NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Induction of labour

Date of Quality Standards Advisory Committee post-consultation meeting:
27 January 2014

2 Introduction

The draft quality standard for Induction of labour was made available on the NICE website for a 4-week public consultation period between 28 November and 2 January 2014. 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.

Comments were received from 13 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, such as changes to the original guideline recommendations, have not been included in this summary. However, the Committee should read this summary alongside the full set of consultation comments, which is provided in appendix 1.

3 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. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

4 General comments

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

- In general it was felt that the quality standard does reflect the key areas for quality improvement.
- Concerns were raised about inequalities in women's experiences of maternity care in black and minority ethnic group women and women living in deprived areas.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Women who have their labour induced as outpatients have the induction carried out in a setting that has safety and support procedures in place, and where the practice of induction is audited continuously.

Consultation comments

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

- Stakeholders suggested that further clarity is needed around the definition of safety and support procedures.
- A concern was raised that this statement is a response to a need to reduce pressure on the labour wards.
- A stakeholder raised a query over how this standard will apply to inductions taking place in a day assessment unit or triage especially where there are bed shortages women may not be on a ward, even for a short time.
- A concern was also raised that the number of women that would need to be involved in a continuous audit of outpatient inductions is likely to be unmanageable as a continuous audit.

5.2 Draft statement 2

Women who are offered induction of labour should be given personalised information about the reasons for induction, the benefits and risks for them and their babies, and the alternatives to induction.

Consultation comments

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

- A concern was raised over how effectively women's involvement in the decision to have their labour induced will be monitored. It was felt this may be helped if the standard outlined the information that should be given to the women.
- Stakeholders queried the wording of the statement. It was felt that it should be made clearer that the decision of whether or not to be induced and the method of induction should be that of the woman.
- A stakeholder queried how a woman's satisfaction with how their decision was made can be measured.

5.3 Draft statement 3

Women who have their labour induced have rapid access to pain relief that is appropriate to their level of pain and to the type of pain relief they request.

Consultation comments

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

- A stakeholder highlighted that timely provision of appropriate pain relief should be clearly identified as a multidisciplinary issue within the standard. It was also commented that measurement of this statement, and the development of local arrangements, should reflect the different aspects of care (e.g. pharmacy as part of multi-disciplinary team) that affect the timeliness of access to pain relief.
- It was commented that the risks and benefits of pain relief options, both for mother and baby, should be part of the initial process of information-giving and decision-making.
- A stakeholder commented that some units would be unable to achieve this standard and further clarification is needed over the definition of pain relief.

6 Suggestions for additional statements

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

- A statement on allowing partners to stay with women throughout their induction in terms of offering support.
- A statement about the practice and auditing of membrane sweeping, as a means to avoid the need for other pharmacological methods of induction.

Appendix 1: Quality standard consultation comments table

ID	Stakeholder	Statement No	Comments Please insert each new comment in a new row.
01	British Maternal and Fetal Medicine Society	General	In the sentence reading: "Induction of labour has an impact on birth experience and the health of women and their babies, and so needs to be clinically justified", the word "clinically" should be removed as there may be occasions when induction of labour is justified on social grounds for the woman (eg an ill partner or a partner in the armed forces).
02	British Maternal and Fetal Medicine Society	General	You asked: Question 1 Does this draft quality standard accurately reflect the key areas for quality improvement? Answer. Yes, although this quality standard is all about women who were offered induction of labour. This quality standard will not pick up poor practice around women should have been eligible for induction of labour (eg women with post dates pregnancy) but who were not given this offer.
03	British Maternal and Fetal Medicine Society	General	You asked: Question 2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures? Answer - yes, although "maternal safety" and "neonatal safety" (page 6) are very broad terms – it might be helpful to have some more specific indicators as outcomes. The only indicators mentioned in detail are process outcomes (eg giving information) and not clinical outcomes (eg proportion of babies with evidence of hypoxic ischaemic encephalopathy).
04	NHS England	General	Thank you for the opportunity to comment on the draft scope for the above quality standard I wish to confirm that NHS England has no substantive comments to make regarding this consultation
05	Barking, Havering and Redbridge Hospitals NHS Trust	General	WHO recommendations for induction of labour are written with under resourced settings in mind. Specifically they contradict the NICE guideline – eg the use of oral misoprostol and balloon induction are recommended by WHO and not recommended by NICE. Therefore it is confusing to state that these quality standard should be considered alongside the WHO recommendations is confusing.
06	National Childbirth Trust	General	The draft introduction reads: "The essential judgment that the clinician and the pregnant woman must make…". We think this should read "The essential judgment that a pregnant woman and her clinician must make…"

