NATIONAL INSTITUTE FOR HEALTH AND
CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1. Quality standard title

Intrapartum care: existing medical conditions or obstetric complications.

Date of quality standards advisory committee post-consultation meeting:
16 October 2019.

1. Introduction

The draft quality standard for intrapartum care: existing medical conditions and obstetric complications was made available on the NICE website for a 4-week public consultation period between 22 August and 23 September 2019. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

18 comment forms were received from 16 organisations which included service providers, national organisations, professional bodies and others.

This report provides the quality standards advisory committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the committee as part of the final meeting where the committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

1. Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be to be for these to be put in place?

3. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

4. For draft quality statement 1 and 2: Could these statements be combined into a single statement which focuses on women developing and reviewing their individualised care plan with the multidisciplinary team? If so, would it be clear from the definitions section that the multidisciplinary team should include a clinician with expertise in the medical condition during pregnancy?

5 For draft quality statement 3: For measurement and quality improvement purposes, at which key contacts should intrapartum risk be reassessed in women with heart disease?

6. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please provide details on the comments form.

1. General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

* The standard covers key areas for quality improvement.
* Many areas reflect what is already happening in practice.
* How do the areas relate to other aspects of maternity care, particularly, antenatal care.
* When do pregnant women with medical or obstetric issues presenting in primary care join these care pathways.
* What are communication mechanisms between primary and secondary care clinicians.
* The standard does not fully support a holistic approach to intrapartum care, and the exclusion of mental health conditions needs to be clearer.
* Care may not be improved for:
	+ women who developed a medical condition during pregnancy
	+ women without antenatal care or intrapartum care planning
	+ women with multimorbidities.
* Instrumental birth and birth-related trauma should be acknowledged, to enhance support for women’s birth choices.
* Reference to the Accessible Information Standard was well received.
* Access to an interpreter and language support to facilitate women’s understanding of choices and options for care was confirmed as being important.
* Equality Impact Assessment:
	+ suggestion to expand the list of defined groups who have a higher likelihood of not having received antenatal care.

### Consultation comments on data collection

* The statements may be difficult to measure.
* Most services could collect and audit data.
* Some data may be already collected in the Maternity Record and be available in the Maternity Services Data Set.
* Ongoing implementation of shared information standards across care settings could support delivering multidisciplinary care.
* Digital Care Records (Pregnancy PHRs) are anticipated to support women’s decision making by providing access to information and in time, support care planning.

### Consultation comments on resource impact

* Potential barriers include clinician roles may need to be backfilled and a lack of resources in local acute neurology services.
* In the long term, the cost of recruiting or reallocating specialist staff may be offset by a reduction in the number of cases resulting in poor treatment outcomes.
1. Summary of consultation feedback by draft statement
	1. Draft statement 1

### Women with an existing medical condition develop their individualised intrapartum care plan with a multidisciplinary team that includes a member with expertise in managing the medical condition in pregnancy.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

* There was general support for the statement, particularly the focus on multidisciplinary, personalised and holistic care.
* The statement should also refer to clinical and midwifery continuity of care roles.
* The statement wording implies that it is relevant to pregnant women with any existing condition but only a subset are defined.
* Query about whether all conditions covered in the source guidance are listed.
* The statement should focus on recording concerns and signs indicating the need for specialist input in the care plan.
* The woman’s role as a decision-maker should be emphasised.
* Concerns regarding the involvement of multiple MDTs were raised, concerning measurement, establishing clinical leadership and delivering consistent messages about care among specialists.
* Clarify the terms ‘expertise’ and ‘include’.
* Specialist involvement depends on the severity of the condition.
* The quoracy of both the MDT and meetings were highlighted as important in managing heart conditions.
* Suggestion to expand the list of MDT roles.
* Allied health professionals may not be funded to join MDTs by existing arrangements.
* Suggestion to include women who were not offered multidisciplinary care to the process measure denominator.
* Query as to whether Maternal Medicine Networks will achieve the standard.

### Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

* Statements should be combined, and it would be clear from the definitions who the MDT should include.
* A single statement may be more straightforward to implement and should focus on involving a clinician with expertise in the condition.
* Focusing on the woman developing and updating their multidisciplinary care plan could support making the statement more woman-centred in its focus and language.
* Suggestion that a revised statement conveys that the woman is central to decision-making, supported by advice and support from the care team.
* Both statements should have equal weight.
* Combining the statement removes the focus away from person-centred care and shared decision making
* Combining the statements would pose additional challenges for measurement.
	1. Draft statement 2

### Women with an existing medical condition are involved in reviewing their intrapartum care plan with the multidisciplinary team.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

* The focus on involvement does not acknowledge the woman’s role in the decision-making process.
* The statement implies that the MDT are the primary decision maker.
* ‘Involved’ should be defined so that it is measured by episodes of meaningful involvement to reduce the risk of overachievement.
* The woman should be involved in writing (not just reviewing) their care plan.
* The process measure does not acknowledge the woman’s role in decision-making.
* ‘Feeling involved’, as an outcome, does not assess whether meaningful involvement has been achieved or provide an incentive to do so.
* Include the woman as an essential member of the MDT.
* Barriers to data collection include interoperability issues and limit reporting.

### Consultation question 4

Stakeholders made the following comments in relation to consultation question 4:

* Statements should be combined, and it would be clear from the definitions who the MDT should include.
* A single statement may be more straightforward to implement and should focus on involving a clinician with expertise in the condition.
* Focusing on the woman developing and updating their multidisciplinary care plan could support making the statement more woman-centred in its focus and language.
* Suggestion that a revised statement conveys that the woman is central to decision-making, supported by advice and support from the care team.
* Both statements should have equal weight.
* Combining the statement removes the focus away from person-centred care and shared decision making.
* Combining the statements would pose additional challenges for measurement.
	1. Draft statement 3

### Pregnant women with heart disease have intrapartum risk regularly assessed.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

* There was support for this statement; stakeholders highlighted the importance of individualised risk stratification.
* It was suggested that the statement should focus on an individualised plan for assessment of risk, which contains a record of the nature and timing of the next assessment.
* It was suggested that the statement should focus on arrangements being made for a clinician with expertise in the specific heart condition during pregnancy to support planning, including planning the nature and timing of the next contact.
* MDTs need experience in both congenital heart disease and cardiac maternity.
* Clarify ‘regular intrapartum risk assessment’: is it regular antenatal assessment of intrapartum risk, or, regular intrapartum risk assessment during labour.
* The importance of both a quorate MDT and MDT meetings was highlighted.
* There was a suggestion to expand the list of roles.
* Documenting MDT activities is important for data collection.

### Consultation question 5

Stakeholders made the following comments in relation to consultation question 5:

* The timing of key contacts would be determined by the type and severity of condition, the individual and their level of risk and referrals for tests and their outcomes.
* The frequency and repetition of assessments are more important than their regularity.
* Specific timeframes were suggested:
	+ by the third trimester
	+ at 34-46 weeks
* 3 times at 12-14 weeks, 24-26 weeks and 32-34 weeks.
	1. Draft statement 4

### Women who have had a previous caesarean section and are in labour know about the potential benefits and risks of different modes of birth.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

* There was limited support for this statement.
* The statement does not clearly acknowledge that risks and benefits of different modes of birth are first discussed during antenatal care, rather than during labour.
* Whether the population includes women who have already chosen to give birth vaginally needs to be clarified as a specific point.
* Reiterating the risks and benefits at this time would put undue pressure on the woman.
* Planning for birth should be done antenatally.
* Instrumental vaginal birth should be mentioned.
* Highlighting the importance of a discussion of the risk and benefits of different modes of birth during labour could undermine prior decisions.
* Measures should focus establishing to what extent women felt supported when clinical factors and preferences changed during labour.
* Measures should focus on establishing to what extent women felt supported in their birth choices.
	1. Draft statement 5

### Women in labour with sepsis or suspected sepsis have observations carried out by a multidisciplinary team at a frequency based on the level of clinical concern.

### Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

* There was general support for the statement.
* It was felt that the statement’s wording does not convey a sense of urgency; a timely and high level of clinical concern helps to reduce the risk of poor outcomes.
* It was suggested that the multidisciplinary team (MDT)’s role is to review and plan ongoing care.
* Whether all the MDT members need to be involved, and to what extent, levels of experience, grades and whether in clinical practice was queried.
* Clarify population it applies to.
* Could the intensivist and senior midwife roles be carried out by professionals in equivalent roles.
1. Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

* Separate statements on the care of pregnant women with mental health conditions, multimorbidities and complex social factors.
* Care for pregnant women with epilepsy.
* Smoking during pregnancy as a risk factor for obstetric complications.
* How data on smoking at the time of delivery (SATOD) should be collected as part of intrapartum care.

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# Appendix 1: Quality standard consultation comments table – registered stakeholders

| **ID** | **Stakeholder** | **Statement number** | **Comments[[1]](#footnote-1)** |
| --- | --- | --- | --- |
| **General**  |
| 1 | Action on Smoking on Health | S1 – General comment  | The guidelines do not acknowledge the increased risk of obstetric complications presented by women who smoke during pregnancy. Smoking during pregnancy significantly increases the risk of a range of adverse birth outcomes including stillbirth, miscarriage, preterm birth, low birth weight, and heart and other birth defects. [1] NICE should provide clear guidance on how and when Smoking at Time of Delivery (SATOD) data should be collected. Implementing this guidance would not require significant resources because the systems to collect and record SATOD are already in place. At present, collection of SATOD is left up to maternity units on CCG footprints and there is no national guidance on precisely how the data should be collected. The NHS guidance on collecting SATOD states that “the exact mechanism for collecting and sharing SATOD data is up to local decision makers to agree” and that “processes at ward level support staff to routinely assess SATOD, and support efficient and accurate data recording” [2]. The document does not specify what these processes should be or what quality assurance measures should be adopted. This gap means that that maternity practitioners are not sufficiently informed about how they should be recording smoking status during the intrapartum stage, resulting in variations in practice and consequent variations in the quality and consistency of national data collection. For example, an evaluation of the Saving Babies Lives’ Care Bundle identified the inadequate collection of data as a major barrier to effective monitoring of birth outcomes and service delivery [3]. SATOD is clinical data which is used to inform clinical practice and resource allocation, and assess the effectiveness of local and national strategies to reduce smoking in pregnancy. As such it is imperative that SATOD data is consistent and reliable. In some areas, there is evidence that maternity practitioners are taking the smoking status from a previous booking appointment and recording it as the smoking status at delivery. Not only does this undermine the reliability of SATOD data, it could also result in women who are wrongly classified as a smoker being treated inappropriately, adding a drain on staff capacity and resources.NICE should develop clear guidance on how SATOD data should be collected and at what point during the intrapartum period. [4] Doing so would ensure that maternity professionals receive the support and guidance they need to routinely assess SATOD, and improve the quality of SATOD data.**References** [1] Smoking in Pregnancy Challenge Group. [Review of the Challenge](http://ash.org.uk/download/2018-challenge-group-report-final/). 2018. [2] NHS Digital. Guidance: [Smoking status at time of delivery](https://digital.nhs.uk/binaries/content/assets/legacy/pdf/k/0/satod-guidance---updated.docx). Feb 2019. [3] Widdows K, Roberts SA, Camacho EM, Heazell AEP. Evaluation of the implementation of the Saving Babies’ Lives Care Bundle in early adopter NHS Trusts in England. Maternal and Fetal Health Research Centre, University of Manchester, Manchester, UK. 2018[4] Smoking in Pregnancy Challenge Group. [Smoking cessation in pregnancy: a call to action](http://ash.org.uk/download/smoking-cessation-in-pregnancy/). 2013. |
| 2 | British Maternal & Fetal Medicine Society | General comment  | The ability to measure all of these standards will be very challenging in practice. For example, does MDT IP planning include one MDT meeting, a single MDT review, a letter…? |
| 3 | Caesarean Birth | General comment  | Would NICE consider including a line explaining that in reality, the nature of intrapartum care can sometimes mean the women doesn’t feel she has a “choice”. In some circumstances, the new information being communicated during labour (e.g. risk of complications for the baby) could mean that there is disagreement between her own choice and that of the lead healthcare professional. Preparing women for managing this situation, if or when it arises, would be very useful in advance of the intrapartum period. |
| 4 | Caesarean Birth | General comment  | Thank you for this opportunity to comment.  |
| 5 | Caesarean Birth | General comment  | Another concern my organisation would like to share here is the absence of any mention of instrumental or assisted vaginal birth (namely, forceps and/or ventouse). The guideline only compares emergency caesarean with “vaginal birth” but the latter is not always a spontaneous delivery. See “Definitions: on page 20: “Mode of birth… Vaginal birth or an emergency (unplanned) caesarean section”. Statement 1….**[NICE analyst comment: see comment 45]**Statement 4 ... **[NICE analyst comment: see comment 96]**On page 27, “Improving Outcomes” includes maternal morbidity, maternal mental health, health-related quality of life, satisfaction with results of care, shared decision-making and confidence in care providers, birth experience and patient safety incidents relating to intrapartum care. Again, and especially given concerns expressed by numerous other maternity care organisations that represent the views and experiences of women injured during birth (including The MASIC Foundation, Birth Trauma Association, Mothers With 4th Degree Tears, for example), it is imperative that instrumental birth, and its increased risk for pelvic floor damage, is included in any intrapartum guideline or quality standard published by NICE. Without this, NICE is not communicating the “informed birth choices” it sets out to provide here. |
| 6 | Maternal Mental Health Alliance with endorsement from the Royal College of Obstetricians and Gynaecologists | General comment  | Additional comments regarding mental health considerations: The MMHA, with endorsement from the RCOG, also expressed the following regarding the consideration of maternal mental health during intrapartum care:• The scope of the guideline seems to exclude the concept that “medical condition” could include a mental illness, but it does not explicitly state this. • For this guideline and quality standard there is no concept that physical and mental health should be equitably considered, nor that medical conditions can impact on mental health and vice versa. There is no concept that many women have co-morbidity of multiple physical and mental illness. It is perfectly possible to have obesity, asthma, hypertension and depression and this guideline and these quality standards do not recognise that. This is despite all the recent MBRRACE maternal mortality reports highlighting this. In 2018 the report recommends***“There is a need for practical national guidance for the management of women with multiple morbidities and social factors prior to pregnancy, and during and after pregnancy.”***• There is no concept that trauma relating to delivery as a result of a medical condition could lead to subsequent PTSD• This lack had been raised prior to the development of the QS by the Birth Trauma Association and the RCM in the [briefing paper](https://www.nice.org.uk/guidance/indevelopment/gid-qs10081/consultation/html-content-2) for the QS, but does not seem to have been considered. • This failure to address the needs of women with multiple problems (both mental and physical) is concerning and the steering group committee does not appear to contain members with a more holistic view. Was the constitution considered adequate?• When any clinician is liaising with a woman during the intrapartum care window there must be some focus on perinatal mental health – at a minimum• The possible diagnosis of tokophobia (which should be captured in mum’s notes) the risk of postnatal PTSD and the general presence of a possible perinatal mental health problem could all impact the mother as she is coping with existing medical conditions / obstetric complications therefore the team mentioned in the guideline need to see the mum holistically not just a patient presenting with a physical need• All of the above is underpinned by the following: *Women, at each and every point of contact with a health or social care professional throughout pregnancy and postnatally are asked specifically about their emotional wellbeing, and referrals should be made to the right care and treatment at the right time Women and their families/partners should be encouraged to tell their healthcare professional about any changes in mood, emotional state and behaviour that are outside of the woman’s normal pattern.* [(SIGN 127, 2.1)](https://www.sign.ac.uk/assets/sign127_update.pdf) ([CG37, 1.2.22](https://www.nice.org.uk/guidance/cg37/chapter/1-Recommendations#maternal-health)) [Quality standard QS115, statement 4](https://www.nice.org.uk/guidance/qs115/chapter/Quality-statement-4-Asking-about-mental-health-and-wellbeing)) |
