National Institute for Health and Care Excellence

Caesarean Section

Quality Standard Consultation Comments Table

21st December 2012- 24th January 2013

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
1	British HIV Association	General	The British HIV Association (BHIVA) has no specific comments to make.	Thank you for your comment.
2	The Royal College of Midwives	General	We are concerned that the implementation of the Maternity Services secondary uses data set is not complete and that this vital data cannot be readily collected at a national level .	Thank you for your comment. We make reference in the document that the data will be available once the dataset is implemented. It is anticipated that including priority statements that relate to areas covered in the dataset, this will add further impetus to the national implementation.
3	The Royal College of Anaesthetists	General	Please note that this response includes the views of Council members of the Royal College of Anaesthetists and the sub-specialty organisation - The Obstetric Anaesthetists' Association (OAA).	Thank you.
4	Healthcare Inspectorate Wales	General	The standard is intended to apply across the UK. However, the wording is very England centric and consideration needs to be given to the frameworks operating in Wales, Scotland and Northern Ireland that are the equivalent of the DOH - NHS Outcomes Framework 2012/13.	Thank you for your comment. Where available we have made reference to specific current practice issues or outcome indicators for Wales. Quality standards do not currently have a remit in Northern Ireland or Scotland
5	Birth Trauma Association	General	We are not sure why 'equality and diversity considerations' only appears under statement 1 and not the others. There is controversy about whether tokophobia classes as a mental health difficulty, but if so then the E&D implications for maternity services must be considered in this context.	In developing the quality standards the Topic Expert Group (TEG) only include equality and diversity considerations where a specific issue has been identified for a specific statement.
6	Csections.org	General	We are concerned by the Drafts repeated reference to the need to measure the CS rate as the Outcome of the majority of the Quality Statements. While such measures are useful and a possible output of some of the Statements there are far more relevant measurements noticeably absent. For example Statement 3 wants to know how many CS occur following the involvement of a consultant obstetrician but does it not also want to know:	Thank you for your suggestions. Outcome measures are stated where the topic expert group felt these were appropriate, measureable and specifically attributable to the action stated in the statement. In addition to this, each statement is now followed by a rationale section which provides a brief explanation for why the statement is important with some reference to the outcomes that the action referred to in the statement has a potential causal link to.

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			• Whether those CS were emergency or planned? • What the intended mode of delivery was? • At what gestational age they occurred? • Whether there were good health outcomes? Whether the women involved were satisfied with the care they received? We feel that **each** Outcome measure needs to be brought in line with **each** Quality Statement and we recommend that when **each** Statement is reviewed, it is done so using the bullet points above so that Outcomes measure something more specific and relevant than simply the overall CS rate. We are concerned that leaving Outcome measurements at the high level of "CS rates" or at best "Maternal Request CS rates" without further categorisation leaves them open to misinterpretation by lobby groups as well as Service Providers. In other words without a more detailed breakdown of rates 'people' can easily take this Draft (given statements in Section 4, pg. 22 beginning "As quality standards are intended…") to mean that they should be encouraging a reduction in the CS rate in particular in the CDMR (Caesarean Delivery on Maternal Request) rate. As we all know, there is NO national CS target rate and WHO retracted all reference to a specific CS target rate several years ago. While individual hospitals and PCTs may choose to specify CS target rates, national guidance do not and the emphasis placed on such measures in this Draft implies that there is both a rate to be aimed for and a desire to reduce the rate. In addition, it is important to recognise that all caesarean data cannot be grouped together. This occurs far too frequently in	The inclusion of CS rates has been amended to be more specific about the rate of planned CS or unplanned depending on the statement. The quality standard doesn't seek to recommend a specific CS rate, but this has been included as an outcome measure where it is deemed to be a measure of the quality of the service. Planned mode of delivery has been included where appropriate. In addition to this, patient experience outcome measures have also been included where appropriate.

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			research papers and each time the paper's results are questionable as a result. For example, grouping together births regardless of the woman's intended mode of birth - A woman choosing a vaginal birth despite having been advised to plan a caesarean, then experiencing a protracted labour followed by an emergency caesarean is NOT, in terms of risks or complication probability, a woman that has planned a caesarean but gone into labour early – yet all too often such births are grouped together into a single statistic. This Quality document really needs to recognise the need to separate out these groups of women if we are to ever understand the implications of birth choices and interventions and we recommend that this principle is applied to each Statement as it is reviewed.	
7	Csections.org	General	We don't understand why the 2004 Caesarean Guideline is still being referenced. This version of the CS Guideline has been totally superseded by the 2011 Caesarean Guideline and should no longer be referred to by this Quality document. We appreciate that some of these recommendations originate in the 2004 document but 2011 is the new version, the **origin** of a recommendation is not relevant, whether or not it is still current. • Statement 3 - This should reference the 2011 document. • Statement 5 - This should reference the 2011 document. • Statement 7 - This should reference the 2011 document. Statement 9 - This should reference the 2011 document What this point unfortunately service to also highlight is the	Thank you for your comment. The 2011 guideline has been used throughout the development of this quality standard as we always use the most up to date version of our clinical guidelines. Where 2004 recommendations are referenced this is due to these recommendations not being changed in the 2011 update, they are referenced as such in the 2011 update.

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			related issue namely that some practitioners (be it due to misguided beliefs, personal agendas or simply not being up to date with research and NICE policies) continue to refer to risks that have been disproven and use documentation that is out of date. For example, we frequently come across women who have been told that by planning a caesarean at week 39 they are putting their baby at increased risk of respiratory problems. The 2011 CS Guideline clearly found in the research evaluation that there was **NO** increased risk at week 39 and that the rates of risk were the same as for vaginal birth at the same gestational period. Yet some staff continue to tell women such things and women find themselves bamboozled by conflicting information. RCOG and NICE have clearly stated in the past that informed decision-making based on evidence-based research is crucial and yet we are frequently being contacted by women who have been given information that it patently untrue. We recommend that in **each** Quality Statement patient satisfaction specifically asks women how much 'trust' they placed in the information being delivered to them.	
8	Csection.org	General	We are assuming that changes recommended within each Quality Statement comment field will be, if accepted, cascaded through into the relevant sentences within the Structure, Process, Outcomes, Description and Definition (etc.) areas for **that and each related Quality Statement**. For example, Statement 4 includes specific recommendations for additions to the Quality Statement itself which, if accepted, require additional Outcome measures. We have fully described these in the comments for this Statement. I have not then gone on to re-write the numerators that are required to provides these measures. We assume that this will be inserted if the changes are taken on board. We would assume this will be the case for each piece of feedback provided	Yes that is correct.
9	Csection.org	General	As cost is a major consideration for the Expert Group we would	Thank you for your comment. Costs is not a primary

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			like to point out: • Money can be saved by ensuring that membership of the maternity team includes 'supportive' practitioners – where 'supportive' refers to practitioners who agree with the principle of CDMR – this may shorten the 'discussion' and 'referral' to counselling periods involved in such cases as those covered in Statements 1, 2, 3 and 4. It is imperative that relevant measurements are specified in the Outcome measures. For example, our experience suggests that many emergency caesarean costs originate from planned vaginal births. Such costs should be separated out from planned CS. Generic statements about overall CS costs are misleading when Service Providers are trying to plan and cost service provision. Practitioners and Service Providers need to understand that costs of CS are a combination of planned and emergency CS but that the two are NOT the same thing and that their policies and practises as well as the information they provide to women should reflect this. They need to be able to plan with the understanding that the risks, complications, physical and emotional outcomes are different depending on whether the CS was planned or an emergency. The intended mode of birth means that each of the following differ: the probability of specific complications arising during the birth, the maternal and infant risks in general and maternal satisfaction (which is likely to be VERY different indeed). All of these have knock on cost implications in terms of care, repair and future birth planning. **PLANNED CS AND EMERGENCY CS ARE NOT THE SAME THING.** The CS Guideline specifically found that CS should not be refused on the grounds of cost, therefore it is important that the Quality Statements support this by ensuring that measurements can effectively confirm (or question) this.	consideration for developing quality standards. Cost effectiveness is considered, via the use of NICE accredited evidence sources that use cost effectiveness when developing guidelines.
10	Csections.org	General	We are concerned that the Draft specifically says it does not specify levels of achievement but then goes on to refer to	Thank you for your comment. The 100% or 0% achievement rate is relevant to the process and structure

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			aspirations of 100% (or 0% where something should not be done). The Draft in its current form suggests Outcome measures for CS rates without further qualification of these rates in relation to the Quality Statement. Outcome measures must reflect the actual Statement for each Quality Statement. The Draft also makes Quality Statements and then takes away the 'strength' of them by effectively saying they can be ignored. **RECOMMENDATIONS:** We would recommend that the following sentences be removed (or if not possible to remove then further clarified) from Section 4 as they leave the way open for practitioners to 'suggest' that CS rates have a target and may be perceived to support the arbitrary reduction of CS rates: • "As Quality standards are intended to drive up the Quality of care, achievement levels of 100% should be aspired to (or 0% if the Quality Statement states that something should not be done)." "However, we recognise that this may not always be appropriate in practice when taking account of patient safety, patient choice and clinical judgement and therefore desired levels of achievement should be defined locally."	measures. The outcomes measures do not state a positive or negative outcome, just the outcome as a measure.
11	electivecesarean.com	General	My organisation welcomes this draft publication of a quality standard that focuses on clinical effectiveness, patient experience and safety, and appreciates efforts by NICE to ensure that input from a wide spectrum of maternity organisations is received. There are some concerns I would like to highlight however, beginning with some general comments and then some suggested additional (or alternative) quality statements. Please note that for each draft quality statement, wherever I have suggested wording changes {**noted in bold or bold inside brackets**}, it is assumed that if changes (or parts of changes)	Thank you for your comments. The use of CS rates as a measure has now been split into planned and unplanned as appropriate. The quality standard doesn't seek to recommend a specific CS rate, but this has been included as an outcome measure where it is deemed to be a measure of the quality of the service. With regard to your comments about the use of the term "normal birth", the quality standard is consistent with

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			are accepted and implemented in the final text, that these will be transferred to all other relevant sentences contained within the Structure, Process, Outcomes, Description and Definition areas of each quality statement. <u>The blanket use of the term 'caesarean section'</u> NICE is fully aware that the risks and health outcomes for different types of surgery can be very different. For example, an emergency CS, a planned CS for a medical reason (often occurring at an early gestational age), a planned CS with no medical reason, a primary CS and a repeat/ multiple repeat CS all have different risks. Therefore it is essential that this quality standard *at least* makes every effort to distinguish between the two main types: emergency and elective CS. This quality standard does not consistently make this important distinction, and I think this is a fundamental necessity going forward. Also, for CG132, the GDG did a great deal of commendable work trying to establish comparisons between *planned* mode of delivery (vaginal and CS), and distinctions were made throughout the document between emergency and elective CS. As such, it would be a serious step backwards if this approach to assessing quality and cost of maternity care is not continued. The distinction of CS type is very important for improving women's understanding and knowledge of different CS risks and outcomes, but also health professionals, many of whom frequently cite risks associated with an emergency CS in the context of discussions on planned CS for example. Also, separation of CS data is essential for improving future outcomes and informing NICE and the NHS about areas of care that need attention. Currently, all too often health and cost complications predominantly associated with emergency CS are dealt with by trying to reduce *all* CS surgeries, including those that are planned, and clinically safer. For example, HES figures show that postpartum haemorrhage occurred in 13.2% of all births; 7.8% of spontaneous, 24% of instrumental and	CG132 in that if refers to vaginal birth and CS respectively with the focus being on women and clinicians make the best possible decision about mode of birth based on the best outcomes for the woman and the child/ children.

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			21.4% of CS.(***1***) Studies have demonstrated higher rates of haemorrhage in emergency CS, but the HES blanket use of *CS* alone doesn't help inform risks with different birth *plans*. Unless this NICE quality standard *does* separate CS data, in every quality statement, it's the same issue. In another example, HES data cites a rate of 1.1% birth injury to scalp, but whereas back in 2004-05, when it also recorded emergency and elective CS occurrence (in that year *none* of the scalp injuries related to elective CS), it has not done this since. The result is that women *planning* a CS are informed of scalp injury risk when in fact it is predominantly associated with *emergency* CS. NICE needs to discontinue this trend in assessing and presenting mixed CS data. <u>The prevailing focus on CS rates</u> There appears to be a consistent theme throughout the quality standard of assessing the outcome of processes in terms of what happens to the overall CS rate. Aside from some of the issues cited above (i.e. an overall CS rate cannot inform strategies to improve quality of care in the absence of separating surgery types), we believe that the obsession with CS rates as a starting point is completely flawed. These are just some reasons: *CG 132 states, "Many of the factors contributing to CS rates are often poorly understood. The guideline has not sought to define acceptable CS rates." *The *World Health Organization*, whose 1985 recommendation for CS thresholds was blindly cited for almost 25 years, admitted in 2009 that in fact "no empirical evidence for an optimum percentage" exists and an "optimum rate is unknown".(***2***) It's crucial to recognise that this country's history of focusing on CS rates was strongly influenced by what we now know was a CS recommendation with no basis in evidence. Even 3 years on, there are health professionals who are not aware that WHO's now recommends, countries "might	

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			want to continue to use a range of 5-15% or set their own standards" (even seen in CG132 comments submitted by maternity organisations). NICE produces evidence-based guidance for the NHS, and as such, I am surprised by the prominence being given to CS rates in this quality standard. If *no one* knows what optimum CS rates (of any type) should be, and there is no evidence supporting a % figure, how can the CS rate be a measure of quality? *The Department of Health, NICE and the NHSLA have all confirmed that they do not advocate CS rate targets, and obstetricians worldwide have condemned the idea of setting CS rate targets.(***3***) <u>The paucity of quality statements for managing risk (prior to labour) in relation to perinatal mortality and morbidity</u> CG132 stated, "The main reason given for preference for CS was that it was perceived to be safest for the baby." RCOG's 2001 audit(***4***) reported, "Almost all mothers expressed a wish to have a birth that was 'the safest option for their baby'." And a "significant proportion of women reported that they would like more information on the risks and benefits of CS." (p.25) There is no evidence that this situation has changed, and given that "surveys of obstetricians express a higher rate of preference for CS for themselves or their partners compared with other groups [and] 50% thought it was the safest option for the baby" (p.104), some women have asked themselves, what information do these doctors have that we need to know? Furthermore, even though the "majority [of obstetricians] agreed that elective CS is not the safest option for the mother (p.104), a large body of research demonstrates that rates of planned CS are still comparatively high among doctors (or doctors' partners) compared with the general population, and that as soon as potential risks for their babies are introduced (e.g. suspected macrosomia) these rates are even *higher* (up to 65%)(***5***)	

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			And so in the context that their babies' health and safety are paramount to most women and doctors, our organisation questions why more of the quality statement outcomes are not concerned with the health outcomes of babies, and in which CS births risks are greatest, rather than simply 'rates of CS'. I would be very concerned if this NICE quality standard was working under the false assumption that lower overall CS rates automatically equals better outcomes for babies. <u>The disagreement that exists between health professionals as to what comprises "accurate information" for women</u> Health professionals in maternity care are currently receiving, and in turn communicating, some very conflicting messages to each other – and by default, to pregnant women and their families. Recent recommendations to Clinical Commissioning Groups (CCGs) for example, published by the RCOG in collaboration with the RCM and NCT,(***6***) were met with anger and disbelief from numerous maternity charities, organisations and health professionals. The recommendations focussed on the importance of increasing 'normal birth' rates and suggested that a 20% CS rate is achievable and sustainable, yet there is *no* empirical evidence or Department of Health backing to suggest ideal CS rates (see above). Worse still, the recommendations for increasing rates of normal birth (defined as "without induction, without the use of instruments, not be caesarean section and without general, spinal or epidural anaesthetic before or during delivery") added, "It is important to try to increase this rate as well as that of vaginal birth, which includes delivery by forceps and ventouse." The suggestion that CCGs try to increase instrumental deliveries does not reflect best evidence, and we know many doctors avoid these for their own births.(***5***) This strategy may reduce CS rates, but it will *not* automatically achieve better outcomes for mothers and babies; instrumental delivery can have serious adverse outcomes and offering a CS	

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			would be safer for some women. NICE has confirmed on a number of occasions that it does not support the use of '*normal*' as a maternity care definition, and it is our understanding that it was *not* the original intention of The Information Centre (when using this term to measure the process of labour) for it to become a goal or target to be facilitated and achieved. And yet many NHS documents, including some of those cited in the Appendix of this quality standard, manifestly extol the virtues of a normal delivery (and the reduction of CS rates), despite the fact that its definition also includes, "antenatal, delivery or postnatal complications (including for example post partum haemorrhage, perineal tear, repair of perineal trauma, admission to SCBU or NICU).". These adverse outcomes may be 'normal' but they are not necessarily acceptable to pregnant women, and may seriously affect their level of satisfaction postpartum – something that the government is seeking to address. Its 2010 White Paper promised "focus on continuously improving those things that really matter to patients - the outcome of their healthcare",(***7***) and this statement – for a significant proportion of women, is NOT commensurate with reduced rates of CS and epidurals (or indeed other medical interventions).(***8***) Please, if time allows, could NICE visit and read some of the comments and articles provided in this reference, which contains four links to articles and forums. Thank you. The RCOG, RCM and NCT say, "Women must receive consistent, positive information and advice from their health professionals if they are to have confidence in a normal birth", while other maternity organisations suggest instead, "Women must receive non-biased, factual and evidence-based information, if they are to have a more positive birth experience and safer birth outcomes."(***6***) We hope NICE recognises this continuing challenge, and understands there is certainly work to be done in achieving the right balance between informing	

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			women about different birth plan risks without scaring them and withholding risk information with the aim of influencing their decision. My organisation is aware of too many cases where babies have died in late gestation without the mothers having ever been informed about an increased risk of stillbirth, or mothers needing pelvic floor reconstruction surgery having never even heard of the word prolapse. For this reason, I ask NICE to begin a process of change in how the quality of clinical effectiveness, patient experience and safety in this country's maternity care is assessed and measured. I ask that NICE views health outcomes as a priority for quality care, and not rates of mode of delivery; let those be a secondary concern.	
12	electivecesarean.com	General	Cost The NICE Scope for this draft guideline (3.4 Economic aspects) states: "The Topic Expert Group will take into account both clinical and cost effectiveness when prioritising the quality statements to be included in the quality standard. The economic evidence will be considered, and the cost and commissioning impact of implementing the quality standard will be assessed." If measuring cost is one of the reasons behind assessing CS rates then it is important that this is considered in the context of there being different costs associated with difference CS types, and the fact that the vast majority of (much higher) emergency CS costs must be attributed to the planned vaginal delivery group when cost comparisons are made – as happened in CG132. NICE guidance very clearly shows that planned CS costs less than emergency CS, so a good outcome measure might be a reduction in the rates of emergency CS - without concern whether the planned CS rate increases. E.g. In addition to CG132 (and in fact there was evidence of	Thank you for your comment. Cost alone is not a primary consideration for developing quality standards. Cost effectiveness is considered, via the use of NICE accredited evidence sources that use cost effectiveness when developing guidelines.

