National Institute for Health and Clinical Excellence

INDUCTION OF LABOUR (UPDATE)

Guideline Consultation Table

14 December 2007 – 7 February 2008

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
SH	Action on Pre-Eclampsia					This organisation was approached but did not respond.	
SH	Addenbrookes Hospital, Cambridge University Hospital NHS Trust					This organisation was approached but did not respond.	
SH	Addenbrooke's NHS Trust					This organisation was approached but did not respond.	
SH	All Wales Birth Centre Group					This organisation was approached but did not respond.	
SH	Alliance Pharmaceuticals Ltd	1		NICE	1.6.10	Misoprostol preparations may become licensed within the lifetime of this document. It might be better to state that misoprostol should not be used outside of a clinical trial because no obstetric formulations are currently licensed.	Thank you for your comments. The GDG have made a recommendation to this effect.
SH	Alliance Pharmaceuticals Ltd	2		Full	Genera l	There is inconsistent use of ug and µg throughout the document	Thank you for your comments. We have made a global revision to replace ug with 'microgram'.
SH	Alliance Pharmaceuticals Ltd	3		Full	Genera l	There appers to be inconsistent use of the term vaginal prostaglandins. Sometimes it refers to any prostaglandin but in other occurrences it appears to be a specific reference to dinoprostone/PGE2	Thank you for your comments. We have made these changes where appropriate.
SH	Alliance Pharmaceuticals Ltd	4	p31 line 46	Full	2.2 and general	Prostaglandins are used in a number of non-obstetric indications. In this guideline 'vaginal prostaglandin' refers specifically to dinoprostone.	Thank you for your comments. We have specified this as vaginal PGE2 and made these changes where appropriate.

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SH	Alliance Pharmaceuticals Ltd	5	p32 line 4	Full	2.2	Misoprostol preparations may become licensed within the lifetime of this document. It might be better to state that misoprostol should not be used outside of a clinical trial because no obstetric formulations are currently licensed.	Thank you for your comments. The GDG have made a recommendation to this effect.
SH	Alliance Pharmaceuticals Ltd	6	p35 line 4	Full	2.4	The guideline notes "… there is a need for substantial trials to establish a safe and effective." This implies that one dosage regimen will suit all women indicated for induction of labour, this is clearly not correct and this phrase should to be rephrased to indicate that	Thank you for your comments. The GDG felt that there have been a considerable number of misoprostol trials. What is needed is availability of low-dose preparations of misoprostol.
SH	Alliance Pharmaceuticals Ltd	7	p51 line 24	Full	5.4	The OR quoted is not in the original paper. In the evidence tables, there is a formatting problem and it is not therefore clear if these figures are in fact correct.	Thank you for your comments. The OR is derived from the incidence of uterine rupture (2/17 [12%] in the misoprostol group vs 0/21 [0%] in the oxytocin group). We have clarified this in the text.
SH	Alliance Pharmaceuticals Ltd	8	p78 line 39	Full	8.2.3	'Small doses' would include 25, as well as 50, micrograms. Cutting of 200mcg misoprostol tablets to achieve these doses is very inaccurate. Accurate dosage is almost impossible. One published study showed that less than half the tablet fragments (100mcg tablets quartered) were within 10% of the anticipated dose (Williams MC et al. American Journal of Obstetrics and Gynecology 2002; 187:615–619.)	Thank you for your comments. The GDG is aware of the problem that low dose misoprostol is not yet available.
SH	Alliance Pharmaceuticals Ltd	9	p80 line 14	Full	8.2.3	The data quoted in the draft was based on the preliminary analysis of the study data. A subsequent post hoc, covariate analysis of the caesarean section rates adjusting for confounding factors for risk of caesarean section such as parity, age, weight and	Thank you for your comments. There have been many trials to evaluate the effectiveness of misoprostol. The GDG considered all the available evidence very carefully before making the recommendations for misoprostol.

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						baseline Bishop Score, found the difference in caesarean section rates between the treatment groups to be non-significant. A manuscript based on this study has been submitted to the BJOG for publication – see below	
SH	Alliance Pharmaceuticals Ltd	10	p81 line 47	Full	8.2.3	This notes that studies including an excess of 30,000 women may be required to determine the incidence of rare adverse outcomes. Such a study or studies are impracticable and an alternative approach may be needed, for example, a patient registry. In addition, long term adverse effects on the child following exposure to misoprostol at term are not predicted, misoprostol has a well recognised safety profile and a very short half life with linear pharmacokinetics. There are reports of in utero exposure in the first trimester, either accidental or for failed attempts at abortion. The recognised adverse effects of such exposure are Mobius syndrome and arthrogryposis (Pastuszak AL et al. N Engl J Med 1998; 338(26):1881-1885. Coelho KE et al. Am J Med Genet 2000; 95(4):297-301. da Silva Dal PT et al. Reprod Toxicol 2006).	Thank you for your comments. There have been many trials to evaluate the effectiveness of misoprostol. The GDG considered all the available evidence very carefully before making the recommendations for misoprostol.
SH	Alliance Pharmaceuticals Ltd	11	p82 line 10	Full	8.2.3	See comment above regarding accuracy of misoprostol fragments	Thank you for your comments.
SH	Alliance Pharmaceuticals Ltd	12	p82 line 13	Full	8.2.3	Cervix should be written in full as it is in line 2	Thank you for your comments. We have made this correction throughout the guideline.
SH	Alliance Pharmaceuticals Ltd	13	p82 line 15	Full	8.2.3	Favourable, unfavourable and cervix should be written in full as it is in line 2	Thank you for your comments. We have made this correction throughout the guideline.

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SH	Alliance Pharmaceuticals Ltd	14	p82 line 23	Full	8.2.3	See comment above regarding substantial clinical trials	Thank you for your comments. There have been many trials to evaluate the effectiveness of misoprostol. The GDG considered the evidence very carefully before making the recommendations for misoprostol.
SH	Alliance Pharmaceuticals Ltd	15	p97	Full	Appen dix D Table D2	Dinoprostone costs quoted in this table are now no longer correct and reference should be made to current drug costs listed in BNF 54. 1mg dinoprostone gel. These costs should also be checked against costs quoted in BNF 55 due for publication in March 2008	Thank you for your comments. We have amended the table so that it reports current drugs costs listed in BNF 54. The costs quoted in BNF 55 are the same as BNF 54.
SH	Alliance Pharmaceuticals Ltd	16	p105 no. 171	Full	Refere nces	A manuscript based on this study has been submitted to the BJOG for publication. The provisional title is: Calder AA, Loughney AD, Weir CJ, Barber JW. Induction of labour in nulliparous and multiparous women: a UK, multicentre, open-label study of intravaginal misoprostol in comparison with dinoprostone	Thank you for your comments. The GDG understands that this paper is unlikely to be published before this guideline is published.
SH	Association for Continence Advice					This organisation was approached but did not respond.	
SH	Association for Improvements in the Maternity Services	1		Full	Genera l	We are very concerned that the grades of evidence have been removed from this guideline	Thank you for your comments. We were advised by NICE that recommendations are no longer graded. . However, the strength of the evidence appraised was graded (evidence levels) throughout this guideline according to NICE methodology.
SH	Association for Improvements in the Maternity Services	2		Full	Genera l	We are concerned that there seems to be no consideration of the potential risk of infection from the additional use of vaginal examination, membrane sweeps and artificial rupture of membranes when	Thank you for your comments. We did not identify any evidence reporting infection as a result of membrane sweeping. The GDG acknowledged your concerns and considered very carefully the balance of

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						inductions are performed; particularly when serious infections such as MRSA are a real threat to mothers and babies.	risks and benefits in any management options.
SH	Association for Improvements in the Maternity Services	3		Full	General	We are very concerned about the inconsistent recommendations made when there is a lack of evidence, for example lack of evidence for induction of breech-presenting baby led to a recommendation that it was alright to do so, but a lack of evidence in relation to alternative therapies led to a recommendation that they should not be used. In cases where evidence does not exist to recommend a particular practice then the recommendation should at least be to inform women that this is the case.	Thank you for your comments. The rationale of making a recommendation is explained in the 'interpretation' section. The GDG considered it important that all cases of clinical management involve a dialogue between the woman and the clinician, taking into account the woman's wishes and her clinical situation. Women are offered information to make informed choice and decision, which must be respected. We have revised the recommendations for women with breech presentation. In the case of alternative therapies, available evidence did not support the use of these as methods of induction. The GDG did not recommend their use to be offered on the NHS.
SH	Association for Improvements in the Maternity Services	4		Full	1.1	Amend 'less than' two thirds of women give birth spontaneously to 'fewer than'	Thank you for your comment. We have revised the text as suggested.
SH	Association for Improvements in the Maternity Services	5		Full	1.1	On the issue of estimating gestational age we are concerned by the comment "indeed nowadays the information from the latter source will take precedence" referring to ultrasound dating taking precedence over information provided by the women. In many cases we deal with women who know when they conceived and are being told that their dating of the	Thank you for your comments. We have revised the text.

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						pregnancy is wrong, and further many are being pressured into accepting induction for a pregnancy they know is not prolonged. It is crucial that what women know about their pregnancies is not dismissed in the light of uncertain information from an ultrasound scan.	
SH	Association for Improvements in the Maternity Services	6		Full	2.1	We feel that in this and all other statements about women agreeing to induction the wording should be made much clearer, so there is no doubt that induction is an intervention that women should be offered and allowed to make an informed choice about whether to accept or decline. Hence we suggest that the following sentence: “When a woman has agreed to avoid prolonged pregnancy, this should be initiated between 41+0 and 42+0 weeks gestation” should be changed to: “Induction of labour to avoid prolonged pregnancy should be offered to women, and initiation of induction of labour should be made available to women between 41+0 and 42+0 weeks gestation”.	Thank you for your comments. We have taken up your suggestion and revised the recommendations to improve clarity.
SH	Association for Improvements in the Maternity Services	7		Full	4.1	Prolonged pregnancy – prolonged pregnancy has already been established to be beyond 42 weeks for the context of this guideline so first the subheading should be "What are the risks of pregnancy beyond 42 weeks gestation?" instead of beyond 40 weeks.	Thank you for your comment. The original question was set to reflect a bigger and fuller picture of the evidence base.
SH	Association for Improvements in the	8		Full	4.1	Given the recommendation “Women with uncomplicated pregnancies should be	Thank you for your comments. Induction is recommended as an option to prevent the

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	Maternity Services					given every opportunity to proceed to spontaneous labour", why then is induction for prolonged labour recommended at all?	risks of prolonged pregnancy. We have reworded the recommendations to improve clarity.
SH	Association for Improvements in the Maternity Services	9		Full	4.1	The guideline fails to clearly summarise any clear benefits of induction for prolonged pregnancy, but yet the guideline fails to recommend that this information is shared with women. Currently women are accepting induction because they believe the risk to their baby is great; this guideline acknowledges that this is not the case, but fails to recommend that this information is shared with the women who need to make the decision about whether or not to accept this intervention which many find extremely distressing.	Thank you for your comments. We have revised and reworded the recommendations to improve clarity and to emphasise the need to share information with the woman concerned. In giving women the information (Ch 3), the reasons for and the risks and benefits of induction would be discussed. Further information is offered to women in the recommendations on prolonged pregnancy (4.1) and membrane sweeping (5.2.1)
SH	Association for Improvements in the Maternity Services	10		Full	4	There is no consideration of ethic or genetic variations in the length of pregnancies, this seems to be a serious omission.	Thank you for your comments. There was one study which examined the relationship between perinatal mortality and gestation weeks in women of different ethnic origin. The GDG considered this evidence very carefully and made a research recommendation.
SH	Association for Improvements in the Maternity Services	11		Full	9.2	Recommendations on failed induction – amend the sentence: "If all is well and the woman is in agreement she could be allowed home" to read: "If all is well and the woman is in agreement she could return home"	Thank you for your comments. We have revised the recommendations.
SH	Association for Improvements in the Maternity Services	12		Full	5.4	It says "The choice between induction of labour and elective caesarean birth is a difficult one and risks and benefits have to be considered carefully." This should also explicitly include consideration of the	Thank you for your comments. The GDG have considered the evidence very carefully and revised the recommendations.

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						option of awaiting spontaneous labour, and considering the balance of risk in the context of the increased risks posed by induction of a scarred uterus and the caesarean being a subsequent and not a primary caesarean.	
SH	Association for Improvements in the Maternity Services	13		Full	5.4	Recommendation on previous caesarean birth – it is important that women are informed about the additional risk of rupture with induction and that a clear comparison with the possible small risk of stillbirth in a prolonged pregnancy is made, along with the consideration of the increased risk of repeat caesarean in comparison with primary caesarean in order that women are able to give informed consent to either induction or a repeat caesarean for the prevention of a prolonged pregnancy	Thank you for your comments. We have revised the recommendations, taking into account the woman's wishes, her clinical situation and the need for informed decision.
SH	Association for Improvements in the Maternity Services	14		Full	5.7	As there is no evidence for the use of induction with a breech presenting baby, women need to be informed that the risks and benefits of induction are not known, so that they can make an informed decision about whether they feel that this intervention is appropriate for them. Research that does not even demonstrate clear benefits for women with a cephalic baby should not be extrapolated to other situations where it has the potential for significant additional adverse effects.	Thank you for your comments. We have revised the recommendations, taking into account the woman's wishes, her clinical situation and the need for informed decision.
SH	Association for Improvements in the Maternity Services	15		Full	5.8	Why is misoprostol being suggested when there has been a fetal death? Surely the same concerns about uterine hyperstimulation and rupture still apply. If this is to be used with women they need to	Thank you for your comments. The GDG agreed that the risks of uterine hyperstimulation and uterine rupture still applied, hence the recommendations stated that the choice and doses of

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						know that this is a drug that is not licenced for this purpose in order to give informed consent for its use.	prostaglandins as induction agents would depend on the clinical circumstances, availability of preparations and local expertise and protocol. We also made a footnote relating to the need for informed consent from women when misoprostol (currently not licensed for use in pregnancy) is used.
SH	Association for Improvements in the Maternity Services	16		Full	7.1	In the absence of evidence about alternative therapies (acupuncture/homeopathy) the recommendation should not be that women should be told not to use them. In the absence of evidence of harm, women should be told that there is no evidence about the risks, it is then the women's decision about whether she wishes to use them or not.	Thank you for your comments. The reasons why any therapies are not recommended are summed up in the evidence statement and interpretation sections. The recommendations should focus on what the healthcare professional should or should not do. We have stated in the interpretation of evidence section that available evidence did not support the use of these therapies. The GDG have made recommendations not to offer these methods on the NHS.
SH	Association for Improvements in the Maternity Services	17		Full	8.1	Any recommendation about membrane sweep should include information to women on the potential for the introduction of infection	Thank you for your comments. We did not identify any evidence reporting infection as a result of membrane sweeping. The GDG acknowledged your concerns and considered very carefully the balance of risks and benefits in any management options.
SH	Association of Anaesthetists of Great Britain & Ireland					This organisation was approached but did not respond.	
SH	Association of the British Pharmaceutical Industry (ABPI)					This organisation was approached but did not respond.	

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SH	Association of the British Pharmaceuticals Industry,(ABPI)					This organisation was approached but did not respond.	
SH	Baby Lifeline					This organisation was approached but did not respond.	
SH	Barnsley Hospital NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Barnsley PCT					This organisation was approached but did not respond.	
SH	Bedfordshire PCT					This organisation was approached but did not respond.	
SH	Birmingham Women's Healthcare Trust					This organisation was approached but did not respond.	
SH	Birmingham Women's Hospital	1	pg 27, line 35. Also pg 31, line 47, also pg 77 line 35	Full	2.1,	This dosage regime does not comply with the maunfacturer's recommendations, and does not stratify for parity, or previous section. See below for further comments	Thank you for your comments. NICE does not offer drug dosages and timing in its guidance. Reference is made to the British national Formulary for the appropriate dosage. Please also see revised interpretation section.
SH	Birmingham Women's Hospital	2		Full	8.2.1	Duplication of 'no previous vaginal birth' and 'absence of a previous vaginal birth' in the same sentence	Thank you for your comments. We have revised the recommendations.(see 4.4)
SH	Birmingham Women's Hospital	3	2.2, pg 31, lines 38-40, and pg 75, lines 25 - 27	Full	8.2.1	Unlike all others, no reason has been given for not using intracervical PGs. This should be added	Thank you for your comments. The reasons why a therapy is not recommended are summed up in the evidence statement and interpretation sections, which states that 'intracervical PGE2 is less effective and more invasive than vaginal PGE2.'
SH	Birmingham Women's Hospital	4	, pg 32, lines 16-18	Full	2.2	Amniotomy and oxytocin is a safe and reliable method of induction with similar efficacy to prostaglandins in some groups of women. The guideline excludes this as	Thank you for your comments. The GDG acknowledged that evidence showed amniotomy plus oxytocin had similar efficacy to vaginal PGE2 in women with

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						an option unless there are contraindications to PGs. If women are fully counselled they may still wish to have this option, and some units may prefer this as an option based on cost in some cases. The guideline is effectively excluding the use of an effective intervention – surely there should be a choice	unfavourable cervix. The GDG considered this very carefully and reached a consensus in making the recommendation, taking into consideration the evidence, the invasiveness of amniotomy and IV oxytocin, necessitating continuous EFM and the impact it has on woman's mobility during induction. The revised recommendation states that 'Amniotomy, alone or with oxytocin, should not be used as a primary method of induction of labour unless there are specific clinical reasons for not using vaginal PGE2, in particular the risk of uterine hyperstimulation'
SH	Birmingham Women's Hospital	5	pp 48-49	Full	5.2.	For clarity in this guideline it would be useful to include the timings of induction ie when should induction be offered (?immediate), and how long should conservative management continue (24 hours? 96 hours?). It will save people having to look up both	Thank you for your comments. We have revised the recommendations, clarifying when induction should be carried out.
SH	Birmingham Women's Hospital	6	pg 49, lines 3-6	Full	5.2,	In the previous IOL guideline evidence showed that there was no difference in outcome in this group between PGs and IV oxytocin, and that either could be used. No new evidence has been discussed, but the recommendation now says use PGs. Why?	Thank you for your comments. The GDG considered the evidence very carefully and recommended that vaginal PGE2 should be the preferred method of induction, taking into consideration the convenience of vaginal PGE2, the invasiveness of intravenous oxytocin (intravenous access) which necessitates continuous monitoring and reduced mobility for the woman concerned. Please see recommendations on vaginal PGE2 (5.1.1) and intravenous oxytocin (5.1.6)
SH	Birmingham Women's Hospital	7	pg 52, lines	Full	5.4,	No studies on mechanical methods of induction in this group of women but	Thank you for your comments. We have revised the recommendations.

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			22-23			recommended to be used. Why? – No evidence to support their use	
SH	Birmingham Women's Hospital	8	pg 82, lines 45-46	Full	8.2.4,	Again, the reason should be included in the recommendation for completeness and uniformity	Thank you for your comments. The reasons why a therapy is not recommended are summed up in the evidence statement and interpretation sections. The recommendations focus on what the healthcare professional should or should not do. Please see the evidence statement and interpretation sections (5.1.9)
SH	Birmingham Women's Hospital	9	pg 83, lines 19-20	Full	8.3.1,	If outcomes are comparable, why are PGs recommended in preference? Why should amniotomy be limited to those where PGs are contraindicated. Not supported by the evidence quoted here.	Thank you for your comments. Please see the revised evidence statements and interpretation sections (5.3.1). In women with a favourable cervix, amniotomy was associated with oxytocin augmentation when compared with vaginal PGE2. The GDG considered carefully the invasiveness and potential risks of infection when amniotomy was performed at the start of labour.
SH	Birmingham Women's Hospital	10	pg 84, lines 7-9	Full	8.4.1,	This recommendation is based on one study from the 1980,s. Choice should be allowed here as outcomes are similar and the guideline is excluding a safe and effective method that some may wish to use.	Thank you for your comments. The GDG considered carefully the effectiveness data, the invasiveness of amniotomy and intravenous oxytocin which necessitates continuous monitoring and reduced mobility for the woman concerned, and have revised the 'interpretation section and the recommendations. On balance, the GDG considered that vaginal PGE2 is the preferred method of induction. Amniotomy with intravenous oxytocin should not be used as a primary method of induction. unless there are specific clinical reasons for not using vaginal PGE2, in particular the risk of uterine hyperstimulation.

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SH	Birmingham Women's Hospital	11	pg 85, lines 17-20	Full	8.5,	As intracervical PG and misoprostol are not recommended, there is no evidence with recommended PGs to support the use of mechanical methods, as the reason is less hyperstimulation without FH abnormality and there has been no comparison thus no evidence. They should therefore not be recommended	Thank you for your comments. We have revised the recommendations.(see 5.3.2)
SH	Birmingham Women's Hospital	12		Full	General	The guideline is far too long – it should just concentrate on the efficacy of the various methods and leave the indications etc. to clinicians. We are still left with preferences for vaginal prostaglandins when the evidence only demonstrates benefit in nullips with unfavourable cervices. The subjective advantages in other groups are speculative and induction-delivery intervals are conveniently ignored. Overall, this may not be a major problem but it does impose constraints that may be inappropriate in some circumstances – again clinicians should be given more say on individual cases.	Thank you for your comments. The GDG was given the task to address all the areas outlined in the Scope. The GDG acknowledged your concerns. Our task involved making recommendations based on the best available evidence and the GDG's clinical expertise relating to the areas outlined in the scope. Induction-delivery intervals outcomes were included when these data were available. In making the recommendations, the GDG considered carefully the importance of establishing a dialogue between the woman and the clinician, taking into account the woman's wishes and her clinical situation, forming a partnership in making a decision about the management plan.
SH	Birth Trauma Association					This organisation was approached but did not respond.	
SH	BMFMS					This organisation was approached but did not respond.	

