Leicester
City Council

MINUTES OF THE MEETING OF THE
LEICESTER, LEICESTERSHIRE AND RUTLAND JOINT HEALTH SCRUTINY COMMITTEE

Held: TUESDAY, 6 JULY 2021 at 5.30pm at City Hall

P R E S E N T :

Cllr Patrick Kitterick – Chair
Cllr Jonathan Morgan – Vice Chair

Cllr S Harvey	Cllr M March
Cllr Dr D Sangster	Cllr G Whittle
Cllr Bray	Cllr L Phillimore
Cllr Grimley	Cllr Hack
Cllr King	Cllr D Smith

In attendance

Andy Williams, Chief Executive CCG LLR – via Zoom
Ian Scudamore Director Women's/Children's Services UHL – via Zoom
Nicky Topham UHL – via Zoom
John Jameson UHL – via Zoom
Floretta Fox Community Midwife Matron UHL – via Zoom
Mark Wightman, Director of Strategy & Communications UHL
Sara Prema Leicester City CCG
Richard Morris Leicester City CCG
Mukesh Barot Healthwatch

*** ** ***

1. CHAIRS ANNOUNCEMENTS

The Chair welcomed those present and led introductions.

2. APOLOGIES FOR ABSENCE

Apologies for absence were received from Councillor Aldred, Councillor Fonseca, Councillor Ghattoraya, Councillor Waller, Councillor Pantling, Ivan Browne, Ruth Lake, Mike Sandys, Dr Janet Underwood and Russell Smalley.

Noted that Councillor Les Phillimore was present as a substitute for Councillor Ghattoraya.

3. DECLARATIONS OF INTEREST

Members were asked to declare any pecuniary or other interest they may have in the business on the agenda. There were no such declarations.

4. MINUTES OF PREVIOUS MEETING

RESOLVED:

That the minutes of the meeting held on 5th March 2021 be confirmed as an accurate record.

5. PROGRESS AGAINST ACTIONS OF PREVIOUS MEETINGS

Item 42 University Hospitals of Leicester NHS Trust Audit
Members noted that more details had been requested of the UHL accounts and a response had been circulated in June. The Chair suggested that response needed to be further considered and informed Members that he would be pursuing that outside this meeting.

Referring to the meeting held on 14 December 2020 Councillor Harvey reminded that she had still not received the information around births, post-natal/partum care as requested in the supplementary questions.
ACTION: Richard Morris to pursue that response from the Clinical Commissioning Groups.

6. COMMITTEE MEMBERSHIP

RESOLVED:

That the membership of the LLR Joint Health Scrutiny Committee for 2021-22 be noted.

7. COMMITTEE TERMS OF REFERENCE - WORKING ARRANGEMENTS

Councillor Hack mentioned that when the meeting was hosted by the County Council there was provision for a general Member Questions item on the agenda.

The Chair was advised that there was no provision within the City Council's constitution for general Member Questions however it could be worked into the Committees Terms of Reference and Working Arrangements if Members were agreed.

The Chair commented that he encouraged questions and participation and would be happy to institute a regular Question from Members item on the agenda. Members were in agreement with this course.

RESOLVED:

That the Working Arrangements and Terms of Reference for the Leicester, Leicestershire and Rutland Joint Health Scrutiny Committee be agreed subject to inclusion of a provision of a

general item for Member Questions on the agenda of future meetings.

8. PETITIONS

The Monitoring Officer reported that a petition had been received which asked the Committee to:

"arrange a meeting, as indicated in its minutes of December 2020,as a matter of urgency to scrutinise the Report of Findings, produced by Midlands and Lancashire Commissioning Support Unit following the public consultation, Building Better Hospitals for the Future, in the autumn. This report was completed in March but has only just been shared with the public. We call upon the Scrutiny Committee to request the three local Clinical Commissioning Groups, which are responsible for the Building Better Hospitals proposals, delay finalising their decision-making until they are able to incorporate the insights of scrutiny into their Decision-Making Business Case, and not to proceed with their meeting planned for 8th June, if this is to approve the Decision-Making Business Case.

The Chair indicated that the points raised in the petition would be considered within the discussion on Item 10 of the agenda "Analysis of UHL Acute and Maternity Reconfiguration Consultation Results."

9. QUESTIONS, REPRESENTATIONS, STATEMENTS OF CASE

The Monitoring Officer reported that several questions had been submitted by members of the public as set out on the agenda.

The Chair outlined the procedure for the meeting and advised that these questions would be taken and responded to within the main item 10 on the agenda "Analysis of UHL Acute and Maternity Reconfiguration Consultation Results." Where a full response was not available at the meeting a written response would be provided outside the meeting and appended to the minutes.

10. ANALYSIS OF UHL ACUTE AND MATERNITY RECONFIGURATION CONSULTATION RESULTS

The Chair explained that a presentation would be received and taken in four subject areas with questions from the public to be taken under the relevant subject area followed by any questions from committee members.

Sara Prema, Leicester City CCG, presented the first subject area and outlined the consultation process and how that was undertaken, this included details of the range of media used such as social media: Instagram, snapchat, twitter as well as live events and the information gathered. Details were also given of the "reach" of the consultation using digital, print and broadcast methods and the work undertaken to engage people of all demographics across Leicester, Leicestershire and Rutland (LLR).

The Chair interposed questions from members of the public and invited officers to provide responses:

The Chair on behalf of Jean Burbridge asked: Following the Building Better Hospitals for the Future consultation, who are the patient representatives who were involved in reviewing the public feedback? In what ways are they representative?

