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The truth behind the NICE guidelines on caesarean section

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Having been involved with the process of devising the NICE (National Institute for Clinical Excellence) guidelines on caesarean section (CS), I believe they have a lot to offer. But we need to look below the surface, to understand the limitations of the research it is based on and to realise what it does not say as well as what it does.

It is undeniably a valuable resource, not least because it has a reference list of 688 papers pertaining to CS. However, the guidelines have a number of inherent weaknesses.

The process of developing guidelines involves setting questions concerning details within an already agreed-upon scope. Researchers then take these questions and search the scientific literature for evidence-based answers.

The Guideline Development Group (GDG) constructed a vast list of interventions and outcomes, along with variables that could affect them. Problems arose when the research literature was unable to answer our questions. In fact, very few could be answered. Consequently, recommendations were made based on what answers were found and, in most cases, the guidelines offer no indications for what was not answerable, despite the fact that the GDG had considered these issues to be important.

Although there are a number of research recommendations in the guidelines, they only go a small way towards bridging the gap between what is known and what the GDG would have liked to know. Often, therefore, when a risk or potential benefit is mentioned in the guidelines, there is no mention of not knowing whether certain factors and/or awareness of potential issues could be important in decision-making. For instance, there is a recommendation not to use routine closure (putting the fat layer back together) for the subcutaneous tissue space as it does not reduce the rate of wound infection. However, there is no mention in this recommendation of what anyone on the GDG felt may be other important, related issues. In this case, there is anecdotal evidence from women about having a dip under their scar which could be due to an unrepaired layer of fat but, as there have been no studies of such cosmetic effects - something that may be very important for some women - this is not mentioned in the guidelines.

Another problem was the various levels of evidence. Within the hierarchy of evidence, RCTs (randomised controlled trials) are at the top of the pecking order. When an RCT was found on a topic, it meant that the search for answers to other questions on the same topic, such as looking at different outcomes,

differences in application of the intervention under consideration or different sample groups, was not undertaken. This led to the problem (discussed later) in the recommendation about birth centres.

There were administrative problems in keeping track of what was happening to the draft guidelines during development. There was no version management in place, and we were unable to properly track the changes being made. So, when a new version was sent to GDG members, we had no idea of what may have changed from the previous version. When you consider that the final document was over 100 pages long, and that frequent revisions were being made to many of its parts - sometimes only a few weeks after the previous set of revisions had been received - focusing attention in the right places was virtually impossible.

Changes were also made without consulting the GDG. For example, I know that comments I made outside of meetings led to changes that other GDG members were most likely unaware of. It was also not uncommon to go back to something that had been agreed on or accepted, only to find that the wording had been changed again and was now unacceptable.

The choice of the key recommendations was initially done in haste and, hence, did not include a GDG discussion. Key recommendations were important because they would receive greater publicity and have their implementation audited. Therefore, selected recommendations went through several changes, but GDG discussion did not precede all changes, and some recommendations were added and removed several times. One that was lost as a key recommendation in the final document was to inform women about home birth and the reduction in the incidence of CS; suspicions have been voiced as to the reasons behind this omission.

Nevertheless, despite the weaknesses, the guidelines also have strengths. They gather together a large amount of research on the subject, providing an excellent springboard for further consideration of the issues. Indeed, some of the well-established information will be drawn to the attention of all medical professionals involved in maternity care, and made accessible to the general public. This should start to address many of the myths surrounding surgical birth that often mislead women when making decisions relating to childbirth. If implemented fully, the guidelines should place many decisions into the hands of the women it affects. It is hoped that they will make the general population aware of the fact that a caesarean birth is not an "easy option", and that it is not without its risks. However, to achieve this, the media have to read what has actually been written, and not make up their own versions in the way they did when the guidelines were launched.

What do the guidelines say, and where do the problems lie with some of the recommendations made?

Chapter 3: Woman-centred care

All of the recommendations in the document need to be considered within the context of the recommendations made in this chapter. The guidance in this chapter alone, if implemented fully, would improve women's control over childbirth. It underpins a woman's right to refuse treatment, including CS, even when it would "clearly benefit her or her baby's health".

