

**National Institute for Health and Clinical Excellence**

**Caesarean Section (Update)  
Scope Consultation Table  
24 February – 24 March 2010**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	A Little Wish	1	2	The remit is for 'evidence based guidelines'. As the department of health and others do not gather all the evidence and decline to keep information and statistics on certain areas we find that this remit is prejudice and discriminatory to vital and necessary changes and outcomes.	Thank you for your comment. The evidence that we review is evidence of best treatment, clinical management and care taken from published literature, rather than specific performance-related statistics held by the Department of Health. As NICE is commissioned by the Department of Health, we are not in a position to change the remit of the guideline. However, we will consider all of the comments received during the scope consultation when determining which specific clinical questions and outcomes to consider
SH	A Little Wish	2	3.1b	Another section that is again being largely underestimated is the scaremongering of doctors. Many women plan a vaginal birth, however they are informed by the doctors that they will kill the baby if they give birth (an independent option states that the information was inaccurate) or that the risk of the uterus rupturing after a previous extraction is inaccurately given as 96%! Generally this is then selected as 'mothers choice' when it is not their choice at all.	Thank you for your comment. We plan to update the guideline sections on VBAC and the table summarising risks associated with caesarean section and vaginal birth. We plan to include hysterectomy as an outcome and, where possible, will make recommendations for practice based on the best available evidence. Also we are including a question about maternal choice and tocophobia.
SH	A Little Wish	3	3.1c	It is noted that mortality risk is increasing, however so is the occurrence of a post pregnancy hysterectomy. We note the statistic for maternal mortality is given but not the post pregnancy hysterectomy statistic.	Thank you for your comment. We assume that by the phrase "post pregnancy hysterectomy" you mean hysterectomy during a caesarean operation ('obstetric hysterectomy'). We apologise if this is not the case. This issue will be addressed when we

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					update Table 3.1 from the original guideline looking at the risks and benefits of caesarean section vs. vaginal birth.
SH	A Little Wish	4	3.2	'inadequate labour progress' is given as a clinic factor. As so many women are given a time allowance for labour, the mother and child are not allowed to progress at their own pace this is causing unnecessary extractions. Time restrictions should be removed and each treated as an individual and unique.	Thank you for your comment. The NICE Intrapartum Care Guideline gives guidance on appropriate care during labour, including prolonged labour, as agreed by the guideline development group based on the evidence reviewed. This states that progress should be based on assessment of multiple factors including rate of cervical dilatation, descent and rotation of the baby's head and the strength and frequency of contractions. This places no time restrictions on the length of labour and encourages individualised, comprehensive assessment as you suggest.
SH	A Little Wish	5	4.3.2c	The scope states that the consent for an extraction will not be updated. As inadequate consent for this operation which can have devastating, irreversible consequences (for example a post pregnancy hysterectomy) we urge this to be reconsidered. We find that the average women has a chat with 'a doctor' (about 10 – 20 minutes) where uninformed consent is obtained for the extraction of. This may be considerably less if the extraction is unplanned. However if the woman in question is a medical negligence solicitor she has a planned meeting with the doctor who will operate AND the anaesthetist to discuss all aspects of the operation to obtain informed consent. This discussion takes three hours! We do not find the discrepancy acceptable. Every woman has the same right to decide how the operation is to be carried out and to protect her body, her quality of life and her future children. As every extraction can have consequences and/or end	Thank you for your comment. Unfortunately we are not familiar with the term "extraction" used in this context and can only assume you mean birth by caesarean section. We agree that informed consent is an extremely important area. However, it was not felt to be necessary to update this section of the guideline as the current recommendations are appropriate. They currently state that "When considering a caesarean section there should be discussion on the benefits and risks of caesarean section compared with vaginal birth specific to the woman and her pregnancy". The guideline also recommends that this discussion needs to be based on evidence. This evidence is provided in a risk table in the guideline (Table 3.1) which we intend to update in the new version of the guideline. The increased risks of hysterectomy associated with caesarean section are stated in this table.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row.	Please respond to each comment
				in a post pregnancy hysterectomy informed consent is vital, and all outcomes and risks of an extraction should be explained and sought during pregnancy.	
SH	A Little Wish	6	4.4b	A post pregnancy is not listed on the possible outcomes.	Thank you for your comment. We are not sure what you mean by "a post pregnancy". From your other comments it seems you may mean hysterectomy. This outcome will be reviewed where it is considered by the guideline development group to be a key outcome and will be included in our update of the risks and benefits of CS table (Table 3.1).
SH	A Little Wish	7	General	<p>It is of grave concern that following the workshop for the scope consultation that post pregnancy hysterectomy is again ignored. One of the first questions was about post pregnancy hysterectomy.</p> <p>A representative from the department of health stated that post pregnancy hysterectomy needs to be included.</p> <p>A representative from the NPEU stated that post pregnancy hysterectomy needs to be included.</p> <p>Others also raised the outcome of a post pregnancy hysterectomy.</p> <p>Since 2000 *a little wish* has been trying to create changes that are vital to the quality and quantity of women's lives and their families. When a post pregnancy hysterectomy is performed it needs to be a legal necessity for it to be reported. There should also be an independent enquiry that the patient has a direct part of and to see what the problems are to be addressed. We know that doctors are allowed to operate on women without adequate training. Victims are told everything was done to try to save the uterus, however when victims ask why certain techniques were not used, doctors often reply that</p>	Thank you very much for your comment. Following stakeholder consultation we now plan to update the risks and benefits table summarising these for caesarean section vs. vaginal birth. This will include hysterectomy as an outcome and will form the basis of information that needs to be given to women as part of the process of giving informed consent. In addition the question looking at the effectiveness of care for women who have a morbidly adherent placenta will include hysterectomy as a key outcome and recommendations made will include care of women who have had a hysterectomy where this is possible based on the evidence. It is very much hoped that this guidance will help to promote high quality care for this group of women.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				<p>they choose not to use them!! We know one of the excuses is that there are no statistics to prove the scale of the problem and that is not acceptable as a) is the responsibility of bodies such as yourselves who are not making it compulsory b) does not help the victims that are being created year after year.</p> <p>A Summary of current practice examples After a post pregnancy hysterectomy</p> <ul style="list-style-type: none"> <li>- a victim may be dumped on a ward after a few hours to fend for herself and a new born baby with only a few paracetamol for pain relief</li> <li>- a victim may not be given any help to feed or change the baby even though she is not supposed to lift a kettle for 6 weeks (not all are helped on a ward or have any help when they return home)</li> <li>- a victim is refused knowledge of who the doctors are that carried out the operation.</li> <li>- a victim is refused to meet with those involved in the situation.</li> <li>- a victim may be told to stop crying as it only a lump of flesh that has been taken</li> <li>- a victim may be told to be a childminder if she wants more children</li> <li>- a victim may be given exercises to help her uterus contract</li> <li>- a victim may be given information about contraception</li> <li>- a victim may be told there is no help available (all hospitals have been given *a little wish*s details however they refuse to give out our details in favour of contraceptive information).</li> </ul> <p>How victims are dealt with after the operation varies</p>	

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>greatly and standardised care needs to be incorporated and paid for. Most victims are very upset that money is there for hysterotomy and hysterectomies that they did not need or want and often refuse consent for, but no money is there for help for the 3 months or so basic recovery, if people are lucky! (Real recovery takes many years, and for some there will never be a full recovery.) Money needs to be there for 24 hour care for at least 6 weeks whilst victims should not be lifting a baby. Elective hysterectomy patients are advised to rest. How is a new mum with a baby, or twins, or other children at home supposed to rest or not lift?</p> <p>The risk of a post pregnancy hysterectomy is greatest after an extraction, so this needs to be incorporated here. Too many people who walk into hospital even for a planned extraction with a 'virgin uterus' are leaving without their organs.</p> <p>This horrific and irreversible outcome needs to be urgently and correctly addressed, ignoring the problem and the victims is and never has been acceptable.</p> <p>PLEASE do not respond with policy and guidelines prevent the above from happening as the victims tell us what is happening.</p>	<p>Please respond to each comment</p>
SH	Association for Improvements in the Maternity Services (AIMS)	1	3	<p>CURRENT PRACTICE "an issue of choice for women as a preferred mode of delivery". Where is the evidence for this statement? We are concerned at the number of reports we have from women, midwives, and antenatal teachers, that hospital records show reason for CS as "woman's request" when the woman reports a different scenario. The</p>	<p>Thank you for your comment. When we wrote this section, the phrase "issue of choice" was meant to indicate that debate continues around the matter of maternal choice, as indicated by your comment and that there is inconsistency across different trusts as to how this is being applied. We agree that women's choice, fear of childbirth and VBAC are important</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>number of possible indications for which a CS may be recommended to the woman appears to have increased.</p> <p>The women who ask us for help in obtaining a planned caesarean are doing so to reduce risk of damage to their mental health and bonding. The majority are doing so to avoid a repetition of a previously traumatic birth - often painful induced labour culminating in emergency CS. On examination of case notes we believe in many cases both trauma and CS could have been prevented with different management. Some other similarly traumatised women ask for a home VBAC. Both types of request may receive an unsympathetic response, though only the latter risk being reported to social services for causing potential damage to the unborn child.</p> <p>The increase in emergency sections to which you refer may have contributed to an increase in caesarean requests at the next birth . Our experience is echoed in the prospective study of Gamble and Creedy (1) and their literature critique (2)</p> <p>There are also some of our contacts with a history of sexual abuse or rape who feel an elective section would be the least traumatic birth for them. Such history is not necessarily revealed to the NHS since there is now no possibility of restricting the information to one trusted professional and such cases are now automatically reported to social services, with invariably damaging outcomes to both women and children in our experience. (A study of outcomes of such referrals would be most welcome). Therefore requests for caesarean birth should be sympathetically heard , although information on</p>	<p>Please respond to each comment</p> <p>issues and following stakeholder consultation all will now be included in the guideline update.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>outcomes and possible alternatives should be offered.</p> <p>Quality and availability of midwifery care is a crucial factor in reducing the caesarean rate, and both continuation or worsening of the current shortage in many hospitals could prevent reduction or cause an increase. We find some women seem more fearful of normal labour after hearing accounts from friends of lack of care and support in busy units. This may affect their preferences, but a caesarean "choice" or acceptance may be the result of reduction in the availability of good care for normal birth.</p> <p>.</p> <p>Among reasons for increase in CS you mention "the safety of the lower uterine segment technique". It is not "safe"; it is a lesser risk. There is a difference.</p> <p>Women who want a VBAC are invariably warned of the risk of uterine "rupture" - which sounds dramatic. Dehiscence or partial separation of the scar should also be explained.</p> <p>.</p> <p>(1) Jenny Gamble &amp; Debra Creedy (2000) Women's preference for caesarean section. Incidence and associated factors. Birth 27(4): 256-263  (2) Jenny Gamble &amp; Debra Creedy (2001) Women's request for a caesarean section: a critique of the literature. Birth 28 (2): 101-110</p>	<p>Please respond to each comment</p>
SH	Association for	2	4.3.1a	Colour-flow ultrasound. We agree that this would be	Thank you for your comment. The potential risks

