not only practical enablers but symbolic indicators of institutional commitment to midwife-led unit success.

Allocated financial resources often acted as a turning point in the implementation process. In the Italian site, the release of funds was described as pivotal: *"when a significant financial budget was released… midwifery leaders felt backed up by the organisation and started actively moving the project forward"* (Batinelli et al., 2023). Similarly, in Canada, government and philanthropic investment provided the foundation for AMU development: *"The project was supported with capital funding from the Ontario Ministry of Health and from the Markham Stouffville Hospital Foundation"* (Darling et al., 2021). Conversely, lack of designated funding hindered implementation, with some services constrained by reluctance to increase staffing (Cheung et al., 2009) or where funding models incentivised intervention: *"MUs [were] a loss-making activity"* (McCourt et al., 2018).

Infrastructure was more than a logistical necessity; it carried cultural weight. Midwives described purpose-built MUs as transformative: *"the physical space shocked them with its positive effect"* and *"your work could become more valuable"* (Rocca-Ihenacho, 2023). Aesthetically aligned environments - welcoming, de-medicalised, and socially integrated - were viewed as central to enacting MU values (Rocca-Ihenacho, 2023; Miah et al., 2015; Cheung et al., 2009).

Strategic human resource allocation further supported readiness. Consultant midwives were seen as essential for ensuring credibility and visibility within hierarchical systems: *"maintaining the profile and role… where the authority of senior midwives is not always recognised"* (McCourt et al., 2018). Investing in research midwives enhanced legitimacy by embedding evaluation into the project design (Darling et al., 2021), while hiring skilled project managers ensured operational coordination and safeguarded existing staff from overload.

### 3.3.8 Communication and Dissemination of Change

***Subthemes: Communication with other MLUs or Implementation Sites, Targeted Benefits Sharing with Medical Team, Transparent & Multi-modal Updates & Knowledge Sharing***

Effective communication emerged as a vital determinant of organisational readiness to implement midwife-led units, with 6 studies highlighting its role in fostering transparency, trust, and interprofessional alignment. Sites that adopted proactive, multi-modal communication strategies demonstrated stronger engagement and coordination during implementation.

Transparent and inclusive communication was central to maintaining momentum and building shared purpose. In the Italian study, midwifery leadership provided structured updates that combined data with vision: *"she gave updates on the MU project to everyone in the room… showed the numbers from the work in 2018… Midwives looked interested and had many questions"* (Batinelli et al., 2023). Canadian leaders applied change management principles to engage stakeholders, describing *"open, timely communication… and face-to-face meetings with every department impacted… to establish processes that met everyone's needs"* (Darling et al., 2021). Such strategies were found to build credibility, reduce uncertainty, and enhance cross-departmental co-operation.

Targeted benefits sharing with medical teams was noted as a uniquely beneficial key readiness strategy. AMU leaders in Canada described deliberately framing the innovation in ways that would resonate with obstetricians, whilst re-iterating shared woman-centred care values:

*"dialogue was used to make visible the potential benefits of the innovation, particularly for obstetricians"* (Darling et al., 2021). In Switzerland, a midwife reported that it was essential to *"reassure the medical staff and integrate them"* (Maillefer et al., 2015), supporting collaborative practice and reducing resistance.

However, a lack of external communication between implementation sites was identified as a limiting factor. In one case, *"lack of cosmopolitanism and regular communication with other realities was noted as a barrier to the innovation"* (Batinelli et al., 2023). By contrast, international partnerships - such as a collaborative initiative between China and the UK - offered vital peer learning and technical support (Mander et al., 2009).

### 3.3.9 Mapping Organisational Readiness Characteristics to CFIR

To support interpretability and transferability of findings to implementation science research, themes and subthemes identified in this review were mapped to the Consolidated Framework for Implementation Research (CFIR), one of the most widely used theoretical models for evaluating implementation processes in healthcare settings (Damschroder, 2022). Mapped and unmapped findings can be seen in Table 5.

**Table 5 Themes and Subthemes Mapped to CFIR**

| Theme | Subtheme | CFIR Domain | CFIR Construct |
|---|---|---|---|
| Organisational Culture & Climate | Collaborative & Respectful Work Environment | Inner Setting | Relational Connections/Culture |
| | Improvement-Oriented Culture | Inner Setting | Culture (Subconstruct: Learning-Centredness) |
| | Service User Involvement | Outer Setting & Inner Setting | Local Attitudes & Culture (Subconstruct: Recipient-Centredness) |
| | Trust & Psychological Safety | Inner Setting | Culture (Subconstruct: Learning-Centredness) |
| Innovation Characteristics & Implementation Process | Bio-Psycho-Social Philosophy | ***Not Mappable*** | |
| | Entrepreneurial thinking, ownership & empowered creativity | ***Not Mappable*** | |
| | Innovation Alignment & Fit | Innovation Characteristics & Inner Setting | All Constructs & Tension for Change/Compatibility/Relative Priority |
| | Process of Implementation | Innovation Characteristics & Process | Adaptability & Tailoring |
| Midwifery Autonomy & Role Empowerment | Expanded & protected roles | ***Not Mappable*** | |
| | Professional Autonomy | ***Not Mappable*** | |
| | Training & Skills Development | Characteristics of Individuals & Process | Implementation Team Members (Subconstructs Capability, Motivation) & Planning/Engaging |
| Leadership & Governance | Change Management Theory Use | Process | Assessing Context/Planning/Engaging |
| | Distributed & Decentralised Leadership | ***Not Mappable*** | |
| | Flexible Bureaucracy | ***Not Mappable*** | |
| | Supportive Leadership Culture | ***Not Mappable*** | |
| External Context & Enabling Conditions | Catalytic or Unique Conditions | Outer Setting | Policies and Laws/Critical Incidents |
| | Policy & Political Support | Outer Setting | Policies and Laws |
| | Wider Cultural Readiness | Outer Setting & Inner Setting | Local Attitudes/External Pressure & Culture |
| Evidence-Inspired Service | Awareness of evidence | Innovation Characteristics | Evidence Base |
| | Clear & Supportive Guidelines | Innovation Characteristics & Inner Setting | Evidence Base & Structural Characteristics (Subconstruct: Work Infrastructure) |
| | Internal data collection | Process | Reflecting & Evaluating |
| Resources & Infrastructure | Dedicated Funding & Infrastructure | Outer Setting & Inner Setting | Financing & Available Resources |
| | Other Human Resources | Outer Setting & Inner Setting | Partnerships & Connections & Available Resources |
| Communication & Dissemination of Change | Communication with other MLUs or Implementation Sites | Innovation Characteristics & Outer Setting | Evidence Base & Partnerships & Connections |
| | Targeted benefits sharing with medical team | Inner Setting | Communications & Culture (Subconstruct: Recipient-Centredness) |
| | Transparent & multi-modal updates & knowledge sharing | Inner Setting | Communications |

