Long-acting reversible contraception

Consultation with stakeholders on the draft scope: comments received and responses made to them by the Institute in collaboration with the NCC-WCH

The National Institute for Clinical Excellence has commissioned the National Collaborating Centre for Women and Children's Health (NCCWCH) to develop a clinical guideline on long-acting reversible contraception for use in the NHS in England and Wales. The draft scope was subject to four weeks' consultation (27 August – 24 September 2002) with stakeholders. This document contains the comments submitted by stakeholders during the consultation period and the responses made to them by the Institute in collaboration with the NCC-WCH.

Only stakeholders who responded to the consultation are listed here. For a complete of stakeholders registered for this guideline, please see the NICE website – link attached - http://www.nice.org.uk/cat.asp?c=33918

Company	Comments	Response
Association of the British Pharmaceuticals Industry,(ABPI)	The Association of the British Pharmaceutical Industry (ABPI) welcomes the opportunity to comment on the draft scope for a clinical guideline on long-acting reversible contraception. Section 3d and 3e We note that uptake of these methods is currently low and that there are a number of likely reasons for this including penetration of the market. However we would point out that industry promotion will also include health professional education and industry will be crucial in implementation of the recommendations of this guideline when finalised. Section 4.1 - Population We believe that the scope needs to add peri-menopausal women as a specific group to be targeted in the light of the peak of abortion rates that occurs in this age group. We also believe that breastfeeding women should be included as a specific target group as these methods are eminently suitable for those women without affecting their ability to breastfeed.	Point noted 4.1.1b: Women who are breastfeeding have not been specified in the scope, However, the Guideline Development Group will consider this group for inclusion. Peri-menopause is mentioned in 4.1.1c. (This will be before the menopause as the use of

	We look forward to being able to contribute further as the guideline develops.	these technologies for non-contraceptive reasons such as HRT is outside the scope.)
British Association for Counselling and Psychotherapy	The purpose of the Guidelines is to encourage greater use of long-acting reversible contraception. In order to do this the Guideline suggests that women are more likely to use such if they have information and advice. Whilst this may be the case, it is my experience of counselling women who have used (or refused to use) such methods, that a key reason for not wishing to use long-acting methods is that the patient does not like the fact that they do not have control over what happens to their body for the duration of the medication. The side-effects can be quite debilitating and though it is possible to reverse them, it takes time - in some cases many months - unlike other forms of contraception. I understand fully why the NHS is trying to address the high rate of unintended pregnancy amongst teenagers and younger women, but this cannot be done by contraception alone. In addition to such methods, a greater understanding of the emotional, psychological and social needs of these women needs to be addressed. The Guidelines should note this.	Addressing the broader context of sexual health is not the focus of this guideline – however, the broader context of the sexual health strategies is now referred to in section 3a of the scope.
British Medical Association	The BMA considers that one area that has not been specifically mentioned, but should be covered by the document, is the use of long-acting reversible contraception for those who lack the capacity to consent. The law courts have made clear that they will only authorise sterilisation of women who are unable to consent in cases where the alternative options, particularly long-acting reversible contraception, have been ruled out as unsuitable. This is an area of law that has a relatively low level of recognition within the UK. The BMA believes that the document should draw attention to, and explore the applicability of, the use of long-acting reversible contraception within this legal framework.	The guideline will not address legal aspects of consent but the Guideline Development Group will consider advice and any generic or specific DH guidance on consent. Specific searches (e.g of court proceedings) on legal issues around consent will not be performed.
British National Formulary (BNF)	2 a)Suggest amend as follows: The National Institute for Clinical Excellence ('NICE' or 'the Institute') has commissioned the National Collaborating Centre for Women and Children's Health to develop a clinical guideline on long-acting reversible contraception for women for use in the NHS in England and Wales. This follows referral of the topic by the Department of Health and the Welsh Assembly Government (see Appendix).	Incorporated