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07	National Childbirth Trust	General	The draft introduction reads: “Following discussion of the relative risk of continuing the pregnancy compared to induction…”. We think this should be reversed to read: “Following discussion of the relative risk of induction compared to continuing the pregnancy…”
08	National Childbirth Trust	General	The draft introduction reads: “the woman’s wishes must be taken into account.” We believe this phrasing is incorrect. A woman’s wishes/ preferences should not simply be 'taken into account' - it IS the woman's decision. She has the legal right to accept or decline this intervention.
09	Royal College of Midwives	General	The RCM was concerned at the review decision in 2011 not to update the guideline on Induction of Labour. As we stated at the time, health professionals involved need to be very up to date with the evidence to inform themselves and women about the risks and benefits of this common but very significant intervention. We are even more concerned to see the production of a quality standard without an up to date in-depth review of the evidence We would like to see a statement about the practice and auditing of membrane sweeping, as a means to avoid the need for other pharmacological methods of induction.
10	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.
11	Association for Improvements in the Maternity Services	General	“Following discussion the woman’s wishes must be taken into account”. This phrase evoked strong criticism from our committee and is unacceptable to us. Firstly it conflicts both with Quality Statement 7 in NICE Guideline CG130 Patient Experience in Adult NHS services “Patients are made aware that they have the right to choose, accept or decline treatment and these decisions are respected and supported” and with DoH Reference Guide to Consent for Examination or Treatment (2nd edition 2009) p. 19 para.44 When consent is refused which says that a woman is entitled to refuse treatment even if this results in the death of an unborn child, whatever the state of pregnancy. Secondly, from numerous calls to our helpline, we know that consent to induction is a major quality issue for women, and that they often report shroud-waving, inaccurate or exaggerated information about risk, and threats of reporting to social services,(sometimes followed through) by health professionals apparently unaware that coerced consent is not valid consent.

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			We would prefer "the woman's decision is paramount" or "it is the woman who decides whether to accept or refuse intervention Moreover validity of consent has a proven effect on mental health outcomes of childbirth, especially risk of PTSD.
12	Association for Improvements in the Maternity Services	General	"if appropriate health professionals should ensure that partners, family members and carers area involved in the decision-making process." We are aware of cases where health professionals have tried to recruit partners, etc. to persuade women to have interventions they do not want. Whilst we support information being given to family members, etc. if the woman agrees, the decision to accept or refuse is hers alone, both legally and ethically. Also it may not be apparent when it is "appropriate". Partners and family members are not always supporters, as Confidential Enquiries into Maternal Deaths (especially from domestic violence and murder) show. We are now seeing an increasing number of cases where women are concealing domestic abuse (physical or mental) for fear of being referred to social services; the perpetrators are almost invariably impressive and persuasive, and come from all social backgrounds, including health care professionals themselves.
13	Association for Improvements in the Maternity Services	General	"women feel satisfied with how their decision was made" and this outcome is to be monitored by local data collection. Exactly how is this to be monitored? We know that the simple question "would you recommend this unit to friends or family" asked when people are still in-patients, is particularly unsuited to maternity care, since criticisms are not voiced until some time after discharge, for a variety of reasons. Only qualitative surveys are likely to provide reliable data.
14	Association for Improvements in the Maternity Services	General	In the NPEU 2006 national survey of women's experiences of maternity care, both Black and Minority Ethnic Group women and women living in deprived areas, were less likely to be offered choice of place of birth, more likely to be treated with lack of respect by staff, and more likely to be given information in a way they did not understand. (M .Redshaw et al (2007) Recorded delivery: a national survey of women's experiences of maternity care 2006. Chapter 8 The care and experiences of specific groups of women, pp 62-77). It may be helpful to quote this, particularly in view of many current criticisms in the press about overseas health tourists.