## 4 DISCUSSION

This review explored organisational readiness characteristics associated with the successful implementation of MUs in public sector maternity services. The synthesis of 19 articles revealed a complex web of interrelated factors, broadly organised under eight themes (Table 4). Collectively, these themes illustrate that organisational readiness characteristics for MU implementation are dynamic, and whole-system-encompassing - underpinned by values of professional autonomy, relational care, and adaptive leadership.

Across the synthesised literature, the most prominent readiness themes found included:

- *Organisational Culture & Climate*
- *Innovation Characteristics & Implementation Process*
- *Midwifery Autonomy & Role Empowerment*
- *Leadership & Governance*

These themes emerged across both high- and low-resource settings and in contexts where MUs were well-established (e.g. the UK) as well as in those where MUs were a novel concept (e.g. China). This reflects the global relevance of these themes and underscores the universality of the underlying conditions required for successful implementation.

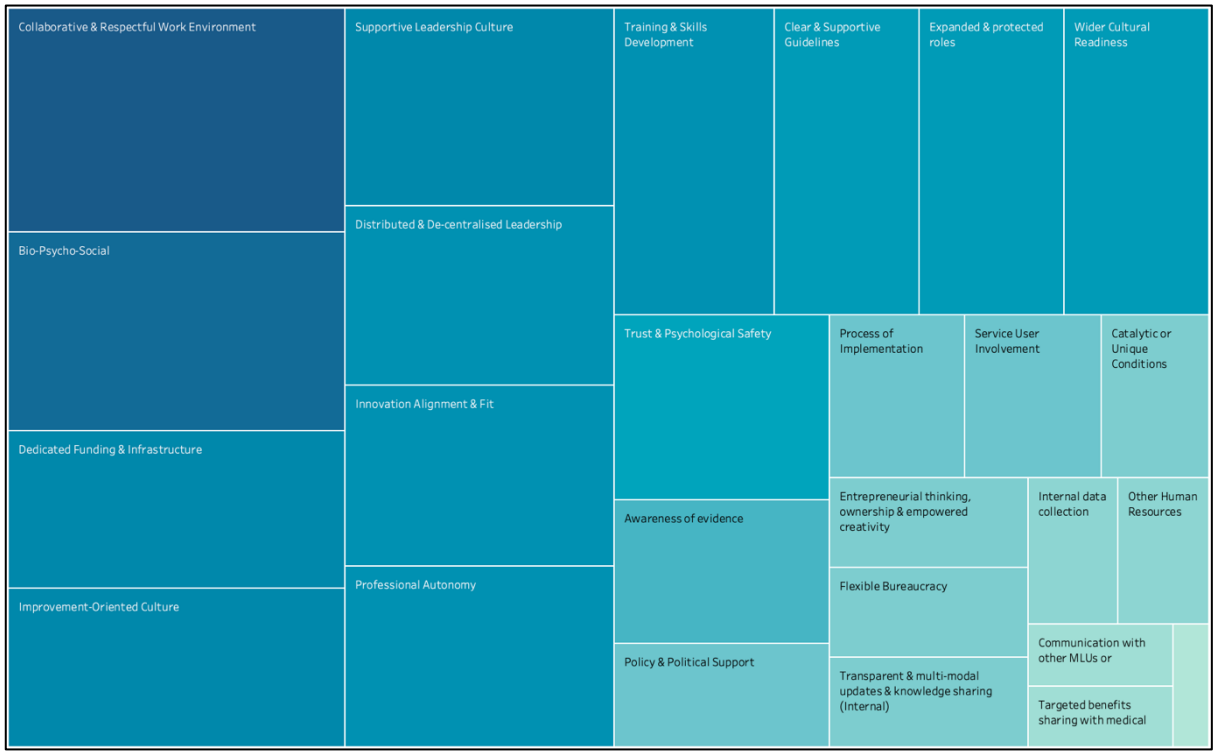


***Figure 3 Treemap Showing Hierarchy of Subthemes Across Reviewed Studies (smallest box: Change Management Theory Use)***

A tree map visualising the hierarchy of subthemes across the literature reviewed can be seen in Figure 3. Critical subthemes included:

- *Collaborative & Respectful Work Environment*
- *Improvement-Oriented Culture*
- *Trust & Psychological Safety*
- *Bio-Psycho-Social Philosophy of Care*
- *Training and Skills Development*
- *Decentralized & Supportive Leadership*

These were particularly impactful when paired with *Midwives in Leadership* positions and *Wider Cultural Awareness* of MUs. Structural support for midwifery autonomy, meaningful investment in training, and a workplace culture that values and protects midwives' full scope of practice were crucial to organisational readiness and mirror findings from Bayes et al. (2019), Filby et al. (2016), Lancet Midwifery Series (2014), and the more recent Midwifery Accelerator (2025); all of whom argue that midwives thrive in settings that value relational care and evidence-based autonomy. Protecting midwives' roles in MUs through hiring by motivation, ring-fencing and adopting a humanised approach to midwives as individuals, not simply a "workforce" to be co-ordinated and dispatched, enhanced work satisfaction, midwife retention and flexibility (Hunter et al., 2019). Leadership - when visionary, decentralised, and supportive of midwifery - was not only an enabler of implementation but a central component of organisational readiness. This echoes findings by Pezaro et al. (2024), who identified investing in midwifery leadership as both strengthening for the profession and as having the potential to improve perinatal outcomes worldwide.