	3 b)Suggest amend as follows: Clinical opinion is that non-user-dependent methods could have a	The phrase "non user dependent" has been removed from the scope to avoid confusion.
	3 c)Suggest amend as follows: By contrast, long-acting reversible methods have high effectiveness which does not dependent on daily compliance. *Comment: Remove implication that contraceptive effectiveness is greater for long-acting contraceptives irrespective of compliance.*	Incorporated long-acting . Noted. The wording (now in 3b) has been altered to reflect this point
	3 d)Suggest amend as follows: Currently there is very low uptake of long-acting contraception (around 5% of contraceptive usage). A number of factors contribute to this; the high initial costs of these methods may put providers off if they think that the methods will not be used or required for the intended duration; the need for specific clinical skills (including current scientific information, insertion practice and information/advice on giving techniques) and facilities. Industry marketing frequently drives current provision of the most recently introduced long-acting methods of contraception, with the support of local clinical champions and of professional organisations.	This is now in section 3c which has been reworded for clarity. The suggested changes have been incorporated where wording remains.
	3 e)Suggest amend as follows: The resulting variation suggests that health professionals need better guidance and training so that they can enable women to make an informed choice from a full range of contraceptive methods	Incorporated
	4 b)Suggest amend as follows: This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health and the Welsh Assembly Government (see Appendix).	Incorporated
	4.1.1 a)Suggest amend as follows: The guideline will offer best practice advice for women of reproductive age who wish to plan their family through the use of long-acting reversible contraceptive methods	"regulate their fertility" remains in the scope as it cannot be assumed that all consumers have a family.
	4.1.1.b)*Comment: How will these groups be identified—,by age, socio-economic status, by disability, by conditions that may affect pregnancy or childcare, underlying disease e.g. epilepsy?*	Some groups are now specified in the scope. The Guideline Development Group may identify other groups during the development process.

	4.1.2 d)Suggest amend as follows: Men, since there are no male contraception methods.	The wording (now in 4.1.2a) has been changed to read "The guideline will not deal with contraception for men because there are currently no long-acting reversible methods."
	4.3.1Suggest amend as follows: The guideline will cover the benefits, risks, interactions, administration or insertion (timing of insertion and removal) side effects and contra-indications to the use of the following methods	Incorporated
	4.3.1 a)Suggest amend as follows: Sub-dermal implants	Incorporated
	4.3.1 b)Suggest amend as follows: non-hormonal methods for women	Incorporated
	Advice on treatment options will be based on the evidence available to the development group. When referring to pharmacological treatment, the guideline will normally make recommendations within the licensed indications. Exceptionally, and only where the evidence supports it, the guideline may recommend use outside the licensed indications.	The wording of this paragraph is standard to a NICE guidelines scope: • The guideline development process includes a hierarchy of evidence and "best" is therefore appropriate. • More than one pharmacological treatment may be considered during the development of the guideline. • The use of the Summary of Product Characteristics is assumed in guidelines and will be referenced.
	4.3.1 b) *Comment: How many prescribers actually use SPCs?*	
	4.3.1 c) *Comment: Would it be possible to elaborate on the type of information that should be provided?*	The type of information that should be provided will be considered by the Guideline Development Group and it is not possible to pre-empt the output.
	4.3.2Suggest amend as follows Guidance on any preliminary assessment required before using the method of contraception and on monitoring and follow-up. *Comment: Should the guideline include any special instructions to women while using this method?*	Incorporated in 4.3.1 The public version of the guideline will be available to consumers. Comprehensive patient information leaflets will not be produced as part of this development process
	4.3.5*Comment: Will any group of women be excluded e.g. women with physical or mental disability, women below 16 years of age, women with underlying disease state including HIV etc?*	We confirm that these groups will not be excluded

