EMPOWERING CHANGE: REALIST EVALUATION OF A SCOTTISH GOVERNMENT PROGRAMME TO SUPPORT NORMAL BIRTH

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Abstract

Objective: Midwife-led care has consistently been found to be safe and effective in reducing routine childbirth interventions and improving women's experience of care. Despite consistent UK policy support for maximising the role of the midwife as the lead care provider for women with healthy pregnancies, implementation has been inconsistent and the persistent use of routine interventions in labour has given rise to concern. In response the Scottish Government initiated Keeping Childbirth Natural and Dynamic, a maternity care programme that aimed to support normal birth by implementing multi-professional care pathways and making midwife-led care for healthy pregnant women the national norm.

Design: The evaluation was informed by realist evaluation. It aimed to explore and explain the ways in which the KCND programme worked or did not work in different maternity care contexts.

Methods: The evaluation was conducted in three phases. In phase one semi- structured interviews and focus groups were conducted with key informants to elicit the programme theory. At phase two, this theory was tested using a multiple case study approach. Semi-structured interviews and focus groups were conducted and a case record audit was undertaken. In the final phase the programme theory was refined through analyses and interpretation of the data.

Setting and participants: The setting for the evaluation was NHS Scotland. In phase one, 12 national programme stakeholders and 13 consultant midwives participated. In phase two case, studies were undertaken in three health boards; overall 73 participants took part in interviews or focus groups. A case record audit was undertaken of all births in Scotland during one week in two consecutive years before and after pathway implementation.

Findings: Government and health board level commitment to, and support of, the programme signalled its importance and facilitated change. Consultant midwives tailored change strategies, using different approaches in response to the culture of care and inter-professional relationships

within contexts. In contexts where practice was already changing KCND was seen as validating and facilitating. In areas where a more medical culture existed there was strong resistance to change from midwives and medical staff and robust implementation strategies were required. Overall the pathways appeared to enable midwives to achieve change.

Key conclusions: Our study highlighted the importance of those involved in a change programme working across levels of hierarchy within an organisation and from the macro-context of national policy and institutions to the meso-context of regional health service delivery and the micro-context of practitioner's experiences of providing care. The assumptions and propositions that inform programmes of change, which are often left at a tacit level and unexamined by those charged with implementing them, were made explicit. This examination illuminated the roles of the three key change mechanisms adopted in the KCND programme - appointment of consultant midwives as programme champions, multidisciplinary care pathways, and midwife-led care. It revealed the role of the commitment mechanism, which built on the appointment of the local change champions. The analysis indicated that the process of change, despite these clear mechanisms, needed to be adapted to local contexts and responses to the implementation of KCND.

Implications for practice:

Initial formative evaluation should be conducted prior to development of complex healthcare programmes to ensure that 1. The interventions will address the changes required 2. Key stakeholders who may support or resist change are identified 3. Appropriate facilitation strategies are developed tailored to context.

Introduction

The Winterton Report (HoC 1992) heralded a profound shift in the direction of maternity care in the UK; mothers and midwives voices were heard in parliament and normal birth and midwife-led care received government endorsement. Subsequent policy reports and guidelines recommended an extended role for midwives (DH 1993, 2004, 2007) and the UK Royal Colleges' Safer Childbirth consensus report (RCOG 2007) highlighted the autonomy and accountability of midwives in the care of healthy pregnant women. However, despite consistent evidence of benefits of midwife-led care (Hatem et al. 2008), implementation in the UK has remained patchy, routine intervention in normal childbirth persists and the rate of caesarean section continues to rise (Kings Fund 2008). It appears that availability of evidence alone has been an insufficient driver for change and further impetus was required. This paper reports on the evaluation of a Scottish Government initiative (Keeping Childbirth Natural and Dynamic -KCND) to support normal birth through increasing access to midwife-led care for healthy pregnant women and introduction of multi-professional care pathways.

Background

The United Nations Millennium Development Goals four and five (UN 2012) aim to reduce infant mortality and improve maternal health. Access to quality midwifery care has been acknowledged to be one of the most cost effective means of achieving these aims (UNEFPA 2011). In low income countries the key issue is lack of access to midwifery care or emergency obstetric facilities. However, inadequate access to midwifery care may also be an issue in high-income countries where over medicalisation of birth, inappropriate use of birth technologies and fragmentation of care between professionals groups has resulted sub-optimal care. Midwife-led care that involves the midwife acting as the lead professional for women experiencing straightforward pregnancies and having a coordinating role within the multidisciplinary team for women with more complex pregnancies (Midwifery 2020) has been shown to be effective in reducing some key birth interventions, with no increase in clinical risks and more positive evaluation of care among women (Hatem et al. 2008).

Scottish Government maternity care policy, in common with UK health policy over 20 years has consistently, endorsed pregnancy and childbirth as normal life events and recommended midwife-led care for healthy pregnant women, provision of care tailored to risk and evidence informed practice (Scottish Office Home and Health Department, 1993; Scottish Executive, 2002; Scottish Government, 2011). Implementation of these policies, however, has been inconsistent. While in some locations considerable progress had been made in fully developing the role of the midwife, others continued to support medical led models of maternity care resulting in fragmentation and poor continuity of care. Interventions unsupported by evidence had become embedded in practice, in particular, routine use of intrapartum electronic fetal monitoring (EFM) and routine admission EFM, while the rate of caesarean section had reached 30% in some hospitals (ISD 2011); in this paper we describe this as a medicalised model of care. In response, the Scottish Government Health Directorates developed and introduced KCND, a maternity care programme which aimed to increase rates of normal birth through provision of evidence based care, reduction of unnecessary intervention and midwife-led care for healthy pregnant women; we describe this approach as pro-normal birth.

The KCND Programme

KCND was initiated in 2007 with step-wise implementation of key elements over a three year period. A national steering group was established to oversee programme development and monitor progress towards targets. The group was chaired by the Chief Nurse for Scotland and comprised representatives of the main professional, policy, consumer and management stakeholder groups involved in maternity care in Scotland. A senior manager in each health board was identified as programme lead with responsibility for reporting back to the national steering group. Central funding was provided for the appointment of a consultant midwife in each health board for a three year period, to support programme implementation. The programme had four specific objectives:

- Discontinuation of routine labour admission EFM. This intervention was specifically targeted as a key practice change to support normal birth (implemented September 2008).
- The lead maternity care professional based on risk. Midwife-led care would be the norm for all healthy women through pregnancy, birth and postnatal care with one to one midwife care in labour (implemented December 2009).
- Development and implementation of multi-professional care pathways (http://www.healthcareimprovementscotland.org/our_work/reproductive,_maternal__child/programme_resources/keeping_childbirth_natural.aspx). The pathways comprised risk assessment tools and care pathways for antenatal, intrapartum and postnatal care. They used a traffic light approach, women identified as low risk (green pathway) received midwife-led care, those identified as higher risk (red pathway) received maternity team care, led by an obstetrician. An amber alert triggered referral for medical assessment but not necessarily transfer to the red pathway. The pathways provided guidance for low intervention care in healthy labour (implemented December 2009).
- Establishment of the midwife as first point of professional contact for women in pregnancy. The midwife would undertake early risk assessment and streaming of women to the appropriate care pathway (implemented 2010).