| 7 | NHS Digital - Digital Maternity Programme | General comment | Statement to consider: Use of electronic record keeping with high data quality is highly endorsed. The maternity record standard ISN will mandate the adoption of a common approach to capturing a pregnant women’s information. Future interoperability solutions will enable sharing of data between care settings to support a multidisciplinary approach and support conversations around any pre-existing medical conditions. |
| 8 | NHS Digital - Digital Maternity Programme | General comment  | Statement to consider: Use of Women’s Digital Care Records (Pregnancy PHRs) throughout the maternity pathway is highly endorsed. Providing Women with digital access to their maternity care records will increase their information provision and empower them in being a decision-maker in their care. Additional benefits from accessing records via devices such as smart phones are emergent; additional features could aid care planning, enhance relationships with clinicians, support specific maternity advice and enhance information facilitating choice. |
| 9 | NHS England/Improvement – Primary Care Team | General comment | There is little that would impact GPs in this standard although it would be beneficial to GPs to have clarity on when women are included in the pathways and to have clarity on contact mechanisms if women present to primary care either with obstetric issues or with issues related to their medical condition. |
| 10 | NHS England/Improvement – Primary Care Team | General comment | It is vital that clarity is given about the role and contact details of the lead clinician to both women and all clinicians involved in their care and communication between primary secondary and tertiary care is timely and clear – without this significant risk could arise to mother and baby |
| 11 | NHS England/Improvement – Primary Care Team | General comment | It would also be helpful to give clarity on what is meant by existing medical conditions eg is hypothyroidism included – clearly specialist advice during pregnancy is needed but not intrapartum- this is about wording and ensuring that patients know what to expect as I would expect clinicians to be able to recognise the different conditions that would and would not need this guidance |
| 12 | Royal College of Nursing  | General comment  | The statements in the draft quality standard seem appropriate. |
| 13 | Royal College of Paediatrics and Child Health | General comment  | The reviewer is happy with this draft quality standard. |
| 14 | Sands, Stillbirth and neonatal death society (Sands) | General  | No comments submitted at this time  |
| **Question 1**  |
| 15 | Caesarean Birth | Q1/General comment  | Qu.1: Does this draft quality standard accurately reflect the key areas for quality improvement?In the context of caesarean birth, my concern with this Quality Standard is that it focuses on intrapartum care, but also refers to information provided during antenatal care. Is the assumption that during antenatal care\*, women will be informed about the risks and benefits of a planned vaginal birth versus a planned caesarean birth (in addition to discussing possible choices once in labour – between continuing with a vaginal birth and having an emergency caesarean)? In other words, if medical and/or obstetrical complications have been identified during pregnancy, both planned birth modes have been discussed, the woman has chosen vaginal birth, and this guideline is specifically for her? Can NICE please clarify? Thank you \*for those women who have received antenatal care |
| 16 | [British Maternal & Fetal Medicine Society](http://niceplan1/guidelines/Stakeholders.aspx?GID=1234&PreStageID=5926) | Q1 | **Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement?Quality improvement depends on women having access to the right specialists during pregnancy to plan intrapartum care but also adequate and robust systems need to be in place for those women who have not had the opportunity to plan their intrapartum care (either because the condition developed or was identified during pregnancy or because the woman has not accessed care during pregnancy). A large proportion of maternal morbidity/mortality occurs in women where intrapartum planning was not possible/feasible – this will not be improved by the quality standard. |
| 17 | Epilepsy Action | Q1 | **Question 1** Does this draft quality standard accurately reflect the key areas for quality improvement?*Given the risk of maternal mortality in women with epilepsy (*[*https://n.neurology.org/content/91/18/e1716*](https://n.neurology.org/content/91/18/e1716)*), and the risks associated with taking a number of antiepileptic drugs (AEDs) during pregnancy (*[*https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3882069/*](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3882069/)*), epilepsy should be given more prominence in the draft quality standard. Statement 3 in the draft calls for women with heart disease to have their intrapartum risk regularly assessed, however, this should also be extended to epilepsy, and other conditions, where there is also a significant risk and should also be regularly assessed.*  |
| 18 | Resuscitation Council UK | Q1 | Our response to this is a cautious ‘yes’ but with the strong caveat that, whilst we have had expert obstetric anaesthesia input, we do not have any specific obstetric expertise on which to base this response. |
| 19 | Royal College of Nursing  | Q1 | Question 1 - *Does this draft quality standard accurately reflect the key areas for quality improvement?*The draft quality standard seems to demonstrate the key areas that are needed for quality improvement. |
| 20 | Royal College of Obstetricians & Maternal Mental Health Alliance coordinated response | Q1 | Yes, but doesn’t help if a woman has multiple problems. The possibility of 2 problems is considered and two experts. Does she have to have a plan for each condition? There needs to be a clinical lead, but who should it be? Concerned about this not making holistic sense. This is a very significant QS missing from the key area for QI, and the guideline must address this as well. Addressing the specific issue of multiple problems (including mental health problems) would be a suitable QS and could be added |
| **Question 2**  |
| 21 | British Maternal & Fetal Medicine Society | Q2  | **Question 2** Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?The data required to audit all of these quality standards (except perhaps number 5) is not in place in most obstetric units and would be extremely difficult to implement. It is not clear what the denominator would be for standards 1,2 and 4? It is also not clear how a unit would quantify “regular” intrapartum reviews or prove that a woman had received counselling regarding outcomes after caesarean when she presented in labour. |
| 22 | Epilepsy Action | Q2 | **Question 2** Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?*NHS Digital has measures in place to collect data, but it is not clear how robust these systems are and how much local data is missing. The Maternity Services Data Set (MSDS), currently captures key information at each stage of the maternity care pathway including mother’s demographics, booking appointments, admissions and re-admissions, screening tests, labour and delivery. This data set could be expanded to include the quality measures in the draft guidance. However, currently there are large differences in how data is provided by local services. These local systems should be standardised to ensure that all data is provided in the same format.**Previously, pre-conception counselling for women with epilepsy was a Quality Outcome Framework (QOF) indicator. However, the QOF was retired in 2014. While the QOF indicator was in place, a 2013 survey highlighted that around a third of women with epilepsy had not received information about pregnancy and possible risks. Following the retirement of the QOF, this figure rose to almost half of women. This suggests that this sort of intervention does have a positive impact.**While there is now a Quality Improvement Activity (QIA) to review and improve the prescribing of valproate, with the retirement of the Quality Outcomes Framework (QOF) indicator for pre-conception counselling, there is currently no formal incentive for clinicians to discuss these issues with patients with epilepsy on other AEDs. We would therefore recommend that discussions with patients that fit the relevant criteria are incentivised:**• Incentivise pre-conception counselling through the development of an enhanced service specification. The specification would require all eligible patients to be proactively recalled for a discussion and epilepsy medicine review with their GP.* |
| 23 | Resuscitation Council UK | Q2 | As we do not have any specific obstetric expertise, we cannot offer a fully informed comment on this. |
| 24 | Royal College of Nursing  | Q2 | Question 2 - *Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?*The majority of services have systems in place locally to implement the quality standard and to collect data for the proposed quality measure and often audit to monitor see progress etc. |
| 25 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | Q2 (Statements 1 & 2) | Difficult to collect data – very subjective what ‘include’ means. Does a phone call to a specialist count as ‘included’? Need for inclusion of specialist will depend on severity of the condition **(NICE analyst comment: comment 61)** |
| **Question 3**  |
| 26 | Birth Trauma Association | Q3 | With regard to question 3, it is important to encourage robust economic appraisal of maternity outcomes. ‘Net resources’ will obviously be a problem where there are insufficient trained staff. However, where there are possibilities to recruit more staff or allocate them more effectively, then short term costs to departments or trusts must not be allowed to dominate costs to the tax payer, or the health of women or their families. Poor outcomes – particularly serious ones – will always cost more than good outcomes. It is the latter that should be the focus and current H/E appraisals are failing to adequately capture longer term outcomes**.** |