	disease state including HIV etc?	
Cochrane Fertility Regulation Group	**General Comment** • The scope looks very comprehensive. • Cochrane responses include the point that data analysis may be a problem. This relates to the fact that there is no consensus approach to analysis or meta-analysis of reference data in trials. • The guideline should address women and men as clients as users, not patients. Users of contraception are not patients. **Specific Comments** ➢ *3. Clinical need for the guideline* Pt a) 'NHS sexual health and HIV strategy'. This needs the correct title 'The national strategy for sexual health and HIV' (DH, 2001). This is produced not by the NHS but by the Department of Health (England). The document, its recommendations and implementation relate only to *England*. Pt e) 'There are no current formal professional or NHS guidelines covering the topic'. There are two very comprehensive guidelines available, they are; - NHS guidelines - PRODIGY Guidance on Contraception – www.prodigy.nhs.uk/clinical%20Guidance - WHO guidelines - WHO Medical Eligibility Criteria for Contraceptive Use (2nd Ed 2002) and WHO Selected Practice Recommendations for Contraceptive Use (2002). ➢ *4. The Guideline* Pt 4.2 Healthcare setting 'The guideline will cover ….. in general practice, community contraceptive clinics and hospital services' – include sexual health services …… 'community contraceptive and sexual health clinics and hospital services.' There is a need to add sexual health clinics as these often provide contraception services as well as STI services. ➢ *4.3 Clinical Management* Pt 4.3.1 The guideline should address benefits (contraceptive *and non contraceptive* benefits), side effects *(and uncertainties)* and contraindications.	The term 'consumer' has replaced the word 'patient' in the scope. Incorporated. The scope now also refers to the implementation plan of June 2002 The guideline has been requested partly to address the need to broaden the distribution of advice to professionals and to tailor international guidance to all UK settings. The scope has been amended with the words "that are widely used or tailored to cover UK practice ". Incorporated The text has been amended (as suggested by BNF above) and also now includes

	- *Uncertainties*. It is vital that uncertainties are addressed as this is where medical practice is often unclear and unhelpful to clients. Example: bone density issues and Depo Provera. There is no clear information on this and it is often discussed in an ill informed and unhelpful way. - *Non contraceptive benefits*. This should be addressed. This aspect is often an important element when choosing a contraceptive method. Importantly, this can be an area where claims are made about a method that research does not substantiate.	contraceptive *and non contraceptive* benefits. However, the use of technologies for other indications is outside of the scope. Uncertainty of risk will be addressed in evaluating evidence and in making recommendations.
	Pt 4.3.1 a) - The list refers to intrauterine systems and implants *and* subdermal implants. Subdermal implants are clear, what does 'implants' refer to? Is this referring to Fibroplant (frameless copper and hormonal beads – a variation of GyneFix)?	Correct
	- Injections. Although combined progestogen/oestrogen injections are not available in the UK (probably will be by 2004), it is assumed this guideline will address all types of injection.	Yes the guideline will address various sorts of injection.
	Pt 4.3.1 b) 'Advice on treatment options ….. to pharmacological treatments, the guideline will *normally* make recommendations within the licensed indications. Exceptionally, and only where the evidence supports it, the guideline *may* recommend use outside the licensed indications.' I do not think this will provide clarity for development of this guideline. How is *normally* defined? The rationale for this question and view is that we are very aware that current SPCs (Summary Product Characteristics) do not always reflect current research and, as such there is conflict for practitioners and clients. Cochrane Fertility Regulation Group believes the purpose of developing and publishing evidence-based guidelines is to provide the best level of knowledge to help practice; this must include how it updates SPCs and patient/client information.	'Normally' is defined by the exception in next sentence. The exception is where the evidence supports a non-licensed product. We agree that the purpose of guidelines is to provide the best level of knowledge.
	Pt 4.3.1 c) See previous point regarding use of terminology 'patient'.	Incorporated
	Pt 4.3.2 Will the guidance address issues of follow up?	Follow-up will be addressed and the scope has been altered to make this explicit...
	Pt 4.3.4 If the guideline is to address these issues, it should include indications for use of emergency contraception.	A review of the effectiveness of all contraceptive emergency measures is outside scope. However, advice on when contraception is less effective should include advice on additional measures, including when emergency contraception is needed.