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15	Royal College of Paediatrics and Child Health	Quality Statement 1	In a setting where the needs of the baby, once born, can be met by an appropriate team, e.g. if there is induction at preterm gestation there must be the appropriate level of neonatal unit on site.
16	Ferring Pharmaceuticals Ltd.	Quality Statement 1	The safety and support measures state that it should be explained to the woman as to how to remove the gel, tablet or pessary that was inserted for induction of labour. It is impractical for midwives or patients to remove the gel from the vagina and there is no procedure stated for this in the product SPC. It is extremely difficult for midwives or patients to remove the tablet from the vagina after it has been inserted due to the process of disintegration of tablet and the fact that the tablet has no retrieval tape to facilitate removal. There is no procedure stated for removal of the tablet in the product SPC. The controlled release pessary is the only product which is designed for easy removal from the vagina facilitated by an integral retrieval tape. It is thus important to inform the woman that once treatment is initiated by insertion of the gel, tablet or pessary, and in the event of evidence of undesired responses such as hypertonus, sustained uterine contractions or fetal distress, the controlled release pessary can be easily removed with the help of the retrieval tape. This information will be important for the woman when she is giving consent.
17	British Maternal and Fetal Medicine Society	Quality statement 1	The last line implies that it is possible to remove the gel inserted to induce labour . Although it is possible to remove the vaginal insert, and perhaps possible to remove the tablets in some women, it is not possible to remove the gel. This sentence needs to be rephrased.
18	Royal College of Obstetricians and Gynaecologist	Quality statement 1	Q1) yes, reflects the key areas for improvement. Q2) yes Page 6 '...remove the gel, tablet or pessary...' Is it actually possible to remove prostaglandin gel?
19	Royal College of Obstetricians and	Quality statement	Rationale in the document – pg 5 states ‘For women who have their labour induced in an inpatient setting, safety and support procedures, including audit, are likely to be in place.’ This conveys a sense

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	Gynaecologist	1	of assumption rather than knowledge based on facts. To underscore the importance of continuous audit could we just state 'For women who have their labour induced in an inpatient setting, safety and support procedures, including audit, should already be in place.' Correspondingly to reiterate this message further, consider including in the QS 'Women who have their labour induced as outpatients have the induction carried out in a setting that has safety and support procedures in place, and where the practice of induction is audited continuously (as with inpatient induction of labour). This would ensure that both inpatient and outpatient IOL are subject to the same rigorous quality assessments and not one at the expense of the other.
20	Royal College of Obstetricians and Gynaecologist	Quality statement 1	Suggest 'checking women for a prespecified time' Suggest 'giving women info about whom to contact and how if regular cont'
21	Royal College of Nursing	Quality statement 1	Audit of out-patient Induction of labour – We welcome this and agree that it should be monitored and audited. The method proposed seems feasible and appropriate.
22	Barking, Havering and Redbridge Hospitals NHS Trust	Quality statement 1	Question 1 yes this quality statement accurately reflects a key area for quality improvement. Question 2 Yes it should be possible to collect the proposed quality measures.
23	National Childbirth Trust	Quality Statement 1	We think this quality standard should apply to both inpatient and outpatient settings. The information reports safety and support are '…likely to be in place…', and we think efforts should be made to aim for this always to be in place, no matter the setting.
24	National Childbirth Trust	Quality Statement 1	We think "…safety and support procedures…" needs to be defined, otherwise neither women nor clinicians will know what is needed to be in place. There are some examples given in the document, but we think there needs to be a checklist of everything needed otherwise it is hard to know if the standard is being met.
25	Royal College of Midwives	Quality Statement 1	This statement is confusing - it appears to be supporting out of hospital induction but very cautiously - hence a very mixed message.

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			Considering the GDG interpretation of the evidence in the original guidance "The GDG is aware that outpatient induction of labour is commonly offered to women with prolonged pregnancy. Evidence from the UK setting is very limited and more safety data are needed" We are surprised to see this now in a quality standard when it was considered then that more data were needed. We are particularly concerned that this statement could be a response to a need to reduce pressure on the labour wards.
26	Royal College of Midwives	Quality Statement 1	There needs to be absolute clarity about what is meant by a setting 'that has safety and support procedures in place'. What safety procedures are supposed to be carried out? The RCM's experience of current staffing levels on antenatal wards is that many women having induction of labour in inpatient settings are left without support, and the fact that midwives are extremely busy may also mean safety is compromised. Further clarity is needed on how this standard will apply to inductions taking place in a day assessment unit or triage. For example, where there are bed shortages women may not be on a ward, even for a short time.
27	Royal College of Midwives	Quality Statement 1	As far as support is concerned, there are an increasing number of maternity units who let partners stay with women throughout their induction, but this remains a minority. Allowing partners could be a useful quality standard in terms of offering support.
28	Royal College of Midwives	Quality Statement 1	The number of women that would need to be involved in a continuous audit of outpatient inductions is likely to be unmanageable as a continuous audit. Already there is a continuous audit on LSCS and adding to this will mean an overload of audit activity.
29	Association for Improvements in the	Quality Statement	SAFETY AND SUPPORT The word "support" is frequently used in this document (and many others). However, there is constant mismatch between what professionals hope to provide, or think

