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Identifying when active labour starts: can we improve the judgement?

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Introduction

There is growing concern about rising intervention rates in childbirth. In the UK a recent consensus statement, *Making normal birth a reality*, highlighted the importance of avoiding interventions where possible (Maternity Care Working Party 2007), yet intervention may be increased simply by early admission to the delivery suite. Several studies have identified that women admitted when they are not yet in active labour experience increased intervention in labour compared to those who are admitted in the active phase (Hemminki & Simukka 1986, Holmes *et al* 2001, Jackson *et al* 2003, Klein *et al* 2003). This poses a considerable problem, both for women and for the health service. The Birthrate audit first published over ten years ago (Ball & Washbrook 1996) reported that around one third of women admitted to UK labour wards were subsequently found not to be in labour. More recent publications have suggested that admission of women who are not yet in labour or who are in early labour is a continuing trend, despite the introduction of a range of initiatives, such as triage or telephone triage (Spiby *et al* 2006).

Although the outcome of early labour ward admission is clearly problematic, the cause or causes of the problem are not yet fully understood. For example, why do some women seek admission early? Why are women admitted to labour wards when not yet in labour and once admitted, why do they receive increased intervention? Is it something intrinsic to this group of women, or something about the clinical management they subsequently receive? Deciding whether or not a woman is in active labour is acknowledged to be one of the most difficult judgements in the care of a woman in labour. We posed the question:

If diagnosis of labour was improved would clinical interventions in labour be reduced?

Here we bring together the results of a series of interlinked studies, which we conducted in seeking to answer this question. Highlighting their strengths and limitations, we discuss what these studies add to our knowledge about early labour management and what questions remain. Although the papers are presented in a step-wise fashion, in practice there was some overlap between studies. Papers 1 and 2 explore diagnosis of labour and the development and preliminary testing of a decision support tool in the form of an algorithm. Paper 3 discusses the development of the main clinical trial and the importance of a feasibility study. Paper 4 presents the results of the main trial which tested the effects of the algorithm. Finally, papers 5 and 6 describe women's experiences of early labour admission.

Paper 1: Cheyne H, Dowding D, Hundley V (2006). Making the diagnosis of labour: midwives' diagnostic judgement and management decisions. *Journal of Advanced Nursing* 53(6):625-35.

Aim: *This paper reports a study examining midwives' perceptions of the way in which they diagnose labour.*
Background: *Diagnosis of active labour is often problematic. A midwifery workforce planning tool identified that up to 30% of women admitted to United Kingdom labour wards subsequently turned out not to have been in labour. There is evidence that if a woman is admitted to a labour ward in early labour, she is more likely to have some form of medical intervention. However, despite the impact of misdiagnosis, there is little research on the process of decision-making by midwives in relation to diagnosis of labour.*
Methods: *This was a qualitative study, employing focus group methods. Participants were a convenience sample of midwives working in a maternity unit in the North of England during 2002. They were asked to discuss their experience of admission of women in labour. Data were analysed using latent content analysis.*
Findings: *Thirteen midwives participated in one of two groups. They described using information cues, which could be separated into two categories: those arising from the woman (Physical signs, Distress and coping, Woman's expectations and Social factors) and those from the institution (Midwifery care, Organizational factors and Justifying actions). Midwives' decision-making process could be divided into two stages. The diagnostic judgement was based on the physical signs of labour: the*

management decision would then be made by considering the diagnostic judgement as well as cues such as how the woman was coping, her expectations and those of her family and the requirements of the institution. **Conclusions:** Midwives may experience more difficulty with the management decision than with the initial diagnosis. It may be that the number of inappropriate admissions to labour wards could be reduced by supporting midwives to negotiate the complex management hurdles, which accompany diagnosis of labour.

Key points in this paper

In this study midwives described using mainly physical cues in deciding whether a woman was in labour or not; these largely agreed with cues described in the literature (Paper 2), and subsequently included in the algorithm. Midwives also considered the woman's appearance and demeanour in making the diagnosis; however, the study found that they had to take into consideration many other factors in deciding whether to admit or discharge the woman. Midwives reported having to negotiate between often competing factors such as the wishes of the woman and her family, pressures of workload and the opinion of colleagues, and that this could result in suboptimal care.