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
	Improvements in the Maternity Services (AIMS)		And b	<p>Please insert each new comment in a new row.</p> <p>a possibly justifiable use of US if it is found to be (a) effective for diagnosis and (b) to improve outcomes for morbidly adherent placenta. However, we remain concerned at the lack of data on safety of exposure for the fetus, with possible long term effects, and we think that investigation of effects of ultrasound (which has increased in intensity and frequency of use) on children is long overdue. What are women to be told in order to obtain valid consent? There is already sufficient research data to demonstrate that telling them it is "safe" (as often currently happens) cannot be justified</p> <p>Morbidly adherent placenta is not on the list of risk of CS in the guideline, and this should be included.</p>	<p>Please respond to each comment</p> <p>associated with ultrasound have been well researched and have shown ultrasound to be acceptably safe. We are unaware of new evidence on long term effects thus we feel it does not merit inclusion at this time.</p> <p>We will add risk of morbidly adherent placenta to the risk table as you suggest..</p>
SH	Association for Improvements in the Maternity Services (AIMS)	3	4.3.1e	<p>Outcomes for planned VBAC or repeat section. We hope this will include women who have had more than one previous section.</p> <p>As with many outcome measures, maternal mental health (including post-traumatic stress reaction or PTSD) is frequently omitted from the list. In this case, we think it essential. In 6 week post-natal checks, women should routinely be asked questions about nightmares or flashbacks. Identification of the problem and appropriate treatment might well reduce future requests for caesareans.</p>	<p>Thank you for your comment. When reviewing for planned caesarean section or vaginal birth after caesarean section we will include sub-group analyses for women who have one vs. more than one previous caesarean section where possible/appropriate.</p> <p>We agree that women's mental health is an important outcome and will be included where possible (i.e. depending on what the reviewed studies report).</p>
SH	Association for Improvements in the Maternity Services (AIMS)	4	4.3.1d	<p>Optimum decision to delivery interval. Looking at our cases where problems have arisen, they include those where there was clearly cause for urgency, but somehow priority did not follow. They seem to have got lost in the system, and the solution is therefore systemic. Whatever the optimum delivery interval or the degree of urgency, action has to smoothly follow the clinical decision.</p> <p>In other cases (often correlating with PTSD outcomes) women knew there was real trouble, but</p>	<p>Thank you for your comment. In light of stakeholder comments the topic of decision to delivery interval is not included in the scope for the update. As you rightly point out it isn't deciding the time interval that is the issue but rather clinical practice surrounding decision-making and communication with women. Recommendations regarding decision-making and communication with women in labour are made in the NICE Intrapartum Care guideline. We agree that emotional care of parents should be an integral</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**



Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. no one would listen - maybe because of staff shortages, but also often because of staff attitudes. And in order to reduce serious and damaging mental health outcomes following such emergencies, emotional care for the parents has to be an integral part of the care.	Please respond to each comment component of care and the recommendation in the Caesarean Section guideline states that women should be given the opportunity to discuss with staff the reasons for the caesarean section and implications for future births.
SH	Association for Improvements in the Maternity Services (AIMS)	5	4.4b	As outlined in our Point 3 above, post-natal maternal mental health check should include questions on nightmares and flashbacks, as a quick indication of likely trauma reaction, to be followed up with appropriate referral if necessary. The effects on quality of life and marital breakdown rate are too serious for this to continue to be ignored.	Thank you for your comment. Postnatal mental health is included in the NICE Antenatal and Postnatal Mental Health guideline and falls outside the scope of the caesarean section guideline as it is not specific to caesarean section.
SH	Association for Improvements in the Maternity Services (AIMS)	6	4.3.2c	Breech presentation is included in the list of areas not to be revised. We would like it to be looked at. New material on longer term outcome of the breech trial has become available since the guideline was published. The availability of experienced staff to care for women who choose a vaginal breech birth is a problem which comes up continually. And there are still women with unexpected breech presentations to be cared for. Whilst there are midwives and obstetricians who have the skills, they should be given the opportunity to use them on women who choose vaginal birth, and to pass on those skills to others.	Thank you very much for your comment. We are aware of the long term outcome evidence from the term trial which followed up approx. 80% of the original sample. This follow-up showed no difference between the 2 groups for long-term morbidity however, the difference in perinatal mortality of course remains unchanged. Given the improved perinatal mortality for breech babies when born by caesarean section compared with vaginal birth the current recommendation is correct. It is not appropriate to recommend any other course of action simply to maintain staff competencies.
SH	Birth Trauma Association	1	2	Remit should be widened as per following comments	Thank you for your comment, we have responded to your individual comments below
SH	Birth Trauma Association	2	3c	Please give the absolute figures in the UK	We apologise but we are uncertain what 'figures' you are referring to here.
SH	Birth Trauma Association	3	3 General	Information in this section needs to be balanced. Women are having bigger babies later in life and whilst there are risks to caesarean there are also	Thank you for your comment. We agree that there is significant maternal and perinatal morbidity associated with the delivery of large babies

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				risks from not doing caesareans. Macrosomic babies are increasing and the overall risk of serious morbidity and mortality is greater than from this cause than from placenta accrete or percreta combined.	especially those that are macrosomic. However, we are unaware of evidence which suggests that the incidence of fetal macrosomia is increasing as you suggest. Nevertheless, we feel that the summary of current practice is a balanced statement.
SH	Birth Trauma Association	4	3.2	Again, the statement of current practice needs balancing. Yes, repeat caesareans do give rise to increased risks but so does the failure to offer caesareans for obstetric complications which are increasing.	We agree that there is significant maternal and perinatal morbidity associated with the delivery of large babies especially those that are macrosomic. Most of the evidence of which we are aware suggests that shoulder dystocia is not increasing. Similarly in recent years assisted vaginal delivery has tended to remain about the same proportion, or to fall slightly, although the proportion of rotational deliveries has fallen substantially as the CS rate has increased. Overall, our interpretation of the evidence is that the incidence of intrapartum complications (apart from CS) has declined. Furthermore, the rate of low five minute Apgar scores has declined substantially.
SH	Birth Trauma Association	5	3.2	Where did the one third planned and two thirds emergency come from? It doesn't seem right. Please check HES and NHS info centre. More like 9.8 v 14-15%?	Thank you for your comment. These data come from the National Sentinel Audit The National Sentinel Caesarean Section Audit' RCOG Clinical Effectiveness Support Unit October 2001. We have checked HES data as you suggest which gives the figures you quote. The scope has now been amended to reflect these figures. Please note that the figures we are referring to relate to the proportion of caesarean sections that are emergency vs planned procedures rather than the proportion of all births that are emergency and planned caesarean sections (the overall figure is given in section 3.1(a).
SH	Birth Trauma Association	6	3.3a	Agree	Thank you

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
SH	Birth Trauma Association	7	3.3b	Please insert each new comment in a new row. Always worth re-evaluating evidence and women should be offered a choice but not a priority as the European collaborative study has broadly confirmed the original recommendation. Clearly going to be a research recommendation – include but not a priority.	Please respond to each comment Thank you for your comment. We are aware that there is new evidence available in this area which suggests that the original recommendation may no longer be appropriate. Given the potential for a large change in practice if the recommendation is amended, we believe that this is an important topic to be reviewed
SH	Birth Trauma Association	8	3.3c	The interval that makes most difference from our user perspective is the interval prior to decision not the decision to delivery. There is need for clarity on exactly when a health care professional capable of making a decision should be called– just a simple table of when referral MUST ALWAYS be made. There is a severe lack of knowledge and skills on the part of some health care providers in this respect and it is resulting in enormous litigation costs. The same mistakes are being made over and over again – making the NHS seem like an organisation with Alzheimer's rather than a memory☺	Thank you for your comment. The NICE Intrapartum Care guideline contains recommendations on key areas of management including when obstetric advice needs to be sought. The areas covered include suspected delay in the first stage of labour, meconium stained amniotic fluid and abnormal fetal heart rate patterns as well as a review of evidence of the decision to intervene interval.
SH	Birth Trauma Association	9	Maternal Request Caesarean	There is total lack of clarity about this issue. The guideline contradicts itself. Women's decisions are to be respected yet women who request c/s can be declined c/s by one HCP but must be referred to another. What if the second declines? Should women be forced to give birth vaginally against their will? NICE and Steven Ladyman (Minister for Maternity services at time of 2004 guideline) have said this is not the position but that is what some trusts are doing e.g. Manchester. The very least a guideline should do is be clear about its meaning. I would urge that this topic be included in the scope	Thank you for your comment. Following stakeholder consultation we have now decided to include maternal choice in this guideline update.
SH	Birth Trauma Association	10	Tokophobic Women	Women who have tokophobia are a small group whose mental welfare is put at risk by the current guideline. It is through the compassion of sensible obstetricians and midwives that the worse effects of	Thank you for your comment. Following stakeholder consultation we have now decided to include maternal choice in this guideline update, including choice for women who have tocophobia.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. the 2004 guideline have not been as severe as they might have been. In the worse trusts, we have seen women who have been driven to abortion or forced to go through vaginal delivery against their will and then suffered mental breakdown. Moreover, it seems to us that the least articulate and the least well supported women are the ones who are unable to get their needs heard and are most likely to be forced into vaginal delivery against their will. Current guidance to women with fear of childbirth is simply incorrect and should be reviewed. Would urge that this topic is included in the scope.	Please respond to each comment
SH	Birth Trauma Association	11	Pain relief and CDMR	Many women who request c/s do so because of fear of pain or poor pain management in previous pregnancies. Problems include 1) epidurals not being offered or being delayed 2) risks of epidurals being exaggerated or remote risks being described without reference to their incidence 3) epidurals being tailed off late in labour when pain is most severe 4) OAs not being recalled when epidurals do not work initially. A genuine reduction in maternal requests for caesareans could be achieved if there were higher standards of both pain management and overall supportive care in maternity units. This topic should be included in the scope.	Thank you for your comment. Following stakeholder consultation we have now decided to include maternal choice in this guideline update, including choice for women who have tocophobia. Recommendations regarding pain management and supportive care in labour can be found in the NICE Intrapartum Care Guideline (2007) and lie outside the scope of the Caesarean Section guideline.
SH	Birth Trauma Association	12	4.3	Clinical Management for issues above should be included – with psychological HCP input where appropriate.	Thank you for your comment. Clinical management and care of women regarding pain relief and support during labour is covered in the NICE Intrapartum Care guideline (2007). We plan to include women's emotional wellbeing after childbirth and appropriate care of women who fear childbirth in this update of the Caesarean Section guideline.
SH	Birth Trauma Association	13	4.3.1	Look at impact of administration of antibiotics in previous c/s to possibly prevent development of	Thank you for your comment. As all women are recommended to receive prophylactic antibiotics at

