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# EVIDENCE BASED MIDWIFERY

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# Understanding intellectual property

*Key words:* Intellectual property, patent, technology disclosure, evidence-based midwifery

For most of you reading this editorial the term 'intellectual property' is probably quite vague. You are wondering what it means and why you should be concerned about it.

Intellectual property (IP) is a descriptive term for outputs from creative activity and includes data from artistic, literary, scientific and industrial developments (UK Copyright Service, 2004). For those of you involved in research at universities, you need to be aware that the IP from your research belongs to the university when you are an employee. This ownership is enshrined in legislation emanating from The Patents Act (1977) (as mended) and the Copyright, Designs and Patents Act (1988) in which it is stated that the '*IP generated by an employee during the course of his/her normal duties belongs to his/her employer*' (Patents Act, 1977 (as amended): section 39).

What about the rights and role of the individual researcher or creator in this legislation? When doctoral students enrol for PhD programmes at universities, they normally sign an IP rights-related agreement on registration. Simply speaking, they sign the IP over to the university. In most cases, this is a requirement for registration and in the majority of cases we give little thought to the process and may leave the institution without reference to IP again. However, in some cases where research leads to the development of potentially commercial outputs, the case is different.

Two years ago, one of my former students developed a product 'Designer Breastfeeding'© (Stockdale, 2007). This was my first experience of learning about the process and procedures involved in protecting the student, the research products and the relevant parties or stakeholders with regard to IP. Lessons learnt are worth sharing with those of you who are about to start your journey or those of you who are, for example, developing applications for valid and reliable tools for measurement.

When we thought we might have a product that could be commercial or exploitable, we contacted our university's office of innovation for advice and they asked a series of questions about the 'invention' and for details about the products of the research, such as publications or conference papers. We proudly presented a profile of dissemination activities. However, we discovered that it is not always in the interest of the research to publish or disclose findings prior to taking their advice – in some incidences publication of research can disclose the novelty of a product. Any disclosure of the research, for example, in poster format, exhibition, or conference, may render the product 'non-patentable' and work against further development.

If you think your research could lead to a new or novel application or product, do not publish until you have filed for the patent. Once you have filed for this and completed the standard paperwork, you can publish and present. This is a major issue and one worth remembering. Fortunately, face-to-face support and advice was available from our office and the next stage for us was the completion of a technology disclosure form. This form was important, because this is the paperwork that determines the proportion of the remuneration that the inventor receives and the other stakeholders.

You will notice the small copyright symbol © after Designer Breastfeeding© and this is a marker to inform all readers that this is copyrighted to the author (in this case Dr Janine Stockdale at Trinity College, Dublin). The correct term should include 'Copyright [dates] by [author/owner]' but a small © is acceptable. Another term commonly used is 'All rights reserved'. Copyright expires 70 years from the end of the calendar year in which the author dies or if there is joint ownership, then the end of calendar year in which last surviving joint owner dies. The UK Copyright Service provides the following statement:

'*Copyright is an automatic right and arises whenever an individual or company creates a work. To qualify, a work should be regarded as original, and exhibits a degree of labour, skill or judgement.*

*Interpretation is related to the independent creation rather than the idea behind the creation. For example, your idea for a book would not itself be protected, but the actual content of a book you write would be. In other words, someone else is still entitled to write their own book around the same idea, provided they do not directly copy or adapt yours to do so.*

*Names, titles, short phrases and colours are not generally considered unique or substantial enough to be covered, but a creation, such as a logo, that combines these elements may be.*

*In short, work that expresses an idea may be protected, but not the idea behind it*' (UK Copyright Service, 2004).

International recognition of a common understanding of copyright has been laid out by what is commonly known as the Berne convention. The World Intellectual Property Organization (WIPO) administers the convention (WIPO, 1979).

Understanding IP is beneficial to all of us so that we can protect our research products and share the remuneration from commercial exploitations in a fair and equitable manner. It is worth remembering there is potential for re-investing all proceeds into generating further research. However, you may be motivated to develop a spin-off company and set up you own small business. Remember research can generate income!

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# A qualitative study exploring women's and health professionals' views of newborn bathing practices

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The paper was the seventh professor of midwifery research paper presented at the Doctoral Midwifery Research Society meeting on 2 October 2009 at the University of Ulster.

## Abstract

*Background*. Over the last decade, health professionals have debated the relative merits and potential harms of various neonatal bathing practices. Two schools of thought exist – those that support the use of water alone, and those who believe that bathing products offer some benefit. However, there is a dearth of empirical evidence on which to inform practice or advise new parents.

*Objective*. The purposes of this study were two-fold: first, to gain insight into current practices and beliefs related to newborn bathing, and secondly, to assess the feasibility of conducting a randomised controlled trial (RCT) of wash products versus water alone.

*Design*. A qualitative study was conducted using in-depth interviews. The authors purposively sampled and interviewed 20 midwives, ten health visitors and 26 women. For some of the latter group (n=22), data were collected longitudinally. Data were analysed thematically.

*Setting*. A large teaching hospital in the north west of England.

*Results*. The overarching theme was 'informed uncertainty'. Three sub-themes were also identified, 'mirage of evidence', 'toeing the party line' and 'influential marketing'.

*Conclusion*. There is confusion around the evidence base of newborn bathing practices. As a consequence, women and health professionals draw on tradition, experience and opinion to inform practice. There was some nervousness around industry-funded trials, nevertheless, there was general agreement that a robust, investigator-led RCT of a baby wash product versus water alone was required.

*Key words*: Bathing, midwife, health visitor, qualitative, newborn, baby, skin care, evidence-based midwifery

## Introduction

A baby's skin prevents infection and loss of water from the body. These functions depend on the maintenance of skin integrity and pH balance. A natural protection against infection is created by babies being born with a pH of 6.4, which reduces over three to four days to 4.9 (Irving, 2001). The vulnerability of babies' skin is manifest, as shown by a number of skin problems that can occur, including atopic eczema, nappy rash, infant *candida* infection, cradle cap and baby acne. For example, an estimated 50% of babies experience at least one episode of nappy rash at some time (Atherton and Mills, 2004). Mothers and health professionals, therefore, have concerns about skincare routines.

There is little good-quality research about neonatal skin care, particularly for the term baby. A systematic review of skin care in the full-term healthy newborn revealed no prospective trials that met the authors' inclusion criteria (Walker et al, 2005a). Since that review was published, only two small trials of baby bathing have

been identified that compared a body wash product with water. Both were published in abstract form only so critical appraisal is limited (Galzote et al, 2007; Bartels et al, 2008). Following a study involving 57 infants, Bartels' conclusion was that skin barrier development of term newborns was not adversely affected by bathing with wash products. Galzote, using a different wash product, found that skin dryness was reported more often in the 'water-only' arm.

An influential observational study including a specific wash product was conducted in the US by a neonatal nurse (Lund et al, 2001a; 2001b). This was initially aimed at babies in the neonatal unit (n=2464), although 'well' babies were also observed (n=356). The researchers concluded that a package of care over an eight-week period improved skin integrity without increasing rates of infection. The recommended package included a decrease in bathing, use of a neutral pH cleanser only, reduction in the use of adhesives and avoidance of solvents and bonding agents.

A survey of maternity units in the north west of England (Walker et al, 2005b) reported that a wide range of products was provided for healthy full-term neonates. Given the absence of UK evidence-based guidelines (Mancini, 2004), this is not surprising. Guidelines vary in their advice. The second draft of National Institute for Health and Clinical Excellence (NICE) guidelines *Routine postnatal care for women and their babies* (NICE, 2006) recommends that cleansing agents added to bath water and use of baby wipes should be avoided in the first month after birth. However, this is not based on robust evidence. The RCM acknowledges the lack of evidence and their guide *Together we care* states: *'There is limited research evidence available in the UK as to the effect of the different bathing and skincare products on the new babies' skin. Mothers should use products that are specifically designed for baby's skins. Some mothers may wish to use plain water to wash their baby during the first few weeks, especially if the skin is dry or there is a family history of conditions such as eczema*' (Camm, 2006: 126).

NICE guidelines for the management of atopic eczema in children (NICE, 2007) recommend avoiding using water on the skin of a baby with the condition and thus appear to conflict with the *Together we care* guide. The American Association of Women's Health, Obstetrics and Neonatal Nursing (AWHONN) (Lund et al, 2001b) produced more ambivalent clinical guidelines that recommend alternating between bathing with water only and bathing with cleansers.

There appear to be two main arguments: one supporting the use of water only and the other supporting the use of mild pH-balanced solutions. A major concern is the rising prevalence of atopic eczema, a condition resulting from the interaction of environmental factors (such as soap and detergents) with changes in several genes (Cork et al, 2006; Bieber, 2008). The prevalence of atopic eczema in children rose from 4% to 5% in the 1940s and from 20% to 28% in 2000 (Taylor et al, 1984; Williams, 1992; Neame et al, 1995). This indicates that environmental factors must be important in the expression of the condition (Williams, 1992). Soap and detergents raise the pH of the skin from the normal 5.5 to 7.5 or even to greater than 10. The proteases are pH-sensitive enzymes with optimal activity at 7.5 to 8.0 (Hachem et al, 2003; 2005). Washing with soap and other harsh detergents can therefore double the protease activity in the skin, leading to severe skin barrier breakdown. Many current infant wash products contain harsh surfactants, which have the greatest effect on skin pH, and are most damaging to the skin barrier. Some groups, therefore, argue that infants should be washed with water alone.

However, water may not be innocuous, water exposure in adults can do damage (Tsai and Maibach, 1999). There is a *prime facie* case that water may be a suboptimal washing agent for newborn infants. First, water is rapidly absorbed into the skin – even within ten seconds (Nikolovski et al, 2008). This could affect the barrier function of the skin by increasing the space between cells. Secondly, disturbing the acidic milieu of the skin can alter its integrity (Cork et al, 2008). Thirdly, tap water has a pH between 7.9 and 8.2, which is relatively more alkaline than the pH of the skin in the weeks following birth. The other problem with water alone is that it is a poor cleanser. For example, in the nappy area this leads to the persistence of faecal proteases, lipases and bacteria that all damage the skin barrier (Adam, 2008).

Given the lack of evidence on which to inform practice, a programme of work aimed at providing appropriate advice to women was embarked upon. Bathing with a specially formulated skincare product was compared with bathing with water. The strategy is to design an adequately powered, pragmatic randomised controlled trial (RCT) based on a pilot study.

As a first step in the design of the pilot study, women's, midwives' and health visitors' views of skincare routines and the use of baby skincare products are explored to gain perspectives from different vantage points. The feasibility and acceptability of an RCT of skincare routines is also explored. Since the programme is supported by a commercial company, the attitude of women and professionals to investigator-led, industry-supported research in this clinical area is also gauged.

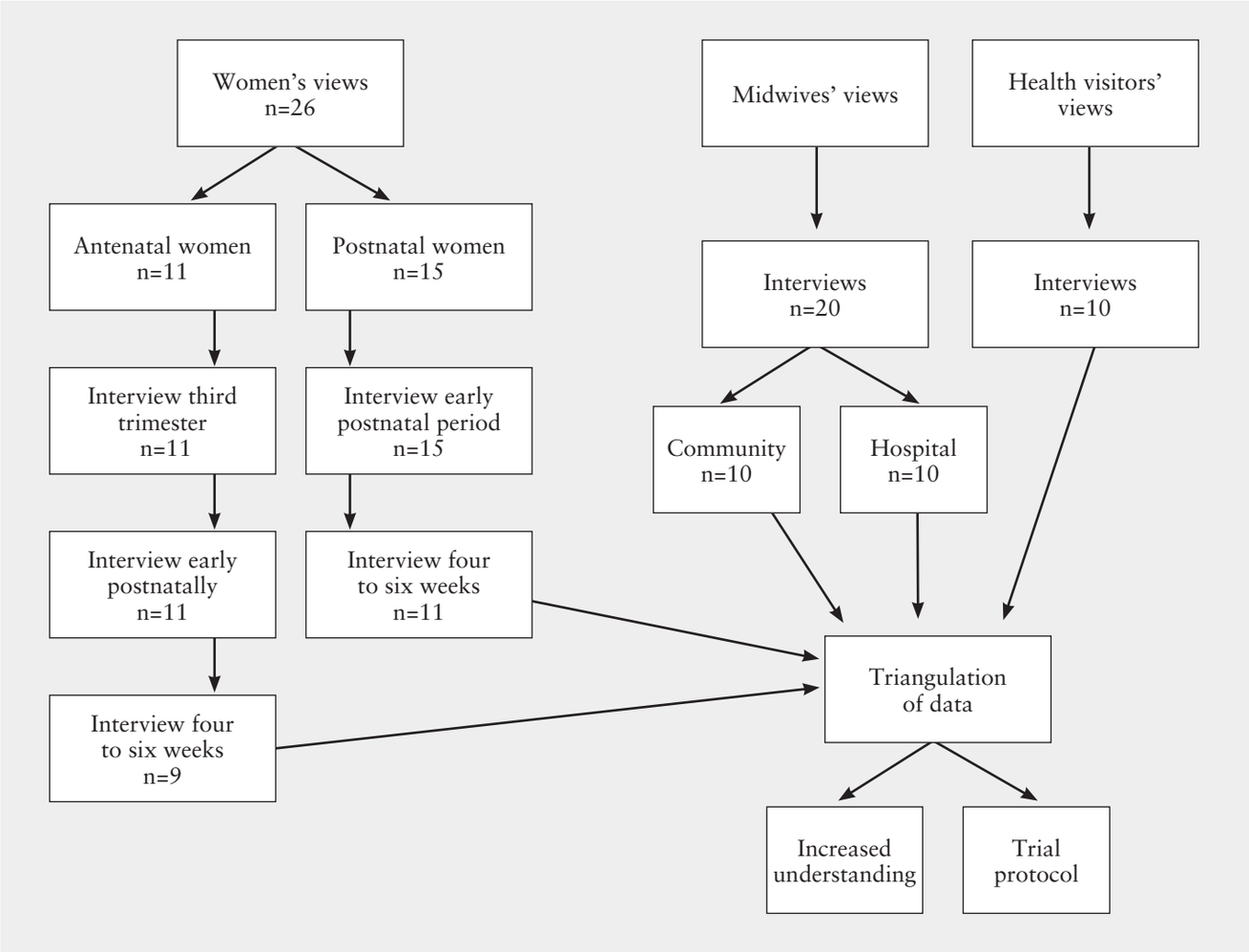
## Method

A qualitative approach was adopted using an interpretive framework (Parahoo, 1997). Ethical approval was sought and obtained from the Stockport Research Ethics Committee (Ref: 08/H1012/24) and the NHS Trust Research Governance before study commencement.

## Sample

A purposive sample of participants who had direct contact with current baby bathing practices was obtained. The sample therefore consisted of expectant and postnatal women, midwives and health visitors. Sample size

Figure 1. Study outline




was determined by the need to obtain views from a diverse range of participants and the desire to adhere to principles of data saturation (Ritchie et al, 2003).