The evaluation

KCND was a complex heathcare programme that comprised multiple components working at multiple levels of the service. Some components represented complex interventions that had been found to be effective in randomised controlled trials ; however, evidence was required about how and why they worked (or not) when implemented together in practice. Therefore, the evaluation, conducted over a three-year period from 2008 to 2011, aimed to explore the ways in which the KCND programme worked in different contexts and its impacts on maternity care practice. .

Theoretical approach

The evaluation drew on the principles of realist evaluation (Pawson and Tilley, 1997) - a theory-driven approach to the evaluation of complex social and healthcare interventions, which aims to understand the mechanisms by which and the contexts in which a programme works or does not work. The realist approach makes explicit the principle that it is not programmes in themselves that work, but rather it is the opportunities/ideas they offer people to make them work. A programme comprises multiple elements or components which introduce ideas and/or opportunities for change into existing social systems; the process of how people interpret and act upon these opportunities/ideas are known as the programme's mechanisms. The social context in which a programme is implemented shapes the mechanisms and resultant outcomes such that a programme will not work in exactly the same way when introduced into different contexts. The context may facilitate or impede the programme because it influences what people do and how they will act. Realist evaluation seeks to explain the complex relationship between the mechanisms activated by the programme components, the context that influences their workings and the outcomes they produce, intended and unintended. It proposes that programmes work (i.e. have successful outcomes) only where they introduce appropriate ideas and opportunities (mechanisms) into appropriate contexts (Pawson and Tilley, 1997, Pawson, 2002).

Realist evaluation has been used in a wide range of healthcare evaluations including individual healthcare interventions aimed at patient/practitioner behaviours (Rycroft-Malone et al, 2010, Fairhurst et al 2005, Tolson et al, 2007), local-level changes to healthcare delivery (Wand et al, 2011, Marchal et al, 2010, Byng et al, 2005) and large scale programmes of health service change (Greenhalgh et al, 2009, Evans & Killoran, 2000, Kennedy et al, 2005). This approach to evaluation has resulted in deeper insights into why a programme/intervention did or did not work and what contextual factors were associated with outcomes. Through its focus on understanding why change

occurs (or not) and in which conditions, realist evaluation allows decision-makers to draw transferrable lessons about effective implementation strategies, thereby lending greater external validity to the findings (Marchal et al, 2010).

Realist evaluation typically involves three broad phases (figure 1). The first seeks to identify the programme theory, that is, how the programme is expected to work, by those developing it, in what contexts, to produce anticipated outcomes. Data is gathered from those who have developed the programme and its key stakeholders. These data are used to build hypotheses about the causal relationships between different contexts (C1, C2, C3…), mechanisms (M1, M2, M3...) and outcomes (O1, O2, O3…); these hypotheses are known as the context – mechanism – outcome (CMO) configurations. The second phase involves testing these theories by gathering data on the way in which the programme unfolds in real life contexts. In the third and final phase, the overall programme theory is refined through analyses and interpretation of the data to provide middle-range theory statements about how, why and for whom programmes work (or not) in what contexts.

Methods

Informed by the realist framework, the evaluation comprised three phases (figure 1); the design and methods used in each are outlined below.

Phase 1 – Identifying the programme theory

Design

An observational approach using semi-structured interviews and focus groups.

Sample and recruitment

All members of the KCND programme steering group (n=14) were invited to participate in individual semi-structured interviews. The 14 consultant midwives employed as part of the KCND programme were invited to attend one of two focus groups. All were given information about the accompanied by a letter of invitation to participate. A member of the research team then contacted them individually to discuss the study, seek consent to participation in principle, and to arrange an interview. Signed consent for participation was obtained prior to the start of the interview or focus group.

Data collection

The interviews explored the stakeholders' accounts of the purpose and key aspects of the KCND programme, its implementation, how it was expected to work, programme facilitators and barriers and its anticipated impact on practice. Consultant midwives were asked to discuss their experience of participating in KCND, the strategies they employed to implement and support the programme and barriers and facilitators. The interviews and focus groups were audio recorded, transcribed verbatim and managed using the software package QSR NVivo 8.

Analysis

Data were analysed using the thematic framework approach, which allows classification and organization of data in terms of key themes, concepts and emergent patterns (Ritchie and Spencer, 1994). A coding framework was developed using data from the first three interview transcripts and the three core concepts of the realist approach – context, mechanism, and outcome. Two members of the research team read and re-read each transcript thoroughly and assigned codes to each section of the text. Codes of the three transcripts were considered together and similar codes were grouped under higher order categories and themes. This process underwent several iterations and revisions resulting in a preliminary framework. The framework was then systematically applied to

the remaining transcripts adding new categories emerging from the data where needed. Finally, the coding framework was refined by searching for similarities and differences among the themes and re-grouping into higher order themes. These data were then summarized and synthesized to generate hypotheses about what mechanisms could or would be generated by the programme components, in what circumstances, to achieve what outcomes. The process was supported by reading and reflecting on the data and through discussion within the wider research team. Through this iterative process, hypotheses about the CMO configurations were generated.

Phase 2 – Testing the programme theory

The programme theories were tested by collecting data at operational and clinical practice level in different contexts to explore how the programme unfolded in practice.

Design

A multiple case study design was used. In Scotland, the maternity service is organised into 14 geographical health boards. Maternity care is provided through 15 consultant led and 25 midwife-led units across a diverse range of geographical and socioeconomic settings. To encompass the contextual conditions at a range of levels, a 'case' was defined as 'the maternity services provided in a particular health board area'.

Selection of cases

Health boards were purposively selected for diversity in case study profiles (table 1). A sampling frame was constructed; parameters included were; configuration of maternity services (number and type of maternity unit), annual births, population demographics, rurality, and the adoption of pro-normal birth practices.

Data collection

Semi-structured interviews and focus groups with staff - A purposive approach to sampling was used. Within each case study site, we sought to interview personnel from both clinical practice and service management. From clinical practice we planned to recruit at least two obstetricians, two GPs and between 10 and 20 midwives, hospital and/or community based. The management sample included the Head of Midwifery, Clinical Director, Director of Nursing for the health board, KCND consultant midwife, and a Supervisor of Midwives in each case. Individual semi-structured interviews were conducted with medical staff and service managers, focus groups were conducted with midwives whose main role was in clinical practice. To facilitate discussion and for practical reasons focus groups comprised midwives from different practice settings.

The topic guides were informed by the realist framework to elicit information on three key elements:

- Context: views about the KCND initiative, programme implementation and facilitation, current practice and culture, and enabling and constraining factors.
- Mechanisms: views of how KCND worked, how the changes were interpreted and acted upon, and experiences of implementing the changes.
- Outcomes: perceived changes in practice and service performance, impact on roles, workload and professional relationships.

Working through the KCND consultant midwife, potential participants were identified through the organisational staff lists and sent the study information. Those who expressed interest were contacted by a researcher to ascertain their willingness to take part and arrange an interview. Written consent was obtained from the participants before the interview. All the interviews and focus groups were audio-recorded and transcribed verbatim.

Case record audit - A national case record audit was conducted at two time periods 'before and after' implementation of the pathways (2009 and 2010). The audit included all births in Scotland occurring during one week in consecutive years. Data was used both to inform the implementation and the evaluation teams; only data for the case study sites, relating to midwife-led care, discontinuation of the admission CTG, and labour intervention are presented here. Audit data provides some indication about programme outcomes, however, these data must be treated with caution as cause and effect cannot be assumed.