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				placenta percreta / accrete.- evidence review?	caesarean section it is not thought necessary at this time to review this as an intervention for reducing placenta percreta/accrete.
SH	Birth Trauma Association	14	4.3.2c	Evidence table 3.1a and associated information for women in the 2004 guideline must surely be reviewed during this update. The contained information is grossly misleading. Elective caesarean has the same or lower maternal morbidity than planned vaginal yet it is shown as five times higher. There are numerous other gross inaccuracies. We have tackled NICE about this in the past and they have held to the position that the guideline would be updated and that at the time of the 2004 guideline the evidence had been presented in good faith and probably that is a reasonable moral and legal defence. However, to pass an update and do nothing about it might well be another matter. Given that 'provision of information is central to the consent process' and this would constitute negligent or wilful misstatement of risk, there are bound to be obstetric litigation practitioners who will consider action against NICE for failure of duty of care – particularly a class action for VBAC women who have suffered uterine rupture with adverse outcomes for the baby where there is no substandard care and therefore no possibility of suing the trust. (Litigants could argue that their choice of VBAC instead of ERCS was solely influenced by the misleading evidence in the NICE guideline). Duty of care judgements seem to be serendipity but given that lawyers have these cases on their books and the size of the damages could be colossal, someone, somewhere is going to be tempted to take a pop – especially given the rather random and ever changing nature of case law in this area.	Thank you for your comment. Following stakeholder consultation we now plan to update this table and will take all stakeholder comments into consideration when doing so.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				Litigation, should however, be a secondary matter and the real issue is that the quality of information NICE provides to women is important in the real world. The quality of the current information on risks and benefits of c/s is not acceptable and I would urge a full review.	
SH	Birth Trauma Association	15	4.4b	Maternal outcomes add - maternal psychological outcomes , infection, perineal trauma, dispareuria, faecal and urinary incontinence	Thank you. The list as it appears in the scope focuses on main outcomes. Other outcomes will be considered on a question by question basis and key outcomes chosen by the guideline development group. Those under consideration will include all those you suggest.
SH	Birth Trauma Association	16	4.4c	Baby outcomes add - mortality SCBU/NICU admission, brachial plexus injury	Thank you. The list as it appears in the scope focuses on main outcomes. Other outcomes will be considered on a question by question basis and key outcomes chosen by the guideline development group. Those under consideration will include all those you suggest.
SH	Birth Trauma Association	17	4.5	Strongly welcome economic re-evaluation which should include litigation and cost of long term outcomes which are available and assessable from a combination of HES data and research.	Thank you very much for your comment. Litigation costs are not generally included when carrying out economic analysis within a NICE guideline, as substandard/negligent care is a distinct issue from clinical and cost effectiveness. Data on long term outcomes will be sought and used where appropriate.
SH	British HIV Association	1	4.3.1c	Need to consider women on HIV therapy or starting HIV therapy for their own health needs separately from women who will take a short course of anti-HIV therapy to prevent HIV mother-to-child transmission. In the latter group need to consider the pregnancy outcomes if combination anti-HIV therapy is given to avoid elective CS.	Thank you for your comment. We will carefully note any HIV therapy being used by women included in the studies reviewed and where this is different we will carry out sub-group analyses as appropriate wherever possible.
SH	British HIV Association	2	4.3.1 c	Should consider the optimal timing of ECS when this is advocated.	Thank you for your comment. We will make recommendations regarding timing of caesarean

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					section for women with HIV if the reviewed literature enables the guideline development group to draw conclusions on this.
SH	CSections	1	2.0	<p>We maintain that the issue of tocophobia should have been included in this update. Evidence around maternal emotional outcomes clearly demonstrate the mismatch between expectations and experience [Ref 1] and show that improved access to planned caesareans for women with significant fear of childbirth (irrespective of the origin of that fear) is urgently needed. The current guideline suggests counselling but does not make it clear that for some counselling will not work as reported in the Saisto study [Ref 2] Tokophobia has been shown to impact negatively upon labour [Ref 3] It needs to be respected as a valid medical indicator for a planned caesarean at 39 weeks for women planning small families. Poor emotional outcomes for those forced down a vaginal delivery route has been shown to be significant. [Ref 4] An excellent review of the issues can be found in [Ref 5] I request that tokophobia be specifically included in the next update of the Caesarean Guideline.</p> <p>[Ref 1] 'More in hope than expectation' JE Lally This article is available from:  <a href="http://www.biomedcentral.com/1741-7015/6/7">http://www.biomedcentral.com/1741-7015/6/7</a></p> <p>[Ref 2] 'Fear of childbirth: a neglected dilemma' by T Saisto. This article is available from:  <a href="http://www.ncbi.nlm.nih.gov/pubmed/12694113">http://www.ncbi.nlm.nih.gov/pubmed/12694113</a></p> <p>[Ref 3] 'Tokophobia: Fear Of Pregnancy And Childbirth' by R. Bakshi et al.  <a href="http://www.ispub.com/journal/the_internet_journal_of_gynecology_and">http://www.ispub.com/journal/the_internet_journal_of_gynecology_and</a></p>	Thank you very much. Following stakeholder consultation we have now decided to include tocophobia in this update.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p><a href="#">_obstetrics/volume_10_number_1_4/article/tokophobia_fear_of_pregnancy_and_childbirth.html</a></p> <p>[Ref 4] 'Tokophobia: an unreasoning dread of childbirth. A series of 26 cases' by K Hofberg This article is available from: <a href="http://www.ncbi.nlm.nih.gov/pubmed/10789333?dopt=Abstract">http://www.ncbi.nlm.nih.gov/pubmed/10789333?dopt=Abstract</a></p> <p>[Ref 5] J Cockburn et al's book 'Psychological challenges in obstetrics and gynachology' A Springer publication ISBN: 13-978-1-84628-807-4</p>	<p>Please respond to each comment</p>
SH	CSections	2	3.2	<p>We are concerned about the implications of the statement in this section about maternal request and an increased caesarean rate. Media hype certainly would have us believe that there is significant number of women doing this. However a trawl of the research by electiveceareans.com shows that there is no reliable evidence to confirm that a significant number of women are requesting caesareans simply because they can. [Ref 7] Much of this research incorporates women with obstetric complications. The 7% figure commonly quoted as representing 'maternal requests' [Ref 6] states quite clearly that these did not exclude those with maternal or fetal complications. Women that do actually want to make an informed choice in favour of a caesarean are generally turned down. Three User Groups (csections.org, electivecaareans.com and birthtraumaassociation.org.uk) representing significant numbers of women receive countless communications from women in this very position. The sentence "More recently caesarean birth has become an issue of choice for women as a preferred mode of delivery" needs to be modified to make it clear that these are not random choices by ill</p>	<p>Thank you for your comment. The scope simply raises the issue and states 'More recently caesarean birth has become an issue of choice for women as a preferred mode of delivery'. This observation is reflected in the fact that we have now included this topic as a key focus for the update in the light of significant stakeholder support.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**



Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>informed women but generally based on the advice of health practitioners or a woman's knowledge of her medical indicators, fear of childbirth or concerns about quality of care i.e. hospital staffing levels etc. Therefore I would suggest the following replacement "Increased safety of the caesarean procedure is leading more women in situations where a caesarean is one 'option' to choose a caesarean rather than a trial of labour with all it's potential outcomes including emergency caesarean".</p> <p>[Ref 6] 'The National Sentinel Caesarean Section Audit' RCOG Clinical Effectiveness Support Unit October 2001-page 23]</p> <p>[Ref 7]  <a href="http://www.electivecesarean.com/index.php?option=com_content&amp;task=view&amp;id=389&amp;Itemid=1">http://www.electivecesarean.com/index.php?option=com_content&amp;task=view&amp;id=389&amp;Itemid=1</a></p>	<p>Please respond to each comment</p>
SH	CSections	3	3.3b	<p>It was agreed at the Scoping meeting that the HIV Beaver documentation was covering this subject and that the Caesarean Guideline would refer to it rather than conducting its own investigation. This topic should not be updated beyond a referral to the appropriate guideline.</p>	<p>Thank you for your comment. Because of NICE methodology, if the previous recommendation needs to be changed, this topic will need to be re-reviewed. It is not possible to change a recommendation based on guidance published elsewhere.</p>
SH	CSections	4	3.3d	<p>We agree that this should be reviewed but would expect to see the importance of maternal perspectives included within that debate as well as the more obvious studies showing definite changes to the risks previously ascribed to caesarean delivery i.e. [Ref 8] The aim should be two fold: to support those women making an informed choice in favour of VBAC; to support those women wanting to choose a planned caesarean (with or without labour commencing). A VBAC will not be appropriate for some women on a physical and/or emotional level. It must not be assumed that a VBAC will be the</p>	<p>Thank you for your comment. We plan to review the evidence including women's emotional wellbeing as a key outcome. Wherever possible we would plan to undertake an intention to treat analysis but, as with all reviews, we are limited by the quality of reporting in the published papers. Where intention to treat analysis has not been undertaken, or where there is uncertainty, this will be highlighted and the quality of the evidence downgraded accordingly.</p> <p>Thank you for the helpful references – these will be considered for inclusion along with the other</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>preference of all women. Studies clearly show that poor emotional outcomes are likely for those women forced down a vaginal delivery route when they have a preference for a planned caesarean. [Ref 4] We would expect to see the review pay particular attention to the quality of the data. "Studies of VBAC versus ERCD have traditionally reported outcomes based upon actual route of delivery rather than intended route. This can lead to misclassification of patients who intend ERCD but go into labour prior to their cesarean or women who intended TOL but who are delivered by cesarean delivery." [Ref 9]</p> <p>[Ref 8] 'Prior cesarean delivery is not associated with an increased risk of stillbirth in a subsequent pregnancy: analysis of U.S. perinatal mortality data, 1995-1997' by Bahtiyar M et al. This article is available from:  <a href="http://www.ncbi.nlm.nih.gov/pubmed/16677588">http://www.ncbi.nlm.nih.gov/pubmed/16677588</a></p> <p>[Ref 4] 'Tokophobia: an unreasoning dread of childbirth. A series of 26 cases' by K Hofberg This article is available from:  <a href="http://www.ncbi.nlm.nih.gov/pubmed/10789333?dopt=Abstract">http://www.ncbi.nlm.nih.gov/pubmed/10789333?dopt=Abstract</a></p> <p>[Ref 9] 'Vaginal Birth After Cesarean: New Insights' Evidence Report/Technology Assessment -Number 191 prepared for Agency for Healthcare Research and Quality  This article is available from:  <a href="http://www.ahrq.gov/downloads/pub/evidence/pdf/vbacup/vbacup.pdf">http://www.ahrq.gov/downloads/pub/evidence/pdf/vbacup/vbacup.pdf</a></p>	<p>Please respond to each comment</p> <p>evidence for this review.</p>
SH	CSections	5	4.3.1c	<p>It was agreed at the Scoping meeting that the HIV Beaver documentation was covering this subject and that the Caesarean Guideline would refer to it rather than conducting its own investigation. This topic</p>	<p>Thank you for your comment. Because of NICE methodology, if the previous recommendation needs to be changed, this topic will need to be re-reviewed. It is not possible to change a recommendation based</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				should not be updated beyond a referral to the appropriate guideline.	on guidance published elsewhere due to the different underlying methodologies in developing the guidance.
SH	CSections	6	4.3.2c	<p>It is very disappointing that 'provision of information' is being excluded from this review. Research clearly shows that a mismatch between expectations and experience results in significant trauma for some women. [Ref 1] Perceptions, fear in particular, are influential in labour [Ref 3] and the education that women receive inform those perceptions. Information favoring a particular mode of delivery exposes women to potential trauma when they are unable to achieve that ideal. [Ref 10]</p> <p>There is a lot of anecdotal information from User Groups (<a href="http://birthtraumaassociation.org.uk">birthtraumaassociation.org.uk</a>, <a href="http://csections.org">csections.org</a> and <a href="http://electivecaesareans.com">electivecaesareans.com</a>) to show that women feel let down by the antenatal information they are receiving. [Ref 11] Research studies [Ref 12] show that the information readily available to women during the antenatal period is unbalanced. Media stories in particular frequently misrepresent information increasing negative perceptions and increasing the likelihood of trauma occurring in instances where women have not achieved their ideal birth. An illustration [Ref 13] Blame, disappointment, guilt and regret become unnecessarily tied up with a caesarean birth through such irresponsible reporting. We believe at a time when the caesarean rate is still climbing it is essential that women are given balanced information about caesarean birth so that they are not afraid of something that 1 in 4 will experience. They must be prepared for it and helped to plan effectively for such an eventuality. Antenatal education fails women in this regard and we believe this really must be part of</p>	<p>Thank you very much for your comment. Whilst provision of information in itself is not included in the update we do intend to update the risks and benefits table comparing caesarean section with vaginal birth, thus improving the evidence base that underpins antenatal information giving. The current guidance recommends that "Pregnant women should be given evidence-based information about caesarean section during the antenatal period, because about 1 in 5 women will have a caesarean section. This should include information about caesarean section, such as: indications for caesarean section; what the procedure involves; associated risks and benefits; implications for future pregnancies and birth after caesarean section." It is maybe not the recommendation that needs updating but rather that its implementation needs to be better.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>the next review if not this one.</p> <p>[Ref 1] 'More in hope than expectation' JE Lally This article is available from:  <a href="http://www.biomedcentral.com/1741-7015/6/7">http://www.biomedcentral.com/1741-7015/6/7</a></p> <p>[Ref 3] 'Tokophobia: Fear Of Pregnancy And Childbirth' by R. Bakshi et al.  <a href="http://www.ispub.com/journal/the_internet_journal_of_gynecology_and_obstetrics/volume_10_number_1_4/article/tokophobia_fear_of_pregnancy_and_childbirth.html">http://www.ispub.com/journal/the_internet_journal_of_gynecology_and_obstetrics/volume_10_number_1_4/article/tokophobia_fear_of_pregnancy_and_childbirth.html</a></p> <p>[Ref 10] 'The childbirth expectations of a self-selected cohort of Western Australian women' by J Fenwick et al. This article is available from: Midwifery, Vol 21, Issue 1, March 2005, Pages 23-35]</p> <p>[Ref 11] What is Normal Birth? by B Lawrence Beech. This article is available from:  <a href="http://www.aims.org.uk">www.aims.org.uk</a></p> <p>[Ref 12] 'Decision support for women choosing mode of delivery after a previous caesarean section: A developmental study' by A. Farnworth et al. This article is available from: <a href="http://ncbi.nlm.nih.gov">ncbi.nlm.nih.gov</a></p> <p>[Ref 13] 'Bonding after birth'  <a href="http://www.nhs.uk/news/2008/09september/pages/bondingafterbirth.aspx">http://www.nhs.uk/news/2008/09september/pages/bondingafterbirth.aspx</a></p>	<p>Please respond to each comment</p>
SH	CSections	7	4.3.2c	<p>It is very disappointing to see that maternal request is specifically excluded from this review. See earlier point (point 1 referring to section 2 in the scoping doc) regarding the implications and impact of fear of childbirth on a women's ability to labour effectively and the negative emotional outcomes likely when pressured into a vaginal birth when they have expressed a desire for a planned caesarean on the</p>	<p>Thank you very much for your comment. Following stakeholder consultation we now plan to include maternal request for caesarean section in the update and women's emotional wellbeing will be considered for inclusion as a key outcome.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row.	Please respond to each comment
				grounds of fear.	
SH	CSections	8	4.5	When looking at the cost effectiveness of each alternative, it is essential that the long-term costs are included for all modes of delivery. It is important therefore that when evaluating the costs associated with vaginal birth that the following be included: emergency caesarean; perineal repair; ongoing urinary problems requiring treatment and psychological issues resulting from traumatic births; treatment resulting from nerve damage to the baby during delivery as well as litigation. It is only when <u>all</u> these factors are included that an accurate picture of the cost of vaginal birth can be achieved. The same applies to caesarean birth.	Thank you very much for your comment. When assessing cost-effectiveness we will use available evidence based data on long term outcomes to estimate "downstream" costs associated with different modes of delivery. NICE guidelines do not include generally include litigation costs in economic analyses as that relates to care delivered sub-optimally in individual cases rather than cost-effectiveness per se.
SH	Department of Health	1	General and 3.3 (C. Fry)	In our opinion, the risk of surgical site infection needs to be considered as a possible complication after caesarean section	Thank you very much for your comment. We have included infection as a key outcome for this guideline.
SH	Department of Health	2	General and 3.3 (C. Fry)	We believe that the increased risk of infection after a caesarean section, compared with a vaginal delivery, needs to be considered.	Thank you very much for your comment. We have included infection as a key outcome for this guideline. In addition we now plan to update the risks and benefits table for caesarean section vs. vaginal birth where infection rates will be reported.
SH	Department of Health	3	General and 3.3 (C. Fry)	In our view, the benefit of post-discharge surveillance of surgical site infection, associated with caesarean section, needs to be assessed.	Thank you for your comment. This area is not being included in this update as there is little new evidence in this area. In addition, surveillance of surgical site infection is included in the NICE Surgical Site Infection guideline.
SH	Department of Health	4	General and 3.3 (C. Fry)	Could you please reconsider the use of a cephalosporin as first line surgical prophylaxis, in light of the general restriction of this agent in the control of <i>C.difficile</i> infection.	Thank you for your comment. The DH recommendation states that third generation cephalosporins are discouraged. However, the guideline recommends the use of first generation cephalosporins.
SH	Department of Health	5	General	Could you please consider the inclusion of looking at	Thank you for your comment. Maternal infection will