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SH	Bournemouth and Poole PCT					This organisation was approached but did not respond.	
SH	Bradford & Airedale PCT					This organisation was approached but did not respond.	
SH	Bradford Teaching Hospitals NHS Foundation trust					This organisation was approached but did not respond.	
SH	Brighton & Sussex University Hospitals Trust					This organisation was approached but did not respond.	
SH	Bristol Health Services Plan					This organisation was approached but did not respond.	
SH	British Association of Perinatal Medicine					This organisation was approached but did not respond.	
SH	British Maternal and Fetal Medicine Society					This organisation was approached but did not respond.	
SH	British National Formulary (BNF)	1				The BNF has no comments.	Thank you.
SH	Calderdale PCT					This organisation was approached but did not respond.	
SH	CIS'ters					This organisation was approached but did not respond.	
SH	City Hospitals Sunderland NHS Trust					This organisation was approached but did not respond.	
SH	Cochrane Pregnancy & Childbirth Group					This organisation was approached but did not respond.	
SH	Commission for Social Care Inspection					This organisation was approached but did not respond.	
SH	Confidential Enquiry into Maternal & Child Health (CEMACH)					This organisation was approached but did not respond.	
SH	Connecting for Health					This organisation was approached but did not respond.	
SH	Controlled Therapeutics Ltd					This organisation was approached but did not respond.	
SH	Conwy & Denbighshire Acute Trust					This organisation was approached but did not respond.	

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SH	Conwy and Denbighshire NHS Trust					This organisation was approached but did not respond.	
SH	Cotswold and Vale PCT					This organisation was approached but did not respond.	
SH	Cytyc UK Limited					This organisation was approached but did not respond.	
SH	Department of Health	1	line 26-28 page 72 line 44	Full	2.1 8.2.1	The Draft Antenatal Guideline does not appear to mention “membrane sweep” for the 38-week visit. We would query the aspect of telling women of a possible intervention, which may cause “pain and vaginal bleeding” at this stage when, in our view, a large number will go into labour spontaneously without the need to worry about it. We feel that full counselling at 38 weeks for something which may not be necessary could be considered a dissipation of, and have resource implications in, midwifery time.	Thank you for your comments. The GDG considered it important to offer women information relating to the possibility of induction of labour to prevent prolonged pregnancy at 38 weeks antenatal visit, to give women time to consider the options such as vaginal examination for membrane sweeping, before their next scheduled antenatal visit. Women may choose to accept or decline this offer of information. Please see the revised recommendations.
SH	Department of Health	2	line 15-17 and page 38 line 37-39	Full	2.2	In our opinion, information leaflets in every language could have considerable resource implications. Could you please consider widening this to read “in her own language or in a form that she can understand” (such as a pictorial explanation, for those with uncommon languages).	Thank you for your comments. The appropriate way to give information to women is addressed in ‘Woman-centred care’ section of the NICE guideline version.
SH	Department of Health	3	line 25-28	Full	2.2	We believe that it would be better to put off until after term, when it becomes relevant.	Thank you for your comments. We have revised the recommendations. The GDG considered it important to offer women information relating to the possibility of induction of labour to prevent prolonged pregnancy at 38 weeks antenatal visit, to

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							give women time to consider the options such as vaginal examination for membrane sweeping, before their next scheduled antenatal visit. Women may choose to accept or decline this offer of information.
SH	Department of Health	4	page 43 line 35-36	Full	4.1	In our view, this is a good suggestion for the use of research money for the inequalities agenda.	Thank you for your comments. The GDG made a research recommendation to this effect.
SH	Department of Health	5	page 46 line 12-13	Full	5.1	Although it says that there is little evidence that intentional delivery beyond 34 weeks adversely affects outcome, we were of the belief that there was emerging evidence that babies born early (but not very early - ie; 30 to 36 weeks) did less well in the long term than had been previously thought. We feel therefore, that there may well be more evidence in favour of leaving babies there for longer.	Thank you for your comments. The GDG considered this but we did not identify any evidence to support this belief.
SH	Department of Health	6	page 49 line 46-48 and page 50 line 2-4	Full	5.3	We would appreciate clarification of certain points. The first part says that *"labour…in the presence of IUGR* ***may result in severe fetal compromise therefore C/S would be indicated****",* but the recommendation says "In the presence of severe IUGR **with suspected fetal compromise, …**C/S should be performed". In our view, this does not appear to be the same. The initial implication in the text to do C/S for every case of IUGR, rather than those with suspected fetal compromise, has significant resource implications and implications for the woman's reproductive future. We feel that this could be rather imprecise, without real definitions of	Thank you for your comments. We have revised the recommendations to improve clarity.(See 4.7)

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						"severe IUGR", "severe fetal compromise" and "suspected fetal compromise".	
SH	Department of Health	7	page 50 line 36-37 page 52, line 12-13	Full	5.4	Could you please clarify whether relating PND due to uterine rupture just to size of unit is appropriate or could there possibly have been other factors that actually made the difference (such as staffing numbers/ratios)? We are concerned that, stated as a bare fact like this, it could well be misinterpreted in reconfiguration arguments.	Thank you for your comments. We have clarified this in the 'Interpretation of evidence' section, that data from one single study may not be generalisable.
SH	Department of Health	8	Page 54, line 2-3	Full	5.	We feel that it would be helpful if the word "choice" could be used, rather than (or in addition to) the word "request". Also, would it be safer to mention the need for information for the woman, including the risks and benefits of choosing induction of labour when there is no obstetric reason? We would be grateful for clarification.	Thank you for your comments. The GDG disagreed and considered 'Maternal request' is more appropriate. The GDG considered the offering and giving of information important and this is addressed in Chapter 3.
SH	Department of Health	9	page 57,line 21-23	Full	5..9	Could you please consider the inclusion of a recommended dosage? As this is a safety issue, our view is that this guideline should indicate the appropriate dosage, lest clinicians should have difficulty in finding this elsewhere.	Thank you for your comments. NICE does not offer drug dosages and timing in its guidance. Referral to should be made to British National Formulary (BNF) and Summary of Product Characteristics (SmPC) as appropriate.
SH	Department of Health	10	page 66 line 22-23	Full	7.1.5	Could you please consider amending the wording – ie; rather than "using" sexual intercourse, could it perhaps say something to the effect of "there is insufficient evidence to suggest that sexual intercourse should be suggested as a method of cervical priming and labour induction."	Thank you for your comments. The reasons why any therapy is not recommended are summed up in the evidence statement and interpretation sections. The recommendations focus on what the healthcare professional should or should not do.

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							In the interpretation section, it was stated that available evidence did not support the use of sexual intercourse as a method of induction. The GDG have made recommendations that this method should not be used.
SH	Department of Health	11	page 84 line 8-9	Full	8.4.1	Although not advocating the use of ARM and Syntocinon except in specific cases, would you consider that it would be safer still to put in the Syntocinon regime and warnings regarding mulation, etc?	Thank you for your comments. The GDG considered the evidence very carefully and reached a consensus in making the recommendation, taking into consideration, the invasiveness of amniotomy and IV oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned. We have revised the recommendation which now states that: Amniotomy with intravenous oxytocin should not be used as a primary method of induction, unless there are specific clinical reasons for not using vaginal PGE2, in particular the risk of uterine hyperstimulation.
SH	Department of Health	12	page 87, line 28	Full	9.2	In our opinion, it seems to be the wrong approach, to wait for failed induction before reviewing the reason for induction. Could you please consider emphasising this at perhaps the beginning? We feel that it is important to ensure that unnecessary interventions are avoided.	When induction fails, the GDG considered it important, as in all clinical practice, to review the situations for subsequent management options on a case-by-case basis. We have revised the recommendations.
SH	Department of Health	13	page 87 line 35	Full	9.2	In our opinion, the word “execution” seems to be inappropriate. Could you please consider re-wording this to include “if there is delay between the decision to carry out C/S and commencing the operation…”	Thank you for your comments. We have revised the recommendations.
SH	Department of Health, Social Security and Public					This organisation was approached but did not respond.	

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	Safety of Northern Ireland						
SH	Derbyshire Mental Health Services NHS Trust					This organisation was approached but did not respond.	
SH	Det Norske Veritas - NHSLA Schemes					This organisation was approached but did not respond.	
SH	Dudley Group of Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	English National Forum of LSA Midwifery Officers	1	page 72 lines 48 - 49	Full	8.2.1	The recommendation for multiparous women needs to be more specific as to which scheduled visit membrane sweep should be offered. The NICE antenatal guideline schedule for visits for multiparous women indicates that they should be seen at about 41 weeks and we suggest that the wording is changed to “scheduled visit at term/41 weeks”.	Thank you for your comments. We have revised the recommendations.(see 5.2.1)
SH	English National Forum of LSA Midwifery Officers	2	Page 15	NICE	1.6.3	The recommendation for multiparous women needs to be more specific as to which scheduled visit membrane sweep should be offered. The NICE antenatal guideline schedule for visits for multiparous women indicates that they should be seen at about 41 weeks and we suggest that the wording is changed to “scheduled visit at term/41 weeks”.	Thank you for your comments. We have revised the recommendations.(see 5.2.1)
SH	English National Forum of LSA Midwifery Officers	3	Page 10	NICE	1.3.8	The recommendation that maternal request in compelling circumstances should be considered at or after 40 weeks gestation should not be offered as it contradicts what is offered to all other women.	Thank you for your comments. The GDG considered it important that all cases of clinical management involves a dialogue between the woman and the clinician, taking into account the woman’s wishes and her clinical situation. Women are offered information to make informed choice and decision, which must be respected.
SH	English National Forum of	4	page	Full	2.2	The recommendation that maternal	Thank you for your comments. The GDG

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	LSA Midwifery Officers		29 Lines 23 - 24			request in compelling circumstances should be considered at or after 40 weeks gestation should not be offered as it contradicts what is offered to all other women.	considered it important that all cases of clinical management involves a dialogue between the woman and the clinician, taking into account the woman's wishes and her clinical situation. Women are offered information to make informed choice and decision, which must be respected.
SH	Evidence based Midwifery Network					This organisation was approached but did not respond.	
SH	Ferring Pharmaceuticals Ltd	1		Full	1.7	We would like to point out a typographical error on line 46 p24 – please change 'Appendix B' to Appendix D'.	Thank you for identifying this error. We have made amendment.
SH	Ferring Pharmaceuticals Ltd	2		Full	2.1 General	Line 30. We would like to request that Propess® is referred to as "controlled release" rather than "slow release" to be consistent with the approved wording in the SmPC Section 5.2. Please can this wording be consistent throughout the document.	Thank you for your comments. We have made this revision, as and when appropriate, throughout the document.
SH	Ferring Pharmaceuticals Ltd	3		Full	2.2	Line 3 p29. The SmPC for Propess® states, under Section 4.4 (Special warnings and precautions for use), that it should be used with caution in patients with ruptured membranes, whereas prostaglandin gel and tablets are contraindicated.	Thank you for your comments. The GDG recognised that vaginal PGE2 is unlicensed for use in certain circumstances However, vaginal PGE2 has been used for two decades in women with rupture of membranes. We have provided a footnote to inform healthcare professionals when vaginal PGE2 is used: Vaginal PGE2 has been used in UK practice for many years in women with ruptured membranes. However, the SPCs (July 2008) advise that in this situation, vaginal PGE2 is either not recommended or should be used with caution, depending on the preparation (gel, tablet or pessary). Healthcare

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							professionals should refer to the individual SPCs before prescribing vaginal PGE2 for women with ruptured membranes, and informed consent should be obtained and documented.
SH	Ferring Pharmaceuticals Ltd	4		Full	2.2	Line 16 p29. Please note that all vaginal prostaglandin products are contraindicated in women who have had a previous caesarean birth.	Thank you for your comments. The GDG recognised that vaginal PGE2 is unlicensed for use in certain circumstances However, vaginal PGE2 has been used for two decades in women with a history of previous caesarean. We have provided a footnote to inform healthcare professionals when vaginal PGE2 is used in this situation: Vaginal PGE_2 has been used in UK practice for many years in women with a history of previous caesarean section. However, the SPCs (July 2008) advise that the use of vaginal PGE_2 is not recommended in women with a history of previous caesarean section. Informed consent on the use of vaginal PGE_2 in this situation should therefore be obtained and documented.
SH	Ferring Pharmaceuticals Ltd	5		Full	2.2	Line 36 p29. Please note that no vaginal prostaglandin product is licensed to be used in women with intrauterine fetal death.	Thank you for your comments. The GDG recognised that vaginal PGE2 is unlicensed for use in certain circumstances. We have provided a footnote to inform healthcare professionals when vaginal prostaglandins are used in this situation: At the time of publication (July 2008), misoprostol was not licensed for use for labour induction in fetal death in utero in the UK. Informed consent should therefore

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							be obtained and documented.
SH	Ferring Pharmaceuticals Ltd	6		Algorithm	2.5	Algorithm. See attached original algorithm with box containing "VE to assess Bishop score: unfavourable and favourable cervix: Vaginal PGE2 tablet or gel (1st dose) or controlled release pessary" highlighted. For added clarity we suggest this box should be split into two boxes to reflect the different dose application recommendations. The flow diagram instructs the reader to assess progress every six hours to allow subsequent dosing of prostaglandin gel or tablet if no progress. Clearly this is not applicable to the controlled release pessary due to its single application for up to 24 hours at which point it is then necessary to evaluate progress. A separate box for the controlled release pessary with a down arrow straight to the box marked "If no progress following vaginal PGE2 tablet or controlled release pessary but normal EFM: failed induction" will avoid confusion and inappropriate use of the controlled release pessary. Also please note that with Propess® the pessary is able to be retrieved which resolves hyperstimulation within 15 minutes of removal of the insert (Rath W, J. Perinat. Med. 33 (2005) 491-499. The proposed changes are shown in the second algorithm attached with this document. We have coloured the arrows	Thank you for your comments. Please see revised algorithm.

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						red only to highlight the changes.	
SH	Ferring Pharmaceuticals Ltd	7		Full	8.2.1	Please note there is a typographical error on line 17 p76 - reference number 159 should read 160.	Thank you for your comments. The chapters and reference numbers have been re-arranged.
SH	Ferring Pharmaceuticals Ltd	8		Full	8.2.1	Line 7 p76. We note the comment regarding a significantly reduced oxytocin augmentation rate with Propess® in comparison with prostaglandin gel 1-2.5mg. However, we also note that this finding has not been mentioned under the 'Interpretation of evidence' section on page 77, where on line 24 it is stated that "There is no added benefit from slow release products such as PGE2 slow release when compared with PGE2 gel." Additionally please see comment below regarding Appendix C.	Thank you for your comments. We have revised the interpretation section as suggested.
SH	Ferring Pharmaceuticals Ltd	9		Full	8.2.1	Line 24 p76. For clarification it may be useful to mention at the end of the paragraph on line 24 that since the 2001 guidelines on induction of labour was published, the 12 hour formulation of Propess® has been replaced by a 24 hour controlled-release formulation. Dinoprostone is released at a constant sustained rate of 0.3mg per hour (*Lyrenas, Sven et al, in vivo controlled release of PGE2 from a vaginal insert (0.8mm, 10mg) during induction of labour, BJOG, February 2001, Vol 108, pp169-178*).	Thank you for your comments. We made reference to this in the recommendations.
SH	Ferring Pharmaceuticals Ltd	10		Full	8.2.1	Line 25 p 76. The subheading "Costs of vaginal PGE2 tablets and gel" should also include the controlled release pessary (Propess®) in the title.	Thank you for your comments. We have amended the heading.

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SH	Ferring Pharmaceuticals Ltd	11		Full	8.2.1	Line 35 p76. We suggest the paragraph beginning “A simple cost analysis” should also include the fact that the reduced oxytocin augmentation rate associated with Propess® when compared to prostaglandin gel leads to cost savings (see separate comment relating to Appendix C).	Thank you for your comments. We have amended this paragraph in light of changes made to Appendix C which address the concern raised here.
SH	Ferring Pharmaceuticals Ltd	12		Full	8.2.1	Line 8 p77. The sentence beginning “There is no evidence….” does not mention Propess®. We suggest the sentence should include the controlled release pessary as one of the commercially available prostaglandins that do offer benefits to women undergoing induction of labour.	Thank you for your comments. We have revised the text.
SH	Ferring Pharmaceuticals Ltd	13		Full	8.2.1	Line 24 p77 states that “There is no added benefit from slow release products such as PGE2 slow release when compared with PGE2 gel”. This does not reflect the reduced number of dosage applications referred to in lines 21-22 p76 (1.4 v 1.9), nor the benefit of reduced oxytocin augmentation rate when compared to the gel. The 24 hour preparation should have added benefit as it is a single application product that requires only one vaginal examination to be performed when the pessary is inserted. On average two prostaglandin gel and tablet dose applications are needed per induction therefore requiring two vaginal examinations) (El-Shawarby et al, Journal of Obstetrics and Gynaecology, 2006; 26: (7) 627-30). The midwife cost of one vaginal	Thank you for your comments. The resource implications of vaginal examinations are now considered in the cost analysis. As stated in the evidence statement section, the need for oxytocin augmentation between controlled release PGE2 pessaries and PGE2 gel cannot be determined due to the heterogeneity of the studies included and different regimes of augmentation used.

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						examination based on 10 minutes of midwife time (MacKenzie I Z et al, Randomised trial of one versus two doses of prostaglandin E_2 for induction of labour: 2. Analysis of cost, BJOG, September 1997, Vol 104, p1070, Table 1) is estimated to be £8.83 (see attached cost model). A more meaningful measure is the midwife time saving associated with each induction and so for every 6 patients treated with Propess® instead of prostaglandin gel, one hour of midwifery time will be released (10mins x 6). This time can be better utilised providing care elsewhere on a busy obstetric unit. Nationally, the potential saving in midwife time is estimated to be 20,000 midwife hours (120,000 NHS inductions, line 6 page 93),	Please refer to Appendix C for the cost analysis of the 3 vaginal PGE2 preparations recommended.
						El-Shawarby (Reference 160 in the 2008 draft) discusses the downsides of repeated vaginal examinations carried out prior to labour when prostaglandin gel is used. The authors also discuss the problems midwives face with inserting repeat dose applications of the gel due to time problems, and the impact this has on protocol adherence on the unit. The discussion further concluded that the fewer the number of applications required per induction the better staff utilisation will be.	The GDG considered this and other evidence reviewed before making the recommendations.
SH	Ferring Pharmaceuticals Ltd	14		Full	8.2.1	Line 29 p77. Considering the reduced vaginal examinations and significantly reduced oxytocin augmentation rate with Propess® we would like to suggest that this	Thank you for your comments. As stated in the evidence statement section, the need for oxytocin augmentation between controlled release PGE2 pessaries and

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						provides benefits for women and healthcare professionals. Could these benefits be reflected under "Recommendation on vaginal prostaglandins" section?	PHE2 gel cannot be determined due to the heterogeneity of the studies included and different regimes of augmentation used. The GDG considered the recommendations adequate and appropriate. Please see also the revised 'interpretation' section and Appendix C for the cost analysis of the three vaginal PGE2 preparations recommended.
SH	Ferring Pharmaceuticals Ltd	15		Full	Appen dix C	In Appendix C, page 92, there is a discussion on the cost saving associated with reduced oxytocin augmentation. On page 76 under 'Overview of available evidence' (lines 7-9) it states that "Oxytocin augmentation was significantly less likely to be required with Propess (controlled release PGE2 pessaries)(10 mg) when compared with prostin (PGE2 gel 1–2.5 mg) (RR 0.55, 95% CI 0.35 to 0.88, 2 RCTs)." This leads to the 'Evidence statement' given on lines 49-51 which is EL=1++. However, we note that the advantage of using Propess®, in terms of this significantly reduced oxytocin augmentation rate in comparison to prostaglandin gel, has not been considered. It has been highlighted on line 3 p92 "the costs of oxytocin augmentation must be taken into account." We attach a cost model based on the methodology used in the NICE guideline calculations that shows a cost benefit with Propess®. Part of the model takes into	Thank you for your comments. We have revised Appendix C to reflect the concerns raised here.