Richard Morris, Leicester City CCG responded that the feedback received through the consultation was independently analysed and evaluated by Midlands and Lancashire Commissioning Support Unit, who produced the Consultation Report of Findings. The Report of Findings was then reviewed by the Public and Patient Involvement Assurance Group for Leicester, Leicestershire, and Rutland. It was not their role to approve the proposals that were being consulted upon. ACTION: Officers agreed to provide a full written answer in due course.

Sally Ruane on behalf of Sarah Patel asked: How does the profile of respondents in terms of a) ethnicity and b) deprivation match that of the population as a whole, taking Leicester, Leicestershire and Rutland each in turn?

Richard Morris replied that all details regarding profile were set out in detail in the report of findings which showed the people who participated in the consultation were statistically representative of the LLR population and endorsed through the Equality Impact Assessment.

Sally Ruane clarified that the question was about how the profile of respondents matched or did not match the profile of the area in terms of the broader population of Leicester, Leicestershire, and Rutland.

Richard Morris explained how the level of responses were reflective of LLR and the findings showed that of the responses received 46% were from Leicestershire, 26% were from Leicester city, and 6% were from Rutland, 28% of responders provided no post code or asked not to be profiled. There were various category breakdowns as an example there was a breakdown by age, this showed typically higher levels of engagement with people over 45 years old but there was another piece of work carried out with voluntary groups to engage with younger people between 25-34 years, this category represented 11.8% of the population, in terms of responses 16.4% of Leicester city replies were within this age category showing a fair representation of that age group. In relation to male/female by and large this was 50/50 across LLR, in terms of consultation responses it was found more women participated with 72% of responses being from women. Regarding ethnicity for example 78.4% of the population of LLR was white and 81.1% of respondents identified as white so again reflective of the population, the same was also found with other demographic profiles. ACTION: Officers agreed to provide that data in a written response with the benchmarks.

Sally Ruane asked: What changes have been made to the Building Better

Hospitals for the Future proposals following public, not clinical feedback?

Richard Morris replied that it was important to note they were trying to achieve a statutory duty and to have a broad demographic view and to meet equality requirements a view was taken with certain voluntary organisations. The CCG looked at several areas across the country who used similar models successfully and decided to use the same model.

Sally Ruane set out her next questions about the use of an "impartiality clause" used by the CCGs during the consultation process which would have had the effect of stifling the expression of points of view at odds with those of the CCGs. Via a Service level agreement with an impartiality clause, the CCGs commissioned and remunerated organisations to undertake engagement with people as “supporters” of the consultation exercise. However, the impartiality clause obstructed the ability of these organisations to inform their members (or those they engaged with) of any concerns they had about the proposals and it obstructed the ability of these organisations to draw on independent sources or their own body of knowledge in responding to members’/followers’ questions. The Impartiality clause stated, “Organisations are not expected to express views or opinions on the consultation when engaging with their communities …and all queries and questions should be signposted to official literature or NHS leads”.
It appears, therefore, that these organisations far from being impartial, could be said to be the voice of the CCGs, able only to point people to the official literature so providing them with a single, very particular narrative.
1. I would like to know if this practice is legal.
2. I would like to know if this is seen as good practice and what dangers were considered in deciding to proceed with these agreements.
3. Are the CCGs able to tell us what steps they took to ensure that organisations under contract informed their members/followers in any engagement they (the organisations) had with their members/followers that they were working under a service level agreement which contained an ‘impartiality clause’.
4. How many of the 5,675 responses to the consultation were as a result of these contracts?

Richard Morris indicated the purpose of the clause was to protect the voluntary and community organisations that were agreeing to promote the consultation to their communities. The clause ensured that they could freely state the organisations views on the proposals and gave them impartiality to be neutral.
ACTION: Officers agreed to provide a full written response that would cite the impartiality clause in full.

Sally Ruane in supplementary response suggested the impartiality clause prevented those organisations from expressing any concerns they may have and expressed concern that this practice was unlawful.

Richard Morris assured that none of those participating was barred from making their own or an organisational response to the consultation and of the total responses received to the consultation approx. 600 came through this

route.

Jennifer Fenelon on behalf of Rutland Health & Social Care Policy Consortium (RHSCPC) asked: We are told approximately £260,000 was spent on consultation by LLR CCGs. The people of Rutland submitted many comments and proposals to mitigate the impact of moving acute services from East to West and consequent increased complexity of journeys and increased travel times making access to services more difficult. The summary of decisions published on 26th June offers no clarity on how services will be delivered closer to home to mitigate these problems. Can the CCG explain why there are none?

Sara Prema responded that the CCG were working to improve place led services and developing that in several ways, with the Health & Wellbeing Board, through Rutland partners and other stakeholders. Many community services were already delivered and that was being built upon and would be refined.

Jennifer Fenelon in supplementary commented that the CCG had an obligation to look at communities and groups. The Rutland Health & Social Care Policy Consortium had submitted a large document that included 26 points made and that had not been responded to.

Sara Prema replied that some of those points had been picked up as pledges within the business case. ACTION: Officers to provide response to the 26 points suggested.

The Chair invited comments from members and the ensuing discussion included the following points:

- Regarding any potential conflict of interest with the impartiality clause it was clarified that all activity undertaken was designed to meet the equality duty. CCG were keen not to rely on just one tool and to give people the chance to take part in the consultation. The total cost of the consultation was £260,000 and a significant portion of that was spent on the analysis and findings of Midlands and Lancashire Commissioning Support Unit. Typically, £2-3k was given to 18 organisations. ACTION: Officers agreed to provide breakdown of cost to each organisation.