The findings of this study provided useful insights into the way in which midwives make diagnostic judgements about labour and is helpful in understanding why a superficially straightforward judgement is often problematic in practice. The study also identified key points at which providing decision support may be beneficial.

Using a qualitative research method in the development stages of a larger study allows for preliminary exploration of an issue and is invaluable in increasing understanding of the topic and its clinical relevance. However, time and resource constraints may have an impact on the scope of the study. This pilot study was conducted in only one clinical area and with a small sample of midwives; therefore the results may not be generalisable to other settings.

Paper 2: Cheyne H, Dowding D, Hundley V *et al* (2008). The development and testing of an algorithm for diagnosis of active labour in primiparous women. *Midwifery* 24(2):199-213.

Objectives: To describe the development and testing of an algorithm for diagnosis of active labour in primiparous women. **Design:** Qualitative and quantitative methods were used. A literature review was first conducted to identify the key cues for inclusion in the algorithm. Focus groups of midwives were then conducted to assess content validity, finally a vignette study assessed the inter-rater reliability of the algorithm. **Setting:** Midwives from two study sites were invited to participate. Data were collected during 2002 and 2003. **Participants:** Midwives from the first site took part in the focus groups

(n=13), completed vignettes (n=19), or both. Midwives from the second site then completed vignettes (n=17).

Findings: An algorithm, developed from the key informational cues reported in the literature, was validated in relation to content validity by the findings from the focus groups. Inter-rater reliability was tested using vignettes of admission case histories and was found to be moderate in the first test (K=0.45). However, after modifying the algorithm the kappa score was 0.86, indicating a high level of agreement. **Key conclusions:** Diagnosis of labour may be straightforward on paper but is frequently problematic in practice. This may be because the diagnosis of labour is made in a high pressured environment where conflicting pressures of workload, limited resources and emotional pressures add to the complexity of the judgement. **Implications for practice:** We offer a valid and reliable decision-support tool as an aid for diagnosis of labour. The evaluation of the implementation of this tool is under way and will determine whether it is effective in reducing unnecessary admissions and improving clinical outcomes for women.

This paper describes the process of developing a decision support algorithm, based on a review of clinical literature regarding diagnosis of labour and informed by decision making theory, which suggests that the introduction of a decision support tool may reduce inconsistency in judgements and thus improve judgement quality (Hamm 1988, Hammond 1996). In order to improve diagnosis of active labour the algorithm would have to demonstrate three main properties:

- it would have to contain the key diagnostic cues for active labour, in the right order (content validity)
- since decision-making literature suggests that it is inconsistency of judgement that leads to error (Rosenthal *et al* 1992, Dawes *et al* 2002), the algorithm would have to promote consistency of midwives' judgements (inter-rater reliability)
- the algorithm would have to produce evidence of improved clinical outcomes for women.

The first two points were addressed in this paper, while the main clinical trial was required to test the third.

Key points in this paper

This paper highlights the importance of rigorous testing of a planned intervention before proceeding to a main trial. Information from the focus groups and the literature review suggested that the algorithm contained the key diagnostic cues and had good face validity. However, pre-clinical testing using vignettes (simulations of real cases) identified several issues, including problems with terminology that led to confusion over which women could be included or excluded. Use of the algorithm initially appeared to reduce the consistency of midwives' judgements, requiring minor modifications to be made and a second round of testing to be conducted. Vignettes

have been used in social and decision making research for 20 years (Flaskerud 1979). The strength of vignettes is that the same information is presented in the same order to every participant and this allowed the inter-rater reliability of the algorithm to be tested. However, there are limitations to this method, in particular, vignettes cannot replicate the uncertainty of clinical judgement in the real world.

The usefulness of the algorithm now required testing in a clinical trial to determine whether its application in a real world setting would result in improved diagnosis of labour, as evidenced by improved clinical outcomes for women. The development of the methods and the importance of conducting a feasibility study are described in paper 3.