	➢ *5.1 Audit support within guideline* 'The audit should compliment other existing and proposed work on relevance, including the sexual health strategy'. See previous point about the scope of this document.	Incorporated. Please note the sentence has been amended to read audit "advice".
Department of Health	Thank you for the opportunity to comment on the draft scope of the long-acting reversible contraception guideline. This letter reflects the views of the Department of Health and the National Assembly for Wales. **Paragraph's 3(a) and 5.1** Would it be possible to note within these two paragraphs that the Welsh Assembly Government's sexual health strategy is the Strategic Framework for Promoting Sexual Health in Wales.	Incorporated
Ealing PCT	Our Family planning lead has had a look at the scope and feels that it is a very thorough proposal and the finished guideline should prove very useful in promoting the uptake of long-acting methods - the only realistic way to reduce unplanned pregnancy in the long term.	Noted
East Kent Coastal PCT	The document seems to have covered everything except possibly for something on issues of consent and ethical considerations given that these methods are likely to be used in women less able to understand the implications eg those with learning difficulties.	Existing guidance relating to consent will be sought and will be considered by the Guideline Development Group.
Faculty of Public Health Medicine	The Faculty welcomes these guidelines and the scope seems eminently sensible. The Faculty would suggest that consideration should be given to including the following: 1. Appropriate follow-up regime for each method. 2. Guidance on clinical situations which may affect the use of these methods – this may be covered under section 4.3.1 or 4.3.2. The issue of the use of IUD/IUS in patients on anti-coagulant therapy should also be addressed.	Incorporated in 4.3.1 Clinical factors such as these will be specified by the Guideline Development Group. The comments will be passed onto them for consideration.
Family Planning Association	**General Comment** • The scope looks very comprehensive.	The term 'patients' has been replaced by

	• The guideline should address women and men as clients as users, not patients. Users of contraception are not patients.	'consumers' in the scope.
	Specific Comments	
	➢ *3. Clinical need for the guideline*	
	Pt a) 'NHS sexual health and HIV strategy'. This needs the correct title 'The national strategy for sexual health and HIV' (DH, 2001). This is produced not by the NHS but by the Department of Health (England). The document, its recommendations and implementation relate only to *England*.	Incorporated
	Pt e) 'There are no current formal professional or NHS guidelines covering the topic'. there are two very comprehensive guidelines available, they are; - NHS guidelines - PRODIGY Guidance on Contraception – www.prodigy.nhs.uk/clinical%20Guidance - WHO guidelines - WHO Medical Eligibility Criteria for Contraceptive Use (2^{nd} Ed 2002) and WHO Selected Practice Recommendations for Contraceptive Use (2002).	The guideline has been commissioned by the DH partly to address the need to broaden the distribution of advice to professionals and to tailor international guidance to the UK setting. The scope has been amended to read "There are no current formal professional or NHS guidelines covering this topic that are widely used or tailored to cover UK practice ".
	➢ *4. The Guideline*	
	Pt 4.2 Healthcare setting 'The guideline will cover ….. in general practice, community contraceptive clinics and hospital services' – include sexual health services ……' community contraceptive and sexual health clinics and hospital services.' There is a need to add sexual health clinics as these often provide contraception services as well as STI services.	Incorporated
	➢ *4.3 Clinical Management*	
	Pt 4.3.1 The guideline should address benefits (contraceptive *and non contraceptive* benefits), side effects *(and uncertainties)* and contraindications. - *Uncertainties*. It is vital that uncertainties are addressed as this is where medical practice is often unclear and unhelpful to clients. Example: bone density issues and Depo Provera. There is no clear information on this and it is often discussed in an ill informed and unhelpful way. - *Non contraceptive benefits*. This should be addressed. This is often an important element when choosing a contraceptive method. Importantly, this can be an area where claims are made about a method that research does not substantiate.	The text has been amended (as suggested by BNF above) and also now includes contraceptive *and non contraceptive* benefits. However the use of technologies for other indications is outside of the scope. Uncertainty of risk will be addressed in evaluating evidence and in making recommendations.

