Complex interventions in midwifery care: Reflections on the design and evaluation of an algorithm for the diagnosis of labour

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ABSTRACT

Randomised controlled trials are the 'gold standard' for evaluating the effectiveness of interventions in health-care settings. However, in midwifery care, many interventions are 'complex', comprising a number of different elements which may have an effect on the impact of the intervention in health-care settings. In this paper we reflect on our experience of designing and evaluating a complex intervention (a decision tool to assist with the diagnosis of labour in midwifery care), examining some of the issues that our study raises for future research in complex interventions.

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Introduction

The randomised controlled trial (RCT) as a research design remains the gold standard for testing 'what works' in health-care settings. RCTs are as applicable for testing interventions that may be delivered by nursing, midwifery and allied health professionals (NMAHPs) (such as targeted health promotion advice or a structured rehabilitation programme) as they are for testing drug therapies or new surgical techniques. NMAHP interventions are often complex, in that they are 'built up from a number of components, which may act both independently and inter-dependently' (MRC, 2000), and are often introduced into equally complex health-care environments. This complexity makes the evaluation of NMAHP interventions, using a design such as the RCT, challenging; in this paper, we reflect on our experience of designing and evaluating a complex intervention (a decision tool to assist with the diagnosis of labour in midwifery care), examining some of the issues that our study raises for future research in complex interventions.

What is a complex intervention?

Complex interventions are essentially complicated (Shiell et al., 2008). Rather than comprising a single active ingredient which may be tested (such as a single drug therapy), they are composed of a number of different interconnected parts which form the intervention to be tested. If we use our study as an example, we developed a decision tool that could be used by midwives to assist them to identify whether or not a woman attending a labour ward was in active labour (Cheyne et al., 2008a, b). In this example, the decision tool (a paper-based algorithm) involved the midwife collecting different items of information and using this information in a structured way to reach a judgement. The success (or not) of the intervention depended on how the midwife interacted with the woman and the decision tool to inform clinical judgements and management decisions. In addition, during the main trial, which was a cluster randomised trial (CRT), the decision tool was implemented within different maternity units, each of which had its own unique organisational characteristics that influenced how the tool was used in practice. It is this combination of multifaceted interventions, plus the influence of different social and organisational contexts, which makes complex interventions methodologically challenging to evaluate (Oakley et al., 2006).

Evaluating complex interventions

To assist researchers with the process, the Medical Research Council (MRC) published a framework for the development of RCTs of complex interventions in 2000 (MRC, 2000). The framework suggested five phases in the development and implementation of a clinical trial, starting with consideration of the

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theoretical basis for the planned intervention, through paper-based modelling and pilot phases, the exploratory trial, definitive RCT and finally consideration of possible long-term implementation. The framework identified important methodological issues to be considered at each phase; for example, at the modelling and exploratory trial stages, the importance of defining the intervention and of identifying the way in which the components of the trial will work together was highlighted (MRC, 2000). Although the framework was originally presented as a linear model, it was emphasised in the document that it was not intended to be a 'stepwise' process, and that, depending on factors such as the quality of existing evidence and the type of intervention being designed, some of the preliminary phases may be unnecessary (MRC, 2000).

The framework has been highly influential and a considerable body of research has now been accumulated in the evaluation of complex interventions (e.g. Wong, 2004; Robinson et al., 2005; Byrne et al., 2006). However, the science of trial development for complex interventions is constantly changing and a number of studies have highlighted limitations of the original framework, such as the implied linearity of the original guidance, the adoption of a model based on the phases of drug trial development, and a lack of consideration of the context in which interventions are introduced (MRC, 2008). In response to these concerns, the MRC published a revised framework in 2008 (MRC, 2008). Although the original stages remain, the revised framework suggests a more flexible model of the process that gives more weight to the development and implementation phases of an evaluation, acknowledges that non-experimental methods may be necessary in some situations, and highlights the importance of including health economics and process evaluations. Including these elements in a trial ensure that researchers can provide evidence on the cost-effectiveness (as well as the clinical effectiveness) of an intervention and can facilitate the interpretation of trial results. However, their inclusion adds further complexity to the trial design, trial management and, of course, to the cost of the trial itself. There is currently no consensus on the optimum means of integrating health economics and process evaluation within a rigorous trial design, nor in interpreting the multifaceted data which result from this type of evaluation.

Using the MRC framework to develop and test an algorithm for the diagnosis of labour

The work on our study began in 2002 and we used the original MRC framework as the basis for our study development. In the following section, we briefly describe our approach and the challenges we faced as the study evolved from what was first anticipated to be a small study to an 'all Scotland' CRT. The full details of the design of the algorithm and the trial results have been published elsewhere (Cheyne et al., 2007, 2008a, b). Key stages of the framework and the stages of our trial are summarised in Table 1.

Background to the study

Although superficially straightforward, deciding whether or not active labour has started has been described as one of the most difficult decisions in the care of a woman in labour (Lauzon and Hodnett, 2003). Admission of women who are not yet in active labour is common (30–45% of admissions) (Ball et al., 1996; Janssen et al., 2003) and has important clinical and resource implications. Several studies have reported that women admitted while not yet in labour are likely to receive higher rates of medical intervention than those admitted during the active phase

Table 1
Stages of the MRC framework related to trial phases

MRC phase	Key points in MRC framework	Aim
Pre-clinical Theory development	Explore relevant theory to ensure best choice of intervention and hypothesis Consider design issues	Clinical and decision-making literature reviews Strategic design development
Phase I Modelling	Identify components of the intervention and likely interactions	Development of the algorithm Preliminary testing of the algorithm
Phase II Exploratory trial	Pilot outcome measures and study design	Feasibility study: to assess the feasibility of conducting a cluster randomised trial of the use of the algorithm for the diagnosis of active labour in term pregnancy in Scotland
Phase III Definitive randomised controlled trial	Conduct a randomised controlled trial	Cluster randomised trial: to compare the effectiveness of an algorithm for diagnosis of active labour, in healthy primiparous women, with standard care in terms of maternal and neonatal outcomes
Phase IV Long-term implementation	Establish long-term effects of intervention	Discussed within this paper

MRC, Medical Research Council.

(Hemminki and Simukka, 1986; Holmes et al., 2001; Jackson et al., 2003; Klein et al., 2003).

Increasing rates of medical intervention in labour are associated with increased morbidity for mothers and babies (Anim-Somuah et al., 2005; Alfirevic et al., 2006; Klein, 2006; Villar et al., 2007) and are an issue of worldwide concern (World Health Organization, 1996). Assisting midwives to accurately diagnose active labour therefore has the potential to reduce unnecessary admissions and, correspondingly, the rate of intervention in labour.

Pre-clinical or theoretical phase

We reviewed both the clinical literature on diagnosis of labour and the theoretical literature on judgement and decision making in health care. The clinical literature indicated that there was considerable uncertainty about the timing and onset of labour, but that there was some agreement about the diagnostic cues for identifying active labour (Cheyne et al., 2006). A Cochrane review found one RCT of the use of strict diagnostic criteria for active labour which showed a reduction in interventions such as oxytocin use (McNiven et al., 1998). However, the study was under-powered and carried out in one labour ward in one country (Canada), so the evidence for the effectiveness of the intervention was limited. The process of diagnosis of labour can be considered as a judgement process, involving the evaluation of information in order to reach an assessment of the individual (in this case, an evaluation of various cues to determine whether or not a woman is in active labour) (Cheyne et al., 2006). The theoretical literature suggests that in making decisions in conditions of uncertainty, people may rely on intuition or heuristic-based decisions which