- None of the voluntary organisations engaged in the consultation were coerced in any way to take part, there was no preferential treatment and those organisations were just as challenging in public meetings as they should be.

- In terms of how far they had exercised their duty to assess the impact on various communities and identify negative impacts it was explained that Equality Impact Assessments (EIA) were undertaken and are included within the business case, these were held up as an example of very good equality impact assessments. A post EIA on the consultation was also undertaken which is included in the appendices of the business case.

- Concerns were expressed that despite taking part in consultation events answers to questions raised there had still not been provided and there was delay in providing responses. ACTION: Officers to provide response to the questions raised by Councillor King at recent public meetings.

- In relation to concerns that the consultation was undertaken during the pandemic it was found that more people were taking part than would normally engage, the reasons for that were tested that out and many said it was because they had more time on their hands. As to whether their responses outside of a pandemic would have been any different, it was always a challenge and can't answer definitively if those responses would have been different but there was monitoring and content with responses and qualitative responses being received.

- Overall responses from Rutland compared to the population of the City and County seemed low and concern was raised that this was such a small response. In answer it was stated that overall population of Rutland was 4% of the City/County yet 6% of responses were from people that declared themselves to be from Rutland, so it was felt to be fairly representative. In terms of overall response rates, it was uncertain what a definition of a good response rate is as every consultation is different. However, nationally 1-2% was good but more emotive subjects achieved higher response rates. The Chair expressed interest in seeing figures of overall responses. ACTION: Officers to provide various breakdowns of overall responses outside this meeting.

- In relation to general digital exclusion, from the outset the CCG were aware of the risk of digital exclusion and determined not just to consult online, a lot of work was done through radio and publicity materials and in other languages too. Materials were handed out in villages/local areas and shops. All virtual meetings were set up to have access to dial in by phone if someone was unable to link in and there was also put in place a dedicated phone line to help people complete the consultation survey that way.

- There were in region of 90,000 visiting the website and there were a lot of views as to why there were only maximum 5-6k responses. It was felt that this has been a dialogue going on over a decade, a lot of people looked at the proposals on the website and where they were generally in agreement with proposals, they didn't feel need to complete the survey. It was suggested that there was a tendency to find those that do respond have a particular view on proposals.

Sara Prema then moved to the second subject area and outlined the process for considering feedback from the consultation and the consultation outcomes noting that 58% of respondents agreed with the proposals.

Also noted:

- During the consultation people wanted to understand the impact of

Covid on plans and whether services would be future proofed by releasing some of the Leicester General Hospital site.

- A Travel Action Plan had been developed to support the reconfiguration in conjunction with the Local Authority's this would include improvements to the bus and hopper routes, increasing park and ride facilities, increasing parking at LRI and Glenfield and improving sustainable travel options.
- The rationale behind the speciality changes in location proposals and the DMBC decision.
- A review was undertaken by clinicians into the impact of Covid which found that if the changes had been in place before the pandemic, they would have managed the pandemic better.
- An analysis of developable land post reconfiguration showed there would be 25 acres of developable space so there would be scope for further development should this be needed in future although it was difficult to say what may happen in terms of medical advancements in 10-15 years' time.
- In relation to the new treatment centre, 60% of respondents agreed with the proposal. The clinical case set out in the pre-consultation business case and the review of proposals post Covid set out the advantages of separating elective and emergency care.
- The outcomes in relation to the proposals including use of new technologies; new haemodialysis treatment units; hydrotherapy pools and a children's hospital that would include a consolidated children's intensive care unit, co-located with maternity service.
- Leicester was one of a few areas without a dedicated children's hospital although it provided one of the biggest services for children across the East Midlands.
- The LRI was chosen as the site for a dedicated children's hospital as it had the children's emergency department and from 2021 it would be the home of children's congenital heart services (CHD). Part of the requirement for continued delivery of CHD services was the formation of a children's hospital.

Public questions on this subject area were then taken as follows:

Sally Ruane on behalf of Godfrey Jennings asked: If adequate additional Public Dividend Capital (PDC) is not forthcoming, which elements of the scheme are you likely to alter? (p25 of the DMBC "Whilst the original funding of £450m PDC has been identified, in the event that further PDC funding is not made available to fund the additional national policy changes such as the requirement for New Zero Carbon and Digital, then the scope of the scheme will be reviewed again
in order to fit the budget available.")

The Chair on behalf of Lorraine Shilcock asked: 1. What is the meaning of the following statement on p25 of the Decision- Making Business Case? "However, work is ongoing with the New Hospital Programme to agree the scope of inclusion in the programme, and the potential sources of capital."
2. Which proposals/services do you plan to cut if the necessary finances

are not forthcoming?

Mark Wightman, UHL Leicester, replied in respect of patients accessing services that of 100% of people 30% would have a slightly longer journey time because of the reconfiguration.

Nicky Topham, UHL Leicester responded to the questions as a whole and outlined the survey findings, noting that when the process started the CCG/UHL were clear that £450m would deliver the scope of services in the business case but what had changed was that any policy changes such as around carbon emissions or digital requirements would have to be factored too.

The Chair questioned the difference between scope and services, and queried, if ambitious environmental efficiency targets were set then what would give in terms of scope or services?

Nicky Topham clarified that the £450m would provide for the move of the clinical services across the three sites and enable delivery of a high quality building. It was the net zero carbon in terms of the scope of the building being discussed, not about clinical services included in the programme.

Mark Wightman explained that the reconfiguration was covered by the £450m but there had to be consideration if the expectation of the modern building requirement changed, this was part of a series of steps in the process. The overall scheme was a solution with a series of interconnected components.