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			this in appendix C of the NICE 2004 guidance), in the Dept. of Health's 2007 'Delivering quality and value…', the table, 'Tariff payments (2005/6) and activity for caesarean section and normal birth', demonstrated that a normal delivery with complications cost £1490 while a CS without complications cost £1489. Just a £1 difference – and this was even though ALL CS costs were merged together, which we know over-inflates the cost of a planned CS. The statement beneath the table reads: "There is a great potential for local health systems to release resources by managing caesarean section rates." But my suggestion would be this: "There is a great potential for local health systems to release resources by managing **complications**." Similarly, the Dept. of Health's 2007 'Maternity Matters' states, "High rates of interventions, such as large numbers of caesarean sections, could lead to worse outcomes for mothers and their babies, as well as being less cost effective for the NHS." Again, this is an example of why separating CS data is so important, both in the context of health outcomes but also (in these times of recession and cost-cutting) cost-effectiveness. CG132 found that planned CS should not be refused on the grounds of cost-effectiveness because once we start doing appropriate and relevant cost-comparisons, based on *planned* mode of delivery and not actual mode of delivery, we start to see the cost of PVD creeping up considerably. And notably, with just one adverse outcome considered – urinary incontinence – the NICE cost model demonstrated a reduced cost between a PVD and a PCD to just £84, so in terms of cost-effectiveness, what we need is to reduce the number of expensive emergency CS, and not focus as much on the less expensive planned CS. The August 2012 recommendations to CCGs by the RCOG,	

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			RCM and NCT(**6**) included this statement, "Every potential caesarean section that is enabled to be a normal birth saves £1200 in tariff price alone. [This] saves the NHS money." Aside from the fact that maternity tariffs are not the appropriate measure of actual overall cost to the NHS, this is simply not the case, [REF CC chp. 11] and yet the myth perpetuates in absence of the true costs (physical, psychological and financial) that we should plan vaginal deliveries for as many women as possible. Cost comparisons should be of *PLANNED* mode of birth outcomes, not outcomes alone, and CG132 estimates that a planned CS costs £710 more than a planned vaginal birth, but once urinary incontinence costs are factored in, this reduces to just £84. Other downstream costs and litigation (e.g. failure to carry out timely caesareans) are huge, and not considered in this CCG guidance – **or indeed in this quality standard**. I think that NICE has a unique opportunity here to strive to improve healthcare outcomes with a fresh perspective on what matters to women and their families, and how best to research and achieve that. It can finally draw a line in the sand and move away from a starting point that is an unhealthy obsession with national or local overall CS rates and efforts to reduce them arbitrarily – and instead, focus on the provision of unbiased evidence-based information in maternity care. I would like to thank NICE again for inviting comments from my organisation and others (a huge step forward in itself), and I trust that it will find some of my comments here useful for the continued development of this CS standard.	
13	Ferring Pharmaceuticals	General	No comments	
14	AIMS (Association for Improvements in the Maternity Services)	General	If drafts 2, 4, 8 and 9 were effectively implemented then the way CS are handled in the UK would change hugely, for the better.	Thank you for your comment.

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15	Royal College of Paediatrics and Child Health	General	Is this statement only for caesarean section (CS) in full term infants?	Thank you for your comment. This standard is for all CS cases.
16	NCT	General	The first standard relates to women requesting a caesarean section where there is no indication, whereas the third standard relates to all women who have a caesarean section. It would seem more appropriate to reorder the first three standards so that the order reflects their importance in terms of the numbers of women to which they would apply. The order seems more appropriate as standard 3, then standard 2, then standard 1. That is: 1. Pregnant women for whom CS is being considered have a consultant obstetrician involved in the decision-making process 2. Pregnant women who request a CS because of anxiety about childbirth are offered a referral to a healthcare professional with relevant expertise. 3. Pregnant women who request a CS (when there is no other indication) discuss this with members of the maternity team within a suitable time frame depending on the number of weeks left in their pregnancy.	Thank you for your comment. The statements have been re-ordered.
17	Department of Health	General	The statements are appropriate and generally comprehensive, so that they should facilitate and aid commissioning of this important area of the maternity pathway.	Thank you for your comment.
18	Kings College London	General	Why is'nt there anything on breech? Every woman should be offered and recommended an ECV (and be able to have it within a week of diagnosis after 36 weeks gestation) before having a CS for breech?	Thank you for your comment. The care of women with a breech birth is outside the scope of this standard. This issue is covered in the published NICE quality standard on antenatal care (quality statement 11 on ECV for breech presentation)
19	Royal College of Nursing	General	These statements by their nature are broad and may not be useful for service commissioners	Thank you for your comment. The TEG have tried to make the statements as specific as possible whilst making sure that they are relevant as many pregnant women as possible.

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20	NCT	General	NCT welcomes the introduction of a quality standard that aims to improve the information available to women who may request or need a caesarean section and that focuses on reducing potential risks or complications for the women or the baby.	Thank you for your comment.
21	Department of Health	General	Middle paragraph – there is a typo – the full list of standards is in section 7.	Thank you for pointing this out.
22	The Royal College of Midwives	Introduction	The incidence of caesarean section reported here is too low. It would be more accurate to link this statement to recent HES statistics, that state "The percentage of caesarean deliveries has remained stable at 25.0% (163,859), a 0.1 percentage point increase from 2010-11" http://www.hesonline.nhs.uk/Ease/servlet/ContentServer?siteID=1937&categoryID=1941	Thank you for your comment, this has been rectified in the document
23	Swansea University	Introduction	The distinction between a 'draft standard' and a 'draft quality standard' could be clearer for lay readers.	Thank you for your comment. The final document refers to *the* quality standard which is made up of individual quality statements.
24	Swansea University	Introduction	The potential for **maternal** mortality might be given more emphasis.	Thank you for your comment. Statement 9 concerning post CS monitoring is intended to help reduce incidence of maternal complications and mortality.
25	Swansea University	Introduction	There is a typographical error 'the first **or** second trimester' instead of the first **of** second trimester'	Thank you for pointing this out.
26	Swansea University	Introduction	We would not normally refer to a pregnant woman as a 'patient', unless she was admitted to hospital for another indication or complication.	Thank you for your comment.
27	Healthcare Inspectorate Wales	Introduction	In the introduction, it refers to Caesarean section (CS) rates which have increased significantly in recent years. The data provided suggests that in the UK 20–25% of births are by CS; this is a significant rise from 9% in 1980. As the focus of the draft standards is on improving the information available to women who may request or need a CS, it would be helpful if these figures were broken down into emergency and elective rates. This would provide some clarity in relation to the number of women choosing to elect for a C/S and enable a	Thank you for your comment. The introduction section is providing a very brief high level description of the topic. The quality standard is focused on all types of CS and therefore it wasn't deemed necessary to differentiate between the different types in the introduction.

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			better understanding of how the standards may aid to reduce current rates.	
28	electivecesarean.com	Introduction	In the UK {**25%}** of births are by CS {**(14.8% emergency and 10.2% elective),**} up from 9% in 1980	Thank you for your comment.
29	electivecesarean.com	Introduction	May I suggest adding some important context in this opening statement (since CG 132 states, *"Many of the factors contributing to CS rates are often poorly understood. The guideline has not sought to define acceptable CS rates."*), lest it be misinterpreted that NICE is concerned by rising CS rates per se, or that its focus on "reducing potential risks or complications for the woman and the baby" is commensurate with (or to be achieved by) arbitrary targets to reduce CS rates. Suggested additional text:(***9***) **Over the same period, rates of infant deaths have decreased significantly. The neonatal mortality rate fell by 62%, from 7.7 deaths per 1,000 live births in 1980 to 2.9 in 2010, and the perinatal mortality rate (which includes stillbirths)* fell by 44% from 13.3 deaths per 1,000 total births in 1980 to 7.4 in 2010.** [*in October 1992, the legal definition of a stillbirth was changed to include deaths after 24 completed weeks of gestation or more, instead of after 28 completed weeks of gestation or more. Therefore improvements in perinatal mortality outcomes may be even greater.]	Thank you for your comment. The point of this section is to provide some context about the specific topic. It is not intended to provide an overview of the related issues linked to this topic. No judgement is made about the increased rated.
30	electivecesarean.com	Introduction	Suggest adding word: "potential {**birth**} risks or complications". Some CS are planned in order to avoid potential problems associated with a trial of labour and the sentence currently reads as though NICE may be referring to CS birth risks only. It's important to note that rates of complications such as perineal laceration (39.9%), long labour (10.3%) obstructed labour, fetal distress and umbilical cord-related complications (30.5%), episiotomies (15.2%) and instrumental vaginal deliveries (13%) have all increased in the last year,(***1***) and while very often the focus is on what's happening with CS,	Thank you for your comment. The TEG were content with the current wording.

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			these rates are hugely concerning for women too, since they can be directly associated with serious infant and maternal morbidity.	
31	electivecesarean.com	Introduction	Suggest adding one other line providing a context for rising CS rates, with regard to increased maternal age, increased maternal weight and increased term birth weights between 1980 and today, all of which introduce well documented obstetric challenges.	Thank you for your comment. The point of this section is to provide some context about the specific topic. It is not intended to provide an overview of the related issues linked to this topic. No judgement is made about the increased rated.
32	electivecesarean.com	Introduction	Pg. 22 Lines 10-11 It is important that the quality standard is considered alongside current policy and guidance documents listed in the evidence sources section. A number of these documents are outdated in terms of CS evidence, and especially planned CS evidence. Another problem is that the "policy context" of some of the documents contains ideological statements and targets related to "normal birth", which it is my understanding NICE does not support. I am not suggesting that there are any easy way to manage this situation, but I genuinely hope that the NICE quality standards will encourage a transitional period towards providing more balanced dissemination of information and training on CS. I'd also like to note the paradox that exists in the very fact that current NICE guidance and standards must be considered alongside some of these more outdated documents, and this is in part what is leading to some of the confusion amongst some health professionals, many of whom have been trained to advise women that a vaginal birth outcome is inherently desirable, and intervention should only to be used when absolutely unavoidable. As one example to demonstrate this point, the Dept. of Health (2007) Delivering quality and value: focus on fractured neck of femur; primary hip and knee replacement; acute stroke; caesarean section; short stay emergency care document states: "Making the decision - birth should be promoted as a normal physiological process…	Thank you for your comment. The primary evidence source for developing the quality standard was CG132. The other documents listed provide a contextual overview of other influential policy and strategy documents that have influence care in this area in recent years. Whilst terminology may differ, these documents are the key policy documents in this area and it is therefore valid to include them.

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			Undertaking a caesarean section - up-to-date, evidence based guidelines, protocols or care pathways, based on national guidelines, should be followed for the management of caesarean sections. There should be a system in place for auditing, monitoring and reviewing processes and clinical practice" The contents of this 2007 document, read from the knowledge and perspective of 2012, could mean different things to different people because of course NICE recommendations on CS have since changed, but other documents still encourage normal birth as a main goal. I am not suggesting that older documents become obsolete, but I think it would be very useful for NICE to state in its quality standard that "promoting normality" on a wide scale is not supported by evidence, and that any reference to measuring different CS rates should not be interpreted as support for trying to *decrease* CS rates or *increase* rates of what some organisations perceive as 'normal'. Many women who need or choose a CS birth would describe their births as normal too, and the negative associations attached to CS birth being somehow 'abnormal' has caused unnecessary angst and feelings of failure in women in the past. Definitions of what is normal in the context of an individual organisation's aims or values is one thing, but for the phrase to be used in the context of national maternity care or quality standards is entirely different. Does NICE recognise that its own decision to avoid talking about what's 'normal' conflicts with the content of some of the documents cited in its Appendix? Lines 12-14 - In the context above, and given the content of some of the documents listed on pg.25, it is important that if the outcomes of these quality standards are not to be viewed as "a new set of targets or mandatory indicators for performance management", we should steer clear of CS rates	

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			being used as outcome measures – because they *will* be viewed as targets, despite NICE's best intentions. My organisation already has evidence of anxiety/tokophobia counselling being used to reduce the CS rate – or increase the normal birth rate – and this should *never* be the primary goal of counselling referral.	
33	NCT	Introduction	Women requesting a caesarean section where there is no indication are a small proportion of all women who have a caesarean section. It would, therefore, seem more appropriate to reword the second sentence to as follows (words removed have been struck through and words added have been put in bold): "The draft standard focuses on improving the information available to women who **need, are offered or** may request ~~or need~~ a CS". Similar to this, the first sentence of the second paragraph should read as follows: "This draft quality standard covers the care of women who **need or may** plan for ~~or may need~~ a CS".	Thank you for your comment. Parts of the introduction have been amended following consultation comments.
34	electivecesarean.com	Overview	Pregnant women who request a {**prophylactic**} CS (when there is no other {**immediate**} indication) discuss {**and decide**} this with members of the maternity team within {**an acceptable**} time frame depending on the number of weeks left in their pregnancy.	Thank you for your suggestion. This was noted by the TEG when amending the statement wording.
35	Royal College of Nursing	Question 1	No, however, we believe that the health risks are not really made explicit in these draft standards and they should be more focused, particularly in respect of infection, wound management, and risks of major surgery	Thank you for your comment. It is anticipated that the issues you have identified will be covered in other quality standards in the library specifically focused on these issues.
36	Swansea University	Question 1	The proportion of infants exclusively*, fully* or partially* breastfed at discharge and 6-8 weeks (below) should be included as outcomes in these statements. Elective, but not emergency, Caesarean sections reduce breastfeeding rates at 48 hours (aOR 0.72, 0.64-0.81, n=44,641) (Jordan et al 2009). This can be explained in terms of the biological changes during parturition. It remains to be	Thank you for your comment. The TEG reviewed your suggestion and agreed that breastfeeding rates are low in this population there is no evidence to suggest that this would be a valid measure for any of the statement. It is anticipated that this may be included in the post natal quality standard in development by NICE.

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			seen whether additional support following Caesarean section can compensate for this disruption to the normal endocrine cascade. Any change in breastfeeding rates is of major public health (Ip et al 2009) and economic (Renfrew et al 2012) importance, and this should be monitored within the quality standard framework. Breast feeding is too rarely measured as a relevant outcome when considering interventions during pregnancy and labour. In view of the adverse effects of formula feeding on infant, child and maternal physical and mental health, this is a chance to correct a major omission.	
37	Department of Health	Question 1	I have no suggestions for additional healthcare outcomes.	Thank you
38	Healthcare Inspectorate Wales	Question 1.	The suggested healthcare outcomes for each individual statement are appropriate. However, a number of the numerators and denominators are based on information that is not currently collected by maternity organisations in Wales. Consideration also needs to be given as to who would be responsible for collecting the relevant data, for example would it be the responsibility of the community / booking midwife to identify and report the proportion of pregnant women who request a CS in the first or second trimester of their pregnancy ?	Thank you for your comment. We recognise that in some cases the data required to carry out the measures are not routinely collected already. The expectation is that local service will prioritise data collection for areas that commissioners want to focus on for quality improvement. The way in which data would be collected and by who is therefore left to local decisions.
39	Department of Health	Question 2	There is no statement relating to provision of choice and range of anaesthesia for caesarean section (CS). I believe that there may be still maternity units that struggle to provide regional anaesthesia for emergency CS, and this is unacceptable.	Thank you for your comment. This was reviewed by the TEG who did not feel that there was sufficient variation in practice to warrant a statement on this.
40	NCT	Question 2	“What important areas of care, if any, are not covered by the quality standard?” Draft quality standard 9 is titled “Maternal complications following caesarean section”, but it only encompasses monitoring for risks and complications until transfer to core	Thank you for your comment. There is currently a postnatal care quality standard in development.