	Pt 4.3.1 a) - The list refers to intrauterine systems and implants *and* subdermal implants. Subdermal implants are clear, what does 'implants' refer to? Is this referring to Fibroplant (frameless copper and hormonal beads – a variation of GyneFix)? - Injections. Although combined progestogen/oestrogen injections are not available in the UK (probably will be by 2004), it is assumed this guideline will address all types of injection. Pt 4.3.1 b) 'Advice on treatment options ….. to pharmacological treatments, the guideline will *normally* make recommendations within the licensed indications. Exceptionally, and only where the evidence supports it, the guideline *may* recommend use outside the licensed indications.' I do not think this will provide clarity for development of this guideline. How is *normally* defined? The rationale for this question and view is that we are very aware that current SPCs (Summary Product Characteristics) do not always reflect current research and, as such there is conflict for practitioners and clients. fpa believes the purpose of developing and publishing evidence-based guidelines is to provide the best level of knowledge to help practice; this must include how it updates SPCs and patient/client information. Pt 4.3.1 c) See previous point regarding use of terminology 'patient'. Pt 4.3.2 Will the guidance address issues of follow up? Pt 4.3.4 If the guideline is to address these issues, it should include indications for use of emergency contraception. ➢ ➢ *5.1 Audit support within guideline* 'The audit should compliment other existing and proposed work on relevance, including the sexual health strategy'. See previous point about the scope of this document.	Correct Yes the guideline will address various sorts of injection Normally is defined by the exception in next sentence. The exception is where the evidence supports a non licensed product. We agree that the purpose of guidelines is to provide the best level of knowledge. Incorporated Incorporated. Follow-up will be addressed and the scope has been altered to make this explicit.. Advice on when contraception is less effective should include advice on additional measures including when emergency contraception is needed. However a review of the effectiveness of all contraceptive emergency measures is outside scope. Incorporated. Please note the sentence has been amended to read audit "advice"
MSSVD/AGUM	I think generally this is a good document.	

	My comments would relate chiefly to the area of sexually transmitted infections, including HIV & AIDS: 1) The guidelines should address issues of using long-acting reversible contraceptive methods in women who are known to be HIV-infected. This will need to include consideration of any drug-drug interactions for women who may be on complex antiretroviral treatment regimens. It should also consider possible influences on transmission of HIV to sexual partners. 2) The guidelines should also consider effects of the methods on acquisition of sexually transmitted infections (including HIV) and also any influence on the development of complications of such infections if acquired (e.g., pelvic inflammatory disease from gonococcal or chlamydial infection). Under "population: specific issues" would it be worth adding "women who have just had a TOP"?	Women with HIV have now been specified in the scope. However, the issues will be addressed from the point of use of these technologies rather than all contraceptive advice to specific groups (e.g. women with HIV etc). The Guideline Development Group will have a doctor from GUM. The Guideline Development Group will consider this question at an early stage of development and consider it for inclusion.
Organon Laboratories Limited	1. Having reviewed the document carefully, we believe the spirit of the guideline, as reflected in the detail of the scoping document, seems to be to deliver clarity on the use of user-independent contraception, which, by nature of this independence, generally acts in the longer term. We note that the title of the guidelines describes the scope as “long-acting reversible contraception” and we believe that this title does not accurately reflect the intention behind this particular guideline. The title requires a somewhat arbitrary definition of “long-acting” to be made. If such a definition is to be included in the guidelines, we believe that it needs further discussion in the light of new and developing methods of contraception before it is adopted. The use of an alternative term in the title, which we feel might be closer to the spirit of the guideline, could potentially remove the requirement for such a definition. Moreover, our experience suggests that the terminology ‘long-acting reversible’ may not be fully understood as also meaning non-permanent, especially by young women, who are identified as one of the target groups. We suspect that this term might create a negative perception amongst these women that is now often unfounded with modern, quickly reversible methods. These guidelines could represent an opportunity to deal with this. 2. With reference to section 4.1.1 we welcome point a) in acknowledging that	The title ‘Long-acting reversible contraception’ has been commissioned by the DH. For clarity, a definition has been added in 2a of the scope, which reads “Long-acting reversible contraception is defined here as methods which require administration less than once per cycle or month”. Issues of reversibility and duration of effectiveness will be addressed within guideline. The aim of the guideline is to increase information on and possibly use of these methods. Informed decision making is central to the