*Selection and recruitment of participants*

The study took place in a large teaching maternity hospital in north-west England where 8000 births occur annually. Data collection was completed in December 2008. Women, midwives and health visitors were sampled (see Figure 1).

**Women**

A purposive sample of women from a variety of social, ethnic and economic backgrounds was obtained. There were two groups of women: those that were recruited antenatally and were interviewed at three time points (once in the third trimester and twice in the postnatal period) and those that were recruited postnatally and interviewed twice (early postnatal period and four to six weeks post-birth). This approach was adopted to maximise the amount of data obtained at each time point and reduce the numbers lost to follow-up. Antenatal women were eligible to take part in the study if they received midwifery care at the study hospital and there were no known fetal malformations. Postnatal women were eligible if they had given birth at term and were admitted to a postnatal ward at the study hospital.

Women in the antenatal group were identified from clinic lists and provided with written and verbal information at their 20-week scan appointments. Women interested in participation supplied contact details in order to arrange a convenient interview appointment when written consent was obtained. After completing their first interview in the antenatal period, women were reminded that they would be approached in the postnatal period for follow-up interviews, provided that they did not give birth prematurely (that is, at 37 weeks or earlier).

Women in the postnatal group were identified from postnatal ward lists; verbal and written information was given to all eligible women. Those interested in participation provided written consent and had their first interview on the postnatal ward before leaving hospital. Those undecided about participation were asked for verbal consent to be contacted by telephone at a later date.

Women completed the first postnatal interview as early in the postnatal period as convenient and then gave verbal consent to be contacted again four to six weeks later to arrange the follow-up interview. Demographic and baseline data were collected for all women.

**Health professionals**

A purposive sample of midwives was interviewed and stratified according to place of work, that is hospital or community. Midwifery managers gave permission to approach hospital and community midwives at the hospital site and passed on verbal information regarding the study. Written information was provided by the research assistant (EO) to midwives in staff rooms, ward areas and community midwives' individual correspondence drawers. Midwives were given the opportunity to consider taking part and to discuss the study before arranging a convenient interview time.

A purposive sample of health visitors from various locations across the area served by the hospital was also interviewed. The first point of contact was neighbourhood nurse managers who were informed of the study and asked for support in identifying potential participants. Health visitor team leaders were contacted and verbal and written information supplied to potential participants before making arrangements for interviews.

## Data collection

A qualitative interpretive approach was adopted using triangulation of data from different sources. Triangulation of data can improve the validity (believability) of the analysis process and the researchers' conclusions (Hammersley and Atkinson, 1983). The five different groups studied comprised antenatal women, postnatal women, hospital midwives, community midwives and health visitors. In-depth, semi-structured interviews were carried out with all groups, by a research assistant (EO). The interview schedule was informed by the debates highlighted in the literature around bathing practices, but areas were left broad to allow respondent direction. Views on an RCT of water versus bath products were, however, specifically asked.

Women were studied longitudinally with a series of interviews to gauge any changes in views pre- and post-birth. At the beginning of each interview, they were requested to complete a short, one-page demographic data sheet. Health professionals were interviewed once only. All participants were given a choice of place of interview, some requested being interviewed at the hospital, while others opted for interview in a community clinic. Interviews lasted between 20 and 90 minutes and were audio-recorded.

## Data analysis

All interview data were transcribed verbatim, using pseudonyms to protect identity. Data were managed manually, with the aid of a word processor. Thematic analysis was conducted, utilising a cyclical yet systematic approach to ensure rigour (Carter, 2004). This process, which drew on that described by Miles and Huberman (1994), involved familiarisation with the data, decontextualising or breaking down of the data, data display and recontextualisation. This process enabled commonalities and differences within and between sample groups to be identified. A formative and iterative process was used to generate codes.

Three researchers (TL, CB and EO) carried out simultaneous analysis to minimise interpreter bias; consensus was reached. The analysing researchers were not neutral observers (Nagel, 1986) – two were midwives (TL, CB) with experience of bathing babies in clinical practice and two had children of their own (TL, EO). Presentation of findings to professional and lay forums was conducted to assess transferability (Pollit and Hungler, 2005). Verbatim quotes have been selected to represent the most frequently occurring themes, negative cases, and cross-sections of participants.

## Results

*Baseline details*

**Women**

Of 136 women provided with study information, 49 expressed an interest in participating and 26 consented. A total of 11 women consented to take part in the antenatal period, nine of whom had three semi-structured interviews and two of whom had two interviews (see Figure 1). In the postnatal period, 15 women consented to take part in the study, of whom, 11 had two semi-structured interviews and four had one interview.

The median age of women was 34 years (range 23 to 41 years). In total, 21 women in the sample were white British and there was one woman from each of the following ethnic groups: Pakistani, Black British African, White other, Welsh, mixed White/Asian and Chinese. A total of 15 of the women in the sample were having their first baby and the remaining 11 had one or more children.

Postcodes were used to identify the Index of Multiple Deprivation (IMD) rank for participants' local authority ward. The IMD is the UK government's official measure of the proportion of households in a defined geographical area using a combination of circumstances to indicate the level of living standards for that area. The IMD rank for an area is categorised as 'very poor', 'poor', 'good' and 'very good' on the Quality of Life Indicator scale. The study sample included 12 women from areas considered 'very good' or 'good' and 14 women from areas with 'poor' or 'very poor' Quality of Life Indicators.

Women were asked to indicate on the data collection sheet any history of family skin conditions. Seven women reported that there was a family history of skin problems with either themselves (n=2), husband/partner (n=3), sibling (n=2), child (n=1) or mother (n=1) being affected. Some women reported one or more family members being affected with one or more skin conditions and one participant stated that 'everybody' in her family was

affected by skin problems to varying degrees. Eczema was the most commonly cited problem (n=6).

**Health professionals**

Ten hospital midwives and ten community midwives took part in one-off semi-structured interviews. Midwives had a median number of years experience of 12 years (range five to 26 years). The majority of midwives had children of their own (n=12).

Ten health visitors took part in one-off semi-structured interviews. Health visitors had a median number of years experience of 18 (range two to 28 years). All of the health visitors had children of their own.

A continual theme that emerged during this study is called 'informed uncertainty'. Although participants received information from multiple sources, the conflict between them raised doubts about appropriate practice. This theme provides insight into the overt and covert confusion around baby bathing and has three main subthemes, which were identified across all sample groups:

- Mirage of evidence
- Toeing the party line
- Influential marketing.

Additionally, participants' views on the need for an RCT of bathing product versus water alone when bathing newborn babies were also received.

*Mirage of evidence*

Women, midwives and health visitors were asked what influenced their practice with regard to bathing newborns. Their responses illustrated multiple ways of knowing, which ranged from perceived empirical evidence to intuition. Midwives, in particular, were adamant that their practice was based on sound empirical evidence:

*"There are several pieces of research that have actually said it was better not to use any products rather than to use them. Don't ask me to name them! I don't know! (laughs) I've got them at home in a file"* (hospital midwife: 11).

However, when the interviewer probed further to identify which evidence the midwives were referring to, none of the midwives were able to identify any specific research papers. This is not surprising, given the lack of empirical evidence in this area:

*"The only evidence base that I know of at the moment is that nothing is recommended, just water… I mean when I say evidence, they're just articles that I've read and things that I've seen in journals"* (community midwife: 09).

*"I think I've read something in a magazine…"* (hospital midwife: 02).

Health visitors, on the other hand, were very honest about their lack of knowledge of empirical work.

"*I don't suppose I'm aware of a lot of evidence to be honest, a lot of what we do tends to be word of mouth and what other health visitors talk about… but I can't say I've ever read studies about it really"* (health visitor: 49).

Unlike the majority of midwives, health visitors were more likely to draw on other forms of evidence, when advising women. This included information passed on from senior colleagues, personal experience with their own children and 'common sense':

*"I couldn't quote you any evidence on that to be honest… No, we just go by instinct really"* (health visitor: 52).

Conversely, women were generally very trusting of any information supplied to them and made assumptions about the evidence behind the information:

*"The advantages are I suppose that there's nothing in it that's going to cause any irritation on his [baby] skin… I've got no reason to doubt what they're [midwives] telling me"* (primiparous: 05, two days post-birth).

Primiparous women were more likely to adhere to the health professional advice given to them, whereas multiparous women often reverted to 'trial and error':

*"It tends to be sort of trial and error… It's my family and friends really who I trust or listen to otherwise I would trial and error myself"* (multiparous: 02, one day post-birth).

However, the information provided to them did not necessarily dictate their practice. Of the six primigravid women interviewed in the antenatal period, four stated that they would use only what was recommended by health professionals. In the early postnatal period, primiparous women continued to conform to the recommended bathing routine (water only). At the second postnatal interview (four to six weeks), all women had changed practice to using products.

*Toeing the party line*

Women and health professionals displayed beliefs that contradicted what they thought were viewed as the 'gold standard' of care. Importantly, as the interviews progressed and participants appeared more relaxed (field note observations), they were more likely to differentiate between what they thought they ought to do and what they actually did. There appeared to be a three-phase process in disclosing the reality of bathing practices. At the beginning of interviews, all participants suggested that they 'toed the party line'. For midwives, this meant stating that they adhered to what they thought was 'hospital policy'. Interestingly, the study hospital did not have a formal policy on bathing practices:

*"We have to advocate water only… that is Trust policy"* (community midwife: 20).

Health visitors acknowledged that there was no written policy on skin bathing, but there was an 'unwritten policy', which everyone conformed to:

*"No, no nothing written down, no policy as such, but we all – we all say the same things you know… I will say just bath them in water…"* (health visitor: 52).

For women this meant saying that they used what they had been advised to use, that is water alone:

*"Yeah when the midwives were in the hospital I did [use water and cotton wool] because I knew they'd shout at you"* (multiparous: 19, four weeks post-birth).

During the middle of the interview, participants were

likely to talk about others not adhering to what was considered the preferred practice. It was as if the participants wanted to gauge the reaction of the interviewer before disclosing something that they thought may be judged. One midwife, for example, transferred some blame onto healthcare assistants for introducing bath products:
*"They [the women] say to me 'Well they [healthcare assistants] used baby bath' when they showed them the baby bath"* (community midwife: 03).

Another talked about the variation in advice given by others:
*"Some [midwives] say 'oh don't use that but it's alright to use a wipe now and again' so I mean, it's the inconsistencies"* (midwife hospital: 04).

As the interviews progressed, participants were more likely to state what they really did. For health professionals, there was an obvious personal/professional dichotomy. This midwife, for example, started off by declaring one practice, but then changed her opinion during the course of the interview:
*"Use warm water and cotton wool... that's what's advocated within the Trust... [later in the interview]... I probably would put a little bit in actually [baby bath]... but I suppose really I shouldn't do if that's not the evidence... but I'm being truthful, I probably would"* (midwife hospital: 07).

Similarly, a health visitor provided information about her own personal experience when providing the rationale for supporting the use of bathing products:
*"Because when I was in hospital having mine it was recommended just water and cotton wool, especially on the newborns. But I was one of those mums that thought a little bit of product won't hurt, you know, it makes the baby smell nice"* (health visitor: 48).

Women also appeared to provide different answers when they became more comfortable. One woman said:
*"You know, now generally as a rule I don't put anything in the bath at all... [later in interview]... once or twice I've put a little bit of the [brand name] wash in the water"* (primiparous: 52, four weeks post-birth).

It was evident that women's and health professionals' ultimate decision-making was influenced more by their personal beliefs and experiences than professional guidance. All participating groups suggested that they behaved differently when there was a chance that they may be observed:
*"I have been a health visitor for a long time and although I know what I ought to tell women [water only for bathing], it is not as simple as that. When you have seen as many babies as I have, you know that you have to do what's best on the day. It's different in hospital when you are being watched. At home you think about the individual mum and baby and don't worry about what you should and shouldn't do"* (health visitor: 45).

*Influential marketing*

All participants talked about marketing of baby bath products in their interviews. Personal beliefs and experiences provoked negative and positive comments. Midwives appeared to believe that they had a responsibility to disparage specific bathing products and promote what they considered to be more 'natural' practice:
*"I remind them [women] that the skin is an organ and it's got to develop its own capacity to produce oils and unblock the sweat glands... really there isn't any necessity to use any soaps or lotions at this time"* (community midwife: 21).
*"Water is natural. Water is no extra cost to the mums and it does the job well"* (community midwife: 17).

In contrast, health visitors, who see more older babies than midwives, were more likely to support whatever the woman was currently using. They did, however, offer advice when they thought it was needed:
*"Our managers will say 'you don't go with the reps or whatever', but I mean our policy is that you can advise the mums, because they have to take the decision themselves; you're not encouraging them, you're advising them. [We say] 'this is what has been proven to be satisfactory on a number of babies' and you get the information to them so they can read it... We used to give samples to parents, but we don't do that anymore, because that's more or less encouraging them to go and buy those particular products"* (health visitor: 53).

Women generally believed that products marketed for babies were safe to use:
*"I mean you see all these words like hypoallergenic and all things like that. I suppose if it's a baby wash then that would convince me that it was safe to use on babies"* (antenatal multiparous: 33).

Furthermore, there was a significant display of 'brand loyalty':
*"Not having anything that's too fragranced or too harsh... brands rather than buying a cheaper supermarket own brand ones... not as kind on the skin"* (antenatal nulliparous: 01).

Health professionals were less convinced, and criticised the advertisements, which they believe to be misleading:
*"Endorsed by a paediatrician, or best for baby, or voted so and so by a magazine, or something and I thought well it's a load of rubbish. You can't ethically test on babies can you?... They wouldn't be able to do that, would they?... so, I'm confused about the labelling"* (health visitor: 45).

Despite the promotion of water-only bathing by midwives, women questioned water's ability to be an adequate cleanser:
*"I wouldn't dream of getting in the shower and not using any soap on myself, so why should it be any different for a baby?"* (primiparous: 01, four weeks post-birth).
*"You know you could be there for ages with water... it's just bizarre but it can almost feel like it's not clean enough"* (multiparous: 02, one day post-birth).

For many women, products were favourable to water because of their smell. Once someone else, for example, friend or relative, endorsed a product, the women were happy to use it:

*"It's usually if somebody recommends something to you or you read something which sounds really good and then I go to the product and I like the smell to be honest. The smell's a big factor!"* (multiparous: 06, four weeks post-birth).

Interestingly, however, the use of products such as oil, despite not being produced for the purposes of baby skin care, was promoted by the majority of midwives (n=16) and health professionals (n=7). Remedies considered more 'traditional' than commercial products were generally accepted as being safe to use:

*"With a normal baby that hasn't got a skin problem, we talk about using, you know, using traditional oils, that you'd have in the house anyway, rather than perfumed products or products you have to buy and minimum additives really"* (health visitor: 49).

*"I don't know what other people are saying but the advice I give is don't use any products… I might even advise something like massage oil, just sunflower oil… but I wouldn't advise any brand of sunflower oil… I'd just say get the cheapest and purest and you'll be fine"* (hospital midwife: 8).