Paper 3. Hundley V, Cheyne HC, Bland JM et al. (2009). So you want to conduct a cluster randomised controlled trial? Lessons from a national cluster trial of early labour. *Journal of Evaluation in Clinical Practice* (accepted for publication – fast track)

As the discipline of health services research has developed, so methods of evaluation have become increasingly sophisticated; where once a ‘simple’ randomised controlled trial would have been considered the gold standard, now terms such as ‘complex interventions’ and the ‘cluster randomised controlled trial’ are hot topics for discussion. The challenges involved in carrying out such studies are rarely presented. In this paper we discuss some of these challenges in relation to ethical and statistical considerations, and illustrate them using a recently completed cluster randomised controlled trial of a decision tool for early labour.

Key points in this paper

Paper 3 described some of the considerations in planning and conducting a cluster randomised controlled trial (CRCT). A CRCT involves the randomisation of groups or clusters (in our study these were maternity units) rather than individuals, as in a simple randomised controlled trial (RCT). The CRCT design is valuable when there is the possibility of contamination between intervention and control groups, and particularly where the clinical practice of professionals is involved. However, choosing to conduct a CRCT raised a number of design issues, most notably relating to statistics, and the early involvement of a statistician was essential. The paper also discusses the complexities of obtaining informed consent. The next paper describes how the algorithm was assessed within a CRCT.

Paper 4. Cheyne H, Hundley V, Dowding D et al (2008). Effects of algorithm for diagnosis of active labour: cluster randomised trial. *British Medical Journal* 337(7683):1396–400.

Objective: *To compare the effectiveness of an algorithm for diagnosis of active labour in primiparous women with standard care in terms of maternal and neonatal outcomes.* **Design:** *Cluster randomised trial.* **Setting:** *Maternity units in Scotland with at least 800 annual births.* **Participants:** *4503 women giving birth for the first time, in 14 maternity units. Seven experimental clusters collected data from a baseline sample of 1029 women and a post-implementation sample of 896 women. The seven control clusters had a baseline sample of 1291 women and a post-implementation sample of 1287 women.* **Intervention:** *Use of an algorithm by midwives to assist their diagnosis of active labour, compared with standard care.* **Main outcomes:** *Primary outcome: use of oxytocin for augmentation of labour. Secondary outcomes: medical interventions in labour, admission management, and birth outcome.* **Results:** *No significant difference was found between groups in percentage use of oxytocin for augmentation of labour (experimental minus control, difference=0.3, 95% confidence interval –9.2 to 9.8; P=0.9) or in the use of medical interventions in labour. Women in the algorithm group were more likely to be discharged from the labour suite after their first labour assessment (difference=-19.2, -29.9 to -8.6; P=0.002) and to have more pre-labour admissions (0.29, 0.04 to 0.55; P=0.03).* **Conclusions:** *Use of an algorithm to assist midwives with the diagnosis of active labour in primiparous women did not result in a reduction in oxytocin use or in medical intervention in spontaneous labour. Significantly more women in the experimental group were discharged home after their first labour ward assessment.*

Key points in this paper

In this study the algorithm which had been developed through a series of step-wise studies (described above) was tested for efficacy in a real world setting. Considering sample size in a cluster trial, the key aspect is the number of clusters in each group. This trial recruited 14 maternity units (clusters), two more than the minimum required. Although the overall number of women in the intervention clusters was less than the control clusters, this was compensated for by the extra clusters recruited and so the sample size was adequate to address the primary outcomes. The study results were paradoxical; while use of the algorithm did result in significantly more women being discharged home ‘not in labour’, there was no corresponding reduction in the overall amount of time women spent in the labour ward or in the number of women who received oxytocin for augmentation of labour. It appeared that women discharged home, quickly returned to the maternity unit.

We concluded that increased rates of intervention among women admitted to labour suites early cannot be fully explained by the failure of clinicians to distinguish between the latent and active phases of labour. To explore this in more depth we need to go beyond the trial and try to understand how the process of hospital admission and discharge works. An important part of this is understanding women's experiences of early labour and the impact that the intervention had on them. The following two papers report the findings from small qualitative studies conducted alongside the CRCT.

Paper 5. Barnett C, Hundley V, Cheyne H et al (2008). 'Not in labour': impact of being sent home in the latent phase. *British Journal of Midwifery* 16(3):144–53.