The classification of CS urgency is covered here. The terms 'elective' and 'emergency' are confusing. 'Elective' is seen by some as a CS done without a medical basis, as the woman's 'choice', while 'emergency' muddles the crisis situation with the unplanned CS. NICE has introduced a four-stage system of classification to provide a better understanding of the true situation. Women should be able to ask what classification their situation is and, if requested at the time, may give them a better idea of their real options, should a CS be offered for a problem in labour.

Chapter 4: Planned CS

Recommendations are all phrased such that a caesarean should be offered to the woman when there is thought to be clear benefit. Taken in the context of the previous chapter's recommendations, the woman should also be able to decline the offer. Bullying (including emotional blackmail) at this point can be considered to invalidate any consent obtained.

When do the guidelines recommend that a CS be offered? Some circumstances, such as placenta praevia, are straightforward. But many need to be considered in the context of the information on which they are based.

Offering CS in cases of HIV infection is recommended, but new developments in treatments may change the risks. The guidelines do not suggest CS for hepatitis C, unless there is co-infection of HIV, or for hepatitis B, provided the baby receives immunoglobulin and vaccination.

CS is recommended for herpes infection, but only if the primary infection was during the last trimester. Although the evidence is flimsy and not statistically significant, the seriousness of disease transmission led to the recommendation for offering CS: "Despite limited evidence, the high mortality associated with neonatal herpes means there is consensus about current practice for primary infection." In the rest of the guidelines, this level of evidence would have been referred to as "no evidence". We may also ask, "Whose consensus?" Women are likely to be told that CS reduces the risk, or even that it prevents transmission, the implication being that a vaginal delivery will mean their baby will be infected. But research shows that, although transmission rates are high (13 out of the 36 cases of primary infection), it is not inevitable, and there are no comparative data for the rate of infection after CS in such cases.

Breech births continue to be contentious; the guidelines state, "The majority of the information ... comes from one international multicentre RCT, which is of good methodological quality" - and therein lies the problem. There are, in fact, some serious issues about this trial related to the fact that it was based on delivering breech babies vaginally, there were no naturally born breech babies in the study and a number of women crossed over from their randomised treatment to the other group.1

Another question is the additional risk that a CS passes to a future pregnancy, referred to by Professor James Walker. However, mothers often claim that, although the evidence led them to opt for a vaginal birth, they ended up with a CS because of a lack of suitably experienced health professionals. If women are to make an informed choice, then the option of vaginal birth needs to be properly supported.

The guidelines do not recommend CS for multiple pregnancies, preterm or small-for-gestational-age babies without other complications. However, it does recommend CS for multiples with a first twin breech, but this is based solely on the research from singleton babies.

The media's favourite recommendation - on maternal requests - was so misquoted as to prompt NICE to make a clarifying statement at the end of July, which was itself misreported as a U-turn when, in fact, no such change had been made. There was never a call for the NHS to refuse women's requests for CS, as was reported.

The recommendations actually state that maternal request is not an indication for CS, and the reasons behind the request should be "explored, discussed and recorded"; that in the absence of an identifiable reason, the risks and benefits should be discussed; that childbirth fears should be addressed by counselling; and that a clinician has a right to decline the request - but also that the woman's decision should be respected and that she should be referred to someone else.

There is little evidence that there are many women who would opt for a caesarean without a medical reason. But I and others suspect that the vast majority are only trying to avoid some of the risks, trauma and degradation that can go with a vaginal delivery in the NHS, and many more may be requesting CS on the misunderstanding that it is advised.

Chapter 5: Factors that may influence the incidence of CS

The first recommendation considers home birth, stating that women should be informed that *'delivering* at home [my emphasis, as the CS rate at home is zero!] reduces the rate of CS"; the data actually showed that *booking* a home birth reduced the CS rate, and that booking for a hospital birth compared with a home birth doubles the incidence of CS.

The recommendation for birth in midwifery-led units has raised an outcry. The information was based on units attached to, and staffed by, large hospitals, and focused on the surroundings rather than the sort of care - the best available research according to the evidence hierarchy. These findings are not comparable with those from birth centres around the country but, sadly, the same level of evidence from this sort of

unit was not available. The better results from stand-alone units were also not acknowledged, though there is a research recommendation to look at the outcomes of this sort of unit.