Medical buy-in was key. In several studies, resistance from obstetricians or general practitioners served to undermine implementation efforts. This aligns with wider literature documenting the tensions between midwifery and obstetric models of care (Kirkham, 2010; Miller et al., 2016; Sangy et al., 2023) and supports repeated calls to foster interdisciplinary understanding and trust (Sandall et al., 2016; Zarbiv et al., 2025). A key organisational readiness characteristic was seen in the expressions of shared values and inter-professional respect - abstract but vitally measurable concepts that could be explored prior to implementation using existing research frameworks such as the Competing Values Framework (Adams et al., 2017).

Some readiness domains were less well represented, particularly *Communication and Dissemination of Change*, and aspects of *Resources and Infrastructure* beyond funding. While the need for protected staffing and adequate spaces was acknowledged, few studies offered detailed strategies for inter-organisational knowledge exchange or system-wide communication. These gaps suggest missed opportunities for both internal and external relationship-building and optimisation of implementation through structured information sharing - a point supported by prior research on knowledge translation in maternity and the wider healthcare services (Watkins et al., 2023; Steward, 2023; Attieh et al., 2013). An outlier example - where an MU was proposed and implemented using change management theory - illustrates the potential of these tools to facilitate readiness. Despite this, such approaches were rarely documented, indicating an underutilisation of implementation science in maternity service development, a point echoed by Dadich et al. (2021) and Reszel et al. (2023) who called for education in implementation theory for the functional implementers of the change.

Emergent subthemes such as *Entrepreneurial Thinking, Ownership & Empowered Creativity*, along with *Dedicated Infrastucture* - though infrequently explored - were seen to enhance readiness not only through enabling implementation but through fostering institutional respect and values alignment. These findings reinforce the notion that midwifery may inherently support a holistic, flexible and values-driven approach to change, which traditional top-down healthcare implementation strategies often overlook (Davis-Floyd, 2001).

The emergence of a theme around *External Context & Enabling Conditions* re-emphasises that organisational readiness is inseparable from broader political, cultural, and spatial dynamics. Although some studies reported unique catalytic factors contributing to change such as policy change or sudden availability of space, the findings suggest that building organisational readiness into the culture of a maternity setting could allow for agile reactivity for change when a window of opportunity arises.

The prominence of *Evidence-Inspired Service* as a theme - with subthemes such as *Clear & Supportive Guidelines* and *Awareness of Evidence* - reflected an overwhelming concern for safety, role clarity, and staff empowerment and support. These connected closely with other findings including *Trust & Psychological Safety*, *Expanded Roles*, and *Respectful & Collaborative Work Environments*, affirming that organisational readiness depends on a belief in - and operationalisation of - evidence and guidelines, which is intertwined with relational and cultural factors (MNSI, 2023).

Perhaps most notably, *Service User Involvement* was one of the least represented characteristics. Despite longstanding recommendations for co-production in maternity care (Filby et al., 2016; NICE, 2021; Makarova et al., 2024), only few studies explicitly addressed this domain. Implementation success was enhanced in sites where engagement with service users was valued, as in one Canadian example, while appeared slower in studies where staff norms and the wider culture did not involve service user input, such as Italy or China.

Finally, variation in findings appeared to reflect some contextual differences across the included studies. Organisational readiness characteristics were shaped by national policy environments, with leadership engagement and midwifery autonomy more frequently reported in high-income settings, which comprised most studies reviewed. Studies focused on the pre-implementation phase tended to emphasise concerns around political will and resource allocation, while post-implementation reports highlighted factors such as staff morale and sustainability. Diverging perspectives were also evident between midwives, managers, and policymakers. In medicalised health systems, structural resistance to midwife-led care deeply influenced readiness, underscoring the role of professional hierarchies and institutional culture in shaping implementation.