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			postnatal care. Should this quality standard be enlarged or a further quality standard added to ensure that adequate monitoring is provided after the mother and baby go home? An appropriate outcome measure could, for example, be rates of wound infections in women who have had a CS, which is important because this impacts on the mother's wellbeing and her ability to provide day-to-day care for her new baby. We also feel that it is important to include a quality standard about ensuring that adequate and appropriate support is given to women who have had a CS who wish to breastfeed because of the additional challenges that these women face, for example simply being able to get into a suitable position.	
41	Mumsnet	Question 2	Many Mumsnet users suggested an increased effort to improve the transition from CS surgery/recovery to general post-natal care. Some suggested offering blood transfusions and ensuring full recovery from anaesthesia, while the majority called for the availability of quiet private rooms or CS recovery rooms/wards for post-CS mothers only. The transition from operating theatre straight to the general ward was said to be distressing and offered poor quality clinical care for those recovering from major surgery (in need of wound cleaning, hydration, rest etc)	Thank you for your comment. Statement 9 is intended to deal with some of these issues.
42	Healthcare Inspectorate Wales	Question 2.	The quality statements appear to cover all important areas of care.	Thank you for your comment.
43	The Royal College of Midwives	Question 3	1. Pregnant women who request a CS (when there is no other indication) discuss this with members of the maternity team within a suitable time frame depending on the number of weeks left in their pregnancy 2. Pregnant women who request a CS because of anxiety about childbirth are offered a referral to a healthcare professional with relevant expertise 4. Pregnant women who have had a previous CS are given the option to attempt a vaginal birth	Thank you for providing your priorities. The quality standard you have prioritised have been retained in some form in the final quality standard, apart from statement 6 which has been removed due to a lack of consensus amongst stakeholders and TEG members about whether this was an appropriate area for a quality statement

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			8. Women who have had a CS are offered a discussion with a health professional about her CS and birth options for future pregnancies We know that good information giving is of paramount importance to women and that health professionals need to keep themselves up to date with the evidence to facilitate these discussions. 5. Pregnant women having a planned CS undergo the procedure at or after 39 weeks 0 days of gestation, unless an earlier delivery is necessary because of maternal or fetal complications We are aware of elective caesarean sections being inappropriately undertaken at earlier gestations. 6. Pregnant women having a planned CS before 39 weeks of gestation due to maternal or fetal complications are offered a course of antenatal corticosteroids It is vital to maintain awareness of this important intervention.	
44	Swansea University	Question 3	These statements relate directly to clinical outcomes which determine the health of women and children	Thank you for your comment.
45	Department of Health	Question 3	Statement 3 is the most important, but should stipulate that a consultant must be involved in decision making for both emergency and elective CS.	Thank you for your comment. This statement has now been split to specifically refer to the points you make about consultant involvement in both planned and unplanned CS
46	NCT	Question 3	"What, in your opinion, are the most important quality statements and why? We feel that all the quality standards are important, but the first three are particularly important because they are about ensuring that women have sufficient information to make an informed decision about their care, taking into account potential risks and benefits to themselves and their babies.	Thank you for your comment.

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47	Healthcare Inspectorate Wales	Question 3.	All nine quality statements are important as they each cover a separate element that is relevant to C/S rates. All 9 statements need to be included to ensure that there is a real focus on reducing C/S rates.	Thank you for your comment.
48	Royal College of Obstetricians & Gynaecologists	Question 4	Section 1.2.6.2 – If a colour-flow Doppler ultrasound scan result suggests morbidly adherent placenta, offer magnetic resonance imaging if following discussion, this is acceptable to the woman Section 1.4.6.19 – 1.4.6.21 – Women undergoing CS should be offered prophylactic antibiotics. These should be administered before skin incision and co-amoxiclav should not be used. *Both of these areas have been identified as key priorities for implementation in NICE clinical guideline 132.*	The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. The TEG agreed that these areas were important but felt that these recommendations had been implemented quite widely and that it wasn't necessary to focus on these
49	The Royal College of Midwives	Question 4	Important areas of care that are not covered by the quality standard are • Methods of anaesthesia • Early skin to skin contact • A clear reference to postnatal care	Thank you for your comment. The TEG reviewed your suggestions and felt that there wasn't significant variation in practice with regard to methods of anaesthesia. The other 2 points were felt to be outside the scope of this quality standard and we would anticipate these issues being covered in the post natal quality standard that is currently in development. This is specifically referenced as a related quality standard in the CS quality standard document.
50	electivecesarean.com	Question 4	Suggestions for additional/ replacement quality statement: Having read through all nine draft quality statements, of which 4 out of 7 have suggested outcomes that measure CS rates (two do not state draft outcomes), and given the concerns I've raised about focusing on CS rates, may I request that NICE reconsiders including any/some of the following CG132 recommendations as the focus of additional quality statements in the CS quality standard please: 1) Offer women prophylactic antibiotics at CS to reduce the risk of postoperative infections. Choose antibiotics effective against endometritis, urinary tract and wound infections, which occur in about 8% of women who	The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. All suggestions for additional statements were discussed by the topic expert group who considered they were inappropriate for inclusion primarily on the grounds that the identified areas had become routine practice in most areas. This was the case for your first suggestion. Your second suggestion was deemed to be already covered by

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			have had a CS. [A] [2004, amended 2011] "Offer women prophylactic antibiotics at CS before skin incision. Inform them that this reduces the risk of maternal infection more than prophylactic antibiotics given after skin incision, and that no effect on the baby has been demonstrated. [new 2011] *Reason:* Research published in BJOG (2012)(***10***) focused on rates of CS infection, and its lead author said, "Although most caesarean section wound infections are not serious, they do represent a substantial burden to the health system, given the high number of women undergoing this type of surgery." The Royal College of Midwives commented that this "further supports the need to ensure that any caesarean section is performed only where clinically indicated." Yet despite the RCM's comment on maternal request CS, the study reported a 9.6% rate of infection for *all* CS, the vast majority of which were emergencies or medically indicated. Of these, 88% were minor infections, which leaves a 1% *total* risk of serious infections for *all* CS. This CG132 recommendation would be a very useful quality statement because NICE could assess whether prophylactic antibiotics *are* being consistently offered, and what the outcomes for infection rates are across different types of CS surgeries. This is a perfect example of where NICE can really help inform women about *specific* CS risks, and not just provide them with inaccurate guestimates based on general CS outcomes. 1) Discuss the risks and benefits of CS compared with vaginal birth with women (see tables 4.5 and 4.6, and also recommendation 118), taking into account their circumstances, concerns, priorities and plans for future pregnancies (including the risks of placental problems with multiple CS). [new 2011] This would be an ideal recommendation for inclusion in terms of measuring women's satisfaction during the decision-making	the existing statements, primarily statements 1-4. Point 3 was deemed to be outside of the scope of this quality standard and related more closely to the scope of the post natal care quality standard currently in development

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			process. Outcomes to be assessed would be whether comparative risks were appropriately discussed with each woman, the subsequent planned mode of birth, the actual mode of birth, and the woman's satisfaction with her birth experience. Mortality and/or morbidity data could be collected too. 2) Women with an uncomplicated pregnancy should be offered induction of labour beyond 41 weeks because this reduces the risk of perinatal mortality and the likelihood of CS. [A] [2004] This recommendation seeks to reduce the risk of perinatal mortality, as well as the likelihood of CS, and it is an interesting one because while some women will accept the offer of induction, others may request a CS. Offer of a CS is not explicitly mentioned, but given the maternal request recommendations, it is possible that some women, having originally planned a VD, may decide to request a CS when they go overdue – often due to concerns for the baby's wellbeing. Other women may feel confident that spontaneous labour will occur and are happy to wait a little longer. Outcomes to be measured would again, include women's satisfaction with the care and advice they receive, planned and actual modes of delivery, and rates of perinatal mortality. 3) Women who have had a CS should be offered additional support to help them to start breastfeeding as soon as possible after the birth of their baby. This is because women who have had a CS are less likely to start breastfeeding in the first few hours after the birth, but, when breastfeeding is established, they are as likely to continue as women who have a vaginal birth. [A] [2004] Many women who want to breastfeed are concerned about how a CS might affect their chances of success, and there are	

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			many comments in online forums from women who say that they did not feel they received as much support as they needed. Some even say they received no support at all, much less “additional support”. I think that women would welcome a quality statement on this, with outcomes to include rates of established breastfeeding (the denominator being all women who had a CS and *wanted* to establish breastfeeding and not *all* women who had a CS), rates associated with different CS type (e.g. emergency and planned), and how many women were satisfied that they were offered – and received – additional support.	
51	electivecesarean.com	Question 4	Suggestion for additional/ replacement quality statements (or information to be added to Definitions in current statements, as some of these issues are not directly linked to a CG132 recommendations but are related) : Women with known pre-labour risk factors for emergency CS or instrumental VD (e.g. primiparous, late EGA, advanced maternal age, suspected macrosomia) are offered an individualized consultation regarding the risks and benefits of their options: awaiting spontaneous labour, planning an induction or planning a CS. *Reason for suggestion*: Healthy pregnancies do not equate to ‘low risk’ throughout labour and birth in all women, and risk factors and risk perspectives can alter at 40+ weeks’ EGA. Women deserve the opportunity to discuss risk factors as they relate to their specific situation specifically, and not a general population of pregnant women. Women with pre-labour risk factors for emergency CS or instrumental VD (e.g. primiparous, late EGA, advanced maternal age, suspected macrosomia, reduced fetal movements) are offered an investigative ultrasound scan in order to assess risk and inform decision-making. *Reason for suggestion*: My organisation feels that this should be available to all women, but a good start would be offering	The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. The statements have to be underpinned by NICE accredited evidence. We couldn’t find recommendations in the primary evidence sources that supported these proposed statements

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			analysis of umbilical cord, amniotic fluid and fetal position to women that have been identified in research as higher risk for intervention and complications during labour. EFM is also very important but it is not always used effectively, and an additional scan in late getstation could help save the lives of many babies	
52	Birth Trauma Association	Question 4	Women who go into labour prior to CS are receiving very poor treatment at the moment. We have encountered very sad cases where a tokophobic woman who has had excellent midwifery care, excellent consultant support but goes into labour prior to the CS date and is left to 'get on with it' by a registrar or the consultant on duty. This can have devastating psychological consequences. We know that the closer the anticipated experience matches the actual experience, the better the outcomes for all women (not simply tokophobics). We would suggest a QS along the lines of; 'Pregnant women having a planned CS are offered a discussion of the procedure involved should they go into labour prior to the date of the ELCS. Women who arrive in labour in these circumstance undergo CS within two hours of arrival' Numerator - number of women who report being advised of procedure and receive CS within 2 hours of arriving in the maternity unit Denominator - number of women who go into labour prior to CS Outcome measure: Number of women who consider they have been advised of the procedure should they go into labour prior to CS and whose CS is carried out within two hours.	The topic expert group prioritised the areas of care they felt were most important for patients, based on the development sources listed. The statements have to be underpinned by NICE accredited evidence. We couldn't find recommendations in the primary evidence sources that supported these proposed statements
53	Birth Trauma Association	Question 4	We would like to see a patient rated quality standard about women's involvement in decision making. 'Women who have requested a caesarean are satisfied with the information they received and their involvement in decision making'. Involvement in decision making is a major factor which is known to prevent adverse perinatal mental health problems	Thank you for your comment. Some patient experience outcomes measures have been added to relevant quality statements in the final quality standard.

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			(Slade et al).	
54	Swansea University	Question 4	Patient satisfaction is a difficult outcome to measure. Ideally, it should be assessed during labour, which poses practical difficulties for busy clinicians. If measured retrospectively, women's reports are likely to be influenced by outcomes. In our view, and given the limited resources available to collect and collate data in practice, it would be better to focus on 'hard' outcomes, with long-term sequelae, such as breastfeeding.	Thank you for your comments. The TEG understand the potential difficulty associated with patient experience outcomes. A number of the statements in this quality standard are concerned with improving the experience of women who need or request a CS. The TEG therefore agreed that including some patient experience outcome measures was relevant and important to assess whether the statements are being implemented successfully
55	Department of Health	Question 4	I do not think any of the statements are inappropriate, but have some concerns about the data collection and whether it is unnecessarily complex. There is no differentiation between maternal choice in first and subsequent pregnancies. There is a difference between those who request CS "when there is no other indication" in their first pregnancy from those who may do so in second or subsequent pregnancy when there must be some reason for the request. Also, some obstetricians do not consider previous CS as a reason to offer CS.	Thank you for your comment. This issues has been clarified in the final quality standard.
56	NCT	Question 4	"Are any of the proposed quality measures inappropriate and, if so, can you identify suitable alternatives?" We do not feel that any of the proposed quality measures are inappropriate but have suggested some amendments and/or additions to them in our above comments.	Thank you for your comment.
57	The Royal College of Anaesthetists	Statement 1	We welcome the recognition that the core maternity team as described on page 6 includes a midwife, obstetrician and anaesthetist, but we are concerned that the team will shrink to exclude the anaesthetist when the statistics are collected locally. We would like to see membership of the team clarified in the opening statement, rather than just in the definition. It is important to emphasise from the beginning that patients, with no medical indication for a Lower Segment Caesarean Section, must be informed about the risks of anaesthesia, both regional and general.	Thank you for your comment. The TEG reviewed your suggestion, but were concerned that the statement would become overly complex with the addition of all members of the maternity team in the actual wording. This detail has therefore been referenced in the rationale section for this statement and also in the definitions section.

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58	The Royal College of Midwives	Statement 1	It should be clear that the risks of elective caesarean section have been presented to the woman.	Thank you for your comment. Advising women of the risks and benefits of planned vaginal birth and caesarean section are referenced in the final standard.
59	Birth Trauma Association	Statement 1	Rates of planned CS in women where there are no indications for CS is not an outcome measure for the quality statement indeed it is likely to increase the number of women who feel 'not listened to'. Relatively few women choose CS but they often do so because they are concerned about perineal trauma or the possibility that pain relief may fail or be inadequate and labour may be protracted. A high proportion of these women, in our experience, have some grounds for their request; they are expecting a large baby, they are older and of small stature etc. Many have thoroughly researched the relative risks and benefits. Some, although not all, of these women have a degree of tokophobia which goes unrecognised. We know that taking control away from women in the decision about the way they give birth is not sensible in terms of perinatal mental health nor is it 'woman centred'. From the NICE guideline, it is clear that whilst the short term costs of caesarean section are higher than vaginal birth, the Health Economic evaluation of the longer term comparators showed a difference of £84.00 between vaginal and caesarean. It is common sense to respect women's choice. The cost relative to the mental health advantages clearly make respecting choice cost effective. Please therefore delete this outcome: 'Rates of planned CS in women where there were no indications for CS'.	Thank you for your comment. The TEG have reviewed the comments made about the use of section rates as an outcome measure against a number of the statements. These have been included where the TEG feel this is an appropriate outcome measure for the statement. With regard to adding timeframes. This was problematic as an appropriate timeframe would depend on the circumstances of the woman and how far into the pregnancy she was. There was also a lack of evidence to support any specific timeframes for this type of support.

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			However, there should be a timeframe measure. We would suggest an outcome measure: 'Women are able to discuss their request for CS within four weeks of the request and are offered a reassurance that their decision will be respected.' The latter statement is probably the most woman centred and cost-effective one that could be made. It will prevent an enormous amount of distress and in some cases, mental illness.	
60	Department of Health	Statement 1	Should this specify first pregnancy since surely consensus would be that women who have had a previous CS even for a non-recurrent cause should be allowed to choose repeat CS without additional counselling? It is a good suggestion to put in a timeframe to encourage timely discussion before decision making. I am not sure that the data collection is feasible or cost effective, or will be sufficiently accurate to be useful. There is nothing in the statement to confirm or encourage the fact that the woman may change her mind about her decision right up to the time of labour/delivery.	Thank you for your comment. The TEG felt that this statement was relevant to all women in this situation even if it wasn't their first pregnancy. The statement no longer includes a specific reference to a timeframe however, this is now covered in the rationale section below the statement that does state that the women should be able to have a discussion at any point during their pregnancy.
61	Royal College of Nursing	Statement 1	We recognise that this statement is aspirational. We support it in principle.	Thank you for your comment.
62	Gloucestershire Hospitals NHS Foundation Trust	Statement 1	For this to be recognised as a request surely the pregnant woman must have discussed this with her community midwife – who is part of the maternity team. Why the 4 and 2 week deadline? Should the denominator be, any women entering labour requesting delivery by LSCS who has not seen or discussed this with an appropriate member of the clinical team in the ante-partum period.	Thank you for your comment. The reference to a timeline has been removed from the statement with clarification provided in the rationale section for this statement.
63	Swansea University	Statement 1	Perhaps this might be clarified. It is not clear what is intended by no '*other* indication'. Is this synonymous with no '*medical*	Thank you for your comment. This has been clarified in the final quality standard

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			indication'? (On page 6 you do refer to 'no other medical reason.')	
64	Csection.org	Statement 1	We believe it is essential women have the opportunity to 'discuss' a CS request (and we congratulate the Draft in presenting a Statement to this effect). However we believe that the Statement does not go quite far enough. The critical factor for both women and those responsible for managing and co-ordinating their care is the decision of whether or not to proceed with a CS not simply the discussion about it as an option. We would like to see the Statement reflect this and replace the term 'discussion' with the term 'decision'. While it is great that a 'suitable time frame' has been defined we feel that 4 weeks is an unacceptable delay for women in their 1st/2nd trimester and it should be reduced to 2 weeks. For women in their 3rd trimester this should be reduced to 1 week. It is highly likely a CDMR will require several further discussions (and counselling in cases of anxiety) before a decision is reached. Our experience shows CDMRs are rarely agreed at the first appointment. Therefore to define four weeks as the point at which it is acceptable for 'discussions' to begin fails to take appropriate account of the lapsed time that can easily become involved in the decision process. Women need reassurance that their request has been heard **and actioned**. We recognize that there are occasions where a woman may agree, as part of their discussion, to wait a few more weeks/months before taking a final decision and that this needs to be managed within this process but to simply leave the Statement as vague as 'discussion' is unfair on those women who know their mind and want to proceed with a CS. This Quality Statement should also specifically state that women may make this request at ANY point during or prior to their pregnancy. While the Draft implies this is the case during pregnancy by measuring a) and b), we frequently receive communications from women who are being refused any	Thank you for your comment. The intent of this statement (statement 2 in the final quality standard) is focused on the opportunity for a woman to have a discussion with the members of the maternity team. This is expected to inform her decision, but is not simply about the decision. Statement 4 and statement 6 in the final quality standard are focused on the decision making process. With regard to the other issues raised. The quality standard is not intended to cover every aspect of the care pathway or all the linked recommendations included in the clinical guidelines. The standard does not supersede the guideline, but is a linked document focusing on key areas for quality improvement.