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
			and 3.3 (H Mellows)	Please insert each new comment in a new row. maternal factors and outcomes relating to infection and antibiotic prophylaxis.	Please respond to each comment be included in relation to clinical questions about antibiotic prophylaxis and wherever this is felt by the GDG to be a key outcome. We plan to include an update of the review relating to antibiotic prophylaxis in relation to timing of cord clamping.
SH	Diabetes UK	1	4.1.1	Diabetes UK is seeking clarification regarding whether or not women with pre-existing diabetes will be included in the population to be covered by this guideline. It is not clear whether pre-existing diabetes is considered a complex co-morbidity and therefore not included. Women with pre-existing diabetes also require specialist care, as their pregnancies are considered to be high risk.	Thank you for your comment. Women with diabetes in pregnancy will not be specifically excluded from the scope for the updated clinical areas. However, whilst recommendations will be applicable to this group, additional care relating to the diabetes itself will not be addressed. The Diabetes in Pregnancy guideline has a specific section on VBAC.
SH	electivecesarean.com	2	3.1a	It needs to be recognised that rising caesarean rates are no longer inherently viewed as a 'bad' thing; it is not the rate that is important, but rather, positive birth outcomes for mothers and babies. Also, any attempt to reduce rates should focus on those that are 'unwanted' and not those that are 'wanted'. It is vital to note that the WHO recommendation of 1985 (that caesarean rates should be limited to 10-15%) has been updated as of its 2009 Handbook (which was not publicised and very few people seem to be aware of it). The WHO now admits that there is no empirical evidence for its 25-years-old recommended figure, and that there is in fact no known optimum rate. More info can be found here: <a href="http://www.medicalnewstoday.com/articles/169058.php">http://www.medicalnewstoday.com/articles/169058.php</a> There is also an issue of morbidity tolerance for women; some will prefer abdominal morbidity in preference to perineal or pelvic floor morbidity – for example, the 2003 U.S. Healthgrades nationwide survey of hospitals uncovered significantly higher than expected vaginal complication rates in hospitals	Thank you for your comment. The statement in this section about the increase in caesarean section rates should not be taken as expressing a value judgement about whether the increase is a positive or negative thing, it is stated simply as fact in order to provide background to the guideline scope.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. with lower than expected caesarean rates, and lower than expected vaginal complication rates in hospitals with higher than expected caesarean rates, 'suggestive of, but not definitive of, inappropriate under-utilisation of preplanned first time caesarean deliveries.'	Please respond to each comment
SH	electivecesarean.com	1	2	Re: 'changes to the evidence base'. As noted below, if this is a condition for an issue review, then I absolutely believe that maternal request is an issue that cannot be left untouched until the next review of the caesarean guideline.	Thank you for your comment. Following stakeholder consultation we have now decided to include maternal request in this update.
SH	electivecesarean.com	3	3c	Placenta praevia risk – It can be unhelpful to quote studies that highlight % 'increased risks' without writing the <i>actual</i> % risk next to it too. The numbers '30-60%' sound alarmingly high, and while more caesareans may mean more cases of placental problems, it is important to identify the TYPE of caesarean during which placental problems most commonly occur (e.g. emergency or elective, and repeat following primary emergency or repeat following primary elective – medical or non-medical) and any maternal factors that may increase the risk.	Thank you for your comment. We have now amended this section to make it clearer and more representative of the literature.
SH	electivecesarean.com	4	3.2	The scope notes that 'caesarean birth has become an issue for women as a preferred mode of delivery' and that 'programmes designed to alter caesarean delivery rates have tended to focus on modifying' this (one of four) indication. If this statement is an acceptance of this strategy, then it needs to be reviewed. There is growing evidence that maternal request is a perfectly legitimate birth choice, and has no greater health risks or indeed cost implications than a planned vaginal delivery (and all its potential	Thank you for your comment. This statement is not intended as an acceptance of the strategy. It is intended to demonstrate current clinical practice. Following consultation on the scope we now plan to review and update the section on maternal choice/request.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. birth outcomes); I have listed this evidence in another point, below.	Please respond to each comment
SH	electivecesarean.com	5	3.3d	Earlier this month, the NIH published the outcome of its 'Consensus Development Conference on Vaginal Birth After Cesarean: New Insights', which should help inform this NICE topic area. <a href="http://consensus.nih.gov/2010/vbacstatement.htm">http://consensus.nih.gov/2010/vbacstatement.htm</a>	Thank you very much for this reference.
SH	electivecesarean.com	6	4.3.2c	Re: Maternal Request Caesarean will not be updated. Since the 2004 NICE Guideline, there has been an unprecedented publication of research studies, surveys and medical opinions on the issue of maternal request. This surely constitutes 'changes to the evidence base' and means that it should be included in this review.  <b>To begin with, there was the March 2006 NIH State-of-the-Science Conference Statement: "Cesarean Delivery on Maternal Request":</b> <a href="http://consensus.nih.gov/2006/CesareanStatement_Final053106.pdf">http://consensus.nih.gov/2006/CesareanStatement_Final053106.pdf</a> While the panel concluded that there 'is insufficient evidence to evaluate fully the benefits and risks of cesarean delivery on maternal request as compared to planned vaginal delivery, and more research is needed', this is largely because there had been no effective clinical trials to compare the two at that time. However, the panel was able to conclude that 'any decision to perform a cesarean delivery on maternal request should be carefully individualized and consistent with ethical principles.' [*note* In 2003, an ACOG ethics committee stated that it is ethical for doctors to perform elective caesarean sections on pregnant women who face no known	Thank you very much for your comment. Following stakeholder consultation we now plan to include maternal request for caesarean section in the update and women's emotional wellbeing will be considered for inclusion as a key outcome.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**



Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				<p>risks from vaginal delivery:  <a href="http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&amp;DR_ID=20658">http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&amp;DR_ID=20658</a>]</p> <p>The panel also concluded that due to the fact that 'the risks of placenta previa and accreta rise with each cesarean delivery, cesarean delivery on maternal request is not recommended for women desiring several children.' [*note* The fertility rate in the UK is less than 2, and the vast majority of women requesting a caesarean are only planning 1 or 2 children; therefore, their maternal request is legitimate within these guidelines.]</p> <p>The panel also concluded that 'cesarean delivery on maternal request should not be performed prior to 39 weeks of gestation or without verification of lung maturity, because of the significant danger of neonatal respiratory complications.' [*note* Again, if a woman stays within this guideline, and does not deliver prior to 39 weeks, she should be allowed to have a caesarean. Furthermore, studies that demonstrate poor outcomes for babies born via planned casearean delivery prior to this gestational age should <i>not</i> be used as evidence against maternal request at 39 weeks.]</p> <p>[<i>NIH background:</i> The National Institutes of Health (NIH) consensus and state-of-the-science statements are prepared by independent panels of health professionals and public representatives on the basis of 1) the results of a systematic literature review prepared under contract with the Agency for Healthcare Research and Quality (AHRQ), 2) presentations by investigators working in areas relevant to the conference questions during a 2-day public session, 3) questions and statements from conference attendees during open discussion</p>	

