National Institute for Health and Care Excellence

12-year surveillance (2017) – Long-acting reversible contraception (2005) NICE guideline CG30

Appendix B: stakeholder consultation comments table

Consultation dates: 27 February to 10 March 2017

Do you agree with the proposal not to update the guideline?

Stakeholder	Overall response	Comments	NICE response
Primary Care Women's Health Forum	No	This guideline was published in 2005. There has been new evidence about the efficacy and acceptability of LARC compared with the user dependant methods.	Thank you for your comment. Every NICE published guideline is included in the ongoing surveillance programme (see surveillance programme interim guide) to examine whether the guideline needs to be updated. This guideline was last updated in 2014. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014.

			Appendix A and Appendix B will be updated based on new product availability.
Brook Young People's sexual health and well being charity	No	The current guideline has a lack of information regarding subdermal implants as a method. The current guidelines contain out of date recommendations which are not in line with best practice guidance No reference to newer products – including Sayana press which is a completely new departure for contraception	Thank you for your comment. The guideline was last updated in 2014 and new recommendations on progestogen-only subdermal implants were added to the Progestogen-only subdermal implants section. Following consideration of all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Appendix A and Appendix B will be updated based on new product availability. In addition, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014.
Pfizer Ltd	No	The guideline is now out of date and would not help to guide good clinical practice	Every NICE published guideline is included in the ongoing surveillance programme (see surveillance programme interim guide) to examine whether the guideline needs to be updated. NICE's Clinical Guidelines Update Programme updated this guideline in 2014. The update is an addendum to NICE clinical guideline CG30. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced

			with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Appendix A and Appendix B will be updated based on new product availability.
Medicines and Technologies Programme, NICE	No	Intrauterine system p18-26: The availability of new LNG-IUDs may have an effect on recommendations in this section. For example the risks and possible side effects recommendations were likely based on Mirena, the only available LNG-IUD at the time. There are now new products which may differ in risks and possible side effects based on trial data and so the recommendations in this section likely need to be updated. Also the recommendation about licensed duration of use being 5 years (in rec 1.3.1.1) is based on Mirena. As you have highlighted in the impact statement (p27) Jaydess and Levosert are licensed for 3 years use. (Note, a further LNG-IUD Kyleena has received UK approval but does not appear to have been launched yet). Progestogen injectable contraceptives p27-33: The availability of the new product Sayana Press has an effect on some of the specific recommendations in this section as highlighted in earlier MTP comments on this and as you have highlighted in the impact statement (p33). We agree that Appendix A and B are also likely to need updating based on new product availability.	Thank you for your comment. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Appendix A and Appendix B will be updated based on new product availability.
Mencap	No	Mencap recommends the guideline is reviewed in order to: a) reflect the current status of the Mental Capacity Act and b) ensure guidance	Thank you for your comment. The guideline makes reference to the Mental Capacity Act 2005 stating "If someone does not have capacity

		around decision making in both the short and full guidelines reflects best practice as defined by the Mental Capacity Act.	to make decisions, healthcare professionals should follow the code of practice that accompanies the Mental Capacity Act". No new edition of Mental Capacity Act has been published since 2005.
MSD Ltd	Yes	No comment	Thank you.
Advisory Group on Contraception (AGC)	No	The guideline has not been reviewed or updated in full since they were issued in October 2005. Since this time, there have been significant changes in the policy environment affected the provision and commissioning of services delivering LARC, which should be reflected in updated guidance to ensure that accountability and responsibility for access to LARC, in line with NICE guidelines, is adhered to. The Health and Social Care Act 2012 significantly changed the commissioning landscape for sexual and reproductive health services. In April 2013, contraception commissioning was shifted from NHS Primary Care Trusts to local government public health teams, who now have responsibility for commissioning all LARC provision for contraceptive purposes, in both community facilities and GP surgeries. The result of this is greater fragmentation of responsibility for LARC provision across health and local government, making it a difficult environment for women to navigate. Moreover, it contributes to greater upfront costs for fitting some LARCs, such as IUS or IUD, which should be avoidable through greater integration and streamlining of services. NICE should be providing guidance to commissioners and providers on how to achieve this. In addition, the current economic analysis is not directly relevant to commissioning decisions made by local authorities, and should therefore be re--assessed with local authority budgets in mind, reflecting the impact on the local health and care economy accordingly. There is existing evidence and tools to support this, such as Bayer's Impact of unplanned pregnancies on local authority budgets cost calculator and the FPA's Unprotected Nation.	Thank you for your comment. Every NICE published guideline is included in the ongoing surveillance programme (see surveillance programme interim guide) to examine whether the guideline needs to be updated. This guideline was last updated in 2014. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between LGB17 and CG30 to address service delivery concerns and link NICE's products on contraceptive services. In addition CG30 indicates that there are many different contraceptive methods available in the UK and women should choose one that suits them: Recommendation 1.1.1.1 Women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods. Recommendation 1.1.1.2 Women should be provided with the method of contraception that is most acceptable to them, provided it is not contraindicated. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated