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			discussion on this specific issue until week 37! And for women experiencing tokophobia some will feel unable to become pregnant in the first place without access to such discussions **and decisions** in favour of a planned caesarean. Delays cause undue distress and for women expressing anxiety or fear of childbirth in particular it is crucial they gain access to a supportive decision-making process in the shortest time frame possible. This Statement also needs to specifically clarify, in line with the NICE guideline on Caesarean Section, that women be referred to someone who will consider a caesarean. We frequently receive communications from women who have come up against a brick wall in their antenatal discussions because of the personal opinion of someone on their maternity team (or hospital policy – written or otherwise). The definition of 'Maternity Team' should therefore be clarified to enable personal agendas regarding CS to be circumnavigated. It is pointless and wastes valuable time and NHS resources having a midwife, obstetrician or anaesthetist on the 'discussion' team who is opposed to the principle of CDMR. Outcome b) does not reflect the numerator details for this Quality Statement. Outcome b) currently appears to measure the rate of planned CS despite the numerator being very specific and asking for the number of women in the denominator who discuss their request with members of the maternity team within 4 weeks of their request. Outcome b) needs to be changed to reflect what the numerator is actually measuring. If it is possible to replace 'discussion' with 'decision', we feel that additional Outcome measures are needed to assess the time taken to reach a decision on CDMRs. As the Draft currently stands there are no means, beyond patient opinion, of assessing whether a maternity team actually delivers a solution to women beyond 'discussion'. While patient opinion is	

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			of course very important, return rates for such subjective feedback is notoriously low and questionnaires can be easily structured to 'manage' women's reporting. (While this latter point may seem an incredibly negative stance for us to take, we have come across questionnaires in the maternity arena that either through naivety or intent restrict the answers women can provide). With this in mind we would like this Statement to look at the actual delivery of a decision, measuring not only the number of CDMRs that occur as a consequence but also the time taken to reach that decision. If a woman has to wait months from the point of request and suffers severe emotional trauma during the interim this impacts both her and her baby. The fact that she may gain agreement in the end may be small consolation. **RECOMMENDATIONS:** Recommendation for revised Quality Statement: *Pregnant women can request a CS (when there is no other indication) at any point prior to or during their pregnancy and reach a decision with supportive members of the maternity team within a suitable time frame depending on the number of weeks left in their pregnancy.* Recommendations for additional Outcome measures: • *b) Rates of planned CS in women where there were no indications for a CS following discussion with supportive members of the maternity team.* • *Rate of satisfaction with the time taken to access supportive discussion.* • *Rate of satisfaction with the time taken to reach a decision about mode of birth.*	

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			• *Rate of satisfaction following CDMR.* Recommendations for the enhancement of the Service Providers definition: • *Service providers ensure systems are in place for women (pregnant or not) who request a CS (when there is no other indication) to discuss and reach a decision with supportive members of the maternity team within a suitable time frame depending on the number of weeks left in their pregnancy. (Where supportive refers to obstetricians who are willing to perform a CS on maternal request.* Recommendations for enhancements to the definitions: • *'Prior to' – Women suffering from tokophobia or severe anxiety should be able to disscuss and reach a decision about a course of action prior to becoming pregnant.* • *'Decision' – Conclusive agreement on a course of action, whether that is to continue with a CS request (where there is no indication) or to make a vaginal birth attempt. Related discussion should include the reasons for the request and ensure that the woman has accurate information about the relative risks and benefits associated with different modes of birth, based on Box A in NICE clinical guideline 132.* • *'Supportive member of the maternity team' – The core membership of the maternity team should include a midwife, an obstetrician and an anaesthetist who are supportive of the principle of CDMR.* *'Suitable time frame' - For women who are in their first or*	

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			second trimester this decision should occur within 2 weeks of their request being made or, where a woman agrees to delay the decision, has an agreement for a specific date on which a decision will be made. For women in their final trimester this decision should happen no later than 1 week after the request was made, and should be sooner for women close to being full term.	
65	electivecesarean.com	Statement 1	I think it's excellent that this area of care is being addressed here and NICE should be commended for its inclusion. I'd just like to suggest some necessary additions and clarifications in order to ensure that it prioritises the outcomes *women* are looking for. Pregnant women who request a {**prophylactic**} CS (when there is no other {**immediate**} indication) discuss {**and decide**} this with members of the maternity team within {**an acceptable**} time frame depending on the number of weeks left in their pregnancy. The words 'prophylactic' and 'immediate' help to recognise the various reasons women may request a CS (e.g. safety of baby, protection of pelvic floor, avoiding unpredictability of labour) and move away from the incorrectly perceived idea that women are choosing surgery purely for convenience or some similarly arbitrary reason. The word 'decision' is explained below. The word 'acceptable' is somewhat less subjective than 'suitable', but more importantly, it is more directly aligned with patient satisfaction (e.g. what's acceptable to the woman rather than what's suitable for the maternity team). The feedback my organisation receives from women, overwhelmingly, is that their request is *not* listened to or respected (and this is since the NICE 2011 CS update), and that midwives and/or doctors flat out state that NICE recommendations on maternal request are now irrelevant at their hospital, and that crucially, they must wait for an unknown period of time for a decision to be finally made (often after	Thank you for your comments and suggestions. The topic expert group prioritised areas of care where practice is variable, or where implementation could have a significant impact on patient care and improved outcomes, and where there is potential to generate measurable indicators. The quality standard is not intended to cover the whole care pathway or all the recommendations in the key evidence sources.

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			being made to meet with numerous different medical professionals throughout the course of their pregnancy – to make the exact same request). In one case (others similar but this was the worst), a woman was refused confirmation of a surgery date late in the 38th week of pregnancy because the midwife said, "If you were having a normal delivery you wouldn't know the date of your baby's birth, so there's no reason for you to know it with a CS". This 'not knowing' whether their maternal CS will be supported – even in those without tokophobia – causes unjustifiable anxiety and undue stress in a pregnant woman. As such, one of the key changes in this quality standard must be to promise to measure not just the 'discussion' time frame but more importantly the 'decision' time frame. This is because if a request is going to be declined, and the NICE guidance of referral to an obstetrician who WILL support a woman's request is to occur, then there must be sufficient time for this to happen a.s.a.p. I suggest replacing "discuss" with "decide" or if necessary, incorporating the two. For example, in Process a): The proportion of pregnant women in the first or second trimester of their pregnancy who request a CS (when there is no other indication) who {receive a decision on} this with members of {**a supportive**} maternity team… Two grammatical points: Denominator – in the first {**or**} second trimester [and again,] Denominator – the number {**of**} Additional note: May I request that NICE considers suggesting that some women should be offered the same discussion and decision *prior* to becoming pregnant please, as some women do not want to become pregnant without assurance that maternal request will be supported at their local hospital. Family planning is an important aspect in terms of maternal request CS, and is an essential part of a woman's risk-benefit analysis (e.g. how many children she plans to have), so it	

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			makes sense to offer discussion and decision of maternal request at this stage too. Under 'Discuss': May I suggest adding that this discussion, the woman's reasons, and ultimately the decision, must all be written in the woman's file. It saves the woman having to repeat everything all over again at each meeting, but also, it makes very clear to all members of the maternity care team that in the event of early onset of labour and/or the absence of the agreeing obstetrician, this woman is *not* to be taken to the labour ward to continue in labour while a fresh discussion is had about whether her maternal request should be supported; she must be treated as a CS patient and taken to theatre at the soonest opportunity. Suggested changes to Outcomes: **a) Rate of satisfaction with time taken to confirm discussion and decision of maternal request** **b) Rate of satisfaction following maternal request CS** **c) Rate of perinatal mortality (or other adverse outcome) in planned CS** My organisation finds it very concerning that "rates of planned CS" has been drafted as a suitable outcome for this quality statement. As stated in detail earlier, the focus of maternity care and good quality health outcomes and patient satisfaction, regardless of where that leaves planned CS rates. The suggestion of maternal request CS rates as outcomes here – in the context of "Expected levels of achievement", and "desired levels of achievement should be defined locally", outlined on pg.22 of the draft quality standard – will be interpreted by some maternity teams as meaning that their role in these processes of discussion and decision-making should be to ensure that as few women go ahead with their CS request as possible. This attitude already exists in some maternity teams, and my organisation hopes that this CS standard will clearly refute and not encourage it further	

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			Suggested change to text of Service providers, given some of issues cited above: "who request a {**prophylactic**} CS (when there is no other {**immediate**} indication) to discuss {**and decide**} this with members of {**a supportive**} maternity team within an {**acceptable**} time frame depending on the number of weeks left in their pregnancy. Also suggest adding: "**Service providers ensure that its maternity team includes obstetricians who are willing to perform a CS on maternal request.**" CG132 states, "An obstetrician unwilling to perform a CS should refer the woman to an obstetrician who will carry out the CS", but I've had cases where the woman has been referred to an obstetrician who is also unwilling to perform a CS, or an obstetrician who is junior to the first obstetrician and does not feel in a position to then agree to it. In fact, my organisation has experience of women who have had to transfer to different hospitals in order to have their request supported, so surely it would save a great deal of patient and NHS time and resources if maternal request discussions are not repeatedly carried out with team members who are opposed to it in principle from the outset. One of the most common questions I receive on maternal request CS is this, "Do you know the name of a supportive obstetrician or hospital in my area?" May I suggest, if not for this quality standard perhaps, that in future, hospitals record and can provide names and contact details of midwives and/or obstetricians who are willing to discuss maternal request in a supportive setting – in the same way that contact details are readily available for women who are interested in discussing a preference for homebirth? Once the taboo of discussing (and agreeing to, in principle) maternal request CS has dissipated, and NHS doctors are relieved of pressures to reduce CS rates (maternal requests traditionally being the easiest targets for	

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			this), then I believe quality of care and patient satisfaction can only improve in this area. I think that it should be stressed that the number of weeks for a discussion to take place (within 4 and within 2), suggested by NICE, is a *maximum* timeframe, and not an ideal one. Ideally, women should be able to discuss their request *much* sooner than this, especially in the third trimester. pg. 6 line 4 typo – pregnant wom**en** Data source – some questions for NICE: I've had a look online and don't believe that it does, but can NICE confirm please whether the "*Maternity services secondary uses dataset*" will record maternal request CS as its own classification please? Also, will the CS 'number' be recorded (e.g. if it's a repeat CS, whether it's 2nd, 3rd, 4th etc.)? And finally, is it possible for multiple classifications to be recorded? e.g. a case where a CS is requested and granted, but in the third trimester, a medical reason becomes evident, so it is *both* maternal request and medical (currently the initial request is very often lost in the data). Maternity team – the core membership of the maternity team should include a midwife, an obstetrician and an anaesthetist {**who are supportive of maternal request prophylactic planned CS in principle.**} I think it's important that women feel – from their very earliest discussion – that there is no ethical or ideological opposition to maternal request CS within the maternity team. Following publication of the NICE 2011 recommendations on maternal request, there was some *very* strong opposition from some groups of midwives (and the reality is that many of their mind-sets against maternal request will not have been resolved barely one year later), and their focus is very much on a discussion of "women's perceptions of vaginal birth, including misconceptions and lack of knowledge about birth."(CG132)	

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			Obviously, it is vital to discuss reasons behind the woman's request, but so much time and money is being wasted on consultations with medical professionals who have no intention of ever agreeing to the request, regardless of the woman's reasons, and my organisation is aware of cases where the resources wasted on antenatal counselling and meetings, then postpartum trauma counselling and pelvic floor injury repairs (following forced vaginal delivery) could have paid for the requested planned CS many times over. It also saves valuable time if discussion with the maternity team concentrates immediately on the risk-benefit analysis of the individual woman making the request (her age, weight, family plans, medical history etc.), rather than questioning her sanity, berating her, or giving reasons why maternal request CS is such an ill-informed birth choice. Also, it is well documented that in many areas of the country, maternity services are severely stretched, and so the skills of the many midwives who are often present at these repeated maternal request meetings would surely be better utilised on labour wards where women need more one-to-one care. Please note that this is not in any way a suggestion that planned CS should be *encouraged* or *promoted*, but rather that discussions with women are carried out in the knowledge that for this group of women – who are *requesting* a CS – their perception of different birth plan risks and benefits, and their reasons for requesting a CS, may not always be fully understood or respected by health professionals who perceive planned vaginal birth as the categorically 'safest' plan. My organisation has communicated with many midwives and some doctors who say they'll accept maternal request in the end, as long as the woman is 'fully informed' of the risks, but what they mean is, 'as long as the woman understands that she is taking unnecessary increased risks'. Again, there are clearly challenges ahead to ensure that the information women receive in these decision-making discussions is unbiased and evidence-based, and that also, the maternity team are kept	

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			fully informed of the latest research in this area too. Just one example of outdated information that persists in maternal request risks cited by some health professionals is the risk of stillbirth or fertility problems in subsequent pregnancies. These is no *increased* risk of these as a consequence of choosing a planned CS(***11***) and yet it is a very common belief that there is.	
66	AIMS (Association for Improvements in the Maternity Services)	Statement 1	Should "when there is no other indication" be clarified? "When there is no medical indication" would be clearer?	Thank you for your comment. This point has been clarified in the final quality standard.
67	Royal College of Paediatrics and Child Health	Statement 1	The statement is vague. Measures should include maternal and infant complications following CS with no indications.	Thank you for your comment. The focus of this statement is on woman being able to make an informed decision and choice, with input from the relevant members of the maternity team depending on what the woman's concerns are.
68	Mumsnet	Statement 1	'Discuss' & 'Suitable timeframe' – a few Mumsnet users indicate that earlier requests for an elective caesarean section (ELCS) with general practitioners and consultants are not followed by discussions with maternity teams. Worse still, more users say these early requests are sometimes dismissed or forgotten, requiring a woman to restate (and re-defend) her choice at a later stage of pregnancy, when there is limited scope and time to prepare for ELCS. Users suggest a clearer (minimum) timeframe for when a choice can be declared; ensuring a proper discussion with maternity teams takes place; and proper recording of this choice in medical records.	Thank you for your comments. The TEG recognised the need for women to be able to have a discussion at any point in their pregnancy and this point has been referenced in the rationale section for this statement. Timeliness is also referenced. The statement includes reference to the discussion being documented.
69	Kings College London	Statement 1	Is the time period of a month too long? (if women don't book till 3 months this ends up being a high proportion of any pregnancy).	Thank you for your comment. The time limit has been removed from the final quality statement, with a general point around timeliness of access being included in the rationale section for this quality statement.
70	The Royal College of Midwives	Statement 1 & 2	An important measure that there has been shared decision making, would be signed documentation that the woman has understood the risks.	Thank you for your comment. The need for the discussion to be documented has been included in the final quality statement.
71	Birth Trauma Association	Statement 2	Rates of planned section is definitely not an outcome measure for QS2. Psychiatrist Kristina Hofberg is the only researcher to	Thank you for your comment. This is no longer referenced as an outcome measure against this

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			have looked at this and interventions that improved outcomes did not decrease the caesarean rate in this group of women. Tokophobics can be divided into those who want to overcome their fear and those for whom the thought of vaginal birth is so horrific that even discussion of it provokes anxiety. The former group do well if offered support and counselling. The latter group need immediate reassurance that they will not be forced to go through vaginal birth. Unfortunately, there is little training of maternity professionals in the treatment of tokophobics and we have heard of cases where 'success' was being measured by the number of women opting for vaginal birth with no attention being paid to the postnatal psychological outcomes. The evidence from our postbag and from the research is the same. Some women who are tokophobic can be 'bounced' into vaginal birth and will have a straightforward experience and be satisfied. However, for the smaller group where perhaps the birth becomes complicated or the mother panics, the results are catastrophic in terms of mental health and seems to unfailingly lead to severe PTSD. The best outcomes are achieved by respecting women's decision and neither pushing vaginal birth nor caesarean section. We would therefore like to delete the existing outcome measure and replace it with the two following patient rated statements: 'The rate of women who report that they had adequate support for their anxiety' 'The rate of women who report that they were reassured that their mode of delivery would be respected within four weeks of their request'	statement. An experience measure has now been included as an outcome measure for this statement.

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72	Birth Trauma Association	Statement 2	This statement causes some concern. Women who have anxiety about childbirth need to be reassured that their choice of mode of delivery will be respected and this needs to happen right at the outset. It is urgent. We have had cases of women who have not been able to secure a decision into their 39th week of pregnancy and describe themselves as suicidal. This is s appalling and detrimental not only to the mother but to the baby. There is strong emerging evidence including the RHEA and Weinstock* studies that this can adversely affect the baby's neurodevelopment. * "Excess amounts of CRH and cortisol reaching the human fetal brain during periods of chronic maternal stress could alter personality and predispose to attention deficits and depressive illness" through changes in neurotransmitter activity'. The simple intervention of offering women the security of choice could change this at negligible cost to the NHS. We would suggest this statement: "Women who request CS because of anxiety about childbirth are offered a referral to a health care professional with relevant experience and are given immediate reassurance that their decision about how they give birth will be respected.'	
73	Department of Health	Statement 2	Should this specify "**All** pregnant women who request…" (i.e. to ensure that it includes primigravida **and** multigravida who have had a bad experience) Again the data requirements are difficult and probably not feasible to collect. Some women may request CS but change their mind after an initial discussion with a consultant or midwife. As long as the reason for CS is recorded as "Maternal request" then it would at least be possible to audit whether appropriate counselling had been offered and given by an appropriate HCP prior to the decision.	Thank you for your comment. This statement has been amended in the final quality standard (statement 3) The TEG didn't feel it necessary to make the specific point that this is relevant to all pregnant women as they thought this was implied already,
74	South London and Maudsley NHS Foundation Trust	Statement 2	We have implementation concerns re referral of women with anxiety regarding normal delivery to a health professional "with relevant expertise". We are concerned that this may result in referrals to perinatal mental health services in secondary care mental health services. This would not lead to women being	Thank you for your comment. This point has been clarified in the final quality standard. The definition of someone with perinatal mental health is consistent with the clinical guideline that does not suggest this person would be from specialist mental health services.

