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Global implications of evidence ‘biased’ practice: management of the third stage of labour

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Increasing attention is being paid to the promotion of clinical and cost-effective care informed by the highest level of evidence to ensure health outcomes are optimised and access to health care is equitable. There are obvious advantages to these approaches, including increased awareness of the importance of rigorous methodology when conducting primary and secondary research, utilising methods which are systematic, robust, transparent and explicit.

Evidence-based practice was introduced to replace the traditional approach of ‘this is how we have always done it’ as an underpinning for clinical practice. Ironically, however, the transition has not been straightforward and there have been criticisms of the way ‘evidence’ to support some areas of practice is perceived and applied in clinical settings. Anecdotally and based on personal experience, there are two main criticisms:

1. Acceptance of evidence without critique: Too much faith (or blind faith) in the process by which ‘evidence’ (authoritative or systematic) is produced.
2. Lack of holistic insight in the application of evidence: Employing ‘one size fits all’ policies ignoring individual needs for required care in conveyor-like processed care provision.

To explore these criticisms, the example of management of the third stage of labour is used.

Acceptance of evidence without critique

The concept of evidence-based practice promotes a triangulated approach to the implementation of evidence supported by the practitioner's expertise and experience as well as considering patients' needs and preferences (Sackett and Rosenberg, 1995), informed by a hierarchy of evidence. Meta-analyses, systematic reviews and randomised controlled trials (RCTs) are placed at the top of the hierarchy. A detailed discussion of the hierarchy is beyond the remit of this paper; however, it should be emphasised that while meta-analyses, systematic reviews and RCTs are viewed as the 'gold standard' for informing health-care interventions, it is important to set these within a broader perspective of other sources of evidence (Sleep, 1999). When implementing evidence into practice, it is just as important to consider an individual patient's circumstances; an aspect not always considered and not easily represented in synthesis and meta-analysis of RCTs. Presentation and application of evidence with respect to the management of the third stage of labour is an example of a confused approach to the critique and application of evidence, where most attention has been focused on the prevention of postpartum haemorrhage (PPH) and the potential harmful effects of (early) cord clamping overlooked, particularly among communities where the timing of cord clamping could be detrimental for neonatal health and well-being. The authoritative statements from two Cochrane systematic reviews likely to inform the basis of local, national and international guidelines for the management of the third stage of labour are quoted and compared below.

Active versus physiological management of labour (Prendiville et al., 2000):

Routine 'active management' is superior to 'expectant management' in terms of blood loss, postpartum haemorrhage and other serious complications of the third stage of labour. Active management is, however, associated with an increased risk of unpleasant side effects (e.g. nausea and vomiting), and hypertension, where ergometrine is used. Active management should be the routine management of choice for women expecting to deliver a baby by vaginal delivery in a maternity hospital. The implications are less clear for other settings including domiciliary practice (in developing and industrialised countries).

Prophylactic oxytocin for the third stage of labour (Cotter et al., 2001):

Oxytocin appears to be beneficial for the prevention of PPH. However, there is insufficient information about other outcomes and side effects, hence it is difficult to be confident about the trade-offs for these benefits, especially if the risk of manual removal of the placenta may be increased.

Consideration of approaches to data abstraction, critique, synthesis and reporting are crucial when reading these two reviews. The first review evaluates the whole 'package' of active versus physiological management (Prendiville et al., 2000), while the second focuses on use of a specific uterotonic drug (oxytocin) (Cotter et al., 2001), but there are overlaps in the intervention they evaluated. The review by Cotter et al. (2001) focuses on one aspect of active management; the use of oxytocic drugs versus no oxytocic drugs, the basic component of active management. The terminology used and the contrast in the review conclusions are interesting and important to consider for the following reasons. Researchers are usually encouraged to avoid judgemental terms in their conclusion; however, in the first statement, the opposite is utilised. The term 'superior' indicates an immediate impression of accepting one way over another which, in terms of its application and remit of focus, can be potentially misleading. However, the second review appears to base its conclusion on the data included and encourages the reader to make their own judgement, looking at the whole picture.

Of course, 'the devil is in the detail'! Nevertheless, many busy clinicians will follow a review's conclusion due to lack of sufficient time to read the complete article or blind faith or lack of confidence in their critical appraisal skills and understanding of the development of systematic reviews. It may also be due to lack of awareness of the need to consider the evidence and its application within the context of the clinical area they work within, and the views and choices of the individual women they care for. The result is that many women may be exposed to interventions that might not necessarily be the best option for them. To support this statement, certain points are extracted from these reviews and discussed further. Firstly, despite the recommendation made by Prendiville et al. (2000), looking at included forest plots¹ for women at low risk of PPH, a statistically significant increase in

need for manual removal of the placenta in the active management group compared with the physiological management group is reported (Fig. 1). Retained placenta and manual removal of the placenta are conditions that may be associated with further complications such as infection. As this is a particularly important consideration for women giving birth in resource-poor settings, a mother with a low risk of PPH could potentially receive an intervention that may increase her risk of morbidity and mortality.