*The need for a randomised trial*

Health professionals and women were asked for their views on the need for a randomised trial of water-only bathing versus bathing with a cleansing product, for newborn babies. Everybody questioned believed that the results of such a trial would be useful:

*"I think it would be a good idea so you could see obvious differences between and if there weren't any then we know that there's no difference between using a product and using warm water"* (hospital midwife: 4).

Some acknowledged the dearth of existing evidence:

*"I think it would be interesting… I went to antenatal classes myself, and I was told not to add anything until they were two years old (laughs)… but there's not much evidence, we all go round saying water's best and happen personally to think that we're all too anti-bacterial now and too this product, that product and the other and too clean if you like, so I suppose that's my belief"* (health visitor: 49).

Others supported the notion of informed choice:

*"It's information for new mums… and then you know you can make a decision based on a bit more evidence or whatever can't you? I think it's better to have a bit more information… so that you can make your own decision definitely, definitely. I mean it doesn't have to say this is better or this is worse, just that these are the findings"* (multiparous: 35, antenatal).

However, some participants did have reservations, depending on how the trial would be funded and designed. One midwife, for example stated:

"*I'd want to know who had produced the evidence. I'd want to see some professional input from you know, dermatologists, say… and proper research done"* (community midwife: 23).

Another said: *"It would have to be more than just a company saying it… you know, done independently… I would want the results to be published, regardless of the findings"* (hospital midwife: 10).

When asked about industry-funded studies, some health professionals expressed an understanding of the difficulties of obtaining research funding for such studies by saying:

"*You've got to get your funding from somewhere*" (health visitor: 52).

Whereas another said: *"Ok, it doesn't quite sit easily with me, but I'm not entirely sure the reasons why. I think I just wonder whether they would be very influential if they funded it… I think they would possibly cherry-pick information, because they wouldn't want information that would destroy their product"* (health visitor: 45).

A different perspective was expressed by another health professional, who saw the potential benefits of a commercial company funding a trial that could result in their product being exposed as inferior to water:

*"If the results [of a trial] come out that it's not good for the baby, then they've just really gone and put themselves in a stupid place… they've funded it and then we've found that now we're not gonna sell it to anyone, you know what I mean? So, that's their choice… So I was quite surprised by that. But no… if they're willing to back it [a trial] then they must have trust, truth in their products mustn't they?"* (hospital midwife: 28).

In addition to confirming the need for a trial, women and health professionals also suggested important aspects of the design of such a trial. In terms of recruitment, women in the antenatal period stated that they would rather be recruited in the postnatal period. However, women in the postnatal period stated that they would rather be recruited in the antenatal period. All participants suggested similar outcomes of importance; these included 'skin dryness,' 'ability to clean', 'rashes and skin problems' and 'smell'. Unsurprisingly, participants proposed minimal inconvenience, in terms of data collection and time commitment. Compliance with the allocated regimen was also discussed and, in the main, was not seen as a problem. However, two women stated that they would only comply if allocated to the 'product group'. A reasonable follow-up period was considered to be six weeks, as this was a time when other products were likely to be introduced, for example, wipes.

## Discussion

Uniquely, this study explored women's and health professionals' views and experiences of baby bathing. The results have highlighted several methodological and practice issues worthy of consideration.

The central theme was entitled 'informed uncertainty', the information coming from a variety of sources and the personal beliefs challenging the national recommendations and thus creating doubt. This is compounded by the fact that many health professionals believe that there

is a strong evidence base, despite the empirical evidence not being there. This raises issues around how practice changes occur within a culture of evidence-based care. It also raises awareness of the power and potential influence of health professionals on the actions of women. All women undoubtedly want to do the best for their baby and, for those without any personal experience, ie primiparous women, look to those considered more knowledgeable for advice.

There is much written about multiple ways of knowing in healthcare settings (Carper, 1978; Belenky et al, 1986; Jordon, 1997) and participants drew on these different ways when making decisions regarding newborn bathing. Like Hunter (2008), it was possible to identify three alternative ways of knowing, related to baby skin care. First, there was self-knowledge generated from the belief system of the woman or health professional. Secondly, there was grounded knowledge from the participant's personal experience, for health professionals this was personal and professional experience, for multiaparous women this was their previous lived experience. Finally, there was informed knowledge, from the NICE postnatal care guidelines (NICE, 2006) and professional papers (Trotter, 2002; 2004; 2006). However, in this study the 'informed knowledge' was a misnomer as the evidence base was lacking. This raises the issue of health professionals' ability to review the evidence critically.

The change in newborn bathing practice in the UK appeared to coincide with the publication of some influential opinion (Brennan, 1996; Trotter, 2002). These were most likely the papers being referred to by health professionals, although there was no evidence of critical evaluation. These papers were published prior to the growing recognition of the importance of evidence-based care and at a time when midwives' and health visitors' training had less emphasis on critical analysis of practice. They may not have had such an influence if published for the first time today.

As experts in maternity care, health visitors and midwives should incorporate an approach to intuitive and reasoned decision-making that employs a variety of evidence (Gregson et al, 2002). However, in the present study, conflict between the different ways of knowing was found. This caused uneasiness for women and health professionals who wanted to provide the optimum care for babies, but were struggling with balancing what they believed to be authoritative knowledge (informed knowledge) with what they felt to be intuitively correct (self knowledge). However, the hierarchy of evidence, which emphasises the importance of empirical evidence appeared to denigrate other forms of knowledge, creating an environment that promoted using intuition in private. Grounded knowledge was influenced by tradition, which also made a pivotal contribution to decision-making and practice. As articulated by Polanyi (1962), by being in the presence of a 'master' and watching their example, '*the apprentice unconsciously picks up the rules of the art*' (Polanyi, 1962: 53). However, these hidden rules can only be absorbed if the learner is uncritical of the action (Dean, 1989). In this study, bathing practices were passed from senior to junior health professionals and from family members to individual women. The level of critical analysis was limited, therefore the unspoken rules became embedded. It is also clear from this study that further work is required to train health professionals in the critical evaluation and subsequent implementation of available evidence.

*Methodological issue*

The authors acknowledge a number of limitations to this study. This study obtained views from only one hospital and surrounding area; the hospital is not dissimilar, however, to others within the NHS in England. Also, the health professionals were a self-selecting sample; there could therefore be views from those with a bias in favour of one particular bathing practice. However, the findings suggest that the sample comprised those with varied views on skincare practices. Furthermore, on presentation of the findings at international professional and consumer forums, the findings resonated with those in the audience.

Consumers' involvement in research has become increasingly important internationally (Matrice et al, 1992; Meredith, 2000; Hanley et al, 2001; Oliver et al, 2004), yet unfortunately all too often only lip service is paid in the design phase. This qualitative study provides a good example of the importance of conducting exploratory work with key stakeholders prior to an RCT. In addition to exploring consumers' views, health professionals' views have also been recorded. This study confirmed that women and health professionals believe a trial is warranted – this is important in terms of recruitment and compliance. Furthermore, this study provided useful information to inform the trial design.

An interesting aspect of this study was the disclosures regarding use of bathing products as interviews progressed. This highlights the importance of creating an unthreatening environment when conducting interviews. Furthermore, it illustrates that the duration of an interview should be sufficiently long to enable a degree of trust to be built between interviewer and interviewee; this ensures that the participant can gauge the potential verbal and non-verbal reactions of the interviewer.

*Implications for practice*

A key component in the delivery of good-quality health care is clinical effectiveness, that is, doing more good than harm (Maxwell, 1984). This can only be achieved if relevant research findings and valid guideline recommendations are appropriately incorporated into practice. In this study, it was clear that health professionals' perceptions were that 'Trust policy' complied with the principles of clinical effectiveness, that is, water doing more good than harm. The fact that water is 'natural' provided some confidence that it was safe. To advocate

a bathing product would be considered to go against this, as there was no evidence of benefit and a perceived potential for harm. Similar principals were applied to other skincare practices. The use of oils, in particular, were believed to be doing more good than harm, despite there being no evidence of clinical effectiveness. Again, these were considered 'natural' and recommended liberally. Importantly, however, there is some evidence suggesting that oils have the potential to damage babies' skin, depending on their ingredients (Jiang and Zhou, 2003). One of the common ingredients in 'household' oils is oleic acid. Topical application of oleic acid induces stratum corneum lipid structure disorder by increasing the epidermal permeability. Until robust evidence is available, health professionals should not be recommending the use of oils for newborn skin.

The fact that women explicitly stated that they were not confident in water's ability to be an effective cleanser and health professionals implicitly suggested the same, needs consideration. Health professionals are more likely to draw on intuitive processes when there is a degree of uncertainty (Schon, 1983). Practitioners should be alerted to the possibility that their professional culture may prevent them from questioning certain ways of knowing, influencing them to behave in a particular way. It is likely that women do the same. Until there is a stronger evidence base for newborn bathing, one needs to be mindful of the complexities surrounding knowledge use in the clinical and home setting.

### *Implications for research*

Given the lack of empirical evidence, there is a real need to conduct an RCT of bathing newborn babies with a bath product versus bathing newborns with water only. This is particularly important given the readiness to use wash products among mothers, as illustrated in this study. This is something recommended by the RCM (Steen and Macdonald, 2008). Furthermore, a recent European round-table of dermatologists recognised the urgent need for an improved evidence base for skin care given within six weeks of term birth (Blume-Petavi et al, 2009). An important element of this evidence base will be RCTs comparing different skincare routines.

Despite the support for an RCT, concerns were raised regarding industry's influence on the trial design and the potential for publication bias. Although industry plays a pivotal role in funding many clinical trials, their input is fiercely debated (Bodenheimer, 2000; Chopra, 2003). The relationship between the academic researcher and the company is of particular importance. In this study, participants suggested that they would only have confidence in a study that was independently managed by an appropriately-qualified team of researchers and clinicians. Furthermore, participants stated that they would want to be reassured that the results of any trial would be published regardless of the findings. The potential for bias occurring in the reporting of industry-funded clinical trials is well known (Chalmers, 1990; Bodenheimer, 2000) – withholding the publication of unfavourable results, for example, is not unusual.The participants looked favourably on a company who is prepared to risk a negative result.

## Conclusion

To the authors' knowledge, this is the first study to explore newborn-bathing practices from different vantage points. Although women and health professionals draw on different types of knowledge to inform their decisions, the lack of empirical evidence is creating inconsistencies in advice and care. Furthermore, the recommendations in the NICE guidelines (2006), adopted by health professionals, has created an environment in which women, midwives and health visitors feel it is necessary to conceal their practice.

It is imperative that well-designed RCTs are conducted to guide future newborn bathing practices. This study will inform such a trial. However, evidence-based practice is only possible when one can distinguish between what is known about skin care and how individuals come to know it; it is only then that such understandings can be used to develop appropriate communication and implementation strategies.

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# Assessing the feasibility of a randomised controlled trial of birth on a birthing seat

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## Abstract

*Background*. Previous research has shown advantages of upright birthing positions; however, randomised controlled trials (RCTs) of interventions to encourage this are limited. The objectives of this feasibility study were to assess the possibility of a full-scale trial to test the hypothesis that birthing on a birth seat would result in a reduction in instrumental birth for women who had previously planned a vaginal birth.

*Methods*. This feasibility study was carried out as an RCT in Sweden to study birth outcomes of women planning a first vaginal birth. In total, 68 women were randomised to birth on the seat (experimental group) or birth in any other position (control group). The primary outcome measurement was the number of instrumental deliveries. Secondary outcome measurements included administration of oxytocin for augmentation of labour, length of the second stage of labour, perineal trauma, perineal oedema, maternal blood loss, haemoglobin, APGAR scores, umbilical cord pH and transfers to the neonatal intensive care unit (NICU).

*Results*. There were no significant differences between the birth seat group (the experimental group) and the control group for any of the outcome measurements.

*Conclusions*. The size of this feasibility study limits the generalisability of the findings. It has been considered that a full-scale trial is feasible if lessons learned about a number of methodological problems, including the internal drop-out rate are addressed.

*Key words*: Birthing seat, childbirth, instrumental delivery, upright position, evidence-based midwifery

## Background

Birthing in a recumbent position has been the norm in the industrialised world over the last three centuries (de Jong et al, 1997; Gupta and Nikodem, 2000; de Jonge et al, 2004; Coppen, 2005). The French obstetrician Mauriceau (†1709) advocated delivery in bed rather than using a birthing chair and introduced the recumbent position in 1663 (Drife, 2002; Coppen, 2005). The introduction of the recumbent position into the normal labour process was carried out without any evidence of its benefit compared to other positions (de Jonge et al, 2008). The medicalisation of childbirth, which included the confinement of the birthing woman to bed, may have been one factor involved in the increase in instrumental deliveries (Gardosi et al, 1989; de Jonge et al, 2004).

Instrumental delivery is used extensively and can lead to an increased risk of maternal and infant morbidity (Coppen, 2005; Baskett et al, 2007). The infant has an increased risk for cephalhaematoma, facial palsy and headache (O'Grady et al, 2000; Baskett et al, 2007). The birthing woman is also exposed to an increased risk of serious tissue damage to the vagina, perineum and anal sphincter, resulting in dyspareunia and postpartum perineal pain (Schytt et al, 2005). Assisted vaginal delivery is also associated with increased blood loss, urinary incontinence and a negative birth experience, which may result in disinclination for further children (O'Grady et al, 2000; Waldenström et al, 2004).

Today, most women in the industrialised world give birth in a semi-recumbent position (de Jonge et al, 2004; Waldenström et al, 2004) and in a national study from Sweden, Sandin-Bojö and Kvist (2008) found that only 34.7% of the women gave birth in a non-supine position. Alternative birthing positions have gained in popularity in industrialised countries during the last 20 to 25 years, perhaps as a counterbalance to the medicalised view of childbirth (Wagner, 2001; Geissbuhler and Eberhard, 2002; de Jonge et al, 2004). A review of the literature identifies advantages and disadvantages of upright birthing positions. In a systematic review of randomised controlled trials (RCTs) concerning such positions, the authors had difficulty in analysing the results due to variation in the quality of the studies (Gupta et al, 2004). However, they concluded that there were some advantages to upright positions – shorter second stage of labour, mothers' experienced their pain as easier to handle, and fewer episiotomies (Gupta et al, 2004). It has been suggested that upright positioning may also

improve newborn outcomes (Yildrim and Beji, 2008).

The review by Gupta et al (2004) also included two studies that showed an increase in second-degree tears when giving birth on a birth seat (Allahbadia and Vaidya, 1993; de Jong, 1997) and a similar tendency, though not statistically significant, was found in the review by de Jonge et al (2004). A RCT (de Jonge et al, 2007) showed that blood loss greater than 500ml was independently associated with perineal damage regardless of birth position.

de Jong et al (1997) suggested that pregnant women should be informed of the benefits of upright birthing positions and be encouraged to adopt such positions during labour. They also suggested the need for further research to find methods to help women maintain such a position through the second stage of labour.