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			seen promptly (if at all) because such services will not usually see women that do not have severe mental illness. Psychological therapy services in primary care would not usually have perinatal expertise. Most maternity services do not have a midwife with relevant clinical experience who could take the referrals proposed. Such services (ie psychologist or midwife with relevant experience) would therefore need to be commissioned and would "fit" best within maternity services.	
75	Royal College of Nursing	Statement 2	We need to acknowledge that there have been discussions with commissioners about what is an appropriate pathway, and we remain concerned that commissioners may choose not to commission caesarean section for anxiety.	Thank you for your comment. This was noted by the TEG.
76	Royal College of Obstetricians & Gynaecologists	Statement 2	*Measure:* Suggest changing the outcome of quality statement 2 to: the proportion of pregnant women requesting CS for anxiety who decline the offer of referral to a healthcare professional with relevant expertise.	Thank you for your comment. The outcome measure for this quality statement is now focused on the experience of the woman and the extent to which she felt supported.
77	Northumbria Healthcare NHS Trust	Statement 2	No concerns	
78	Swansea University	Statement 2	A woman is to be referred to a healthcare professional with relevant expertise – *to do what?* Timeframes (4 weeks and 2 weeks) are only mentioned at the end of this statement instead of throughout it as you do in statement 1.	The intention is that the healthcare professional would support them to deal with their anxiety. It is not possible to detail all the potential interventions that are used to provide this kind of support within the quality statement.
79	Csection.org	Statement 2	It is fantastic that there is a Quality measure regarding the availability of support for women requesting a CS on the basis of anxiety. However, we feel there needs to be specific timescales defined within which such support is delivered. Fear of childbirth can be so severe that some women may even choose to abort a much wanted baby [Ref 1] so timely referral to a supportive healthcare professional with relevant expertise is crucial. We are concerned that this Statement only describes the offer of a referral and not the timescales within which the appointment itself occurs. For women in their 1st/2nd trimester it should be an immediate referral with their appointment	Thank you for your comment. Following consultation comments, the timeframe for this quality statement has now been removed. It is anticipated that local arrangements would be put in place to ensure that these referrals are dealt with in a timely manner.

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			occurring within 2 weeks. For women in their 3rd trimester this should be an immediate referral with their appointment occurring in 1 week. For some women this support process is unlikely to be concluded in a single appointment so the sooner it commences the better. The Draft indicates that the healthcare professional may be a midwife. We do not dispute the validity of the latter however we do feel there needs to be great clarification regarding 'relevant expertise' of such providers. For example. including the term 'supportive' where the definition means someone who is open to the principle of CDMR. Aside from the fact that some women themselves may feel that support closely associated with their maternity team may be biased, particularly if their hospital has a ban on what is frequently termed "unnecessary caesareans", it is our experience that this unfortunately can indeed be the case. With this in mind it may be that some women will need to be able to request support from outside their immediate maternity team without incurring personal costs (e.g. costs associated with a private counsellor). We frequently receive communications from women whose maternity team have personal or PCT agendas relating to caesareans. This Quality Statement needs to specifically state that women can request a referral from outside their existing immediate maternity team. It should also ensure that women are not penalised for refusing the opportunity of a referral. There is the generalised assumption that women only request because they are afraid or 'selfish' when in actual fact some requests are based on an informed analysis of the facts as they relate to them – such women are still likely to find themselves in a situation where they may be 'referred' for counselling – these women should not be penalised for stating they do not require counselling because their decision is an informed one. **RECOMMENDATIONS:** Recommendation for a revised Quality Statement:	

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			Pregnant women who request a CS because of anxiety about childbirth are offered an immediate referral to a supportive healthcare professional with relevant expertise and reassured that maternal request caesareans can be supported. To refuse a referral should not penalise their request in any way. Recommendations for additional Outcome measures: • *The number of women taking up the offer of a referral* • *The number of weeks it takes to access the support of a healthcare professional* • *The duration of support required from a healthcare professional* • *The number of women requesting an alternative source of relevant expertise* Recommendations for additions and enhancements to the definitions: • *Referral – The referral must be immediate and, for those women who accept a referral, they should be seen within 2 weeks if in their first or second trimester or within 1 week in the third trimester. To refuse a referral should not penalise their request in any way.* • *Supportive healthcare professional with relevant expertise - this includes but is not limited to a psychologist interested in perinatal mental health or a midwife with counselling skills and expertise, (all of whom are open to the principle of CDMR regardless of whether a woman exhibits anxiety) allowing for the onward referral to a professional not associated with*	

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			the immediate maternity team. • *Suitable time frame - Pregnant women who accept a referral should be seen within 2 weeks if in their first or second trimester or within 1 week in the third trimester.* *[Ref 1]* K. Hofberg, M. R. Ward, 'Fear Of Pregnancy And Childbirth' *Postgraduate Medical Journal* 79 (2003) 505-510	
80	electivecesarean.com	Statement 2	Pregnant women who request a CS because of anxiety about childbirth are offered {**immediate**} referral to a healthcare professional with relevant expertise, {**and assured that maternal request is supported by the maternity team**}. My response here is similar to comments submitted for draft statement 1, but even more so with this group of vulnerable women. It needs to be made clear that maternal request is supported in principle, and that they are not required to accept the offer of referral to a healthcare professional with relevant experience in order for a planned CS to be arranged. Counselling is *not* compulsory, and a discussion about birth plan risks and benefits with the maternity team is acceptable too. Outcomes: The draft outcome here, related to "rates of planned sections" is wholly inappropriate. What matters is that women are offered good quality counselling and that this is delivered in an unbiased manner with the woman's best interests the priority. The CG132 GDG believed that through discussion, "the anxieties can often be reduced to the point where the woman is able to choose a planned vaginal birth", and this is absolutely true, but if help and support becomes coercion and frustration (if CS is still preferred by the woman), then this is not acceptable. Similarly, the GDG "felt that there was potential for the extra resource required to provide additional psychological support to be offset by resources saved where a request for planned CS was appropriately	Thank you for your comment. Following consultation comments, the timeframe for this quality statement has now been removed. It is anticipated that local arrangements would be put in place to ensure that these referrals are dealt with in a timely manner. The quality standard is based on the premise that all care will be patient centred, supporting patients choice. It is therefore expected that any woman is supported in making a choice that it most appropriate for her.

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			changed to a planned vaginal birth as a result". As a justification for *provision* of support, this is acceptable, but if this switches so that PVD becomes a goal *because* the money's been spent, then it is not. My concern is that women will have no confidence in a process that measures itself by CS rates, and maternity teams may also feel pressure to 'convince' women not to have a planned CS so that the outcome by which they are being measured is not adversely affected (I am aware of numerous cases to date where maternal requests have been refused purely due to pressure from hospital trusts to lower CS rates – and not that vaginal delivery was felt to be in the woman's best interests). Also, the draft Outcome refers to "Rates of planned sections in those with **previous** anxiety about childbirth". Does this refer to the group of women with initial anxiety prior to the offer of counselling (i.e. all the women) or the smaller group, who had anxiety previous to having counselling (and had the counselling)? Suggested Outcomes: **a) Rates of women who accept referral to a healthcare professional with relevant expertise** **b) Rates of women who decline referral to a healthcare professional with relevant expertise** **c) Patient satisfaction with referral to a healthcare professional / that experience** Please note that my organisation is not opposed to collecting data on the rates of planned CS – whether because of anxiety or any other maternal reason. On the contrary, collation of this data would be invaluable, and it is hoped that it will be gathered as part of hospital maternity data collection more generally. It is simply the idea that rates of planned CS might somehow indicate levels of quality of care that is an issue. Definitions - Referral – Again, the timeframe for these referrals is too long, particularly given that this group of women are	

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			suffering with anxiety. Is it possible to please change to: "pregnant women who accept a referral should be seen {**as early as possible**} within 4 weeks if in their first or second trimester or within { **as early as possible**} within 2 weeks in the third trimester. Also suggest adding: **The process for pregnant women who decline a referral should be the same as outlined in quality statement 1** As with statement 1, I'd like to suggest that women with anxiety are offered the same discussion and decision *prior* to becoming pregnant, as some women do not want to become pregnant without assurance that maternal request will be supported at their local hospital. Our organisation has experience of tokophobic women who have terminated their much-wanted pregnancies when maternal request was refused, and many more women who are too terrified to even become pregnant before being given reassurance about their preferred birth plan. Again, family planning is an important aspect in terms of maternal request CS, and is an essential part of a woman's risk-benefit analysis (e.g. how many children she plans to have), so it makes sense to offer discussion and decision of maternal request at this stage too.	
81	AIMS (Association for Improvements in the Maternity Services)	Statement 2	This is a very long sentence and could do with a comma at least. Possible alternative - "Where anxiety surrounding childbirth is the reason behind a CS request, a referral to a healthcare professional with relevant expertise should be offered.	Thank you for your comment. Editorial issues are dealt with by our internal editorial team.
82	Royal College of Psychiatrists	Statement 2	With regard to standard 2: Pregnant women who request a CS because of anxiety about childbirth are offered a referral to a healthcare professional with relevant expertise My concern is that this group will contain women with a wide spectrum of conditions - from non pathological levels of understandable anxiety and in whom simple reassurance and support may be appropriate - through to women with significant	Thank you for your comment. This statement is not intended to cover women with more complex mental health issues linked to their pregnancy. As stated in the final quality standard, this is for women with anxiety about childbirth that is leading to them not wanting to attempt a vaginal birth. It is not anticipated that all these cases would be referred to secondary mental health service, accepting that there will be cases where someone might

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			mental illness. There are two issues I think. 1. A recognition that this may be the presentation of a significant mental illness requiring input from specialist perinatal services. I don't think this can easily be part of the Draft Quality Measure but it may be that we can ask them to acknowledge the issue. With that in mind, perhaps the change we need to ask for is: 2. In the section on "definitions" - Healthcare professionals with relevant expertise - are listed as Psychologist interested in perinatal mental health or a midwife with counselling skills and expertise. I wonder if there needs to be a recognition that the appropriate referral for some women will be to a Perinatal Mental health service - and that the generic term Perinatal Mental Health Professional (including, psychiatrist, CPN, psychologist) be used.	be.
83	Mumsnet	Statement 2	Some Mumsnet users claim that their anxiety about childbirth (VB) is based on rational concerns, and this is not always recognised by consultants. For example, one user said her ELCS request was based on medical reasons, to which she provided a reference and note from her physiotherapist. Her consultant was initially dismissive and interpreted her choice as a 'too posh to push' fear. Many users who choose ELCS following a previous birth complication express frustration that their consultants were too quick to judge their anxieties as irrational. This could be addressed in this statement – one user suggested making a distinction between irrational and rational VB anxieties.	Thank you for your comment. The point about rational and irrational anxieties would be subjective and therefore hard to include in a national quality standard. The TEG feel that the quality standard, if implemented fully, would overcome a number of the issues raised by your users.
84	Birth Trauma Association	Statement 3	Agree	
85	Birth Trauma Association	Statement 3	Outcome measures a) and b) are not measures of the draft quality statement which is about women having choice. They seem completely unrelated. We would suggest that the numerator is the number of women	Thank you for your comment. This quality statement has been split in the final quality standard focusing on the role on a consultant obstetrician in a planned and an unplanned CS. Relevant measures have been identified by the TEG.

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			who report being offered a choice of mode of delivery and denominator - the number of women who have had more than 1 CS. The outcome measure should be the number of women who report being offered a choice of mode of delivery.	
86	Birth Trauma Association	Statement 3	Agree	
87	NCT	Statement 3	The draft quality standard states that "Pregnant women for whom CS is being considered have a consultant obstetrician involved in the decision-making process". The definition of "involved" should be made clearer and more explicit. The current definition of "involved" is "direct involvement", which seems to be repetition, rather than explanation. Although the definition does give examples of the mode of involvement (by phone or in person), it not does give direction about which is desirable or about the information or value that it is expected that the involvement of an obstetrician should provide for the woman.	Thank you for your comment. The purpose of the consultants involvement is now explained in the rationale section of the quality statement. The form of that involvement is either in person or on the phone as the involvement could be while a consultant is on call and immediate advice is required,
88	The Royal College of Midwives	Statement 3	We do not consider that the level of involvement of senior staff in this important discussion is adequate if it has only taken place through a phone call.	The TEG accepted that involvement in person was the most preferable. However, in cases where a consultant is on call and immediate advice is required then the timeliest way of doing this is via the phone.
89	Department of Health	Statement 3	This is the most important statement but should make it clear that this refers to elective as well as emergency CS. In my experience, women with previous CS are less likely to opt for VBAC if seen by trainees in clinic than if seen by consultant.	Thank you for your comment. This statement has now been split into 2 separate statements, focused on consultant involvement in planned and unplanned CS
90	Royal College of Obstetricians & Gynaecologists	Statement 3	*Statement:* This standard proposes that pregnant women for whom CS is being considered have a consultant obstetrician involved in the decision-making process. This is based upon recommendation 1.3.2.4 in NICE clinical guideline 132 (Consultant obstetricians should be involved in the decision making for CS, because this reduces the likelihood of CS'). This recommendation is in section 1.3: factors affecting likelihood of CS during intrapartum care yet the standard does	Thank you for your comment. We understand that RCOG guidelines are in line with recommendation 1.3.2.4 in NICE clinical guideline 132 that a consultant should be involved in all decisions about whether a CS should be carried out or not.

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			not specifically refer to CSs in labour (intrapartum). *General:* At present, there are situations where senior trainees (ST7s) especially those who have completed the Advanced Training Skills Module in advanced labour ward practice, and Staff Grade/Associate Specialist doctors have had their capabilities and experience individually assessed, and are not expected to discuss every CS with a consultant. We believe that a standard proposing that all CSs are discussed with a consultant would have a negative impact upon the development of these competent doctors.	
91	Northumbria Healthcare NHS Trust	Statement 3	Agree, important all women have access to Consultant Obstetrician.	Thank you for your comment.
92	Swansea University	Statement 3	Midwives may seek clarity over the implications of *consultant obstetrician involvement*. It is referred to in your definition at the foot of page 9 but as this might be the most contentious quality statement affecting consultant obstetricians' workload perhaps this needs to be set out more robustly.	Thank you for your comment. It was felt that the level of consultant involvement will depend on the complexity of the case. The key point is that they are involved and then able to decide the extent to which they need to be involved in the care of the women.
93	Csection.org	Statement 3	We are particularly concerned with the idea that important discussions with a woman regarding her specific case in relation to CS may be carried out over the phone (we recognise that in the case of an emergency CS this might not be avoidable but this is not the case for CDMRs). We recognise that scheduling may be difficult but unless a woman stipulates that a phone conversation will suffice we would not be happy with the Statement suggesting that involvement of senior staff may simply be by phone. We feel that it is insufficient to state that the outcome for this Quality Statement is simply CS rates. This requires the assumption that the involvement of a senior staff member will influence the CS rate one in a particular direction. If the Draft believes the involvement of a senior staff member warrants a specific Quality Statement it also warrants a specific measure. For example - the rate of involvement of a senior staff member,	Thank you for your comment. This statement has now been spilt into 2 separate statements concerning consultant obstetrician's involvement in decisions about planned and unplanned CS. It is anticipated that for decisions about planned CS the consultant's involvement would be in person. As you suggest, in emergency situations, if a consultant is on call, the phone may be the timeliest way of getting advice. An outcome measure concerning the woman's experience has been included for both statements (4&6)

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			women's satisfaction with the involvement of a senior staff member etc. Given the specific skill set of the senior staff member as defined in the description of the Healthcare Professionals, the title of the Statement can be clarified to show that this senior staff member is a consultant obstetrician. **RECOMMENDATIONS:** Recommendation for alteration of Quality Statement title: *Involvement of a consultant obstetrician in decision-making for caesarean section.* Recommendation for revised Quality Statement: *Pregnant women for whom CS is being considered have a supportive consultant obstetrician involved in the decision-making process.* Recommendations for additions and clarifications to the Outcomes measures: • *Rate of involvement of a consultant obstetrician in decision-making for CS.* • *Patient satisfaction with the decision-making process involving a consultant obstetrician.* Recommendations for additions and enhancements to the definitions: • *Supportive consultant obstetrician – an obstetrician who is supportive of the principle of CDMR.* *Involved - this should include direct involvement in the decision, and should be documented in the woman's maternity*	

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			notes. This should include documentation of the mode of involvement, for example, by phone or in person and should only be accepted 'by phone' where the woman has stipulated that this is acceptable to her.	
94	electivecesarean.com	Statement 3	Pregnant women for whom CS is being considered have a consultant obstetrician involved in the decision-making process This is another example of where CS rates are considered to be the key outcome to be measured. CG132 states (and note, the evidence for this statement had not been reviewed since the original CS 2004 guideline), "Consultant obstetricians should be involved in the decision making for CS, because this reduces the likelihood of CS." This statement also appears in the Dept. of Health 2007 'Delivering quality and value' document, and it is my opinion that this is *not* why consultants should be involved in the process; they should be involved because their knowledge and experience of the risks and benefits of surgery is greater. In the NICE quality standard Briefing Paper, under clinical and cost-effectiveness evidence, the CG132 GDG's review of RCOG's 2001 audit(***4***) is cited. It says that consultant involvement led to crude and adjusted CS rates being lower. However, there is no actual cited evidence that NHS costs were lower as a result – only that the CS rates were lower. How many of the cases resulted in instrumental VD morbidities (maternal or infant)? How many of the cases resulted in litigious outcomes? How many of the women involved required post-traumatic counselling? Obviously I am not suggesting that any of these adverse outcomes are any *higher* with consultant involvement, but that cost-effectiveness if not achieved simply by lowering CS rates, and that lowering rates should not be an outcome focus. May I ask why other outcomes – e.g. maternal and perinatal mortality and morbidity – are not more important, or at least *as*	The topic expert group reviewed all measures in the draft quality standard and have prioritised and refined those they considered most important to measure the quality statements in the final standard. The measures have been revised for the final quality standard to improve clarity.