Although current evidence shows a statistically significant difference in blood loss associated with active management (Prendiville et al., 2000), a comprehensive picture of its impact on maternal and neonatal outcomes in practice is missing. In addition, there are serious issues with different aspects of active management of the third stage of labour which could have considerable implications for neonatal health and well-being. A recent survey of 14 European countries showed considerable variation in the perception and practice of active management (Winter et al., 2007). Despite this, active management, based on the findings of the Cochrane review (Prendiville et al., 2000), includes immediate clamping of the cord, administration of oxytocic drugs and controlled cord traction. The timing of cord clamping was not the focus of the review and therefore potential adverse consequences were not reported or commented on, but the conclusion seems to be recommended for all women and their babies. Immediate cord clamping is increasingly a cause for concern among clinicians and researchers because of potential harmful effects. Van Rheenen and Brabin (2006) in their meta-analysis of RCTs (four trials from developing countries: 317 babies) have shown that delaying cord clamping (about 3 minutes) reduces infant anaemia and improves infant survival, particularly in resource-poor settings. They suggest that the benefits seem to be for all infants regardless of gestational age. Hutton and Hassan (2007) confirmed the beneficial effects of delayed cord clamping (minimum of 2 minutes) in another systematic review. They included 15 controlled trials (1912 newborn infants) and showed a reduced risk of neonatal anaemia. Although increased polycythaemia was reported in infants who had delayed cord clamping, it was asymptomatic and benign. This is important, considering the specific needs of people in different cultures and environments whose health priorities may be different. The prevalence of anaemia in infants and young children (0–4 years) is

estimated to range from around 20% in industrialised countries to 39% in non-industrialised countries (WHO, 2001). Early clamping is suggested to deprive neonates of around 100–200 ml of blood (Gunther, 1957) with potential to lead to anaemia. Anaemia adversely affects infants' cognitive development and immune system, and increases the risk of infection and overall infant mortality (WHO, 2001).

Hutchon (2006), in a rapid response letter to the British Medical Journal, suggests, 'Before we can conclude that active management of the third stage, incorporating immediate cord clamping, is safe for the newborn infant we need medium and long-term follow-up for anaemia and neurodevelopment'. He raised awareness regarding the importance of adequate time for neonates to adapt to extra-uterine physiological changes which immediate cord clamping can abruptly curtail, and argued that in many cases of fetal distress, immediate cutting of the umbilical cord after birth may hinder neonatal resuscitation. Hutchon (2006) explained how important it is to be able to resuscitate neonates in these circumstances, while the cord is intact and facilitates the passage of oxygenated blood to the babies.

International guidelines (Federation of International Gynecology and Obstetrics and International Confederation of Midwives (Lalonde et al., 2006) and WHO (2006)) have omitted early cord clamping from their recommendations, although the National Institute for Health and Clinical Excellence guideline on intrapartum care (NICE, 2007) includes this as part of its active management recommendations. The main justification was that much of the relevant evidence comes from developing countries with a high prevalence of anaemia, with significant variation in the optimum timing of cord clamping. These reasons do not seem to be convincing as there is evidence to suggest a considerable level of iron-deficiency anaemia in developed countries such as the UK and USA (Eden, 2005), which makes it very relevant to some groups of women in developed countries. There is also variation in other aspects of active management such as timing or route of oxytocic administration, which has not impacted on the decision to offer active management to all women.

Lack of a holistic insight in the application of evidence

Many studies of management of third stage of labour focus on PPH, the basis for this being that haemorrhage is the main cause of maternal death especially in developing countries (Prendiville et al., 2000). Indeed, maternal PPH is an issue of major importance. According to WHO (2004), PPH claims 150,000 women's lives each year worldwide, with the vast majority of deaths (99%) occurring in developing countries (WHO, 2007). However, the extent to which routine active management saves lives and improves maternal and neonatal well-being in specific settings has not been investigated holistically.

Fig. 2 shows the dramatic decline in maternal deaths in the UK since 1952. This achievement has been associated with undeniable improvement in nutrition, women's socio-economic status, living conditions and advances in public health. Universal free access to health care as well as peace and stability are also immensely important contributing factors for maternal and neonatal survival. All of these issues continue to impact on maternal and neonatal mortality and morbidity in developing countries.

Women in developed countries generally enjoy better health and nutrition than those in developing countries. Routine active management of the third stage of labour with the specific objective of reducing statistically significant postpartum blood loss, and its relevance to maternal mortality rates in developed countries seem to be questionable. This becomes even more important with emerging evidence on the adverse outcomes of immediate cord clamping. The disparity of the argument becomes more pertinent when the same justification (maternal mortality due to PPH) is applied to management in industrialised and developing countries. It raises questions with regard to the relevance of statistically significant outcomes versus clinically significant outcomes when informing clinical decisions. In circumstances in which the dynamics of maternal and neonatal health are established with a satisfactory level of background facilities, a selective approach based on the mother's needs and risk status seems to be more appropriate. Informed choice, given adequate knowledge and sufficient time to discuss advantages and disadvantages of each approach, can also be helpful in appropriate application of evidence to inform individual health outcomes.

In summary, there seems to be a need to develop systematic reviews that comprehensively compare different packages of management of the third stage of labour. Based on the current evidence indicating adverse neonatal outcomes and increased risk of manual removal of the placenta in low-risk women, routine active management of the third stage of labour should be reconsidered and a targeted approach, sensitive to the needs of individual women, should be encouraged for both developed and developing countries.

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¹ Forest plots are typical graphs that are used to present the results of data synthesis. The squares show the results of each included study and the horizontal lines usually show the 95% confidence intervals. The diamond at the bottom indicates the overall effect of the study; if it does not cross the 'line of no effect' (in the middle of the graph), the observed effect is statistically significant.