		There have also been year--on--year cuts to public health budgets, which fund contraception. Following an in--year cut of over six percent to public health budgets in June 2015, the 2015 Spending Review set out annual cuts of an average 3.9 per cent over the Spending Review period. By 2018, public health budgets will have been cut by £360m – the guidelines issued by NICE on LARC must therefore be reviewed in light of the significantly changed funding environment, which is increasingly seeing restrictions in access to LARC for financial reasons, as local authorities seek to provide high--quality services for less money. The combination of the above two points has led to a lack of accountability for ensuring availability and training for workforce that can fit LARCs such as IUS or IUD. This should therefore be including within the guidelines, to ensure a requirement and accountability for having a trained IUS or IUD fitter accessible to all women who are seeking this form of contraception. The guidelines should also be updated to reflect indications for the non--contraceptive benefits of LARC, for example in treating heavy menstrual bleeding and managing endometriosis. This is important to ensure holistic care for women, bringing cohesion to the commissioning environment where the delivery of LARC services for non--contraceptive purposes is the responsibility of clinical commissioning groups, whereas for contraceptive purposes responsibility lies with local authorities. Since 2005 new methods of LARC have become available, including Jaydess, Levosert and Sayana Press, which are not accounted for within the existing guideline. Moreover, more robust information and understanding of the benefits and risks of LARC have come to light since the guideline's initial publication, which can have a significant impact on reducing complications for women with LARC. This includes better understanding of how intrauterine methods relate to uterine perforation, and the use of the copper IUD for emergency contraception.	recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Appendix A and Appendix B will be updated based on new product availability.

		Finally, the guideline should be updated to reflect the decision by Public Health England to distinguish between vLARC from LARC, the latter of which includes the contraceptive injection.	
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	No	No comment	Thank you.
Royal College of Nursing	No	We consider that the decision that NICE has made not to review and update this guideline is not only inadequate but potentially dangerous. To continue with a 2005 guideline with only one chapter (implants) updated is inappropriate, particularly as we know that the guideline does not relate to current practice and so much research has been done on this subject over the last 12 years. For example, recommendation 1.1.3.4, 1.1.3.5, 1.1.64, 1.1.6.5 ideally should make reference to Faculty of Sexual and Reproductive Healthcare (FRSH) letters of competency to evidence this. Recommendation 1.1.3.6, current practice is that informed consent should be obtained regardless of use outside terms. It needs to be updated to include the statement that additional discussion and consent should be obtained if product is being used outside UKMA. Recommendation 1.1.5.1, in current practice, Child Protection/Safeguarding proformas are usually completed on U19 not just the u16. Recommendation 1.2.1.1, again this should make some reference to IUD being used as an emergency contraception as well? Recommendation 1.2.1.1 with reference to "effect on periods – Heavier bleeding…" current practice is '3-6 months following insertion the patient may experience this but bleeding patterns tend improve with time' FSRH (2015) 1.2.2.3 IUS is listed as if it is one system, there are three. 1.2.6.4 the IUS, needs to mention other systems. 1.2.2.3 Testing for STIs not recommended in women not at risk.	Thank you for your comment. Every NICE published guideline is included in the ongoing surveillance programme (see surveillance programme interim guide) to examine whether the guideline needs to be updated. This guideline was last updated in 2014. The update is an addendum to NICE clinical guideline CG30. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services. In addition, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Guideline users are not expected to use guidelines in isolation, but to consult other sources where needed. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will