Women who were sent home from hospital in the latent phase of labour were asked to keep a diary to reflect on their experiences. Twenty-one women consented to complete the diary, but only six returned it. These six women were approached to participate in a one-to-one interview at home to further explore the effect that discharge home had on them. Five women agreed to be interviewed. Interviews were tape-recorded and transcribed verbatim. The data were analysed using latent content analysis. Five themes were identified: influence of others, reassurance, coping/pain, sleep deprivation and undervaluing of the latent phase. Women were strongly influenced regarding when to go into hospital by the anxiety of family and partners. Most women sought reassurance, but being sent home made them feel unsupported and it is possible that this may have actually increased their anxiety. Further research is needed for women planning a hospital delivery into how best to support them in the latent stage of labour at home.

Key points in this paper

This study raised a number of interesting issues about hospital admission in early labour; for example the fact that anxiety from family and partners played a major role in decisions about when to seek hospital admission. The findings highlighted the importance of preparation for labour, as women reported being unaware that they could be sent home and they found this distressing. Reducing anxiety and managing labour pain were given as reasons for attendance, however being sent home actually increased these. The study concluded that further research is needed for women planning a hospital delivery into how best to support them in the latent phase of labour at home.

Although the diary method is a good way of obtaining rich 'real-time' data (Wyness *et al* 2004), this study had a number of limitations. Despite recruiting 21 women, only six diaries were returned, giving a response rate of 29%. Completion of diaries is time consuming, but this response rate is lower than in previous maternity studies (Pittman *et al* 1997, Moffat *et al* 2007). It is possible that only those women who had a bad experience returned

their diary (ie they had something they wanted to say). Despite this the findings go some way to explaining the paradoxical results of the CRCT.

Paper 6. Cheyne H, Terry R, Niven C et al (2007). 'Should I come in now?': a study of women's early labour experiences. *British Journal of Midwifery* 15(10):604–9.

In spite of the advice from midwifery staff to stay at home for as long as possible after the perceived onset of labour, many women still present at hospital in the very early stages of labour. In this qualitative study, 21 women discussed their early labour experiences, and factors which influenced their decisions regarding when to go to hospital. The data were transcribed verbatim and subjected to latent content analysis. We found a combination of uncertainty, pain and anxiety influenced women's early labour decisions and that whilst many felt they were coping well with their labour on admission, women often wanted to be in hospital 'just in case', and lacked the confidence to cope with labour at home. We suggest that the relationship between anxiety and timing of admission should be investigated further and that the value of midwifery support and reassurance in the latent and early stages of labour should not be underestimated.

Key points in this paper

In this study, interviews were conducted with women in three pre-existing postnatal support groups. Both primiparous and multiparous women were included and a semi-structured interview method was used. Although most of the women interviewed had attended antenatal classes, first-time mothers in particular were uncertain about whether labour had started and about the timing of hospital admission. Pain and anxiety about their ability to cope with future pain were the main reasons why women sought admission. Experiences of being sent home following hospital assessment were very varied; while some women felt that they had received the reassurance they required, others were disappointed and felt that more support was required. The main limitation of this study was in how the sample was obtained; a convenience sample comprising members of existing postnatal support groups was used. The women in these groups were well educated, most having either degrees or professional qualifications, therefore the sample lacks generalisability and this must be taken into account when considering the results. Nevertheless, the findings reflect those from the previous paper, suggesting a common thread that needs further exploration.

Conclusion

What have we learned from the findings of the six papers presented here?

Developing a trial of a midwifery intervention is a complex and lengthy process with many twists and turns and lessons to be learned at each stage. The investigative process described here took more than seven years.

We aimed to test one apparently distinct aspect of midwifery care in labour — diagnosis of labour. However, we found that even a relatively simple intervention can have unexpected outcomes. In this case, although midwives' diagnostic judgements appeared to be changed by use of the algorithm (more women were sent home), that did not reduce the amount of intervention subsequently experienced by women. Thus improving the decision does not necessarily improve the outcome of care. Diagnosis of labour is a complex intervention (MRC 2000), which requires further research if we are to ensure that women receive the optimal care they deserve without running the risk of increased intervention.

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