The Chair commented that concerns were not allayed by the response and expressed concern that there was not sufficient reassurance.

Mark Wightman acknowledged these were valid questions and that concerns could not be fully allayed other than to say there was still a way to go in the process to reach a full business case and full business case approval. The project was however based on a thorough understanding of clinical strategy and parts of that could not be dismantled.

Andy Williams, CCG Leicester, Leicestershire and Rutland, confirmed the reconfiguration proposals had been agreed as a package in their entirety but in approval terms each scheme would have to be planned and implemented individually.

Jennifer Fenelon on behalf of RHSCPC put that: The CCGs have refused to say how alternative services will be funded where patients are unable to access the new facilities (They estimated this to be about 30% of patients in the PCBC). The consequences of this will result in more patients accessing services outside Leicester, Leicestershire and Rutland. As the CCGs will have to meet these costs can they supply the cash flow estimates for this work which will relocate
elsewhere as a result of Reconfiguration? ACTION: Officers to provide figures in writing outside the meeting to this question.

During the ensuing discussion the following points were noted:

Concerns were raised about the UHL Financial arrangements, deficit budget and whether that would impact on service delivery. It was advised that the £450m was capital funding which was a separate allocation of funding although the revenue consequences of that had to be managed locally. The rationale was that efficiencies come from managing the estate more effectively and so reducing estate was another way of achieving that. Regarding the deficit position LRI was currently spending more than allocated. Recovering the deficit required achieving certain levels of efficiency. The second issue to address was the imbalance as a system, to readdress that and optimise by moving secondary care business into primary services. It was expected over time growth will gradually close the gap. Assurance was given that there was no decreasing budget and there was no loan of money, the UHL were authorised to pull down a certain amount of budget each year. The financial recovery plan was to close the gap between the agreed budget total the treasury would like the hospital to live within.

The Chair drew discussion back to the agenda and advised that a separate discussion on the UHL financial arrangements and deficit would be arranged outside this meeting.

Andy Williams agreed to provide a level of detail in terms of the emerging strategy and patterns of activity and how that would develop over next few years in relation to primary care for a future discussion.

Discussion progressed onto the Travel Action Plan, concerns about accessibility to service/hospitals from rural communities and included queries about carbon emissions and environmental impacts.

Councillor Harvey on behalf of Dr Janet Underwood, Healthwatch put: The UHL reconfiguration plans were discussed and agreed at the CCG governing body meeting on 8th June 2021. However, the Chair of the CCG governing body noted the increased inequalities in accessing health care for those living in rural communities; especially in the east of the city.

The UHL Travel Plan creates improved and environmentally sustainable travel around and within the city but no mention of improved travel facilities or better accommodation of the needs of those who live in rural areas.

Healthwatch Rutland asks what plans, other than a trial park and ride for just 80 cars at Leicester General Hospital, UHL, working with partners in the Integrated Care System, they have to mitigate these inequalities?

Responding to points made about taking into account any potential increase in carbon emissions caused by more people travelling from rural areas it was recognised that the LRI was in a central position and the plan was to take up to 35% of activity off the LRI site to Glenfield so that would improve the impact of pollution around LRI. Officers agreed to share details of the BREEAM sustainability assessment.

Despite the Travel Action Plan, it was suggested that some would face difficult journeys, congested roads and junctions, and lengthy bus journeys so people would not be discouraged from using their cars if they have one. Public transport was not always a viable option particularly in more rural areas and it was noted that the Travel Action Plan did not go beyond the city borders although considerable engagement had taken place with groups to inform the travel plan, this included with patients, partners, local authorities, bus and train operators and did included Healthwatch too.

Responding to concerns about the number of car parking spaces in the proposals it was clarified that this was not a total of 300 spaces but 300 additional spaces to the Glenfield and LRI sites.

The CCG acknowledged that travel was a difficult issue to address as it went to wider infrastructure issues outside of UHL/CCG control. The CCG had tried to set proposals that disadvantaged as few people as possible. It was asserted that the reconfiguration proposals overall, either make no or little difference, or would be better for the vast majority of people across LLR. Everyone would get qualitative benefits and the CCG were trying to mitigate the downside of centralising services and continuing to develop other services such as the community hospital. The wider issue relating to rural infrastructure was a bigger question than the UHL/CCG could address but with the reconfiguration proposals for the hospitals the UHL/CCG were trying to get the best result they could.

In relation to the speciality changes around ophthalmology and any effect of moving their location it was confirmed that lower acuity eye problems were dealt with at Rutland and other ophthalmology issues at LRI and that would not change.

Regarding paediatric outpatients' services, most children's outpatient services would continue at LRI although there would be some services exported into the community.

The dedicated children's hospital would be developed through the refurbishment of the Kensington Building, this was considered an elegant solution given that the CCG were not able to say, "money is no object". In August 2021 the first stage to move children's services from Glenfield to Kensington would begin and progress on that transition could be shared with members.

The Chair moved the meeting on to the next subject area and Sara Prema presented details of the proposal to create a primary care urgent treatment centre at Leicester General Hospital site and the consultation outcomes around that.

The Chair referred to questions received from the public and on behalf of Giuliana Foster asked: What are the estimated costs of the primary care urgent treatment centre and other community services planned for the site of the

Leicester General Hospital and where will these funds come from?