	women who choose long-term reversible methods of contraception are not prevented from using them due to difficulty with access or economic reasons. In our experience patient choice is a critical element that underpins prescribing and contributes to a woman's acceptance of, and continuation with, any contraceptive method. Therefore, we believe point b) requires clarification. It is not clear whether the intention, as stated here, is to try to identify which women would benefit most from long acting reversible methods (which appears to contradict the previous point); or if it is to try to find sub-groups of women for whom one method might be more suitable than another. We would be somewhat concerned if this process did not place patient choice at the centre throughout, because our experience suggests that women frequently choose not only the method, but also the actual device or medication for their contraception.	guideline. Point 3e in the scope states that the guideline will assist health professional and "enable women to make an informed choice from a full range of contraceptive methods". Long-acting reversible contraception is thought to be under-used and it is acknowledged that further information is required for healthcare professionals and consumers generally and specifically for women where contraceptive choices are limited by other factors such as peri-menopause, teenagers, specific medical conditions etc.
	We would also like to clarify why certain age groups have been singled out in point c). Given that the scope states that it will not consider the non-contraceptive uses of these agents, we are unsure as to why women during the menarche and before the menopause would not continue with their chosen method of contraception if they are content with it, unless it is for reasons outside the proposed remit of these guidelines.	The Guideline Development Group will address the use of these technologies in these groups and not address all contraceptive advice to specific groups (i.e. is not guideline on contraception in peri-menopause/ teenagers/HIV positive women etc). As risks relating to other contraceptive methods change with age, women maybe advised to consider alternatives (e.g. to stop COCP).
	3. Under 4.3.1 part a) the scope refers to vaginal rings. As a developer of such a product we can confirm that at present no such devices are licensed for use in this country and there is no application for marketing authorisation planned before 2004. There is no decision pertaining to the time of launch of this product in the UK. Consequently, there will be no Summary of Product Characteristics or price of the product available for inclusion into submission of evidence, which we understand will be required by the end of this year. Furthermore, the ongoing trials in the UK are unlikely to be published in time for review by the guideline developers. Given that only published evidence will be considered and commercial in confidence data will not be accepted, we would like clarification on how this review will be approached given these additional challenges. We make these comments as a constructive appraisal of the draft scope document and we hope that they will add to its clarity. In view of the issues raised above in points 2 and 3, we would welcome the opportunity for direct dialogue with the Institute either through a meeting or telephone discussion prior to the final scope being released. We seek such clarification in order that we may co-operate fully and submit pertinent information to the guideline developers.	The challenge of confidential data and the licensing position are common to the development of NICE clinical guidelines. NICE confirm that all stakeholders will be invited to submit evidence but that commercial-in-confidence data is not used during the development of clinical guidelines. With regard to licensing in the UK, as the scope indicates, where the evidence supports it, non-licensed products can be recommended by the Guideline Development Group. It is understood that this product is licensed and used outside the UK. We anticipate therefore that data from non-UK sources should be available. We welcome your cooperation and trust that you understand our position of not accepting confidential data. Hopefully when the review of this guideline takes place in future years,

		evidence for your product in development will be available.
Pharmacia Limited	**Comments:** • We suggest the definition of 'long-acting reversible contraceptives' be clarified in the document. The document suggests it is dosing that requires at most 'monthly' (once per cycle?) administration in section 4.3.5, and then 'non-user dependent' methods in section 3b. It is suggested that a clearer definition could be 'administered at most once per cycle'. Within this class of interventions, non-user dependent methods comprise a significant proportion. • We request that the reason for developing the guideline be clarified, or objective of the completed guidance be explicit. For example, is the guidance expecting to evaluate the effectiveness of LARCs, or provide guidance to increase awareness of LARCs among GPs, or provide a wider choice of interventions for women? Is the focus therefore one of evaluating the effectiveness of these interventions where used, or, communicating and educating doctors and more importantly consumers over the value of these alternative interventions? Section 2a of the scope -states that it will 'provide recommendations for good practice', though it does not state whether this relates to whether or not the products should be used (addressing the effectiveness question) or when and where they should be offered (communication and education) or both.	Noted – a definition has been added to the scope. Paragraphs 3 b and c have been swapped around and non-user dependent has been changed to long-acting reversible contraception. The guideline will address issues of effectiveness, and communication and education. The aims of a good clinical guideline are: • to provide recommendations for the management of patients/consumers by healthcare professionals • to be a basis for the development of standards to assess clinical practice • to provide a resource that can be used in the education and training of healthcare professionals • to help patients to make informed decisions and improve communication between the patient and healthcare professional. The 3 versions of the guideline will support these aims.
Royal College of Nursing	**Section 3** Clinical need for the guideline. Point (d). Cost is a key factor here as even if benefits are clear for women, providers may be reluctant to encourage uptake because of cost implications. However, this misses the 'big picture' because if an unwanted pregnancy is terminated, the costs to the woman and the health services are likely to be much greater. **Section 4** Population. 4.1.1. The clinician should of course discuss with the client whether long acting reversible contraception is the most appropriate, but guidance on	Noted Noted - Thank you for referring us to the work of Guillebaud