## 4.1 Organisational Readiness Characteristics for MU Implementation & CFIR

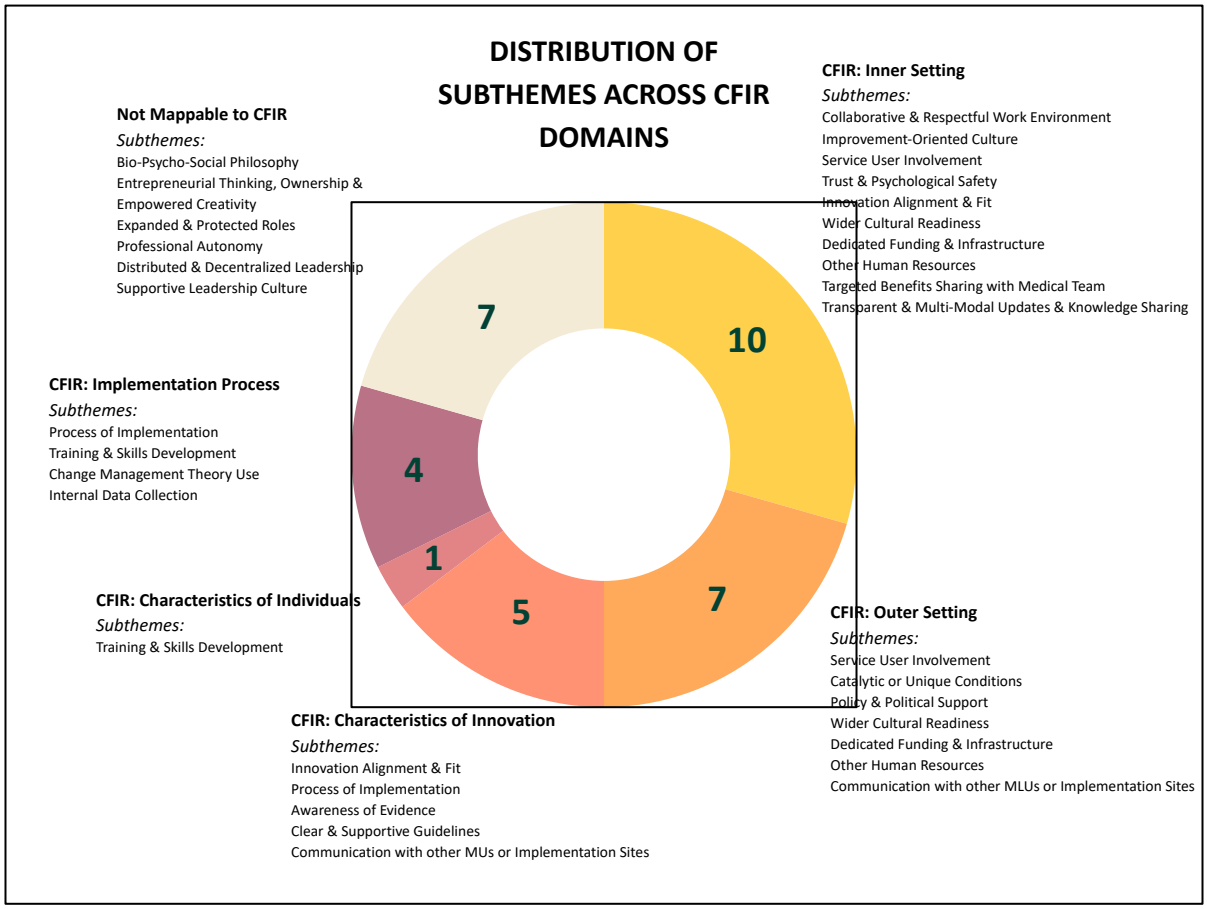


***Figure 4 Distribution of Subthemes Across CFIR Domains***

Most major organisational readiness for change characteristics identified in this review were found to align with at least one of CFIR's five domains, supporting its utility as a conceptual framework for examining organisational readiness in the context of MU implementation (Table 5 & visually in Figure 4). The predominance of subthemes within the CFIR "Inner Setting" domain underscore the significant role of organizational culture, infrastructure, and leadership engagement in the shaping readiness for change and reflect the findings of wider research that has mapped existing organisational readiness assessment tools to CFIR (Miake-Lye et al., 2020; Kononowech et al., 2021).

Notably, subthemes linked to "Innovation Characteristics" and "Process" were evenly represented, reflecting the dual importance of understanding the nature of the change and its implementation strategy. The inclusion of themes connected to the "Outer Setting" and "Characteristics of Individuals" domains illustrates the broader socio-political and individual-level considerations that interact with and influence change in maternity systems. Yet the low frequency of the "Characteristics of Individuals" domain also reflects the superseding importance of a wider team-based perspective of organisational readiness for implementation, rather than an individual-level focus.

However, several themes and subthemes - particularly those centred on philosophical alignment, entrepreneurial creativity, midwife autonomy, and the cultural aspects of flexible, supportive leadership - were not fully mappable to CFIR constructs. This gap suggests limitations in the framework's capacity to capture the cultural, values-based, and affective components of readiness that are especially important in midwifery-led models of care.

For example, the subtheme of *Entrepreneurial Thinking, Ownership, and Empowered Creativity* - which described a grassroots sense of agency and innovation within MU teams - could only partially align with CFIR's constructs such as "Culture" or "Adaptability". Literature on ground-up innovation suggests that such freedom and even necessity to create change - what Lipsky also called "street level bureaucracy" (1980) - is often overlooked in top-down frameworks (Cai et al., 2019; Church, 2024). These concepts, closely linked with midwifery autonomy, decentralized leadership, and psychological safety, imply a nuanced practice dynamic that extends beyond what CFIR currently accounts for, and resonate with findings from midwifery research that position autonomy, ownership, and professional identity as vital drivers of high-quality, person-centred care (Hunter, 2005; Sonmezer, 2020).

Similarly, the subtheme of *Bio-Psycho-Social Philosophy of Care* - an important innovation characteristic for readiness referring to the shift away from technocratic, risk-focused paradigms - extended beyond CFIR's conventional and bio-medical scope. While some conceptual fit could be found within constructs such as "Culture" and "Human-Centredness" or "Recipient-Centredness", the rich cultural and knowledge shift from technocratic and risk-dominant paradigms that this model entails is more fully explored in critical theory midwifery literature and midwifery philosophy (Kirkham, 2010; Davis-Floyd, 2001) and may be better understood through lenses such as values-based care e.g. the Quality Maternal Newborn Health Framework (De Jonge et al., 2019).

The subthemes of *Decentralised Leadership* and *Supportive Leadership Culture* were also only partially reflected in CFIR, under multiple constructs such as "Networks & Communications", "Individual Characteristics" and "Culture". Recent critiques of CFIR have noted its limited capacity to account for meso-level relationality such as team dynamics and emotional intelligence in team leadership - factors increasingly recognised as critical for sustainable change (Miake-Lye et al., 2020). Midwifery-specific research has emphasised the importance of emotionally intelligent leadership in cultivating psychologically safe workplaces (Pezaro et al., 2024). The ICM similarly advocates for midwfery leadership to be supported at the national and global level (ICM, 2022).

Most notably, the subthemes of *Professional Autonomy* and *Expanded & Protected Roles* - both central to the identity and function of midwifery - did not map clearly onto any CFIR construct. These appear to be distinct to the midwifery context and reflect the ongoing global struggle to embed midwife-led care within predominantly medicalised health systems. Despite the robust evidence base for the benefits of midwife-led models, barriers to professional autonomy persist (Sangy et al., 2023; Zarbiv et al, 2025). This finding underscores a critical gap in existing readiness frameworks and supports the need to tailor implementation tools to better reflect the unique professional, cultural, and philosophical conditions of midwifery.

These findings suggest that while CFIR offers a robust organising framework for examining organisational readiness, it may benefit from supplementation with theories that centre

emotional, relational, and cultural dimensions of change when assessing midwifery contexts. Integrating CFIR with a midwifery philosophy of care framework, such as the MU-specific Midwifery Unit Standards (Rocca-Ihenacho et al., 2018), could provide a more holistic understanding of the mechanisms underpinning successful MU implementation.

This review contributes to a growing body of literature arguing that implementation success is not merely a matter of structural alignment but of cultural resonance. In the case of MUs, readiness is most effectively fostered where the values of the organisation and the model of care align, enabling staff to work in ways that are both professionally meaningful and contextually supported.