Jennifer Fenelon on behalf of RHSCPC put that: Any attempt to clarify with the CCGs how much capital and revenue has been allocated to community services has not been answered on the grounds that only UHL acute capital is being considered. We were, therefore pleased the June CCGs Extraordinary Board Meeting approved "creating a primary care urgent treatment centre at Leicester General Hospital site and scope further detail on proposals for developing services at the centre based upon feedback and further engagement with the public." Can the CCG explain why proposals did not also included community services for residents across LLR which are needed as a consequence of reconfiguration?

Responding to both questions' it was advised that the consultation dealt with the proposals outlined in the Pre Consultation Business Case, which included the future of the Leicester General Hospital campus.

The ongoing work to improve community services for residents across Leicester, Leicestershire, and Rutland to provide more care closer to home was part of separate and ongoing work around a number of key programmes. This included the Better Care Fund (a programme that supports local systems to successfully deliver the integration of health and social care in a way that supports person-centred care, sustainability and better outcomes for people and carers), Ageing Well (an NHS programme to support people to Age Well) and Place-Led Plans. Improvement work would be funded through a mixture of funds available to the NHS e.g. baseline commissioning budgets and through the Ageing Well programme.

The Chair commented that there had been some concern about the publicity used for the General Hospital site proposals, in particular the image portraying what the centre may look like.

Sara Prema answered that there was public support for the primary care urgent treatment centre and the CCG were keen to do it as it would relieve pressure on services elsewhere and was in line with National policy. There were no circumstances envisaged in which the primary care urgent treatment centre would not be delivered as it was part of the overall package although the CCG cannot say it would look exactly as the artist impression used but there was a firm intention to have a primary care facility at that site.

With regard to land at the General being sold off because there was land available at Glenfield for expansion in future, and the suggestion that the General Hospital could be used post pandemic to address backlogs and waiting times, members were reminded that during the 1st phase of the pandemic Nightingale hospitals were set up but not put into use as they couldn't be staffed. This situation was similar, although currently the General Hospital could be used, longer term there would be the issue of spreading staff too thinly across the sites and the reconfiguration was about getting the most out of the facilities in the future and the staff resources too. In terms of backlogs, UHL/CCG were hopeful those would not take too long to address,

whereas this reconfiguration programme was not due to complete until 2027.

The CCG said they were committed to continuing an ongoing dialogue with communities on the further scope of primary care and what the end process would look like. The next step was to take that conversation out of the consultation process and move to informal discussions with communities.

In relation to the hydrotherapy proposal to move to community facilities it was explained that when scoping this proposal, the CCG did a piece of work to look at existing facilities and created a list of those. The list would need to be reviewed to ensure facilities would remain available into the future and each facility would be assessed to strict criteria including looking at issues of safeguarding and accessibility to determine which could be used. In due course that list of hydrotherapy services could be shared with members.

It was noted that there was a general perception and fear within some communities that services could be lost, and the CCG sought to assure that they were doing their best to do what was needed for all patients.

There was further discussion regarding developable land, its commercial value and whether there was a link between the Community Infrastructure Levy (CIL) and Section 106 funding to this for the primary care unit. It was noted that the Hospital Close site had been acquired by the City Council and the reference within the presentation to £16m was for the main General site. The CCG advised that in relation to any large housing development the CCG would put in an application for developer contributions if there was any impact on primary care, no differently to if there were large developments in other parts of the county.

Discussion then moved on to the final subject area and Sara Prema presented the proposals and outcomes in relation to the new maternity hospital, breastfeeding services and the standalone midwifery led unit.

It was noted that the decision regarding maternity services sat within the ongoing strategic improvement work across maternity care. It had also been established that the standalone midwifery led unit could not be assessed in one year and that would take longer with a commitment to assess over 3 years.

The Chair referred to questions submitted by members of the public and read Giuliana Foster's question: "You set out the estimated capital costs of the various parts of the proposals on pages 23 and 113 of the DMBC but these do not include the estimated capital costs for the freestanding midwife led unit on the site of Leicester General Hospital. What are the estimated costs for both the trial and the ongoing existence of the unit and where will these funds come from?

Sara Prema replied that the capital figure of £450m for the reconfiguration project included the cost of the standalone midwifery led unit which would cost in estimate circa £1m.

Sally Ruane on behalf of Brenda Worrall asked: Why has a target of births of 500 been set when this is larger than all other Free Standing Midwife led units (FMUs) in the country. Is the FMU being set up to fail?

Ian Scudamore, Director of Women's & Children's Services UHL, responded that the target was based on the point of viability and explained how it was recognised by organisations providing obstetric and maternity services that for a standalone unit to be sustainable long term and financially viable there needed to be around 500 births a year and it was therefore appropriate to have a target of 500.

The Chair enquired whether there was a need to have 500 births to deliver a quality clinical service? Ian Scudamore replied that the standalone unit would be a midwife led service and would not provide any different clinical service from a home birth service or an alongside birth service. In practical terms there would be the same services across all four settings and in those terms more resource. Financial viability however was achieved at 500 births.

Sally Ruane in a supplementary comment expressed concern that there was the perception that there was no real commitment to the standalone unit.

Ian Scudamore confirmed there was an absolute guarantee that UHL and the local health care community were committed to providing maternity health care options across LLR and to provide the four NICE options for maternity care but there needed to be the numbers to make it sustainable and so it needed to be located in a place where more people could use it.

Floretta Cox, Community Midwifery Matron UHL, commented that Leicester was the first to create the home alone service however the birth rate at St Mary's was not as high as they would like it to be and that was because of its location. There was a dedicated home birth team already in place and they supported St Mary's at night. It was expected that the St Marys staff would be used at the new standalone unit and the unit could also be used for pre-natal services too which was something that women wanted.