**PLEASE NOTE:** Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				periods that are part of the public session, and 4) closed deliberations by the panel during the remainder of the second day and the morning of the third.]	
SH	electivecesarean.com	7	4.3.2c	<p><b>Secondly, there are a large number of studies that point to better health outcomes for babies born via elective caesarean delivery at 39 weeks,</b> so why not allow women the opportunity to choose the safest birth for their baby if that's their informed conclusion? For example (note: <i>PCD = planned caesarean delivery</i>):</p> <p>*Canadian study of almost 40,000 term deliveries, 1994-2002 comparing outcomes of PCD for breech presentation with spontaneous labour with anticipated vaginal delivery (i.e. PVD) at term in pregnancies with a cephalic-presenting singleton. Life-threatening maternal morbidity was similar in each group. Life-threatening neonatal morbidity was decreased in the CS group. It concluded that 'elective pre-labour Caesarean section...at full term decreased the risk of life-threatening neonatal morbidity compared with spontaneous labour with anticipated vaginal delivery.' (Dahlgren et al, 2009)</p> <p>*Californian study of almost 2m babies born 1999-2003 excl. EGA &lt;38w0d, or &gt;42w6d. [In the knowledge that CDMR is recommended at 39 weeks EGA:] Infants born beyond 41w0d EGA have greater neonatal mortality relative to term infants born between 38w0d and 40w6d. (Bruckner et al, 2008)</p> <p>*U.S. analysis of Ovid Medline over the past 10 years incl. intrauterine fetal demise: 'Copper</p>	Thank you very much for your comment. Following stakeholder consultation we are now including maternal choice in the update. We will also be updating the risks and benefits table (Table 3.1) comparing caesarean section and vaginal birth. Thank you very much for the references you provide, we will consider each of them when we update the relevant reviews.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				<p>reported that the rate of stillbirth is consistent from 23 to 40 weeks EGA with about 5% of all stillbirths occurring at each week of gestation. Yudkin reported a rate of 0.6 stillbirths per 1000 live births from 33 to 39 weeks EGA. After 39 weeks EGA, a significant increase in the stillbirth rate was reported (1.9 per 1000 live births). Fretts reported on fetal deaths per 1000 live births from 37 to 41 weeks of gestational age, showing that the rate progressively increased from 1.3 to 4.6 with each week of gestation. It can be estimated that delivery at 39 weeks EGA would prevent 2 fetal deaths per 1000 living fetuses. This would translate into the prevention of as many as 6000 intrauterine fetal demises in the U.S. annually-an impact that far exceeds any other strategy implemented for stillbirth reduction thus far.' (Hankins et al, 2006)</p> <p>*UK study of 37 of the 873 cases of intrapartum-related deaths reported in the 1994-1995 national enquiry. 'When cranial traumatic injury was observed, it was almost always associated with physical difficulty at [VD] delivery and the use of instruments. The use of ventouse as the primary or only instrument did not prevent this outcome. Some injuries occurred apparently without evidence of unreasonable force, but poorly judged persistence with attempts at VD in the presence of failure to progress or signs of fetal compromise were the main contributory factor regardless of which instruments were used.' (O'Mahony et al, 2005)</p> <p>*U.S. study of 97 infants (65 VD, 23 CD) found a 26% prevalence of intracranial hemorrhage in asymptomatic neonates with VD; "ICH was</p>	

**PLEASE NOTE:** Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				<p>significantly associated with vaginal birth." (Looney et al, 2007)</p> <p>*Canadian study of 305,391 VDs found vacuum extraction may 'increase risk of cephalhematoma and certain types of intracranial hemorrhage (e.g., subarachnoid hemorrhage)'. (Wen et al, 2001)</p> <p>*Californian study of 583,340 infants born to nulliparous women, 1992-1994. The rate of intracranial hemorrhage is higher among infants delivered by vacuum extraction, forceps, or CD during labor... the rate among infants delivered by CD before labor is not higher, suggesting that the common risk factor for hemorrhage is abnormal labor. (Towner et al, 1999)</p> <p>*U.S. analysis of Ovid Medline over the past 10 years found that 'Overall, the frequency of significant fetal injury is significantly greater with VD, especially operative VD, than with CD for the nonlaboring woman at 39 weeks EGA or near term when early labor has been established... infants born to nonlaboring women delivered by CD had an 83% reduction in the occurrence of moderate or severe encephalopathy' and brachial plexus palsy with VD ranges from 0.047% to 0.6% compared with CD 0.0042% to 0.095%. "It is reasonable to inform the pregnant woman of the risk of each of the above categories, in addition to counseling her regarding the potential risks of a cesarean section for the current and any subsequent pregnancies. The clinician's role should be to provide the best evidence-based counseling possible to the pregnant woman and to respect her autonomy and decision-</p>	

**PLEASE NOTE:** Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				<p>making capabilities when considering route of delivery." (Hankins et al, 2006)</p> <p>*England's 2007-08 NHS Maternity Statistics report that birth injury to scalp occurs in 09% of births (est. as 5,400 babies in 2004-05, and confirmed that: 'none related to elective CD.' This breakdown has not been made available for 2009) (HESonline, 2009)</p>	
SH	electivecesarean.com	8	4.3.2c	<p><b>There is also evidence of better outcomes for mothers with elective caesarean delivery;</b> again, maternal request allows women to decide which birth morbidity they find most tolerable – planned vaginal or planned caesarean:</p> <p>*Australian retrospective review of 2,212 singleton CDs 2004-5 found that 14 women (0.63%) required a blood transfusion, and while the 'risk of blood transfusion for elective and emergency CD are 3.9 per 1000 and 9.8 per 1000', in 'the absence of risk factors identified in this study, no women (of a total of 1,293 elective CD) required blood transfusion.' (Chua et al, 2009)</p> <p>*UK study of more than 2m women (CEMACH) &gt;24 weeks EGA found fewer deaths occurred with PCD (n7; 0.31 per 10,000) than any other delivery type. (Treadwell M, BTA, 2008)</p> <p>*U.S. study in Massachusetts 1995-2003; risk of maternal death with primary ECD is less than that associated with VD; also, death directly due to surgery itself is extremely rare (Berger M and Sachs BP, 2006)</p>	<p>Thank you very much for your comment. Following stakeholder consultation we are now including maternal choice in the update. We will also be updating the risks and benefits table (Table 3.1) comparing caesarean section and vaginal birth. Thank you very much for the references you provide, we will consider each of them when we update the relevant reviews.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				<p><b>*Protection of the pelvic floor:</b>  <a href="http://www.prlog.org/10462391-planned-cesarean-delivery-offers-protection-against-pelvic-floor-disorders.html">http://www.prlog.org/10462391-planned-cesarean-delivery-offers-protection-against-pelvic-floor-disorders.html</a></p> <p><b>*Greater satisfaction and psychological wellbeing:</b>            *Australian anonymous postal survey of 78 women who had maternal-request primary CDs in eastern states private maternity hospitals. Most common reason for CDMR was 'concerned about risks to the baby' (46%) and on a scale from 1 (totally unsatisfied) to 10 (completely satisfied), the mean satisfaction rating reported was 9.25/10. 'Respondents were highly satisfied with their delivery'. (Robson et al, 2008)</p> <p>*Swedish study of CD 'in the absence of medical indication' compared 2 groups from 357 healthy primiparas: CDMR (n.91) and PVD controls (n.266) with 3 self-assessment questionnaires in late pregnancy, 2 days after delivery and 3 months after birth. 'After PCD, women reported a better birth experience compared to PVD women. They were breastfeeding to a lesser extent 3 months after birth [but] there were no differences in signs of postpartum depression between the groups 3 months after birth. (Wiklund et al, 2007)</p> <p>*Swedish study of women via questionnaires, incl. 124 emergency CD, 70 ECD, 89 instrumental VD and 96 normal VD. 'The women reported more post-traumatic stress reactions following EmCS as well as after instrumental VD, than after elective CD or</p>	

**PLEASE NOTE:** Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>normal VD...The psychological well-being of mothers is generally not so favourable after emergency CD and instrumental VD, than after elective CD and normal VD. (Ryding EL, 1998)</p> <p>*UK observational study at University College Hospital, London of 102 consecutive women undergoing CD. 'Women undergoing CD were well informed and took a considerable part in the decision-making process... High levels of satisfaction with both the decision and the procedure itself indicate that CD is an acceptable method of delivery, particularly when an elective procedure. (Mould et al, 1996)</p>	Please respond to each comment
SH	electivecesarean.com	9	4.3.2c	<p>Tokophobia as an indication for caesarean delivery can often fall between two stools, and these women are particularly vulnerable when being forced to have a vaginal delivery. Some doctors view tokophobia as a medical indication, and permit the 'maternal request' on those grounds while others view it as 'irrational' state of mind, controllable with counselling and/or adequate pain relief during a trial of labour. This 2000 study should be noted and recognised in the discussion on maternal request:</p> <p>*Queen Elizabeth Psychiatric Hospital in Birmingham, England, interviews with 26 women 'noted to have an unreasoning dread of childbirth'. 'Pregnant women with tokophobia who were refused their choice of delivery method suffered higher rates of psychological morbidity than those who achieved their desired delivery method...Close liaison between the obstetrician and the psychiatrist in order to assess the balance between surgical and psychiatric</p>	Thank you very much for your comment. Following stakeholder consultation we are now including maternal choice in the update. This will include women with tokophobia and women's emotional wellbeing as a key outcome.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>morbidity is imperative with tokophobia.' (Hofberg K, 2000)</p> <p>I would add that I am aware of two women for whom a refusal of maternal request caesarean delivery resulted in their termination of viable and much-wanted pregnancies.</p>	Please respond to each comment
SH	electivecesarean.com	10	4.3.2c	<p>The maternal request statement in the 2004 NICE guideline, as it stands, is wholly inadequate and open to different interpretations. I am contacted by numerous women who say that their request is being denied – including those that have asked for a second referral. I have also spoken with a number of NHS doctors about this subject, and they confirm that this is happening – especially in hospitals outside the South East of England. I have also been told that some doctors do not even write down 'maternal request' as an indication for a caesarean because they fear the repercussions from their NHS Trust; instead, they write down non-existent medical indications in order to support women that they believe are making a perfectly legitimate decision. The situation is a mess, and it is not being helped by the current 2004 maternal request statement. Finally on this point, some doctors are speaking out about maternal request, including the very high profile Dr Mark Porter:  <a href="http://www.timesonline.co.uk/tol/life_and_style/health/expert_advice/article6897399.ece">http://www.timesonline.co.uk/tol/life_and_style/health/expert_advice/article6897399.ece</a>  Please note what I have written in the 'Comments' section below the main article, and more importantly, Dr Porter's positive reaction to what I've said.</p>	Thank you very much for your comment. Following stakeholder consultation we are now including maternal choice in the update. This will include women with tocophobia and women's emotional wellbeing as a key outcome.
SH	electivecesarean.com	11	4.5	Appendix C of the 2004 NICE guideline reads: 'The	Thank you for the comment. The content of