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			important, alongside the CS rates, as outcome measures? In other words, if NICE wants to know how many CS occur following the involvement of a consultant obstetrician – ok – but does it not *also* want to know whether those CS were emergency or planned? Or whether there were good health outcomes? Or whether the women involved were satisfied with the care they received? It is my understanding that quality standard outcomes are there to achieve improvements in healthcare, and so it must be reiterated that if CS rates have been suggested as outcomes *purely* because of a preconceived idea that high CS rates = bad and low CS rates = good, then outcomes like this one in quality statement 3 need to be urgently reconsidered. And at the very *least*, if a decision is made to capture data on CS rates like this, please ensure that the rates are separated into different CS types – because an overall rate that includes every type of CS surgery provides information that is of very little use at all. Suggested outcomes: **a) Rates of perinatal mortality in pregnant women who have a consultant obstetrician involved in the decision-making process for CS.** b) **Rates of satisfaction in women who have a consultant obstetrician involved in the decision-making process for CS.** Definitions - Involved – Is it a rare occurrence for consultant involvement to be by phone only? – should this be clarified?	
95	AIMS (Association for Improvements in the Maternity Services)	Statement 3	Whom CS" should read "whom a CS"	Thank you for your comment.
96	Birth Trauma Association	Statement 4	We are unclear as to why the definition of 'given the option' is stated as *'Pregnant women should be advised that if they wish they can attempt a vaginal birth and advised that in women who have had up to and including 4 CS the risk of fever, bladder injuries and surgical injuries does not vary with*	Thank you for your comment. As you state the information included in the definition is consistent with the recommendation in the primary evidence source for this quality standard – NICE clinical guideline 132. The TEG

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			planned mode of birth and the risk of uterine rupture, although higher for planned vaginal birth, is rare. This offer should be documented in the women's notes.' Although this is from the NICE guideline, it is insufficient as a standalone summary of the information women should be offered and for certain groups of women will be unbalanced. There are different risks according to whether the woman has had a previous vaginal birth and whether she needs induction. The RCOG 'Birth after caesarean section' Greentop has an excellent summary of the risks and benefits and we would like to see women offered more comprehensive information in accordance with this document in addition to that of the NICE Guideline. Many women who contact our charity for support following a pregnancy after caesarean section are distressed because they feel they are being denied the choice of repeat section or feel pressured into VBAC. There are repeated postings on website forums about the same issue and we are aware of some hospitals who do not offer women choice of repeat section. (See below). Coercion works in both directions but there are more cases of women being pushed towards VBAC than there are of women being denied VBAC. We would suggest: 'Pregnant women who have had a previous CS are given objective information about the risks and benefits of VBAC versus repeat caesarean and are then offered choice'. This should keep both groups of women happy - both those who want VBAC and those who want a repeat CS. The current statement only supports the group of women who want VBAC and does not address the distress caused by women which you can see expressed in the posts below: http://www.mumsnet.com/Talk/childbirth/1199678-Can-you-be-refused-a-repeat-c-section/AllOnOnePage http://www.netmums.com/coffeehouse/pregnancy-64/birth-labour-256/344963-can-i-forced-into-vbac-after-previous-emergency-section.html	were happy that this was sufficient for this statement.

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			http://www.pregnancyforum.co.uk/labour-birth/209224-can-hospital-refuse-do-c-section.html http://www.mumsnet.com/Talk/childbirth/a1444533-Can-I-refuse-to-try-VBAC-at-Queen-Charlottes	
97	NCT	Statement 4	The draft quality standard states that "Pregnant women who have had a previous CS are given the option to attempt a vaginal birth". This should read (words removed have been struck through and words added have been put in bold): "Pregnant women who have had a previous CS are given the option to ~~attempt~~ **plan** a vaginal birth". Women also need to know the pros and cons of both the options of planned vaginal birth and planned repeat CS and the description of what the quality standard means for each audience should incorporate responsibility for this.	Thank you for your comment. The wording of this statement has been amended in the final quality standard.
98	The Royal College of Midwives	Statement 4	It is important, in the context of current evidence, that where there are no known contra-indications, women are encouraged to attempt for a vaginal birth and health professionals are skilled at offering the advice. The language in the statement should reflect this, rather than using the passive phrase 'given the option'.	Thank you for your comment. The intention is that the women is supported to make an informed choice rather than encouraged either way to make
99	Department of Health	Statement 4	Is it old-fashioned to ask if this could be "pregnant women who have had a previous caesarean section **for non-recurrent cause** are given…"?	Thank you for your comment. The TEG did amend the wording for this statement, but did not want to be prescriptive about women who may have recurrent causes for a CS as a vaginal birth could still be attempted, accepting the potential risks.
100	Royal College of Nursing	Statement 4	We consider that this statement could be made more directive - Pregnant women suitable for VBAC should be encouraged to birth vaginally and reduce associated morbidity of an invasive birth choice.	Thank you for your comment. The intention is that the women is supported in her choice rather than encouraged either way as this is not supported by the evidence.
101	Royal College of Obstetricians & Gynaecologists	Statement 4	This standard proposes that pregnant women who have had a previous CS are given the option to attempt a vaginal birth. *Statement:* The standard should recognise that in some cases it would not be appropriate to attempt a vaginal birth (for example structural uterine abnormality, previous myomectomy	Thank you for your comment. The TEG did amend the wording for this statement, but did not want to be prescriptive about women who may have recurrent causes for a CS as a vaginal birth could still be attempted, accepting the potential risks.

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			or women who have previously had an abdominal suture inserted). *Statement & Definitions:* The standard says 'a CS' (implying one previous section) yet in the definitions section it says 'up to and including 4 CS'. *Measure:* Suggest outcome measure: the rates of CS amongst women who have previously had a CS and who attempted a vaginal birth.	
102	Northumbria Healthcare NHS Trust	Statement 4	These patients should have the opportunity to discuss VBAC with a Consultant Obstetrician and a midwife with a special interest in achieving vaginal delivery. This can be both postnatal after the CS and in the subsequent pregnancy. Resources are also required to enable women to achieve VBAC i.e. CTG machines without attachments (e.g. wi-fi and telemetry) to allow mobilisation. Midwives and junior doctors should have the training and expertise to support these women in labour.	Thank you for your comment. This quality standard does not go into the detail concerning how VBAC can be facilitated. We would hope that the statement could be used as a tool to encourage greater service provision to enable women who choose to attempt a VBAC to be able to do this.
103	Swansea University	Statement 4	In this draft statement you frequently refer to 'pregnant women who have had **a** previous CS, but you also include a section on women who have had more than one CS; this is unduly confusing. In the 'Definitions' section there is much more detail than in previous statements. Perhaps this might be structured in the same way as the word 'Discuss' on page 6.	Thank you for your comment. This point in clarified in the statement contained in the final quality standard.
104	Csections.org	Statement 4	This is an important Quality Statement and should make clear that the reasons for the previous CS need to be taken into account when offering the 'option' of a VBAC. Maternity teams, the media and mothers themselves are rather prone to promoting vaginal birth as the ideal delivery scenario but there are specific cases where a VBAC may not be in the best interests of the mother and/or baby and the Quality Statement should reflect the need for balanced information in the decision-making process. We would like to ask - is this Statement attempting to measure the number of women being given the 'option' to attempt a	Thank you for your comment. The intention of the statement is to enable the women to make an informed choice and not encourage her either way. One of the outcome measures for this quality statement relates to the woman's experience of feeling supported in her choice. With regard to the other suggested statements. The quality standard is not intended to cover all aspects of the care pathway and all the different circumstances that may occur. The TEG have focused on the key areas for improvement at a national level.

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			VBAC or the number of women 'opting' for a VBAC? Both terms are used in this Statement. Ideally the Statement should be requiring maternity teams to measure both. In which case far greater clarification of the Process and Outcomes is required, for example: the numerators are not specific enough. They need to identify that women have chosen to 'opt' for an attempted VBAC as well as that they have been given the 'option'. Without this clarification it is not possible to generate Outcomes a) and b) which use the word 'opt' in their measure. Ideally we would like to see this Quality Statement also measure the actual outcome of women's choices. We recognise that this is not strictly within the scope of the Caesarean Guideline recommendation that is behind this Quality Statement but we feel that this is a significant piece of data that is currently missing. (We highlighted it in our original Guideline feedback for the 2011 publication). Positive and negative outcomes need to be associated with the intended mode of birth. All too often adverse outcomes (including emergency caesareans following attempted vaginal deliveries) are included in overall caesarean data. This produces data that far from reflects actual scenarios. A woman attempting a VBAC against the recommendations of her maternity team and who once in labour experiences 'negative' outcomes including emergency caesarean should not be grouped with women who planned a caesarean). **RECOMMENDATIONS:** Recommendation for revised Quality Statement: *Pregnant women who have had a previous CS are given the option to attempt a vaginal birth once in receipt of case specific risk / benefit information.* Recommendation for clarifications to the Process: *a) The proportion of pregnant women who have had 1 previous*	

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			CS who were given the option to attempt a vaginal birth in their current pregnancy *Numerator – the number of women in the denominator who were given the option to attempt a vaginal birth.* *Denominator – the number of pregnant women who have had 1 previous CS.* *b) The proportion of pregnant women who have had more than 1 previous CS who were given the option to attempt a vaginal birth in the current pregnancy.* *Numerator – the number of women in the denominator who were given the option to attempt a vaginal birth.* *Denominator – the number of pregnant women who have had more than 1 previous CS.* *c) The proportion of pregnant women who have had 1 previous CS who chose to take up the opportunity to attempt a vaginal birth in their current pregnancy* *Numerator – the number of women in the denominator who chose to take up the opportunity to attempt a vaginal birth.* *Denominator – the number of pregnant women who have had 1 previous CS.* *d) The proportion of pregnant women who have had more than 1 previous CS who chose to take up the opportunity to attempt a vaginal birth in the current pregnancy.* *Numerator – the number of women in the denominator who chose to take up the opportunity to attempt a vaginal birth.*	

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			Denominator – the number of pregnant women who have had more than 1 previous CS. *e) The proportion of women (who have had 1 previous CS and opted to attempt a vaginal birth) experiencing each mode of birth including: unassisted and spontaneous vaginal birth, assisted vaginal birth, emergency caesarean and last minute conversion to a planned caesarean.* *Numerator – the number of women experiencing each mode of delivery in the denominator who chose to take up the opportunity to attempt a vaginal birth.* *Denominator – the number of pregnant women who have had 1 previous CS.* *f) The proportion of women (who have had more than 1 previous CS and opted to attempt a vaginal birth) experiencing each mode of birth including: unassisted and spontaneous vaginal birth, assisted vaginal birth, emergency caesarean and last minute conversion to a planned caesarean.* *Numerator – the number of women experiencing each mode of delivery in the denominator who chose to take up the opportunity to attempt a vaginal birth.* *Denominator – the number of pregnant women who have had more than 1 previous CS.* Recommendations for additional Outcome measures: *a) The rate of women who have had previous CS who were given the option to attempt a vaginal birth.* *b) The rate of women who have had more than 1 previous CS*	

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			who were given the option to attempt a vaginal birth. *c) The rate of women who have had 1 previous CS who chose to take up the opportunity to attempt a vaginal birth in their current pregnancy* *d) The rate of women who have had more than 1 previous CS who chose to take up the opportunity to attempt a vaginal birth in their current pregnancy* *e) The rate of each mode of delivery for women who have had 1 previous CS (and who chose to take up the opportunity to attempt a vaginal birth in their current pregnancy). Where mode include: unassisted and spontaneous vaginal birth, assisted vaginal birth, emergency caesarean and last minute conversion to a planned caesarean.* *f) The rate of each mode of delivery for women who have had more than 1 previous CS (and who chose to take up the opportunity to attempt a vaginal birth in their current pregnancy). Where mode include: unassisted and spontaneous vaginal birth, assisted vaginal birth, emergency caesarean and last minute conversion to a planned caesarean.* In addition: • *Patient satisfaction with their birth, categorised by actual birth mode, not intended birth mode, (where mode includes: unassisted or spontaneous vaginal birth, assisted vaginal birth, emergency caesarean and last minute conversion to a planned caesarean).* Recommendation for clarification of definition: *Case specific risk / benefit information – The information provided to women takes account of the reasons for the*	

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			previous CS and specifically tailors the recommendation to be given the 'option' on this basis.	
105	electivecesarean.com	Statement 4	Pregnant women who have had a previous CS are given the option to attempt a vaginal birth Some general comments on this statement: It is very important that women are given the option to attempt a vaginal birth, and it may be that my concerns are considered part of the consultation process risk-benefit analysis with each woman, and therefore not necessary to highlight specifically in this statement. However, what is striking in this statement is the very general term "previous CS", when we know that in the context of VBAC safety, the reasons for the previous CS , plus other factors such as whether the woman has had a previous VD, all affect the level of risk. I wonder whether this statement shouldn't be written more in line with no. statement 1, in which maternal request CS must be discussed and decided upon within an acceptable timeframe – rather than the current wording that women should be "given the option to attempt". It is a very subtle difference, and obviously in both cases, the same principle of support should be provided in the event that the woman *does* decide to plan a CS – or a VBAC. Suggested Outcomes: **a) The rate of perinatal mortality in attempted vaginal birth following a previous CS.** **b) The rate of women's satisfaction following an attempted vaginal birth following previous CS** Reasons: The current outcomes appear more to be targets, which is not our understanding of a quality standard and how it will measure patient satisfaction and improve health outcomes. Definitions – May I suggest changing the two uses of the word "advised" to "**informed**", and "can" attempt to "**may**". Also, following the words, "is rare", suggest additional text to	Thank you for your comment. The intention of the statement is to enable the women to make an informed choice and not encourage her either way. One of the outcome measures for this quality statement relates to the woman's experience of feeling supported in her choice. The proposed measures were not deemed to have a clear causal link to the actions described in this quality statement.

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			include more of RCOG's wording on VBAC risk of uterine rupture, e.g. "serious adverse outcomes… serious maternal and perinatal morbidity and perinatal mortality… identify the indication, type of uterine incision and any perioperative complications…" Litigation cases clearly demonstrate that many women feel they were not fully informed of the potentially catastrophic outcomes of uterine rupture, and while this risk should not be used as a reason *not* to allow VBAC (as happens in other countries sometimes), it's equally important not to underestimate its impact when informing women either. A final observation on the 'proposed quality statement' in the briefing paper on this draft quality statement. In the context that no birth plan is risk free, and that NICE now recommends support for both VBAC and maternal request CS, I cannot imagine a proposed quality statement like this VBAC one (i.e. women "are informed that there are little or no increased risks of complications.") being written in this way for maternal request CS. Nuances in language are very important if choice in maternity care is to be considered fair to every woman.	
106	Sheffield NHS Teaching Hospitals Foundation Trust	Statement 4	Feel the evidence is not strong enough to justify offering women who have previously had 4 caesarean sections a vaginal delivery. We would feel uneasy offering this as the evidence about the safety decreases with each subsequent caesarean section.	Thank you for your comment. The statement is consistent with the recommendation in the clinical guideline 132. The clinical guideline development group recognised the issues with the evidence and were confident that the available evidence suggested there weren't significant differences in the risks after 4 previous CS. The only reason they didn't go beyond 4 was due to a lack of available evidence,
107	AIMS (Association for Improvements in the Maternity Services)	Statement 4	I think this is a great addition to the statements. However, the word attempt is slightly concerning. Whilst I appreciate the reason for its use, language which has the potential to undermine, even at this level, can have huge knock on effects. How about - "Pregnant women who have had a previous CS	Thank you for your comment. The wording of this statement has been amended, to recognise the option to attempt a vaginal birth.

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			are made aware of the option of giving birth vaginally."	
108	Mumsnet	Statement 4	Most users agreed with this statement, though some observations were made. Many commented on high pressure from consultants and GPs to opt for a VBAC, as opposed to simply offering it as an 'option'. One mother who had opted for VBAC wanted clearer guidance and information on VBAC. She noted that her worries about childbirth (her first by VB) were not allayed or discussed as it was supposed, because she had already given birth (albeit by CS), that she fully understood and was unconcerned about the VB procedure.	Thank you for your comment. The focus of the statement is on information giving through a discussion between members of the maternity team and the woman.
109	Kings College London	Statement 4	Are we are expecting to see that every woman (up to 4CSs) is genuinely offered trial of labour?	The intention is that all women should be given relevant information so that they can make an informed choice.
110	NCT	Statement 5	This draft quality standard states that "Pregnant women having a planned CS undergo the procedure at or after 39 weeks 0 days of gestation, unless an earlier delivery is necessary because of fetal or maternal complications". Should a recommended latest gestation for the CS be added?	Thank you for your comment. A latest gestation was not identified as an area for inclusion in this quality statement as this is not possible due to the varied circumstances that can be experienced by different women.
111	Healthcare Inspectorate Wales	Statement 5	Quality statement 5. With reference to pregnant women who have opted for a planned C/S, consideration should be given, (unless an earlier delivery is necessary because of maternal or fetal complications), to the procedure taking place at 41 weeks. This would bring the statement in line with the NICE guidance for Induction of Labour, unless an earlier delivery is necessary because of maternal or fetal complications.	Thank you for your comment. 39 weeks 0 days is deemed appropriate as leaving it to 41 weeks would increase the likelihood that labour could start before the section is carried out with the potential that they could present outside of routine theatre hours already in active labour increasing risks to the woman and the child.
112	Birth Trauma Association	Statement 5	We have real issues about this QS. In our experience, most HCP who become involved in NICE guidance and quality standards have high standards of professional practice themselves and usually come from good hospitals. There is therefore an understandable failure to understand quite how bad the practice is in some NHS hospitals. We have experience of women with severe tokophobia who had been offered a c/s and who were being given a date at 40+6. This is psychological torture for these women and wholly	Thank you for your comment. The TEG did not feel it was realistic to give a very specific timeframe for when a CS should be conducted by. The focus of this statement is on reducing cases of respiratory distress and the evidence suggests that the risk of this is reduced when a CS is carried out after 39 weeks.