		1.3 IUS again needs to say IUSs to include other systems. 1.4.1.1 Risk of HIV acquisition, this is highlighted in the FSRH guidance and should be highlighted in this guideline. The FSRH recently published guidance on contraception after pregnancy is relevant to this document. A wider acknowledgement should be made of the role of community pharmacist in provision of injectable contraception. Some difficulties exist which were unknown before the split in commissioning arrangements and need a mention if LARC is to be seen as key to giving women a reliable method of contraception. In light of the above comments, we, therefore, do not support the proposal not to update the guidelines and are concerned that continuing to use the recommendations in the 2005 guidelines could potentially lead to dangerous practice.	prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Appendix A and Appendix B will be updated based on new product availability.
Faculty of Sexual and Reproductive Healthcare (FSRH)		FSRH is extremely concerned at the decision not to update the CG30 guideline. We believe that by not taking a comprehensive approach to reviewing CG30, NICE risks undermining the relevance of this guidance to commissioners and clinicians and ultimately risks compromising the quality of clinical care available to women. Changes in the commissioning landscape Since the publication of the original guideline in 2005 the commissioning landscape of sexual and reproductive healthcare and consequently LARC has changed dramatically. The responsibility for commissioning LARC for contraceptive purposes now resides with Local Authorities. This shift in commissioning responsibility means that the existing CG30 economic analysis is not entirely relevant to Local Authorities who are keen to work with the most up-to-date evidence and economic evaluation when commissioning care for their respective areas. At a time when public health budgets are significantly reduced and local authorities are looking to provide high-quality services for less money, evidence-based, economic evaluation of LARC as part of an updated CG30 guideline is integral in ensuring that commissioners	Thank you for your comment. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines on contraception to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services. In addition CG30 indicates that there are many different contraceptive methods available in the UK and women should choose one that suits them: Recommendation 1.1.1.1 Women requiring contraception should be given information about and offered a choice of all methods, including long-acting reversible contraception (LARC) methods.

| | | duly consider the costs averted by the local health economy through the commissioning of LARC e.g. Bayer's Impact of unplanned pregnancies on local authority budgets cost calculator. In addition, Local Authorities are increasingly keen for the social impact and impact on social care costs of health interventions to be clearly demonstrated, again highlighting the need for an updated CG30 guideline that is relevant to the current commissioning landscape.
Similarly, it is important to recognise that in the new commissioning landscape service providers of contraceptive care are changing, increasingly including private providers who may not have a strong internal clinical culture surrounding LARC and so have a clear need for the most up-to-date, relevant guidance on LARC methods to drive safe and cost effective service delivery.
Reduction in access to LARC
Further, at the time of its publication CG30 helped to increase access to LARC through its presentation of up-to-date evidence and economic evaluation within the historic commissioning landscape. This then in turn incentivised the provision of LARC for commissioners. FSRH is concerned that without a reviewed and updated economic evaluation and evidence base, commissioners will be less incentivised to commission LARC, reducing provision of LARC for women.
IMS Health MAT data to November 2016 also illustrates a worrying decline in LARC uptake: Nexplanon (subdermal implant): -5.44%; Mirena (intrauterine system): -0.38%; Depo-Provera (contraceptive injection): -1.45%1. These falling levels of LARC suggest restrictions in access and potential issues surrounding the commissioning of LARC across care settings; issues that may be compounded if the cost benefits of this extremely effective health intervention are not clearly restated in relevant terms to local authority commissioners.
In addition, it is important that CG30 is updated to reflect the wider benefits of LARC in terms of treating heavy menstrual bleeding and | Recommendation 1.1.1.2 Women should be provided with the method of contraception that is most acceptable to them, provided it is not contraindicated.
Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions.
Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014.
Appendix A and Appendix B will be updated based on new product availability. |