	groups who may benefit is welcomed. Some health care professionals do not consider that younger women should use these contraceptive methods because of issues of non-compliance, although Professor John Guillebaud highlighted two years ago the advantages for young people, especially teenagers, who are going through difficult formative years. Efforts should be made to ensure they also have equal access to this method of contraception. 4.3.1. We were surprised to see vaginal rings included in the list of methods to be addressed by the guideline. Although they cover a cycle, some women can remove the rings quite easily, which possibly alters the definition of long-term reversible methods. A definition of long-term would be helpful, as this could assist health care professionals and women to reach a decision as to which contraceptive method to use. 4.3.3. Training is a major issue for doctors and nurses, in terms of numbers of courses available and the location of these. The RCN has developed a guideline for both the fitting of Implannon and IUDs by nurses, which should be included in advanced course for nurses in contraception. Only a few nurses are trained to perform these procedures at the moment, but there is no reason that nurses who are appropriately trained should not take on these additional roles. We welcome this guideline and hope that all women have access to these methods of contraception – long-term reversible methods should not simply be offered to more 'mature' women because their compliance may be better. The need for reliable, safe, effective and acceptable contraception is likely to be greater among younger women who are coping with increasingly difficult demands on aspects of their daily lives.	Long-acting reversible methods included in the guideline are now defined section 2a: "methods which require administration less than once per cycle or month". These methods depend less on user compliance however women may remove/discontinue with some methods, for example, rings Noted – the Guideline Development Group will Be asked to consider Noted. The guideline will be for all women of reproductive age
Royal Pharmaceutical Society of Great Britain	We believe that the scope is reasonable and have no suggested alterations. We would suggest that the Guideline Development Group would benefit from having a pharmacist as a member. The Society would be happy to supply names of suitable pharmacists to join the Guideline Development Group.	Noted with thanks
Schering Health Care Ltd	Section 3 deals with the clinical need for the guideline and the draft refers to teenagers and younger women being at the highest risk of unintended pregnancy. The target population is further referred to under Section 4.1 where it is stated that the guideline will "offer best practice for women of reproductive age" and "address specific issues ..... in women during the menarche and before menopause". We would like to impress on the development committee that there are peaks in abortion rates (and presumably therefore unintended pregnancy) that occur in pre- and peri-menopausal women, as well as in younger women and it is therefore crucial that these women are included in the guideline.	The Guideline Development Group will consider the use of these technologies for all women of reproductive age. Specific issues before the menopause will also be addressed. It is necessary to keep the scope to a manageable size and so issues around, for example, breastfeeding have not been specified. However, the Guideline Development Group will be made aware of

	Furthermore, generally older fertile women, tend to believe that they have a more restrictive choice of methods and so it is crucial that we ensure that this group are also included. Furthermore on this theme, breast feeding women are a further target group who are likely to benefit from methods covered by this guideline. Section 4.3.1 states that the guideline "will cover the benefits, side-effects and contraindications". This appears to be at variance with the statement in the same section (4.3.5) which states the use of technologies for other than non-contraceptive reasons (e.g. menorrhagia) will not be considered. It would seem impractical for clinicians and women to make informed choices without understanding all the benefits and risks of all methods. Finally, we have some concerns relating to comments that appear in section 3(d) and (e). In 3(d) the statement is made that "industry marketing frequently drives current provision of the most recently introduced methods.....". Whilst this may be correct, it is inconsistent with the earlier statement that there is very low uptake of such methods and it seems to be an unnecessary and inappropriate comment in the context of this guideline. Indeed, in section 3(e) the suggestion is further developed that health professionals need "additional guidance and training" to counter the effects of local variations induced by the marketing activities of the industry. We do not see that this statement is of any constructive value in this document.	your comments and asked to prioritise issues for other groups (e.g. breastfeeding women) as time permits. For clarification this guideline will address issues for women as they relate to long-acting reversible methods of contraception. The guideline line will not provide advice for other types of contraception. Non-contraceptive benefits have been incorporated but to clarify the use of these technologies for non-contraceptive reasons (e.g. heavy periods/HRT) is not included in the scope of this guideline. Incorporated – the scope has been amended so that the reference to industry marketing is removed.
Tower Hamlets PCT	Will the guidelines address the issue of women on Depo-provera experiencing amenorrhoea for more than 2 years?	Amenorrhoea maybe a side effect of Depo-Provera and is therefore included within scope.
Royal College of Midwives	Introductory Comments The Royal College of Midwives (RCM) welcomes this opportunity to comment on the scope consultation on long-acting reversible contraception. Family planning is an important topic for midwives, especially those who are family planning trained and/or work in programmes that provide holistic care to targeted groups of women of reproductive age. **Specific Comments** The RCM is pleased that the work on NICE guidelines for long-acting reversible contraception will commence in January 2003. Our specific comments are as follows:	