BirthRite® is a birthing seat designed by a German midwife living in Australia (Birthrite, 2009). It has been on the commercial market since 2000. The seat is designed in such a manner that the woman, if she wishes, can deliver her baby in an upright position without strain on her legs and with less risk for perineal oedema because the angle of the seat widens the pelvic diameters, while pressure on the perineum and associated venous congestion are greatly reduced (Birthrite, 2009). As of 2005, the birthing seat had not been subject to a scientific evaluation.

## Objective

This feasibility study aimed to assess the possibility of a full-scale trial to test the hypothesis that birthing on the BirthRite® seat would reduce the number of women who planned to have their first vaginal birth, but who delivered instrumentally.

## Methods

Women were randomly allocated to one of two groups – either to the experimental group, giving birth on the BirthRite® seat or to the control group, which involved vaginal birth in any other position.

## Trial size

At the study hospital in Sweden, the total number of deliveries during 2004 was 2873 and the level of instrumental deliveries in primiparous women was 15% – the national statistic is 14% (The Swedish National Board of Health and Welfare, 2009). A calculation of statistical power was carried out ($\alpha$=0.05, ß=0.2) and showed that in order to test for a 40% reduction in instrumental deliveries, the requirement was 460 participants in each of the two groups.

It was decided, because of the substantial investment such a large study would entail, to carry out a feasibility study, pending an application for a research grant. The feasibility study continued during a seven-month period until funding was granted and during that time 68 women were recruited to the study.

## Inclusion criteria

The study included primiparous women who had sufficient proficiency in Swedish to receive information and give informed consent for participation. The inclusion criteria were a normal pregnancy, a singleton fetus in cephalic presentation and spontaneous labour occurring between 36 full weeks and 41 weeks and six days' gestation. Also included were women planning a vaginal birth after a caesarean section (VBAC) and those induced because of premature rupture of membranes. In this study, premature rupture of the membranes was defined as ruptured membranes after 36 gestational weeks without concurrent contractions.

## Exclusion criteria

Women planning a first vaginal birth were excluded when labour occurred before 35 weeks and six days' gestation or after 42 full gestational weeks. Women with breech presentation, with a body mass index over 30, multiple pregnancies, with an infectious disease, pre-eclampsia or other conditions that required medical care were also excluded.

### *Recruitment of study participants*

The trial was conducted from November 2005 to May 2006. Prior to the start of the study, all midwives working at antenatal clinics, private clinics, the labour ward and perinatal ward within the uptake area received oral and written information about the goals and administration of the study. Midwives were encouraged to watch a video about birthing on the BirthRite® seat.

Midwives in the antenatal clinics gave oral and written information and invitations to join the study to women who had reached 34 weeks' gestation. All participants gave written consent, which was sent to the delivery ward where the study was conducted and documented in the mothers' case notes. On admission to the delivery ward, the midwives assessed whether the women were still eligible to participate in the trial.

## Randomisation

Opaque and sealed envelopes of the same weight contained whether the participant should deliver on the seat or in any other position (the control group). These were randomly mixed, numbered and placed ten at a time in a tray in the central office on the delivery ward. Each envelope also contained a data collection sheet. When the participant's cervix was fully dilated, the midwife confirmed with the woman that she was still willing to participate and, if so, drew an envelope in strict number succession.

## Birth on the seat

The midwives on the labour ward were instructed in the use of the birthing seat by the first author. Participating women randomised to the seat, sat on it during the second stage for periods of no longer than 20 minutes, unless good progress in descent of the fetal head was apparent. The number of 20-minute periods was not fixed. The rationale was to avoid prolonged pressure to the perineum, which may result in oedema (Shermer and Raines, 1997). When the fetal head presented at the perineum, the midwife encouraged the birthing woman to avoid forced pushing (Valsalva manoeuvre) by breathing through

contractions and thereby accomplish a slow, gentle delivery of the baby.

### Outcome measurements

The primary outcome measurement was the number of instrumental deliveries in the experimental group versus the control group. Instrumental deliveries were considered as births assisted by vacuum extraction or forceps (O'Grady et al, 2000). Secondary outcome measurements were administration of oxytocin for augmentation of labour, length of the second stage, perineal trauma, perineal oedema, maternal blood loss and haemoglobin levels, APGAR scores, cord pH and transfers to the neonatal intensive care unit (NICU).

### Data collection

Data collection sheets contained the mother's date of birth, identification number and randomisation number. Duration of time spent sitting on the birthing seat was recorded and, where applicable, the reason why birth did not occur according to randomisation. The mother's most recent antenatal haemoglobin level was recorded and postnatal haemoglobin was tested between three and five days' postpartum. Between 24 and 36 hours' postpartum, the perineum of the participants was examined for oedema. Oedema was measured according to a visual analogue scale (VAS) where 0 is no oedema and 10 is extreme oedema. For the sake of analysis a VAS score for oedema of at least 3 was considered as physiological oedema after childbirth. All other secondary outcome measurements were available from the electronic case notes.

### Statistical analysis

Analysis was by intention to treat (Altman et al, 2001) and the data were analysed using SPSS version 11.5 (SPSS, 2002). Documents were found to be missing for one participant and therefore the analysis included 67 participants – 34 in the experimental group and 33 in the control group. Variables were dichotomised to allow calculation of odds ratios (OR) with 95% confidence intervals (CI). These were normal vaginal/instrumental vaginal delivery, administration/no administration of oxytocin, blood loss more/less than 1000ml, perineal oedema more/less than VAS 3, trauma/no trauma to labia minora, clitoris, vagina, perineum and anal sphincter, APGAR scores >7/≤7 at five minutes and umbilical cord pH >7.05/≤ 7.05.

All tests were two-sided and significance was assumed at the 0.05 level. Means for continuous variables that were normally distributed were compared using the Student's t-test.

### Ethical considerations

All participants in the study were cared for by midwives during labour. If a woman regretted consenting to participate in the study, the midwife unconditionally accepted this. Copies of the mother's charts and the data collection sheets were handled as all other medical documents and only the medical staff at the clinic had access to them. The committee for research ethics in Lund granted permission for the study (protocol number 214/2005).

## Results

Approximately 400 women fulfilled the inclusion criterion at the point of recruitment and 150 (37. 5%) agreed to participate in the RCT. Of these, 68 (46%) were randomised and 82 (54%) were not randomised for the following reasons: 28 had obstetrical complications occurring either before or during labour, 22 regretted agreeing to participate when the time for randomisation approached and 32 were not randomised because the midwife realised too late that the woman wished to participate in the study.

Three women were randomised despite the fact that they fulfilled exclusion criterion since they had passed 41 weeks plus six days' gestation (all three allocated to the experimental group). One regretted participation after randomisation (allocated to the control group). In total, 56 (82% of all participants) were delivered as randomised. Some 12 (35%) participants in the experimental group did not give birth as randomised. No participant in the control group gave birth on the BirthRite® seat. The final analyses included 34 women in the experimental group and 33 in the control group. Figure 1 shows the flowchart of the randomisation process.

### Primary outcome

The difference in numbers of instrumental deliveries between the experimental group (n=4) and the control group (n=7) was not statistically significant, OR=0.50 (95% CI=0.14-1.80). Instrumental deliveries were due to maternal exhaustion, uterine dystocia or presumed fetal hypoxia.

### Secondary outcomes

*Oxytocin for augmentation of labour*

Of the 67 participants, 42 (63%) had oxytocin administered intravenously some time during labour. Augmentation of labour with oxytocin occurred in 15 women in the experimental group and in 14 women in the control group. A further nine women in the experimental group and four in the control group received oxytocin during the second stage, making a total of 24 (71%) versus 18 (55%). There were no significant differences between the two groups for the use of oxytocin during the first stage of labour: OR=0.95 (95% CI=0.32-2.80) or during the second stage: OR=3.02 (95% CI=0.74-14.67).

*Length of the second stage of labour*

No significant difference was found for the length of the second stage of labour between the experimental group (46±26 min) and control group (54±31 min), t=-0.31, p=0.76.

*Perineal lacerations and episiotomies*

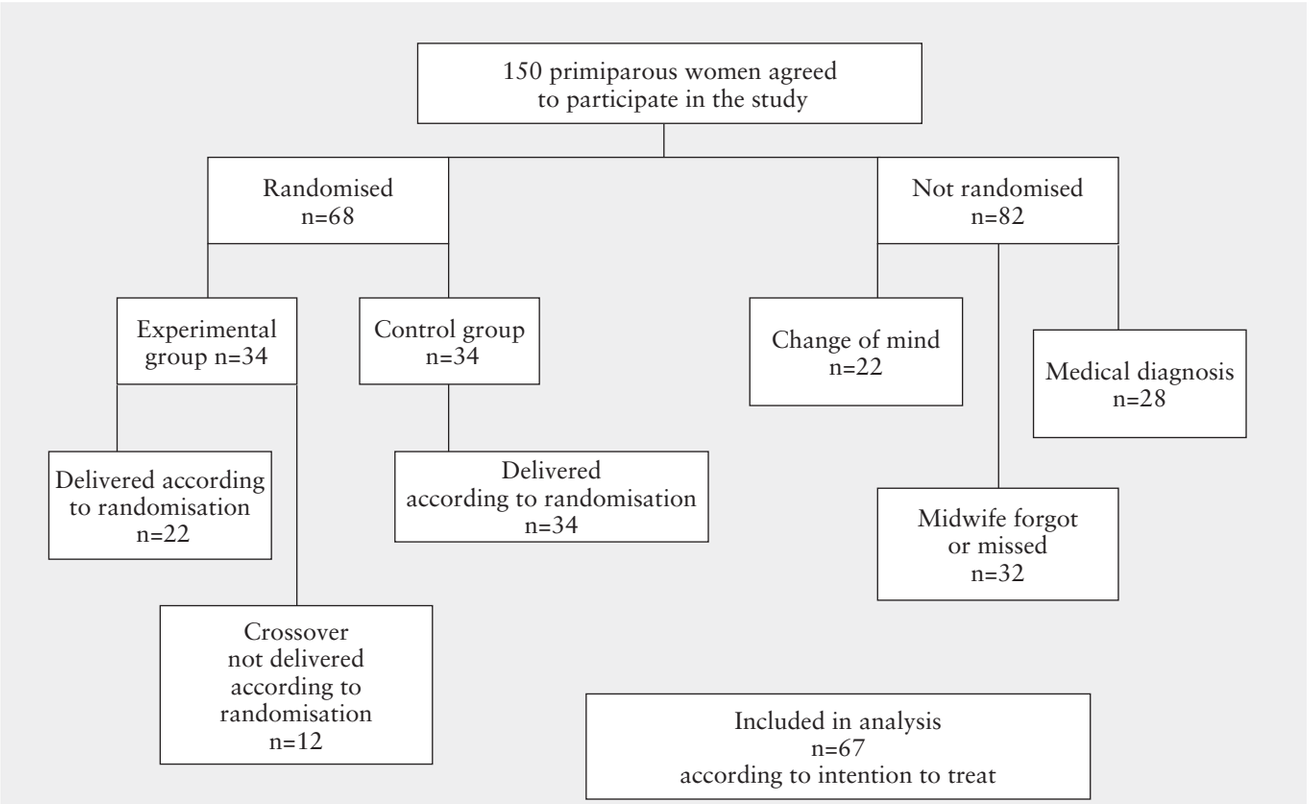
The number of women who sustained perineal traumas and degrees of lacerations are shown in Table 1. In total, 24 women had multiple perineal traumas, including six episiotomies – two (5.8%) in the experimental group and four (12%) in the control group.

*Perineal oedema*

In the experimental group, 20 of 34 participants had their perineum observed for oedema and in the control group 16 out of 33 participants were observed for oedema. The mean

**Figure 1. Flowchart of the randomisation process**




VAS scores for perineal oedema were not significantly different, p=0.53.

*Blood loss and haemoglobin levels postpartum*

Among the participants in the experimental group, ten women (30%) had a blood loss ≥500ml, the number of women with a blood loss ≥500ml in the control group was seven (21%): OR=1.55 (95% CI=0.52-4.60). Three women in each group had a blood loss greater than 1000ml from birth and up to two hours after delivery. Mean haemoglobin levels at approximately 36 hours' postpartum were 116g/l for the experimental group and for the control group 118g/l. This difference was not significant, p=0.80.

*APGAR scores, umbilical cord pH and transfer to NICU*

All infants in the study had an APGAR score ≥7 at five minutes and one had an umbilical cord pH lower than 7.05. One infant from the experimental group was transferred to NICU for observation because of spontaneous rupture of the umbilical cord at birth.

## Discussion

This feasibility study was carried out to test the possibility of a full-scale trial and it has been concluded that a full-scale study is possible. There was a large loss of recruited participants to an extent due to forgetfulness on the part of the midwives. It became clear that giving information to staff involved in the recruitment and running of a research study is of the greatest value. Planning for the full-scale study extended and improved information to all involved. Sandin-Bojö and Kvist (2008) showed that Swedish midwives gave evidence-based intrapartum care to only a limited degree and the loss of recruited participants in the present study may suggest that midwives have not yet fully accepted the usefulness of midwifery research. Improvement in continuing professional education for midwives in Sweden may help increase awareness of the need for evidence-based care and therefore improve its provision for birthing women.

Another reason for the high internal drop-out rate could be the point of time chosen for randomisation. According to Hundley and Cheyne (2004), there are large drop-out rates in intrapartum trials and levels of non-compliance tend to be high. In retrospect, the authors consider it to be less acceptable to randomise women when the cervix is fully dilated and they are in a state of dependence. In the full-scale trial, randomisation will be carried out as soon as the woman is in established labour, rather than at full dilation of the cervix.

The use of the VAS for the measurement of perineal oedema was arbitrary and its use has not been validated, therefore the results in this study must be interpreted with caution. Although the internationally agreed cut-off point for

**Table 1. Perineal trauma sustained by the women in the trial according to the World Health Organization's 10 codes on international statistical classification of diseases and related health problems (WHO, 2007)**

| | Experimental group n=34 | Control group n=33 | Odds ratio 95% CI | p |
|---|---|---|---|---|
| First-degree tears: involving clitoris, fourchette, hymen, labia, skin, vaginal mucosa | 11 | 7 | 2.70 (0.70-11.20) | 0.20 |
| Second-degree tears: involving pelvic floor, vaginal muscle, perineal muscle | 23 | 13 | 2.50 (0.84-7.50) | 0.11 |
| Third-degree tears: involving anal sphincter, recto-vaginal septum | 2 | 1 | | |
| Fourth-degree tears: involving complete disruption of internal and external anal sphincter and mucosa | 0 | 0 | | |

pre-term is 37 gestational weeks, 36 weeks was used because in Sweden, midwives care independently for these mothers even though the chief obstetrician is always notified. A weakness in the study is that it was not possible to identify how many of the women who were eligible for inclusion were actually asked to participate in the study. Attention will be paid to this in the full-scale study.

A total of 11.8% (4/34) of participants in the experimental group compared to 21.2% (7/33) in the control group had instrumental deliveries. There appears to be a difference between the experimental and the control groups, however, the numbers were too small to determine any statistical significance. This indicates that this variable requires further investigation.