### 4.2 Strengths and Limitations

The strengths of this review include its comprehensive, multi-database search strategy, use of a theoretical framework (CFIR), and rigorous thematic synthesis methodology. A rapid scoping review was undertaken prior to protocol development to understand the conceptual terrain of organisational readiness and its relevance to midwifery care. This helped to shape eligibility criteria and ensure focus on readiness characteristics rather than outcomes or barriers alone.

However, limitations do exist. The exclusion of grey literature may have limited the breadth of perspectives, and sparse literature was available from LMIC contexts. Additionally, although thematic synthesis allowed in-depth interpretation, the analysis process involved subjective decisions and may have been influenced by researcher perspectives. Not all included studies focused explicitly on readiness, requiring inferential interpretation of relevant data. The bespoke quality assessment tool utilised for appraisal in this review, was adapted from existing frameworks to enhance sensitivity to qualitative literature and developed by the third reviewer. While this may introduce potential bias, the third reviewer was not personally involved in the quality assessment stage, which mitigates this risk. Finally, five included articles were authored by the third reviewer and may have implications for bias towards their inclusion, however adherence to rigorous protocol and inclusion/exclusion criteria throughout the process minimised this possibility.

### 4.3 Implications for Practice and Policy

This review offers a practical and values-informed basis for assessing and strengthening organisational readiness for midwife-led unit implementation in public sector maternity settings. The findings suggest that readiness is not merely a technical or operational challenge but a deeply cultural and relational process. For maternity service leaders, this means adopting pre-implementation strategies that address both structural and human elements of change.

Key recommendations include:

- Strengthening distributed leadership by recognising and investing in midwives as clinical and managerial leaders, supported inter-professionally and by implementation science-informed leadership development programmes;

- Co-developing clinical guidelines with all levels of staff, ensuring contextual relevance and promoting shared understanding and opportunities for team building across professional groups;
- Embedding relational practice principles that enhance engagement through initiatives that foster psychological safety, team cohesion, and a sense of shared mission.

For policymakers and commissioners, the findings underscore that MU implementation cannot be achieved through infrastructure investment alone. While funding and space are essential, readiness also hinges on cultivating cultures that:

- Legitimate midwifery leadership;
- Value and fund non-interventionist, evidence-based care; and
- Prioritise staff wellbeing, reflective practice, and continuous professional development.

These principles should be embedded in national maternity transformation programmes and policy frameworks, alongside strategies to build public and professional confidence in midwife-led care.

Additionally, engagement with service users must be prioritised - not only in care planning, but in the design, evaluation, and implementation of services. Despite strong global advocacy for co-production in maternity care, this review identified a significant gap in user involvement at the implementation level.

### 4.4 Future Research Directions

The findings of this review highlight a critical need for the co-development of a tailored organisational readiness for change assessment tool for MUs in public maternity systems. Such a tool could support maternity leaders to anticipate barriers, align change strategies with values, and enhance the sustainability of MU implementation.

Recommended next steps:

1. Co-design an assessment tool incorporating the themes identified in this review, the CFIR framework, and an existing MU framework (e.g. MUSA, 2018). This should include participatory design with frontline midwives, managers, and service users.
2. Conduct research to pilot and further evaluate whether high organisational readiness (as measured by such tools) is associated with more successful and sustained implementation of MUs over time.
3. There is a pressing need for more research in LMIC contexts where, by necessity, private midwife-led units are more common (ICM, 2025) and the organisational and cultural conditions for public sector midwife-led unit implementation may differ. Comparing studies between high-, middle-, and low-resource settings could help adapt readiness tools and frameworks to diverse health systems.

### 4.5 Conclusion

Building readiness for MU implementation in public sector maternity settings requires more than funding or policy mandates; it necessitates a shift towards relational, inclusive, and values-led approaches. Embedding midwifery philosophy into organisational culture, investing in midwifery leadership, fostering team confidence in physiological birth, co-producing guidelines, and protecting time for team-building and reflection are concrete strategies that align with the readiness characteristics identified here.

The studies reviewed here consistently demonstrate that readiness is enhanced when these characteristics are present. For example, the ethnographic studies by Rocca-Ihenacho et al. (2021–2023) emphasize autonomy, ownership, and interprofessional respect as central to sustaining well-functioning MUs. Similarly, studies from Canada and Italy show that stakeholder engagement and change management strategies improve organizational commitment and capacity. Conversely, studies in China and India illustrate how resistance from biomedical structures, lack of role clarity, and cultural barriers undermine readiness. These findings align with the Organisational Readiness for Change Theory's assertion that implementation success is not only about structural readiness but also concerned with the collective psychological state of those involved in the change process.

Ultimately, this review shows that assessing organisational readiness to implement midwife-led units at the pre-conceptualisation stage is not only possible but vital. Readiness assessment tools grounded in the characteristics identified here could help anticipate challenges, align teams, and improve the long-term sustainability and success MU implementation. In doing so, they offer an important strategy for advancing global maternal health goals and realising the full potential of midwifery care.

### 4.6 Ethical approval

Ethical approval was not required for this systematic review.


### 4.7 Funding sources

The review did not receive any funding.


### 4.8 Systematic review protocol registration number

This protocol is registered with the International Prospective Register of Systematic Reviews (PROSPERO 2020). Registration Number: CRD420251009197.

### 4.9 Declaration of Competing Interest

The authors have no conflicts of interest to declare.


### 4.10 Acknowledgements

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### 4.11 Author Contributions

M. Cross was the primary researcher conducting the initial scoping and subsequent systematic review, data extraction and synthesis. E. Buckingham contributed to study selection, screening and quality appraisal, as the second reviewer. L.H. Jackson provided additional expertise and support. L. Rocca-Ihenacho provided overall supervision and conceptual support throughout the review process.