[1] IMS Health, XBPI, Units data, MAT November 2016

		managing endometriosis. Highlighting the wider health benefits of LARC that extend beyond contraception will help to promote holistic women-centred healthcare commissioning, as opposed to siloed pathways of care that are fragmented according to whether LARCs are used for gynaecological or contraceptive purposes and therefore commissioned respectively by CCGs or local authorities[1]. New methods, understanding and research Likewise, since the publication of CG30 new methods of LARC have become available and widely used, such as Jaydess, Levosert and Sayana Press, as well as 120 new references that NICE cite in their surveillance proposal. Without CG30 accounting for these new methods and new evidence, the guideline is not up to date, risking that clinicians extrapolate incorrect information from CG30 as it stands and that the economic analysis of LARC is not reflective of the use of new methods. In addition, since 2005 we have obtained better information and arrived at a better understanding about the risks and benefits of certain contraceptives. For example, intrauterine methods and how they relate to uterine perforation, the use of the copper IUD as emergency contraception, as well as sub-dermal methods and complications with impalpable devices and the migration of devices. This information and understanding is not reflected in the current CG30 guidance, yet the inclusion of such information could potentially have a positive impact, reducing complications for women with LARC, as well as better equipping women to make more informed choices about the range of LARC methods available to them. Evidence In terms of the quality and quantity of new evidence in this field, FSRH believes it is important to recognise the current research culture within this area of medicine is very small and still emerging. It is also important to note that research culture in this area has expanded since the publication of CG30 and so the updating of CG30 has the potential to cultivate a renewed research interest in	

		this area and drive further evidence on which to base future guidance in this field.	
FPA	No	Given the research that has been carried out since the last review it is FPA's view that this decision is not only disappointing but potentially dangerous. The clinicians we work with tell us that, to continue with the 2005 guideline (which includes only a brief review on the chapter on implants in 2014) is wholly inadequate.	Thank you for your comment. The guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Appendix A and Appendix B will be updated based on new product availability.
University Hospitals Birmingham / Umbrella Sexual Health services	Yes	No comment	Thank you.

Do you agree with the proposal to put the guideline on the static list?

Stakeholder	Overall response	Comments	NICE response
Primary Care Women's Health Forum	No	I believe this guideline needs to be updated in view of the new products and recent evidence to support the use of LARC	Thank you for your comment. Every NICE published guideline is included in the ongoing surveillance programme (see surveillance programme interim guide) to examine

			whether the guideline needs to be updated. This guideline was last updated in 2014. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014.
Brook Young People's sexual health and well being charity	No	No comment	Thank you.
Pfizer Ltd	No	No comment	Thank you.
Medicines and Technologies Programme, NICE	No	No comment	Thank you.
Mencap	Not answered	No comment	
MSD Ltd	Yes	No comment	Thank you.
Advisory Group on Contraception (AGC)	No	The guideline should be reviewed in 2017 to take into account the changing landscape for service provision and commissioning, as well as additional evidence on indications for LARC, complications	Thank you for your comment. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or

		associated with LARC, and new methods of delivery. As such, it should not be moved to the static list at this time.	contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines on contraception to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services.
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	No	No comment	Thank you.
Royal College of Nursing	No	We note that it is proposed to put the guideline onto the 'static' list. This means it is still regarded by NICE as current and to be referred to by clinicians while containing out of date recommendations which are not evidence-based and not in line with current, best practice in the UK, Europe or the US. In addition, the health economic aspects need updating from a more public health and local authority perspective. The Care Quality Commission (CQC) makes references to NICE guidelines as evidence in their inspections so this has an impact too. In the light of the above comments, we do not support the proposal to move the guideline to the static list.	Thank you for your comment. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Appendix A and Appendix B will be updated based on new product availability.Health economic modelling was conducted when the

			guideline was originally written, and concluded that all forms of long-acting reversible contraception were cost-effective.
Faculty of Sexual and Reproductive Healthcare (FSRH) Faculty of Sexual and Reproductive Healthcare (FSRH)	No	As Above	Thank you.
FPA	No	Given that this means that 2005 guidance will still be considered current, whilst containing out-of-date recommendations and contradict current best practice, we urge NICE to review this decision. We are particularly concerned that it has not been updated to make reference to new dose products (Jaydess and Levosert) or Sayana Press, a new delivery system for injectable contraception. We are concerned that 120 new studies have been excluded from consideration by NICE because they are qualitative, despite the fact that their findings are important and relevant to issues including access and patient care.	Thank you for your comment. The guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Appendix A and Appendix B will be updated based on new product availability. During a 12-year surveillance review of NICE guidelines, we search for systematic reviews and randomised controlled trials to identify new evidence that could have an impact on current recommendations, as well considering other types of evidence when highlighted by topic experts as long as it is within the evidence types specified in the relevant review question.
University Hospitals Birmingham / Umbrella Sexual Health services	No	As commented in appendices – updates needed to reflect significant changes in provision of LARC since the guideline was last reviewed. Contraception now commissioned by local authorities in conjunction	Thank you for your comment. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or

		with genito-urinary medicine, despite other women's health being split between CCGs and NHS England as commissioners. These impacts greatly on the ability to provide LARC, often adversely. New guidance on Contraception after Childbirth from FSRH encourages provision of LARC but does not take into account these commissioning and training barriers.	contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines on contraception to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services.