Bodner-Adler et al (2003) observed a decrease in the use of oxytocin in women giving birth in an upright position, but this was not observed in this study, where oxytocin was administered intravenously at some point during labour to 63% of the study population. Similar results have been reported in a recent descriptive study from Sweden (Svärdby et al, 2007), which showed that 70% of primiparous women were given oxytocin for augmentation some time during labour and birth. It is surprising that such a large majority of the participants in this study required augmentation of their labour, since they were pre-defined as healthy women without expected labour or birth complications. This will be an important outcome variable in the full-scale RCT.

A Cochrane systematic review (Gupta et al, 2004) included two studies showing an increase in second-degree tears when birthing on a birth seat (Allahbadia and Vaidya, 1993; de Jong et al, 1997). This finding was not confirmed in this small study. It will be important in the future study to determine whether the birthing seat can reduce the occurrence of instrumental deliveries and thus counterbalance any increase in vaginal and perineal trauma. Traditionally, primary postpartum haemorrhage (PPH) is defined as blood loss of 500ml or more from the genital tract and severe PPH as 1000ml or more in the third stage of labour and in the first 24 hours following the delivery of the baby (Su et al, 2007). Two studies in the review (de Jong et al, 1997; Waldenström and Gottvall, 1991) also showed an increased risk of a blood loss in excess of 500ml when birth seats were used. In this study, a cut-off point for bleeding at 1000ml was used since a blood loss postpartum of up to 1000ml may be considered as physiological in a healthy population (World Health Organization, 1996). Approximately 8% of the participants in each of the groups had blood loss of more than 1000ml. This rate does not differ to any extent from the average percentage of postpartum bleeding greater than 1000ml generally reported at the unit where the study was conducted.

Many of the measurements of postpartum haemoglobin were lost to analysis due to non-compliance. The 53% who had their haemoglobin levels measured were equally divided between the groups. No significant differences could be determined and although no conclusion can be drawn from this, it could indicate that blood loss when birthing on the birth seat is comparable to other positions in spontaneous birth. In this study, infant outcomes were not affected which is in accordance with the results from a meta-analytic review concerning maternal position during second stage (de Jonge et al, 2004; Gupta et al, 2004). It was considered that the transfer of one infant to NICU was not caused by maternal birthing position.

Despite a drop-out rate of more than 60% and a cross-over rate of 18%, a full-scale study is considered to be possible if feedback is given to midwives about the feasibility study drop-out rate and information that is given to all midwives involved in the trial is improved. The participating midwives' commitment to the trial and their compliance increased towards the end of the study period. This could indicate that they gained insight as to why the trial was important, as well as gaining confidence in assisting birth seat deliveries.

During the present study, some midwives expressed

problems in finding a comfortable position for themselves that would allow them an overview of the perineum. It is possible that there may be an exaggerated belief that perineal ruptures can be prevented by observing the perineum (Eason et al, 2000). According to Albers et al (2005), interventions used for protection of the perineum have little effect. The problem of uncomfortable working positions for midwives cannot be ignored and for the full-scale study a midwife chair designed by the makers of the BirthRite® seat has been purchased.

## Conclusions

The small trial size limits the generalisability of the findings in this study. It has been considered that a full-scale trial is feasible if lessons learned about a number of methodological problems including the drop-out rate are addressed. To the authors' knowledge, no large RCT has been carried out to study the frequency of instrumental delivery in the context of birth seat deliveries. Therefore, it is important to undertake a full-scale study to determine the outcomes of birth on a birthing seat.

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# Men and women's perceptions and experiences of attending an abusive behaviour management programme

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## Abstract

*Background*. Domestic violence is a global and pernicious problem affecting all spheres of society. It has traditionally been seen as a social problem, but is now recognised as a public health issue and reducing the incidence is a 'priority action one within Public Service Agreement 23' (Home Office, 2007). It has been identified as a significant contributor to maternal and fetal morbidity and mortality, through both direct and indirect means. This paper describes the first phase of a study exploring the views of men and women who had attended a behaviour management programme organised by a charity based in Leeds, UK, called Start Treating Others Positively (STOP). The adapted appreciative inquiry model of behavioural change underpins the work of STOP.

*Aim*. To explore the perceptions and experiences of participants attending STOP sessions.

*Method*. The design was exploratory and descriptive involving 20 participants – 15 men and five women – who were parents and attended STOP voluntarily. Ethical approval was granted by the University of Central Lancashire's health ethics committee and guidance cited in the NHS Research Governance Framework was adhered to throughout the study. Semi-structured interviews were undertaken during December 2007 and January 2008. Data were analysed by using thematic analysis.

*Findings*. Six sub-themes emerged from the data: emotional regulation, emotional understanding, developing empathy skills, changed behaviour, developing conflict resolving skills and coping strategies. These were integrated into three overarching themes: emotional stability, cognitive empathy and conflict competency. Following synthesis, these were summarised into one major theme 'positive life skills'. Data from the interviews demonstrated an overall belief that domestic violence was inexcusable. However, STOP was perceived to be a positive means to achieving a change in personal behaviour.

*Conclusion*. Domestic violence has enormous implications for the health sector in general and within maternity services. Preventing future cases of domestic violence will reduce both maternal and fetal mortality and morbidity rates. The government has made the reduction in the prevalence of domestic violence a high priority, yet there is limited research to demonstrate effective preventative measures.

*Key words*: Pregnancy, domestic violence, behaviour change strategies, Appreciative Inquiry, conflict resolution strategies, evidence-based midwifery

## Background

Throughout the world, conflict between human beings occurs in everyday life and can escalate with devastating consequences to health and wellbeing, the most severe being loss of life. In the UK, recent evidence reported in the latest British Crime Survey (Home Office, 2008), showed that in 2007, there were 734 homicides, (547 victims were male and 187 were female). Of these, 5% of males were killed by a partner/ex-partner, and 8% by another family member. In contrast, 44% of females were killed by a partner/ex-partner and 12% by another family member. In addition, 33 children were murdered by their parents in the year 2006/07. The most at-risk group were children under one year old, and it was estimated that 28% of

women and 18% of men (16 to 59 years) may become a victim of domestic violence at some point in their lives.

There is evidence that domestic violence in some cases can replicate itself across generations (Ehrensaft et al, 2003; Magdol et al, 1998). Given that the family is the primary focus of human socialisation and development, it is possible that patterns of behaviour learned in the home are replicated in wider society (Browne and Herbert, 1997). When reviewing theories of intimate abuse, social learning theory proposes a relationship between experiencing abuse or witnessing domestic violence as a child and the risk of becoming an abuser as an adult (Bandora, 1973). This theory also links the lack of development of conflict resolution strategies as a child and then during adolescence with increased risk of intimate partner violence. The attachment theory proposes that intimate relationship abuse is more likely to occur when there has been an early attachment problem in the parent-child relationship (Bowlby, 1969) and an insecure child will then go on to have relationship attachment difficulties.

Mutual aggressive relationships are not uncommon and relationship theories propose that abuse can occur when an on-going pattern of aggressive behaviour encourages a hostile and coercive relationship to develop (Scott, 2004). Continuous patterns of aggressive and often abusive behaviour are contributed by both partners (Hanson and Harway, 1993). Change in one partner's behaviour results from a change in the relationship dynamics and couples therapy may be helpful to shift the relationship balance (Gelles and Maynard, 1987). Concerns, however, by feminist theorists who believe that abuse of women by their partners is influenced by a patriarchal society that allows men to control and dominate, view couple therapy as an opportunity to victim blame and can put the woman at risk (Dobash and Dobash, 1979).

It is recognised that women are more likely to be at risk from domestic violence than men (Home Office, 2008; Department of Health, 2005) and it often can start or escalate during pregnancy and during the transition to parenthood (Confidential Enquiry into Maternal and Child Health, 2008). Evidence of prevalence rates for domestic violence during pregnancy vary greatly and can often go undetected, but it has been estimated that approximately 23% of pregnant women are in abusive relationships and between 40% and 60% of women experiencing domestic violence are abused during pregnancy (Stark and Fitcroft, 1996; British Medical Association, 1998). Domestic violence, therefore, has been identified as a significant contributor to maternal and fetal morbidity and mortality, through both direct and indirect means (Torres et al, 2000). Therefore, this constitutes a serious public health issue for individuals and groups. Reducing the incidence is a priority action one within Public Service Agreement 23 published by the Home Office (2007).

The estimated annual cost of domestic violence and child abuse to the NHS is £1.2bn (Department of Health, 2005). Health practitioners play an important role in routinely enquiring about the possibility of domestic violence and then supporting and caring for victims of abuse. However, they also have a responsibility to gain knowledge about, and an understanding of preventative measures (Taket et al, 2003). There is a clear rationale for clinicians to prioritise the prevention of domestic violence where possible (Jewkes, 2002). Unfortunately, effective preventative treatments are not well established or researched.

Over the last decade, the British government has implemented a number of policy interventions to deal with family violence, and, specifically, violence against women. Positive steps to educate and train health professionals to understand, recognise, and offer support, care and advice to women who are being abused has been advocated (Department of Health, 2000; 2005). The government has made domestic abuse a very high priority, with the focus on three main areas:

- Bring to justice perpetrators of domestic violence
- Support women and children who experience abuse
- Prevent future cases of domestic violence.

The former home secretary Jacqui Smith launched a violent crime action plan, which included an increase in the number of domestic violence courts and trained domestic violence advisors to support victims (Home Office, 2008). Preventative measures, however, such as developing and funding programmes, with the aim to educate both men and women on how to manage their abusive behaviour, do not appear to have been given priority and support. This means that health professionals may be better at recognising incidences of family violence, but that many are unable to find an effective referral route for the perpetrators.

*Description of the intervention*

Start Treating Others Positively (STOP) is a Leeds-based charity, which facilitates abusive behaviour management sessions for adults. The first STOP session began in November 1989 and its overall aim was to reduce abuse in the home. Several organisations fund the programme. These include the West Yorkshire Police, the National Lottery and a range of Trust funds. Initially, STOP only facilitated sessions for male abusers, but in June 2000 it also began sessions for female abusers. STOP also works collaboratively with Leeds Women's Aid to provide a support group for female victims. Since 2000, STOP has been working very closely with Leeds Teaching Hospitals NHS Trust and Leeds Primary Care and Mental Health Trusts. It receives self-referrals, and referrals from a range of professional groups in the health sector (STOP, 2008).

The first step in the STOP programme involves a client completing a short application form, a self-assessment form and an interview to establish the areas they need to work on. Their partner is also sent a self-assessment form to gain an insight into their experiences as victims of the abuse. STOP offers a rolling programme. Clients are encouraged to attend for a minimum of 16 weeks, after which the assessment process is repeated. Clients are

advised to continue to attend for up to a year for further support. STOP has an 'open door' philosophy and many clients choose to continue to attend intermittently for a number of years. The programme includes group sessions that cover a range of issues and techniques:

- Understanding family violence
- Managing negative emotions
- Children and domestic violence
- Understanding masculinity – men and emotions, power, self-esteem and shame
- Challenging denial, minimisation and blame
- Challenging irrational thinking
- Developing victim empathy
- Relapse prevention
- Becoming assertive as opposed to aggressive.

Clients are also encouraged to read a chapter of the STOP manual in between sessions (STOP, 2009), to help them gain a deeper understanding and knowledge of the issues covered. Approximately, eight to ten clients attend each group session.

STOP has found that levels of denial and minimising are very high with new clients. Initially, asking them to recognise their violent behaviour has been shown to be unhelpful. A priority for STOP is that all clients are treated with absolute respect from the time they first start the programme. This differs from other perpetrator programmes that adopt an 'offence-focused' programme. STOP works on the premise that what has happened cannot be undone but that, from this point forward, positive change in social behaviour can happen, and that this will prevent the continuation of abuse in the home. This positive stance aims to focus on strengths to enable an abuser to take responsibility for their actions, and to develop empathy and conflict resolution skills. This in turn is intended to promote learning on how to deal with emotions and relationship conflict in a positive way:

- STOP: Stop and see what is happening. Don't just react!
- THINK: What is important here? What could be the threat?
- OBSERVE: Calmly work out the problem
- PROCEED: Take time out. Be assertive.

The before and after self-assessment forms offer some insight into self-reported and partner-reported change associated with the programme. The STOP programme has been positively evaluated by the children's charity Dr Barnardo's: '*…the Barnardo's service recognises the excellent work of STOP and the impact that it has on people's lives, both directly and indirectly and we would like to wish them every success in striving to achieve their aims and in their continuation of their support to the people and families in Yorkshire*' (STOP Evaluation Report, 2007: 27).

This study was designed to obtain more in-depth data to ascertain the perceptions of the attendees about the impact of the programme, with a view to adapting it to other settings, and to consider its potential for use in pregnancy.

## Aim

The aim of the study is to explore the experiences of adults who are parents and attending STOP.

## Ethical consideration

Ethical approval was sought and given by the University of Central Lancashire's Faculty of Health Ethics Committee. The participants were not NHS patients, but guidance cited in the NHS Research Governance Framework (Department of Health, 2002) was adhered to throughout the study, including informed consent, voluntary participation, confidentiality, participants' and interviewers' safety and the reporting of data anonymously.

## Design

The design was exploratory and descriptive. Data were collected using a semi-structured face-to-face interview.

## Methodology

Between December 2007 and January 2008, all STOP participants attending one of the four weekly sessions (three men's groups and one women's group) were given information about the study a week before being recruited. This was to give them an opportunity to consider if they would like to take part and give their consent. The following week, at the beginning of each session the lead researcher (MSG) discussed the aim and study details with the participants and answered any queries. Those recruited had to be a parent with a history of relationship conflict. A purposive sample of five from each group session was then recruited. Following further explanation and agreement, written consent was obtained.

Participants were interviewed in a private consulting room at the STOP offices by the lead researcher (MSG) and two fourth-year medical students trained in Socratic questioning (Paul and Elder, 2006) from the University of Leeds who were on community placement. Interviews lasted approximately 45 minutes and STOP trained the medical students. One support meeting was set up following the interviews with the lead researcher and the director of STOP to allow the students to reflect on their experience.

During each interview, the researcher and participant sat diagonally opposite each other to achieve good eye-to-eye contact and to promote a comfortable environment. This was designed to encourage participants to speak freely, and reduce some of their anxiety. Participants were informed of the approximate length of the interview and that it would be semi-structured.

### *Data collection and analysis*

A total of 20 interviews were conducted, each lasting an average of 45 minutes (range 35 to 70 minutes).

During the interviews, participant responses were written down and recorded on a log sheet by a researcher. They were not audiotaped on request from the participants and STOP due to the sensitive nature of the data. Their responses were fed back to them at the end of the interview to cross-check the information. The written logs were then typed up within 24 to 48 hours. The participants were given a further opportunity to cross-check the written transcript the following week. This was to give them the opportunity to amend any misinterpretations

and to confirm that it was a true representation of their perceptions and experiences.