| 27 | British Maternal & Fetal Medicine Society | Q3 | **Question 3** Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.For women with known medical conditions who are engaged with care, the majority of units will be compliant with the standards as set – although it will be difficult to measure this. As stated above this does not improve outcomes for women who present with a medical condition outwith the maternity unit or present without prior intrapartum planning. |
| 28 | Epilepsy Action | Q3 | **Question 3** Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.*Given the resources that will likely be needed to achieve these statements, we do not think that local services have the necessary resources, particularly in relation to epilepsy and other neurological conditions. There is currently a shortage of neurologists, and epilepsy specialist nurses, and the commitment to develop personalised intrapartum care plans with multidisciplinary in statements 1 and 2 will place further pressure on already stretched services.* *Neurologists are only commissioned in 83% of CCGs. For every neurologist in the UK France has five, and Italy has eight. In the UK, there are over 600,000 people with epilepsy, and Epilepsy Action is only aware of 448 ESNs. This is for adults, children and people with learning disabilities. In comparison, there are currently 245 multiple sclerosis (MS) nurses in the UK for a population of 100,000 people with MS.**In addition, research we commissioned showed a large regional disparity for epilepsy services between areas of the UK. The likelihood of a patient with a neurological condition being seen by a neurologist continues to vary dramatically depending on where they are admitted with a handful of hospitals having no acute neurology service at all and others having access to a neurologist on three days or fewer a week.**The neurology workforce is currently under-supported, and in order to meet the draft quality standard, this needs to be addressed.* |
| 29 | Resuscitation Council UK | Q3 | As we do not have any specific obstetric expertise, we cannot a fully informed comment on this. |
| 30 | Royal College of Nursing  | Q3  | Question 3 - *Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.*Yes this is achievable provided that clinicians can be resourced (back fill of staff would need to be provided as this can be an issue in clinical practice) |
| **Question 6 (examples of local practice)** |
| 31 | Resuscitation Council UK | Q6  | Sorry – no examples to offer. |
| 32 | Royal College of Nursing  | Q6 | Question 6 *- Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please provide details on the comments form.*None specifically. Our reviewers, have however, commented in general that some of the quality standard statements are already anecdotally happening in some trusts and is also reflected in some individual trust guidance.The categories of medical conditions are all captured. The members of the multidisciplinary team are all 'flagged up'.Our reviewers commented that they are aware that patient safety is taken into account as is the importance of the patient’s (woman and family) experience. It is helpful to see the sepsis chart in the draft quality standard. |
| **Statement 1** |
| 33 | Birthrights | S1 | Rationale – we welcome the reference to the importance of personalised, holistic care, and suggest that the rationale should include a reference to the need for personalised care to be shaped to ensure women’s needs and preferences are met, and the need for additional time in consultations (particularly at the beginning of care) to “listen to [the woman] and discuss and document her specific needs, abilities, expectations and preferences” (Hall et al 2018). This section also needs to make clear that the woman is the decision maker about her care, as per comment 2 **[NICE analyst comment – comment 55]** |
| 34 | Birthrights | S1  | Structure – this quality statement should include reference to providing the woman with continuity of carer within the multidisciplinary team. The Birthrights research Hall et al 2018 identified the particular importance of continuity for women with medical conditions “to ensure that appropriate accommodations and supports are in place”. |
| 35 | Birthrights  | S1 | Process – the dominator for the measure needs to include the number of women who were not offered individualised intrapartum care planning with a multidisciplinary team, as well as those women whose team did not include an expert in managing their condition(s) during pregnancy. Depending on the scope of this quality statement (see comment 8) **[NICE analyst comment: comment 37]**, there may be significant numbers of women who are not offered – or decline – multidisciplinary team care. For example, NICE guideline NG121 covers women with obesity, women with asthma etc and it is likely that a number of women in these situations are not offered specialist care team support. |
| 36 | Birthrights  | S1 | ‘Women with a medical condition’ - the statement “The team works with the woman to plan holistic care tailored to support the best possible outcomes for mother and baby” needs to be amended to read “The team works with the woman to plan holistic care that meets the woman’s needs, choices and preferences in order to support the best possible outcomes for the woman and her baby”. |
| 37 | Birthrights  | S1 | Query – is this quality statement intended to cover all conditions covered by NICE guideline NG121 as those set out under ‘definitions’ are only a subset. It is not clear why those conditions have been chosen compared to the conditions under NG121. |
| 38 | Birthrights | S1 | Multidisciplinary team – the named healthcare professional leading the team should provide continuity of care for the woman, alongside any additional midwifery continuity of carer. |
| 39 | Birthrights  | S1 | Equality and diversity - We welcome the specification of the need for accessible information and interpretation where required (a major finding of Hall et al 2018). Women should also be provided with access to support where this would be beneficial – that is, for women who would be better able to understand choices, advice and recommendations and to express themselves through interpretation (Birthrights and Birth Companions (2019). Holding it all together: Understanding how far the human rights of woman facing disadvantage are respected during pregnancy, birth and postnatal care. London [online]. (Available at: https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf )). Women’s choices and options should not be |
| 40 | Birth Trauma Association | S1  | This will be a marked step forward and highly welcome. We will leave health care professionals to judge resource and delivery issues but as a user group, we are currently seeing women, whose care would have been much better and outcomes safer, if there had been multi-disciplinary involvement throughout pregnancy and birth (in particular diabetes, colorectal, cardiac problems and bleeding disorders). Glad to see the careful consideration given to equality and diversity issues given the risk factors of this group.*One significant regret for us is the omission of mental health, which in some years has been the leading cause of death (indirect). Perhaps this could be noted as a comment for future updates.* |
| 41 | Birth Trauma Association | S1 | There needs to be a bit more emphasis on ensuring the messages women get from this melee of health care professionals are consistent rather than conflicting. That needs to be part of the quality standard. |
| 42 | Birth Trauma Association  | S1 – General and Q4 | Simple, clear messages are always more effective so a single statement would be better. However, the key point is the involvement of a clinician with expertise in the medical condition. Simplicity must not result in the loss of this central message. |
| 43 | British Dietetic Association | S1 | For pregnant women with acute or chronic kidney disease, access to a renal specialist dietitian throughout intrapartum care is essential. Most patients with kidney disease will have some form of dietary restriction (low salt, low potassium etc.), so professional guidance regarding restrictions, whilst providing a healthy diet to support fetal development are vital. This needs to be specified in these guidelines. |
| 44 | [British Maternal & Fetal Medicine Society](http://niceplan1/guidelines/Stakeholders.aspx?GID=1234&PreStageID=5926)  | S1  | **Structure**Evidence that multidisciplinary teams planning individualised intrapartum care for women with an existing medical condition include a member with expertise in managing the medical condition in pregnancy. The term “expertise” is ambiguous. This is also referred to in the definitions section of this QS. The list of conditions is arbitrary – whilst I accept not all conditions can be listed some of the examples represent very rare conditions such as AV malformations – how many physicians in the country could describe themselves as “experts” in the management of these women in labour? How many women with a certain condition does one need to manage to be qualified as an expert? This is surely an impossible term to define and I’m not sure such a subjective term is useful in a QS as a metric to measure quality? Surely we should be ensuring MDT discussion to formulate an IP plan which describes the concerns and potential red flag signs which could herald a problem and alert to the need for specialist input during labour? |
| 45 | Caesarean Birth | S1  | Statement 1On page 6, it reads: “Outcomes… Incidence of maternal morbidity associated with an existing medical condition.”Will these outcomes include 3rd and 4th degree tears, birth trauma and/or satisfaction? |