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## APPENDIX I - Rocca-Yuill Quality Assessment Tool

| Article Number | First Author | Year | Review 1 | Review 2 |
|---|---|---|---|---|
| | | | | |

**Scoring directions**

1. Read the full article and refer to your Inclusion/Exclusion. If the article does not meet you Inclusion/Exclusion criteria then do not commence scoring.
2. Prior to starting the Quality Assessment Scoring, add Article Number, First Author, Year, Reviewer 1, Reviewer 2 (if applicable).
3. Start the Quality Assessment from "Rationale".
4. Give a score of 0-2 depending on whether the defined concept/item is discussed in the article. Scoring is 0-2 for each item to denote the quality and/or quantity of each item in an article. 0 = Not present or low quality, 1 = medium quality, 2 = high quality.
5. Each reviewer should score articles independently and then discuss scoring to agree on the final score.

| Stages | Specific elements | Essential criteria | Score |
|---|---|---|---|
| Rationale | Scope and purpose | 1. Contextualization with literature | |
| | | 2. Aims | |
| | | 3. Research question or objectives stated | |
| Design | Methodology | 4. Rational for using qualitative design | |
| | | 5. Description of theoretical background | |
| | | 6. Description of methodology | |
| | | 7. Methodology appropriate for research question or objectives | |
| | Methods | 8. Description of methods | |
| | | 9. Methods appropriate for research question or objectives | |
| | Sampling strategy | 10. Rational for sampling strategy explained | |
| | | 11. Selection criteria described | |
| | | 12. Thickness of description likely to be achieved from sampling | |
| | Data collection | 13. Description of data collection | |
| | | 14. Data collection strategy appropriate to capture complexity of events and highlight context | |
| | Analysis | 15. Analytical approach explicit | |
| | | 16. Analytical approach appropriate for methodology | |
| | | 17. Analysis grounded in the data | |
| | | 18. Evidence of participants' involvement in analysis | |
| | | 19. Saturation addressed | |
| Interpretation | Clear audit trail given | 20. Demonstration of thorough interpretive pathway and 'decision trail' | |
| | Description of context | 21. Description of social, physical and interpersonal contexts of data collection | |
| | Interpretation grounded in the data | 22. Extensive use of field notes entries/verbatim interview quotes in discussion of findings | |
| | | 23. Provides new insights and increases understanding | |
| Discussion | Contextualization with literature | 24. Findings compared and contrasted with other literature | |
| | Relevance and transferability | 25. Interpretation interwoven with existing theories and other relevant literature drawn from similar settings | |
| | | 26. Discussion of how explanatory proposition/emergent theory may fit other contexts | |
| | | 27. Limitations and weaknesses of study clearly outlined | |
| | | 28. Significance for current policy and practice outlined | |
| | | 29. Outlines further directions for investigation | |
| Reflexivity | Researcher reflexivity demonstrated | 30. Discussion of relationship between research and participants during fieldwork | |
| | | 31. Discussion about how issues/complications met were dealt with | |
| Ethical dimensions | Ethical committee approval | 32. Evidence of ethical approval and following ethical procedures | |
| | Sensitivity to ethical concerns | 33. Documentation of how autonomy, consent, confidentiality, anonymity were managed | |
| | | **Total** | |

**APPENDIX II - CFIR 2.0 Updated 2024 Generic Codebook**

**Framework Guidance:**
The CFIR is intended to be used to collect data from individuals who have power and/or influence over implementation outcomes. See the CFIR Outcomes Addendum for guidance on identifying these individuals and selecting outcomes.
The CFIR must be fully operationalized prior to use in a project:
1) Define the subject of each domain for the project (see guidance for each domain below).
2) Replace broad construct language with project-specific language if needed.
3) Add constructs to capture salient themes not included in the updated CFIR.

| **I. INNOVATION DOMAIN**<br>**Innovation: The "thing" being implemented, e.g., a new clinical treatment, educational program, or city service.**<br>**[Document the innovation being implemented, e.g., innovation type, innovation core vs. adaptable components, using a published reporting guideline. Distinguish the innovation (the "thing" that continues when implementation is complete) from the implementation process and strategies used to implement the innovation (activities that end after implementation is complete).]** | |
|---|---|
| **Construct Name** | **Construct Definition** |
| A. Innovation Source | The degree to which the group that developed and/or visibly sponsored use of the innovation is reputable, credible, and/or trustable. |
| B. Innovation Evidence-Base | The degree to which the innovation has robust evidence supporting its effectiveness. |
| C. Innovation Relative Advantage | The degree to which the innovation is better than other available innovations or current practice. |
| D. Innovation Adaptability | The degree to which the innovation can be modified, tailored, or refined to fit local context or needs. |
| E. Innovation Trialability | The degree to which the innovation can be tested or piloted on a small scale and undone. |
| F. Innovation Complexity | The degree to which the innovation is complicated, which may be reflected by its scope and/or the nature and number of connections and steps. |
| G. Innovation Design | The degree to which the innovation is well designed and packaged, including how it is assembled, bundled, and presented. |
| H. Innovation Cost | The degree to which the innovation purchase and operating costs are affordable. |
| **II. OUTER SETTING DOMAIN**<br>**Outer Setting: The setting in which the Inner Setting exists, e.g., hospital system, school district, state. There may be multiple Outer Settings and/or multiple levels within the Outer Setting (e.g., community, system, state).**<br>**Project Outer Setting(s): [Document the actual Outer Setting in the project, e.g., type, location, and the boundary between the Outer Setting and the Inner Setting.]** | |
| **Construct Name** | **Construct Definition** |
| A. Critical Incidents | The degree to which to large-scale and/or unanticipated events disrupt implementation and/or delivery of the innovation. |
| B. Local Attitudes | The degree to which sociocultural values (e.g., shared responsibility in helping recipients) and beliefs (e.g., convictions about the worthiness of recipients) encourage the Outer Setting to support implementation and/or delivery of the innovation. |
| C. Local Conditions | The degree to which economic, environmental, political, and/or technological conditions enable the Outer Setting to support implementation and/or delivery of the innovation. |
| D. Partnerships & Connections | The degree to which the Inner Setting is networked with external entities, including referral networks, academic affiliations, and professional organization networks. |