Phase 3 – Refining programme theory

Qualitative data were analysed using a framework approach as described for stage one; the programme theory provided the framework categories and analysis focused on understanding the ways in which the proposed mechanisms unfolded or did not unfold in practice, identifying alternative mechanisms and explanations. Initially data were organised for each of the proposed CMO configurations separately for each site, cross comparisons were then made. Data from case record audit were entered onto SPSS and analysed using descriptive statistics.

Ethics and research governance

The evaluation was reviewed by the scientific advisor for MREC Scotland and deemed not to require NHS research ethics approval. Ethics approval was granted by the University of Stirling School of Nursing, Midwifery and Health ethics committee and complied with research governance procedures in each health board. Studies involving interviews with high profile participants may pose challenges in ensuring anonymity as individuals may be easily identified. In this case the process of summary and synthesis of data meant that data were presented at a higher level of abstraction rather than at the level of the individual/representing group, reducing the potential to attribute data to any individual participant.

Findings

Phase one- developing the programme theory.

Twelve stakeholders consented to take part in individual interviews and thirteen consultant midwives participated in one of two focus groups (table 1). Describing the programme theory started with an account of the drivers behind the KCND programme in terms of the stakeholders perceptions of problems in existing practice and underlying associated issues. This was followed by an account of the different components the programme introduced in order to address the problems, explanations about how these were expected to work and facilitating or impeding factors.

The main programme driver was a concern over perceived rising rates of childbirth interventions including caesarean section. Stakeholders suggested that there was a culture of intervention and a hierarchical relationship between medical staff and midwives which reduced the opportunity for midwives to fulfil their role optimally. They felt that although there was strong evidence for midwife-led care for women with low risk pregnancies, and consistent policy support, implementation across Scotland had remained variable. The longstanding practice of obstetricians being named as the lead carer for women, regardless of risk status was considered to still continue (denoted by the consultant's name on the maternal case record). This was described as largely nominal; however, there was considered to be reluctance on the part of obstetricians and midwives to transfer responsibility entirely to midwives. Stakeholders suggested that to enable women to have the opportunity to experience normal pregnancy and childbirth, midwives needed to be able to take responsibility for women's care, make their own decisions and communicate more effectively with the multi-disciplinary team.

A second driver was stakeholders' concern about variation in practices and quality of care. Stakeholders felt that this was due to use of different criteria for risk assessment and use of different local policies and care guidance.

The programme components and anticipated mechanisms

The programme introduced three main components: the appointment of consultant midwives, multiprofessional care pathways, and midwife-led care, specifically, making the midwife the first point of professional contact for all pregnant women and midwives as lead care providers for healthy pregnant women. The consultant midwives were expected to facilitate practice change through negotiation with all stakeholders, gaining multi-professional engagement, acting as champions of normality, providing training and problem solving. It was anticipated that the consultant midwives' experience, special interest in normal birth, and additional leadership training would increase their credibility and effectiveness as programme leads. However, hurdles were envisaged in engaging the multidisciplinary team and in potential role conflicts with senior midwife managers. The care pathways were expected to standardise care and reduce interventions for low risk women by introducing a risk-screening tool and care guideline which would be used by all members of the multi-professional team. The pathways were anticipated to be used by all professionals as they were endorsed by multi-professional organisations at national level, developed through a consensus-based process and evidence-based. Midwife-led care was expected to reduce interventions, improve communication and multidisciplinary working by setting women on a 'normal' path from the start of their pregnancy and by empowering midwives to adopt pro-normal practice, make their own decisions, challenge the existing models of care, take responsibility for women's care and practice with greater confidence. CMO theories for the three components are depicted in figure 2.

Phase two – testing the programme theory

The contexts

Table 1 describes the case study sites and participant samples. These were achieved with the exception of GPs in two case study sites. Participants described the context and culture of maternity care, specifically: the existing practice models, staff attitudes and relationships between professional groups (table 2). Case study sites A and B had contexts that appeared favourable to programme implementation. The culture in both was described as pro-normal and clinical practices relevant to KCND had been, or were being adopted although intrapartum care in site A was described as medicalised. In site B midwives reported having good working relationships with the obstetricians, they were described as supportive of midwife-led care. In both sites A and B midwives were described as working relatively autonomously. In contrast case study site C had a context which appeared unfavourable for programme implementation with a culture of medical dominance and intervention. Few pro-normal practices were in place or planned and strong resistance to change was anticipated.

Case record audit

At the first audit (table 3) midwives were undertaking the initial antenatal risk assessment(although there was a decline in sites A and C at audit two) and were the lead carers for low risk women in the majority of cases. By audit two, the objective for the midwife as first point of contact appeared largely to have been achieved. In site C there was a reduction of almost 40% in use of admission EFM and in site A an increase in women receiving no intrapartum intervention by the second audit.

The way in which the programme unfolded in practice within each case study site is presented in Appendix tables 4-6. These case-specific CMOs were compared and contrasted with each other and synthesised to develop middle-range theories in relation to each programme component. Although these middle-range theories relate to workings of the KCND programme specifically, the findings

also provide transferrable lessons for the development, implementation and evaluation of large scale healthcare programmes. The refined programme theory is presented below with figures depicting the refined CMOs (figures 3-6)

Phase three - refining the programme theory.

Component one appointment of consultant midwives

At the health board level the opportunity to appoint consultant midwives triggered an additional mechanism, we termed the 'commitment' mechanism (figure 3), across all of the case study sites. There was strong 'buy in' from senior staff, manifested through their active support of the programme, working closely with and supporting the consultant midwives (appendix table 3). The consultant midwife posts were made substantive and full time (although this was not the case in all health boards). This signalled the importance of the KCND initiative and the high-level management commitment to drive it forward.

The consultant midwives in each site, tailored implementation to their understanding of local context (appendix table 3). In site A implementation was highly visible; with multidisciplinary staff meetings, involvement and consultations on different aspects of the programme. In contrast, the implementation in site B was more subtle, changes to practice were integrated with local protocols with less badging of the KCND programme. The consultant midwife in site C engaged in a range of highly visible and robust implementation strategies adapting these in response to the stakeholder reactions.

Despite significant efforts on the part of the consultant midwives to engage the multidisciplinary care team, responses were mixed. Midwifery staff across sites generally welcomed KCND's move to restore the focus on normality and saw it as advancing midwifery practice and supporting autonomous working of midwives, although there was reluctance to engage by midwives in some areas. Obstetricians in all the sites perceived KCND to be mainly a midwifery initiative. However, the

local culture seemed to shape the way they responded to the consultant midwives' efforts. Where the culture was pro-normality (site B), the obstetric team provided support and co-operation to implementing the changes, which were perceived as confirming and validating current good practice. Here, the subtle implementation strategy appeared to be successful, perhaps as there was less obvious requirement for change. In contrast, where the culture was described as highly medically dominated (site C) there was strong resistance to change from both midwives and medical staff. In response, the consultant midwife adopted a series of tough 'head-on' strategies (appendix table 3). Medical staff felt that their authority was being eroded while midwives felt that they were being unduly pressured to conform.

Refined CMO for consultant midwives (figure 3).

The appointment of consultant midwives worked by signaling the high-level commitment to driving the programme forward and was instrumental in preparing the context for implementation through a range of facilitation and support mechanisms. However, these mechanisms were only triggered successfully where the culture was more pro-normality, obstetricians supportive and midwives were recognised as equals. In such supportive contexts, the subtle implementation strategy of integrating KCND principles with local protocols resulted in greater adherence as it appeared to create less obvious requirement for change. Where the culture was highly medically dominated and an unequal balance of power and authority between midwives and obstetricians tough implementation strategies were required, but there was considerable resistance from both obstetricians and midwives.

