Changing attitudes

Professor Della Forster describes the importance of having a wide range of clinicians with different skills and knowledge in her research team, which is exploring diabetes and antenatal milk expressing

Why is it that, anecdotally, evidence-based medicine has seemingly been overlooked in favour of the emotional fervour surrounding antenatal expressing for women with diabetes?

Clinicians are very keen to help women, and so having something that they can recommend to women which seems to make sense and seems to be unlikely to cause harm is very understandable. Some women with diabetes in pregnancy have said they feel a sense of failure, so it is a very positive thing clinically to be able to offer such women something they can do.

Is this advice dangerous to mothers with diabetes or, indeed, their children?

Advising women to express antenatally does not intuitively feel like it could cause harm I think. We know that some will be continuing to breastfeed an older child, and there is no evidence that these women labour earlier. However, women with diabetes are a high-risk group and we do not know what the effect of advising an intervention such as this could be. It may mean that their blood glucose levels drop and that this could affect the baby; it may be that some women experience contractions and then go into labour earlier than they would have; it may make no difference at all. If it is the latter, it means that they may have wasted their time doing this relatively uncomfortable practice. However, it may make a difference and lead to more positive outcomes.

How might clinicians' attitudes be changed on this issue?

Highlighting the importance of evidence-based practice is crucial. If this can be achieved, then once evidence is available it will more readily be able to be translated into practice (whatever the outcome). I think an important element of changing people's attitudes is to teach them about research. So I do things like run monthly journal clubs for the lactation consultants (LCs) at the Royal Women's Hospital (RWH) and have done so now for a number of years. It has been amazing to watch how the LCs have grown and developed in their knowledge and thinking over this time. They really do understand now that they need to carefully consider evidence, and that just because something is published does not mean it is necessarily true. They now read the 'Methods' sections of papers, and critically review the tables and participants, etc. Likewise, colleagues and I regularly run one-day workshops about research at various conferences, and this really raises people's awareness and knowledge.

Your team comprises investigators at RWH and Mercy Hospital for Women (MHW). How did this network form, and what have been the benefits of sharing expertise in this way?

We have included researchers from all the relevant disciplines in an effort to ensure the success of our trial. I have a strong belief in and commitment to undertaking research in teams, as without the relevant players I think research is often lacking in key aspects. It is important to have content expertise, research expertise and key stakeholders involved, and this differs according to the project. So in our diabetes and antenatal milk expressing (DAME) trial, for example, we have an obstetrician, paediatricians, midwives, LCs, a GP (who is an LC and expert in breastfeeding research), diabetes educators, a health economist and a statistician.

In terms of how this specific group came together, in part it is a reflection of my own clinical and research journey – I have worked at both the RWH and MHW, and have worked previously with many of the team. This points to the benefits of continuing to have a clinical role while developing and maintaining a research career.

What is the likelihood of setting up further study sites in the UK or New Zealand, and how might geographical, socioeconomic and cultural difference impact on results?

As a team, we have had initial discussions about overseas sites in the two countries where antenatal expressing is as widespread as it is in Australia. We are not yet sure if we will go down this path as there are a number of issues. One is that there may be differences in the rates of breastfeeding – although this would not have such an impact, as all randomisation is first stratified by site, to ensure equal numbers of the two trial arms at each site. Bigger issues would be different guidelines about when infants get admitted to the special or neonatal intensive care nurseries, as well as ensuring the rigour of the trial processes at distant sites. The other major issue for opening up trial sites in other countries is funding. With RCTs, as with most quantitative designs, it is really important that where possible all potentially eligible women are identified and approached for participation. This requires a paid research midwife to be at each site to undertake this process, which can be costly.

Where is the evidence for expressing?

An **Australian research team** is working on understanding the effects of antenatal milk expressing by women with diabetes in pregnancy. The widespread practice has no supporting evidence and small studies have indicated that the process may have some risks

DIABETES IS A growing issue in much of the world, and affects the lives of millions of people. But perhaps less well known are the problems associated with diabetes in pregnancy. Women in this situation may have difficulty producing early milk, known as colostrum, for their newborn babies. Compounding the issue, babies of women with diabetes in pregnancy may be smaller (or larger) than average and have a greater risk of hypoglycaemia (low blood sugar) than others.

If newborn babies cannot access their own mother's milk there are three options open to their parents and clinicians: to use donor milk, infant formula or intravenous glucose. The first is by far the preferable option because the proteins in formula are from cow's milk and notably different from their human counterparts, therefore most hospitals with access to donor milk will use this source in appropriate situations. Unfortunately, however, the infrastructure for the supply of donor milk is often poor and many areas are without a donor milk bank. This means that mothers who are having difficulty producing colostrum must feed their babies with formula. The wall of the infant's gastrointestinal tract (GIT) is still developing after birth and is highly sensitive. It is now known that cow's milk proteins can cross the infant GIT, causing diabetes and other ill-health effects. As a result, the World Health Organization (WHO) recommends that newborn babies should, wherever possible, be fed by breast milk alone.