| | |
|---|---|
| E. Policies & Laws | The degree to which legislation, regulations, professional group guidelines and recommendations, or accreditation standards support implementation and/or delivery of the innovation. |
| F. Financing | The degree to which funding from external entities (e.g., grants, reimbursement) is available to implement and/or deliver the innovation. |
| G. External Pressure | The degree to which external pressures drive implementation and/or delivery of the innovation. Note: Use this construct to capture themes related to External Pressures that are not included in the subconstructs below. |
| 1. Societal Pressure | The degree to which mass media campaigns, advocacy groups, or social movements or protests drive implementation and/or delivery of the innovation. |
| 2. Market Pressure | The degree to which competing with and/or imitating peer entities drives implementation and/or delivery of the innovation. |
| 3. Performance-Measurement Pressure | The degree to which quality or benchmarking metrics or established service goals drive implementation and/or delivery of the innovation. |
| **III. INNER SETTING DOMAIN**<br>**Inner Setting: The setting in which the innovation is implemented, e.g., hospital, school, city. There may be multiple Inner Settings and/or multiple levels within the Inner Setting, e.g., unit, classroom, team.**<br>**Project Inner Setting(s): [Document the actual Inner Setting in the project, e.g., type, location, and the boundary between the Outer Setting and the Inner Setting.]** | |
| **Construct Name** | **Construct Definition** |
| *Note:* | *Constructs A – D exist in the Inner Setting regardless of implementation and/or delivery of the innovation, i.e., they are persistent general characteristics of the Inner Setting.* |
| A. Structural Characteristics | The degree to which infrastructure components support functional performance of the Inner Setting. Note: Use this construct to capture themes related to Structural Characteristics that are not included in the subconstructs below. |
| 1. Physical Infrastructure | The degree to which layout and configuration of space and other tangible material features support functional performance of the Inner Setting. |
| 2. Information Technology Infrastructure | The degree to which technological systems for tele-communication, electronic documentation, and data storage, management, reporting, and analysis support functional performance of the Inner Setting. |
| 3. Work Infrastructure | The degree to which organization of tasks and responsibilities within and between individuals and teams, and general staffing levels, support functional performance of the Inner Setting. |
| B. Relational Connections | The degree to which there are high quality formal and informal relationships, networks, and teams within and across Inner Setting boundaries (e.g., structural, professional). |
| C. Communications | The degree to which there are high quality formal and informal information sharing practices within and across Inner Setting boundaries (e.g., structural, professional). |
| D. Culture | The degree to which there are shared values, beliefs, and norms across the Inner Setting. Note: Use this construct to capture themes related to Culture that are not included in the subconstructs below. |
| 1. Human Equality-Centeredness | The degree to which there are shared values, beliefs, and norms about the inherent equal worth and value of all human beings. |
| 2. Recipient-Centeredness | The degree to which there are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of recipients. |
| 3. Deliverer-Centeredness | The degree to which there are shared values, beliefs, and norms around caring, supporting, and addressing the needs and welfare of deliverers. |

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| 4. Learning-Centeredness | The degree to which here are shared values, beliefs, and norms around psychological safety, continual improvement, and using data to inform practice. |
| *Note:* | *Constructs E – K are specific to the implementation and/or delivery of the innovation.* |
| E. Tension for Change | The degree to which the current situation is intolerable and needs to change. |
| F. Compatibility | The degree to which the innovation fits with workflows, systems, and processes. |
| G. Relative Priority | The degree to which implementing and delivering the innovation is important compared to other initiatives. |
| H. Incentive Systems | The degree to which tangible and/or intangible incentives and rewards and/or disincentives and punishments support implementation and delivery of the innovation. |
| I. Mission Alignment | The degree to which implementing and delivering the innovation is in line with the overarching commitment, purpose, or goals in the Inner Setting. |
| J. Available Resources | The degree to which resources are available to implement and deliver the innovation. Note: Use this construct to capture themes related to Available Resources that are not included in the subconstructs below. |
| 1. Funding | The degree to which funding is available to implement and deliver the innovation. |
| 2. Space | The degree to which physical space is available to implement and deliver the innovation. |
| 3. Materials & Equipment | The degree to which supplies are available to implement and deliver the innovation. |
| K. Access to Knowledge & Information | The degree to which guidance and/or training is accessible to implement and deliver the innovation. |
| **IV. INDIVIDUALS DOMAIN**<br>**Individuals: The roles and characteristics of individuals.**<br>**Project Roles: [Document the roles applicable to the project and their location in the Inner or Outer Setting.]**<br>**Project Characteristics: [Document the characteristics applicable to the roles in the project based on the COM-B system or role-specific theories.]** | |
| **Construct Name** | **Construct Definition** |
| A. High-level Leaders | Individuals with a high level of authority, including key decision-makers, executive leaders, or directors. |
| 1. Need | The degree to which high-level leader(s) have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which high-level leader(s) have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which high-level leader(s) have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which high-level leader(s) are committed to fulfilling Role. |
| B. Mid-level Leaders | Individuals with a moderate level of authority, including leaders supervised by a high-level leader and who supervise others. |
| 1. Need | The degree to which mid-level leader(s) have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which mid-level leader(s) have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which mid-level leader(s) have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which mid-level leader(s) are committed to fulfilling Role. |
| C. Opinion Leaders | Individuals with informal influence on the attitudes and behaviors of others. |
| 1. Need | The degree to which opinion leaders have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |

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| 2. Capability | The degree to which opinion leaders have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which opinion leaders have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which opinion leaders are committed to fulfilling Role. |
| D. Implementation Facilitators | Individuals with subject matter expertise who assist, coach, or support implementation. |
| 1. Need | The degree to which implementation facilitators have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which implementation facilitators have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which implementation facilitators have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which implementation facilitators are committed to fulfilling Role. |
| E. Implementation Leads | Individuals who lead efforts to implement the innovation. |
| 1. Need | The degree to which implementation leads have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which implementation leads have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which implementation leads have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which implementation leads are committed to fulfilling Role. |
| F. Implementation Team Members | Individuals who collaborate with and support the Implementation Leads to implement the innovation, ideally including Innovation Deliverers and Recipients. |
| 1. Need | The degree to which implementation team members have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which implementation team members have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which implementation team members have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which implementation team members are committed to fulfilling Role. |
| G. Other Implementation Support | Individuals who support the Implementation Leads and/or Implementation Team Members to implement the innovation. |
| 1. Need | The degree to which other implementation support have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which other implementation support have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which other implementation support have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which other implementation support are committed to fulfilling Role. |
| H. Innovation Deliverers | Individuals who are directly or indirectly delivering the innovation. |
| 1. Need | The degree to which innovation deliverers have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which innovation deliverers have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which innovation deliverers have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which innovation deliverers are committed to fulfilling Role. |