A thematic analysis was used, which was based on some of the traditional processes and techniques described by Miles and Huberman (1994), who are renowned for their systematic methods, and the constant comparative method was also used in the analytic process (Glasner and Strauss, 1967). This entailed the identification of primary emerging themes, secondary core themes, then a final core theme, and the development of a synthesis statement. The anonymised typed transcriptions were then read by the three authors independently and a thematic analysis was used to interpret the meaning of the data. The three researchers made marginal notes, identified key phrases and concepts and then grouped these together. Following identification of sub-themes, overarching themes were identified. These were then synthesised into a final summary statement.

## Findings

Some demographic and characteristic details were recorded at the start of the interview. These are summarised in Table 1. Figure 1 demonstrates a flowchart of identified codes, primary emerging themes, secondary core themes and then a final core theme. Six sub-themes emerged: emotional regulation, emotional understanding, developing empathy skills, changed behaviour, developing conflict resolving skills and coping strategies. Further analysis of the data led to a categorisation of the emerging sub-themes into three core themes: emotional stability, cognitive empathy, conflict competency. These were synthesised into one core theme: positive life skills.

The data suggest that many of those who attended STOP were stuck in vicious cycles of violence, both between generations, and across individual lives. There were three clear 'virtuous cycles' of change in the data and these are presented below.

### *From emotional instability to emotional stability*

Several of the participants discussed their emotional insecurities before attending STOP and how they had difficulties in managing their emotions and this led to anger and abuse. However, it was clear that emotional development and regulation was occurring:

*"STOP has helped me greatly, I am now more in control of my emotions and feelings. I recognise the warning signs when I am getting emotional and this could lead to anger. It's a state of mind thing, and I know when I am getting angry now. I don't jump to conclusions like I used to and I don't jump down people's throats, I can control my emotions better and this makes me feel good"* (participant 17).

*"I'm not evil and even rational people do anger! It's ok to fail as I am human. As humans we are not expected to be perfect and we can slip up and make mistakes. I'm not a bad person when I've failed and got angry. 'Progress not perfection' is the key message STOP has taught me. Attending STOP has helped me cope with situations better and I can see anger signs now and manage anger. I also like coming as everyone is in the same boat. You can open your heart here and peer support from the other men is a positive benefit"* (participant 15).

These data are interesting both in the illustration of the change process, but also (and possibly more importantly) in illustrating the underlying philosophy of the programme. While STOP does not articulate this, there is a clear resonance with appreciative inquiry-type (AI) approaches (Cooperrider et al, 2003). AI is based on a process of identifying what works well, in order to build on the positive. Classically, it takes a so-called '4-D approach'. Adapted for this situation, this approach could be described as:

- DISCOVER what works well
- DREAM up a future in which things will continue to work well
- DESIGN for processes that can make the future work well
- DELIVER the positive future.

Importantly, this kind of approach does not demonise the individual, which risks leaving them in the vicious cycle, but emphasises what they can do to change, giving them access to what we have termed the virtuous cycle.

### *Lack of understanding and empathy moving to cognitive empathy*

Cognitive empathy (also termed empathetic perspective-taking) is the term used to describe mental perspective taking, whereas emotional empathy is the vicarious sharing of emotion (Smith, 2006). The findings from this study demonstrated that the men developed cognitive empathy and this is similar to that reported by Scott and Wolfe (2003):

*"I could bypass large things, but would get really annoyed and frustrated by small things, such as other drivers and bad manners from strangers, I think my army background was part of the reason why I was aggressive with people, but the thing that scared me into coming to STOP was that I made my 12-year-old son cower in the corner of the room because he was so fearful of me and that I was going to really hurt him. Since this incident I have felt ashamed and disgusted at myself and when I begin to get angry now I think about this and stop myself, I never want to get like that again. I have learnt to not hurt and that there are no excuses"* (participant 5).

*"STOP has helped me understand and recognise why I am getting angry. I recognise when I need to take time out and I find writing helps. I am able to see the other side of the story now and I can see and understand it from my wife's side now"* (participant 15).

*"I used to rehearse arguments and was misguided by other people, which got me wound up. I had irrational thoughts, for example, thinking that it could happen, might happen before it has happened. I would get frustrated, lose my temper and explode with my wife and one of my daughters even when I knew deep down what*

**Table 1. Paricipants' details**

| Gender | Age range | Ethnicity | Employment history | Marital status | Disability | Referral history | Time attending STOP |
|---|---|---|---|---|---|---|---|
| Male 15<br>Female 5 | 28-60 (mean 38 years) | White UK: 17<br>Irish: 1<br>Black UK: 1<br>Middle east: 1 | Employed: 11<br>Self employed: 1<br>Unemployed: 6<br>University students: 2 | Married: 10<br>Separated: 4<br>Divorced: 1<br>Co-habitating: 1<br>Single: 4 | 4 | Health professional: 8<br>Other public sector professional: 4<br>Self/family member: 8 | Two months to ten years (intermit-tent) |

*I was doing was wrong. I now feel good about myself and I am aware about how to treat others with respect. I have learnt to stop and think and I understand that red rage means beyond no return point. I have turned the corner and I listen and don't get ahead of myself now. I don't mind being judged and I have learnt to trust and share my feelings with others. I was brought up not to show my feelings, the boy's code but I can and do now"* (participant 16).

Prior to attending STOP, participants lacked awareness, ability to empathise and understand their partner's point of view. They had a tendency to be egocentric, self absorbed and disrespectful, blame their partner and were unwilling to listen to them. However, it is clear from the transcripts that participants started going through a transition phase and were developing some empathy skills. They started to listen, became more tolerant and developed empathy. They were learning how to treat others with respect, to appreciate other people's feelings, to recognise when they were in the wrong, and to stop blaming others.

*Conflict incompetency to conflict competency*

Before attending the STOP programme, some participants lacked the ability to control their aggression and angry outbursts, which often escalated to violence. They did not like themselves and recognised they needed help. There was evidence that attending STOP enabled participants to develop coping strategies and conflict competency:

*"Before I attended STOP, I had bad anger, it was out of control. I was always kicking off all the time, swearing, always angry, I'm much more calmer now and I can handle things better. I tell people about my experience, I share it with them, my attitude has changed, I don't shout, swear, smash things, yell like I used too. I'm past that. I know now how to deal with it. It has been about one and a half years now that I have been less angry, I can now control it. I wanted to be a better person I didn't want to be like I was. I made a mistake, I beat my son one time, I went to the social services, I wasn't hiding it, I was horrified at what I'd done. I made a mistake"* (participant 12).

It was not an easy task to admit to having an anger problem and to admit abuse of close family members and members of society. During the interviews, a few participants revealed that they were afraid to attend STOP initially. Others were ashamed to tell people they attended STOP:

*"I am ashamed to tell someone that I attend STOP, even though I come here and have benefited greatly. In fact, the shame held me back from coming here much earlier. So, I am very careful who I tell as people could take it out of context. The fear of initially coming was a real concern, other people attending and their anger problems. Nobody attacks you though! Initially, you think you are going to be strung up, but it isn't like that"* (participant 16).

For another participant, the release and support offered by STOP led to a desire to spread the word:

*"Anger builds up for years, deep anger, it can be dangerous, especially if you can't control it. Thankfully STOP can literally stop this, I didn't think I'd enjoy the course but I have, I couldn't cope without STOP and the people at STOP. I tell all my friends, go to STOP. It is the only way to be successful, you can change and manage your anger"* (participant 6).

Some participants who were brought up in a violent home reported that they were able to engage with their peers, parents and their own children better, and that they had a strong intention not to intimidate them anymore:

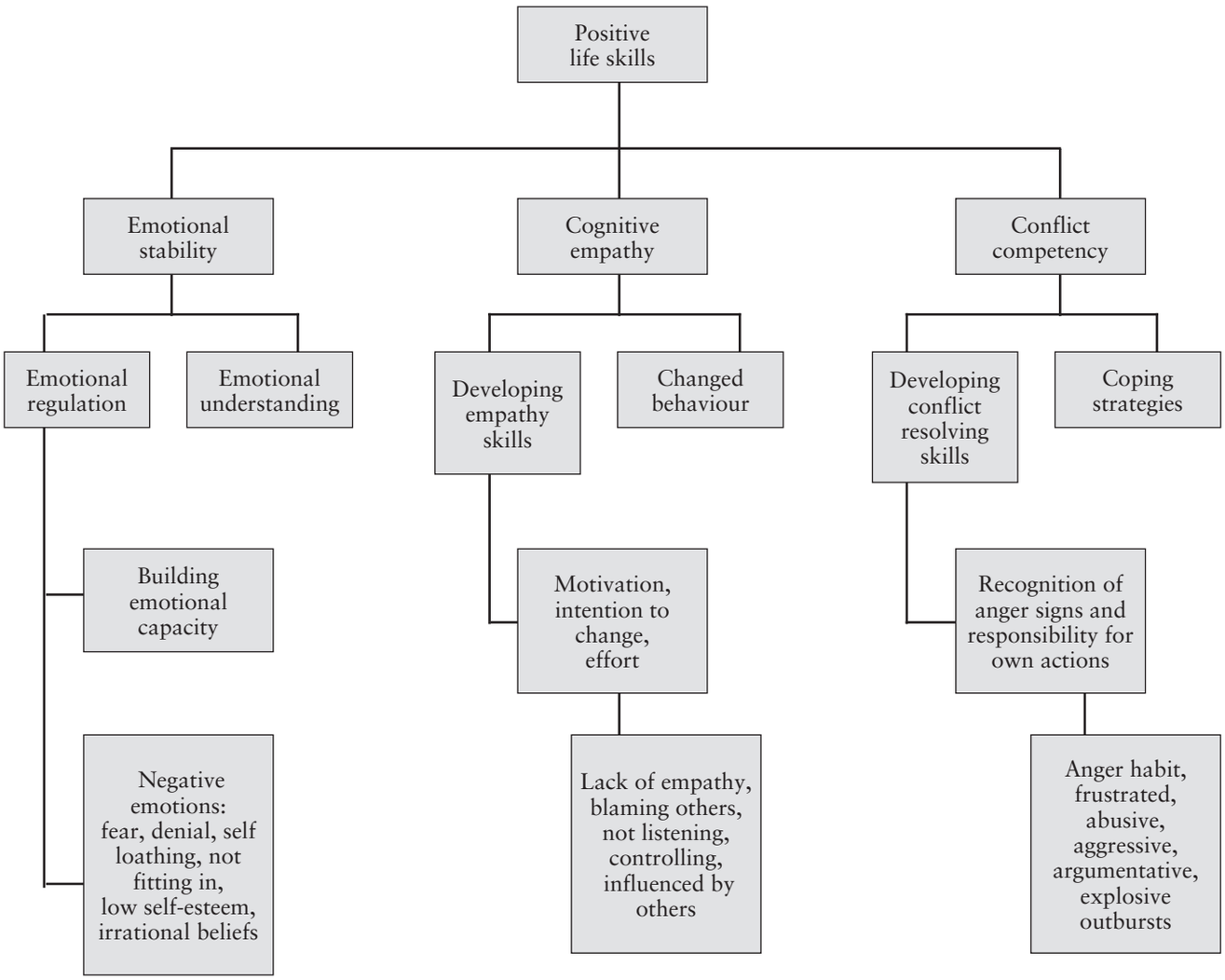
*"I was brought up to use my fists if I didn't get my own way and I was self-destructive. During an argument, I wrecked my ex-wife's house and when she got in the way I attacked her. Now you can't get a reaction out of me. I say "it's your problem not mine" and I have never hit or raised my voice at my new girlfriend. STOP has given me the coping strategies to get on with my life"* (participant 4).

*"Attending STOP has helped me understand my emotions and how to deal with my anger. I used to feel isolated and like a victim of circumstances. I felt completely shut down of feeling. If you had asked me two years ago, I wouldn't have taken part in this research and I would have purposely intimidated the interviewer to not ask questions. I have got my identity back, STOP has released me and I can now have a conversation with my mum as I have more respect for her and no longer blame her for not sticking up for me when I was a child"* (participant 2).

It was also evident that some of the participants were putting into practice what they were learning and were

**Figure 1. Managing relationship conflict and emotions**




in turn teaching their own children the STOP skills: *"I see the signs now, I chill you know, it's not worth my time or patience to get wound up. My daughter is 13 and we are able to talk. Other people see the difference in me. I was always angry before but I'm not now. I am more aware now so I stop myself before I get angry. My mum is disabled now and needs help – I try not to dwell on the past and help her. My grandma was the same to her, hitting her and hurting her and I never got on with her. My mum had the wrong lessons too! But I'm not going to be like that to my daughter, we talk and I'm teaching her how to manage her feelings and that violence doesn't get you anywhere"* (participant 8).

*"My little girl had to present some work at school on personal relationships and she asked her classmates the million dollar question "who can make you angry? Yourself of course, no-one else", she informed them"* (participant 20).

*"I am sharing my learning and experiences with my girls. I have shown my two girls the exercises, and I have bought them a book each. STOP has been a great help"* (participant 16).

This illustrates that there were positive cross and inter-generational benefits that suggest a positive societal gain to the STOP programme. There was clear evidence from all 20 participants that they had gained and were continuing to gain positive benefits by attending STOP. These participants volunteered to be interviewed and their particular findings cannot be generalised to others in the same situation.

The data led to the formation of a tentative theory about the mechanisms underpinning the STOP programme. The positive appreciative inquiry-type approach adopted by STOP created virtuous cycles in the place of vicious cycles, through the use of an appreciative inquiry-type process. This process generates motivation, effort and intention to change. The development of this change promotes emotional stability, capacity and

changed behaviour, leading to cognitive empathy and conflict competency. These skills and behaviour patterns are in turn transmitted to others.

## Discussion

Understanding change behaviour in abusers to become non-abusers is complex. Change behaviour theories have proposed that people can modify their abusive and destructive behaviour through a series of identifiable stages (Scott, 2004). A person can positively change their behaviour from one stage to the next or negatively change back. Scott describes and discusses an integration of stage change theories. Abusers can move from denial (abuser avoids taking responsibility for their violent behaviour by denying, minimising or blaming), to a crisis of self-recognition stage, (start to recognise their abusive behaviour and the harm it causes), then a pre-change preparation stage, (involves testing out change strategies, for example, self restraint, not reacting and jumping to conclusions, use of positive language), towards an enacting behaviour change stage (fully recognising their problem, taking responsibility and having a commitment to change and stop being violent), and finally, a personal transformational stage, (commitment to lifelong change, ability to see the bigger picture and adopt ethical and equality principles to prevent abuse).

There was evidence that prior to attending the programme, participants were on a vicious cycle of self-perpetuating abusive behaviour. They tended to have a negative view of themselves, blamed others, used controlling behaviour, and were abusive to their partners, children and others. They had developed an 'anger habit'. The participants went through a behaviour change process similar to that identified by Scott (2004). This was not easy and did not happen overnight; it involved a huge amount of effort and self-motivation and continual support from STOP. However, participants started to change their intended behaviour. Based on their self reports, this seemed to be having an effect on actual behaviour. The link between intention and action has been explored in detail by Azjen (1985). While there are detractors from some of the specific elements of Azjen's theory, there does seem to be an empirical basis to the broad link between intention to change and change itself. Indeed, this is the principle that underpins a range of public health interventions, such as smoking cessation programmes.