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			unacceptable. Obviously from the point of view of respiratory distress in the baby, it is sensible to plan for a CS at 39 weeks but we cannot agree with the 'at or after 39 weeks' statement. We would like to see this changed to 'between 39 weeks and 39 +2'.	
113	The Royal College of Anaesthetists	Statement 5	The OAA feels strongly that women undergoing planned Caesarean section should have their delivery scheduled on a dedicated and time protected elective Caesarean section list. In the majority of hospitals (OAA survey data evidence), elective procedures are carried out in an ad-hoc manner and are frequently interrupted by emergency Caesarean sections, other operative deliveries or obstetric procedures in theatre, or by obstetric, midwifery or anaesthetic staff becoming unavailable because of unforeseen demands on the labour ward. The consequence is that elective sections are often postponed to the next working day or later, despite the mother having been fully prepared and fasted, and often having placed other children into childcare arrangements for the day (audit data from Nottingham and other hospitals available to support this). No other elective surgery in the NHS works to this haphazard model.	Thank you for your comment. We were unable to find any NICE accredited guidelines that recommended the use of dedicated caesarean section list to improve clinical outcomes. The TEG did support this point, and reference has been added to the supporting information for this statement about the use of a dedicated list as a potential model to deliver this statement. This point is also referenced in the support for commissioners tool, published with this quality standard.
114	Royal College of Obstetricians & Gynaecologists	Statement 5	*Definitions:* In the definitions section, suggest change the term 'intrauterine growth restriction' to 'fetal growth restriction'.	*Thank you for your comment. This has been added to the final quality statement supporting information.*
115	Northumbria Healthcare NHS Trust	Statement 5	Agree	
116	Csections.org	Statement 5	The Statement needs to be clarified to ensure that women who go into labour prior to the date of their planned caesarean are able to continue with that birth plan. We recognise that theatre requirements for emergency CS need to take priority but a woman who has had a CS planned must be permitted to continue with that plan as soon as a theatre becomes available	Thank you for your comment. The quality standard is not able to cover all potential issues associated with the caesarean section care pathway. The issues you raise are relevant, however, these are not issues that have been raised as priorities or covered in any clinical guidelines. These situations would require a judgement

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			even if this means that other planned CS have to be delayed. This should be the case regardless of the woman's reason for requesting a CS. Horrifyingly we have had cases of women who have planned a CS but whose labour starts early being told to 'get on with it'. What needs to be remembered is that in the same way that women wanting a vaginal birth can frequently be found to know nothing about CS, the same can be true of women planning a CS – they can be totally uninformed about and unprepared for vaginal birth. To tell such women to just 'get on with it' is highly irresponsible. There is no Outcome identified for this Quality Statement. One is required which reflects the Statement namely to measure the rate of CS performed prior to 39.0 weeks where no maternal or fetal complications have been identified and labour has not commenced. **RECOMMENDATIONS:** Recommendation for revised Quality Statement: *Pregnant women having a planned CS undergo the procedure at or after 39 weeks 0 days of gestation, unless an earlier delivery is necessary because of maternal or fetal complications or labour has commenced.* Recommendations for additional Outcome measures: • *The rate of women having a planned CS prior to week 39.0 where no maternal or fetal complications have been identified.* • *The rate of women having a planned CS where labour has commenced prior to their planned CS date.* Recommendation for an additional definition: *Undergo the procedure – women whose labour commences*	call by local clinicians taking into consideration the different circumstances each woman is in and the available clinic space. It is anticipated that this scenario is less likely to occur through the increased involvement of consultants obstetrician involvement as described in statement 4 and statement 6 of the final quality standard..

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
			prior to or within hours of their planned CS date have their decision for a planned CS upheld.	
117	electivecesarean.com	Statement 5	This is an excellent area of care to focus on in relation to CS birth, and I'm very pleased that NICE has included it. I have made one suggestion for additional text below, although I have not inserted a number: Pregnant women having a planned CS undergo the procedure at or {**up to *X* days**} after 39 weeks 0 days of gestation, unless an earlier delivery is necessary because of maternal or fetal complications. My concern is the need to clarify a cut-off point for women to undergo the procedure. I have suggested the text highlighted above, but would rather leave it to medical professionals to confer and decide on an appropriate timeframe. What is not acceptable is the current situation where some women are left to wait so long, or a date is not scheduled, that they go into labour and either the CS becomes an emergency instead of a (safer) planned, or in worse case scenarios (for those who requested a CS) the woman is made to continue with labour and attempt an unwanted vaginal delivery. There are no Outcomes listed for this statement. Suggested outcomes: **a) The rate of transfer to NICU for infants born at or after 39 weeks 0 days of gestation [OR] Rates of respiratory morbidity in babies delivered by planned CS at or after 39 weeks 0 days of gestation.** **b) The average gestational week and day of delivery by women in the denominator** **c) Rates of stillbirth and/or perinatal mortality – and at what gestational age** Finally, one recently published research paper that I would like	Thank you for your comment. A latest gestation was not identified as an area for inclusion in this quality statement as this is not possible due to the varied circumstances that can be experienced by different women.

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
			to mention here is: *Neonatal Outcomes After Implementation of Guidelines Limiting Elective Delivery Before 39 Weeks of Gestation, Ehrenthal et al. Obstetrics & Gynecology: November 2011 - Volume 118 - Issue 5 - p 1047–1055* The researchers found that, "A policy limiting elective delivery before 39 weeks of gestation was followed by changes in the timing of term deliveries. This was associated with a small reduction in NICU admissions; however, macrosomia and stillbirth increased." I think that this is important to bear in mind in the context of this quality statement, and I would suggest that something is added in the 'Definitions' section perhaps to emphasise that there remains a need for some flexibility here – and this is also why I have suggested the outcome c) above.	
118	AIMS (Association for Improvements in the Maternity Services)	Statement 5	I note that under the definition of maternal or fetal complications diabetes and gestational diabetes are included. I wonder if within the data collected a subgroup could be created for these women. We hear of a lot of women having CS early for this reason. In the interest of lowering rates, as this standard aspires to do, we feel that further knowledge could be instrumental in clarifying the situation	Thank you for your comment. We would anticipate that local areas would prioritise certain populations that they may want to collect data on depending on what local priorities are. This was not identified as a national priority.
119	Mumsnet	Statement 5	One user noted a timing issue with the statement. She said that her hospital only offered planned caesarean sections once a week, so her choice is 38weeks 6days, or 39weeks 6days. According to the 39weeks 0days minimum gestation for an ELCS, this woman could only choose an ELCS at 39weeks 6days, which she regards as too late for a planned CS: *"There is a good chance I'll go into labour before 40 weeks and would then need an emergency c-section".*	Thank you for your comment. The TEG recognise that due to constraints caused by clinic times there may be occasions where someone will be offered a planned CS a day or 2 before 39 weeks. This was deemed to be acceptable by the TEG.
120	Kings College London	Statement 5	This is the most important of the standards. But why not offer as late as in labour if no 'medical' reason. Avoids the need to give steroids when >39 weeks (with long term implications), and will ensure baby determined date of birth/ less respiratory complications.	Thank you for your comments. The TEG did not feel that it would be sensible to wait for labour to start in all planned CS as it would be impossible to plan theatre time and suitable clinical coverage for an approach that doesn't have an available evidence base.

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
121	British Maternal & Fetal Medicine Society	Statement 6	(this is a distillate of members of the BMFMS membership comments): The Caesarean section quality standard is difficult to read with complex prose and “high jargon content”. The amount of repetition within the document is large. However, we wanted to comment specifically on the recommendation “to give a course of steroids for CS before 39 weeks”. The evidence base for this decision is unclear and appears weak. The RCOG greentop guideline, from which it comes, gives as the sole evidence the Stutchfield trial (BMJ 2005;331:662). This is despite the statement in the same section of the guideline that "There is an absence of evidence available for the safety of antenatal corticosteroids in babies born after 36+0 weeks of gestation". Recent evidence (see attached) suggests that it may not be safe. Moreover, the low rate of TTN/RDS in South Asian and black African babies suggests that administration of steroids to women of these ethnic groups may not be necessary after 35 weeks gestation. The Stutchfield trial showed benefit only in relation to RDS and overall rates of admission to SCBU were not reduced significantly by antenatal steroids.	Thank you for your comments. The intention is that the quality standard is as clear as possible to its readers. We invest a lot of time trying to make sure that it is understandable, accepting that for some topics the type of language used within clinical settings can have a high jargon content. Where possible we do try to reduce this. With regard to your other point about statement 6. This statement has not been included in the final quality standard due to a lack of consensus amongst TEG members and stakeholders about whether this should be included as a descriptor of high quality care. This statement was based on an RCOG guideline. The TEG chair has referred the concerns of the BMFMS to the Chair of RCOG Guidelines committee and withdrawal of the RCOG recommendation is being considered.
122	Royal College of Nursing	Statement 6	This statement is a significant change in practice, as steroids would not normally be administered at 37 and 38 weeks gestation. We wonder if a cost benefit analysis is evident to support this statement.	This statement has not been included in the final quality standard due to a lack of consensus amongst TEG members and stakeholders about whether this should be included as a descriptor of high quality care.
123	Royal College of Obstetricians & Gynaecologists	Statement 6	*Statement:* Suggest change the standard: ‘pregnant women having a planned CS before 39 week of gestation due to maternal or fetal complications are offered a course of antenatal corticosteroids’ to ‘pregnant women having a planned CS before 38+6 weeks of gestation due to maternal or fetal complications should receive a course of antenatal corticosteroids’. This change in wording better reflects the wording and tone of the RCOG Guideline recommendation (upon which it is based).	This statement has not been included in the final quality standard due to a lack of consensus amongst TEG members and stakeholders about whether this should be included as a descriptor of high quality care. This statement was based on an RCOG guideline. The TEG chair has referred the concerns of raised by stakeholders to the Chair of RCOG Guidelines committee and withdrawal of the RCOG recommendation is being considered.
124	Nottingham University Hospitals NHS Trust	Statement 6	It may be potentially hazardous to give corticosteroids to women with diabetes where CS is planned at 38-39 weeks, as is common practice, as steroids cause hyperglycaemia. The	This statement has not been included in the final quality standard due to a lack of consensus amongst TEG members and stakeholders about whether this should be

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			balance of benefit / risk is unclear but many clinicians would be reluctant to give steroids approaching 39 weeks in this cohort	included as a descriptor of high quality care. This statement was based on an RCOG guideline. The TEG chair has referred the concerns of the BMFMS to the Chair of RCOG Guidelines committee and withdrawal of the RCOG recommendation is being considered.
125	Northumbria Healthcare NHS Trust	Statement 6	Agree	
126	Gloucestershire Hospitals NHS Foundation Trust	Statement 6	The RCOG guideline concluded the following: • There is an absence of evidence available for the safety of antenatal corticosteroids in babies born after 36+0 weeks of gestation. Elective lower segment caesarean section should not normally be performed until 90+0 weeks of gestation, rather than the administrations of antenatal corticosteroids This does not equate to the guideline that has been suggested. It suggests that more evidence is required before this is implemented de-facto.	This statement has not been included in the final quality standard due to a lack of consensus amongst TEG members and stakeholders about whether this should be included as a descriptor of high quality care.
127	electivecesarean.com	Statement 6	Pg. 14 Pregnant women having a planned CS before 39 weeks of gestation due to maternal or fetal complications are offered a course of antenatal corticosteroids Suggested additional outcomes: **a) The rates of women who accepted a course of antenatal corticosteroids** **b) The rates of women who accepted a course of antenatal corticosteroids** c) **The rates of respiratory morbidity in babies delivered by planned CS before 39 weeks of gestation in each of the groups above**	This statement has not been included in the final quality standard due to a lack of consensus amongst TEG members and stakeholders about whether this should be included as a descriptor of high quality care.
128	Sheffield NHS Teaching Hospitals Foundation Trust	Statement 6	Agree with this. Would it be possible to have some guidance for patients who have a planned caesarean section 38 weeks to 38 weeks +6 days, perhaps that it is encouraged rather than essential?	Thank you for your comment. The TEG recognise that due to constraints caused by clinic times there may be occasions where someone will be offered a planned CS a day or 2 before 39 weeks. This was deemed to be acceptable by the TEG.

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129	Birth Trauma Association	Statement 7	Agree	
130	NCT	Statement 7	The process draft quality measure b) should be made clearer. Should it read as follows (words removed have been struck through and words added have been put in bold)? b) The proportion of women in labour where a fetal blood sample was attempted and successfully obtained ~~and a~~ **where** a reading **was** made. Numerator – the number of ~~attempted fetal blood samples that were successfully obtained~~ **women in the denominator** ~~and a~~ **where** a reading **was** made. Denominator – the number of ~~pregnant~~ women **in labour** in whom a fetal blood sample was successfully obtained.	Thank you for your comments. The measures have been reviewed and amended where required.
131	Royal College of Nursing	Statement 7	It is difficult to comment here on the draft quality statements as they stand. Broad statements about fetal blood sampling to aid decision making may result in KPIs that are ill informed.	This was noted by the TEG
132	Department of Health	Statement 7	Would it be possible to emphasise the "**suspected**" because one would not want to encourage delay in cases of acute fetal distress. Data collection will be difficult for b). It would be better to set an audit requirement that there should be review of notes of every CS for acute or suspected fetal compromise to make sure that FBS had been used appropriately.	Thank you for your comment. Within the supporting information the point about not delaying urgent CS if required is made. The measures have been reviewed and amended where required.
133	Royal College of Obstetricians & Gynaecologists	Statement 7	*Statement:* Suggest change the standard; 'women in labour for whom a caesarean section is being considered for suspected fetal compromise are offered fetal blood sampling to inform decision making' to 'women in labour for whom a caesarean section is being considered for suspected fetal compromise are offered fetal blood sampling to inform decision making if it is technically possible and there are no contraindications'. This is the wording of the recommendation in the NICE clinical guideline 132.	Thank you for your comment. This detail is included in the definition section for this quality statement. We do not include reference to contraindications in quality statements as this could be relevant for every action described in a quality statement. It is expected that clinicians will always use their clinical judgement and decide where an action is contraindicated.

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			Measure: There is no 'outcome' given in this section. *Measure:* It is felt that it will be difficult to generate meaningful numbers and proportions not least because there may be more than one reason to perform a CS, of which suspected fetal compromise is one.	
134	Northumbria Healthcare NHS Trust	Statement 7	Agree	
135	Swansea University	Statement 7	Item b) of the quality measure is very confusing – it conflates offering of appropriate fetal blood sampling with • access to functioning and serviced FBS machines • skilled staff to attempt and successfully obtain the FBS and successful reading of the FBS. In the section 'Description of what the quality statement means for each audience', why is FBS is referred to as '*a procedure called* fetal blood sampling'? In the Definitions section, the definition of *Fetal blood sampling* includes much more detail than previous statements. Again, the structure might emulate page 6. It might be helpful to include more explanation or references to explanations of what constitutes contraindications to fetal blood sampling.	Thank you for your comment. The TEG identified an issue relating to access to function fetal blood gas analysers. The audience descriptors are different so they are more relevant for the specific audiences they are intended for. Details about contraindications are included in the definition section. These would include the opposite to what is described as technically possible and include any other issues identified by the clinician or the woman involved.
136	electivecesarean.com	Statement 7	Women in labour for whom a caesarean section is being considered for suspected fetal compromise are offered {**timely**} fetal blood sampling to inform decision making There are no Outcomes listed for this statement. Suggested outcomes: **The rate of perinatal mortality following labours where fetal blood samples were successfully obtained and a reading made.** **The rate of perinatal mortality following labours where**	Thank you for your suggestions. The TEG identified 1 outcome for this statement that they felt had a direct causal link to the action described in the quality statement. The outcomes you propose, are important, but would be affected by a large number of other factors outside the control of this statement.

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			fetal blood samples were offered / not offered. **The rate of women who accepted the offer** **The rate of women who declined the offer** **The rate of perinatal mortality/ serious morbidity with/without blood sampling** My concern is with the originating CG132 recommendation behind this quality statement, which begins, "EFM is associated with an increased likelihood of CS." It is *vital* that fetal blood sampling be offered in this context, so that the woman is absolutely aware that this is one of its purposes. If she is a woman who is very keen to experience a vaginal birth, and this helps to inform her decision making about whether to continue labouring, it is an excellent resource. However, in the case of a woman who is in labour, is aware of fetal distress on the monitor, and is not happy with the situation, her concern for the safety of her baby should be respected and fetal blood sampling should not be the only option being discussed. Definition – May I suggest that some information is included here about how long fetal blood sampling takes? I found one study that reported a median time of 18 minutes (interquartile range 12-25 minutes) and for 9% of women, longer than 30 minutes. It states, "This is important clinically when repeated testing is required or in the second stage when operative vaginal delivery is achievable. Furthermore, when retrospectively analysing cases with a poor outcome, the time to obtain a result needs to be taken into account when determining the time at which a baby could have been delivered."(***12***)	
137	AIMS (Association for Improvements in the Maternity Services)	Statement 7	In order to get the complete picture here, I wonder if also collecting data regarding maternal trauma may be useful. Both physical and psychological.	Thank you for your suggestion. The TEG did not feel this was a relevant measure for this statement which is about the use of fetal blood sampling to help inform decision making.
138	Royal College of Paediatrics and Child Health	Statement 7	The timing of emergency CS after the decision is made should also be included in the statement.	Thank you for your comment. The TEG agreed that timing is a separate issue to this statement.