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						account the reduction in oxytocin augmentation rate compared to prostaglandin gel (23.3% v 41.3%). This part of the model demonstrates there is a saving of at least £2.65 per induction with Propess® when compared with prostaglandin gel.	
SH	Ferring Pharmaceuticals Ltd	16		Full	Appendix C	We note the estimated cost of midwife contact time per hour is shown as £26 under 'Staff time' line 27 page 92 and 'Notes on the estimated cost of midwifery services' line 4 page 93. However, in Appendix D, Table D2, page 97, the cost of a midwife –hospital appointment is shown as £53 per hour. We would like to make you aware of these possibly contradictory midwife costings.	Thank you for your comments. We have amended these costs so that they are consistent. Previously one value was based on per hour costs and the other on per hour of patient contact. All midwife costs are now based on per hour of patient contact.
SH	Ferring Pharmaceuticals Ltd	17		Full	Appendix D	Table D2 p97. Whilst the prices for prostaglandin vaginal gel and tablet are correct in the main body of the text, in Section 8 this table shows incorrect prices for these products at £9.76 per 3mg tablet and £15.25 and £16.80 for the 1mg and 2mg gel formulations. The correct price is £13.28 for both gel and tablet formulations (BNF 54).	Thank you for your comments. We have amended the table so that it reports current drugs costs listed in BNF 54.
SH	Ferring Pharmaceuticals Ltd	18			Docs	 NICE letter calculations 2007 v3.:  IOL algorithm.doc  ltr NICE electronic version Feb08 v2.doc	Thank you

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SH	Gloucestershire Acute Trust					This organisation was approached but did not respond.	
SH	Group B Strep Support	1		Full	General	At GBSS, we're regularly asked by pregnant women whether induction is recommended when intravenous antibiotics are indicated against EOGBS infection but where the Mum is – usually because her labour is expected to be very fast or because she lives a long way from the maternity hospital she's planning to deliver at – unlikely to receive 2+ of 4+ hours of these before delivery. This issue should be addressed in the IoL document.	Thank you for your comments. GBSS in the context of labour induction is not within the remit of this guideline.
SH	Group B Strep Support	2		Full	General	At GBSS, we're regularly asked when the intravenous antibiotics should be given against early-onset GBS infection in her baby when a woman is being induced. This issue should be addressed in the IoL guideline.	Thank you for your comments. GBSS in the context of labour induction is not within the remit of this guideline.
SH	Group B Strep Support	3		Full	General	There's no mention of concerns about membrane stripping in women known to carry group B Streptococcus (GBS), despite there being research which seems to indicate this may be contraindicated (see http://findarticles.com/p/articles/mi_m0CYD/is_20_36/ai_80744157)	Thank you for your comments. GBSS in the context of labour induction is not within the remit of this guideline.
SH	Group B Strep Support	4		Full	Glossary of terms	GBS is mentioned several times in the document but not in the glossary – it should be explained in the glossary	Thank you for your comments. We have revised the Glossary.
SH	Health and Safety					This organisation was approached but did	

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	Executive					not respond.	
SH	Healthcare Commission					This organisation was approached but did not respond.	
SH	Heart of England Acute Trust					This organisation was approached but did not respond.	
SH	Independent Midwives Association					This organisation was approached but did not respond.	
SH	Infermed Ltd					This organisation was approached but did not respond.	
SH	Kirklees Primary Care Trust					This organisation was approached but did not respond.	
SH	La Leche League GB					This organisation was approached but did not respond.	
SH	Leeds PCT					This organisation was approached but did not respond.	
SH	Leeds Teaching Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	Liverpool Women's NHS Trust					This organisation was approached but did not respond.	
SH	Luton & Dunstable Hospital NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Maidstone and Tunbridge Wells NHS Trust					This organisation was approached but did not respond.	
SH	Medicines and Healthcare Products Regulatory Agency (MHRA)					This organisation was approached but did not respond.	
SH	Mental Health Act Commission					This organisation was approached but did not respond.	
SH	Mid and West Regional Maternity Service Liasion Committee (MSLC)					This organisation was approached but did not respond.	
SH	MIDIRS (Midwives Information & Resource Service)					This organisation was approached but did not respond.	

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SH	Midwifery Studies Research Unit	1		Full	general	In general, we believe that this is a well written and fully referenced guideline, which offers a clear and women-centred approach to this topic. We only have one specific comment	Thank you for your comments
SH	Midwifery Studies Research Unit	2		Full	2.2	There is a potential confusion between the statements in lines 25-29 and line 36: the discussion suggested in the former might imply to women that induction of labour is being offered at that stage, and raise the possibility of early labour induction in women's minds. This contravenes the statement in line 36. We are not sure what the consequences of this might be in terms of maternal request for induction of labour before 41+0	Thank you for your comments. We have revised the recommendations to improve clarity.
SH	National Childbirth Trust	1		Full	General	Key points are highlighted in bold.	Thank you for your comments
SH	National Childbirth Trust	2		Full and NICE	General	These draft guideline is, in general, an improvement on the 2001 guideline, in that it points out more clearly that the woman should be able to make her own informed choice, and that all potential risks and complications should be discussed with the her. While this is suggested in the 2001 guidance, it's not laid down in quite the same way. Also the discussion of the woman possibly requiring additional analgesia because induced labours can be more painful is stated more explicitly than in the 2001 guidance.	Thank you and the GDG very much appreciate your comments.
SH	National Childbirth Trust	3		Full and NICE	General	However, we are still concerned that: 1) There is no grading of the recommendations 2) It would be helpful to be more specific	Thank you for your comments. 1) We were advised by NICE that recommendations are no longer graded However, the strength of the evidence

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						about the information which should be given to women regarding the known benefits and harms of options being offered. 3) There is inconsistency regarding recommendations when the research evidence is limited or not available. 4) Some of the details of the evidence available is not reported in the guideline and may be useful to women and clinicians trying to make informed decisions.	appraised was graded (evidence levels) throughout this guideline according to NICE methodology. 2) We have revised the recommendations, which explicitly inform women the risks and benefits of the options offered 3) When research evidence is limited or not available, this is explained in the 'interpretation of evidence' section. Recommendations are made based on the effectiveness data (if any), balance of risks and benefits, the woman's wishes and her clinical situations. 4) We have to strike a balance in presenting evidence relevant to the questions and the details can be found in the evidence tables. We have revised the content where appropriate to reflect this.
SH	National Childbirth Trust	4		**Full and NICE**	**General**	**We believe it is crucial to report the grading/level evidence supporting each recommendation if NICE is to retain its credibility for evidence-based guidelines. Readers need to know if the recommendation is based on high level evidence or whether it is the opinion of the GDG (a good practice point, GPP, in previous guidelines). A great deal of effort goes into assessing the strength of evidence and this appears to be a waste of time if readers are not informed on what basis the recommendation is made. This was particularly problematic in some areas of this draft guideline.**	Thank you for your comments. We were advised by NICE that recommendations are no longer graded. However, the strength of the evidence appraised was graded (evidence levels) throughout this guideline according to NICE methodology.

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SH	National Childbirth Trust	5		Full and NICE	General	It would be helpful to add something to the effect that: "If women ask for information about induction of labour at any stage during pregnancy, they should be told about the general approach to this aspect of care. However, women should be told that they will be given individualised information about induction for post-term pregnancy from about 40 weeks of pregnancy, according to need."	Thank you for our comment. We have revised the recommendations. Please also see revised recommendations on prolonged pregnancy (4.1) and membrane sweeping (5.2.1).
SH	National Childbirth Trust	6		Full	General	It would help to know the number of participants when the individual outcomes are reported, not just the number of participants on the overall systematic review. This is particularly relevant on page 75.	Thank you for your comments. We have added the details requested
SH	National Childbirth Trust	7		Full	General	Two mothers who have recently experienced induction of labour sent their comments which we have included within our text below. One was a mother of three whose first CS was for a failed induction, and she subsequently had two further CSs. The second was a mother of four, who had had two induced labours – one satisfactory in outcome, one not - and two normal deliveries at natural term of pregnancy.	Thank you for your comments.
SH	National Childbirth Trust	8	P7 onwards	Full		There is a missing abbreviation for tocolysis.	Thank you for your comments. We have added tocolysis in the Glossary.
SH	National Childbirth Trust	9	Page 19 line 21	Full	1.1 Introduction	It is also the aim to reduce the number of inductions performed – stated at the implementation of guidelines meeting in	Thank you for your comment. We have revised the text.

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						Dec 2007.	
SH	National Childbirth Trust	10	Page 20 line 40	Full	1.1	How reliable is ultrasound as a method of assessing gestational age? If it is only 80% accurate, this leaves room for a wide margin of error in which it is judged right to do induction.	Thank you for your comment. The GDG considered ultrasound to be more reliable than any other methods available in assessing gestational age.
SH	National Childbirth Trust	11	Page 20 line 42	Full	1.1	To suggest the ultrasound dates '…will take precedence' presumably comes from the clinicians' perspective. Parents often believe the woman's menstrual dates are more accurate, and sometimes couples know the exact date of conception and will work out the most accurate due date from that. It would seem preferable to say: **'..from the latter source often takes precedence from the clinician's perspective though many women are clear about their own due dates'**.	Thank you for your comment. We have taken on your suggestion and amended the text.
SH	National Childbirth Trust	12	Page 20 line 46	Full	1.1	This is a positive statement supporting women's choice and it would be helpful to make this a recommendation as it is rather lost here in such a large document: **"If after discussion of the relevant issues, the woman chooses to decline the offer of labour induction, she must not be made to feel alienated from her healthcare professionals and further discussion is required regarding the measures needed for ongoing monitoring of the pregnancy".**	Thank you for your comment. We have included this as part of the recommendations in the section under 'Prolonged pregnancy'.(4.1)

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SH	National Childbirth Trust	13	Page 21 line 22	Full	1.2	It would help to define “prolonged pregnancy” here.	Thank you for your comment. Definition of prolonged pregnancy is provided in the Glossary and in section 4.1.
SH	National Childbirth Trust	14	Page 27 line 11	Full	2.1	We welcome the recommendation to inform women that induction is likely to be more painful than spontaneous labour, and that it may not succeed.	Thank you very much for your comments.
SH	National Childbirth Trust	15	Page 27 line 11	Full	2.1	It would be helpful also to inform women that prostaglandin induction can produce quite severe pains but not initiate labour (sometimes referred to as prostin pains/false labour pains). Proper pain relief should be available in such circumstances, for example TENS, Entonox etc.	Thank you for your comments. This was addressed in the recommendations, that induced labours maybe more painful than spontaneous labour. Women should be given pain relief appropriate to their pain.
SH	National Childbirth Trust	16	Page 27 line 14	Full	2.1	Page 40 says there is racial variation around the risks identified, and it would seem important to include this here.	Thank you for your comments. The GDG have considered this carefully and made a research recommendation into identifying racial differences in the distribution of such risks.
SH	National Childbirth Trust	17	**Page 27 line 7**	**Full**	**2.1**	**It would be important, when explaining the risks and benefits of induction of labour, to be clear that the Cochrane review is underpowered to assess PNM and there were problems with the methodological quality of some of the included studies, particularly with protocol violations which were as high as 30% and many studies were small with unclear concealment of allocation which can introduce bias.** Gülmezoglu AM, Crowther CA, Middleton P. Induction of labour for improving birth	Thank you for your comments. These methodological details are in the evidence tables and have been added to the text.

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						outcomes for women at or beyond term. *Cochrane Database of Systematic Reviews* 2006, Issue 4.	
SH	National Childbirth Trust	18	**Page 27 line 14**	**Full**	**2.1** **Prolonged pregnancy**	**What women want to know is whether there is a time after which the balance of benefits and harms tips in favour of induction over awaiting spontaneous labour. The answer seems to be there is no good evidence for a specific date, and the decision needs to be made on an individual basis weighing up what evidence there is and the woman's wishes and beliefs.** NB We note that The Cochrane review concludes that "Labour induction should be offered to women after 41 completed weeks". This is non-specific and therefore leaves much open to interpretation. We welcome the clearer guidance for initiation of induction of labour, but feel that it would be helpful to indicate the level of evidence, as the 42^{+0} cut-off is a GPP rather than being based on stronger evidence. **The indicated upper limit of 42^{+0} weeks is likely to be mis-interpreted to mean that inductions need to happen before 42 weeks on safety grounds, yet the Cochrane review was underpowered to assess this and there is no good evidence that benefits outweigh harms.**	Thank you for your comment. The GDG have considered very carefully and have revised the interpretation of evidence and recommendations. The GDG considered that the concept of induction, in the context of this guideline, is to prevent prolonged pregnancy (beyond 42 weeks). There is epidemiological evidence, which we reviewed, to suggest that the risks rise after 42 weeks. The recommendations were made based on the epidemiological data (that the upper limit is after 42 weeks), trial data and health economic analysis which, on balance, induction of labour for prevention of prolonged pregnancy should be offered from 41 weeks onwards.

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						We suggest amending the recommendation to read: **Induction of labour to avoid prolonged pregnancy should <u>usually</u> be initiated between 41+0 and 42+0 weeks gestation, <u>if the woman is agrees with this course of action.</u> The exact timing should take into account the woman's preferences and local circumstances. <u>Women should be informed that there is no clear upper limit for induction of labour based on robust evidence.</u>**	
SH	National Childbirth Trust	19	Page 27 line 26	Full	2.1	The statement that "Membrane sweep should be discussed with women at their 38 week antenatal visit." Seems unnecessarily early and could be very misleading. As there is no statement as to when membrane sweeping is recommended, this may be interpreted as meaning that membrane sweep is being recommended to be undertaken at 38 weeks. It is critical to clarify this. The Cochrane review concludes that membrane sweep should be offered when it is decided to induce labour. Membrane sweep may not be a formal method of induction, but it is an intervention none-the-less. The evidence for undertaking membrane	Thank you for your comments. The GDG considered it important to offer women information relating to the possibility of induction of labour to prevent prolonged pregnancy at 38 weeks antenatal visit, to give women time to consider the options such as vaginal examination for membrane sweeping, before their next scheduled antenatal visit. Women may choose to accept or decline this offer of information. Thank you for your comments. We have revised the recommendations.

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						sweep is across a range of gestational ages. The recommendation would be better as: **"Membrane sweeping can be discussed with women as an option at their 40 week antenatal visit. Women should be informed of the increased chance of going into labour, and effectiveness without the use of formal induction of labour. Women should be informed of the possibility of discomfort, pain or vaginal bleeding from the procedure but also of the discomfort and pain associated with formal induction of labour."** Boulvain M, Stan C, Irion O.Membrane sweeping for induction of labour. *Cochrane Database of Systematic Reviews* 2005, Issue 1.	
SH	National Childbirth Trust	20	Page 27 line 30	Full	2.1	The Cochrane review identifies a statistically significant increase in hyperstimulation with FRH changes, PPH and maternal side effects with the use of PGs, these should be acknowledged in this recommendation. Women need this information. Kelly AJ, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. *Cochrane Database of Systematic Reviews* 2003, Issue 4	Thank you for your comments. We have revised the recommendations that women should be informed of the risks of uterine hyperstimulation when vaginal PGE2 is used to induce labour.
SH	National Childbirth Trust	21	**Page 27 line**	**Full**	**2.1**	**Women and partners are likely to be utterly confused at the suggestion that**	Thank you for your comments. The GDG acknowledged your concerns and have

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			41 And page 28 line 1			**they go home and await spontaneous labour when induction has failed. Either induction is required for the increased safety of baby or mother, or it is not. Parents are likely to be able to understand that induction has not worked and they can wait a little and try again and can go home in the meantime, but to go home to await spontaneous labour does not make sense.**	revised the recommendations which clarify the options the woman can choose.
						A mother of four commented: *"Failed induction must be recognised as an extremely distressing circumstance for the mother and appropriate support should be offered."*	The GDG acknowledged these comments.
SH	National Childbirth Trust	22	**Page 28 line 7**	**Full**	**2.2**	A mother of four commented: *"Information should be offered **honestly**. Too often the risks of an induced labour to both mother and infant are understated, if not also underestimated."*	Thank you and the GDG acknowledged these comments
SH	National Childbirth Trust	23	**Page 28 line 9**	**Full**	**2.2**	**It will be important to let women know about the increased risk of hyperstimulation with fetal heart changes, PPH and maternal side effects that come with PCG induction, something which the GDG seems to have glossed over in these guideline recommendations.**	Thank you for your comments. Please see revised recommendations. To inform women of the risks of uterine hyperstimulation associated with the use vaginal PGE2 is integrated into the recommendations for vaginal PGE2 (5.1.1)
SH	National Childbirth Trust	24	Page 28 line 16	Full	2.2	Some women cannot read (even their own language); in these cases, alternative formats will be required.	Thank you for our comment. We have revised the recommendations. The appropriate way to give information to

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							women is addressed in 'Woman-centred care' section of the NICE guideline version.
SH	National Childbirth Trust	25	**Page 28 line 25**	**Full**	**2.2**	A mother of four commented: "*One thing I would stress is the distress induction causes, especially when a precipitate labour is induced. It is vitally, vitally important that women undergoing IoL get one-to-one, named, and, if possible, known midwifery care. By a midwife with experience of all that can go wrong and confident enough to deliver a baby in situ on the AN ward and then resuscitate it if necessary. All the while still comforting and supporting the mother."* **We feel this should be a recommendation**	Thank you and the GDG acknowledged these comments. However, service configuration is not within the remit of this guideline.
SH	National Childbirth Trust	26	Page 28 line 26	Full	2.2	Whilst discussion of induction of labour at 38 weeks provides women with more time to gather information and think about their choices, it seems very early for such discussions. We suggest the 40 week appointment would be better. A mother of four commented: "*There is no need to raise the issue of induction at 38 weeks. Induction is a major medical intervention which should not be brought into the arena of preparation until it is clear that it may be warranted. If we do not discuss the potential arrangements for CS unless warranted, neither should we do so for induction – the two methods of intervention should be represented as on a*	Thank you for our comment. The GDG considered that women should be offered this information at 38 weeks. If the woman chooses to accept the information, she will have time to consider the options such as vaginal examination for membrane sweeping prior to labour induction before her next antenatal visit. We have revised the recommendations. Please also see recommendations for prolonged pregnancy (4.1) and membrane sweeping. (Chapter 3 and 5.2.1).

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						par with one another. To introduce the subject of induction at 38 weeks – when pregnancy might quite reasonably be expected to continue to 42 weeks, is undermining to the mother and denotes a presupposed lack of confidence in her ability to give birth without assistance. This is particularly true when in relation to primagravidae." We suggest this recommendation reads: **"The possibility of induction of labour should be discussed with the woman at her 40 week appointment."** This still gives her time to consider the options.	
SH	National Childbirth Trust	27	Page 28 line 34	Full	2.2	We welcome the recommendation that "Women with uncomplicated pregnancies should be given every opportunity to proceed to spontaneous labour" and that "Induction of labour should not routinely be offered to women before 41 weeks gestation (41^{+0})." Though it would read better as **"Induction of labour should not be offered routinely to women before 41 weeks gestation (41^{+0})."**	Thank you for your comments. We have reworded the recommendations to improve clarity.
SH	National Childbirth Trust	28	**Page 28 line 37**	**Full**	**2.2**	**See comments above.**	Thank you for your comments. We have reworded the recommendations to improve clarity.

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SH	National Childbirth Trust	29	Page 29 line 12	Full	2.2	Where is the evidence that induction is safe for women with a previous CS? There appears to be no high level evidence to support this recommendation and much is based on low level evidence and small studies. It would help to include this within the recommendation (if grading of evidence is not to be given) as many will assume that this is based on good evidence. If induction is to be supported it would seem appropriate to recommend the information that women should receive e.g. the increased risk of hyperstimulation. It seems that particular care needs to be give to all women with a previous CS because all have an increased risk of rupture – small though the risk may be. A mother of four commented: "*Women with previous CS should **never** be offered Prostin induction when it is patently true that a violent reaction – and concomitant vicious and rapid labour – can occur in any woman with the use of Prostin gel."* However, we think that women should be given a choice as the risk of rupture is very low We suggest the recommendation would be better as: **"Women with a previous caesarean section may be offered induction of labour on an individual basis taking into account the woman's circumstances**	Thank you for your comments. The GDG acknowledged your concerns and have revised the recommendations as suggested, taking into account the woman's wishes and her clinical situation, the risks and the need for informed decision.

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						and wishes. Women should be informed of the increased risk of hyperstimulation and uterine rupture with induction of labour"	
SH	National Childbirth Trust	30	P29 Line 18	full	2.2	A mother of four commented: "*No woman with a history of precipitate labour should be offered induction. As my case shows, the chance of grave injury to both mother and baby is just too great."*	Thank you and the GDG acknowledged these comments.
SH	National Childbirth Trust	31	Page 29 line 26	Full	2.2	Where is the evidence that drugs to induce labour are safe for breech babies? What of the risk of hyperstimulation of breech babies? This seems to be a 'Good practice point' and again it needs to be included within the recommendation that this has no good evidence base to support it, women need to know this. Maybe again these decisions needs to be made on an individual basis taking into account the woman's circumstances and wishes. This recommendation would be better as: **"Women with a breech presentation may be offered induction of labour on an individual basis taking into account the woman's circumstances and wishes. Women should be informed of the lack of evidence for induction with breech babies and the increased risk of hyperstimulation with induction of labour"**	Thank you for your comments. The GDG acknowledged your concerns and have revised the 'interpretation of evidence' section and the recommendations, taking into account the woman's wishes and her clinical situation, the risks and the need for informed decision.

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SH	National Childbirth Trust	32		Full	2.2 Page 29 line 42	We welcome the recommendation "Induction of labour should not be undertaken when there is suspected fetal macrosomia alone" as we understand that the assessment of the size of the baby is very inaccurate.	Thank you for your comments. Please see revised recommendations.
SH	National Childbirth Trust	33	Page 29 line 46	Full	2.2	A mother of four commented: "*Induction of labour should only ever be carried out on the labour ward with appropriate facilities for delivery, as labour may well be precipitate and this cannot be predicted. Many hospitals, such as the one I was in, have antenatal facilities quite far removed from the labour ward proper."* It seems that close midwifery support and careful monitoring for an hour after any formal induction would be helpful. We feel this should be incorporated within one of the recommendations. Women also need information on the risk of hyperstimulation with induction of labour.	Thank you and the GDG acknowledged these comments. The risks of induction of labour are part of the information giving to women as addressed in Chapter 3. To inform women of the risks of uterine hyperstimulation associated with the use vaginal PGE2 is integrated into the recommendations for vaginal PGE2 (5.1.1)
SH	National Childbirth Trust	34	Page 29 line 48	Full	2.2	This would read better as "…vaginal prostaglandins should be offered in the morning…' not '…should be initiated…' as this implies women do not have a choice.	Thank you for your comments. We have revised the wording of the recommendation.
SH	National Childbirth Trust	35	Page 30 line 15	Full	2.2	A mother of four commented: "*The document seems to indicate, but does not make abundantly clear, that induction of labour may result in the need for pain relief (for Prostin pains) <u>prior to</u> the commencement of active labour."*	Thank you for your comments. This was addressed in the recommendations, that induced labours maybe more painful than spontaneous labour. Women should be given pain relief appropriate to their pain.