| 46 | Epilepsy Action  | S1  | (Multidisciplinary Team)We believe that specialist nurses, such as epilepsy specialist nurses, should also be included in the multidisciplinary team, given their expertise, and involvement with the care of patients. This is the same for the definitions for each statement. |
| 47 | Epilepsy Action | S1  | (definitions of terms used in this quality statement) We are concerned that epilepsy has not been included in the list of medical conditions associated with a higher risk of adverse outcomes. This is especially concerning given the increased risks associated with pregnancy in women with epilepsy, particularly those with severe epilepsy. It is estimated that 1 in 1000 women died from epilepsy during for shortly after pregnancy. We would therefore suggest that epilepsy should be included in this list of conditions. This is the same for the definitions for each statement. |
| 48 | NHS England/Improvement –Chief Allied Health Professionals Officer | S1  | A key challenge for this standard is how involvement of the members of the Multi disciplinary team would be resourced for this potential additional activity when many AHP services that this would include are not covered by PBR arrangements. |
| 49 | Royal College of Midwives  | S1  | This statement doesn’t include any reference to continuity of midwifery care, despite the need of women to be cared by a disciplinary team and expert in medical condition in pregnancy the named midwife should still coordinate the care and provide most of it. |
| 50 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S1  | The guideline only covers a specific list of medical conditions where additional input into intrapartum care is required, but the quality standards are worded as if they apply to women with ANY existing medical condition. For example, the way it is worded at the moment, a woman with mild eczema could be defined as having an existing medical condition but may not require the individualised intrapartum care plan. The QS should be more specific. |
| 51 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S1 | A perinatal psychiatrist may also be included as part of the multidisciplinary team  |
| 52 | Royal College of Pediatrics and Child Health | S1 | It is not enough to develop a plan as the plan must be followed and there must be assurance that that has been done. |
| 53 | Royal College of Paediatrics and Child Health | S1  | The reviewer is happy with the document and provided a personal experience stating that they recently had a mother who had cytomegaolvirus infection in pregnancy and she was managed by a multidisciplinary team before she gave birth to a severely disabled child. Regarding page 7 of the document 'The team works with the woman to plan holistic care tailored to support the best possible outcomes for mother and baby.', this was put in place which gave this mother a huge amount of support before and after delivery and it was felt that it had been extremely helpful for her acceptance of her situation because the baby also had a severe hearing loss. |
| **Statement 2** |
| 54 | Action on Smoking and Health | S2 - General comment  | Smokers carry a higher risk of surgical complications, to the extent that it is not always safe for surgery to take place when a patient continues to smoke. [1] This is of critical importance given the high proportion of UK births which occur via caesarean section (26.2% in 2015). [2] This is particularly relevant for women with existing medical conditions who are more likely to have a planned caesarean section.Smokers are 38% more likely to die after surgery than non-smokers. Following surgery smokers have impaired wound healing, higher risks of lung and heart complications and higher risks of post-operative infection. [1] The risks are significant enough that some surgeons will not carry out procedures until a patient is able to abstain from smoking, an option which is not available in the case of emergency caesarean sections which account for around 16% of all deliveries. [3] NICE must develop guidance which clearly sets out how maternity practitioners should identify women who are smokers at the point of delivery to ensure that medical staff are aware of their elevated risk of surgical complications and are able to take necessary precautions.References[1] Action on Smoking and Health. [Joint briefing: Smoking and surgery](https://www.rcoa.ac.uk/sites/default/files/Joint-briefing-Smoking-Surgery.pdf). 2016. [2] Wise, J. [Alarming global rise in caesarean births, figures show](https://www.bmj.com/content/363/bmj.k4319). 2018. [3] NHS Digital. Maternity Services [Monthly Statistics May 2019, experimental statistics](https://digital.nhs.uk/data-and-information/publications/statistical/maternity-services-monthly-statistics/may-2019). 2019 |
| 55 | Birthrights | S2 – General comment  | This is an inappropriate statement in law as it implies that the multidisciplinary team are the primary decision makers about a woman’s care. We have significant concerns over the use of the description of a woman being “involved in reviewing” her care plan as we do not believe this reflects either the legal position following the judgements in Montgomery v Lanarkshire and related case law, or the professional regulatory position on patient consent taken by the General Medical Council. We contend that ”Supporting Patient decision making” as described in the latest draft GMC guidance on decision-making and consent (see link below) or another similar term is preferable to “shared decision making” to clearly indicate that ultimately decision making is not “shared”. We recognise the importance of ensuring the full range of medical insight in supporting a woman to make the right decisions for her, particularly in the context of existing medical conditions: medical professionals have an essential part to play in providing relevant information, and in fully discussing all reasonable options, and being able to give the benefit of their experience and expertise. However, our view remains that in law there is only one decision maker and that is the patient. We have not commented further on the detail of quality statement 2 because it is inappropriate and we believe incorrect in law and thus all references to the woman having a role ‘reviewing’ her care plan are inappropriate for professional guidance or quality standards. However, we have commented in detail on quality standard 1. |
| 56 | Birthrights  | S2  | The phrase “the multidisciplinary team should regard the woman as a member of the team” could be strengthened to say “the multidisciplinary team should regard the woman as *an essential* member of the team” and could also be included within QS1 so long as it remains clear that the woman is the decision maker about her care, so the team revolves around her. |
| 57 | Birthrights | S2  | In view of our comments above **[NICE analyst comment: see comment 55]**, it is highly concerning that the proposed data collection measure is a measure of the proportion of care plan reviews involving the woman concerned. Whilst it might be appropriate for the clinical team to discuss options and recommendations, the care plan cannot in our view be agreed or updated without the woman as decision maker and therefore the data collection measure is not appropriate.  |
| 58 | Epilepsy Action  | S2  | (measures)It is unclear how it will be ensured that women are involved in their care plan. We would welcome further clarity on how it will be ensured that women will have meaningful involvement. |
| 59 | Epilepsy Action | S2  | (outcome) We are concerned that the outcome measure suggests that women with an existing condition should simply “feel” that they were involved, rather than having meaningful involvement in preparing and reviewing their intrapartum care. This statement should be strengthened, as the way it is currently worded will do little to encourage teams to ensure women have meaningful involvement. |
| 60 | NHS England/Improvement –Chief Allied Health Professionals Officer | S2  | This statement may be hard to measure due to the recording systems used by the multidisciplinary team which can have issues with interoperability and limit reporting.  |
| 61 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S2  | Quality statement 2 about involvement of the woman in her care plan. How 'involvement' is defined is not clear. Involvement could be a confirmation of the plan at an ANC, a discussion about advance directives, to a letter being sent to her asking her to get in touch if she disagrees. This lack of clarity could falsely allow more cases to be considered as involvement and a falsely high quality standard achieved. It does say that the number of women who felt involved - but when is this question asked /when is it measured? |
| 62 | Royal College of Paediatrics and Child Health |  S2  | Women with an existing medical condition should be involved in writing (not just reviewing) their intrapartum care plan with the multidisciplinary team. |
| **Statements 1 and 2 – question for consultation 4** |