This study appears to demonstrate some support for the link between changed intention and changed behaviour. The participants started to develop positive life skills, such as empathy for others, taking responsibility for their actions and learning how to deal with their emotions and relationship conflict. There was clear evidence that following this change in their behaviour, this specific group were now on a virtuous cycle that improved their self-esteem, confidence, social behaviour and family relationships. Interestingly, participants discussed how they were now able to recognise anger in others. Most were now not ashamed to tell others that they had had anger issues and how STOP had helped them to manage their anger and abusive behaviour towards others in a positive way.

This positive transformation in participants' behaviour appears to be promoted by the adoption of an approach that can be characterised as a 4-D cycle approach based on an AI-type philosophy (Cooperrider and Whitney, 2005). This is in contrast to the more usual 'offence focused programme' approach to domestic violence (Integrated Domestic Abuse Programme 2005; 2008). STOP has now specifically designed its own 4-D cycles that demonstrate the negative downward spiral participants adopted prior to attending STOP and then the positive upward spiral they began to use following their attendance at STOP weekly meetings (see Figures 2 and 3).

There are inevitably some limitations when undertaking research. Participants for this study volunteered to be

**Figure 2. Relationship conflict and emotions (4-D Cycle)**

*Vicious cycle*

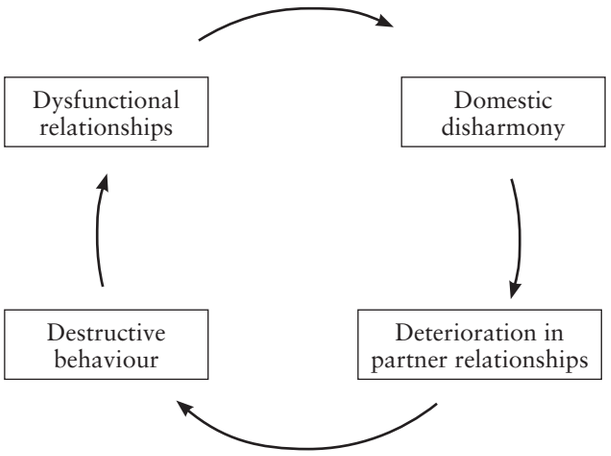
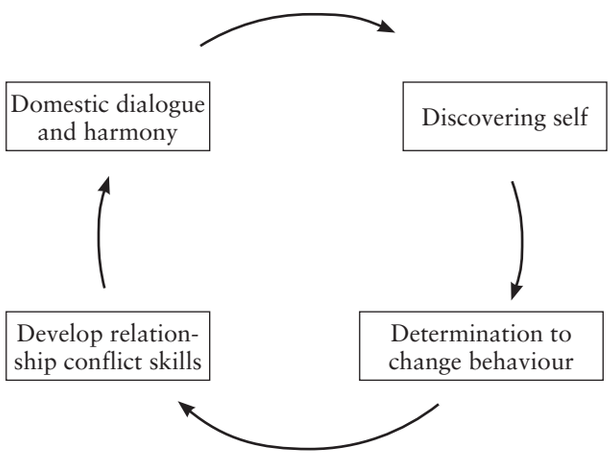



**Figure 3. Managing relationship conflict and emotions**

*Virtuous cycle*





interviewed and voluntarily attended the STOP programme. This may indicate that they were highly engaged in the process, and, therefore, more likely to be motivated to change their abusive behaviour. The demographics show that a wide range of individuals were included, and that they came from a range of referral routes.

## Conclusions

Anger and abusive behaviour affects not only the individual's health and wellbeing, but also that of their families, friends and colleagues. This has important implications for society in general and for health services, in particular. Interventions based on the theories, philosophies and tools used by STOP may be highly cost-effective and help reduce the estimated annual cost of domestic abuse and child abuse to the NHS, and the estimated cumulative costs of all public services, which is in excess of £23bn a year (Department of Health, 2005).

Effective preventative measures to reduce the potential risk of domestic violence during pregnancy and transition to parenthood are important and urgently needed. A preventative approach that can enable expectant parents to manage their emotions, behaviour and any relationship conflict during pregnancy and following birth would be a valuable tool. The second phase of this study explores a possible basis for such an approach.

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# Setting the ripples in motion

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This is the second paper in a series that aims to celebrate the contribution of academic midwives to the profession.

**Abstract**

The dominant model of maternity care in Ireland is one of consultant-led, hospitalised birth. A number of midwifery-led initiatives, such as 'early transfer home' and 'Domino' schemes have been introduced recently, in addition to two pilot midwifery-led units in Drogheda and Cavan.

The School of Nursing and Midwifery in Trinity College Dublin opened in 1996 and is now the largest in Ireland, with 1500 students and 110 staff. Midwifery programmes include the direct-entry BSc in midwifery, the 18-month post-registration higher diploma in midwifery and the MSc in midwifery. A number of midwives also register for MSc and PhD research degrees.

Personal reflections of the chair of nursing and midwifery in Trinity College Dublin are given, followed by an outline of the professor's role and contribution to midwifery research and normal childbirth, and some advice to midwives contemplating a career in research. The conclusion highlights the usefulness of all research conducted by midwives, which together contribute to improving the care given to women in pregnancy and childbirth.

*Key words:* Professor's role, normal childbirth, midwifery education, midwifery research, evidence-based midwifery

## Introduction

I am a midwife, and will always be a midwife. But I started as a nurse as one had to in those days and, after qualifying and working for nine months as a staff nurse, I joined the midwifery profession. Twelve happy years followed as student, staff midwife, midwifery tutor and research fellow before I took the step to move into third-level (colleges and universities) teaching and research. I did this because as a teacher I realised that, like dropping pebbles in a pond and setting the ripples in motion, one can do more good for more people by teaching others how to give superb care and support to women, than by just caring for one woman at a time yourself. As a researcher, I also realised that potentially one can change the care for whole cohorts of women, by demonstrating beyond reasonable doubt that a certain action, treatment or method of care is better than another. I just had to do that. Seeing research findings being successfully implemented and making a real difference to women's experience of childbirth is very satisfying, but the penalty is missing the satisfaction of giving 'hands-on' care to women, except in short bursts. Someday, I will be a full-time clinical midwife again.

## Background

There are 20 maternity hospitals or units in Ireland, 19 publicly funded and one private institution. Together they catered for 70,620 births in 2007, giving a birth rate of 16.3 per 1000 of the population (Central Statistics Office (CSO), 2009). As 44% of the Irish population now hold private health insurance (Wiley, 2005), maternity care has become


 

increasingly medicalised and consultant obstetricians are seen as the principal care providers for women in pregnancy and childbirth. The provision of community midwifery care decreased in Ireland from the 1960s onwards and, in the last decade, a number of smaller community-based maternity units have been closed down.

The dominant model of maternity care in Ireland is thus one based on consultant-led, hospitalised birth (Wagner, 2001; Devane et al, 2007). Recently, however, a number of midwifery-led initiatives such as 'early transfer home' and 'Domino' schemes have been introduced, in addition to two pilot midwifery-led units in Drogheda and Cavan. These midwifery-led units have been evaluated by a rigorous randomised trial, known as the MidU study, the report of which is due to be launched this month (Begley et al, 2009a in press).

A recent report of the independent review of the maternity services in the Greater Dublin area carried out by KPMG consultants was published in February 2009 and set out a new vision for the future model of maternity and gynaecological care. The recommendations included the development and expansion of midwifery-led units and community midwifery initiatives, stating that *'only those women with high-risk pregnancies will require an obstetrician'* (KPMG, 2009: 229). It was also recommended that this model of community and midwifery-led services should be extended nationwide. This report, together with the published outcome of the MidU study (Begley et al, 2009a), provides the evidence and stimulus needed to expand midwifery-led care throughout Ireland.

## Place of midwifery in Trinity College Dublin

The School of Nursing was opened in Trinity College Dublin in September 1996, with two members of staff, myself as head and one lecturer to run the new three-year diploma in nursing. Within three months, I had negotiated a change in name to School of Nursing and Midwifery, as we were planning to collaborate with a linked maternity hospital and validate their midwifery education programme at postgraduate diploma level. For the next six years, the school grew and developed, with 15 members of staff and 16 courses by July 2002. Very rapidly, top-up Bachelor and Master programmes were introduced for those midwives and nurses who had undertaken certificate courses in the past to educate themselves to a higher level. In the late 1990s, the postgraduate diploma in midwifery became a university-validated course, taught by midwifery tutors in the maternity hospitals and taking in qualified nurses for two years' post-registration education. The MSc in midwifery began in October 1997 on a one-year full-time or two-years' part-time basis. Some midwives were also accepted to undertake MScs or PhDs by research and three of these have been fully funded by health research board fellowships, with five others funded by competitive grants.

In 2002, the BSc nursing education programme began nationwide in all third-level institutes providing nursing education. Similarly, in 2006 the BSc direct-entry programme in midwifery started throughout the country and the post-registration programme decreased to 18 months and became a higher diploma course run entirely by the third-level sector, in conjunction with the linked hospitals. In tandem with this change, all midwifery tutors in the linked hospitals who held Master's degrees transferred into the third-level institutes. By 2009, the School of Nursing and Midwifery in Trinity College Dublin had 1500 students, over 70 academics and 30 plus support staff.

## Personal reflections

I am so lucky to have been born at the right time, and to have experienced an initial apprenticeship training, followed by advanced education. That might sound a strange statement coming from a professor of midwifery, who presumably supports the importance of third-level education for midwives (as I do, strongly). But I and my contemporaries had lots of experience as students and junior staff that one would not necessarily want students today to have, but which rapidly gave me tremendous confidence and deep knowledge and skills that could not have been achieved over a number of years working as practitioners do now, with increasing medicalisation and the rising threat of litigation.

I had experience as a nursing student of managing full wards at night, with responsibility for drug administration and intensive and emergency care that would not be permitted today. I enjoyed the drama and rose to the challenge of dealing with every emergency that came through the door. The lack of support and leadership was, of course, not ideal for either giving quality patient care or receiving an education, but I enjoyed it at the time and wish that present-day students could have some of those experiences within a controlled and safe environment.

As a student and junior midwife, I again had responsibility for the care of wards full of women, or full case-loads in the delivery suite, including 'acting up' for senior staff on a frequent basis. I experienced 'hands-on' care of women labouring with breech presentations, twins, and persistent occipito-posterior positions that nowadays often end with caesarean sections rather than vaginal births. I developed a deep appreciation of women's natural resilience and ability to birth normally when supported through labour, that maybe recently-qualified midwives today cannot develop if they work within tertiary level hospitals using active management of labour and epidurals on demand.

My luck continued as I was offered full funding to undertake the tutor's course in University College Dublin and then work as a midwifery tutor. I was able to learn through six years of solid teaching in classroom and clinical areas so that my education skills are ingrained. Nowadays, it is hard for young lecturers entering the universities to come to grips swiftly with their teaching role. Clinical teaching is time-consuming and, as research is the main area examined for promotion, and classroom teaching is the main documented form of education, it can be hard to undertake sufficient practice teaching to become skilled and confident at it.

One innovation that we have introduced in Trinity College Dublin is the employment of clinical tutors. These are

 

all qualified midwife teachers, registered as such with our Nursing (sic) Board and educated to MSc level. They have no research remit and their sole obligation is to teach. They conduct approximately 100 hours classroom teaching per year (lectures, tutorials and clinical skills laboratory work) and the remainder of the time they are in clinical practice, working alongside students, teaching and guiding them. The students appreciate the teaching they receive and the tutors love their job – a nice mixture of clinical practice and teaching. Working for a few years in that role might be a stepping-stone between clinical practice and academia for those who like doing research, want a lecturer's post but are under-confident in their teaching role. It also suits those who do not want to undertake research, but who love teaching students and make the career move into a solely teaching post.

My love of research started when I did the tutor's course and we were introduced to the research process and learnt how to read research papers. In 1983, while working as a tutor, I undertook a retrospective study of perineal trauma that led to changes in midwives' practice in the Coombe Hospital where I worked. When I repeated the study six months' later and found that the changes had saved 678 women per year from having perineal sutures (Begley, 1987), I was 'bitten by the bug' and knew that I had to continue researching midwifery practice. The next study was a randomised clinical trial comparing active with physiological management of the third stage of labour, which gained me an MSc degree through research.

After that, I knew my future had to be where research was encouraged, so I took up a post as the sole lecturer in the Faculty of Nursing in the Royal College of Surgeons in Ireland (RCSI). At that time, no entry-level midwifery or nursing programmes were taught in the universities and there were no plans for them to move from hospital schools to other institutions. The RCSI was the only place in Ireland that provided post-registration diploma courses for midwives and nurses to help them educate themselves after qualifying through a certificate programme. Again, I was lucky to be in the right place at the right time, as I had eight years there as lecturer and senior lecturer, building up the diploma courses, developing a Bachelor's degree for registered midwives and nurses and a draft MSc programme and undertaking a PhD myself. When the news broke in 1995 that schools of nursing were to be opened in all universities around the country, I was ready with the qualifications and experience necessary to develop one of those schools.

For the past 12 years, I have been leading the team that built the school in Trinity College Dublin from its initial opening position, with two members of staff and 79 students on a part-time diploma course to one where it is now the largest school of nursing and midwifery in the country, with 1500 students and 110 staff. Initially, as I was head of a school that included both midwives and nurses, and later as chair of nursing and midwifery, my remit had to cover both professions. Now, however, I have passed on the headship and am free to research solely in the field of midwifery and women's health, which is wonderful.

## The role of professor in developing midwifery education and research

A professor's role encompasses the development of both education and research. However, as there are a number of senior midwife and nurse educators in the school, and our educational programmes and systems had been well developed in the first seven years, my remit on appointment was mainly to concentrate on research development.

When I took up the chair of nursing and midwifery in Trinity College Dublin in 2004, I set five research goals to be achieved in the following five years. These illustrate the research role of the professor as I see it, which is to:

- Develop the research strategy contributing to the College's theme 'Meeting the challenges of establishing and applying new knowledge in health sciences and health management'
- Support research – both at individual and school level
- Conduct research – both as an individual and while leading groups
- Develop collaborative research
- Publish and disseminate findings.

Five years later, we have achieved all the goals set and surpassed some of them. For example, because we had taken in a large number of midwife and nurse tutors with Master's degrees who needed support to become career researchers, we had set the target that by 2010, 75% of the academic staff would hold, or be undertaking, a PhD. That target has already, in April 2009, been met. Similarly, other targets such as a 20% annual increase in conference presentations and peer-reviewed publications have also been achieved. PhD student numbers have increased exponentially, with 57 research students now registered with the school. During this time, midwifery education also blossomed, with our school chosen by the Department of Health and Children to undertake the pilot direct-entry midwifery programme from 2000 to 2003. As a result of the successful evaluation of this course, the BSc in midwifery began nationwide in 2006.