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| I. Innovation Recipients | Individuals who are directly or indirectly receiving the innovation. |
| 1. Need | The degree to which innovation recipients have deficits related to survival, well-being, or personal fulfillment, which will be addressed by implementation and/or delivery of the innovation. |
| 2. Capability | The degree to which innovation recipients have interpersonal competence, knowledge, and skills to fulfill Role. |
| 3. Opportunity | The degree to which innovation recipients have availability, scope, and power to fulfill Role. |
| 4. Motivation | The degree to which innovation recipients are committed to fulfilling Role. |
| **V. IMPLEMENTATION PROCESS DOMAIN**<br>**Implementation Process: The activities and strategies used to implement the innovation.**<br>**Project Implementation Process: [Document the implementation process framework and/or activities and strategies being used to implement the innovation. Distinguish the implementation process used to implement the innovation (activities that end after implementation is complete) from the innovation (the "thing" that continues when implementation is complete).]** | |
| **Construct Name** | **Construct Definition** |
| A. Teaming | The degree to which individuals join together, intentionally coordinating and collaborating on interdependent tasks, to implement the innovation. |
| B. Assessing Needs | The degree to which individuals collect information about priorities, preferences, and needs of people. Note: Use this construct to capture themes related to Assessing Needs that are not included in the subconstructs below. |
| 1. Innovation Deliverers | The degree to which individuals collect information about the priorities, preferences, and needs of deliverers to guide implementation and delivery of the innovation. |
| 2. Innovation Recipients | The degree to which individuals collect information about the priorities, preferences, and needs of recipients to guide implementation and delivery of the innovation. |
| C. Assessing Context | The degree to which individuals collect information to identify and appraise barriers and facilitators to implementation and delivery of the innovation. |
| D. Planning | The degree to which individuals identify roles and responsibilities, outline specific steps and milestones, and define goals and measures for implementation success in advance. |
| E. Tailoring Strategies | The degree to which individuals choose and operationalize implementation strategies to address barriers, leverage facilitators, and fit context. |
| F. Engaging | The degree to which individuals attract and encourage participation in implementation and/or the innovation. Note: Use this construct to capture themes related to Engaging that are not included in the subconstructs below. |
| 1. Innovation Deliverers | The degree to which individuals attract and encourage deliverers to serve on the implementation team and/or to deliver the innovation. |
| 2. Innovation Recipients | The degree to which individuals attract and encourage recipients to serve on the implementation team and/or participate in the innovation. |
| G. Doing | The degree to which individuals implement in small steps, tests, or cycles of change to trial and cumulatively optimize delivery of the innovation. |
| H. Reflecting & Evaluating | The degree to which individuals collect and discuss quantitative and qualitative information about the success of implementation. Note: Use this construct to capture themes related to Reflecting & Evaluating that are not included in the subconstructs below. |
| 1. Implementation | The degree to which individuals collect and discuss quantitative and qualitive information about the success of implementation. |
| 2. Innovation | The degree to which individuals collect and discuss quantitative and qualitative information about the success of the innovation. |

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| I. Adapting | The degree to which individuals modify the innovation and/or the Inner Setting for optimal fit and integration into work processes. |
| **CFIR OUTCOMES ADDENDUM** | |
| **I. ANTECEDENT ASSESSMENTS** | |
| **Name** | **Definition** |
| A. Acceptability | The extent to which an innovation is perceived as “agreeable, palatable, or satisfactory" (Proctor et al., 2009). |
| B. Appropriateness | The “perceived fit, relevance, or compatibility of the innovation […] for a given practice setting, provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem" (Proctor et al., 2009). |
| C. Feasibility | The extent to which an innovation “can be successfully used or carried out within a given agency or setting" (Proctor et al., 2009). |
| D. Implementation Climate | The extent to which the Inner Setting has a climate for implementation. |
| E. Implementation Readiness | The extent to which the Inner Setting is ready for implementation. |
| **II. IMPLEMENTATION OUTCOMES** | |
| **Name** | **Definition** |
| A. Anticipated Implementation Outcomes | The likelihood of future implementation success or failure, i.e., implementation outcomes that have not yet occurred. These outcomes are forward-looking; constellations of CFIR determinants across domains predict these outcomes. |
| 1. Adoptability | The likelihood key decision-makers will decide to put the innovation in place/innovation deliverers will decide to deliver the innovation. |
| 2. Implementability | The likelihood the innovation will be put in place or delivered. |
| 3. Sustainability | The likelihood the innovation will be put in place or delivered over the long-term. |
| B. Actual Implementation Outcomes | Current (or past) implementation success or failure, i.e., implementation outcomes that have occurred. These outcomes are backward-looking; constellations of CFIR determinants across domains explain these outcomes. |
| 1. Adoption | The extent key decision-makers decide to put the innovation in place/innovation deliverers decide to deliver the innovation. |
| 2. Implementation | The extent the innovation is in place or being delivered. |
| 3. Sustainment | The extent the innovation is in place or being delivered over the long-term. |
| **III. INNOVATION OUTCOMES** | Outcomes that capture the success or failure of the innovation, based on the impact of the innovation on three important constituents: Innovation Recipients, Innovation Deliverers, and Key Decision-Makers. Impact is defined by: Reach ("The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program") x Innovation Effectiveness ("The impact of an intervention on important outcomes, including potential negative effects, quality of life, and economic outcomes" (Glasgow et al. 2019). |
| **Name** | **Definition** |
| A. Innovation Recipient Impact | Recipient Reach x Innovation Effectiveness |
| B. Innovation Deliverer Impact | Deliverer Reach x Innovation Effectiveness |
| C. Key-Decision Maker (or System) Impact | Key-Decision Maker Reach x Innovation Effectiveness |