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**



Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>estimated cost of maternal request can change depending on the cost value entered in the model... If the lowest vaginal birth costs reported in the review and highest caesarean cost reported in the view are used, the additional cost for accepting 8,747 maternal requests for caesarean is around £21.2m. [But] since the highest cost for vaginal birth in the review is higher than the lowest cost for caesarean, if these values were entered into the model, the model would show that increasing planned caesarean due to maternal request would lead to savings, which is not a realistic conclusion.' This is an incredible admission in the compilation of caesarean cost statistics - that we can only accept the conclusion if it is the conclusion we expect or endorse. Again, this area of the guideline in relation to maternal request and cost is in urgent need of review.</p> <p>On the subject of cost, I can provide other quotes and studies, but as one example, in 2008, an ACOG Committee Opinion concluded that it 'is not clear whether widespread implementation of elective cesarean birth would increase or decrease resources required to provide delivery services.' (<a href="http://www.acog.org/from_home/publications/ethics/co395.pdf">http://www.acog.org/from_home/publications/ethics/co395.pdf</a>)</p> <p>Finally, it is important to note that current cost comparisons are flawed in terms of maternal request, as they contain medical and/or emergency surgical costs, but more crucially, vaginal delivery costs repeatedly fail to include the financial impact of:</p> <ol style="list-style-type: none"> <li>1. all planned vaginal delivery outcomes, including</li> </ol>	<p>Please respond to each comment</p> <p>Appendix C is likely to be updated as part of the update. Any future analysis will consider evidence based data on long term outcomes to estimate "downstream" costs associated with different modes of delivery. NICE guidelines do not include generally include litigation costs in economic analyses as that relates to care delivered sub-optimally in individual cases rather than cost-effectiveness per se.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				<p>spontaneous, instrumental and emergency caesareans.</p> <p>2. short and long-term perineal and pelvic floor repair (e.g. prolapse) and counselling when trauma occurs.</p> <p>3. huge litigation bills when vaginal delivery goes wrong and a baby/mother is injured or dies. For NICE to discount the cost of litigation to the NHS when it comes to evaluating the cost of maternal request versus trial of labour is a colossal error of judgement, and I would urge a reconsideration of this issue.</p>	
SH	ElectiveCaesarean.com	12	General	<p>When reviewing caesarean evidence, it is important to be aware of a bias that exists in some research and reporting on the subject of maternal request. For example, the recent the recent publication of a survey by The World Health Organization contained a seriously flawed and unsubstantiated conclusion in relation to caesarean delivery 'with no indication', and yet was published in The Lancet and subsequently received mass media coverage. This is what Nigel Hawkes, director of the pressure group Straight Statistics wrote about it:</p> <p>Nigel Hawkes: A bad case of bias against Caesareans  <a href="http://www.independent.co.uk/life-style/health-and-families/health-news/nigel-hawkes-a-bad-case-of-bias-against-caesareans-1883667.html">http://www.independent.co.uk/life-style/health-and-families/health-news/nigel-hawkes-a-bad-case-of-bias-against-caesareans-1883667.html</a>            Funny Figures from WHO on Caesareans:  <a href="http://www.straightstatistics.org/article/funny-figures-who-caesareans">http://www.straightstatistics.org/article/funny-figures-who-caesareans</a></p>	<p>Thank you very much for your comment. Following stakeholder consultation we now plan to include an update of the section on maternal request. We note your comment regarding bias in the reporting of results and will take this into consideration when reporting the evidence. We would like to point out however, that when reviewing we focus on the research methodology and findings rather than the authors' introductions and discussion, which as you rightly say, may be flawed.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row.	Please respond to each comment
SH	electivecesarean.com	13	General	<p>When compiling tables of data, this latest development is of great importance:</p> <p>The Department of Health has stopped publishing the table of birth data that links infant birth injuries with delivery type, which makes comparative assessment of infant risk extremely difficult. I noticed this while I was responding to a journalist's request for information on the incidence of scalp injuries with planned delivery. I knew that the 2007-08 data (births that occurred in 2004-05) showed that not a single case occurred with planned elective caesarean sections - and yet scalp injury as a risk is frequently cited as a serious risk for women who choose maternal request caesareans. As of 2008-09, this data is no longer available. Women deserve to know what risks their babies face with different delivery types, and given the research on babies' health outcomes cited above, again, I would reiterate that this is cause to review the 2004 statement on maternal request.</p>	Thank you very much for your comment. Following stakeholder consultation we now plan to include an update of the section on maternal request.
SH	electivecesarean.com	14	General	<p>Table 3.1a on page 22 of the 2004 NICE guideline is in urgent need of review, and cannot be allowed to stand as it is. There are a number of out-of-date inaccuracies within the table – most notably that a woman is 5 times more likely to die with a caesarean. Also, the table would be of far more value for women <i>planning</i> their births, if it separated risks into each birth plan's potential OUTCOME. The overwhelming majority of emergency caesareans are outcomes of planned vaginal deliveries, and yet this table mixes these negative surgical outcomes with planned caesarean deliveries – of which an emergency caesarean is a comparably rare outcome. At the very least, elective caesareans</p>	Thank you very much for your comment. Following stakeholder consultation we now plan to include an update of the section on maternal request.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. should command their own column alongside emergency caesareans and vaginal deliveries.	Please respond to each comment
SH	electivecesarean.com	15	General	During the January scoping meeting, I specifically suggested a clinical question to be added to the Draft Scope, and it was written, word-for-word, on the flipchart next to our table. However, it does not appear in the notes that have been made available online. While I understand that suggestions cannot be guaranteed a place in the review, I am concerned that there is no log of it ever being suggested – I would appreciate feedback on what may have happened here please. Many thanks.	Thank you for your comment. We have kept a log of all the notes made during the scoping workshop and discussed the points raised at internal meetings. The notes published on the website were a short summary of the points raised by all three groups at the workshop and so are not comprehensive.
SH	Ferring Pharmaceutical Ltd	1	General	Thank you for allowing us the opportunity of commenting on the Scope, we have no comment on the scope.	Thank you.
SH	Health Protection Agency	1	4.4b maternal outcomes	When carrying out searches on the maternal outcome 'infection', as related to c-section delivery, then 'surgical site infection' and 'endometritis' should be used as search terms.	Thank you for your comment. Outcome terms are not always used in developing the search strategy but are considered on a case by case basis depending upon the sensitivity/specificity balance of the search strategy. The search terms you suggest will be considered where this is appropriate.
SH	La Leche League	1	3.2	Rise in c-section rates seems to be presented in this section of the draft as a positive thing. But to what extent is 'failure to progress' actually a failure of medical staff to be patient and let labour take its course, and support the woman adequately, including providing her with a relaxing environment so important in facilitating labour? Therefore, why should the labouring woman, and not the medical establishment, take ownership of the 'failure?'	Thank you for your comment. The statement included in this section about the increase in Caesarean section rates should not be taken as expressing a value judgement about whether the increase is a positive or negative thing. The term "failure to progress" is commonly used in clinical practice. It was used in the original guideline. It can occur for a number of reasons related to the woman, her baby and/or her carers. It is not conventionally used to imply blame or judgement. We agree that "failure to progress" (or 'inadequate labour progress') is an inappropriate term since it

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					does not relate to the underlying pathophysiology. We have now replaced this with 'prolonged labour' though this still fails to address the issues of possible underlying pathophysiology
SH	La Leche League	2	3.2	'Inadequate labour progress' – this is very value-laden - when there is such a variation in the length and progress of labour, who decides what is inadequate and why? Again, is it the labour progress that is inadequate, or should the blame lie with the woman's carers and birthing environment?	Thank you for your comment. Although no "blame" was intended we understand and accept your comment that the phrase may be suggestive of this. There is no intention to "blame" anyone for the length of labour and we have rephrased this to read "prolonged labour". It would be hoped that both the woman and her carers would be working together to decide when this would be appropriate.
SH	La Leche League	3	3.2	Nothing is mentioned about the link between rising c-section rates and the use of continuous foetal monitoring.	Thank you for your comment. We acknowledge this link and have included this now in the scope. This link is also mentioned in the full version of the NICE Intrapartum Care guideline.
SH	La Leche League	4	3.2	What about mention of the potential loss of skills to support a woman to deliver naturally, which would be a bi-product of rising c-section rates?	Thank you for your comment. Although theoretically this could become a problem if the CS rate were to rise very high we feel it is not at present a problem and does not need to be stated within the background to the scope for this guideline.
SH	La Leche League	5	3.2	Foetal malpresentation. Midwives specialising in natural births have many strategies for supporting women to birth babies naturally where there is an issue of malpresentation. Shouldn't these be adopted more often as an alternative to c-sections?	Thank you for your comment. Whilst we acknowledge that there are a number of strategies midwives may employ to help women achieve a vaginal birth where there is a fetal malpresentation if this is what the woman wants, this does not remove from the statement here that malpresentation remains a major indication for caesarean section.
SH	La Leche League	6	4.3	In terms of caring for the mother following a c-section, it would be of tremendous help if partners could stay with women overnight, as there is little	Thank you for your comment. The option of a partner staying after birth is dependent upon the availability of suitable accommodation (i.e. Single rooms for all

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. support on many postnatal wards for women at night-time, despite the best will of maternity staff.	Please respond to each comment women who would like their partner to stay overnight). This is a matter for local service provision rather than evidence-based clinical guidance.
SH	La Leche League	7	General	Regarding equality of opportunity, the language used in the document has a gender bias – women are labelled as failures and their labour inadequate. These terms need to be changed so that medical practitioners also take their share of responsibility for medical intervention (e.g. instead of 'failure to progress', how about 'failure to provide adequate support to allow the labour to progress at its own course'?) Labelling women as failures and their bodies as inadequate can have a negative impact on a woman's confidence to be a good mother to her baby, and on her confidence in her ability to breastfeed.	Thank you very much for your comment. Any inference of failure or inadequacy on the part of women was not intended. We will change these terms as you suggest.
SH	La Leche League	8	3.1	The draft scope notes that CS rates have increased since 1992 from 13% to 23% in 2004. No evidence has been presented for any benefit from this dramatic rise. But the costs are immense, including the massive financial cost to the NHS, as well as medical harm done to women, complications arising. Therefore the guidelines should recommend a reduction in the CS rates at least to 1992 levels.	Thank you for your comment. The statement included in this section about the increase in caesarean section rates should not be taken as expressing a value judgement about whether the increase is a positive or negative thing. Any recommendations about caesarean section rates included in the guideline will need to be based upon the evidence reviewed and it would not be appropriate to prejudge what the recommendations will say at this stage.
SH	Royal College of Anaesthetists	1	4.3.2	It is disappointing that the issue of post partum pain management is not being reviewed. The current guidelines recommend the use of both intrathecal diamorphine and PCA analgesia after a LSCS whereas most clinicians agree that if intrathecal diamorphine is used most mothers require minimal opiates in addition and the use of PCAs for these patients is unnecessary. This is one part of the	Thank you very much for your comment. We plan to amend the recommendation to better reflect what was meant, this will remove the implication that a woman may need both forms of postnatal analgesia.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. guideline that is generally not complied with and would benefit from reconsideration.	Please respond to each comment
SH	Royal College of Midwives	1	General	The Royal College of Midwives welcomes the opportunity to comment on the scope of this guideline. The comments in this response are based on feedback from midwives who reviewed and responded to the RCM on the draft Guidance  The key clinical issues that will be covered appear appropriate	Thank you for your comment and your support for the included topics.
SH	Royal College of Midwives	2	4.1	We are pleased to see the inclusion of women with HIV both high and low viral loads. The blanket guideline that all women who were HIV positive should have a caesarean section has meant these women do not have access to a real choice. Is it anticipated that the use of ARVs administered to babies at the time of birth will make a difference to the decision about caesarean vs vaginal birth?	Thank you very much for your comment supporting this addition to the guideline. We plan to document the adjuvant treatment of the newborn with ARV as part of the review strategy. Where possible this information will be used to inform the recommendations made.
SH	Royal College of Midwives	3	4.3.1	We welcome an evidence based guideline for decision to incision based upon clinical indication and likely outcomes.	Thank you for your comment
SH	Royal College of Midwives	4	4.3.1	The outcome of the recommendation for imaging techniques for morbidly adherent placenta will be helpful as this was a CEMACH recommendation.	Thank you for your comment
SH	Royal College of Midwives	5	4.3.1	'at improving maternal and neonatal outcomes' The RCM considers it is important to make clear the inclusion of psychological as well as physiological outcomes here.	Thank you for your comment. We agree and have included psychological outcomes in our list of main outcomes (section 4.4b).
SH	Royal College of Midwives	6	General	It is disappointing to find there is no suggestion of looking in more depth at ways of changing clinical practice around decision making behind either first or subsequent caesarean section.	Thank you for your comment. Following stakeholder consultation we now plan to update the table of risks and benefits associated with caesarean section and vaginal birth. We also plan to update the section on birth after caesarean section.
SH	Royal College of	7	4.3.2	We think it is important to examine in more depth the	Thank you for your comment. Whilst this is an