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SH	National Childbirth Trust	36	**Page 30 line 16**	**Full**	**2.2**	This recommendation would be better as: Women undergoing induction of labour should be prepared for the likely pattern of labour and supported withy one-to-one midwifery care from a known midwife, as induction can be a difficult experience.	Thank you for your comments. The GDG acknowledged the importance of support to women undergoing induction of labour. However, how the service is delivered is outside the remit of this guideline.
SH	National Childbirth Trust	37	Page 30 line 17	Full	2.2	Some women give birth following induction using only their own coping mechanisms and no additional analgesics. I think this should be made clear – as information for both parents and clinicians. So it would read better as "…This can range from women using their own coping strategies to epidural analgesia'.	Thank you for your comments. We have revised the recommendations as suggested.
SH	National Childbirth Trust	38	Page 30 line 25	Full	2.2	It seems too early, at 38 weeks, to be discussion induction, this will worry many women unnecessarily. We suggest these discussions wait for the 40 week appointment.	Thank you for your comments. The GDG considered that women should be offered this information at 38 weeks. If the woman chooses to accept the information, she will have time to consider the options such as vaginal examination for membrane sweeping prior to labour induction before her next antenatal visit.
SH	National Childbirth Trust	39	Page 30 lines 28 to 46	full	2.2	**As a general principle re:** ***Herbal supplements*** ***Acupuncture*** ***Homeopathy*** ***Castor oil, hot baths and enemas*** ***Sexual intercourse*** ***Breast stimulation***	Thank you for your comments. The GDG have revised the recommendations, where appropriate.

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						…The phrase 'should not be used' is inappropriate as women have the right to use any of these activities if they choose to do so. A more appropriate phrase would be 'should not be offered or recommended', or in the case of sexual intercourse and nipple stimulation simply 'should not be recommended"!	
SH	National Childbirth Trust	40	**Page 30 line 45**	**Full**	**2.2**	**However, see below:** **It is critical for the GDG to explain the basis on which they are making their recommendations as there appears to be considerable inconsistency. Breast stimulation is not recommended because of limited, conflicting evidence and safety concerns, yet PGs are recommended when there is evidence of increased hyperstimulation with FHR changes, increased PPH and increased side effects for women. Also sexual intercourse, homeopathy etc. are not to be used because of insufficient evidence, yet induction for women with previous CS and for breech babies is supported though there seems similarly insufficient evidence.**	Thank you for your comments. The interpretation of the evidence for breast stimulation is problematic because of poor quality studies involving a heterogenous population from developing countries. The methods and frequency of breast stimulation were inconsistent across the studies reviewed, making guidance on this method difficult. Please see the revised 'interpretation of evidence' section. The GDG did not make a recommendation. A research recommendation was made. The GDG considered the evidence very carefully and acknowledged that the evidence for the use of vaginal PGE2 for the primary outcome of 'vaginal delivery not achieved within 24 hours' is based on a small sample size; but vaginal PGE2 were significantly more effective than placebo in improving cervical status, reducing oxytocin augmentation and meconium-staining in studies with bigger sample.

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							In addition, the GDG reached a consensus that, on clinical grounds, and on the basis of comfort, convenience and acceptability to the woman (less invasive than other methods such as amniotomy and intravenous oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned during induction), vaginal PGE2 is the preferred method of induction of labour. In the case of induction for women with previous caesarean or breech presentation, the GDG considered it important that all cases of clinical management involves a dialogue between the woman and the clinician, taking into account the woman's wishes and her clinical situation. Women are offered information to make informed choice and decision, which must be respected. Available evidence did not support the use of sexual intercourse and homeopathy etc as methods of induction. The GDG did not recommend herbal supplements, homeopathy, acupuncture to be offered on the NHS.
SH	National Childbirth Trust	41	Page 30 line 45	Full	2.2	The decision whether to use breast stimulation or not needs to be made within the context of the alternatives available. If this is vaginal PGs with its known increased risks, women should at least be given the information so they can make informed choice.	Thank you for your comments. The evidence reviewed was based on comparisons between breast stimulation and no breast stimulation and intravenous oxytocin. We did not identify any trial data which compared breast stimulation with vaginal PGE2.

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							The interpretation of the evidence for breast stimulation is problematic because of poor quality studies involving a heterogenous population from developing countries. The methods and frequency of stimulation were inconsistent across the studies reviewed, making guidance on this method difficult. Please see the revised 'interpretation of evidence' section. The GDG did not make a recommendation. A research recommendation was made. We have revised the recommendations for vaginal PGE2 that women should be informed of the risks of uterine hyperstimulation associated with the use vaginal PGE2 (5.1.1).
SH	National Childbirth Trust	42	Page 31 line 19	Full	2.2	**Membrane sweeping should be considered <u>as the first level of intervention,</u> whenever induction of labour is offered.** **In primigravidae membrane sweeping should be offered at their 40 week antenatal visit and again at 41 weeks if they have not gone into spontaneous labour. For multiparous women the offer should be made at their scheduled <u>post-40 weeks</u> antenatal visit.**	Thank you for your comments. We have revised the recommendations as suggested.
SH	National Childbirth Trust	43	**Page 31-32**	**Full**	**2.2 Chapte r 7 and Chapte**	**The presentation of the recommendations in these chapters is confusing. Chapter 7 is 'Methods of induction of labour of uncertain efficacy' and Chapter 8 'Effective**	Thank you for your comments. We have re-structured the chapters and put all the induction methods in one chapter (Chapter 5).

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					r 8	**methods of cervical priming/labour induction.** **Yet in chapter 8 there are recommendations <u>not to use</u>:** • **Oral prostaglandins;** • **IV prostaglandins;** • **Extra-amniotic prostaglandins,** • **Intracervical prostaglandins** • **IV oxytocin alone** • **Misoprostol** • **Mifepristone** • **Amniotomy on an unfavourable cervix** **These would seem more appropriate in Chapter 7 such that when the reader scans their eye across chapter 8, there are only effective methods being recommended. However:** **It would be easier for the reader if:** **1) the recommended methods of induction are reported first in chapter 7** **2) all the methods that are not recommended either because they are proven do more harm than good, or there is insufficient evidence to recommend them, are reported in chapter 8.** **The readers can then easily see what is recommended and what is not. Chapter 8 might be called 'Ineffective or unproven methods of induction of labour' or 'Methods of induction which are ineffective or of unproven efficacy'.**	

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SH	National Childbirth Trust	44	Page 32 line 3	Full	2.2	Intravenous oxytocin: It would help to be specific here and say when IV oxytocin can be used, i.e. with what other interventions?	Thank you for your comments. Intravenous oxytocin is not recommended because it is less effective than vaginal PGE2 as an induction method. (5.1.6) The revised recommendation states that 'Amniotomy, alone or with oxytocin, should not be used as a primary method of induction of labour unless there are specific clinical reasons for not using vaginal PGE2, in particular the risk of uterine hyperstimulation' (5.1.7)
SH	National Childbirth Trust	45	Page 32 line 17	Full	2.2	This recommendation would be better worded as **"Amniotomy plus IV oxytocin should only be offered when there are specific contraindications for the use of vaginal prostaglandins (e.g…….), when the head is not high and when the balance of benefit and harms weighs in favour of this intervention."**	Thank you for your comments. Please see revised interpretation of evidence 'section and the revised recommendations.(5.1.7)
SH	National Childbirth Trust	46	Page 32 line 24	Full	2.2	A mother of four commented: "*In my case, and, I suspect others, there would not have been time for tocolysis for hyperstimulation. I delivered, from a standing start (ie - no discernible dilation though some effacement) to baby-on-the-floor in less than one hour. Assuming I had had a decent midwife, it would have been a good half hour before it could have been established that baby was indeed on the way, and, once that was established, all that could have been done would have*	Thank you and the GDG acknowledged these comments.

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						been to comfort me as best as possible and to get ready to catch the inevitably high speed baby. Some coaching to help me avoid the hideous injury I sustained would also have been beneficial. However, this section may be referring to even more extreme reactions than mine - when the uterus clamps down and stays down. In such cases an antidote would be necessary, I imagine."	
SH	National Childbirth Trust	47	Page 32 line 27	Full	2.2	See comments on failed induction from previously	Thank you for your comments.
SH	National Childbirth Trust	48	Page 32 line 47	Full	2.2	This warning to avoid amniotomy if there is a high head needs to come with the recommendation where amniotomy is being suggested.	Thank you for your comments. We have now put this recommendation in the cord prolapse section. (8.3)
SH	National Childbirth Trust	49	Page 33 line 1	Full	2.2	This warning to check there is no low-lying placenta before doing a membrane sweep needs to come with the recommendation to offer membrane sweep, otherwise it may be missed.	Thank you for your comments. This forms part of the recommendations in the section of cord prolapse. (8.3)
SH	National Childbirth Trust	50	Page 33 line 41 to 42	full	2.4	We back this recommendation. The number of weeks gestation 'ON ITS OWN 'should not be the driving force behind the decision to induce.	Thank you for your comments.
SH	National Childbirth Trust	51	P35	Full	research recs	If induction is suggested for breech presentation babies then studies need to be done to check the safety of this recommendation	Thank you for your comments. Please see the 'interpretation of evidence' section for the reasons behind making the recommendations, taking into account the woman's wishes, her clinical situation, the risks and the need for informed decision.

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SH	National Childbirth Trust	52	P35	Full	research recs	Women want to know if sexual intercourse and breast stimulation are effective methods of bringing labour on as these are methods they have control of themselves and do not rely on healthcare professionals to undertake. This sort of control is really important to many women. This would seem more important than research on mechanical methods and has more a valid rationale for its use.	Thank you for your comments. Please see revised recommendations. The GDG acknowledged the importance of women able to take control themselves using these methods. We have made a research recommendation for each of these two methods.
SH	National Childbirth Trust	53	Page 37 line 35 and 41 and 49	Full	3	For the first study the guideline provides information about when the study was carried out, e.g. 1977. It would help to have the same information for the other surveys (which seem to be 1977, 1987 and 2005). This may be important when considering the type of care offered at these times and in these settings.	Thank you for your comments. We provided this information in this section to highlight the currency of the limited evidence available. We have put in this information for the other two studies. The GDG highlighted the limited status of available evidence in the 'interpretation of evidence' section to support the recommendations which were based on good practice.
SH	National Childbirth Trust	54	Page 38 line 29	Full	3	We think this wording is wrong. We believe it should read – "Women, for whom induction of labour is proposed, should receive the following information:".	Thank you for your comments. With the help of the NICE editors, we have reworded the recommendations to improve clarity.
SH	National Childbirth Trust	55	Page 38 line31	Full	3	We think this bullet point will read better as "The risks and benefits of induction and the alternatives." – thus taking the word "management" out.	Thank you for your comments. With the help of the NICE editors, we have reworded the recommendations to improve clarity.
SH	National Childbirth Trust	56	Page 38	Full	3	Similarly this bullet point would read better as "The alternative options should	Thank you for your comments. With the help of the NICE editors, we have

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			line36			induction be declined" and not 'alternative management options'.	reworded the recommendations to improve clarity.
SH	National Childbirth Trust	57	Page 38 line 47	Full	3	Care needs to be taken when discussing prolonged pregnancy at 38 weeks. The information will turn out to be not relevant to most of these women and they need to know this is the case to help to put the information into context. We think discussion at 40 weeks would be better.	Thank you for our comment. The GDG acknowledged this but considered that women should be offered the information at 38 weeks. If the woman chooses to accept the information, she will have time to consider the options such as vaginal examination for membrane sweeping prior to labour induction before her next antenatal visit. Women may choose to accept or decline this offer of information.
SH	National Childbirth Trust	58	Page 40 line 4	Full	4.1	This question would be better as 'What are the risks of pregnancy beyond 42 weeks'	Thank you for your comment. We have reworded the question, to give a bigger and fuller picture of the evidence base.
SH	National Childbirth Trust	59	Page 40 line 31	Full	4.1	What were the confounders that were adjusted for in this assessment? Readers will be interested to know.	Thank you for your comments. The confounders reported were: placental abruption, congenital abnormality, low birth weight, birth weight < 10th centile, meconium passage, fever, maternal body mass index≥30 and maternal age ≥30. These have been added to the text.
SH	National Childbirth Trust	60	Page 40 line 33	Full	4.1	The statement that '… a policy of induction to prevent prolonged pregnancy at 41 to 42 weeks may not be appropriate for all women' suggests that a research recommendation should be included regarding timing of induction of labour for Asian women. Ought there to be a recommendation regarding more careful monitoring of this group as a GPP?	Thank you for your comments. The GDG have considered this carefully and made a research recommendation.
SH	National Childbirth Trust	61	Page 40 line	Full	4.1	To say n= 19 RCTs is confusing as n is usually used to indicate the number of	Thank you for your comments. We have made global amendments in the

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			37			events. It would seem better to say 'One systematic review (19 RCTs involving 7948 women…'	guideline.
SH	National Childbirth Trust	62	Page 40 line 40	Full	4.1	We think it is not quite accurate to report the all-cause mortality here, as one study in this systematic review (Hannah 1992) excluded seven women after randomisation because of major congenital anomolies. So the all-cause mortality will be inaccurate, as will the statement 'Excluding deaths due to congenital abnormalities (n=3)…' though there seems to be no information about which groups babies were withdrawn from in the Hannah 1992 study. So there is pooling of different outcomes is misleading. Hannah ME et al. Induction of labor as compared with serial antenatal monitoring in post-term pregnancy. NEJM 1992;326:1587-92.	Thank you for your comments. In making the recommendations, the GDG acknowledged that the Hannah study was insufficiently powered to detect the change in perinatal mortality. However the GDG was concerned with the epidemiological evidence of increasing perinatal mortality as pregnancy progresses.
SH	National Childbirth Trust	63	Page 40 line 40	Full	4.1	There is reporting bias here in giving details to the deaths in the expectant management group but not the induction group. Also these differences may have been due to chance because this assessment is underpowered, it would also be helpful to discuss the reasons for the deaths and whether they were potentially avoidable.	Thank you for your comments. We have amended the text to put in these details. In making the recommendations, the GDG considered the evidence very carefully and acknowledged that the Hannah study was insufficiently powered to detect the change in perinatal mortality. However the GDG was concerned with the epidemiological evidence of increasing perinatal mortality as pregnancy progresses.

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SH	National Childbirth Trust	64	Page 41	Full	4.1	It would help considerably to quote here the guidance in the Antenatal care guideline about monitoring women who choose to go beyond 42 weeks.	Thank you for your comments. We have made this reference to the Antenatal care guideline and quoted this ANC recommendation to support our recommendations.
SH	National Childbirth Trust	65	Page 41, line 36	Full	4.1	It would help to say in the evidence statement that the increased risk identified it very small.	Thank you for your comments. We already stated this in the evidence statement section (4.1): 'Compared with expectant management, induction of labour after 41 completed weeks is associated with fewer perinatal deaths. The absolute risk is extremely small.'
SH	National Childbirth Trust	66	Page 42 line 39	Full	4.1	It would be important to say in the evidence statement that the size of the study on which the mortality was derived, it was really too small to give confident findings. Also it would help to contact the authors of the Hannah 1992 study to ask about the deaths due to congenital abnormalities which were excluded so they can be added back to give an accurate report of the all-cause PNM.	Thank you for your comments. In making the recommendations, the GDG acknowledged that the Hannah study was insufficiently powered to detect the change in perinatal mortality. However the GDG was concerned with the epidemiological evidence of increasing perinatal mortality as pregnancy progresses.
SH	National Childbirth Trust	67	Page 42 line 40	Full	4.1	It would help to report the risk of PNM in terms of the number of deaths and the number in the group – so that this can be seen in context. The data is really too small to give a reliable estimate.	Thank you for your comments. We have put in these details. We agreed that the data is too small to give a reliable estimate.
SH	National Childbirth Trust	68	**Page 42 Line 46**	**Full**	**4.1**	**The evidence statement that 'Commonly women were reluctant to accept expectant management' does not do justice to the 31% of women who**	Thank you for your comments. We conducted a very comprehensive search and found very limited evidence

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						did want to await spontaneous labour and not be induced. This evidence seems to be from a limited source with a sample of only 500 women and does not give the full picture. There must be more evidence on women's views of induction. Many women do not want to be induced and want to start on their own and they get very anxious as they go over their dates. On the other hand, some women get tired of waiting – there is a huge variation which this evidence statement does not capture.	relating to women's views and experience of labour induction.
						Even within this one study, 31% of women not wanting induction of labour and happy to go with awaiting spontaneous labour, is still a large percentage of women even if more in this particular sample did not want to wait. We see many women who do not want induction of labour and these are women having their first babies. Women who have had induction are even more determined too try to avoid it next time. Is there more evidence about what women thought who had had induction and those who had expectant management – this is helpful information for women choosing what to do.	We have clarified this in the 'Interpretation of evidence' section. As suggested, the majority would still want to await spontaneous labour.
SH	National Childbirth Trust	69	Page 42 line 48	Full	4.1	"The differences in outcome between each of the three induction strategies for first offering induction of labour is small. However, it is clear that inducing labour	The three induction strategies are referred to in the section on the 'health economic evaluation' immediately preceding the evidence statement.

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						does produce additional health gain and that this health gain can be achieved within a threshold willingness to pay of £20,000." It would help to explain what this statement means. What are the 3 induction strategies, what is the health gain, has anyone assessed the adverse effects if induction which is how many women dislike intensely being induced so there is a psychological impact here, and what does a threshold willingness to pay of £20,000 mean?	This section also refers the reader to Appendix D for more detail of this analysis. This Appendix makes reference to the psychological impact and notes that, although this was not factored into the model (for reasons outlined), the GDG considered this in making recommendations. NICE uses a threshold of £20,000 per QALY to assess cost-effectiveness with interventions with an ICER (see glossary) of less than £20,000 per QALY being considered a cost-effective use of NHS resources. We have amended the text to try and clarify what is meant by a 'willingness to pay threshold of £20,000'.
SH	National Childbirth Trust	70	Page 43 line 17	Full	4.1	The evidence statement "Women may be unwilling to accept conservative management if their pregnancy goes beyond 41 weeks". This does not really reflect what we know about women's views of induction of labour. There is still, even within this study, a large proportion of women who do want to await spontaneous labour and this needs to be reflected in either the evidence statement, the GDG interpretation and recommendations. If the GDG had found evidence of what women thought of induction after they had had it then	Thank you for your comments. We have revised the evidence statement. We have clarified this in the 'Interpretation of evidence' section, as suggested.

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						women's views would have been reported differently. The evidence statement would be better as **"Some women may be unwilling to await spontaneous labour when they go beyond 41 weeks, and others will be keen to avoid induction and will be happy to wait".** We are sure if the GDG looks further it will find additional information on women's views of induction of labour.	We conducted a very comprehensive search and found very limited evidence relating to women's views and experience of labour induction.
SH	National Childbirth Trust	71	**Page 43 line 21**	**Full**	**4.1**	**We welcome the recommendation that "Women with uncomplicated pregnancies should be given every opportunity to proceed to spontaneous labour". and "Induction of labour should not routinely be offered to women before 41 weeks gestation". We believe these should be a main recommendation.**	Thank you for your comments. Please also see revised recommendations.
SH	National Childbirth Trust	72	Page 43 line 31	Full	4.1	The research should also look at all these aspects of induction of labour as well as awaiting spontaneous labour. There is no evidence reported here of women views once they have had either induction or expectant management. There seems to be a bias against expectant management, see Menticoglou & Hall 2002. Menticoglou SM, Hall FH. Routine	Thank you for your comments. We conducted a very comprehensive search and found very limited evidence relating to women's views and experience of labour induction. The GDG had considered this paper. The

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						induction pf labour at 41 weeks gestation: nonsensus consensus. BJOG 2002;109:485-491.	GDG's recommendations are consistent with the views expressed, namely that pregnancy should not usually extend beyond 42 weeks.
SH	National Childbirth Trust	73	Page 44	Full	4.1	It would be helpful in the 'Table of maternal complications' to know the positions women were in during labour, as with bigger babies are likely to need more room and this will come with women not on their backs.	Thank you for your comments. We found no data reporting the women's positions during labour in these studies.
SH	National Childbirth Trust	74	Page 45	Full	4.1	It would be helpful for readers to know that definitions vary between different countries so direct comparisons cannot be made.	Thank you for your comments. Definitions of complications were not reported in all studies. The GDG considered that definitions of caesarean section, instrumental vaginal delivery, maternal haemorrhage >500 ml, antepartum stillbirth, intrapartum stillbirth, perinatal death are self-explanatory.
SH	National Childbirth Trust	75	**Table 4.1 and Table 4.2**	**Full**	**4.1 4.2**	**It would help to know for the figures in these tables, how many of the babies were induced and how many went into spontaneous labour. We would expect many of those born after 41 weeks wil have had induction of labour.**	Thank you for your comments. Data from these studies included both induced labours and spontaneous labours. These details are available in the evidence tables. We have also added this information in tables 4.1 and 4.2.
SH	National Childbirth Trust	76		**Full**	**5.1 Induction of labour for specific circumstance**	**An additional 'Important circumstance' to add here is 'When the baby shows signs of compromise'. Is it better to induce (with its increased risk of hyperstimulation)? Is it better to wait do CS? If induction is better which method is best?** **One of the criticisms of the Hannah study of 1992 (which provides most of**	Thank you for your comments. The situation 'When the baby shows signs of compromise' referred to was one of the important outcomes considered with every method of labour induction (see page 7) in this guideline and under each of the specific circumstances, and this outcome was reported as and when data were available.