| 63 | Birthrights | S1 and S2 – Q4 | Quality statement 1 is an appropriate standard for services (subject to our comments below) **[NICE analyst comment: this was the first comment listed on the form]** to ensure that they are providing women with the multidisciplinary support to make decisions that are right for them about their care. QS1 specifies that the multidisciplinary team needs to include experts in managing the medical conditions during pregnancy – this is a need identified in Birthrights’ research on the experiences of disabled women during pregnancy: Hall, J Collins B, Ireland J, and Hundley V. (2018) The Human Rights & Dignity Experience of Disabled Women during Pregnancy, Childbirth and Early Parenting. Centre for Midwifery Maternal and Perinatal Health, Bournemouth University: Bournemouth. (Available at: <https://birthrights.org.uk/wp-content/uploads/2019/05/Disability-research-publication-version-March-2018-Updated-save-Mar19.pdf>). Any revised QS must make it clear that the woman is the decision-maker about her care and that the team provides advice and support to enable her to make her decisions. Although this is not our specific expertise, we were surprised to see no reference made to the proposals for Maternal Medicine Networks outlined in NHSE’s long-term plan. The service specification for Networked Maternal Medicine Services outlined three models of care including the Maternal Medicine Centre (MMC) offering advice about delivery before referring the woman back to the local unit, shared care with the unit or taking over the woman’s care – presumably all of these options would meet the standard but this is not clear. Our understanding is that there are very few obstetricians specialising in maternal medicine/obstetric physicians at present which will presumably make this quality standard difficult to achieve at first, although others are best placed to comment on this. We note that the quality standard does not provide any guidance on what the “next best” option is where a clinician with expertise in managing the condition during pregnancy is not available. We have a number of women who have contacted our advice line distressed at a contradiction between what the specialist in their condition has advised them about giving birth, and what their obstetrician has told them. We would like to understand how “expertise” in managing a condition during pregnancy will be assessed, and recognition of teams who attempt to involve other relevant specialties (even if their experience of managing pregnancy is limited) over teams who do not involve other specialities, to ensure a woman has the best available information to make informed choices about her care. |
| 64 | British Maternal & Fetal Medicine Society  | S1 & S2 – Q 4 | In our opinion, the statements could be combined but the comment above regarding the definition of expert still exists. **[NICE analyst comment: comment 44]**. |
| 65 | British Maternal & Fetal Medicine Society  | S1 & S2 – Q4 | **Question 4 For draft quality statement 1 and 2:** Could these statements be combined into a single statement which focuses on women developing and reviewing their individualised care plan with the multidisciplinary team? If so, would it be clear from the definitions section that the multidisciplinary team should include a clinician with expertise in the medical condition during pregnancy?Yes |
| 66 | Caesarean Birth  | S1 & S2 – Q4 | For draft quality statement 1 and 2: Could these statements be combined into a single statement which focuses on women developing and reviewing their individualised care plan with the multidisciplinary team? Yes, they could be combined. |
| 67 | Epilepsy Action  | S1 & S2 - Q4 | *For draft quality statement 1 and 2: Could these statements be combined into a single statement which focuses on women developing and reviewing their individualised care plan with the multidisciplinary team? If so, would it be clear from the definitions section that the multidisciplinary team should include a clinician with expertise in the medical condition during pregnancy?**While the statements these statements could be combined, we believe that they should be kept separate, as this would highlight the importance of involving women with an existing medical condition in their intrapartum care plan. Merging the two statements risks undermining the commitment to involve women in their intrapartum care plan. Keeping the two statements separate highlights the importance of both involving the woman in her care, and having a multidisciplinary team including a member with expertise in the medical condition. We would therefore advise keeping the statements as they are.* |
| 68 | Resuscitation Council UK | S1 & 2 – Q4 | Whilst they could be combined, to do so would detract from the specific focus in statement 2 on person-centred care and shared decision-making, and from the specific focus in statement 1 on ensuring that there is involvement of an MDT that includes an expert in the patient’s specific medical or obstetric condition. For example, for a woman with a heart condition, that should be a cardiologist with expertise in managing the woman’s specific heart condition during pregnancy. We suggest that the wording be amended to make this intended meaning clearer, maybe by just stating ‘…managing **each woman’s specific** medical condition during pregnancy’. If statements 1 and 2 were combined, measurement would become more difficult. The person may be supported by an MDT with the correct expertise but not involved adequately themselves or may be involved themselves but not have the correct type or level of expertise within the MDT, so we suggest keeping these statements separate to facilitate measurement of each quality standard. |
| 69 | Royal College of Midwives  | S1 – Q4 | Could these statements be combined into a single statement which focuses on women developing and reviewing their individualised care plan with the multidisciplinary team? YES If so, would it be clear from the definitions section that the multidisciplinary team should include a clinician with expertise in the medical condition during pregnancy? YES |
| 70 | Royal College of Midwives  | S2 – Q4 | Could these statements be combined into a single statement which focuses on women developing and reviewing their individualised care plan with the multidisciplinary team? YES If so, would it be clear from the definitions section that the multidisciplinary team should include a clinician with expertise in the medical condition during pregnancy? YES |
| 71 | Royal College of Nursing  | S1 & S2 – Q4 | Question 4 - *For draft quality statement 1 and 2: Could these statements be combined into a single statement which focuses on women developing and reviewing their individualised care plan with the multidisciplinary team? If so, would it be clear from the definitions section that the multidisciplinary team should include a clinician with expertise in the medical condition during pregnancy?*We would agree with this proposal. |
| 72 | Royal College of Paediatrics and Child Health | S1 & S2 – Q4 | These could be combined, which would include the woman in the multidisciplinary team and cover the comment above. **[NICE analyst comment: comment 62]**  |
| 73 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S1 & S2 – Q4 | Yes, could be combined (question 4 below) **[NICE analyst comment: comment 74]** |
| 74 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S1 & S2 – Q4 | Needs to have more clarity to put women at the centre of their care as is written rather paternalistically. They could be combined and this should happen, because the plan needs to evolve with time and be kept up to date. |
| **Statement 3** |
| 75 | Birth Trauma Association | S3  | Good to see the focus on heart disease. |
| 76 | Birth Trauma Association  | S3  | OutcomesMortality is not a good sole indicator for this outcome. It is too rare and there is the danger that high risk cases end up in the best units and these units seem ‘worse’ whereas in reality they just have a more complex case mix. Looking at individual case reviews where there are adverse outcomes would be more valuable measure. |
| 77 | British Maternal & Fetal Medicine Society | S3  | Quality measures The phraseology is potentially misleading. Does the phrase “regular intrapartum risk assessment” actually mean regular antenatal assessments of the intrapartum risks? Or does the phrase mean regular intrapartum risk assessment, if so how frequently would a cardiologist be expected to provide this assessment in labour? It is not usual for a cardiologist to review a woman in labour unless there is a significant change in the clinical condition. |
| 78 | NHS England - Congenital Heart Disease Clinical Reference Group | S3  | NHSE Congenital Heart Disease Clinical Reference Group Response to: NICE Quality Standards Briefing paper: *‘’Intrapartum Care: Women with Existing medical conditions or obstetric complications and their babies’’, Section 4.2 Heart Disease.*The 2018 MBRRACE-UK: found that 50% maternal death was due to indirect causes, the leading cause of which was heart disease. A significant proportion of cardiac maternity cases are due to congenital heart disease.See NHSE CHD Service standards and specifications May 2016<https://www.england.nhs.uk/wp-content/uploads/2018/08/Congenital-heart-disease-standards-and-specifications.pdf>:Sections J (L1 and L2) detail the standards pertinent to Pregnancy in CHD, including Intrapartum care.Key to the optimum management and outcome of cardiac maternity cases, including during Intrapartum Care is:1. Patient Education and assessment pre pregnancy, in the case of congenital heart disease this should *begin* during the process of transition.
2. Optimisation of the cardiac condition and risk factors pre pregnancy. In the case of congenital heart disease this may include earlier intervention/surgery to reduce per-pregnancy risks and optimise outcome for mother and baby.
3. Multi-disciplinary teams experienced in *congenital heart disease and cardiac maternity* care
4. Joint cardiac-obstetric clinics. In the case of congenital heart disease this must include a congenital cardiologist with experience in cardiac maternity care.
5. Joint cardiac-obstetric clinics in Level 1 and or 2 ACHD Centres with access to other co-dependent services.
6. Risk stratification of each women and pregnancy and in the case of congenital heart disease counselling by a congenital cardiologist with experience in cardiac maternity within a multidisciplinary team setting.
7. Individualised care planning covering all stages of pregnancy, delivery and post-partum formulated by Multidisciplinary Team(s) and parturient and disseminated to all care givers.
8. Multidisciplinary team and meetings should be quorate, documented (use of video/teleconference to encourage participation of all care givers) and ALSO (as indicated) include