Andy Williams commented that the CCG motivation was to ensure a positive future for this birthing option across LLR, trying to locate it and support it to ensure its future as part of the maternity services landscape but there was a need to balance the resource that's committed and provide a genuine option for women.

The ensuing discussion with members included the following points:

- In relation to community services and breastfeeding levels in the community and the funding around that, Sure Start centres were dependent upon local authority funding, current services provided included liaison in homes, peer support and the CGG were looking to employ more community support workers.

- The standalone midwife led unit would be co-located with LRI, this would provide bigger and better facilities including a pool in every delivery

room which more women preferred as an option for analgesia. Community midwives would stay in the community, so for example Melton midwives would continue to be based in local communities and at GP surgeries. The plan was that staff at St Mary's would be relocated to the new unit although those staff would all be given options.

- Returning to the issue of viability it was confirmed there was a commitment to develop a framework to assess the financial viability of the standalone midwife led unit and that would be done with those who had a vested interest in maternity services and meeting maternity care needs.

- In terms of current and projected birth rates across LLR and the percentage needed at the unit it was advised that often women choose a maternity service based on experience or word of mouth. There were currently 10,000 women delivering in UHL, 2000 chose to deliver outside LLR and of those 2,500 were at co-located birth centres. A target of 500 therefore equated to about 5% of the current level of births needed to migrate to the unit.

- It was noted that the co-located design work could begin at any time, but the changes would not be enacted immediately. The process of talking to groups would be started and a piece of work undertaken to see what the co-located design may look like and the time frames, this could then be brought to a future meeting. The difference at the General will be that it is totally midwife led but if there was an emergency they would be transferred to the LRI and that journey would be a lot shorter and thereby quicker than from St Mary's so more women may choose it.

The Chair thanked officers for their responses and commitments given during the meeting and asked to be kept informed of progress.

RESOLVED:

1. That CCG/UHL officers provide full written responses/information to the actions set out in the body of the minutes of the meeting, as soon as possible.
2. That CCG officers provide a level of detail in terms of the emerging strategy and patterns of activity and how that would develop over the next few years in relation to primary care for a future discussion.
3. That a progress report on the first stage to move children's services from Glenfield to Kensington and transition be provided for the next meeting.
4. That a list of hydrotherapy services be shared with members in due course.

11. COVID-19 VACCINATION PROGRAMME UPDATE

The Chair commented that given the late hour of the meeting he would move straight to taking any questions from Members on the Covid-19 vaccination

programme.

There were no questions from Members.

Andy Williams, CCG Leicester, Leicestershire and Rutland confirmed there were no exceptional issues around the vaccination programme to raise at this time and a report on the work for the Autumn/Winter vaccination programme would be provided in due course.

RESOLVED:

That a report on the work for the Autumn/Winter vaccination programme be provided in due course.

12. WORK PROGRAMME

RESOLVED:

That the item on Integrated Care Systems be rescheduled to an earlier date than March 2022.

13. ANY OTHER URGENT BUSINESS

Councillor Hack made the following submission:

In recent weeks there has been a raising of the profile of the medical procedure surrounding the fitting of Intrauterine devices,

The NHS website states:
'Having an IUD fitted can be uncomfortable and some people might find it painful, but you can have a local anaesthetic to help.'…'you can ask to stop at any time.'

1) Do we have the information on the % of IUD procedures that are performed with a Local Anaesthetic?
    a. Dr Louise Massey of the Faculty of Sexual and Reproductive Health Care of the Royal College of Obstetricians and Gynaecologists said on the BBC last week
    'the procedure can always be stopped if there is too much pain, discomfort or distress. It is always an option to abandon it; it can even be done under General anaesthetic if necessary and appropriate'
    Do we offer and what % of IUD are fitted with a General anaesthetic across the Trust?
2) What % of procedures are unsuccessful and are stopped from completion in Leicester, Leicestershire and Rutland?
3) What % of IUD's need removing due to complications post procedure?
4) If the data is not collected routinely is there any expected change in policy in light of the spotlight that has been placed on the procedure?
5) The anecdotal evidence that has been collected and published so far, has indicated that the procedure is far from routine for some. I note that the guidance on the procedure was recently updated on the national

NHS website, but has there been any recent policy updates provided for those that fit IUD's in LLR? Particularly on pain management or device fitting triggering past trauma. If not, when will this be provided?

The CCG confirmed they had received these questions and gave a commitment to provide a response in writing outside this meeting.

RESOLVED:

That the relevant officers of the CCG provide a written response to these questions as soon as possible which will be read into the minutes of the next meeting.

14. DATES OF COMMITTEE MEETINGS 2021/22

Future scheduled meetings noted as follows:

- Tuesday 16th November 2021 at 5.30pm
- Monday 28th March 2022 at 5.30pm

The Chair noted there had been comments about the timings of meetings and confirmed they would start at 5.30pm with an aim not to go beyond 9pm.

There being no further business the meeting closed at 9.10pm

Minute Item 10

Questions and answers – JHOSC

FORMAL RESPONSES TO QUESTIONS ASKED BY THE PUBLIC IN ADVANCE OF THE MEETING

From Jean Burbridge:

- Following the Building Better Hospitals for the Future consultation, who are the patient representatives who were involved in reviewing the public feedback? In what ways are they representative?

Response

The feedback received through the consultation was independently analysed and evaluated by Midlands and Lancashire Commissioning Support Unit, who produced the Consultation Report of Finding.