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
139	Healthcare Inspectorate Wales	Statement 8	Debriefing. There needs to be a recommended period of time for these important discussions i.e. within 6 weeks post delivery.	Thank you for your comment. The definition states that this should be offered whilst in the post natal ward or if the woman is in the postnatal ward or at a later date if preferred by the woman. The timescale for this could then be agreed between the woman and the relevant member of staff.
140	Birth Trauma Association	Statement 8	'Within a suitable timeframe' for this should be explicit in the quality statement rather than just mentioned in the definitions section. Processes should be in place to ensure that women who request this debrief at a later date ie not on the post natal ward do not fall off the radar and miss out all together. There is a problem with the quality of information being given by hospitals. For instance, one hospital's leaflet lists a '2% risk of the baby being lacerated' during caesarean' This would make many women feel that they should opt for VBAC when in fact, the risk of laceration is many times higher for emergency caesarean which is only going to happen if they opt for VBAC. There are many, many examples of poor explanation of risks where women are not being given the risks of ELCS but the much higher risk of the combined risk of ELCS and EMCS as a result of which women are misled. (NB this is mentioned in litigation). Perhaps we could add an additional Q S; 'There is a regular interprofessional audit of the verbal and written information given to women to ensure its accuracy'	Thank you for your comments. The timeframe is clarified in the rationale section for this quality statement and also in the definition section. The focus of the statement is therefore on the fact that the discussion happens. With regard to the information. This has not been covered in this quality standard, but the TEG recognised this as an important issue and would anticipate that local organisations would ensure the quality and accuracy of information they provide to patients through their internal governance structures, seeking up-to-date information from available sources.
141	The Royal College of Midwives	Statement 8	This statement should include a discussion with a **'senior'** health professional again in this context. A consultant midwife would be appropriate where available.	Thank you for your comment. The definition for this statement says that the healthcare professional should have suitable training and expertise to provide this information. The level of experience needed will depend on the complexity of the case.
142	Royal College of Nursing	Statement 8	The advice to women about the consequential morbidity needs to be clear and informed choice should include the language	Thank you for your comment. The information that should be provided to women has not been covered in this

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			option. There is now more research to show additional risks of haemorrhage and placenta accreta. Having clear advice regarding driving post operatively or lifting and moving children and babies would be helpful especially as experiment suggests that these are often common complaints from women who have had a caesarean section without appropriate information.	quality standard, but the TEG recognised this as an important issue and would anticipate that local organisations would ensure the quality and accuracy of information they provide to patients through their internal governance structures, seeking up-to-date information from available sources.
143	Department of Health	Statement 8	De-briefing is not a good word to use. Should this QS specify when the discussion should take place – i.e. in PN period and again at postnatal appointment. Also should it say that this must be an appropriately experienced clinician since it may not be appropriate for a GP to counsel and really the person needs to have access to the notes of the CS and be fully aware of the circumstances leading to CS.	Thank you for your comment. The term “debriefing” has been changed in the final quality standard. The points about when the discussion should take place and who should conduct the discussion are referenced in the rationale and the supporting information for this quality standard.
144	Royal College of Obstetricians & Gynaecologists	Statement 8	*Definitions:* Please clarify the term ‘trainee obstetrician who has completed at least 5 years of training’. (for example does this mean an ST6 or ST7 doctor or an ST4 trainee who has completed 3 years of specialty training and 2 years of foundation year training?)	Thank you for your comment. This reference has been removed from the final quality standard/.
145	Northumbria Healthcare NHS Trust	Statement 8	Very important but will need to be resourced. Agree needs to be experienced obstetrician or midwife with special interest and appropriate training.	Thank you for your comment.
146	Swansea University	Statement 8	***From the perspective of the Head of Midwifery Education, this is the most problematic statement. *** Debriefing is a highly skilled activity with unproven outcomes. It also holds many potential legal and professional risks for those undertaking it. Whilst it is not true of all women, some women who have experienced an emergency CS might be highly traumatized, and we suggest that, to take full account of these risks, this quality statement needs more detailed work before it is included in this standard. If ALL women who have a CS are to be offered ‘debriefing’, it will take more consideration and planning to develop a standard that will be likely to achieve the *‘patient’* satisfaction that is aspired to. One might suggest that, much the same as in any other surgical operation, it is the role of the obstetrician who carried out the operation to discuss this with the woman during her	Thank you for your comment. The definition for this statement says that the healthcare professional should have suitable training and expertise to provide this information. The level of experience needed will depend on the complexity of the case.

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			recuperation.	
147	Csections.org	Statement 8	In line with the original recommendation in the Briefing document, this Statement needs to specify a start point from which such debriefings should occur. Some women are ready for a debrief far sooner than others and some will need information and 'closure' far sooner than others. Caesareans are frequently blamed as the cause of adverse psychological outcomes for mothers. Debriefings can go a long way to reducing adverse reactions by being conducted earlier for some women. To this end, debriefings should be possible while the mother is still in hospital. In our experience it is not clear whether women fully understand the importance of debriefs and may miss them entirely or agree to them when they are not actually in a fit state to 'take it all in'. Given that this Quality Statement also dictates the debrief should include discussion about future birth options following CS we recommend that this discussion be documented (as the Briefing document suggests). The additional recommendation that we would add to this is that the "printed information" should relate to the woman's **specific case** (not generic pamphlets).	The timeframe is clarified in the rationale section for this quality statement and also in the definition section. The focus of the statement is therefore on the fact that the discussion happens. We have also included the need for written information so women can review this at a time that is appropriate for them and their family.
148	electivecesarean.com	Statement 8	Women who have had a CS are offered a discussion with a health professional about her CS and birth options for future pregnancies Looking at the original CG132 recommendation, and the statement above, the focus is on reasons for the request and choices in next pregnancy (i.e. VBAC, repeat CS), but there is no mention of 'quality of or satisfaction with care'. Many women are happy with CS reasons but not the level of care received; can this aspect be included in the quality statement outcomes? Suggested outcomes: **a) The number/rate of women who *have* this discussion**	Thank you for your suggestion. A patient experience outcome measure has been added for this quality statement. The methodology for measuring outcome measures is not decided by NICE and is left for local development. NICE do provide implementation tools including audit tools where appropriate.

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			b) Patient satisfaction with postnatal debriefing and information. **c) Patient satisfaction with the reasons for their CS (with data separated into type of CS)** Question: How will patient satisfaction be measured by NICE? Will it be in a 'tick box on a scale of 1-5, where 1 means X and 5 means Y'? Or more of a qualitative style with open text box for comments? Discussion – an opportunity for women to discuss the reasons for the CS and how successful the procedure was with healthcare professionals and receive verbal and printed information about birth options {**and risks**} for future pregnancies. The discussion that takes place will very much depend on the type of CS the woman has experienced, the reason/s for the CS, and her satisfaction with the whole experience. All of these factors will also have an impact on the information on possible birth options and risks presented by the health professional. RCOG's 2001 national sentinel caesarean section audit states (p.95 12.3), "One of the priorities of maternity care is to enable women to make informed decisions regarding their care or treatment. To do so, they require access to evidence-based information, to help them in making their decisions." However, as outlined above, one of the greatest challenges for NICE with these quality standards (and also other guidelines) is getting health professionals to a point where they *agree* on the risks and options that women should be informed about. There is still so much mixed data when it comes to CS birth, especially emergency versus planned/elective but also planned with and without medical indications, and at different gestational ages. There are also still so many outdated documents in circulation within the NHS, and there is an urgent need to ensure that maternity teams are up to date with the latest evidence-based research.	

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149	Mumsnet	Statement 8	Mumsnet users expressed huge support for this statement, due to their many experiences of poor information and a lack of (or incomplete) debriefing following a CS. Many said that their prenatal care and surgical teams were excellent, but that post-natal care failed to equip them emotionally for the immediate future (with newborn) and for future childbirth choices. Discussions about future pregnancies were not offered and debriefs came too little too late, often in the month following.	Thank you for your comment. The TEG recognised the issues in relation to post natal care and support for women who have had a CS and therefore included this statement and statement 9 to help overcome some of these issues.
150	Kings College London	Statement 8	We are anxious about 'satisfaction' with the debriefing is not the right outcome to use. There is evidence that debriefing improves satisfaction but increases postnatal depression. http://www.bmj.com/content/321/7268/1043 http://www.ncbi.nlm.nih.gov/pmc/articles/PMC558531/ What is the appropriate training that "an appropriately trained midwife, a consultant obstetrician or a trainee obstetrician who has completed at least 5 years of training" is supposed to have?	Thank you for your comment. The TEG have retained a satisfaction measure for this statement, focused on the information provided and the discussion they experienced. With regard to the expertise required to carry out this discussion, this has become less prescriptive about specific staff members, but suggests the seniority of the member of staff will depend on the complexity of the case.
151	The Royal College of Anaesthetists	Statement 9	This is an invaluable statement that will be of great benefit to those organising clinical frontline services who find that these standards are frequently being eroded. Some additional comments from the OAA on draft quality statement 9: *"After recovery from anaesthesia, observations (respiratory rate, heart rate, blood pressure, pain and sedation) should be continued every half hour for 2 hours, and hourly thereafter provided that the observations are stable or satisfactory. If these observations are not stable, more frequent observations and medical review are recommended". However,* the OAA would point out the logical impossibility of following this direction where there is no defined end-point for these hourly observations except for those women in whom intrathecal opioids are used. Even in these women (see next paragraph) the standards are unduly restrictive and not evidence-based. *"For women who have had intrathecal opioids, there should be a minimum hourly observation of respiratory rate, sedation and*	Thank you for your comment. With regard to your first point. This has been retained in the definitions as the TEG felt that this was still relevant and that clinicians would use judgement about when this monitoring should be stopped. The other 2 sections have been removed from the definition as the TEG were in agreement with your comments.

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			pain scores for at least 12 hours for diamorphine and 24 hours for morphine." The OAA commented on these standards for monitoring in their feedback to Clinical Guideline 132 and wish to reiterate their view that these are unnecessarily restrictive on the mother and demanding upon midwifery time. There is no evidence to our knowledge that intrathecal diamorphine or morphine in the doses now in routine use in the UK can cause delayed respiratory or cardiovascular depression in women of child-bearing age. Extended hourly monitoring of cardiovascular or respiratory parameters predicated solely on the use of these drugs via these routes, and for no other clinical indication, is therefore not evidence-based. Additionally, we would point out that the standard: "*For women who have had epidural opioids … there should be routine hourly monitoring of respiratory rate, sedation and pain scores throughout treatment and for at least 2 hours after discontinuation of treatment."* makes no sense. Epidural opioids are usually given as a single bolus administration at or immediately after Caesarean section, so there can be no valid concept of "throughout treatment" or "discontinuation of treatment".	
152	Department of Health	Statement 9	This is important but also it needs to be clear that women need the core care all the time – e.g. so that they do not miss out on breast feeding support just because they are e.g. in HDU – as well as the additional care they may need because of having CS and intervention.	Thank you for your comment. The TEG agreed with your point and have clarified this in rationale section for this statement.
153	Birth Trauma Association	Statement 9	Excellent to see that this important quality statement included The problem with the outcome measure is that high levels of complications could represent better detection and better care so what does that outcome measure actually tell us? It could actually result in worse results for the best units. Adequate care is defined in your definitions section for this QS	Thank you for your comment. This was reviewed by the TEG who accepted your point but still felt that this was a relevant outcome measure. The measure does not suggest that a higher rate of identified complications would suggest poor care, but recognises this as a possible outcome from implementation of the statement.

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			and it would seem appropriate to frame the outcome around whether this is delivered.	
154	Northumbria Healthcare NHS Trust	Statement 9	Agree	Thank you
155	Swansea University	Statement 9	Oxygen saturation should be included in the list of patients' vital signs to be monitored, alongside respiratory rates. In practice, recording of respiratory rates is time consuming, and sometimes overlooked by busy clinicians. Pulse oxitmeters are convenient, painless and reliable. Emesis should be monitored alongside pain, to minimize distress and risks of aspiration in sedated patients, and observe for sudden falls in blood pressure (Jordan 2010). These are discussed fully in the standard text for student midwives (Jordan 2010). Most UK (and Australian) teaching departments have adopted this book, so many midwives will be familiar with this.	Thank you for your comment. The TEG have kept the definition consistent with the definition included in the NICE caesarean section clinical guideline 132.
156	Swansea University	Statement 9	Please define or refer to a definition of *'core postnatal care'*. In the Definitions section why not simply refer readers to the NICE clinical guideline 132 instead, and reduce detail?	This was deemed to be a routinely used term that didn't need defining. Some of the detail has been removed from the definition section.
157	Csections.org	Statement 9	The title of this Statement is misleading. Reading the detail this Statement shows it relates purely to the post-operative management process not to the measurement of maternal complications. The title should be altered to reflect the content of the Statement We are rather perplexed as to the objective of the measure in this Statement. We agree that it is important to measure complication rates, but this Statement is not about complication rates it is about the monitoring and management process. The measure is therefore the number of CS women who were successfully monitored for potential risks and complications	Thank you for your comment. This was reviewed by the TEG who accepted your point but still felt that this was a relevant outcome measure. The measure does not suggest that a higher rate of identified complications would suggest poor care, but recognises this as a possible outcome from implementation of the statement.

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			prior to being transferred to postnatal care. **<u>If</u>** such an Outcome measure were to remain in this Statement it requires significant qualification at the very least in terms of intended mode of delivery and a categorisation of the various complications that occur (See earlier General Comments 01 and 04). Without these clarifications this Outcome measure is biased and open to significant abuse by the anti-caesarean lobby. **RECOMMENDATIONS:** Recommendation for alteration of Quality Statement title: *Maternal monitoring and management of immediate post CS care.* Recommendations for additional Outcome measure: *Categorise rates of <u>each</u> complication in women who have had a CS coded by intended mode of delivery and actual mode of delivery*	
158	electivecesarean.com	Statement 9	Maternal complications {**immediately**} following caesarean section I think the title of the quality statement as it stands infers a more thorough and longer term assessment of CS complications than it actually offers. Hence the suggested addition of 'immediately'. The Structure, Process and Outcomes here is another example of where we are not convinced that the quality standard being measured is appropriate. Firstly, it is essential that the information is separated into those women who had an emergency or a planned CS – if the suggested draft outcome is to have any actionable meaning at all (or further inform birth plans). Secondly, surely it would be more useful to know what rate of complications (and what types) there were in women	Thank you for your comment. The point about timing has been clarified in the rationale and definitions section for this quality statement. The outcome measure concerning complications was retained. The measure does not suggest that a higher rate of identified complications would suggest poor care, but recognises this as a possible outcome from implementation of the statement.

Row	Stakeholder	Section	Comments Please insert each new comment in a new row.	Response
			who were monitored versus women who were not – rather than simply the rates of complications in all women who had a CS? Isn't the goal to measure the effectiveness of monitoring, and whether this significantly *reduces* rates of complications? In which case it would be important to know: **a) Rates of complications in the women who had their potential risks and complications monitored** **b) Rates of complications in the women who had their potential risks and complications monitored** **c) The type of caesareans in each group – i.e. emergency/ elective (as a starting point) numbers** Definitions – Just asking why CG132 rec. on management to avoid thromboembolic disease is not included here?	
159	Mumsnet	Statement 9	A few Mumsnet users suggested that blood transfusions should be offered for those who suffered severe blood loss from a CS. One user felt strongly that healthcare teams be made aware of the physically debilitating and psychologically harmful effects of general anaesthetic (GA) to mothers after a CS (exhaustion and emotional distance/not conscious of child)	Thank you for your comment. The use of blood transfusions should be decided by the relevant clinician caring for the woman. Statement 3 in this quality standard includes access to an anaesthetist who can explain to women considering a CS under general anaesthetic what the potential side effects can be.
160	Birth Trauma Association	Appendices	Delivering quality and value: Focus on fractured neck of femur, primary hip and knee replacement; acute stroke, caesarean section; short stay emergency care. (2007) Please remove this document - it is five years old and thinking has moved on from seeing the tariff as indicating real costs to the NHS. The tariff is a short term cost of an intervention. There are all sorts of savings on the tariff that are financially disastrous for the NHS and service users. It does not take into account the cost of not doing the intervention. This is very pertinent to, for instance, tokophobia, where we have seen women being offered extensive pre- labour counselling by several midwives, followed by several consultant appointments, followed by final reluctant agreement	Thank you for your comment. The purpose of this section is to provide an overview of what policy documents, guidelines and national audits and indicators are available to provide a national context within which the quality standard is being developed and implemented. This document is a national document that has been judged to be of relevance to the context of this topic. .

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			to vaginal birth which leaves them with PTSD, depression and needing cognitive behaviour therapy. The £84.00 saving on a CS is dwarfed by the other costs and results it a very negative outcome. There needs to be more intelligent thinking about the broader context of health care and documents like this that look at NHS costs as only the cumulative short term costs of individual interventions should be excluded from consideration.	
161	electivecesarean.com	Appendix 1	Firstly, I'd like to thank NICE for the excellent compilation of this page of sources, and the active links to them. It saved a great deal of time in terms of accessing and reading them, and was much appreciated. A few comments: Why was the National Institutes of Health Statement of Science on Cesarean Delivery on Maternal Request, published in 2006, not included in the Appendix of resources? It is a hugely important document in the context of maternal request CS, and I submitted it as evidence as part of the CG132. It was not used in CG132 due to restraints about what research NICE could look at for its guideline, but as a background document for information, I think that it would be a useful addition here? The Royal College of Obstetricians and Gynaecologists cites a 2000 NIH consensus statement on corticosteroids as level 1 evidence on pg. 9 of its 2010 Antenatal corticosteroids to reduce neonatal morbidity (Green-top 7) publication, so NIH evidence is certainly valued in the UK despite differences in hospital practice and delivery of care.	Thank you for your comment. For quality standards we use NICE accredited guidelines as our evidence sources. The other documents listed provide are used to provide details of the national context within which the quality standard is being developed and implemented.
162	Birth Trauma Association	Evidence	Please list the RCOG Greentop on Birth after CS	Thank you for your suggestion. It was felt that this area of care was suitably covered by the NICE Caesarean section clinical guideline 132 and that RCOG Greentop 45 pre-dates NICE accreditation of RCOG guidelines and is therefore not an accredited guideline..