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	Maternity Services	1	they are providing under this label, and what women feel they are receiving (or rather not receiving). With high endogenous oxytocin levels at this time, women are particularly vulnerable to damage from brusque, insensitive, or absent carers. Their definition of safety includes emotional safety; support includes emotional support. This also affects how information is received and understood. Support is best provided by continuous carers, and if outpatient induction is part of fragmented care, outcomes are less likely to be optimal. However, if it is part of continuous care (preferably by one midwife) this may improve outcomes. Jane Sandall et al (2013) Midwife led continuity models versus other models of care for childbearing women. The Cochrane Collaboration
30	Association for Improvements in the Maternity Services	Quality statement 1	This includes local data collection to see what percentage of induced women are induced as outpatients. It does not, however, include an important question for women what percentage of women at or near term are induced at that unit at all, compared with others, and national average? We suggest that monitoring this should also be part of the quality standard. We know that there is wide variation which is unlikely to be entirely accounted for by local risk factors. One study found more than a quarter of inductions were unexplained by case mix factors (T. Humphrey & J. S. Tucker (2009) Rising rates of obstetric interventions: exploring the determinants of induction of labour. Journ. Pub Health 31(1) 88-94
31	Royal College of Midwives	Quality Statement 1 What the statement means for women…	The examples of safety and support here are alarmingly unclear "checking women for a time after the induction before they go home"…. What does this mean? For example, if it includes continuous fetal heart monitoring, what length of time is appropriate? "explaining how to remove the gel, tablet, or pessary that was inserted" - this piece of information needs a lot more context, for example who to contact if there are any problems, and demonstrates the potential risks of normalising this intervention.
32	Ferring Pharmaceuticals Ltd.	Quality Statement	Individual obstetric units differ in the method of administration of PGE2 for induction of labour and it is important to highlight to the women that there are differences in regard to the likelihood of further

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		2	interventions the women may experience (such as oxytocin augmentation, number of vaginal examinations etc.) depending on which product is used to induce labour. Kelly AJ, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. Cochrane Database of Systematic Reviews 2003;(4):CD003101 Key area for quality improvement - Reducing the need for vaginal examinations and oxytocin augmentation following induction of labour using PGE2 Measure 1. Impact on the need and costs of oxytocin augmentation based on the method of administration of PGE2 for induction of labour. Measure 2. Impact of the method of administration of PGE2 on the number of vaginal examinations required. Kalkat RK, McMillan E, Cooper H, Palmer K. Comparison of Dinoprostone slow release pessary (Propess) with gel (Prostin) for induction of labour at term - a randomised trial. Journal of Obstetrics and Gynaecology 2008;28(7):,695-699 El-Shawarby SA, Connell RJ. Induction of labour at term with vaginal prostaglandins preparations: A randomised controlled trial of Prostin vs Propess. Joumal of Obstetrics and Gynaecology October 2006; 26(7): 627 – 630) It is imperative to inform women about the risks associated with lack of regulatory approval and appropriate safety data for off-licence therapies and formulations (eg. misoprostol tablet) used for induction of labour. The status of the off-label therapies should be briefed to the woman and made clear so the woman is able to use this information to consider her options and to reach a decision about which agent to choose for induction of labour. This is also particularly important as the NICE guidelines have a global reach and influence local markets.
33	Royal College of Obstetricians and Gynaecologist	Quality statement 2	Q1) yes Q2)I have my doubts as to how can we evidence personalised info. Usually information sharing is evidenced by the giving of a leaflet. With personalised info, would the healthcare professional be expected to document individual risks etc? if so this would be too time consuming for the hcp and may

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			carry the risk of detracting from patient care.
34	Royal College of Obstetricians and Gynaecologist	Quality statement 2	Needs a full stop at the end.
35	Barking, Havering and Redbridge Hospitals NHS Trust	Quality statement 2	This quality statement only partially reflects a key area for quality improvement. It is appropriate to emphasise 'personalised' information on indications for induction of labour, but it is disappointing that there is no quality statement related to information provision during induction specifically when induction has failed. Only 50% of women will be in spontaneous labour 24 hours after prostaglandins. Further management of these women should be consultant led and it would be helpful to have this acknowledged by NICE with a quality statement.
36	Barking, Havering and Redbridge Hospitals NHS Trust	Quality statement 2	It is only possible to collect information on the documentation within the notes. This is not always an accurate reflection of the information given. It is particularly difficult to determine the extent to which the information provided has been personalised to the individual woman's circumstances. More guidance may be needed as to how this should be audited. It is only ever possible to audit women who are actually induced or possibly women who are booked for induction. It is impossible to collect information on women who are offered induction, but decline or women who request induction but it is not offered. Therefore numerator and denominator need to be reconsidered.
37	National Childbirth Trust	Quality statement 2	We think this QS should include the phrase "and interpreters should be available to assist with this discussion if the woman does not speak or understand English well".
38	Royal College of Midwives	Quality Statement 2	The RCM is pleased to see this as a statement and the definition which includes giving information on 'alternative options' is useful. However we have concerns about how effectively women's involvement in this decision will be monitored. If the standard defined the information to be given, this could then be used as part of an audit tool. Of course information in the discussion should be personalised, but much of the process of induction should be standardised along with pain relief options. The discussion about induction of labour is often focussed on the risks of expectant management and limited on the risks of the intervention. We know that many women do not feel well informed about the process and expectation of pain and this is an area that significantly needs quality