Component two -multidisciplinary care pathways.

In sites where practice had already changed or was changing the pathways validated existing practice and enabled midwives to work more confidently (appendix table 5). In the more medically

dominated site C the pathways enabled midwives to achieve change, by legitimising their decisions and actions. The effect of the pathways on midwives' clinical judgment varied. In case study sites where staff felt encouraged to use clinical judgment and supported by managers in case of deviations from the pathways, midwives reported that pathways supported and complimented clinical judgement, however, in site C midwives felt their judgement constrained and resisted pressures to conform. Across the sites the pathways were perceived to have resulted in increased efforts to support normal birth and a perception that interventions had been reduced. However, there was a concern that the focus on low risk pregnancy excluded higher risk women.

Refined CMO for multidisciplinary care pathways (figure 4)

In contexts in which a pro-normality and supportive culture existed the pathways worked by validating and legitimising existing good practice, supporting midwives to work confidently and complimenting clinical judgement. In more medically dominated context pathways were seen as constraining clinical judgements and there was considerable resistance to their use. Nevertheless, in this context (characterised by unequal balance of power between midwives and obstetricians), the pathways appeared to enable midwives to withstand pressure against change from obstetricians and considerable change was ultimately achieved.

Component three - Midwife-led Care

Implementation of midwife as the first point of contact and midwife-led care impacted on the balance of power and authority between midwives, obstetricians and GPs and created some tensions between groups (appendix table 6). In general GPs appeared to be accepting of the changes while dissatisfied with the process of change, which was seen as 'top-down' and prescriptive. GPs expressed concerns about loss of skills in the longer term and midwives were concerned over potential loss of GP co-operation in care for more complex cases. There was no process to facilitate

information sharing between midwives and GPs in many areas and this was a major barrier to communication.

In areas where it was already happening, midwife as lead for low risk pregnant women worked by formalising and validating this practice. However, this component impacted on the roles of and relationship between obstetricians and midwives differently in different contexts. In the medically dominated site C, some obstetricians and midwives raised concerns about midwives' preparedness and confidence to take a lead clinical role and the potential risk to women's safety (appendix table 6). As a result, obstetricians were reluctant to hand over responsibility to midwives. In the site described as most pro-normality with equal balance of authority, midwives were empowered to work autonomously without medical input but concerns were expressed about care quality due to midwives' increased workloads, restriction of women's choice to see an obstetrician during pregnancy, and their loss of rapport with women. Overall it was felt that more time was required for all stakeholders to come to terms with changes in roles and responsibilities and develop new ways of working.

Refined CMO for midwife led care (figures 5 and 6)

The midwife-led care component worked by empowering the midwives to practice more autonomously in contexts where the overall model was pro-normality, and midwives were supported by obstetricians and GPs in making the transition to assuming full responsibility for care. However, where midwives were perceived to lack confidence and skills, this component led to obstetricians concerns about women's safety, and reluctance to relinquish responsibility to midwives. GPs' dissatisfaction with the national implementation process created feelings of alienation and resulted in their withdrawal from maternity care.

Discussion

The Scottish Government aspired to support normal birth through a national programme of change in maternity care, introducing multidisciplinary care pathways, midwife–led care for healthy pregnant women and reducing routine intrapartum intervention. By the end of the programme these objective appeared, to have been achieved to some extent. However, the purpose of this evaluation was not primarily to identify whether the programme 'worked' but rather to provide explanations of how and why it worked in real-life healthcare contexts. The realist approach focusses on development of initial programme theory in the form of hypothesised CMO configurations which are subsequently refined to understand how change unfolds in practice. Some findings have particular relevance to maternity care while others have broader application for those concerned with implementing and evaluating healthcare programmes.

We found that the 'commitment mechanism' was a powerful change agent. This combined with local programme champions, employing strategies tailored to context (subtle strategies in favourable contexts and tough approaches in unfavourable contexts) provided considerable power for change, in particular in settings where an unequal balance of power and authority existed between midwives and obstetricians and strong resistance was encountered. This approach drew on underlying theories of change suggesting that both top-down drivers along with local, practical engagement, appropriate structures, attitudes and processes are necessary to effect change in complex healthcare systems..

Introduction of the KCND pathways and the focus on 'normal birth for normal women' raised concerns about the impact on women labelled high risk. Although it is not clear whether there was an actual increase or whether the increased focus on risk assessment raised midwives awareness. This issue requires further research, there is theoretical evidence to suggest that labelling women

high risk may create a 'self-fulfilling prophesy' through the 'nocebo' effect (Olshansky, 2007) which suggests that negative beliefs about health or healthcare may have a significant impact on health outcomes. It is possible that the focus on risk screening and allocation of risk based pathways could have the unintended consequence of reinforcing and formalising high-risk attribution, thus leading to higher use of intervention in this group of women (Cheyne, 2013).

The KCND programme challenged long accepted role boundaries. While all parties appear to have been relatively comfortable with the previous practice of delegation of care to midwives, acknowledging midwives lead role created considerable dissatisfaction, resistance to change and resulted concerns over GPs further withdrawing from maternity care. Bick et al (2009) similarly found that tensions between staff groups increased when introduction of a normal birth pathway made roles more explicit. Similarly, in evaluating the implementation of the All Wales Clinical Pathway for Normal Birth, Hunter (2010) found that medical staff felt excluded and as a result were unsupportive of its implementation. KCND was strongly badged at the outset as a multi-professional programme, all relevant groups participated in the steering group. However, despite this, it was largely seen as an initiative for and by midwives and in all case sites and there was some degree of alienation of obstetricians and GPs. It appears that multi-professional engagement at the top level is not in itself, a guarantee of involvement at clinical levels.

In looking for transferrable lessons for those involved in developing, implementing and evaluation healthcare programmes, it is the programme mechanisms rather than the maternity care specific components that offer the opportunity for learning. We found that successful activation of the anticipated change mechanisms is dependent on the context's readiness to change, the existing models of care, power relationships among professional groups and stakeholders' attitudes.

Unfavourable contexts require tougher implementation strategies and in any context programme components and contexts may interact to produce unanticipated or undesired outcomes. The realist evaluation approach taken in this study enabled the research team to make explicit the assumptions and propositions that inform programmes of change (which are often left at a tacit level) and to explore the complex interactions between healthcare programmes, their implementation, and context. Using this approach at the development stage of healthcare programmes offers the potential to predict possible negative component/context interactions, anticipate 'unanticipated' consequences and to prepare the contexts and shape healthcare programmes accordingly. This would lead to more successful implementation of programmes.

Limitations

In cases of complex and multi-faceted change programmes, it is difficult to unpick the influences of different aspects of a programme, which in any case are likely to work in an iterative manner. The sample was appropriate and included a range of practice contexts, however, it was only possible to interview two GPs and data collection was focused entirely on staff perspectives. Recognising that women's views have not been included, a national survey of women's experience of maternity care in Scotland will be conducted in 2013.