The Report of Findings was then reviewed in a number of ways:

1. *By the Public and Patient Involvement Assurance Group (PPIAG) for Leicester, Leicestershire and Rutland (LLR). This group, which reports to the LLR System-wide Partnership Group, brings together people passionate about health and social care. They provide creative, fresh and independent thinking to public engagement and provide judgement on whether health and social care commissioners and providers have engaged and understood local people and that their insights are influencing the way we design local health and care. The group was independently recruited to in December 2019. The PPIAG role, in relation to the consultation, was to form an overall view as to whether the consultation process was appropriate and proportionate in terms of its attempts to reach the population, and to seek assurances that the views put forward by people in the consultation had been considered. It was not their role to 'approve' the proposals that were being consulted upon. This was the role of the CCG Governing Bodies.*

   For further information relating to the group visit: https://www.leicestercityccg.nhs.uk/get-involved/. No small group can claim that is it fully representative of a population and the socio-demographics of an area. However, the PPIAG includes a range of people from different ethnic groupings and backgrounds. It should be noted that the Report of Findings was statistically representative of the LLR population, which was endorsed through our Equality Impact Assessment.

2. *By North of England Commissioning Support (NECS), who reviewed the Report of Findings to produce a post-consultation Equality Impact Assessment which can be viewed at https://www.leicestercityccg.nhs.uk/about-us/future-governing-body-meetings/2021-governing-body-meetings/llr-ccgs-governing-bodies-meeting-june-2021/. The conclusions were:*

   a) *LLR CCG and UHL have both demonstrated significant respect and understanding in their discharge of their Equality Duty and the wider duties to reduce inequalities conferred on the CCG under the NHS Act 2006?*
   b) *The efforts since 2018 to engage with representatives of those from protected groups is significant and has generated immensely useful feedback that is already being actively used to inform continued engagement and future decision making.*

c) *The responses are largely proportionate to the broad geographic and demographic diversity of the LLR population, indicating that a comprehensive range of views have been garnered.*
d) *Engagement with diverse communities that has now commenced, is appropriately regarded as a steppingstone, is ongoing and yet to fully reach potential.*
e) *Through the introduction of their Inclusivity Decision Making Framework, there is a commitment to embed such approaches routinely in practice.*
f) *The value of material arising from the views of the local and diverse population of Leicester, Leicestershire and Rutland is potentially rich, and to be capitalised upon. Feedback will inform decisions over many years to come. Those decisions are based upon the belief that service providers are accountable to the population they serve in promoting equality, reducing inequalities, determining resource allocation in modernised, cost effective and efficient ways.*

3. *By the Governing Bodies of the three CCGs, which comprises of local GPs and Independent Lay Member representation. The role of the lay members is to bring specific expertise and experience to the work of the Governing Body. Their focus is strategic and impartial, providing an external view that is removed from the day-to-day running of the organisation.*

From Giuliana Foster:

1) You set out the estimated capital costs of the various parts of the proposals on pages 23 and 113 of the DMBC but these do not include the estimated capital costs for the freestanding midwife led unit on the site of Leicester General Hospital. What are the estimated costs for both the trial and the ongoing existence of the unit and where will these funds come from?

Response

The capital investment required to convert the Coleman Centre at the Leicester General Hospital into the freestanding Midwifery Led unit is estimated to be £1 million. This money will come from within the overall capital allocation of £450 million. The ongoing costs of running the service will come from the revenue budget, currently allocated to run the St Mary's Birthing Centre.

The model we intend using in the new birth centre will be based on Midwifery Continuity of Carer (MCoC) principles, promoted and supported by the Royal College of Midwives. This outlines that the provision of care by a known midwife throughout the pregnancy, labour, birth and postnatal period is associated with improved health outcomes for the mother and baby, and also greater satisfaction levels. It is mandated by NHS England and NHS Improvement as an improved way of providing maternity care to improve outcomes.

2) What are the estimated costs of the primary care urgent treatment centre and other community services planned for the site of the Leicester General Hospital and where will these funds come from?

Now that the Decision Making Business Case has been agreed by the Governing Body of the Clinical Commissioning Groups we can take the next steps in developing detailed plans for the primary care led services at the Leicester General Hospital campus. This will include detailed financial planning.

As part of this process we are committed to considering the suggestions made by the public regarding the services that they wished us to consider at the Centre. Our principles for implementation also include ensuring that further engagement with the public is undertaken as plans take shape. As opportunities arise we will submit bids for external funding including additional system capital allocations, which will help us realise this project.

From Brenda Worrall:

- Why has a target of births of 500 been set when this is larger than all other Free Standing Midwife led units (FMUs) in the country. Is the FMU being set up to fail?

Response

One of the key elements of the consultation was testing public appetite for a standalone midwife led unit. We were delighted with the response to the consultation and, based on this, both the CCG and UHL are anticipating that the standalone unit at the site of Leicester General Hospital will succeed. By locating it in a more central location we believe more people will use it – including women from a more diverse range of backgrounds.

UHL are proud advocates of midwifery-led care and this will continue to be the case both now and in the future. We believe the underutilisation currently of the unit at St Mary's is due to concerns regarding proximity to emergency care and acute support as well as accessibility for a greater catchment of women in LLR. The new maternity hospital, and the midwifery-led unit on the site of Leicester General Hospital, will allow for women to be closer to support services should they be needed. We believe that this will be a key step in ensuring that the unit is a success going forward, supported by word of mouth from mum's based on their own local.

Work will be undertaken to define how the long-term viability of the unit is assessed. The CCgs and UHL recognise the fact that the new unit is unlikely to attract 500 births in its first year and viability will, therefore, be based on a phased approach over three years. Work will also be undertaken to develop promotional plans for the unit. Both aspects of this work will involve staff, stakeholders and patients/patient representatives.