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
					s **Page 46**	**the evidence to the meta-analysis on timing of induction and makes the data questionable) is that women in the expectant management arm, when it was decided they should be induced because of fetal compromise, were not given prostaglandins when they were induced but amniotomy and IV oxytocin. This was based on views of methods of induction at the time. This guideline could see what evidence there is to help such decisions for the future.**	Thank you for your comments. The GDG acknowledged the limitation of the Hannah study. The GDG considered this evidence very carefully and recommended that in this updated guideline, vaginal PGE2 is the preferred method of induction, taking into account the invasiveness of other methods such as amniotomy and IV oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned during induction.
SH	National Childbirth Trust	77	Page 49 line 48	Full	5.3	There seems to be no evidence presented here to support the recommendation of caesarean section for IUGR at term. The evidence statement says (line 39-40) "..there is insufficient evidence to determine whether immediate or delayed delivery is beneficial (EL = 1+].	Thank you for your comments. We have revised the recommendations to improve clarity.
SH	National Childbirth Trust	78	Page 50 line 9	Full	5.4	It would be better to say "…pregnant women with a previous caesarean section may be considered for possible induction of labour." rather than "…may require induction of labour" as this wording seems to fit better with informed choice.	Thank you for your comments. We have amended the text as suggested.
SH	National Childbirth Trust	79	Page 50 line 31	Full	5.4	It would be better to say "…women with one pervious caesarean birth who choose to labour at or after 41 weeks gestation,…" rather than '…attempted vaginal birth…' which is undermining for women.	Thank you for your comments. We have amended the text as suggested.
SH	National Childbirth Trust	80	**Page 50 line**	**Full**	**5.4**	**Interpretation of the evidence: The evidence for better outcomes in units**	Thank you for your comments. We have clarified this in the 'Interpretation of

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
			14			**over 3000 births is underpowered for assessing death. There was 1 death reported due to uterine rupture in each group, and the difference comes only because this was out of 1300 births in units < 3000 births, and out if 4700 births un units > 3000 births. This is also data from non-randomised studies and not good enough evidence to be used to make this statement.**	evidence' section, that data from one single study may not be generalisable.
SH	National Childbirth Trust	81	Page 50 line 14	Full	5.4	It is difficult to see how induction can be so clearly recommended for women with previous caesarean section when there is increased hyperstimulation and uterine rupture, all-be-it from non-randomised studies. Surely women need to be given the evidence we have, and each needs to be decided in individual basis taking women's views into account.	Thank you for your comments. We have amended the recommendations as suggested, taking into account the woman's wishes, her clinical situation, the risks and the need for informed decision.
						One mother of three reported to us *"Anecdotally many women have all their babies naturally at 42 or 43 weeks without fail, some seemingly just take longer to finish than others. And also who is to say that the dates were correct in any case. But have the findings regarding uterine rupture and IoL changed so that it is now considered perfectly safe to induce a woman with a scarred uterus? I know I wouldn't have been at all happy to be induced post c/sect based on what I have read previously.*"	Thank you and the GDG acknowledged these comments.
						It seems that the evidence since 2001	Please see the revised recommendations

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						confirms the increased risk of uterine rupture. Women need to be given this information and as estimate of the risks involved of the different possible course of action, including awaiting spontaneous labour.	(4.4)
SH	National Childbirth Trust	82	**Page 52 line 19**	**Full**	**5.4**	**The evidence for induction of labour for women with a previous caesarean section seems poor with a probable increase in hyperstimulation.** **The evidence seems to suggest that if women are offered induction when they have had a previous CS, women should be informed that the chance of another CS may be greater than is they waited for spontaneous labour, though the evidence is not of the best quality (see line page 50 line 46 and 53).** **So this recommendation would read better as:** **"Women with a previous caesarean section may be offered induction of labour, caesarean section or awaiting spontaneous labour, and the benefits and harms of these three options need to be discussed. Decisions should be made on an individual bases taking women's views into account."** **"Women with a previous caesarean section should be informed that induction of labour will increase the**	Thank you for your comments. We have amended the recommendations as suggested, taking into account the woman's wishes, her clinical situation, the risks and the need for informed decision.

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						chance of another caesarean section compared with awaiting spontaneous labour and may also increase the chance of hyperstimulation, though the evidence is not of the best quality."	
SH	National Childbirth Trust	83	Page 54 line 16	Full	5.7	When reporting the findings of the Term breech trial, it is helpful to also mention that when assessed in the Cochrane review, the authors state "However, the results of this review cannot be generalized to settings where women labour and birth at home, or where caesarean section is not readily available, or to methods of breech delivery which differ materially from the clinical delivery protocols used in the trials reviewed. Also, as is the case with all randomized controlled trials, uncertainty remains as to whether results may be generalised to those who would not have agreed to randomization because of strong views as to their preferred method of delivery."	Thank you for your comments. Issues other than methods and circumstances related to induction of labour were not within the scope of this guideline. The GDG made the recommendation in this case, taking into account the woman's wishes, her clinical situation, the risks and the need for informed decision.
SH	National Childbirth Trust	84	Page 54 line 37	Full	5.7	It is very misleading to say "It reported no significant difference in the rates of vaginal birth (66% vs. 68% vs. 0%), caesarean birth (34% vs. 32% vs. 100%) and Apgar scores <7 ". There is surely a significant difference in vaginal birth and caesarean section where there is elective CS (where vaginal birth is 66% vs. 0% and CS is 35% vs,. 100%) and the morbidity associated with CS, particularly in a subsequent pregnancy and birth.	Thank you for your comments. We have revised the text for clarity.

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
SH	National Childbirth Trust	85	Page 55 line 3	Full	5.7	It is important to recommend that women are told that the evidence on induction of labour with a breech presentation is poor, hence women should be supported in their choice for induction or waiting for spontaneous labour. e.g. **"When indications for birth arise in the presence of a breech presentation women should be informed of the lack of good quality evidence comparing awaiting for spontaneous labour, induction or caesarean section. These decisions need to be made on an individual basis".**	Thank you for your comments. We have revised and reworded the recommendations, taking into account the woman's wishes, her clinical situation, the risks and the need for informed decision.
SH	National Childbirth Trust	86	Page 55 line 3	Full	5.7	It would be better if this recommendation offered women choice as well: **"When indications for birth arise in the presence of a breech presentation but elective caesarean section is declined and women have chosen induction over awaiting spontaneous labour, the normal protocol for methods of induction for cephalic presentation can apply"**	Thank you for your comments. We have revised the recommendations.
SH	National Childbirth Trust	87		Full	7 & 8 Chapte rs	The layout of these chapters is very confusing. Chapter 7 is 'Methods of induction of labour of uncertain efficacy' and Chapter 8 'Effective methods of cervical priming and labour induction'. See earlier comments on page 31-33 of the Full GL.	Thank you for your comments. We have re-structured the chapters and put all the induction methods in one chapter.

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SH	National Childbirth Trust	88	Page 64 line 38	Full	7.1.2	There seems to be just one RCT on acupuncture that can provide information and with just 56 women involved, we would suggest that the evidence statement reads **"There is insufficient evidence on the use of acupuncture as a form if cervical ripening and induction of labour"** or as for homeopathy **"Available evidence was poor and insufficient to determine the effectiveness of acupuncture as a method of labour induction".** And that the recommendation reads: **"Acupuncture as a method of cervical ripening and labour induction is not recommended because there is insufficient evidence."**	Thank you for your comments. The reasons why any therapies are not recommended are summed up in the evidence statement and interpretation sections. (see 5.2.3) The recommendations focus on what the healthcare professional should or should not do. Available evidence did not support the use of acupuncture. The GDG have made recommendations not to offer this method on the NHS.
SH	National Childbirth Trust	89	Page 66 line 20	Full	7.1.5	Telling couples not to have sexual intercourse is an intervention in people's lives. There is insufficient evidence to support this dictat. The guideline recommends the use of drugs that are known to increase hyperstimulation with FHR changes, and this is inconsistent with banning a natural activity of people's lives which stimulate the natural release of hormones. We suggest this recommendation reads: **"Women should be informed that semen contains prostaglandins but there is insufficient evidence to say whether sexual intercourse will**	Thank you for your comments. The reasons why any therapy is not recommended are summed up in the evidence statement and interpretation sections. The recommendations focus on what the healthcare professional should or should not do. Available evidence did not support the use of sexual intercourse as a method of induction. The GDG have made recommendations not to use this method. However, we acknowledged that women might use this method as they wish.

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						stimulate labour in women who are beyond their due dates."	
SH	National Childbirth Trust	90	Page 66 line 37	Full	7.1.6	How small was the trial? It would help to report the number of participants and to report the reference..	Thank you for your comments. We have put in these details.
SH	National Childbirth Trust	91	**Page 66 line 37**	**Full**	**7.1.6**	**This systematic review is too small to provide any meaningful data on PNM and yet this seems to be reason for recommending breast stimulation should not be used.** **The Cochrane review points out that evidence on PNM comes from one study based in India of 57primagravida, high-risk women, >37 weeks gestation all with reactive NST (non stress tests). Indications for IOL were post-term pregnancy (n=25), hypertension (n=22) and IUGR (n=10). 17 women were allocated to breast stimulation, 20 to no intervention and 20 to oxytocin. Breast stimulation was for one hour three times a day changing every every 10 minutes. PNM of 3/17 is high (0/20 in no intervention group and 1/20 in the oxytocin group), but is this high for high risk women in India? The study was also poor quality in that there was no information on randomisation nor on concealment allocation. In addition, the study was stopped early because of reported outcome data – and this contributes additionally to the high risk of bias in this study.**	Thank you for your comments. The GDG considered the evidence very carefully. There is evidence that breast stimulation maybe effective as a method of induction. However, interpretation of the results was problematic due to the poor quality of the studies reviewed and the heterogenous populations including high risk women from developing countries. There is inconsistency in the timing, methods and frequency of breast stimulation described in these studies, making guidance in this method difficult. The GDG made a research recommendation.

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						The Cochrane review concludes: "There are valid reasons not to use breast stimulation in a high-risk population until safety issues have been evaluated further. However, this form of care is likely to be beneficial in a low-risk population. The 84% reduction in postpartum haemorrhage, seen in the breast stimulation arms of two trials including 300 women, may be of particular interest to women and their healthcare providers in developing countries." and "Breast stimulation appears beneficial in terms of a reduction in the number of women not in labour after 72 hours, and a reduction in postpartum haemorrhage. Until safety issues have been fully evaluated it should not be considered for use in a high-risk population." **Whilst the GDG does not need to agree with the Cochrane authors, we believe they should provide further justification for saying breast stimulation should not be used. Though possible, it is hard to see a natural release of oxytocin (through self or partner administered breast stimulation) being more dangerous that an intravenous drip of oxytocin which is known to increase hyperstimualtion. There is inconsistency in the use of evidence in this guideline.** **We suggest this recommendation**	

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						should read: **"Women should be informed that there is some evidence to say that breast stimulation, on one breast at a time, will increase the chance of the baby being born within 72 hours and reduce postpartum haemorrhage though more studies are needed to be confident of this."** Kavanagh J, Kelly AJ, Thomas J. Breast stimulation for cervical ripening and induction of labour. *Cochrane Database of Systematic Reviews* 2005, Issue 3. Art. No.: CD003392. DOI: 10.1002/14651858.CD003392.pub2.	
SH	National Childbirth Trust	92	Page 72 line 45	Full	8.2.1	When women are being told of the possible discomfort and vaginal bleeding with membrane sweep they also need to be informed of the advantages. It is important not to assume that this information will be given automatically.	Thank you for your comments. Please see revised recommendations.(Chapter 3)
SH	National Childbirth Trust	93	Page 72 line 46	Full	8.2.1	We think the recommendation should read **"Membrane sweep should be offered to women when ever induction of labour is being offered. The pros and cons should be explained to women, particularly with respect to the outcomes with other methods of induction."**	Thank you for your comments. We have revised the recommendations.(Chapter 3 and 5.2.1)

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SH	National Childbirth Trust	94	Page 72 line 47	Full	8.2.1	What is the evidence that primagravida women should be offered membrane sweep at 40 weeks? This is not in keeping with the guidelines recommendation that "Women with uncomplicated pregnancies should be given every opportunity to proceed to spontaneous labour" and that "Induction of labour should not routinely be offered to women before 41 weeks gestation (41^{+0})." Normal pregnancy lasts until 42 weeks, so what is the justification for intervening before then? The Cochrane review concludes: "For women thought to require induction of labour a reduction of the use of more formal methods of induction could be expected. For women near term 37-40 weeks gestation, in an uncomplicated pregnancy, there seems little justification for performing routine sweeping of the membranes." This does not equate to saying that at 40 weeks women should be offers membrane sweeping, it says that where induction is being considered then women should be offered membrane sweeping – this according to the guideline should be after 42 weeks when prolonged pregnancy is present by definition. Or maybe when the women agree to induction this is the first method to be tried – this would solve the problem of trying to make one size fits al recommendation. The one study looking at membrane sweep after 40 weeks where not having given birth at 48 hours was assessed, showed a significant	Thank you for your comments. There is evidence that membrane sweeping is effective in increasing the rate of spontaneous labour and reducing the need for formal induction. The GDG considered that, based on the evidence, information about membrane sweeping, with the risks and benefits involved should be offered to women at 38 weeks. Women can choose to accept or decline this offer of information. If women choose to accept this information at 38 weeks, they will have time to consider this option before their next scheduled antenatal visit. We have revised the 'Interpretation of evidence' section and the recommendations.

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						benefit from membrane sweeping compared with no intervention (Allott HA, Palmer CR. Sweeping the membranes: a valid procedure in stimulating the onset of labour?. *British Journal of Obstetrics and Gynaecology* 1993;**100**:898–903.)	
SH	National Childbirth Trust	95	Page 72, line 47	Full	8.2.1	Women should be informed that membrane sweep is as likely to stimulate labour that prostaglandins. Boulvain M, Stan C, Irion O.Membrane sweeping for induction of labour. *Cochrane Database of Systematic Reviews* 2005, Issue 1. Art. No.: CD000451. DOI: 10.1002/14651858.CD000451.pub2.	Thank you for your comments. This information is included in the introductory paragraph for membrane sweeping. Please also see revised recommendations.
SH	National Childbirth Trust	96	Page 72 line 52	Full	8.2.1	Future research should assess the benefits of membrane sweep being used instead of prostaglandins for induction. Women's views should be sought around both these interventions.	Thank you for your comments. The GDG have made a research recommendation.
SH	National Childbirth Trust	97	Page 75 line 52	Full	8.2.1	It is misleading here not to report the number of women in the individual parts of this systematic review as it gives the impression that all the outcomes are based on 10,039 women when in fact 'Vaginal delivery not achieved within 24 hours (which is the outcome which shows of the intervention works or not) is only on a study of 345 women with favourable cervix and 39 women with unfavourable cervix.	Thank you for your comments. We have added the details requested

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
SH	National Childbirth Trust	98	**Page 77 line 107**	**Full**	**8.2.1**	**There seems to be no evidence to support using prostaglandins with an unfavourable cervix an there is only one study of 39 women and there was no significant difference between vaginal prostaglandin and placebo/no treatment RR 0.88 (95% CI 0.67-1.15). There seems therefore no evidence to support the statement "Prostaglandins, administered vaginally as gel, tablet or slow-release pesseries, are the induction method of choice, irrespective of cervical status and parity."** Kelly AJ, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. *Cochrane Database of Systematic Reviews* 2003, Issue 4.	Thank you for your comments. The GDG considered the evidence very carefully and acknowledged that the evidence for the use of vaginal PGE2 for the primary outcome of 'vaginal delivery not achieved within 24 hours' is based on a small sample size; but vaginal PGE2 were significantly more effective than placebo in improving cervical status, reducing oxytocin augmentation and meconium-staining in studies with bigger sample. In addition, the GDG reached a consensus that, on clinical grounds, and on the basis of comfort, convenience and acceptability to the woman (less invasive than other methods such as amniotomy and intravenous oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned during induction), vaginal PGE2 is the preferred method of induction of labour.
SH	National Childbirth Trust	99		Full	Genera l	**It appears that only two studies looked at whether prostaglandins were effective at inducing labour as only 2 studies assessed 'Vaginal delivery not achieved within 24 hours'. This is the main outcome that should have been assessed – to answer the question 'does it work?'** **One study involved 59 women with unfavourable cervix (Bishop < 5)**	Thank you for your comments. The GDG considered the evidence very carefully and acknowledged that the evidence for the use of vaginal PGE2 for the primary outcome of 'vaginal delivery not achieved within 24 hours' is based on a small sample size; but vaginal PGE2 were significantly more effective than placebo in improving cervical status, reducing oxytocin augmentation and meconium-staining in studies with bigger sample.

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						allocated into 3 groups: prostglandins, placebo and oxytocin. This study found for 'Vaginal delivery not achieved within 24 hours': **PG = 15/19 = 78% so a success rate of 22%** **Control = 18/20 = 90% so a success rate of 10%** **(Ulnsten 1985. Archives of Gynecology 1985;236;243-8)** **The other study was in 345 women with favourable cervices (Bishop >4).** **'Vaginal delivery not achieved within 24 hours':** **PG = 21/180 = 12%, so success rate of 88%** **Ctrl =165/165 = 100%, so success rate = 0%** **(Egarter 1989. Gynecologic and Obstetric Investigation 1989;27:6-9)** **The Egarter study is very surprising that none of the control group achieved birth within 24 hours when all these women had favourable cervix, and this study did not report on the methods used so methodological quality is questionable especially since the groups were not even with 180 in the PG group and 165 in the control group. Yet, this is the study on which all the weight of using prostaglandins for IOL is held.** **Women need to be informed of the**	In addition, the GDG reached a consensus that, on clinical grounds, and on the basis of comfort, convenience and acceptability to the woman (less invasive than other methods such as amniotomy and intravenous oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned during induction), vaginal PGE2 is the preferred method of induction of labour.

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						strength of evidence on which PG for IOL is being offered. It is very dubious and hard to believe that in a systematic review of over 10,000 women, only one study of 365 women, with high risk of methodological bias shows PG to be an effective drug for inducing labour. Kelly AJ, Kavanagh J, Thomas J. Vaginal prostaglandin (PGE2 and PGF2a) for induction of labour at term. *Cochrane Database of Systematic Reviews* 2003, Issue 4.	The rationale for making the recommendation is explained in the 'interpretation of evidence' section. The GDG acknowledged your concerns and considered very carefully the balance of risks and benefits in any management options.
SH	National Childbirth Trust	100		**Full**	General	I have looked at the Cochrane review of 'Breast stimulation for cervical ripening and induction of labour' (Kavanagh, Kally and Thomas, 2005) since replying to the consultation on Induction of Labour. The authors conclude that 'this form of care is likely to be beneficial in a low-risk population'. There seems therefore no reason why women should be advised against nipple stimulation. Indeed, the opposite would seem to be the case for low risk women. The studies generally prescribed three hours of nipple stimulation per day. Women in their own homes using nipple stimulation informally are unlikely to be using a 'dose' of this magnitude. Any possible risks of them stimulating their nipples are therefore likely to be small.	Thank you for your comments. The GDG considered the evidence very carefully. There is evidence that breast stimulation maybe effective as a method of induction. However, interpretation of the results was problematic due to the poor quality of the studies reviewed and the heterogenous populations including high risk women from developing countries. There is inconsistency in the timing, methods and frequency of breast stimulation described in these studies, making guidance in this method difficult. A research recommendation was made.
SH	National Patient Safety Agency					This organisation was approached but did not respond.	