Conclusions

The findings discussed here were focused on attempts to support normal, physiological birth in the face of rising national intervention rates through appointment of consultant midwives as clinical leads, establishing evidence-based care pathways for women with different risk profiles and through authorising and formalising midwife-led care for women at low-risk of obstetric complications. However, they also have resonance and applicability for other programmes of change, within maternity care internationally and for other areas of health and social care. They indicate that change programmes need to be informed by clear and well-founded theories of change, sensitivity

and responsiveness to the context in which it will be implemented and unfold and to develop mechanisms which are carefully tailored to both the context and the objectives of change (Dixon-Woods et al. 2012).

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Figure 1 The realist evaluation process

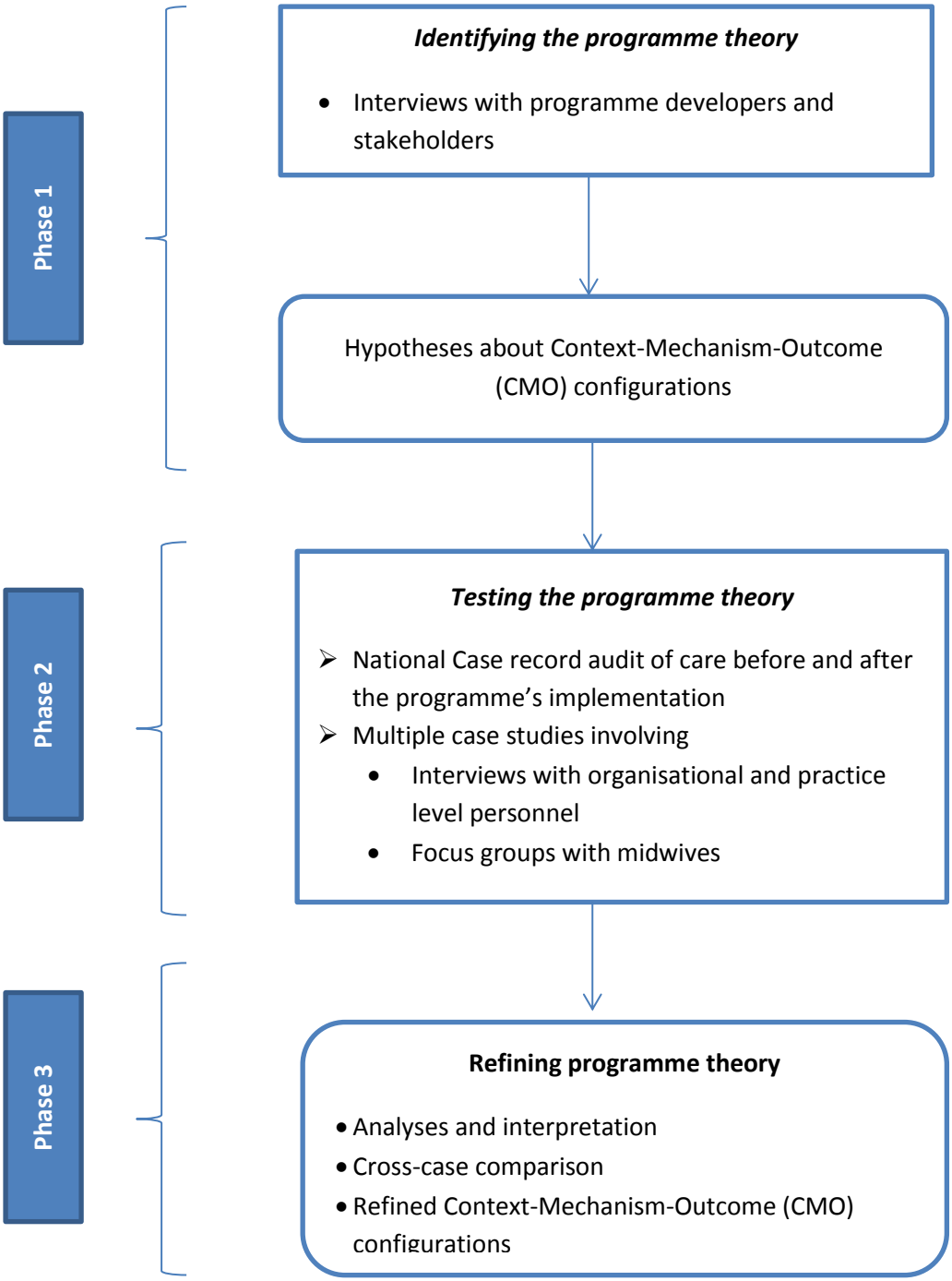

Table 1. Study sample and description of case study sites

Phase one			
National stakeholders	n = 12		
Consultant midwives	n = 13 2 focus groups 1 video link interview		
Phase two Case studies	Site A	Site B	Site C
Health board maternity service configuration	1 consultant-led unit, 1 alongside midwifery-led unit 1 community midwifery-led unit	2 consultant-led units, 1 alongside midwifery-led unit, 1 community midwifery-led unit, 3 three birth units.	1 consultant-led unit.
Health board annual births (2010)	3781	6360	6221
Socio-economic characteristics	Mixed rural and urban population; majority with a high deprivation index*	Mixed urban and rural population; majority with a low deprivation index. Wide geographical spread of maternity services	The population mixed urban and rural; majority with a high deprivation index.
Pre-existing care model pro-normality/ midwife-led care	Medium	High	Low
Case study sample: Senior clinical management**	4	4	4
Senior clinical midwives	4	2	2
Obstetricians/ medical	2	1	2
GPs	2		
Midwives (focus groups)	21 (3 groups)	15 (3 groups)	10 (2 groups)
National audit Year 1 (2009) Year 2 (2010)	 83 73	 96 99	 108 68

* Scottish Index of Multiple Deprivation **included obstetricians

Table 2. Context and culture of case study sites

Site A	Site B	Site C
Existing practice models pro normal /medicalised model • Midwives undertake the antenatal risk assessments • No routine use of labour admission EFM • Intrapartum care described as 'medicalised' • EFM and active labour management was the norm. • An obstetrician's name was routinely on the maternity case record. **Staff attitudes** • Staff felt supported by managers if deviating from pathways • Intrapartum care staff's mind-set was described as pro-intervention. **Relationship between professional groups** • Conflicting philosophies of medicine and midwifery led to disagreements	**Existing practice models pro normal /medicalised model** • Most practices in relation to KCND were already in place • The model of intrapartum care was described as 'low intervention' • Midwives did not undertake the initial antenatal risk assessment. • An obstetrician's name was routinely on the case records. **Staff attitudes** • Staff inertia to change was described as biggest hurdle. • Managers appreciated that 'change' is a slow process and perseverance essential **Relationship between professional groups** • Midwives reported working autonomously and taking responsibility for decision making in the care of low risk women • Geographical distance between maternity units results in inconsistent practice and poor communication • Obstetricians were supportive of midwife-led care trusting midwives' capabilities	**Existing practice models pro normal /medicalised model** • Highly 'medicalised' model of care • Few of the policies in relation to KCND in place • No plans to discontinue admission EFM. • Electronic fetal monitoring and 'active labour management' was the norm • An obstetrician's name was routinely on the case records. **Staff attitudes** • Staff's mind-set was described as 'pro-intervention'. • Resistance from midwives to changes was anticipated • Strong resistance to change from obstetricians **Relationship between professional groups** • Obstetricians were described as dominating the intrapartum setting.