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			improvement. The publication of a quality standard is the opportunity to make information giving on the subject accurate.
39	Royal College of Midwives	Quality Statement 2	An audit tool should involve examining the quality of experience that could be used for national as well as local audit.
40	Association for Improvements in the Maternity Services	Quality Statement 2	"the woman should be able to use this information… to reach a decision that is supported by her healthcare professionals". We find this wording unacceptable, since it may be interpreted in different ways. There are professionals who will see it as the woman reaching only a decision which they are happy with – and we have numerous examples in our case files. Those who remember CG130 will think it means that they will support and respect her decision whatever it may be. We would expect wording which makes clear that women do not lose their rights as adults because they are pregnant. We would prefer a phrase such as "the woman should be able to use this information…… to reach her decision" We would also like reference to be made to CG130 and the professional's duty to support, whatever that decision may be.
41	Association for Improvements in the Maternity Services	Quality statement 2	Pain relief options are mentioned as part of the information given. However, the risks and benefits of those options, both for mother and baby should be part of the initial process of information giving and decision-making. "It may be more painful but don't worry - we can give you an epidural" is a phrase common reported to us. We receive a number of reports from women unhappy about having had an epidural, who realise that induction or augmentation had put them in a position where they had little choice. Agreeing to the first almost inevitably led to the second.
42	Midwife expert.com	Quality Statement 2	Satisfactory level of quality and personalised information for women
43	Ferring Pharmaceuticals Ltd.	Quality Statement 3	No comments
44	Royal College of	Quality	Q1) yes

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	Obstetricians and Gynaecologist	statement 3	Q2) yes
45	Royal College of Obstetricians and Gynaecologist	Quality statement 3	Process with numerator and denominator
46	Royal College of Obstetricians and Gynaecologist	Quality statement 3	Does it need an 'of' to clarify as in 'Women who have their labour induced have rapid access to pain relief that is appropriate to their level of pain and to the type of pain relief they request.'
47	Royal College of Nursing	Quality statement 3	'Rapid access to pain relief' – how is this to be interpreted or measured? We note that no type of pain relief is specified.
48	Barking, Havering and Redbridge Hospitals NHS Trust	Quality statement 3	Yes, this quality statement accurately reflects a key area for quality improvement. However, it is not clear if it should be part of induction of labour or of intrapartum care. There would be inequality of access if women whose labours are induced are offered effective pain relief as soon as they request it but women in spontaneous labour are forced to wait longer.
49	Royal College of Midwives	Quality Statement 3	In the context of outpatient induction, rapid access to regional analgesia and opiates is clearly unachievable. There are also many units that have protocols to reserve epidurals for those in established labour or where the cervix allows an artificial rupture of the membranes and use of syntocinon.
50	Royal College of Midwives	Quality Statement 3	It is also likely to be unachievable for some units and clarification is needed on what 'pain relief 'is expected to consist of. There are a multitude of non- pharmacological interventions which could be tried. Many complaints are in relation to early labour/prostin contractions and not in relation to established labour. Antenatal information and preparation is essential – women need to know that induction can be painful and take several days. Drugs given at this time can significantly impact on women's birth choices e.g. opiates and pool birth.
51	The Royal Pharmaceutical Society	Quality Statement 3	The timely provision of appropriate pain relief should be clearly identified as a multidisciplinary issue within the standards and the process of data collection and the development of local arrangements in place should reflect the different aspects of care that could impact on the timeliness in treatment. Pharmacists as part of the multi-disciplinary team have an important role in ensuring that adequate

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			supply systems are in place to ensure clinical areas have access to medicines needed routinely as well as providing other services which would support this quality standard such as providing advice on choice and use of medicines in intrapartum care.