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SH	National Perinatal Epidemiology Unit	1		Full	General	We found the guideline easy to read, well signposted and clear.	Thank you and the GDG very much appreciate your comments.
SH	National Perinatal Epidemiology Unit	2	lines 20-22	Full	1.1	We were confused by this paragraph. Presumably this refers to the need for a review of the guideline rather than the scope of the guideline itself. It implies that the sole purpose of the review is to reduce the incidence of unsuccessful inductions leading to caesarean section.	Thank you for your comment. We have revised the text.
SH	National Perinatal Epidemiology Unit	3	lines 38-44	Full	2.1	We feel this section should be reworded. As it is, it implies that only if the justification for induction is unclear should the condition of the pregnancy be reappraised in order to plan subsequent management. There will be a number of women with a 'failed induction' who are being induced for clear reasons e.g. at 41 weeks for avoidance of prolonged pregnancy, in whom continuation of the pregnancy could legitimately be reassessed.	Thank you for your comments. We have revised the recommendations.
SH	National Perinatal Epidemiology Unit	4	p29 Lines 22-24	Full	2.2	Could the GDG provide some examples of 'exceptional circumstances' for the benefit of the lay reader?	Thank you for your comments. We have given examples of these 'exceptional circumstances' in the introductory paragraph, for example, partners soon to be posted abroad in armed Forces.
SH	National Perinatal Epidemiology Unit	5	p32 lines 28-34	Full	2.2	See comment above for section 2.1 lines 38-44	Thank you for your comments. We have revised the recommendations to improve clarity.
SH	National Perinatal Epidemiology Unit	6		Full	2.5	Algorithm section 'Induction not recommended'. Could IUGR and suspected macrosomia be further qualified within the algorithm e.g. severe IUGR with suspected fetal compromise or suspected macrosomia (EFW>90th centile)	Thank you for your comments. Please see revised algorithm.
SH	National Perinatal Epidemiology Unit	7		Full	4.1	The meaning of the figures in the studies from Denmark are not immediately clear.	Thank you for your comments. Each section within Table 4.1 and 4.2

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					Table 4.1	Could this be clarified e.g. 37-41 weeks, 82 maternal complications.	refers to maternal complications and perinatal complications respectively. In this instance, it means there were 82 caesarean births/1000 births between 37 to 41 weeks.
SH	National Perinatal Epidemiology Unit	8		Full	4.2 Table 4.2	See comment above for table 4.1	Thank you for your comments. Each section within Table 4.1 and 4.2 refers to maternal complications and perinatal complications respectively. In this instance, it means there were 82 caesarean births/1000 births between 37 to 41 weeks.
SH	National Perinatal Epidemiology Unit	9	p48 lines 38-41	Full	5.2	It would be helpful to know the grad of evidence behind the intrapartum care guideline recommendation	Thank you for your comments. We have revised this section. The recommendations behind the Intrapartum Care guideline was based on systematic reviews of RCTs (EL=1+]
SH	National Perinatal Epidemiology Unit	10	p49 lines 46-48	Full	5.3	This statement is made on the basis of very little, if any, evidence. Potentially this may result in a number of women undergoing caesarean section and not being allowed to labour. It may also have medico-legal implications. We would suggest that the GDG define IUGR more clearly in this context e.g. growth below the 10th centile in the presence of umbilical Doppler flow abnormalities.	Thank you for your comments. IUGR and SGA were defined in the introduction of section 4.7.
SH	National Perinatal Epidemiology Unit	11	p75 line 7	Full	8.2.1	What was the total number of women included in these trials?	Thank you for your comments. We have put in the total number of women included added this information.
SH	National Perinatal Epidemiology Unit	12	p83 lines29 -31	Full	8.4.1	What was the total number of women included in these trials?	Thank you for your comments. These details have been added. Please see revised text.
SH	National Public Health Service - Wales					This organisation was approached but did not respond.	

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SH	National Treatment Agency for Substance Misuse					This organisation was approached but did not respond.	
PR	NCCHTA (1)	1		Full		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)**	Please see responses below.
PR	NCCHTA (1)	2				None apparent, this work is comprehensive and has used relevant and appropriate material. The process is appropriate.	Thank you for your comments.
PR	NCCHTA (1)	3				Evidence base changes are applied to the work ie to reduce unsuccessful inductions of labour at or near term.	Thank you for your comments.
PR	NCCHTA (1)	4				Ranges of difference in Clinical practice is acknowledged as are improvements in outcomes resulting from application of evidence.	Thank you for your comments.
PR	NCCHTA (1)	5				**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).**	Please see responses below.
PR	NCCHTA (1)	6				Appears to be an extensive review of the literature.	Thank you for your comments.
PR	NCCHTA (1)	7				methods and application appear to have been conducted to generate an appropriate level of evidence for the recommendations.	Thank you for your comments.
PR	NCCHTA (1)	8			1	Interesting that women with breech presentations are included as most advice is (after Hannah report in 2003/4) that these women undergo caesarian delivery	Thank you for your comments. Issues related to induction of labour in breech presentations are within the scope of this guideline.

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						by choice if cephalic inversion is unsuccessful.	
PR	NCCHTA (1)	9				**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.**	Please see responses below.
PR	NCCHTA (1)	10			1 & App B	The question posed by HEcs is appropriate and forms the basis upon which many decisions are taken in obstetrics now.	Thank you for your comments.
PR	NCCHTA (1)	11				Analysis illustrates the cost-effectiveness of induction methods and potential savings from each decision -tree.	Thank you for your comments.
PR	NCCHTA (1)	12				Qalys are not likely to be a useful measure to underpin modeling in these circumstances as long term studies are insufficient.	Thank you for your comments. QALYs are the preferred measure of NICE for economic evaluation in clinical guidelines. Also, as perinatal death is an outcome (with a very large concomitant QALY loss) we believe that our use of QALY was appropriate.
PR	NCCHTA (1)	13				**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?**	Please see responses below.
PR	NCCHTA (1)	14				Recommendations appear to be based on the major findings with adequate justification	Thank you for your comments.
PR	NCCHTA (1)	15				All aspects of evidence available appear to have been considered.	Thank you for your comments.
PR	NCCHTA (1)	16				The findings are in line with professionals' expectations of best practice and therefore based on current understandings of practice and standardised circumstances.	Thank you for your comments.

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PR	NCCHTA (1)	17				**3.2 Are any important limitations of the evidence clearly described and discussed?**	Please see responses below.
PR	NCCHTA (1)	18				Where appropriate, the design, methodology and generalisability of relevant studies is described and discussed. Health economic data and findings are applied through the section. This may be emphasised more if there were a section attributable to these findings.	Thank you for your comments.
PR	NCCHTA (1)	19				**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.**	Please see responses below.
PR	NCCHTA (1)	20				Points of issue appear from a sound argument. the report is written in an easy read style. where complex issues are raised these are dealt with in a logical manner with an evidence based outcome.	Thank you for your comments.
PR	NCCHTA (1)	21				Recommendations are justified.	Thank you for your comments.
PR	NCCHTA (1)	22				**4.2 Please comment on whether the research recommendations, if included, are clear and justified.**	Please see responses below.
PR	NCCHTA (1)	23				Recommendations for further research are comprehensive clearly stated and justified.	Thank you for your comments.
PR	NCCHTA (1)	24				**Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.**	Please see responses below.
PR	NCCHTA (1)	25				A rise in teen pregnancies and confinements mean there may be an age	Thank you for your comments. Issues relating to labour induction in this guideline

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						related issue for delivery with induction. This is not addressed in research.	applied to **all** women undergoing induction, as specified in the scope.
PR	NCCHTA (2)	1		Full		**1.1 Are there any important ways in which the work has not fulfilled the declared intentions of the NICE guideline (compared to its scope – attached)**	Please see responses below.
PR	NCCHTA (2)	2			General	The work has fulfilled the declared intentions	Thank you for your comments.
PR	NCCHTA (2)	3				**2.1 Please comment on the validity of the work i.e. the quality of the methods and their application (the methods should comply with NICE's Guidelines Manual available at http://www.nice.org.uk/page.aspx?o=guidelinesmanual).**	Thank you for your comments. This guideline was developed in accordance with the guideline development process outlined in the NICE Technical manual. http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/theguidelinesmanual2007/the_guidelines_manual_2007.jsp
PR	NCCHTA (2)	4			General	I could not refer to the NICE Guidelines Manual as the web page given above is 'temporarily unavailable'. However, the methods used appear to be excellent. Any problems with their application are noted in subsequent sections	Thank you for your comments.
PR	NCCHTA (2)	5				**2.2 Please comment on the health economics and/or statistical issues depending on your area of expertise.**	Please see our comments below.
PR	NCCHTA (2)	6			General	The effects of different treatments on a particular outcome are sometimes reported as being 'similar', with no data given. In such cases we don't know whether the RR was near 1, or whether it was quite different from 1, with wide confidence intervals. It may be that the authors have generally reported when this was so, but it would be helpful if they could	Thank you for your comments. To strike a balance between presenting too much or too little data, summary statistics of primary outcomes rather than all outcomes are presented when appropriate. These details are provided in the evidence tables.

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						check this, and replace 'similar' by 'no evidence of difference' where confidence intervals are wide around a RR different from 1.	
PR	NCCHTA (2)	7			7.1.2	An example. In section 7.1.2 (acupuncture) a small RCT is reported, with the statement that there was no significant difference between the two groups in maternal and fetal outcomes; no data is given. In fact spontaneous labour occurred in 70% of women in the acupuncture group vs 50% in the controls (p=0.12), and caesarean section occurred in 17% vs 39% respectively (p=0.07), suggesting a distinct difference. On this basis (unless there is evidence for huge bias in this study!) the recommendations made about acupuncture should be amended (see my comments in section 3.1 and 4.2)	Thank you for your comments. We have added these data details into the text. The differences in these outcomes (spontaneous labour and caesarean rate), however, were not statistically significant, with very wide confidence intervals. The GDG considered the evidence from one RCT with small sample to be insufficient to determine the effectiveness of acupuncture as an induction agent. However, the GDG revised the recommendation and made a research recommendation.
PR	NCCHTA (2)	8				**3.1 How far are the recommendations based on the findings? Are they a) justified i.e. not overstated or understated given the evidence? b) Complete? i.e. are all the important aspects of the evidence reflected?**	Please see responses below.
PR	NCCHTA (2)	9				My comments below refer only to problems - otherwise I judge the recommendations to be justified and complete	Thank you for your comments.
PR	NCCHTA (2)	10			7.1.2	Acupuncture, evidence statement reads: 'Available evidence suggests that acupuncture is not effective in cervical priming/induction of labour'. This is not accurate (see my comments above). Rather, there is insufficient evidence to determine the effectiveness of	Thank you for your comments. We agreed. Please see revised recommendation.

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						acupuncture.	
PR	NCCHTA (2)	11			7.1.2	Acupuncture recommendation, states 'Acupuncture as a method of cervical priming and labour induction should not be used because evidence shows it to be ineffective.' Rather, there is insufficient evidence.	Thank you for your comments. We agreed. Please see revised text. The GDG was advised by NICE editors that the reasons why acupuncture (or any therapy) is not recommended are summed up in the evidence statement and interpretation sections. The recommendations focus on what the healthcare professional should or should not do. The GDG have revised the recommendation and made a research recommendation.
PR	NCCHTA (2)	12			8.2.1	In vaginal PGE2 subsection, the effect of repeat doses of PGE2 (gel or tablet) is not stated either in the overview of available evidence, or in the evidence statements. Nevertheless several statements about the effects of repeat doses are made in the interpretation of evidence section, and in the recommendations.	Thank you for your comments. The GDG agreed that the use of vaginal PGE2 should be in accordance with the Manufacturers' instruction as, stated in the summaries of Products Characteristics. We have revised the text.
PR	NCCHTA (2)	13			8.2.1	Vaginal PGE2 subsection, interpretation of evidence section states 'There is no added benefit from slow release products such as PGE2 slow release when compared with PGE2 gel.' This contradicts the evidence statement: 'Compared with PGE2 gel, oxytocin augmentation was less likely to be needed with the use of controlled release PGE2 pessaries'.	Thank you for your comments. We have revised this section.
PR	NCCHTA (2)	14			8.2.1	Vaginal PGE2 subsection, interpretation of evidence states 'There is no evidence that products inserted in the vagina other than the commercially available 2 mg gel or 3 mg tablets offer any benefits.' But slow-release pessaries are later recommended	Thank you for your comments. We have amended the section.

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						(correctly).	
PR	NCCHTA (2)	15			8.2.1	Vaginal PGE2 subsection. Interpretation of evidence. 'In women with an unfavourable cervix undergoing cervical priming, 2 mg PGE2 gel or 3 mg tablet once was associated with…an increased likelihood of maternal side effects'. The side effects should be enumerated	Thank you for your comments. Please see revised interpretation section. The side-effects in this case referred to uterine hyperstimulation with FHR changes.
PR	NCCHTA (2)	16			8.2.1	Vaginal PGE2 subsection. The final evidence statement, and the Interpretation of evidence section state that costs between PGE2 tablet, gel and slow release pessaries are comparable/ roughly similar at 2007 prices. There is a contradictory opinion (in relation to the same prices) in the evidence overview, which states: 'The drug cost of the slow release pessary tablet is greater than that of either the tablet or the gel - £30 per pessary compared with £26.56 per dose of either tablet or gel.'	Thank you for your comments. We have changed the wording to make it consistent and to reflect changes made to Appendix C.
PR	NCCHTA (2)	17			8.2.1	Vaginal PGE2 subsection. Evidence statement that 'uterine hyperstimulation with FHR changes and the need for oxytocin augmentation were less likely with the use of PGE2 gel (2.5– 5 mg) when compared with PGE2 suppositories/pessaries (3–5 mg).' This statement is true with respect to hyperstimulation, but not so for the need for oxytocin augmentation. (Oxytocin augmentation is stated in evidence overview to be less likely to be required with tablets compared with	Thank you for your comments. The suppositories and the pessaries related in the studies are different. The comparison between vaginal PGE2 *gel* and suppositories (**not** pessaries) showed a significant association with uterine hyperstimulation with FHR changes. There were no data for oxytocin augmentation. The comparison between vaginal PGE2 *tablet* and suppositories (**not** pessaries) showed a significant association with oxytocin augmentation. There were no

Status	Organisation	Order no.	Page Line no.	Ver-sion	Sec-tion	Comment	Response
						suppositories/pessaries and with slow-release pessaries compared with gel).	data for uterine hyperstimulation with FHR changes. Comparison between vaginal PGE2 *tablet* and controlled release pessary showed a significant association with oxytocin augmentation. Other maternal and fetal outcomes were comparable between vaginal PGE2 *tablet* and controlled release pessary. We have made correction in the text, in clarifying suppositories and controlled release pessaries.
PR	NCCHTA (2)	18			8.2.1	Intra-cervical PGE2. States that IC PGE2 was significantly associated with vaginal birth within 24 hours …and a reduced need for caesarean birth (RR 0.88, 95% CI 0.77 to 1.01, 27 RCTs) when compared with placebo/no treatment.' The reduction in risk of caesarean birth is not statistically significant.	Thank you for your comments. We have revised the text.
PR	NCCHTA (2)	19			8.2.3	Oral misoprostol, evidence statement. 'Using oral misoprostol (200 µg) rather than intracervical PGE2 women were more likely to achieve vaginal birth within 24 hours and less likely to require oxytocin augmentation.' I cannot find the evidence for this.	Thank you for your comments. We have checked the evidence. This was an error. There was no significant difference in maternal and fetal outcomes between oral misoporatol (200 microgram) and intracervical PGE2. We have amended the text.
PR	NCCHTA (2)	20			8.2.3	Vaginal misoprostol evidence statement. 'Vaginal misoprostol (50–150 µg) was more likely than vaginal prostaglandins to produce a favourable cervix within 24 hours, achieve delivery within 24 hours, cause uterine hyperstimulation and meconium-stained liquor. Women given vaginal misoprostol 30–75 µg were likely to require oxytocin augmentation.' I cannot	Thank you for your comments. We have checked the evidence and revised the text.

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						find the evidence regarding meconium-stained liquor, nor are the doses specified in the overview of evidence.	
PR	NCCHTA (2)	21			8.2.3	Vaginal misoprostol evidence statement. 'Vaginal misoprostol gel (50 µg) were (sic) less likely than vaginal misoprostol tablet to cause uterine hyperstimulation with FHR changes, but more likely to need oxytocin augmentation and epidural analgesia.' I cannot find the evidence relating to epidural.	Thank you for your comments. We have checked the evidence and revised the text.
PR	NCCHTA (2)	22			8.2.3	Vaginal misoprostol, final evidence statement. 'There were more reports of headaches, nausea and dizziness in the IMN group'. I cannot find the evidence for this.	Thank you for your comments. We have checked and revised the evidence section.
PR	NCCHTA (2)	23			8.2.3	Interpretation of evidence states that higher doses are associated with higher rates of potentially serious side-effects.' These side-effects should be stated.	Thank you for your comments. We have amended this section.
PR	NCCHTA (2)	24			8.2.3	Vaginal misoprostol, interpretation of evidence section. Interpretation is given for 'oral and vaginal misoprostol, favourable and unfavourable Cx.' But it is then stated, quite inconsistently, that that was not enough data about vaginal misoprostol with favourable Cx, to allow interpretation.	Thank you for your comments. The interpretation referred to women with undefined and variable cervix. We have amended the text.
PR	NCCHTA (2)	25				**3.2 Are any important limitations of the evidence clearly described and discussed?**	Please see responses below.
PR	NCCHTA (2)	26			General	I am unclear how the levels of evidence were assigned. According to Table 1.1 they are so finely graded that I don't see how they can be assigned reliably in a study of this breadth. I note that individual	Thank you for your comments. A high quality systematic review or meta-analysis (of RCTs) is generally regarded as evidence level 1++. By 'high quality', it means the systematic review uses robust

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						RCTs have sometimes been graded 1++ and sometimes 1+. How did the GDG distinguish between these 2 gradings? Also, I note that two case-control studies (section 5.7) have been assigned 2-, while most (all?) cohort studies have been assigned 2+. Could I suggest a) that the method of assigning the E scores is made explicit, and b) that studies judged to be biased are omitted, at least where there is other, more reliable evidence? There seems little point in cluttering up the guidelines with possibly misleading evidence.	review methodology to appraise the methodological merits and limitations of the RCTs included in the review. The Cochrane systematic reviews, with their requirement of rigorous review methods, are generally in this category (evidence level 1++). No individual RCT in this guideline was given an evidence level of 1++. The grading was guided by the Methodology check lists in the NICE Technical Manual. a) These two studies were graded 2– because they were judged to have a high risk of confounders b) These two studies were included to inform the GDG that evidence on the method of induction for breech presentation was very limited and poor.
PR	NCCHTA (2)	27			6.3	Under the heading 'What is the evidence that induced labours are more painful than spontaneous labour?' we read 'Women may experience induced labour as more painful than spontaneous labour.' This statement is given prominence in the Interpretation of evidence section, and in the Recommendations for pain relief section. The limitations of the evidence for this statement are not made clear. Two studies are quoted to support the statement: refs 118, 119. However, as described, ref 118 compares epidural vs no epidural in induced labours. Only ref 119, a small cohort study, suggests that induced labour	Thank you for your comments. We have re-structured this section to improve clarity.

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						requires more pain relief than spontaneous labour. Unless there is more compelling evidence that induced labours are more painful, the assertion should be given less emphasis.	
PR	NCCHTA (2)	28				**4.1 Is the whole report readable and well presented? Please comment on the overall style and whether, for example, it is easy to understand how the recommendations have been reached from the evidence.**	Please see responses below.
PR	NCCHTA (2)	29			General	Given the requirement for detail and comprehensiveness, the report is generally readable and well presented, though I wonder whether it needs to be quite so repetitive. I noted rather a lot of typos, missing words etc.	Thank you and the GDG very much appreciate your comments. We have made corrections and revised the content.
PR	NCCHTA (2)	30			4.1	Overview section. Tables 7.1 and 7.2 referred to - should be 4.1 and 4.2	Thank you for your comments. We have made the correction.
PR	NCCHTA (2)	31			5.1	Interpretation of evidence section starts 'The GDG were concerned about…' This wording is more than interpretation of evidence.	Thank you for your comments. We have revised the text.
PR	NCCHTA (2)	32			5.4	In 'Risk of induction of labour in women with previous caesarean section'. I found the following very confusing (the results were well expressed in the original paper): Vaginal birth was significantly less likely after labour induction than no induction (spontaneous birth) in women without a previous vaginal birth (51% vs 65%, OR 0.57, 95% CI 0.51 to 0.63), than in women	Thank you for your comments. We have revised the text to improve clarity.

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						with a previous vaginal birth (83% vs 88%, OR 0.6, 95% CI 0.56 to 0.78). In women with no previous vaginal birth, uterine rupture was significantly more likely after induction than no induction (spontaneous birth) (1.5% vs 0.8%, OR 1.84, 95% CI 1.11 to 3.05) than in women with previous vaginal birht (sic) (0.6% vs 0.4%, OR 1.39, 95% CI 0.62 to 3.13).	
PR	NCCHTA (2)	33			5.7	Overview of evidence, other induction methods. I found the following confusing: One retrospective case control study compared the effects of labour induction (nipple stimulation, Prostin and oxytocin) in women with breech induction (n=53), breech birth (n=58) and breech elective caesarean (n=64). It reported no significant difference in the rates of vaginal birth (66% vs 68% vs 0%), caesarean birth (34% vs 32% vs 100%) and Apgar score < 7	Thank you for your comments. We have revised the text for clarity.
PR	NCCHTA (2)	34			7.2.5	First evidence statement does not make clear that vaginal glyceryl trinitrate is being compared with vaginal PGE2.	Thank you for your comments. We have added this information.
PR	NCCHTA (2)	35			8.2.3	Misoprostol. I found this section hard going. It's long, reports many complicated comparisons, not always very clearly, and is very repetitive - the evidence statements more or less repeat the statements in the evidence overview. Since misoprostol is not licenced for use in pregnancy in the UK, this section seems overlong.	Thank you for your comments. We have revised to shorten the section.
PR	NCCHTA (2)	36			8.2.3	Vaginal subsection. Statement that 'additional RCTs identified showed that vaginal misoprostol 50 µg was associated increased (sic) likelihood of birth within 24	Thank you for your comments. We have revised the text.