Table 3. Case record audit outcomes before and after KCND pathway implementation

Audit	Site A		Site B		Site C	
	2009 n= 83 births	2010 n=73 births	2009 n= 108 births	2010 n= 69 births	2009 n=96 births	2010 n= 99 births
Midwife 1st point of contact (% of cases)	n/a*	78% (n=57)	n/a	74% (n= 51)	n/a	92% (n=91)
Midwife undertaking initial risk assessment (% of cases)	87% (n=72)	66% (n=66)	94% (n=102)	91% (n=63)	99% (n=95)	80% (n=79)
Midwife lead for low risk women for antenatal care (% of cases)	79% (n=37)	98% (n=45)	83% (n=57)	84% (n= 36)	87% (n=60)	89% (n=50)
No use of routine admission EFM for low risk women in labour (% of cases)	92% (n=33)	81% (n= 22)	85% (n=39)	97% (n= 34)	36% (n=15)	73% (n=30)
Low risk women having no labour intervention (% of cases)	33% (n=12)	30% (n=8)	20% (n=43)	54% (n= 18)	45% (n=19)	41% (n=17)

* pre implementation of Multidisciplinary care pathway

Table 4. Unfolding Mechanisms and outcomes– Component 1 appointment of consultant midwives

Site A	Site B	Site C
Mechanisms • Managers supported the consultant midwife and actively involved in implementation • Pathways distributed through small group meetings and briefing sessions • Pathways made visible and accessible at point of care • Active encouragement to change practice – through group discussions, one to one contact **Outcomes** • Obstetricians initially reluctant to engage, perceived implementation as a top-down, midwife initiative. • Obstetricians felt alienated with little say in programme direction or implementation. • Slowly obstetricians realised KCND was formalising and structuring existing practices. • Midwives – KCND appealed only to midwives with particular focus on normal birth. • Midwives with less focus on normality remained unaffected.	**Mechanisms** • Managers supported and worked with the consultant midwife • KCND integrated into a wider consultant midwife role • Advisory group initiated to plan implementation • Changes not packaged as KCND but integrated with existing practices • Local protocols updated with KCND pathways but adapted to local circumstances **Outcomes** • Obstetricians were engaged in early discussions but not implementation • Obstetricians were supportive and co-operative but distant, perceiving KCND to be for and by midwives • Staff would have liked more troubleshooting sessions once pathways were rolled out	**Mechanisms** • Senior management support, KCND implementation discussed at senior strategy meetings • Tailored implementation to setting e.g. small group sessions in the community, 'hands-on' leading by example, in labour areas. • Multi-disciplinary discussion and debates • Joined obstetricians advisory group, • Held drop-in sessions, sent letters to GPs and distributed newsletters. • Monitored clinical practice through regular audits. **Outcomes** • Obstetricians hard to engage. Felt implementation was rushed and changes imposed. • They felt their role and authority was eroded and put up strong resistance to changes. • Some midwives felt constrained and pressured to change. • GPs were initially unresponsive to letters but gradually began to engage

Table 5. Unfolding Mechanisms and outcomes – Component 2 introduction of KCND Pathways

Site A	Site B	SiteC
Mechanisms • Pathways served to legitimise and validate existing practice by making it explicit and endorsing it. • Empowered midwives to work autonomously and confidently • Complimented clinical judgement **Outcomes** • Perceived increase in efforts towards normality and reduction in intervention rates. • Concerns that high risk women were 'excluded from normality' and deviations from normality stigmatised. • Perceived increase in choice giving (e.g. place & mode of birth) and helping women make informed choice	**Mechanism** • Pathways served to standardise and structure practice within and across geographically distant units. • Midwives often used their own judgement rather than simply following pathways. • Prompted staff to think about risk assessment and appropriate pathway. **Outcomes** • Perception that communication between units had improved due to standard criteria • Perceived that more 'normality' policies were implemented locally. • Concern that high risk women were 'excluded from normality'	**Mechanism** • Pathways empowered midwives to withstand pressures from medical staff to conform to pre-existing medicalised care models. • Frequent monitoring of adherence increase negative attitudes to pathways • Perceived to undermine clinical judgement **Outcomes** • Perception that some interventions were being reduced. • Obstetricians felt that there was an increased risk of clinical error by midwives. • Obstetricians felt that women's choice was constrained

Table 6. Unfolding Mechanisms and outcomes –Component 3 Midwife- led care

Site A*	Site B**	Site C**
Mechanism • Not seen as a major change in some areas, made existing practice explicit and official • GPs had embraced the change long ago and agreed that there was no need for their involvement in healthy pregnancies, midwives made appropriate referrals. • GP dissatisfied with communication from the national steering group • GPs felt excluded, KCND was seen as primarily as a midwife initiative imposed on them. • No procedure in place for sharing information between midwives and GPs, potential for missing important information • Some obstetricians were still involved in care of low risk women • Some midwives felt unprepared for lead role and responsibility and initially continued to seek approval from obstetricians. **Outcomes** • GP concern about de-skilling in the longer term. • Strained relations between primary care and maternity services • The programme empowered midwives to manage caseloads autonomously and work alongside obstetricians without seeking approval.	**Mechanism** • GPs were felt to be mostly welcoming of change but appeared to feel excluded. • GPs appeared dissatisfied with the implementation process • In some areas there was no procedure in place for sharing information between midwives and GPs, potential for missing important information • The two part booking system added to the midwives workload in busy and short-staffed clinics. • Obstetricians were supportive and co-operative. • Obstetricians expressed concern that increasing midwives caseloads would affect care quality • Obstetricians expressed concern over reduction of women's choice to see an obstetrician if preferred. **Outcomes** • Midwife as first point of contact was perceived to be increasingly the norm • Concern over withdrawal of GPs from maternity care and risk of de-skilling	**Mechanism** • In some areas where practice had already changed GPs reacted favourably • Some GPs appeared resistant but gradually engaged after seeing the process work in practice • In some areas there was no procedure in place for sharing information between midwives and GPs, potential for missing important information • Obstetricians were supportive in principal • Obstetricians concerned that midwives lacked necessary skills and confidence without additional training to undertake the new roles. **Outcomes** Midwife as first point of contact perceived to be a success Obstetricians were reluctance to hand over responsibility Reported confusion over roles. The two part booking a challenge for midwives due to lack of time and accommodation in community venues

* Includes interviews with 2 GPs **reports other participants perceptions of GP reactions