It has become common practice for clinicians to advise pregnant women with diabetes to express milk from some time in the last trimester of their pregnancy in preparation for the arrival of their babies. The immunoglobulin- and protein-rich colostrum is then frozen. The benefit of such a practice is that if milk is not available directly from the infant's own mother in the immediate time following birth, the previously expressed colostrum can be fed to the infants. This avoids the well-understood and negative effects of formula. Intuitively this seems to be a beneficial practice and it is likely that many pregnant women welcome the ability to perform a positive and preparatory process in a situation that they have little control over. However, expressing breast milk during pregnancy is not grounded in evidence, and there is some evidence that it may actually trigger early labour and an increased risk of illness in the infant.

FEASIBLE AND IMPORTANT

Considering this situation, the need for a trial to elucidate any effects, either positive or more worryingly negative, was clear. It was this need that prompted Professor Della Forster from Mother and Child Health Research at La Trobe University and the Royal Women's Hospital in Australia to conduct a small-scale pilot study along with her team back in 2008. The pilot study (conducted at the Mercy Hospital for Women) included 43 pregnant women with diabetes in pregnancy who required the use of insulin. While the sample size in this pilot study was too small to make any firm conclusions,

DIABETES & ANTENATAL MILK EXPRESSING (DAME): A RANDOMISED CONTROLLED TRIAL

OBJECTIVES

To establish whether, compared to standard care, the practice of antenatal breast milk expressing from 36-weeks gestation for women with diabetes in pregnancy: increases the proportion of infants who require admission to the special or intensive care nursery; decreases the mean gestation at birth; and increases the proportion of infants receiving exclusive breast milk at three months of age; increases the proportion of infants receiving exclusive breast milk during the hospital stay after birth.

KEY COLLABORATORS

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Women bring their own expressed milk to hospital ready for their baby when it is born, if the baby needs extra milk.

it did serve to highlight questions that need answering and also support the feasibility of a large-scale randomised controlled trial.

Five of the 43 participants from the pilot study experienced Braxton Hicks contractions (tightening of the womb) as a result of expressing, and one participant ceased the practice due to this. However, the majority of the participants were happy with the process. Despite the willingness of 95 per cent to continue expressing and repeat the process with future pregnancies, the pilot results suggested that infants of mothers who expressed were more likely to be admitted to special care nurseries or neonatal intensive care than infants of similar mothers who were not advised to express. Spurred on by the need to confirm their results, Forster and her team sought funding for a large-scale study from the National Health and Medical Research Council (NHMRC) of Australia and were successful.

DAME

Forster's group is now conducting the diabetes and antenatal milk expressing (DAME) randomised controlled trial: "The main objective of the DAME trial is to provide evidence about the safety and benefits of advising women with diabetes in pregnancy to express breast milk from 36-weeks gestation onwards," identifies Forster. The trial is relatively unusual as it is an analysis of the benefits of a practice already relatively widespread. Whilst it continues, Forster and her colleagues have recommended that clinicians do not advise women with diabetes in pregnancy to express breast milk before birth. This recommendation has met with some opposition and surprise in the community; highlighting the difficulty of communicating new research-based knowledge relevant to an already widespread practice. Once the results are analysed, any changes in practice would require a widespread dissemination process: "We design all our research with dissemination in mind," acknowledges Forster. "In this particular study, I think it is even more important than usual given the current widespread nature of this untested practice."

The current trial consists of 658 pregnant women with diabetes in pregnancy. The participants are being recruited from the Royal Women's Hospital and Mercy Hospital for Women, both of which are in Melbourne. Another Melbourne hospital – Monash Medical Centre at Southern Health – has also recently signed up, and the team is looking at the feasibility of including hospitals from further afield in Australia, New Zealand and the UK. This time, the number of participants will be sufficient to generate the statistical power needed to provide firm conclusions.

The trial is designed to answer a number of central questions. First and foremost is the need to quantify whether expressing increases the likelihood of infants being admitted to special care nurseries or neonatal intensive care. Secondary aims include exploring whether the practice causes earlier labour, or conversely if it increases the proportion of infants who are able to receive breast milk exclusively.

The team understands the importance of elucidating risks, whether that understanding comes after clinical implementation (not the preferred option) or during the development of a new technique or practice

OVERCOMING BARRIERS

While the design of the study is relatively simple and based on observation, the researchers have had to overcome considerable hurdles: "The most challenging aspect of the trial is finding adequate numbers of eligible women to offer trial participation," highlights Forster. The number of women with diabetes during pregnancy is increasing, but only 35 per cent of the women who have been approached by the team have agreed to take part. Forster and her colleagues have also had to cope with the considerable scepticism from the clinical community that such a trial is needed at all, although they are making some progress in overturning this attitude: "At a recent conference for lactation consultants, there was a sense in the room that some people were thinking they should wait until they hear the results of the DAME trial before introducing the practice," she notes.

Despite the reluctance of some clinicians, the team understands the importance of elucidating risks, whether that understanding comes after clinical implementation (not the preferred option) or during the development of a new technique or practice. The research group wants their work to inform future practice in this area, and the study will stand alone as having the statistical power to form useable conclusions and hence recommendations regarding expressing antenatal milk. Regardless of the results, such an analysis is important, perhaps more so than a similar analysis of new practices, and may point the finger towards other medical recommendations with no evidential grounding.