1) a congenital cardiologist and congenital cardiac nurse specialist experienced in cardiac maternity care (recommendation 1.3.1)2) Cases may need to be discussed in Level 1 ACHD (Adult congenital heart disease disease) MDT meetings to optimise/plan care.3) Specialist haematology input is required (not considered) for those with mechanical heart valves (recommendation 1.3.6) or anticoagulated for other cardiac indications.i) Patient registers/databasesj) Regular continuous audit and quality improvementk) Robust local and network governance arrangements to review incidents, morbidity/mortality and agree, ratify and disseminate CHD Network cardiac-obstetric pathways and protocols |
| 79 | Action on Smoking and Health  | S3 – Q2  | Statement 3 states that women with heart disease should have their intrapartum risk regularly assessed. Not only does smoking increase intrapartum risk: it also increases the risk of heart disease by between 2 and 4 times. [1] [2] This means that pregnant women with heart disease who also smoke have significantly elevated intrapartum risk. Consequently, establishing the smoking status of pregnant women with heart disease is central to accurately assessing their intrapartum risk. NICE must clarify where the collection of SATOD fits in with the regular assessment of intrapartum risk for women with heart disease to enable health professionals to deliver appropriate care.[1] Smoking in Pregnancy Challenge Group. [Review of the Challenge.](http://ash.org.uk/download/2018-challenge-group-report-final/)v 2018. [2] Action on Smoking and Health. Smoking, the heart and circulation. 2016**. [NICE analyst comment: this document is available here - replacement link to online file:** <https://ash.org.uk/information-and-resources/fact-sheets/smoking-the-heart-and-circulation/>**]** |
| **Statement 3 – question for consultation 5** |
| 80 | British Maternal & Fetal Medicine Society | S3 – Q5 | **Question 5** For draft quality statement 3: For measurement and quality improvement purposes, at which key contacts should intrapartum risk be reassessed in women with heart disease?Surely this depends on the type and severity of the heart disease. The planning needs to be responsive to changes in the clinical condition – a provisional plan should be made by the third trimester. More important than the planning well all is well though is documentation of who to contact and what to do in the event that either the condition changes or an intrapartum complication arises. |
| 81 | Resuscitation Council UK | S3 – Q5 | It is impossible to generalise on this, as it will vary from person to person, according to their specific cardiac condition and the nature and degree of risk that it could pose for them. Those may change as the pregnancy progresses, depending on the progress of the pregnancy and on any change in their heart condition during the pregnancy. We think that the intended outcome may be for the intrapartum risk to be assessed **frequently** or **repeatedly** rather than ‘regularly’. However the nature of reassessment and frequency needed will vary for each individual and their specific type of heart disease, so we suggest that this statement should refer to each person having an individual plan for reassessment of risk, and to that plan containing a clear record of the nature and timing of the next reassessment of risk. The ‘key contacts’ for undertaking risk assessment should be planned on an individual basis, so the measurable aspect will be (1) whether there is an individualised plan that states the nature and timing of the next risk assessment and (2) whether arrangements are in place for a clinician with expertise in managing the woman’s specific condition during pregnancy to plan with her the nature and timing of each subsequent risk assessment. |
| 82 | Royal College of Midwives  | S3 – Q5 | For measurement and quality improvement purposes, at which key contacts should intrapartum risk be reassessed in women with heart disease?34-36 weeks |
| 83 | Royal College of Nursing  | S3 – Q5 | Statement 5 - For draft quality statement 3: *For measurement and quality improvement purposes, at which key contacts should intrapartum risk be reassessed in women with heart disease?*Women with heart disease should be seen by specialists and risk assessed at booking history and throughout the pregnancy. There would be referrals for tests and the outcomes of these would probably determine appointments and take into consideration the wishes of the woman. |
| 84 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S3 – Q5 | I think it’s important to define significant heart disease here e.g. many mothers classified with mWHO I can be seen once, and do not necessarily need cardiology input at all (e.g. ventricular ectopic beats), whereas those with mWHO III or IV may need intensive input more frequently than ‘regularly’ [note also that for example ‘annually’ is still ‘regularly’ and therefore relatively meaningless in this context]. |
| 85 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S3 – Q5 | At which key contacts should intrapartum risk be reassessed in women with heart disease? I think the three times areA. Early in 2nd trimester after routine screening is offered say 12–14 weeks.B. Early in 3d trimester - so contingency plans can be made for early pre term birth and assessment of other risks such as GDM 24–26 weeks.C. Late in the 3rd trimester - so that a term / intra partum plan can be made in light of the effect of the physiological changes in pregnancy most of which have been completed 32–34 weeks. |
| **Statement 4** |
| 86 | Birthrights | S4  | This is a strange choice of quality statement. The appropriate time to discuss mode of birth and the woman’s choices is significantly before the woman is in labour. Indeed, the appropriate time to begin discussions is when the woman wishes to begin them (which may be earlier than birth choices are standardly ‘scheduled’ on antenatal care plans). Given the increased risks on unplanned caesarean it would be hard to justify waiting until labour commenced to offer a VBAC vs an *unplanned* caesarean as opposed to the option of a *planned* caesarean that might be offered antenatally. We are concerned that “reminding” this group of women of the risks and benefits of alternative modes of birth during labour this may cause unwarranted anxiety at this time. We agree that it is crucial that a woman who has had a previous caesarean, or indeed any other woman regardless of their history, be able to make a timely choice *when factors change* during labour, however this is not what is stated. (Birthrights has worked with NHS England to develop an intrapartum consent tool called IDECIDE which helps healthcare professionals and women to discuss reasonable options to enable the woman to make an informed decision under the challenging conditions of labour. We are happy to supply further details) |
| 87 | Birthrights | S4 | Rationale – we agree that it is very important that a woman is able to make a timely decision when clinical or other factors (including her preferences) change during labour (see comment 12 above) **[NICE analyst comment: comment 86]**. However “Reiterating the benefits and risks [associated with different modes of birth] during labour” may result in women feeling pressured or coerced when they have already made a decision that is right for them. Repetitive and unwanted discussion of risks may constitute undue influence (see https://www.birthrights.org.uk/factsheets/consenting-to-treatment/ ) and result in further care lacking lawful consent. |
| 88 | Birthrights  | S4 | Structure – it is important that local processes are in place to ensure that women who have had a previous Caesarean section are able to access care and support to make the decision that is right for them. This must take place before a woman is in labour (see comment 12) **[NICE analyst comment: comment 86]**; focussing on the risks/benefits of mode of birth only at the point where a woman is in labour risks the woman being subject to undue influence and feeling under pressure or scrutiny for her choices (see comment 13) **[NICE analyst comment: comment 87]**. |
| 89 | Birthrights | S4 | Process – in light of comments 13 and 14 **[NICE analyst comment: comments 87 and 88]** it is particularly concerning to see that the measure is one of how many women in labour are reminded of the benefits and risks of different modes of birth. This risks institutionalising perceived pressure, coercion and undue influence on women who have chosen not to have a Caesarean birth. A more appropriate quality statement and measure would focus on the number of women supported to make the right choice for them about their mode of birth, and are supported to make the right choices for them if and when clinical indications change. As noted above, Birthrights has worked with NHS England to develop an intrapartum consent tool called IDECIDE which helps healthcare professionals and women to discuss reasonable options to enable the woman to make an informed decision under the challenging conditions of labour. NHS England has now appointed a project manager to lead on national roll out. The tool includes a woman-reported experience measure of the consent process. In time there is potential for this tool to form part of a quality standard, subject to evaluation. In the meantime it is critical that in addition to the quality measure being “women supported to make the rights choices for them” (see comment 15) **[NICE analyst comment: as stated, comment 89]**, that the success of this measure is judged by women themselves and support the use of a patient survey or similar. |
| 90 | Birthrights | S4 | Data collection – data collection needs to encompass the women supported to make the right choices for them and not solely mode of birth, which may or may not represent the woman’s choice/preference. |