	2 b)	The role of guidelines in supporting the implementation of National Service Frameworks (NSFs) is recognised, however it would also be helpful to state which NSFs they are predicted to contribute to.	Sexual Health strategy rather than NSF – although the guideline may be relevant to the Maternity NSF post-birth group with regard to post-natal contraception
	3 a)& b)	Although it is not explicit, it is suggested that long-acting reversible contraception will be promoted for groups that are associated with so-called "problematic" unintended pregnancy such as teenagers. It is inappropriate for NICE guidelines to even hint at such a purpose. There must be no question that the guidelines will be developed for <u>all</u> women of reproductive age and that safety thresholds must be the same for all groups. Prevention of teenage pregnancy is sometimes regarded as a consequence that justifies the toleration of higher risks and side effects. Again, the RCM believes that NICE guidelines must be developed without a political agenda.	The guideline will be developed for all women and this is now explicit in the scope
	3 c)	This point must acknowledge that while daily compliance is less of a concern with long-acting reversible contraceptives, there are issues around compliance with follow-up appointments for continued contraception and/or health monitoring. Tracking systems to reinforce compliance with long-acting methods should be included in the scope and looked at when developing the guidelines.	(This comment refers to 3b in the final scope) Incorporated – follow-up and monitoring have been added to the scope in 4.3.2. The term "reinforcing compliance" should be avoided as implies coercion.
	3 d)	In addition to the cost of these contraceptive methods providers' views of these methods and their ability to help women decide which methods are best for them, considering their plans for child spacing, are crucial. Furthermore, providers such as General Practitioners and others may need more than implant-insertion training in order to prescribe, dispense and manage the full-range of long-acting reversible contraceptives.	(now 3c) Noted. The cost to providers is one contributory factor noted in the scope alongside clinical skills and facilities.
	3 e)	The RCM heartily agrees with this point, and we hope to see training standards and resources properly emphasised and resourced as a result of these guidelines. Health professionals who are family planning trained should have the knowledge to counsel the women on <u>all</u> family contraceptive methods. We expect to see midwives centrally included in this training. Guidelines without corresponding training are not productive.	Noted. Training of professionals is likely to be an implementation issues for providers to note once the development of the guideline is complete.
	4.1.1 b)	These guidelines should explicitly identify the groups that are <u>least</u> likely to benefit from these contraceptive methods as well as those	Identifying least likely will be an issue for the Guideline Development Group to consider.

		that are most likely to benefit. Also groups that are vulnerable to coercion should be identified for ethical reasons.	The section now specifies issues for groups (e.g. consumers with leaning disabilities). Contra-indications or risks will be identified – but will not exhaustively look to cover those "least likely to benefit".
	4.2 a)	NICE should acknowledge the roles of private practice settings in relation to the guidelines.	NICE guidelines are primarily intended for the NHS
	4.3.1 b)	It is controversial for NICE guidelines to recommend the use of pharmacological agents outside licensed indications. The RCM expects NICE to address whether this is within the scope of NICE's role and to collaborate with other stakeholder agencies.	It is the policy of NICE to make recommendations of the use of non-licensed pharmacological treatments but only when evidence supports such a recommendation.

Summary of issues raised by non-registered stakeholders

- Number of contacts required by professionals carrying out clinical procedures in order to maintain skills and expertise