The guidelines acknowledge that support by a female companion and involvement of a consultant obstetrician in decision - making reduce CS incidence, while electronic fetal monitoring (EFM) increases it, and fetal blood sampling (FBS) should be used to minimise this increase. The recommendation for induction at 41 weeks comes from the Induction Guideline, with no consideration of this by the CS GDG.

The recommendation "A partogram with a four-hour action line should be used" as it reduces the CS rate is a misinterpretation of the research. One paper compared a partogram with a four-hour action line with no partogram, but did not report on CS rates; another that showed a difference in CS rate compared different action lines, where all the women had partograms (no controls). What this recommendation should say is, if a partogram is used, then a four-hour action line reduces the CS rate. The recommendation also omits the word 'offered' despite the invasive procedure of cervical dilation for assessment.

Chapter 5 concludes with a list of 'interventions' shown not to influence the likelihood of CS, such as "walking in labour" and "non-supine position during the second stage of labour". The fact that these are seen as interventions is disturbing. Furthermore, the research on walking referred to "ambulation", conveying the feeling that the women were marched around in circles rather than being about facilitating freedom of movement in labour.

Chapter 6: Procedural aspects of CS

Although it is acknowledged that "Techniques may need modification in situations such as repeat CS ...", at no point in the guidelines is any consideration given to whether the risks of subsequent caesareans are any different from those of the first CS.

There are also 10 recommendations on anaesthesia and 21 operative techniques, ending with the recommendation, "Women's preferences for the birth, such as music playing in theatre, lowering the screen to see the baby born, or silence so that the mother's voice is the first the baby hears, should be accommodated where possible." Interestingly, with the late reordering of the guidelines, the information about the incidence of fetal laceration at CS has been placed solely in this chapter, and does not feature as a risk to the baby.

Chapter 8: Care of women after a CS

This chapter includes observations required following anaesthesia and analgesia. The recommendations on pain relief are extremely limited, and not within the context of what is normally available and used.

How different the lay and medical viewpoints can be was evident in the issue of women receiving food and drink after a CS. With no evidence to stop women receiving either food or drink if they felt well, I was subsequently shocked by the draft recommendation: "There is not enough evidence to evaluate early

feeding after CS" and "Feeding after CS should be individualised". I pointed out that "babies and animals are fed - women eat and drink". The recommendation was then reworded as: "There is insufficient evidence to support the restriction of food and drink after CS. Women who are recovering well and who do not have complications can eat and drink when they feel hungry or thirsty."

Chapter 9: Recovery following CS

This recommends that women be provided with specific care related to recovery after CS (but makes no reference to what this might be). It also suggests different pain relief from that considered in the previous chapter, and makes no distinction between immediate postoperative pain relief and that in the later recovery period. It recommends monitoring for fever, signs of wound or urinary infection, and a warning that irregular bleeding post-CS is more likely to be caused by infection than "retained products of conception".

There is a recommendation to inform women who have a CS that they are not at increased risk of difficulties with breastfeeding, depression and post-traumatic stress disorder (PTSD) - true only if you look at longer-term studies. It is wrongly concluded that if the rates have levelled out after a number of months, then no harm has been done. Yet, more women have problems in the early days. Regarding breastfeeding, the number of babies deprived of early breastmilk will be significant, with long-term health implications.

Comparisons were made between CS and all vaginal deliveries. This was particularly true with PTSD. However, the same results tell a different story when divided into CS, spontaneous vaginal delivery (SVD) and operative vaginal delivery, with the lowest incidence of problems for those that had a SVD, followed by CS, and the highest incidence among those who had a forceps or ventouse delivery.

Conclusion

The value of having consumers involved in the development of guidelines goes beyond the content. It provides an insight into the process, the strengths and weaknesses, the inclusions and what is left out. This wider perspective may enable consumers to benefit from such publications, rather than just be dictated to by them.

There are several versions of the guidelines: the complete document includes explanations; the Quick Reference Guide, for health professionals, contains only the recommendations; and there's a version for women. All are available as printed versions, but they can also be downloaded, at no cost, from the NICE website: www.nice.org.uk/CG013.

References

1. Robinson J. Breech babies: caesarean or vaginal birth? AIMS Journal, 2000; 12 (4)