Figure 2. CMO theories for KCND programme components

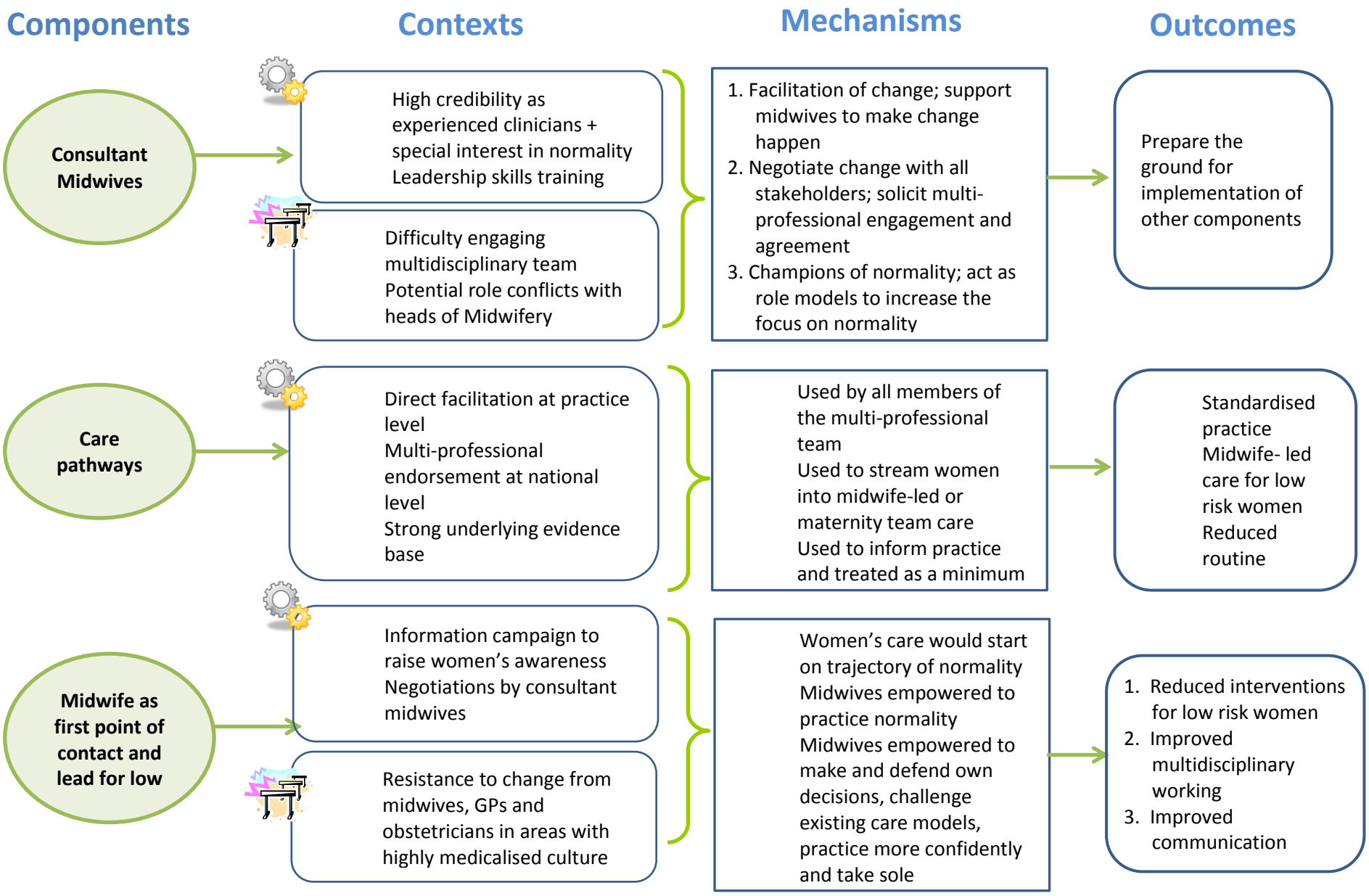

Figure 3. Refined CMOs for Component 1: Appointment of Consultant Midwives

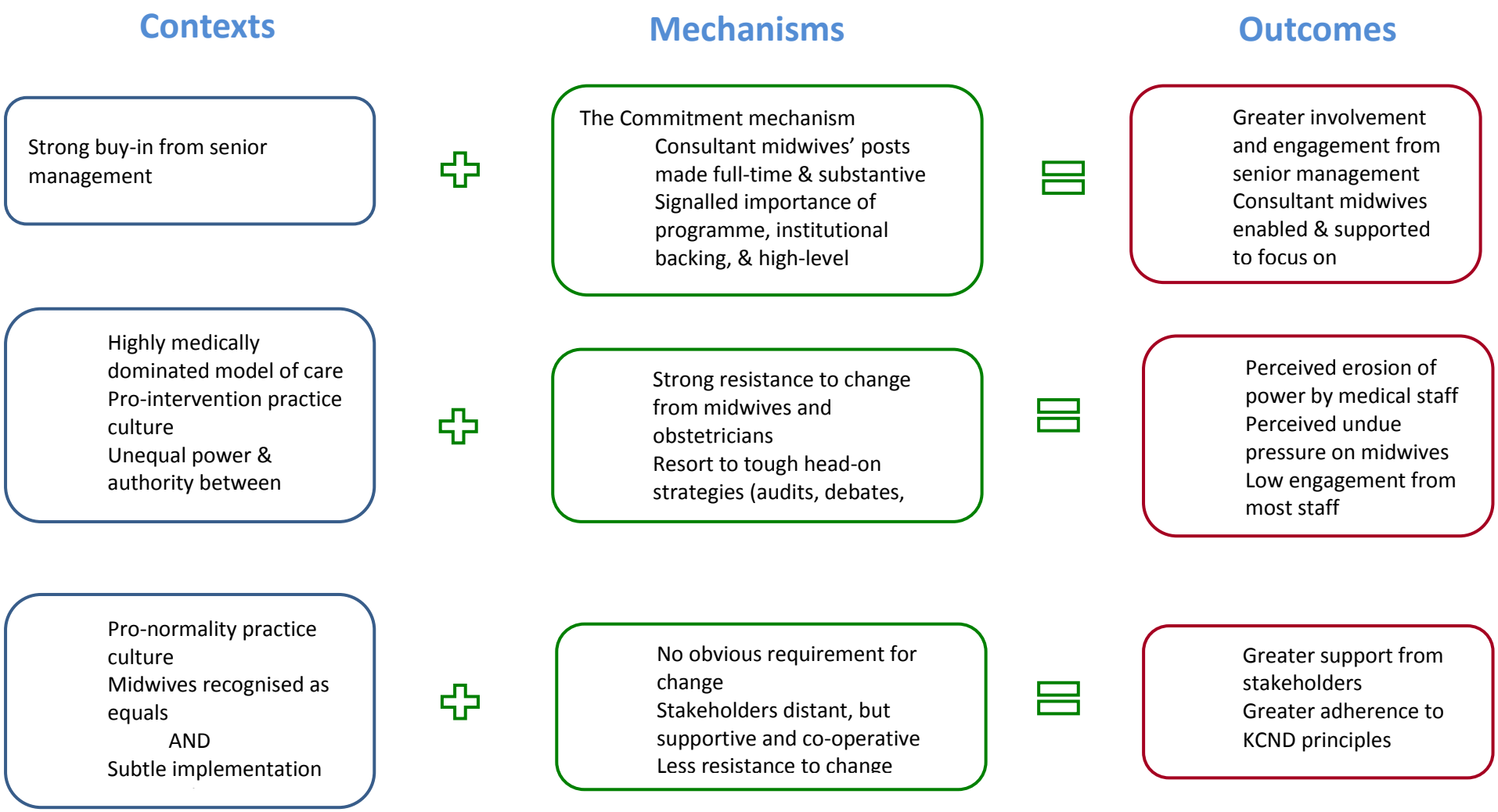

Figure 4. Refined CMOs for Component 2: KCND care pathways