Do you have any comments on areas excluded from the scope of the guideline?

Stakeholder	Overall response	Comments	NICE response
Primary Care Women's Health Forum	Yes	Since the Health and Social Care Act 2012 the commissioning responsibility of LARC has been transferred to Public Health. This has fragmented the commissioning from that of core contraception (NHSE) and abortion care (CCGs). Updating this guidance would be timely to reinforce the importance of the choice of contraceptive methods including a full range of LARC methods and there would be an opportunity to do an updated cost-evaluation of LARC methods.	Thank you for your comment. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines on contraception to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services. Following consideration of all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the

			different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014.
Brook Young People's sexual health and well being charity	Not answered	No comment	
Pfizer Ltd	Yes	Sayana Press is a LARC that has been available in the UK since 2013 with a self-administration licence granted in 2015. This is not included in the guideline and is the only LARC to offer the option for patient self-administration by subcutaneous injection which has the potential to reduce NHS resource use[1]. This product is also useful in overweight/obese women where it can be difficult to reach muscle with Depo-Provera[2]. Additionally, there has been new evidence on bone mineral density loss and fracture data[2,3] with Depo-Provera as well as new data on weight gain[2], VTE risk[2], ovarian cancer risk[4], HIV acquisition and transmission[2] and comparative data on the incidence of bleeding between different LARCs[5].	Thank you for your comment. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions. Furthermore, the guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014.
Medicines and Technologies Programme, NICE	No	No comment	Thank you.

Mencap	Not answered	No comment	
MSD Ltd	No	No comment	Thank you.
Advisory Group on Contraception (AGC)	Yes	Whilst the guidelines provide guidance on specific LARCs available, it does not provide clarity on lines of responsibility and accountability to ensure that the guidance is being met by providers across clinical commissioning group and local authority-- commissioned services. As per the response to the above questions, the guidelines should be amended to reflect environmental factors that are affecting the provision of LARC--fitting services – including commissioning responsibilities, new funding flows and economic relevance, and responsibilities for ensuring a trained workforce.	Thank you for your comment. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services.
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	See comments	1.2.1.1 (" the risk of uterine perforation at the time of IUD insertion is very low (less than 1 in 1000)") and 1.2.2.7 ("IUDs can be safely used by women who are breastfeeding") There is a significantly increased (although still small) risk of perforation if a woman is post-natal or breastfeeding. 1.2.2.3 ("testing for the following infections should be undertaken before IUD insertion: CT in women at risk of STIs") This would appear to preclude insertion of an IUD (and in the next section, an IUS) for a young woman who has not had a Chlamydia test. There is no evidence of an increased risk of ascending infection if testing is not done prior to insertion. 1.2.3 ("Provided that it is reasonably certain that the woman is not pregnant, IUDs may be inserted :").	Thank you for your comment. The guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC) published 2014. Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions.

		Does not include immediate postplacental insertion at LSCS or vaginal delivery which is an important current strategy to increase post natal uptake of contraception. 1.2.4.1 ("A follow up visit should be recommended after the first menses, or 3–6 weeks after insertion, to exclude infection, perforation or expulsion.") We do not consider that a routine follow up visit is required – this has become a "Choosing Wisely "recommendation. 1.3.1.1 ("The licensed duration of use for the IUS is 5 years for contraception.") Jaydess® is now widely available and is licensed for 3 years for contraception, not 5. 1.3 – the comments above regarding the copper IUD in section 1.2 (perforation, STI testing and follow up also apply to the IUS) 1.4.1.1 ("DMPA should be repeated every 12 weeks"). DMPA is now available as Depo Provera® and as Sayana Press®. Sayana is administered at 13 week intervals 1.4.2.3 ("there is no evidence that DMPA use increases the risk of STI or HIV acquisition") There is in fact some evidence regarding HIV. There is likely to be further international debate in this regard in the near future (WHO statement 2/3/17). 1.4.3.1 ("Injectable contraceptives should be given by deep intramuscular injection into the gluteal or deltoid muscle or the lateral thigh. [2005]") Sayana Press is given by subcutaneous injection in the lower abdominal wall or anterior thigh, and may be self administered.	Appendix A and Appendix B will be updated based on new product availability.
Royal College of Nursing	Yes	Since this guideline has not been updated it contains no reference to newer dose products such as Jaydess, Levosert or particularly Sayana Press, a completely new delivery system for injectable contraception which has been shown to improve access for women.	Thank you for your comment. The guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible