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						hours' does not give comparator.	
PR	NCCHTA (2)	37				**4.2 Please comment on whether the research recommendations, if included, are clear and justified.**	Please see responses below.
PR	NCCHTA (2)	38			General	Research recommendations are generally clear and justified	Thank you and the GDG very much appreciate your comments.
PR	NCCHTA (2)	39			5.2	There is no evidence relating to induction for PRoM at term, and no recommendation for research. Surely research is needed into this topic?	Thank you for your comments. The NICE Intrapartum Guideline addressed this question and we made reference to this guidance in our recommendation. We have revised this section.
PR	NCCHTA (2)	40			7.1.6	Further research on breast stimulation, reads: Further research is required to evaluate the effectiveness, safety and maternal satisfaction of non pharmacological methods for labour induction, which could include breast stimulation and homeopathy.' There is not much justification from the evidence for further research on homeopathy.	Thank you for your comments. We have revised the research recommendations.
PR	NCCHTA (2)	41			7.1.2	There is however justification for further research on acupuncture. (See my comments in sections 2.2 and 3.1 of this form)	Thank you for your comments. Please see revised research recommendations.
PR	NCCHTA (2)	42			8.2.1	Research recommendation on policies for failed PGE induction would be better placed in section 9.2.	Thank you for your comments. We have moved the research recommendation accordingly.
PR	NCCHTA (2)	43				**Please make any additional comments you want the NICE Guideline Development Group to see, feel free to use as much or as little space as you wish.**	Please see responses below.
PR	NCCHTA (2)	44			Glossary	Some terms are mentioned in the glossary in bold, but are not in fact defined. The	Thank you for your comments. We have revised the Glossary.

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						following list shows the section in which the term is mentioned: missing term(s) Bias: selection bias, performance bias, information bias, publication bias. Bishop score: ripe (there is an entry 'cervical ripeness') Blinding or masking: single blind study, triple blind study Clinical trial: controlled clinical trials Consensus methods: Delphi, nominal group Observational study: experimental studies, selection bias Placebo: placebo effect Qualitative research: In depth interviews Quasi experimental study: controlled clinical trial Random allocation or randomisation: cluster randomisation Rupture of membranes: preterm rupture of membranes. (There is an entry prelabour rupture of membranes which includes mention of preterm ROM). Sensitivity: specificity Trust: acute trust, mental health trust	
PR	NCCHTA (2)	45			Glossary	There should be an entry for tocolysis	Thank you for your comments. We have added tocolysis in the Glossary.
PR	NCCHTA (2)	46			Glossary	Some statistical terms could be better defined: Confidence interval: a way of expressing the degree of uncertainty about the findings…. Data set: a collection of information, mainly numerical, relating to a particular subject Intention to treat analysis: …..Intention-to-	Thank you for your comments. We have revised the Glossary.

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						treat analyses are favoured in assessments of clinical effectiveness because they maintain the balance in basic characteristics between groups achieved by random allocation. Moreover, they mirror the non-compliance and treatment changes that are likely to occur when the treatment is used in practice.	
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	1		Full	General	This document is excellent in many respects.	Thank you. The GDG very much appreciate your comments.
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	2	p38, lines 37-39		3	We would love to (and no doubt should) provide all women with written information about their IOL, whatever their language. This is presently impractical in Newcastle and I suspect would also be so elsewhere. If NICE make this recommendation, does it plan to back it up by producing a basic information leaflet available in all languages currently spoken in the UK?	Thank you for your comments. Please see the revised recommendation (Chapter 3) in conjunction with the 'Women-centred care' section of the NICE guideline.
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	3	p 83-84, lines 30-36	Full	8	Should specify Prostaglandin E2 throughout as misoprostol is also a prostaglandin!	Thank you for your comments. We have made these changes where appropriate.
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	4		Full	8 in general	The argument for PGE2 in all women with a favourable cervix rather than amniotomy +/- syntocinon is very weak. Because of this, our opinion is that the guideline should not be specific in recommending PGE2 above amniotomy in this group of patients. With this in mind, there is particular concern about the preference of PGE2 over amniotomy in women with a favourable cervix and high parity.	Thank you for your comments. For women with favourable cervix, amniotomy with intravenous oxytocin was associated with postpartum haemorrhage and reduced maternal satisfaction when compared with vaginal PGE2 (5.1.7) The GDG considered the evidence very carefully and reached a consensus that vaginal PGE2 should be the preferred method of induction, taking into consideration the convenience of vaginal

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							PGE2, the invasiveness of intravenous oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned during induction.
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	5		Full	8	Amniotomy with a high fetal head: could we at least acknowledge that this is occasionally necessary (as is the case) and suggest appropriate precautions? …theatre team available, consultant aware or present, maybe even a foley at hand, attached to a bag of fluid for bladder filling in case of cord prolapse? If we are too negative about this we will be condemning some women to an unnecessary caesarean section.	Thank you for your comments. The GDG disagreed that amniotomy is necessary in the case of a high fetal head. (see 8.3)
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	6		Full	8 in general	The use of a third and fourth PGE2 should be expanded upon. We would consider a third PGE2 after medical review and a fourth PGE2 after consultant review. Some women do labour and deliver vaginally after four doses despite unfavourable cx after three. Local audit data backs this intervention up.	Thank you for your comments. The use of vaginal PGE2 should follow the manufacturers' instruction, as reported in the Summaries of Products Characteristics or British National Formulary.
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	7		Algorithm		Worth avoiding the word 'abnormal' in conjunction with EFM as this has specific meaning wrt features of a CTG in NICE guidelines. 'EFM abnormality' would however be fine!	Thank you for your comments. Please see revised algorithm.
SH	Newcastle Upon Tyne Hospitals NHS Foundation Trust	8		Summary document	1.3.6	'…no previous vaginal birth…' is repeated twice in the same sentence.	Thank you for your comments. Please see the revised recommendations.
SH	NHS Plus					This organisation was approached but did not respond.	

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SH	NHS Quality Improvement Scotland					This organisation was approached but did not respond.	
SH	North Tees and Hartlepool Acute Trust					This organisation was approached but did not respond.	
SH	Northumbria Healthcare NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Obstetric Anaesthetists Association					This organisation was approached but did not respond.	
SH	Partnerships for Children, Families, Women and Maternity					This organisation was approached but did not respond.	
SH	Pelvic Partnership, The	1	(p5)	NICE	Key priorities: induction of labour to prevent prolonged pregnancy	The women contacting our organisation have severe pelvic joint pain and are often offered induction at 37 weeks + to avoid prolonging the pregnancy , and they are not made aware of the risks of induction or the likelihood of necessary intervention. I would like to see clarification that these risks should also be explained to women who are usually having an otherwise normal pregnancy, and often find that their pelvic pain symptoms are exacerbated after an induced labour.	Thank you for your comment. This forms part of the 'risks of induction of labour' in the recommendations under 'Information giving' (chapter 3).
SH	Pelvic Partnership, The	2	(p6)	NICE	Failed induction	The use of the word failed implies that the woman has failed – could another word such as "unsuccessful" or "if induction is not effective"	Thank you for your comments. The GDG considered 'failed induction' is a recognised clinical term in obstetric practice and any change in terminology would not be appropriate.
SH	Pelvic Partnership, The	3	(p6)	NICE	Failed induction	Again, a language comment: The woman could be "allowed" home – this does not sound like a joint decision, it sounds like someone else is in control. Maybe "she could choose to go home" would be better.	Thank you for your comments. We have revised the recommendations.
SH	Pelvic Partnership, The	4	Line 37, 38	Full	2.1 Failed	As above, the use of the word failed implies that the woman has failed – could another word such as "unsuccessful" or "if	Thank you for your comments. The GDG considered 'failed induction' is a recognised clinical term in obstetric

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					inducti on	induction is not effective"	practice.
SH	Pelvic Partnership, The	5	Line 41	Full	2.1 Failed inducti on	As above, a language comment: The woman could be "allowed" home – this does not sound like a joint decision, it sounds like someone else is in control. Maybe "she could choose to go home" would be better.	Thank you for your comments. We have revised the recommendations.
SH	Pelvic Partnership, The	6		NICE	1.1.2	I agree that this should happen but wonder, in the hospitals I have visited recently where there are up to 42 languages spoken, is it possible to provide this information in all the languages required in each hospital? Are there enough translators to make sure this happens for every woman? How will this be funded?	Thank you for your comments. The appropriate way to give information to women is addressed in 'Woman-centred care' section of the NICE guideline version.
SH	Pelvic Partnership, The	7		NICE	1.3.7	Are there specific risks that women should be told about?	Thank you for your comments. Please see the revised recommendation.
SH	Pelvic Partnership, The	8		NICE	1.3.10	How long will expectant management go on for – is there an upper limit?	Thank you for your comments. The GDG considered that this would form part of the case-by-case individual approach, taking into account the woman's clinical circumstances in a very traumatic and tragic personal situation.
SH	Pelvic Partnership, The	9		NICE	1.4.1	Does this mean that it can be carried out in a midwifery led or birth unit, or at home?	Thank you for your comments. We did not identify any evidence relating to home induction. The GDG recommended that induction of labour should only be carried out if appropriate safety and support procedures are in place and the process/practice should be continuously audited.
SH	Pelvic Partnership, The	10		NICE	1.4.7	Is there any need for her to return to hospital if she wishes to stay at home?	Thank you for your comments. The woman should contact the obstetricians/midwives

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							when contractions begin or if there is no progress 6 hours after vaginal PGE2 gel/tablet insertion. Pleas see revised recommendations (see 7.1)
SH	Pelvic Partnership, The	11		NICE	1.4.12	We are very pleased to see that birthing pools can be used for induced labours	Thank you for your comments.
SH	Pelvic Partnership, The	12		Full	7.1.1 – 7.1.6	The wording of "should not be used because of lack of evidence" makes this read as if using these methods is dangerous and potentially harmful. To say that they "should not be recommended as effective because of lack of evidence" then allows women to choose to use them should they wish to do so, while being clear that there is no evidence to support the practice.	Thank you for your comments. The reasons why any therapies are not recommended are summed up in the evidence statement and interpretation sections (see 5.2.2 to 5.2.6). The recommendations focus on what the healthcare professional should or should not do. Available evidence did not support the use of these non-pharmacological methods. The GDG have made recommendations not to offer these methods on the NHS.
SH	Pelvic Partnership, The	13		NICE	1.7.2	Use of "failed" induction – again, as above, "unsuccessful" or "not effective" would be more positive use of language	Thank you for your comments. The GDG considered 'failed induction' is a recognised clinical term in obstetric practice and any change in terminology would not be appropriate.
SH	Pelvic Partnership, The	14	p 25 lines 33 and 35	full	1.7	Should this read "serious" rather than "serous"?	Thank you for identifying this error. It should read 'serious'. We have made amendment.
SH	Pelvic Partnership, The	15		full	6.1	It is not clear from these studies whether a woman can safely choose to remain at home to have her baby once labour commences but there seems to be nothing to suggest that she cannot do so. This was discussed at the implementation planning meeting where it seemed that	Thank you for your comments. The GDG felt that this would depend on the indications for induction of labour. However, the evidence we identified on outpatient induction of labour relate to non-UK setting. The recommendations stressed the

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						there was no evidence to suggest this would be a problem. I would like to see this stated clearly within the guideline so that women can take this option should they wish to choose to do so.	importance that induction of labour should only be carried out if appropriate safety and support procedures are in place. The process/practice should be continuously audited.
SH	Pelvic Partnership, The	16		full	general	The Pelvic Partnership supports women with SPD (Symphysis Pubis Dysfunction) also known as PGP (Pelvic Girdle Pain) and we are frequently contacted by women being encouraged to have induction prior to 40 weeks in the mistaken belief that their pain will disappear as soon as they have had the baby. They then contact us after the birth, often with problems that have been exacerbated by induction followed by instrumental delivery (so it is really helpful to see here the evidence that this is not just our anecdotal experience, but is supported in the literature).	Thank you for your comments.
						I think this guideline will be very helpful in allowing us to give them accurate information about the possible risks of induction, which in my experience are often not explained to them.	Thank you for your comments.
						I am particularly pleased to see the flexibility about place of birth and use of water, which makes a huge difference to many of the women in our group as they have great difficulty mobilising on dry land.	
SH	PERIGON Healthcare Ltd					This organisation was approached but did not respond.	
SH	Pfizer Limited					This organisation was approached but did not respond.	
SH	Princess Alexandra Hospital NHS Trust					This organisation was approached but did not respond.	

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SH	Queen Mary's Hospital NHS Trust (Sidcup)					This organisation was approached but did not respond.	
SH	RCM Consultant Midwives Forum					This organisation was approached but did not respond.	
SH	Royal College of Anaesthetists					This organisation was approached but did not respond.	
SH	Royal College of General Practitioners					This organisation was approached but did not respond.	
SH	Royal College of Midwives	1		NICE	General	RCM welcomes the general introduction and the acknowledgement of a philosophy throughout the document that induction of labour has a significant impact on women.	Thank you and the GDG very much appreciate your comments.
SH	Royal College of Midwives	2	p3	NICE	Introduction	It may be appropriate to add that because of the possible impact and implication of IOL, the indication for and decision to undertake IOL needs to be clear and clinically justified.	Thank you for your comments. We have added this in the introduction.
SH	Royal College of Midwives	3	**P5**	NICE	Key priorities for implementation	Information and decision making: very good and helpful section	Thank you for your comments.
SH	Royal College of Midwives	4	(p8)	NICE	1.2.3	Should this section include reference to the risks of post term pregnancy?	Thank you for your comment. We have revised the recommendations, which stated that induction of labour was to avoid the risks of prolonged pregnancy.
SH	Royal College of Midwives	5		NICE	1.3.3 1.6.12 and 13	The College notes that there is no reference to the Bishops Score Assessment Tool in the NICE version. As the majority of practitioners will be guided by this document should there be a statement on what is meant by a favourable/unfavourable cervix?	Thank you for your comments. The definitions of 'favourable/unfavourable cervix' and details of Bishop scores are in the Glossary and Appendix B of the main guideline, respectively. We have put these definitions in the NICE version.

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SH	Royal College of Midwives	6		NICE	1.3.8	This statement is unclear – what might be considered as “compelling” circumstances. There needs to be clear recommendation that induction of labour on maternal request is not an option. Each woman should be assessed for psychological and physical wellbeing when considering induction of labour.	Thank you for your comments. We have revised the recommendations. We have given examples of these ‘exceptional circumstances’ in the introductory paragraph, for example, partners soon to be posted abroad in armed Forces. The GDG considered it important that all cases of clinical management involves a dialogue between the woman and the clinician, taking into account the woman’s wishes and her clinical situation. Women are offered information to make informed choice and decision, which must be respected.
SH	Royal College of Midwives	7		NICE	1.3.9	Given the lack of evidence of harms/benefits of induction in breech presentation, we would prefer that the recommendations would follow a cautious approach.	Thank you for your comments. Please see the revised recommendations.
SH	Royal College of Midwives	8	(p12)	NICE	1.4.5	Timing of EFM with prostaglandin IOL: it is recommended that this is not necessary until contractions begin, for some women this may be some time or possibly even days. Is this based on evidence?	Thank you for your comments. The GDG considered this carefully and reached a consensus in making this recommendation.
SH	Royal College of Midwives	9	(p13)	NICE	1.4.12	Pleased to see this recommendation	Thank you for your comments.
SH	Royal College of Midwives	10		NICE	1.5.5	The statement would read better if the word “used” was changed to “recommended”	Thank you for your comments. The terms used in the recommendations are advised by the NICE editors.
SH	Royal College of Midwives	11		NICE	1.7.2	There needs to be clarification of what is meant by failed induction within the NICE (short) guideline or a link reference to the NICE intrapartum care guideline as the origin for the care recommendation.	Thank you for your comments. We have defined this in the NICE version.

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SH	Royal College of Nursing	1			General	It is an important document with far reaching impacts on women, their families and their carers and will guide health professionals in giving appropriate care and support to women in labour.	Thank you and the GDG very much appreciate your comments.
SH	Royal College of Obstetricians and Gynaecologists	1		Full	General	We welcome this guideline and agree with much of the content . We are generally happy with the document but wish to draw your attention to a number of issues which you may wish to consider.	Thank you and the GDG very much appreciate your comments.
SH	Royal College of Obstetricians and Gynaecologists	2		Full	Glossary of Terms	There is no definition for induction. Failed induction definition should also include ' when the cervix remains unfavourable'	Thank you for your comments. We have revised the Glossary to include failed induction. Favourable and unfavourable are defined separately in the glossary.
SH	Royal College of Obstetricians and Gynaecologists	3		Full	Interpretation of data	Please review as we do not share the interpretation of the data comparing prostin E2 tablets versus gel –we would welcome a review of the recommendation.	Thank you for your comments. We have revised the section.
SH	Royal College of Obstetricians and Gynaecologists	4		Full	General	We would welcome further attention to induction in the context of intrauterine fetal death.	Thank you for your comments.
SH	Royal College of Obstetricians and Gynaecologists	5		Full	General	It would be helpful to present induction statistics for primiparous and multiparous women to aid in counselling women about induction of labour.	The GDG considered this carefully and there was a consensus at the outset that cervical status would be the population criteria of interest in this guideline.
SH	Royal College of Obstetricians and Gynaecologists	6	page 27 and page 45	Full	2.1	*Induction of labour between 41-42 weeks* We are particularly pleased to see clarification of gestations as 14+0 etc.	Thank you for your comments. We gather you are referring to 40+0 week? Please see revised recommendations.

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SH	Royal College of Obstetricians and Gynaecologists	7	page 27, line 30, 33	Full	2.1	*Vaginal prostaglandins* Please explain 'irrespective of cervical status and parity'	Thank you for your comments. The GDG considered vaginal PGE2 to be the preferred method of induction for women irrespective of their Bishop score, or if the women were nulliparous or multiparous. Please see the revised recommendations.
SH	Royal College of Obstetricians and Gynaecologists	8		Full	2.1	Women undergoing induction of labour should receive the following information: Suggest this should read – Women being advised about induction of labour	Thank you for your comments. We have reworded the recommendations to improve clarity.
SH	Royal College of Obstetricians and Gynaecologists	9	– lines 6 to 12	Full	2.1	Suggest add the flip side – The risks of not undergoing induction of labour	Thank you for your comment. The forms part of the recommendations which included informing women about the risks and benefits of induction of labour.
SH	Royal College of Obstetricians and Gynaecologists	10	line 25	Full	2.1	***Membrane sweeping*** Should the recommendation advise when (gestational age) and where membrane sweeping should be done.	Thank you for your comments. Please see revised recommendations.
SH	Royal College of Obstetricians and Gynaecologists	11	Lines 31-32	Full	2.2	***Intrauterine fetal death*** *If the woman appears to be physically well, her membranes are intact and there is no evidence of infection or bleeding, then they can be offered a choice of immediate induction of labour or expectant management.* Suggest adding 'or pre-eclampsia' to the recommendation.	Thank you for your comments. Please see the revised recommendations. Pre-eclampsia is outside the scope of this guideline.
SH	Royal College of Obstetricians and	12	page 30, line	Full	2.2	*Sexual intercourse as a method of cervical priming and labour induction should not be*	Thank you for your comments. Please see revised recommendations and research

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	Gynaecologists		42			*used because there is insufficient evidence*. Suggest that it may be more correct to state 'should not be recommended'.	recommendation.
SH	Royal College of Obstetricians and Gynaecologists	13	Line 2	Full	2.2	*Intravenous oxytocin* *IV oxytocin as the sole intervention should not be used in women undergoing induction of labour.* Suggest the reason for this recommendation is given – ineffective, unsafe, lack of evidence.	Thank you for your comments. Intravenous oxytocin alone is not recommended because it is less effective than vaginal PGE2 as an induction method. The reasons why a therapy is not recommended are summed up in the evidence statement and interpretation sections before the recommendations. The recommendations focus on what the healthcare professional should or should not do. Please see the revised recommendations.
SH	Royal College of Obstetricians and Gynaecologists	14		Full	2.2 Surgical method s	*Amniotomy* *Amniotomy should not be used as method of induction when the cervix is unfavourable.* What if PGs are used x2 doses and still unfavourable?	Thank you for your comments. Please refer to the section and recommendations on 'failed induction'. (8.2)
SH	Royal College of Obstetricians and Gynaecologists	15	page 47	Full	5.1	We would welcome a further review of the use of prostaglandin versus oxytocin for induction following prolonged rupture of membranes. Please see RCOG Green-top Guideline No.44 *Preterm Prelabour Rupture of Membranes*, 2006 for details.	Thank you for your comments. The GDG considered this carefully and recommended that vaginal PGE2 should be the induction method of choice in women with rupture of membranes, taking into consideration the invasiveness of intravenous oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned. Please

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							see revised recommendations (4.2) We also made reference to the RCOG Green-top Guideline on *Preterm Prelabour Rupture of Membranes*.
SH	Royal College of Obstetricians and Gynaecologists	16		Full	7.	The recommendation on role of prostaglandin in induction where the cervix is very favourable (high Bishop score_) appears to be out of keeping with clinical practice – we would welcome further review.	Thank you for your comments. For women with favourable cervix, amniotomy with intravenous oxytocin was associated with postpartum haemorrhage and reduced maternal satisfaction when compared with vaginal PGE2 (5.1.7). The GDG considered the evidence very carefully and reached a consensus that vaginal PGE2 should be the preferred method of induction, taking into consideration the convenience of vaginal PGE2, the invasiveness of intravenous oxytocin (intravenous access) which necessitates continuous monitoring and reduced mobility for the woman concerned.
SH	Royal College of Obstetricians and Gynaecologists	17	page 43, line 23	Full	4.	*Recommendation: Induction of labour should not be routinely offered to women before 41 weeks gestation (41+0)* This risks stratification. Does this also apply for women age 40 and over?	Thank you for your comments. Please see the revised recommendations. Unless specified, the evidence and recommendations in this guideline apply to *all* women with uncomplicated pregnancies and who choose to have induction of labour.
SH	Royal College of Obstetricians and Gynaecologists	18	page 50, lines 1-4	Full	5.3	***Presence of fetal growth restriction*** The data does not seem to support such a strong statement that caesarean section should be performed in all cases of severe	Thank you for your comments. We have revised the recommendations to improve clarity.