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
	Midwives			Please insert each new comment in a new row. evidence behind debriefing and caesarean section clinics since the publication of the last guidance.	Please respond to each comment interesting area it was not felt to be key to informing current practice at this time.
SH	Royal College of Midwives	8	General	We think it would also be useful to look at evidence around using Robson grouping to focus in on methods of changing/reducing intervention rates.	Thank you for your comment. Whilst this is an interesting topic it was not felt to be of sufficient clinical importance to be included in the caesarean section scope for the present update.
SH	Royal College of Nursing	1	General	The Royal College of Nursing welcomes proposals to update this guideline. The draft scope is clear and comprehensive.	Thank you for your comment
SH	Royal College of Nursing	2	4.3.2	<u>Clinical issues not covered</u>  We note the proposal is that guidance on caesarean section and multiple pregnancy would not reviewed at this stage.  It is worth noting, that the current guidance does not address the question of the mode of delivery for monochorionic twins. We would like to request that this is included in this update.	Thank you for your comment. This update will not include the section on multiple pregnancy as a large multi-centre randomised controlled trial (the Twin Birth Study: planned caesarean section vs. planned vaginal birth for twins 32 to 38 weeks' gestation) is underway that will report after publication of the guideline.
SH	Royal College of Obstetricians and Gynaecologists	1	3.1	There should be mention of fetal morbidity/mortality in epidemiology section as some reports suggest an increased still birth rate in next pregnancy after C/S	Thank you for your comment. This is true and we have included a statement to that effect in the relevant section of the scope.
SH	Royal College of Obstetricians and Gynaecologists	2	3.1c	Could the overall risk of placenta praevia be stated and the relative risk be included rather than just stating an increased risk of 30-60%	Thank you for your comment. We have amended the text to make the statistics clearer and more representative.
SH	Royal College of Obstetricians and Gynaecologists	3	3.1c	"There is also an increased mortality risk, although the reported maternal mortality rate due to this condition in the UK is not high, being less than 1 in 100,000 maternities." -This is counter intuitive as we are quoting overall risk of LSCS mortality as 1 in 12000 so to consider this mortality in isolation is not helpful.	Thank you for your comment. We agree that this statement at first glance is counterintuitive. However, the denominator here is total maternities not cases where morbidly adherent placenta occurs. The mortality in that subgroup is significantly higher.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**



Type	Stakeholder	Order No	Section No	Comments	Developer's Response
SH	Royal College of Obstetricians and Gynaecologists	4	3.3	Please insert each new comment in a new row. Should C/S for maternal choice be reviewed? Is there any new evidence to advise women who request a primary C/S for fear of childbirth and how they should be managed?	Please respond to each comment Thank you for your comment. Following stakeholder consultation we now plan to update the section on maternal request and to include fear of childbirth.
SH	Royal College of Obstetricians and Gynaecologists	5	3.3a	Please advise whether they should be referred to a regional centre for this imaging. It would also be useful to include a recommendation as to where women with a morbidly adherent placenta should be advised to give birth.	Thank you for your comment. Following a review of the evidence the guideline development group will make recommendations for practice which may include aspects of service provision as you suggest. It is not possible to state at this point what those recommendations might be, but place of birth will be one of the issues under consideration.
SH	Royal College of Obstetricians and Gynaecologists	6	3.3b	Should include recommendation as to timing of C/S for HIV positive women with detectable viral load as currently variation in practice	Thank you for your comment. We hope to be able to make recommendations on the timing of caesarean section for women with HIV once we have reviewed the relevant literature.
SH	Royal College of Obstetricians and Gynaecologists	7	3.3c & 3.3 d	These are both very important clinical areas	Thank you for your comment – please see responses below.
SH	Royal College of Obstetricians and Gynaecologists	8	3.3c	It states 30min has been adopted as a threshold, however the original guideline did not recommend this, [Rec in original stated 1.4.1.2 Delivery at emergency CS for maternal or fetal compromise should be accomplished as quickly as possible, taking into account that rapid delivery has the potential to do harm. A decision-to-delivery interval of less than 30 minutes is not in itself critical in influencing baby outcome, but has been an accepted audit standard for response to emergencies within maternity services]. The scope states it wants to find the “ <i>Optimum</i> decision-to-delivery interval in caesarean section in cases of maternal or fetal compromise” “optimal is very	Thank you for your comment. Following stakeholder consultation it has been decided that there are other areas which are more important to update given that, as you point out, the original guideline makes a reasonable recommendation which remains pertinent. The guideline recommendation does, as you rightly point out, not state that a 30 minute decision-to-delivery interval is important for neonatal outcome but is noted as an audit standard for emergency deliveries. Misinterpretation of the recommendation and its use in medic-legal situations is acknowledged but the recommendation itself is correct.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				Please insert each new comment in a new row. difficult to ascertain, but I assume this aim means the time which minimises the probability of harm to mother and baby, as harms are rare events it can be difficult to be certain of these estimates but given the previous misinterpretation of the recommendation perhaps it would be clearer if the aim was minimising harm.	Please respond to each comment
SH	Royal College of Obstetricians and Gynaecologists	9	3.3d	Areas/Groups that will be covered: The major groups of women having CS are included- emergency and VBAC. It is incorrect to state in 3.3d that VBAC was not included in the first CS guideline as there is a whole chapter/recommendations in section 1.8 Pregnancy and childbirth following CS of the first guideline. However reviewing the evidence at that time it was clear that both decisions were usually safe, but also both could also sometimes be associated with very poor outcomes, for both the chance of this was very small and it was not possible to say if they were different. It is important to update the review about the overall risks and benefits of CS, in the first guideline the estimates for these were conflated only because of the paucity of evidence. If possible if the evidence exists these could be separated into first CS and repeat CS, planned or emergency this will help to provide women/carers with the evidence to make informed decisions.	Thank you for your comment. We have now removed the phrase saying VBAC was not included in the previous guideline, as you point out, this is a mistake. We will be updating the risk table as you suggest. Depending upon the quality of the underlying evidence base we will attempt to separate out emergency and planned caesarean births and, first vs. subsequent caesarean births, although we are not able to say at this stage whether this degree of detail will be possible.
SH	Royal College of Obstetricians and Gynaecologists	10	4.1.1	Should there be a section on morbidly obese women who require C/S and/or the place of planned C/S for this group? This is an increasing clinical problem and there is research in the area. It is unlikely to be covered by other NICE guidelines relating to the obese pregnant woman	Thank you for your comment. This group has now been included in the scope as a sub-group for particular consideration. This means that whilst updating the selected topic areas where data is available we will undertake sub-group analyses for this group of women. In addition, the guideline development group will take care to consider any special needs that obese women may

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					have when they are formulating recommendations.
SH	Royal College of Obstetricians and Gynaecologists	11	4.1.1b	Information for women who have had more than 1 prev C/S should be reviewed	Thank you for your comment. We will be updating the risk table and, if possible, presenting data for women who have had one previous caesarean section separately from those who have had more than one.
SH	Royal College of Obstetricians and Gynaecologists	12	4.3.1c	If it is at all possible for a HIV-woman to have a vaginal birth, this should be positively encouraged, and the information within the guidance needs updating as a matter of urgency. Crucially it would reduce the stigma of the woman's HIV status at what is one of the most important events in a woman's life	Thank you for your comment. We agree that this is an issue in need of review and we will be updating the guidance in this area.
SH	Royal College of Obstetricians and Gynaecologists	13	4.3.1e	Updating the guidance in relation to vaginal birth compared with previous caesarean section would ensure that women receive appropriate and accurate information after having had a previous caesarean in order to prepare for the next birth.	Thank you for your comment. We do now plan to include an update of this risk table in the updated guideline.
SH	Royal College of Obstetricians and Gynaecologists	14	4.3.1e	"Effectiveness of planned vaginal birth compared with planned caesarean section at term at improving maternal and neonatal outcomes in women who have had a previous caesarean section." Please clarify meaning as wording confusing	Thank you for your comment. This question aims to compare maternal and neonatal outcomes for women who plan a vaginal birth after a previous caesarean section compared with those who plan a repeat caesarean section. The hypothesis as it is written assumes planned vaginal birth will improve outcomes although it is entirely possible this will not be the case. This question will take into account women's choice and emotional outcomes.
SH	Royal College of Obstetricians and Gynaecologists	15	4.3.1e	In supporting and encouraging women to attempt a vaginal birth after caesarean section, a discussion pertaining to the advantages along with the long-term problems needs to take place. Please include what information should be given to women	Thank you for your comment. Following a review of the evidence it will be possible to make recommendations regarding risks and benefits and this will form the basis of recommendations for information-giving.
SH	Royal College of Obstetricians and Gynaecologists	16	4.3.1f	Information on safety of antibiotics to the fetus should be discussed	Thank you for your comment. We plan to include neonatal outcomes when reviewing timing of antibiotic administration in relation to cord clamping in order to provide recommendations about what is

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					the best course of action balancing risks and benefits to both the woman and the baby.
SH	Royal College of Obstetricians and Gynaecologists	17	4.3.2c	Procedural aspects. There are new recommendations on screening for MRSA which should be included.	Thank you for your comment. It is not necessary to include screening procedures in the update as these are not specific to caesarean section.
SH	Royal College of Obstetricians and Gynaecologists	18	4.4	Diagnostic accuracy of colour-flow ultrasound and MRI."- should read "colour flow Doppler Ultrasound and MRI"	Thank you for your comment, we have changed this to read as you suggest.
SH	TAMBA	1	4.3.2 c	NICE Guideline 'Caesarean Section' 13 only covers a small number of multiple pregnancy related scenarios and almost exclusively relates to the care of singleton babies. Furthermore, it was inferred in the response to the scope consultation for the multiple pregnancy guideline, which is currently under development that this would be the case. In response to our concern that these issues are not addressed in any practical detail, the Institute stated that, "There is an opportunity to look at some aspects of multiple pregnancies and caesarean section in the caesarean section update planned for next year." <a href="http://www.nice.org.uk/nicemedia/pdf/MultiPregScopeCommentsTable.pdf">http://www.nice.org.uk/nicemedia/pdf/MultiPregScopeCommentsTable.pdf</a>	Thank you for your comment. This update will not include the section on multiple pregnancy as a large multi-centre randomised controlled trial (the Twin Birth Study: planned caesarean section vs. planned vaginal birth for twins 32 to 38 weeks' gestation) is underway that will report after publication of the guideline. Findings from this study will inform decision-making around the issue of mode of birth for monochorionic twins. We are sorry to disappoint you at this stage but feel sure you will understand that to update the guideline prior to the publication of this very important piece of work would not be appropriate.
SH	The British Dietetic Association	1	General	No comment	Thank you.
SH	The Multiple Births Foundation	1	3.3	Topics to be updated:	Thank you for your comment.
SH	The Multiple Births Foundation	2	General	At the Multiple Births Foundation (MBF) we often have enquiries from women expecting twins who have had a previous caesarean birth and would like a vaginal delivery. Although in our experience the usual practice would be to discuss this with the woman on a case by case basis it would be helpful to address it generally in the revised guideline if	Thank you for your comment. It is felt this is an area where there is unlikely to be good quality underlying evidence to underpin any general conclusions and that this issue is best considered on a case by case basis as you note since many factors would need to be taken into consideration for each individual woman. There is currently an international multi-