## Contribution to research and impact of author's work

The women and children's health research strand in our school is one of the most vibrant, with 13 PhD students, over €3m in funding achieved in the past six years and numerous publications emanating from the group (Trinity College Dublin, 2009). My main area of research is in normal childbirth (decreasing episiotomy rates, expectant management of the third stage of labour, midwifery-led care, fetal auscultation versus admission cardiotocography), but I also undertake funded research projects for various bodies. At present, we have just completed a national infant-feeding survey (Begley et al, 2009b) and are conducting two studies, one on the strengths and weaknesses of publicly-funded Irish health services provided to women with disabilities in pregnancy, childbirth and early motherhood. The second one is on an evaluation of clinical midwife and nurse specialists and advanced midwife and nurse practitioners in Ireland.

The impact of my research is seen most clearly in the practice areas, where midwives often approach me and


 

state that they have read my work and have implemented new ideas or approaches to care because of it. My most important publication is probably the paper reporting the 'Dublin trial' of third-stage management (Begley, 1990), as it has been commented upon across the world and is used for teaching and developing evidence-based guidelines. I hope in the future, though, that if I am remembered for anything, it is for my work on midwifery-led, women-centred care.

In the past, I have explored the experiences of student midwives (Begley, 1999) and conducted studies of assertiveness and self-esteem among student nurses (Begley and White, 2003; Begley and Glacken, 2004) and midwives (Begley and Carroll, 2005). Such research as this or other educational projects, however, are unlikely to be funded as they are not seen as priority issues. With the present pressures on university staff to obtain external competitive grants to support their research work, the amount of educational research is likely to decrease. This presents the challenge that leaders face when developing new models of education, of trying with minimal funding, to achieve high-quality educational programmes that are truly fit for purpose and are based on evidence, just as we expect our care to be.

## Career advice for midwives in research

It can be hard for midwives with experience in an intensely practice-orientated profession to know whether or not they would like a research career. The best plan is to try it out first if you are not sure. You could do a small retrospective study in your own area of practice, on a topic that you feel passionate about, and then publish it. Do an MSc degree, either a taught one that includes some element of research practice, preferably a full research thesis, or a research degree if your knowledge of research methods is good. On completion of your thesis, do not stop there, publish from your findings so that we can all benefit and learn from your work.

If you think a research career is for you, link yourself early in the process to a well-known midwife researcher who will help and guide you. Academics have a good knowledge of how and where to get funding that will help you on your chosen path. Offer to take part in a research team on a voluntary basis, as you will learn from the best researchers around. If your contribution is good, you may co-author one or more of the team's papers, which will enhance your CV. Learning to write and write well will stand you in good stead in your career as a researcher. Take every opportunity given to you; if you are asked to take on supervision of junior researchers undertaking BSc literature reviews – do it – you will learn a lot and can move on later to supervising students' research proposals and eventual studies. Try also to get some experience of teaching, either in the classroom or practice areas, as it will assist you to gain a lecturer's post in the future.

## Conclusion

To return to the concept of dropping pebbles in the water and seeing the ripples spreading out: I have seen students of mine who undertook their first literature review, with much toil, time and tears, on small diploma courses in the RCSI in the 1980s, come back to do a BSc, then a MSc and finally sail gloriously on to gain a PhD on a three-year fully-funded scholarship. In the process, they have been teaching other midwives their skills, passing on their expertise and starting their own little ripples. Every piece of research conducted by every midwife goes some way towards improving the care we all give women in pregnancy and childbirth. That is the beauty of research and the pleasure of being a professor of midwifery.

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# Obesity in pregnancy: an evidence-based commentary

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**Abstract**

*Background*. Obesity is a growing problem for women of reproductive age and about one fifth of pregnant women in the UK are obese.

*Aim*. To explore the literature and provide an evidence-based commentary on maternal obesity during pregnancy and its effects on birth outcomes. The effectiveness of weight management strategies are also reviewed.

*Findings and conclusions*. Considering the rising rates of obesity and the strong evidence for the severity of adverse outcomes of obesity in pregnancy, further high-quality research evidence is required to identify short- and long-term outcomes of weight management strategies during pregnancy. More robust guidelines for the management of weight gain during pregnancy are also required.

*Key words*: Obesity, pregnancy, weight gain, birth outcome, evidence-based midwifery

## Introduction

Obesity is characterised with excess accumulation of weight and defined as body mass index (BMI) of 30 or more (World Health Organisation (WHO), 2003). BMI is calculated by dividing body weight (kg) over height squared ($m^2$). Obesity is described as a major public health challenge of the 21st century across the globe (WHO, 2003). According to the WHO report (2003), adult obesity ranges from below 5% in China, Japan and some African countries to over 75% in urban Samoa. However, even in countries with a low prevalence of obesity such as China, there is a wide variation in the extent of the problem, reaching 20% in some cities. In the UK, 23% of the population are obese and it is predicted that more than half of the adult population will be obese by 2050 (McPherson et al, 2007). It is also a growing problem for women of reproductive age and about one fifth of pregnant women are obese in the UK (Kanagalingam et al, 2005).

## Effects of obesity on pregnancy and birth outcomes

According to the Confidential Enquiry into Maternal and Child Death (CEMACH, 2007), obesity is associated with over half of the total maternal deaths from direct and indirect causes. There is also clear evidence that it is associated with considerable adverse outcomes during pregnancy and birth. These include congenital anomalies (Watkins et al, 2003), intrauterine infant death and macrosomia, as well as an increased risk of caesarean section (CS) (Weiss et al, 2004), induction of labour, instrumental birth, gestational diabetes, pre-eclampsia, postpartum haemorrhage, urinary and genital tract infection and wound infection (Sebire et al, 2001).

Obesity in pregnancy has considerable implications for health service provision. A qualitative study of 16 maternity units in the north east of England confirmed that there was an increased health burden on maternity service providers (Heslehurst et al, 2007). There is no reliable, national information on the actual cost of obesity in pregnancy on the health services due to the complexity of contributing factors and a lack of robust, routinely collected data within maternity units. However, it is estimated that obese mothers stay in hospital on average 4.43 days longer and their babies are 3.5 times more likely to be admitted to the special care baby units than normal weight women. Therefore, it is reported that the cost of obese pregnancy care is at least five times greater than that of normal weight mothers (Galtiere-Dereure et al, 2000).

The adverse outcomes of pregnancy seem to be exacerbated by excessive weight gain during pregnancy (Guelinckx et al, 2008). This is particularly pronounced in the women who were obese before conception. Guelinckx et al (2008) in their literature review showed a positive

  

linear trend between CS and maternal pre-pregnancy BMI, which amplified in magnitude when combined with excessive weight gain during pregnancy. They included six studies to compare the CS rates in the group of women defined as obese in comparison with women who were considered to be of normal weight.

In addition to the increased risk of complications during pregnancy and birth, excessive weight gain (Öhlin and Rossner, 1995) and pre-pregnancy obesity (Soltani and Fraser, 2000) can lead to additional retention of fat and further development of obesity at the postpartum period in the obese mothers compared to those who were of normal weight before pregnancy. Excessive gestational weight gain is also associated with obesity in the offspring (Oken et al, 2007).

## Weight management strategies

Weight management strategies during pregnancy are increasingly favoured among healthcare providers and researchers in the field. In 1990, the Institute of Medicine (IOM, 1990) in the US suggested specific weight gain criteria according to women's pre-pregnancy BMI (BMI kg/m$^2$), including a gestational weight gain of 13kg to 18kg for underweight women (BMI <19.9), 11.3kg to 15.9kg gain for normal weight women (BMI of 19.9 to 26), a gain of 6.8kg to 11.4kg for overweight women (BMI of 26.1 to 29) and 6.8kg weight increase for obese women (BMI >29).

This has been recently updated (IOM, 2009) and the new recommendations for weight gain during pregnancy are based on the WHO standard BMI classifications as presented in Table 1. The IOM report emphasised that in order to achieve optimum outcomes for mothers and their babies, it is not only important for women to begin pregnancy within a normal BMI range, but also to adhere to the recommended weight gain ranges. This highlights the pertinence of preconception care and counselling for all, especially those who are overweight and obese.

Primary and secondary research evidence has reported the effectiveness of various weight management strategies during pregnancy and their impact on different antepartum, intrapartum and postpartum outcomes. In a case control study, Claesson et al (2008) studied the effects of a weight management programme on a total of 348 obese women during pregnancy. The weight management programme was aimed at minimising obese women's gestational weight gain to be less than 7kg. They showed that the weight management intervention was effective in limiting the gestational weight gain to less than 7kg, without any adverse effects on birth or neonatal outcomes.

A recent US review of the outcomes of maternity weight gain (Viswanathan et al, 2008) included 150 mostly observational research studies written in English, which were selected based on their quality and sample sizes and were published from 1990 until October 2007. They concluded that there was a lack of adequate evidence to allow an objective assessment of risks and benefits of weight change recommendations for all women collectively. They suggested that factors such as age, ethnicity and pre-gravid BMI are significantly important to be considered for designing weight management strategies during pregnancy.

Another review by Birdsall et al (2009) explored the efficacy of weight management interventions during pregnancy. Their results highlighted the challenging nature of using such interventions and that most of these studies did not show the interventions to yield any consistent trend in weight changes compared to the control group, particularly in the overweight group. Although this review lacks methodological rigour (as being a structured review rather than a systematic one), they identified a number of factors that may influence the effectiveness of the interventions including ethnicity, income status, parity, cigarette smoking, diet composition and the gestational stage at which the interventions were applied.

## Guidance on managing obesity

There is no clear guidance, especially in the UK, with regard to a safe approach in the management of obesity in

**Table 1. New recommendations* for total weight gain during pregnancy, by pre-pregnancy body mass index (BMI). Reprinted with permission from IOM's *Weight gain during pregnancy: re-examining the guidelines. Report brief* (2009) by the National Academy of Sciences, courtesy of the National Academies Press, Washington DC.**

| Pre-pregnancy BMI | BMI kg/m$^2$ | Total weight gain range (lb) | Total weight gain range (kg) |
|---|---|---|---|
| Underweight | <18.5 | 28-40 | 12.5-18 |
| Normal weight | 18.5-24.9 | 25-35 | 11.5-16 |
| Overweight | 25.0-29.9 | 15-25 | 7-11.5 |
| Obese (includes all classes) | ≥30.0 | 11-20 | 5-9 |

*The guidelines and supporting recommendations are intended to be used in concert with good clinical judgment and should include a discussion between the woman and her care provider about diet and exercise. Calculations assume a 0.5-2kg (1.1-4.4lb) weight gain in the first trimester, based on studies from Siega-Riz et al, (1994), Abrams et al (1995) and Carmichael et al (1997).

pregnancy. Women are weighed routinely at the booking visit, but regular weight measurement during pregnancy, is not recommended by the National Institute for Health and Clinical Excellence (NICE, 2008). There is, however, a growing awareness of the need for a robust clinical guidance in managing obesity and weight gain during pregnancy. Hence, several projects have been commissioned to address this highly important but sensitive issue. There has been a rapid review commissioned by NICE, which is due to be published this month. Recently, a systematic review has been awarded funding by the National Institute for Health Research Health Technology Assessment (NIHR HTA) to evaluate obesity management during pregnancy. A Cochrane protocol (Muktabhant et al, 2008) is also proposing to systematically evaluate the effectiveness of interventions for preventing excessive weight gain during pregnancy using randomised controlled trials.

The IOM recommendations (2009) have shown to be beneficial in improving pregnancy and birth outcomes, mainly from observational studies. It should, however, be noted that they originated in the US and their applicability to the rest of the world, particularly to the UK population remains to be investigated.

## Conclusion

Considering the growing rates of obesity and the clear strong evidence on the severity of adverse outcomes in pregnancy, further high-quality research evidence is required to identify short- and long-term outcomes of weight management strategies. Establishing routine standardised databases for maternity services can be a step forward for a better monitoring of this condition and its adverse outcomes.

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# Information for authors

*Evidence Based Midwifery* is published quarterly and aims to promote the dissemination, implementation and evaluation of midwifery evidence at local, national and international levels. Papers on qualitative research, quantitative research, philosophical research, action research, systematic reviews and meta-analyses of qualitative or quantitative data are welcome. Papers of no longer than 5000 words in length, including references, should be sent to: maura@redactive.co.uk in MS Word, and receipt will be acknowledged. Suitable papers are subject to double-blinded peer review of academic rigour, quality and relevance. Subject area and/or methodology experts provide structured critical reviews that are forwarded to authors with editorial comments. Expert opinion on matters such as statistical accuracy, professional relevance or legal ramifications may also be sought. Major changes are agreed with authors, but editors reserve the right to make modifications in accordance with house style and demands for space and layout. Authors should refer to further guidance (RCM, 2007; Sinclair and Ratnaike, 2007). Authorship must be attributed fully and fairly, along with funding sources, commercial affiliations and due acknowledgements. Papers that are not original or that have been submitted elsewhere cannot be considered. Authors transfer copyright of their paper to the RCM, effective on acceptance for publication and covering exclusive and unlimited rights to reproduce and distribute it in any form. Papers should be preceded by a structured abstract and key words. Figures and tables must be cited in the text, and authors must obtain approval for and credit reproduction or modification of others' material. Artwork on paper is submitted at the owner's risk and the publisher accepts no liability for loss or damage while in possession of the material. All work referred to in the manuscript should be fully cited using the Harvard system of referencing. All sources must be published or publicly accessible.

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# News and resources

**Manifesto for motherhood**

A manifesto to increase political and financial support for maternal, newborn and child health and survival, particularly in developing countries, has been created by a coalition of organisations, including the RCM.

The recommendations include scaling up financing for maternal, newborn and child health and realising the UK's international commitments on sexual and reproductive health and rights.

The report can be found at: www.rcm.org.uk/college/international/women-and-children-first

**Insect repellent may increase birth defect risk**

The use of insect repellent in early pregnancy may increase the risk of the birth defect hypospadias, according to new research.

Researchers compared 471 babies born with hypospadias (the premature shortening of the urethra that carries urine from the bladder to the opening of the penis) and 490 randomly selected babies born during the same period, and quizzed their mothers about their lifestyles and certain environmental factors, like the use of insect repellents.

After taking account of confounding factors, the authors found that the use of repellents in the first three months of pregnancy was associated with an 81% increased risk of hypospadias.

*Reference*

Dugas J, Nieuwenhuijsen MJ, Martinez D, Iszatt N, Nelson P, Elliott P. (2009) Use of biocides and insect repellents and risk of hypospadias. *Occupational and Environmental Medicine* doi:10.1136/oem.2009.047373.

**Obesity research**

The NIHR Health Technology Assessment and Public Health Research programmes are launching a joint themed call for obesity evaluation research. The research should be designed to inform NHS and/or public health decision-makers. The deadline for submission is 20 January. More information can be found at: www.hta.ac.uk/funding/themedcalls/obesity.shtml

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