| 91 | Birthrights | S4  | Outcomes – the numerator needs to encompass the number of women who felt supported to make the right choices for them when clinical factors/preferences changed during labour. Outcome data collection also needs to reflect the proportion of women who felt supported to make choices, and had their choices respected if clinical factors/preferences changed during labour. |
| 92 | Birthrights | S4 | What the quality statement means for different audiences – this section emphasises the focus on reiterating risk and benefit information during labour, not solely if and when clinical indications or a woman’s preferences have changed. As described above **[NICE analyst comment: no specific comments appear to be referenced]**, we are concerned that this may institutionalise coercion or pressure on women. |
| 93 | Birthrights | S4  | Equality and diversity - We welcome the specification of the need for accessible information and interpretation where required (a major finding of Hall et al 2018). Women should also be provided with access to support where this would be beneficial – that is, for women who would be better able to understand choices, advice and recommendations and to express themselves through interpretation (Birthrights and Birth Companions (2019). Holding it all together: Understanding how far the human rights of woman facing disadvantage are respected during pregnancy, birth and postnatal care. London [online]. (Available at: https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf ). This is particularly important for decisions being made in labour. |
| 94 | Birth Trauma Association | S4 | This is the section we are least happy with. It is using data to inform women based on previous NICE guidelines. NICE provides population level data for women. Montgomery has said this is unacceptable: women must be counselled individually and account must be taken of the risks and benefits that matter to them. For instance, women with extreme fear of childbirth should be consented differently to women who clearly express a strong desire to give birth vaginally. Some of this information is also out of date. Given the Pasupathy study in Scotland on Intrapartum related death, you could not possibly say outcomes are the same for planned caesarean as planned VBAC. VBAC is higher risk for the baby. The RCOG leaflet for women agrees. <https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-birth-options-after-previous-caesarean-section.pdf> The section on benefits and risks of different modes of birth following section needs reviewing and changing. There is a great danger that women (and possibly health care professionals in error) will think the risks of emergency caesareans (which are a result of trial of VBAC) are the risks of planned caesarean. This is immensely dangerous because to so do could now result in a successful multimillion claim for brain damage purely on failed consent even if the other care was good. This urgently needs to be tabulated differently: one column or section, the risks of planned VBAC and in the other planned caesarean. There must be absolutely no scope for confusion. Severe tears are a 1/5 risk of VBAC and that is a very significant risk. It cannot be omitted. |
| 95 | Birth Trauma Association | S4 - Measures | Dubious to use the hospital’s own data collection & surveys for this. Quite subtle differences in the phrasing of the questions will result in huge differences in the responses. This will simply measure how clever hospitals are at framing questionnaires. There needs to be a standard NHS template specifically for this outcome if it is to be a reliable measure. |
| 96 | Caesarean Birth | S4  | Statement 4“Informed birth choices for women in labour with previous caesarean section”On page 20, there is a list of “Benefits and risks of different modes of birth”. There is no reference to pelvic floor trauma and/or damage for women, including (various degrees of) tearing, urinary and/or faecal incontinence, pelvic organ prolapse). In terms of shared decision making, and balanced information, this would appear an important omission. Could NICE include these?  |
| 97 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S4  | It is most important that this plan should be made antenatally. Labour is a poor time for a detailed nuanced chat. |
| **Statement 5** |
| 98 | British Maternal & Fetal Medicine Society | S5 | (MDT)With respect to the involvement of a critical care specialist for a woman with sepsis, is it evidenced-based that oliguria is a reliable sign of sepsis *in labour* requiring critical care? Women in advanced labour are frequently oliguric as a result of head compression. |
| 99 | NHS England/NHS Improvement - National Medical Director for Professional Leadership and Clinical Effectiveness | S5  | Regarding the one on sepsis, please can you clarify that its not just women in labour but women in the early post-partum period who need regular assessment (linked to level of clinical concern) if they are suspected of having sepsis? |
| 100 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S5  | A senior intensivist is not defined in terms of years of speciality training in the way obstetrician is in the same section. Experienced SAS doctors are not incorporated into this definition and may well be considered 'senior' with ample experience as compared to ST5. What is a senior midwife? Can this be the same person as the LW co-ordinator? |
| 101 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S5  | Not really correct to say that ‘observations [should be] carried out by a multidisciplinary team. More that the MDT should review the observations and plan on an ongoing basis. |
| 102 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance (coordinated response) | S5  | Can’t read Table 4 in the original guideline, but isn’t oxygen sats missing as one of the obs needed on 2nd page of this description |
| 103 | Resuscitation Council UK | S5  | Urgency - The wording of this statement seems to lack the sense of urgency that should be present in anyone with sepsis or suspected sepsis. One of the problems with sepsis has been an inadequate level of clinical concern, leading to failure of or delayed diagnosis and treatment. We suggest that the wording be amended to reflect the urgency of action required to maximise the chance of a successful outcome. |
| 104 | Royal College of Paediatrics and Child Health | S5 | These MDT reviews look very nice in a document, but are they practical in reality? In what way do all those members of the team to be involved in sepsis in labour need to be involved? |
| **Equality impact assessment**  |
| 105 | Birthrights | 1.1 | This is an incomplete list of the groups of women who are at higher likelihood of not having received antenatal care. The group needs to be expanded to include women in temporary housing, women who are recent migrants or asylum seekers, woman concerned about NHS charging, women facing multiple disadvantage, women whose language needs are not met and others. See Birthrights and Birth Companions (2019). Holding it all together: Understanding how far the human rights of woman facing disadvantage are respected during pregnancy, birth and postnatal care. London [online]. (Available at: <https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf> ). |
| 106 | Birthrights | 2.1 | It is concerning that women who are less likely to access antenatal care because of the factors identified (and others) are being viewed as a separate population to women with existing medical and obstetric conditions. This is not the case, women facing factors of disadvantage are more likely to experience physical and mental health conditions and are overrepresented in maternal deaths including from obstetric conditions. For more see Birthrights and Birth Companions (2019). Holding it all together: Understanding how far the human rights of woman facing disadvantage are respected during pregnancy, birth and postnatal care. London [online]. (Available at: <https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf> ) and references in that report. |
| 107 | Birthrights | 2.3 | As stated under the relevant quality statements above **[NICE analyst comment: comments 39 and 93]**, women should have access to interpreter and language support where this is needed or would be of benefit – that is, for women who would be better able to understand choices, advice and recommendations and to express themselves through interpretation (Birthrights and Birth Companions (2019). Holding it all together: Understanding how far the human rights of woman facing disadvantage are respected during pregnancy, birth and postnatal care. London [online]. (Available at: <https://www.birthrights.org.uk/wp-content/uploads/2019/09/Holding-it-all-together-Full-report-FINAL-Action-Plan.pdf> )) |
| 108 | Royal College of Obstetricians & Gynaecologists and Maternal Mental Health Alliance coordinated response | 1.1 | I think there may be equality issues for women with ongoing psychiatric problems and women who have been victims of human trafficking.With psychiatric problems there may be issues in delivery of acute intrapartum care due to delays with communication / consent and the same applies for trafficked women, who may also have additional language barriers. |

## Registered stakeholders who submitted comments at consultation

* Action on Smoking and Health
* Birth Trauma Association
* Birthrights
* British Dietetic Association
* British Maternal and Fetal Medicine Society
* Caesarean Birth
* Epilepsy Action
* Maternal Mental Health Alliance (additional comments on mental health endorsed by the Royal College of Obstetricians and Gynaecologists)
* NHS Digital - Digital Maternity Programme
* NHS England/Improvement
	+ Chief Allied Health Professionals Officer
	+ Congenital Heart Disease Clinical Reference Group
	+ Primary Care Team
* Resuscitation Council UK
* Royal College of Midwives
* Royal College of Nursing
* Royal College of Obstetricians and Gynaecologists, responding in collaboration with the Maternal Mental Health Alliance
* Royal College of Paediatrics and Child Health
* Stillbirth and neonatal death society (Sands)
1. PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees. [↑](#footnote-ref-1)