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				possible.	centre randomised controlled trial underway (the Twin Birth Study: planned caesarean section vs. planned vaginal birth for twins 32 to 38 weeks' gestation) which it is anticipated will report in late 2011 which may provide some evidence upon which to base such decisions.
SH	The Multiple Births Foundation	3	4.3.2	<p>Clinical issues not covered: c. we appreciate that you are intending not to review planned caesarean section after a multiple birth at this time, but we would like to ask you to consider whether it would be possible to address the question of delivery of monochorionic twins. At the MBF we are frequently contacted by women who have received conflicting information and advice about whether to have a caesarean section. or vaginal delivery with monochorionic twins. In our experience based on anecdotal feedback there is an increase in vaginal deliveries being suggested in some cases while other obstetricians strongly advocate a caesarean delivery. This can be very distressing for women who may have already had a pregnancy fraught with anxiety if twin-to-twin transfusion syndrome has developed. It would be very helpful if the evidence could be reviewed and a recommendation made.</p> <p>Thank you for considering our comments.</p>	Thank you for your comment. This update will not include the section on multiple pregnancy as a large multi-centre randomised controlled trial (the Twin Birth Study: planned caesarean section vs. planned vaginal birth for twins 32 to 38 weeks' gestation) is underway that will report after publication of the guideline. Findings from this study will inform decision-making around the issue of mode of birth for monochorionic twins.
SH	The Pelvic Partnership	1	General and 4.1.2	We have a concern that neither the original guideline nor the update addresses the issues for women with physical disabilities such as Pelvic Girdle Pain (PGP) who have very limited mobility (may be requiring crutches or a wheelchair to mobilise) and who wish to have a c-section as they are worried about how they will cope with labour. Many of these women end up either with an emergency section or	Thank you for your comment. Following stakeholder consultation we have now decided to include maternal request/choice in the update. This will include consideration of all issues relating to choice including fear of childbirth and concerns about not managing labour well. We hope in this review to be as inclusive as possible and women with physical disabilities, including pelvic girdle pain, are included

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>with long-term (several months or years) mobility problems as a result of not labouring well, and we feel that they should be able to choose an elective section. PGP cannot be considered to be a "rare" condition, but is not currently addressed specifically in this guideline.</p> <p>Women with physical disabilities such as PGP are currently not "allowed" by many consultants to choose an elective c-section. However, in some units they are told that they <u>must</u> have a c-section if they have PGP even if they wish to have a vaginal birth. The psychological as well as physical impact of these issues about choice and long-term recovery/disability can be very far-reaching. We would like to see this update address this issue. Thank you.</p>	<p>Please respond to each comment</p> <p>in the scope of the guideline.</p>
SH	The Pelvic Partnership	2	General	<p>I attended the scoping workshop and I shared the concern that was expressed there that as c-section affects from around a fifth to over a quarter of women giving birth in most UK hospitals, (and the budget that therefore has to be spent on their maternity care is greater than that for a vaginal birth) that this is only a partial update. I felt that a full update may be more appropriate to make sure all areas of the topic can be fully covered.</p>	<p>Thank you very much for your comment. The decision to conduct a partial update rather than a full update was based upon the opinions of the original GDG members and a scoping search of the included topics in order to find areas where there has been a good amount of new evidence published. Following this, it was felt that a full update is not necessary at this time. The update process is a rolling programme however, and this guideline will be assessed for update at regular intervals.</p>
SH	The Pelvic Partnership	3	General	<p>GDG composition: I believe that a psychologist or psychiatrist with a specialism in perinatal mental health should be included in the group, and that at least 3 lay members should be included.</p>	<p>Thank you very much for your comment. We plan to recruit a perinatal mental health specialist as an expert advisor to the guideline development group. We feel that two lay members will be sufficient to maintain a balanced GDG.</p>
SH	The Royal College of Paediatrics and Child Health	1	GDG membership	<p>The RCPCH thinks it is essential that a consultant neonatologist is recruited as a full, voting member of the GDG. We therefore request that the NCC-WCH</p>	<p>Thank you very much for your comment. We appreciate that input from a neonatologist is important for some sections of the guideline.</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>add a role for a consultant neonatologist on the GDG.</p> <p>We would like to emphasise the importance of NICE and the NCC-WCH engaging with neonatologists and paediatricians on this guideline. Indications for Caesarean section often relate to the foetus and chapter 7 of the current guideline covers care of baby born by Caesarean section. Given this, it is imperative that the guideline is developed with the involvement of a neonatologist.</p> <p>A neonatologist will ensure that standards for the care of the baby delivered by Caesarean section meet the standards for the care of the mother.</p> <p>A neonatologist's expertise will be particularly required for sections on HIV and antibiotics prophylaxis</p>	<p>Please respond to each comment</p> <p>However, the specific areas that are being updated do not all have a strong need for neonatal involvement. We plan to have a neonatologist as an expert advisor who can be invited to attend guideline development meetings where the clinical question under consideration is directly related to neonates e.g. when assessing the risks and benefits of caesarean section vs. vaginal birth. For other questions e.g. diagnosis of morbidly adherent placenta it is felt this will not be necessary.</p>
SH	The Royal College of Paediatrics and Child Health	2	3.3	<p>The RCPCH thinks that the topics areas to be updated are appropriate. However, we think that the use of antenatal steroid in elective Caesarean Section should be added. We note this is probably not indicated if all elective Caesarean Sections are done after 39 weeks as in the 2004 guideline, and would like clarification on whether there is audit data on the timing of Caesarean Section.</p> <p>We note that the RCOG Respiratory Distress Syndrome, Antenatal Corticosteroids (2004) guideline does not cover elective Caesarean Section either.</p>	<p>Thank you for your comment. The recommendation to carry out elective Caesarean sections at 39 weeks will not be revised in this update and so will stand. As you rightly point out this means it would not be appropriate to include a review of the use of corticosteroids for elective caesarean section. We have not sought audit data on this issue so are unable to advise whether this exists.</p>
SH	The Royal College of Paediatrics and Child Health	3	4.3.2c	<p>The RCPCH would like the care of the newborn to include delayed cord clamping after Caesarean Section.</p>	<p>Thank you for your comment. The new evidence on timing of cord clamping is not specific to caesarean birth. The NICE Intrapartum Care guideline contains a section on timing of cord clamping and given the</p>

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>McDonald SJ, Middleton P. Effect of timing of umbilical cord clamping of term infants on maternal and neonatal outcomes. <i>Cochrane Database of Systematic Reviews</i> 2008, Issue 2. Art. No.: CD004074. DOI: 10.1002/14651858.CD004074.pub2</p> <p>Rabe H, Reynolds GJ, Diaz-Rosello JL. Early versus delayed umbilical cord clamping in preterm infants. <i>Cochrane Database of Systematic Reviews</i> 2004, Issue 4. Art. No.: CD003248. DOI: 10.1002/14651858.CD003248.pub2</p>	Please respond to each comment new evidence in this area it is likely this section will be considered when this guideline is reviewed for update.
SH	University Hospitals Coventry & Warwickshire NHS Trust	1	3.1c  page 2: If a woman has had a previous caesarean section there is an increased risk of placenta praevia. The literature reports risk increases of between 30 and 60%. Of women who have a placenta praevia following a previous caesarean	<p>THE RCOG Green Top Guideline 27 refers to 4 items that give an estimate of the incidence of placenta accreta after a previous CS. The figures are much higher than in the scope and may have been misinterpreted in the text</p> <p>Miller DA, Chollet JA, Goodwin TM. Clinical risk factors for placenta praevia–placenta accreta. <i>Am J Obstet Gynecol</i> 1997;177:210–14.</p> <p>“Among women with placenta previa, the risk of placenta accreta ranged from 2% in women &lt;35 years old with no previous cesarean deliveries to almost 39% in women with two or more previous cesarean deliveries and an anterior or central placenta previa”</p> <p>Clark SL, Koonings PP, Phelan JP Placenta praevia/accreta and prior caesarean section <i>Obstet Gynecol</i> 1985;66:89–92.</p>	Thank you for this contribution and the references you provide. We did use the more conservative end of the published data. However, we have amended the text to make the statistics clearer and more representative.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**



Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>section, 2% will have a morbidly adherent placenta. The risk of this complication increases with the number of previous caesarean sections: 2% with one, 16% with two and 24% with three previous caesarean births.</p> <p>“with a placenta previa and one previous cesarean section, the risk of placenta accreta was 24%; this risk continued to increase to 67% (two of three) with a placenta previa and four or more cesarean sections. Possible mechanisms and clinical implications are discussed”</p> <p>Zaki ZMS, Bahar AM, Ali ME, Albar HAM, Gerias MA. Risk factors and morbidity in patients with placenta praevia accreta compared to placenta praevia non-accreta. Acta Obstet Gynecol Scand 1998;77:391–4.</p> <p>The percentage of accreta increased linearly from 4.1% in patients with no CS to 60% in patients who had had three or more CS.</p> <p>There has been one subsequent reference.</p> <p>Sisir K. Chattopadhyay, Hessa Kharif and Mariam M. Sherbeeni Placenta praevia and accreta after previous caesarean section European Journal of Obstetrics &amp; Gynecology and Reproductive Biology Volume 52, Issue 3, 30 December 1993, Pages 151-156</p> <p>After one caesarean section, placenta praevia was complicated by accreta in 10% of cases and after two or more this was 59.2%. The risk of hysterectomy with placenta praevia and uterine scar was 10% but with placenta praevia accreta it was 66%.</p> <p>Theer has also been an excellent article in The</p>	<p>Please respond to each comment</p>

**PLEASE NOTE:** Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.

Type	Stakeholder	Order No	Section No	Comments	Developer's Response
				<p>Please insert each new comment in a new row.</p> <p>Obstetrician and Gynaecologist recently by Prof Steer which gives similar figures            With the considerable rise in the rate of caesarean section in recent years, the incidence of placenta praevia and placenta accreta has risen substantially. The risk of placenta praevia in a first pregnancy is only about 1 in 400, but it rises to 1 in 160 after one caesarean section, 1 in 60 after two, 1 in 30 after three and 1 in 10 after four.<sup>36</sup> If the placenta is over the lower segment scar, then there is an attendant risk that the placenta will invade into (or occasionally through) the myometrium. This risk is about 1 in 50 if there has been one caesarean section, 1 in 6 after two, 1 in 4 after three, 1 in 3 after three or four and 1 in 2 after five.</p> <p>The reference cited is Zaki</p>	<p>Please respond to each comment</p>
SH	University Hospitals Coventry & Warwickshire NHS Trust	2	References	Should include RCOG Green Top Guideline 27	Thank you for your comment. The review for this NICE guideline update will be based upon a systematic review of the evidence and will update the RCOG Green Top guideline 27 on placenta praevia and placenta accrete. The RCOG guideline itself will not form a basis for this review as our methodology involves reviewing original published evidence.

**PLEASE NOTE: Comments received in the course of consultations carried out by the Institute are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that the Institute has received, and are not endorsed by the Institute, its officers or advisory committees.**