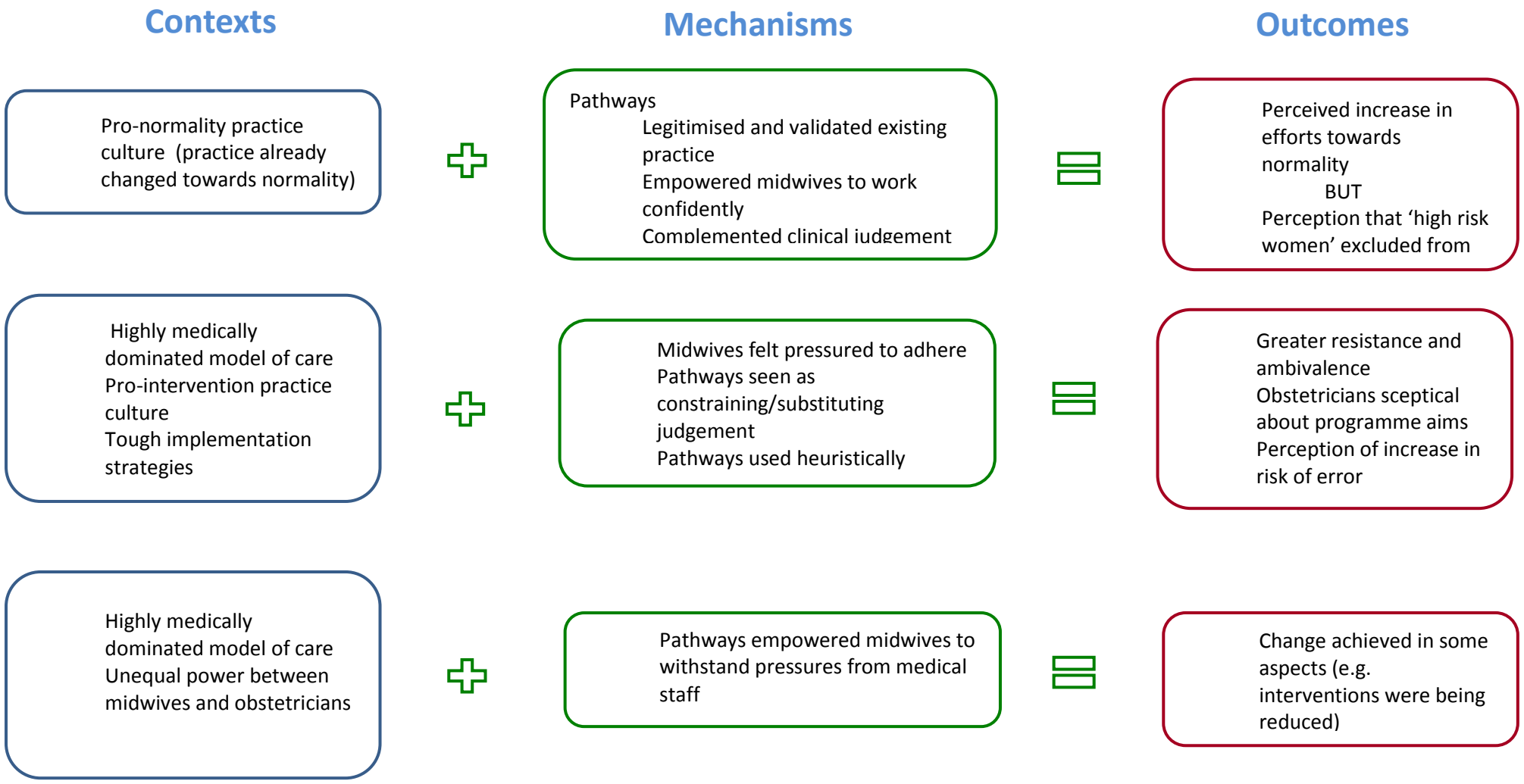

Figure 5. Refined CMOs for Component 3: Midwife as first point of contact

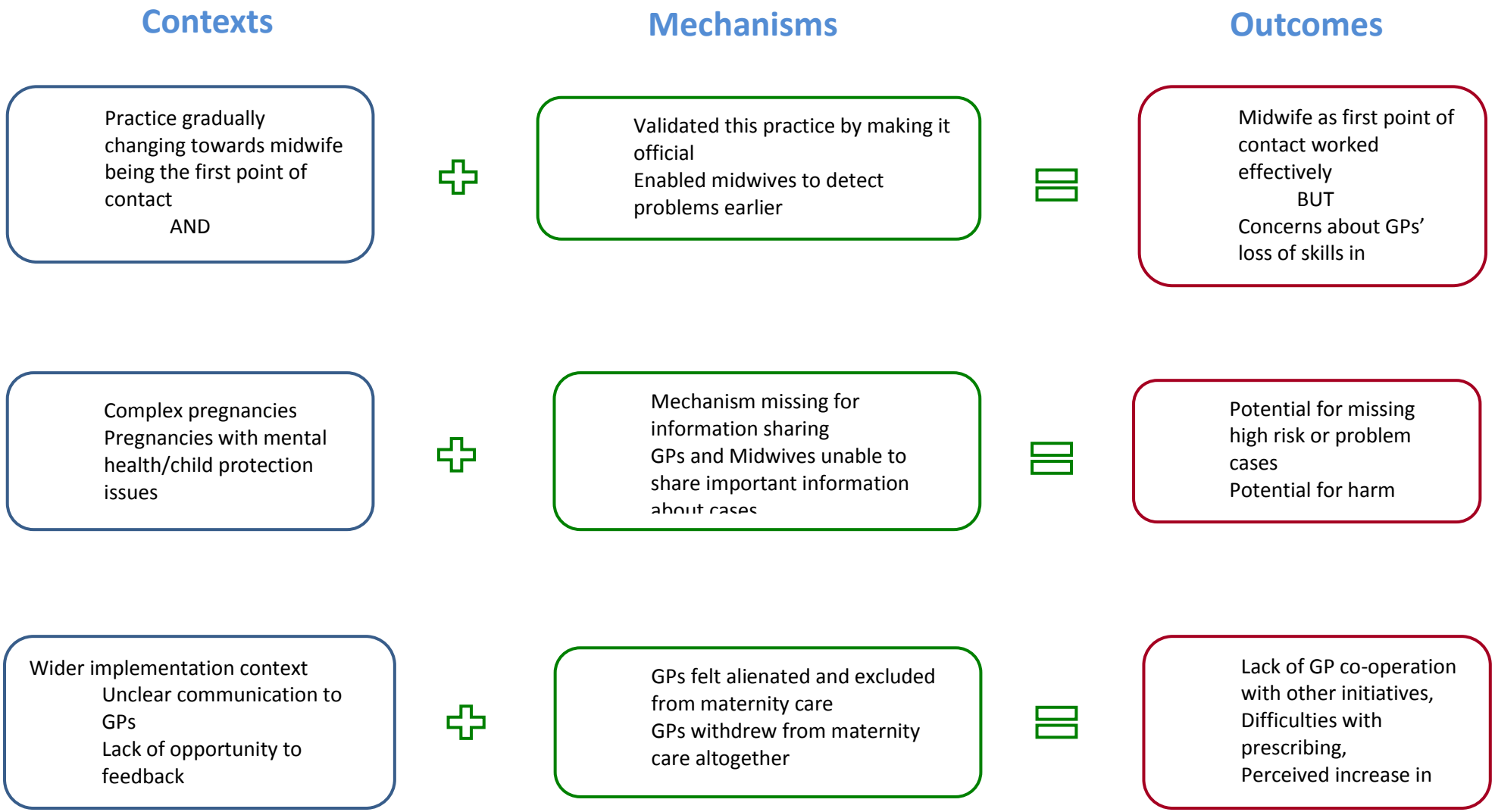

Figure 6. Refined CMOs for Component 3: Midwife as lead carer