		We are concerned that the proposal seems to have excluded 120 new evidence/references that have been cited in this 'surveillance proposal' mostly because they are qualitative rather than, NICE's preferred, quantitative studies, despite the obvious impact these have on issues such as access and service delivery rather than the more narrow safety aspects.	contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC). Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or options grid) that health professionals can use with patients during consultations to support shared-decisions.
Faculty of Sexual and Reproductive Healthcare (FSRH)	Not answered	As above	Thank you for your comment.
FPA	No	No comment	Thank you.
University Hospitals Birmingham / Umbrella Sexual Health services	Yes	As above – commissioning and training are key areas which require improvement.	Thank you for your comment. Provision and commissioning of services delivering LARC and training health professionals were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services.
Do you have any comments on equalities issues?			

Stakeholder	Overall response	Comments	NICE response
Primary Care Women's Health Forum	Yes	The commissioning changes have produced a variance in accessibility to LARC provision. This is causing concerns about equity as those who are most vulnerable and compromised are those who are least able to access the reduced numbers of care providers.	Thank you for your comment. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the provision of contraceptive services. We will make cross referrals between the two guidelines to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services.
Brook Young People's sexual health and well being charity	Not answered	No comment	
Pfizer Ltd	Yes	The 2005 guideline does not meet the need to "increase the use of long-action reversible contraception by improving the information given to women about their contraceptive choices. "Women who consult these guidelines may be unaware of developments in the LARC arena such as the availability of newer medicines such as Sayana Press which can be self-administered following training by a healthcare professional.	Thank you for your comment. The guideline should be read in conjunction with NICE evidence summary on Jaydess; ESNM41 Long-acting reversible contraception: levonorgestrel 13.5 mg intrauterine delivery system and the NICE evidence summary on Sayana Press; ESNM31 Long-acting reversible contraception: subcutaneous depot medroxyprogesterone acetate (DMPA-SC). Following consideration of new evidence and all comments received during consultation, the medicines and prescribing team at NICE will prepare a medicines prescribing briefing to provide evidence based information for the different types of LARCs. The outdated recommendations in the guideline will be stood down and replaced with a cross referral to this medicines prescribing briefing as well as a link to the BNF. In addition, NICE will produce a resource (icon array or

			options grid) that health professionals can use with patients during consultations to support shared-decisions.
Medicines and Technologies Programme, NICE	No	No comment	Thank you.
Mencap	Not answered	No comment	
MSD Ltd	No	No comment	Thank you.
Advisory Group on Contraception (AGC)	No	No comment	Thank you.
Clinical Effectiveness Unit of the Faculty of Sexual and Reproductive Health	No	No comment	Thank you.
Royal College of Nursing	No	We do not have further comments to make at the present time	Thank you.
Faculty of Sexual and Reproductive Healthcare (FSRH)	No	No comment	Thank you.
FPA	No	No Comment	Thank you.
University Hospitals Birmingham / Umbrella Sexual Health services	Yes	Above barriers impact disproportionately on vulnerable women, who can be discouraged from accessing (or unable to access) integrated sexual health services.	Thank you for your comment. Provision and commissioning of services delivering LARC were outside the original scope which focused on the clinical management of LARC and not commissioning of LARC or contraceptive services. Certain service delivery elements are covered in NICE PH51 Contraceptive services for under 25s published 2014 and recommendations are specifically directed at Local Authorities in that guideline. Additionally NICE has published LGB17 Contraceptive services: a Local Government Briefing on Contraceptive Services which specifically highlights Local Authority responsibilities for the

			provision of contraceptive services. We will make cross referrals between the two guidelines to mitigate some of the service delivery concerns and show a more holistic picture of NICE's products on contraceptive services.