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						intrauterine growth restriction. There is concern that this statement will be interpreted in everyday practice as caesarean section for all small babies. In the recommendation, we would suggest defining 'severe intrauterine growth restriction. E.g. include 'with abnormal umbilical artery dopplers and reduced liquor volume'	
SH	Royal College of Obstetricians and Gynaecologists	19	page 54, lines 1-3	Full	5.6	Please clarify whether an individual may request induction of labour	Thank you for your comments. The GDG agreed with the importance of a case-by-case approach, taking into consideration of the woman's clinical and personal circumstances, and the need for informed decision.
SH	Royal College of Obstetricians and Gynaecologists	20		Full	8.4.1	Suggest adding an additional sentence to this section: amniotomy followed by intravenous syntocinon may be used if labour has not ensued following the use of prostaglandins and the cervix is favourable. The option of amniotomy followed by syntocinon should be mentioned in the text as it is in the algorithm.	Thank you for your comments. The evidence showed that, in women with a favourable cervix, amniotomy plus intravenous oxytocin was associated with a significant increase in post-partum haemorrhage when compared with vaginal PGE2.(5.1.7) The recommendation made by the GDG is based on the effectiveness data, the convenience of vaginal PGE2, the invasiveness of intravenous oxytocin which necessitates continuous monitoring and reduced mobility for the woman concerned during induction. On balance, the GDG considered that vaginal PGE2 is the preferred method of induction. Please also see revised recommendations

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							(5.1.6, 5.1.7): Amniotomy, alone or with intravenous oxytocin should not be used as a primary method of induction unless there are specific clinical reasons for not using vaginal PGE2, in particular the risk of uterine hyperstimulation.
SH	Royal College of Obstetricians and Gynaecologists	21	page 48	Full	5.1	*PPROM >34 weeks and caesarean.* The guideline seems to be advocating delivery anytime after 34 weeks (with its natural 'break-point' in neonatal morbidity) but doesn't advise about risks of inducing or not with one or more previous scars in this situation (which will be increasingly common with rising caesarean rate). If neonatal morbidity is higher after caesarean without labour, AND if the risk to mothers is higher if IOL on unfavourable cervix and previous caesarean section isn't there a different risk-benefit calculus to apply and a justification to *avoid* IOL for longer – is it worth putting in these provisos (or 'unknowns' - but things for clinicians to weigh up) into the document somewhere, otherwise the UK may get more IOLs AND caesareans in 34 week PPROM with previous caesarean when obstetricians are presently waiting a bit more expectantly – and the GDG may inadvertently increase both maternal and neonatal adverse outcomes. More data is needed on IOL and caesarean secion rate	Please see revised algorithm. Thank you for your comments. The GDG considered this needs to be determined on a case-by-case basis, taking into account the woman's wishes, the risks involved and her clinical situation. We have revised the recommendations to improve clarity.

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						at 34, 35, 36 and 37 weeks of gestation.	
SH	Royal College of Obstetricians and Gynaecologists	22	page 48	Full	5.2	*Term PROM* It is stated that if women with term PROM want IOL they should have vaginal PGs. The PROM trial found no real difference in method of IOL in this situation (ie syntocinon versus PGs) and mode of delivery. Is there no new evidence? As multiple vaginal examinations are associated with increased pyrexia, and women with IOLs have huge numbers of vaginal examinations, isn't this a bit too prescriptive? If current practice, whereby many people don't use PGs at all or only use one dose to keep vaginal examinations to a minimum, is actually wrong, would it be worth saying so more directly?	Thank you for your comments. Vaginal PGE2 has been used for two decades in women with rupture of membranes. The GDG considered the evidence very carefully and recommended that vaginal PGE2 is the preferred method of induction, taking into consideration the convenience of vaginal PGE2, the invasiveness of intravenous oxytocin, which necessitates continuous monitoring and reduced mobility for the woman concerned during induction.
SH	Royal College of Obstetricians and Gynaecologists	23	page 49 line 39	Full	5.3	***IOL in IUGR*** We disagree with the evidence statement that for IUGR 26-34 there is insufficient evidence to whether immediate or delayed IOL is beneficial. Whilst it might be true for the FETAL outcomes, the evidence given just in the paragraph before suggests that there is a significantly higher chance of caesarean for the mother (OR 2.7 CI 1.6-4.5), and thus delayed IOL must be preferred as beneficial until other evidence comes in.	Thank you for your comments. We have revised the interpretation of evidence section and the recommendations.
SH	Royal College of Obstetricians and Gynaecologists	24	page 49 line 39	Full	5.3	*The GDG considered that labour, either spontaneous or induced, in the presence of IUGR, may result in severe fetal compromise/death. Therefore, in such*	Thank you for your comments. We have revised the interpretation of evidence section and the recommendations.(4.7)

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						cases, caesarean section would be indicated. Please see RCOG Green-top Guideline No.31 *The Investigation and Management of the Small-for-Gestational-Age Fetus.* The risk to the fetus depends on the degree of IUGR (or FGR -fetal growth restriction) as it is a continuum (just like most diseases). It can be mild, moderate or severe. Each test of fetal wellbeing varies in terms of its receiver-operator curve relationship to perinatal mortality. There is a difference between anhydramnios, oligohydramnios and normal liquor, similarly between REDF, AEDF, raised PI to normal UA Doppler etc. Some babies are merely thin while others are very sick. If the babies have normal FMs and a normal CTG does this preclude trial of labour? There are some cases where growth is slowing preterm (eg AC falling, liquor low and PI marginally raised, but good FMs and BPP) where there is a choice of: 1) Waiting – for more maturity but monitoring, as in GRIT, until FMs poor or abnormal CTG (anxiety provoking and small risk of stillbirth) and then doing a definitely indicated CS 2) Doing CS immediately – (risks prematurity, or respiratory complications at term and the mother's health - as GRIT showed) 3) Induction – which might be now or later,	

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						but requires judicious timing as it's a balance of length of labour (which is unknown and unknowable) and stress to a somewhat compromised fetus depending on gestation and other factors. If the baby is being monitored closely it will either demonstrate fetal distress in response to contractions (and one deals with this as per usual - as for the unrecognised growth restricted babies in labour) or it'll be fine. If you don't attempt labour you don't allow all those women who have short labours to deliver (and preserve their future fertility options) and all those babies who are fine to deliver vaginally, with its benefits. If it was suggested that 'IUGR with CTG abnormality' as the definition of evidence of fetal compromise needed CS that would be different. Indeed the very little evidence from GRIT shows that early delivery (which CS is) is NOT better for fetal outcome. And the term IUGR trial (tiny numbers) shows a difference in CS rates – again proving that many IUGR babies are perfectly capable of surviving labour and vaginal delivery. A high percentage of IUGR babies are born in good condition undiagnosed antenatally. Those we do know about we can keep an eye on.	
SH	Royal College of Obstetricians and Gynaecologists	25	page 50 lines 3-4	Full	5.3	*Recommendation: In the presence of severe intrauterine fetal growth restriction with suspected fetal compromise, induction of labour should not be undertaken and*	Thank you for your comments. We have revised the interpretation of evidence section and the recommendations.(4.7)

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						caesarean section should be performed to avoid the stress of labour, both for the woman and her baby. Need details of definition of severe IUGR with suspected fetal compromise e.g. abdominal circumference <3rd centile, low liquor, abnormal doppler flow (UA doppler). The Cochrane review of the RCTs of labour versus elective caesarean (in breech) shows a 30% increase in immediate maternal morbidity for elective caesarean versus labour (which had a 45% or so emergency caesarean outcome) – your reference 85. This suggests that overall women are better off labouring even when there is a high likelihood of abdominal delivery. There are also benefits downstream if they wish to attempt VBAC if they have laboured. There are *deaths from unindicated elective caesarean* in the latest 2007 CEMACH enquiry that the central assessors have commented upon.	
SH	Royal College of Obstetricians and Gynaecologists	26	page 52 line 19	Full	5.4	***Recommendation on previous caesarean birth*** Suggest rewording this recommendation. There is repetition. The absence of a previous vaginal birth is mentioned twice in the same sentence.	Thank you for your comments. We have revised and reworded the recommendations to improve clarity.

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SH	Royal College of Obstetricians and Gynaecologists	27	page 52 line 33	Full	5.5	Where does the definition of precipitate labour <3hrs come from? Other definitions include <1 hr, and <4hrs. If IOL in this situation has potential or real harms and there is no evidence of any harm of home delivery in a low risk woman, would it make sense to say that a better alternative management plan (to avoid BBA in a low risk woman with previous precipitate labour) would be to recommend a planned home delivery?	Thank you for your comments. We have put in the reference for this definition. Thank you for your comments. The place for delivery/birth is not within the remit of this guideline.
SH	Royal College of Obstetricians and Gynaecologists	28	page 57 line 13-14	Full	5.8	Singular to plural – "the woman" to "they can be offered"	Thank you for your comments. Please see the revised recommendations.
SH	Royal College of Obstetricians and Gynaecologists	29		Full	5.8	***Intrauterine fetal death*** Mifipristone is better than placebo in terms of women going into labour (which they will do with an IUFD eventually), and allows an interval before using misopristol or PG, and can be used safely with lower doses. Please consider recommending in low risk women (especially with previous caesarean and thus risk of rupture) that it might be positively better to offer IOL by mifipristone followed by another agent 2 days later? Women will know something is being done, the duration of labour itself is shorter, less drug that causes increased rupture rate is being used, and they get time to go home/ grieve and get used to the bad news. The downside is more autolysis and less informative.	Thank you for your comments. Please see revised recommendations relating to the choice of prostaglandins, preparations availability and local protocol.

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						This section could be elaborated on with more information for women about the pros and cons of immediate versus soon induction versus expectant management rather than just immediate versus expectant	This forms part of the recommendations on information giving (see Chapter 3).
SH	Royal College of Obstetricians and Gynaecologists	30	page 57 line 27	Full	5.8	There two definitions of macrosomia. Is it above 4kg or 4.5kg?	Thank you for your comments. We have revised the text to clarify the definition.
SH	Royal College of Obstetricians and Gynaecologists	31	page 58 lines 7, 16	Full	5.9	***Macrosomia*** There is an evidence level of 1++ (for birth injury) but it is stated that there is no evidence that IOL is beneficial in women with macrosomia? Recommend rephrasing. Suggest including ' all risk factors of past obstetric history should be taken account of'. What about women with a previous big baby and shoulder dystocia who wants to avoid a baby as big/bigger or a caesarean (if offered on the 10% recurrence principle). If previous 5kg baby at 42 weeks and this one 95th centile and heading that way, wouldn't it be sensible to deliver at 38 weeks? Or is that what is intended by your statement 'don't IOL for macrosomia *alone*'	Thank you for your comments. The evidence level 1++ refers to the robust review methodology used to appraise the RCTs included in the review, and not to the results of the RCTS. In this case, it means that there is high quality evidence from systematic review (EL=1++) that induction of labour offers no benefit in women with suspected macrosomia. There were two cases of brachial plexus injury and four cases of clavicular fracture in the control group (1 RCT, 273 women) but the differences were not statistically significant. We have added these details in the text. Thank you for your comments. The GDG considered this carefully and have revised the recommendations.
SH	Royal College of Obstetricians and Gynaecologists	32	page 63 line 24-26	Full	6.3	There are typographical errors in this recommendation.	Thank you for your comments. Please see revised recommendations.
SH	Royal College of Obstetricians and	33	page 85 line	Full	8.5	Suggest replace 'hypertonicity …would pose great risks' with 'pose risks'.	Thank you for your comments. We have revised the recommendation.

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	Gynaecologists		24				
SH	Royal College of Obstetricians and Gynaecologists	34	page 86 lines 8-12	Full	9.1	Does this paragraph belong in the introduction? It seams somewhat odd in having the sentence about complication of amniotomy or cord prolapse or infection in the uterine hyperstimulation section.	Thank you for your comments. We have revised the text.
SH	Royal College of Obstetricians and Gynaecologists	35	page 88 line 3	Full	9.3	Replace 'precautionary measures' with 'precautions.	Thank you for your comments. We have revised the recommendation.
SH	Royal College of Obstetricians and Gynaecologists	36	page 9	NICE	1.3.4	***Term PROM*** IOL after prelabour rupture of membranes at term. The evidence suggests that only one dose of prostaglandin is needed followed by IV oxytocin, and this is not stated in the guideline here. It just says that the usual dose of prostaglandins should be used. Some clarification is needed.	Thank you for your comments. We are not aware of evidence relating to a single dose of PGE2, followed by intravenous oxytocin. The evidence reviewed did not specify regimes but the GDG, after careful consideration, concluded that prelabour rupture of membranes should be managed by the use of standard vaginal PGE2 regime, recognising women's preference to avoid the need for intravenous oxytocin therapy, which necessitates continuous monitoring and reducing the woman's mobility during induction.
SH	Royal College of Obstetricians and Gynaecologists	37		NICE	1.3.6	Repetition : ' women with no previous vaginal birth who should be informed of an increased risk of uterine rupture, particularly in the absence of a previous vaginal birth' suggest redraft.	Thank you for your comments. We have revised the recommendations.
SH	Royal College of Obstetricians and Gynaecologists	38		NICE	1.3.7	Conflicts with the boxes on algorithm. Precipitate labour isn't an indication for IOL, but can be considered on case-by-case basis – so does it actually belong in the middle box?	Thank you for your comments. We have revised the algorithm.
SH	Royal College of	39		NICE	1.3.9	This reads as though elective CS IS the	Thank you for your comments. The GDG

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	Obstetricians and Gynaecologists					management option for breech (which it isn't) and its only when that's declined that you might have to offer IOL.	agreed and have revised the recommendations.
						Please distinguish preterm and term breech.	The evidence and recommendations relate to breech at term. Preterm breech is not within the scope of the guideline.
SH	Royal College of Obstetricians and Gynaecologists	40		NICE	1.3.10	Typo singular to plural - woman to they.	Thank you for your comments. We have made correction.
SH	Royal College of Obstetricians and Gynaecologists	41	page 17	NICE	1.7.1	Methods of tocolysis- are there any recommendations to be made?	Thank you for your comments. The GDG considered that tocolysis, if needed, should follow standard local protocol. This is explained in the interpretation section (see 8.1)
SH	Royal College of Obstetricians and Gynaecologists	42		Algorithm		It is confusing to have a line connecting 'appropriate to deliver before 42' that then goes backwards to 38, 40, 41. Suggest separate the boxes and maybe colour the 3 indication boxes (post dates/ indicated/ not suitable) differently from the procedure boxes.	Thank you for your comments. Please see revised algorithm.
SH	Royal College of Obstetricians and Gynaecologists	43		Algorithm		It is confusing to have *indications* & contraindications for IOL (such as avoid >42, PROM, PPROM, IUGR) and *special situations* (previous CS, breech) as the latter are not reasons for an induction per se, but issues to factor in if there is another reason (such as PROM with previous CS OR breech with preeclampsia). Again some clarification, maybe by colour differences might help or by separating out the boxes.	Thank you for your comments. Please see revised algorithm.
SH	Royal College of Obstetricians and Gynaecologists	44		Algorithm		It may be better to have the box for 'induction for other indications' higher up so that it can be seen at a glance, and	Thank you for your comments. Please see revised algorithm.

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						have the arrow to NICE diabetes guidelines box lower.	
SH	Royal College of Paediatrics and Child Health	1		Full	6.1	We would like consideration to be given to the timing of induction for the fetus with known congenital abnormality likely to require neonatal intensive care services. Examples would be congenital diaphragmatic hernia or complex cardiac or gastroschisis. Whilst we recognise that it is not possible to accurately predict the timing of delivery, the neonatal community is concerned that induction of labour starting in the morning for this vulnerable group of babies will commonly result in delivery occurring in the middle of the night some 12-24 hours later. This is at the time when the availability of senior staff is commonly at its least. Whilst we have no evidence to say that this affects outcome, it is far from ideal for the best delivery of care to the baby. The neonatal community feels sure that mothers would accept induction starting in the evening with the hope that delivery is the following day when the reasons are fully explained to them. We wonder whether there is any evidence about onset of induction and delivery times?	Thank you for your comments. Induction of labour of fetus with known congenital abnormality is outside the scope of this guideline. The evidence identified showed that women were more satisfied when induction took place in the morning.
SH	Royal College of Pathologists					This organisation was approached but did not respond.	
SH	Royal Society of Medicine					This organisation was approached but did not respond.	
SH	Royal Society of Medicine, The					This organisation was approached but did not respond.	
SH	Salford Royal Hospitals Foundation NHS Trust					This organisation was approached but did not respond.	

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SH	Salisbury NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Sands the Stillbirth and neonatal death charity	1	37-38	Full	6.2	Induction after an intra-uterine death, fetal monitoring should not be used.	Thank you for your comments. The GDG agreed.
SH	Sands the Stillbirth and neonatal death charity	2		FULL	6.3	If an IUD, labour likely be perceived as even more traumatic and painful as will end in tragedy, not joy.	Thank you for your comments. The GDG acknowledged this very sensitive situation and have amended the recommendations to reflect this.
SH	Sands the Stillbirth and neonatal death charity	3		FULL	6.3	If an IUD, Increased need for empathy and support	Thank you for your comments. The GDG acknowledged this very sensitive situation and have amended the recommendations to reflect this.
SH	Sands the Stillbirth and neonatal death charity	4		FULL	6.3	If an IUD increased need for privacy away from the sounds of fetal monitors, crying babies and other parents	Thank you for your comments. The GDG acknowledged this very sensitive situation and have amended the recommendations to reflect this.
SH	Sands the Stillbirth and neonatal death charity	5		NICE	1.3.10	Need for increased staff sensitivity and support as labour and birth may be perceived as more traumatic and painful as will end in tragedy not joy	Thank you for your comments. The GDG acknowledged this very sensitive situation and have amended the recommendations.
SH	Sands the Stillbirth and neonatal death charity	6		NICE	1.4.3 and 1.4.4	If an IUD, no fetal monitoring	Thank you for your comments. The GDG agreed.
SH	Sands the Stillbirth and neonatal death charity	7		NICE	1.4.11	Empathy and support especially important when the baby is already dead. Labour and birth may be perceived as more traumatic and painful. And will end in tragedy, not joy.	Thank you for your comments. The GDG acknowledged this very sensitive situation and have revised the recommendations.
SH	Sandwell and West Birmingham NHS Trust					This organisation was approached but did not respond.	
SH	Sandwell PCT					This organisation was approached but did not respond.	

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SH	School of Midwifery					This organisation was approached but did not respond.	
SH	Scottish Intercollegiate Guidelines Network (SIGN)					This organisation was approached but did not respond.	
SH	Sheffield PCT					This organisation was approached but did not respond.	
SH	Sheffield Teaching Hosptials NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Southampton University Hospital Trust					This organisation was approached but did not respond.	
SH	Staffordshire Moorlands PCT					This organisation was approached but did not respond.	
SH	Stockport PCT					This organisation was approached but did not respond.	
SH	Survivors Trust, The					This organisation was approached but did not respond.	
SH	Syner-Med Pharmaceutical Products Ltd					This organisation was approached but did not respond.	
SH	Tameside and Glossop Acute Trust					This organisation was approached but did not respond.	
SH	Tissue Viability Nurses Association					This organisation was approached but did not respond.	
SH	UCLH NHS Foundation Trust					This organisation was approached but did not respond.	
SH	United Lincolnshire Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	University Hospitals of Leicester					This organisation was approached but did not respond.	
SH	Vygon (UK) Ltd					This organisation was approached but did not respond.	
SH	Welsh Assembly Government					This organisation was approached but did not respond.	

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SH	Welsh Scientific Advisory Committee (WSAC)					This organisation was approached but did not respond.	
SH	West Middlesex University NHS Trust					This organisation was approached but did not respond.	
SH	West Yorkshire Strategic Health Authority					This organisation was approached but did not respond.	
SH	Western Cheshire Primary Care Trust					This organisation was approached but did not respond.	
SH	Wiltshire PCT					This organisation was approached but did not respond.	
SH	Wirral Hospital Acute Trust					This organisation was approached but did not respond.	
SH	Wirral University Teaching Hospital NHS Foundation Trust					This organisation was approached but did not respond.	
SH	Womens Health Research Group					This organisation was approached but did not respond.	
SH	Worcestershire Acute Hospitals NHS Trust					This organisation was approached but did not respond.	
SH	Worcestershire Acute NHS Trust					This organisation was approached but did not respond.	
SH	Worthing and Southlands Hospital					This organisation was approached but did not respond.	
SH	Worthing Hospital					This organisation was approached but did not respond.	
SH	York NHS Trust					This organisation was approached but did not respond.	
SH	Yorkshire and the Humber LSA					This organisation was approached but did not respond.	