From Godfrey Jennings:

- If adequate additional Public Dividend Capital (PDC) is not forthcoming, which elements of the scheme are you likely to alter? (p25 of the DMBC "Whilst the original funding of £450m PDC has been identified, in the event that further PDC funding is not made available to fund the additional national policy changes such as the requirement for New Zero Caron and Digital, then the scope of the scheme will be reviewed again in order to fit the budget available.")

Response

The original PCBC described a clinical model which is deliverable for £450m. Since the publication of the PCBC, a 'New Hospitals Programme' has been established by NHS England and NHS Improvement to deliver the national programme of 40 new hospitals. This programme is in the middle of a process which will define the outputs required within these new policy requirements, and the extent to which we, as one of the front running 8 new projects, will be required to deliver this policy change.

We have been clear that the clinical model we consulted upon, which delivers future clinical sustainability, is our priority. Any additional policy requirements since the announcement of the £450m will need to attract additional funding from the centre. Without this, the additional

policy requirements will not be possible to deliver since we do not plan to remove clinical scope from our programme.

From Sarah Patel:

- How does the profile of respondents in terms of a) ethnicity and b) deprivation match that of the population as a whole, taking Leicester, Leicestershire and Rutland each in turn?

Response

Report of Findings shows that the people who participated in the consultation was statistically representative of the LLR population, which was endorsed through our Equality Impact Assessment. This is accessible at https://www.leicestercityccg.nhs.uk/about-us/future-governing-body-meetings/2021-governing-body-meetings/llr-ccgs-governing-bodies-meeting-june-2021/

Attached is a summary document that sets out the overall representation of respondents at an LLR level.

From Kathy Reynolds on behalf of Rutland Health & Social Care Policy Consortium:

1. We are told approximately £260,000 was spent on consultation by LLR CCGs. The people of Rutland submitted many comments and proposals to mitigate the impact of moving acute services from East to West and consequent increased complexity of journeys and increased travel times making access to services more difficult. The summary of decisions published on 26th June offers no clarity on how services will be delivered closer to home to mitigate these problems. Can the CCG explain why there are none?

Response

Discussions are already well underway in Rutland to develop Place Led Plans for what local health and care services should look like in the community These Place-led Plans, developed through the Health and Wellbeing Board for Rutland in partnership with the local authority, Healthwatch and a range of other stakeholders, include GP provision and the usage of local infrastructure, such as the community hospital, to deliver a greater range of services locally. We are committed to continuing these conversations over the coming months.

As part of these discussions it is important that we understand the current position in relation to the delivery of healthcare within Rutland. The below figures are approximate but set out the large amount of healthcare already delivered within the county.

- *c69% of patients accessing same day minor illness and injury NHS services are seen and treated in sites in Rutland*
- *89% of patients accessing an NHS community inpatient service are seen and treated at Rutland Memorial with a small proportion of these at Stamford*
- *100% of patients registered with Rutland practices can access joint NHS and County council in-home services following discharge via the Home First model of care*
- *50% of emergency low acuity NHS eye care is provided within Rutland and this will increase as we launch the new local service through 2 practices with 5 optometrists within Rutland*
- *40% of all NHS outpatient appointments accessed by patients registered with a Rutland practice are seen and treated either virtually or within Rutland*

- *100% of patients registered with Rutland practices have access to virtual IAPT services*
- *100% of patients registered with Rutland practices have access to clinical navigation services and 11 services from their own homes*

2. The CCGs have refused to say how alternative services will be funded where patients are unable to access the new facilities (They estimated this to be about 30% of patients in the PCBC). The consequences of this will result in more patients accessing services outside Leicester, Leicestershire and Rutland. As the CCGs will have to meet these costs can they supply the cash flow estimates for this work which will relocate elsewhere as a result of Reconfiguration?

Response

It is important to stress that the PCBC does not suggest that 30% of patients will be unable to access the new facilities. It says that whilst journeys will become shorter for around 70% of patients journey times are likely to increase for the remaining 30%.

In the event that a patient decides to take up treatment outside of LLR the current financial regime would mean that the CCG would still pay for that treatment. This is because CCGs are given a population based allocation.

The revenue impact of any capital case will be included in future revenue planning assumptions but, at present, the NHS works on annual budgets. As we move towards the development of an Integrated Care System for Leicester, Leicestershire and Rutland the NHS financial regime will allow for greater revenue and capital freedoms so that systems can determine the movement of funds to be based on the most effective pathway for patients, thereby enabling more community based services.

3. Any attempt to clarify with the CCGs how much capital and revenue has been allocated to community services has not been answered on the grounds that only UHL acute capital is being considered. We were, therefore pleased the June CCGs Extraordinary Board Meeting approved "creating a primary care urgent treatment centre at Leicester General Hospital site and scope further detail on proposals for developing services at the centre based upon feedback and further engagement with the public." Can the CCG explain why proposals did not also included community services for residents across LLR which are needed as a consequence of reconfiguration?

Response

The consultation dealt with the proposals outlined in the Pre Consultation Business Case, which included the future of the Leicester General Hospital campus.

The ongoing work to improve community services for residents across Leicester, Leicestershire and Rutland to provide more care closer to home is part of separate and ongoing work around a number of key programmes. They include the Better Care Fund (a programme that supports local systems to successfully deliver the integration of health and social care in a way that supports person-centred care, sustainability and better outcomes for people and carers), Ageing Well (an NHS programme to support people to Age Well) and Place-Led Plans. Improvement work will be funded through a mixture of funds available to the NHS e.g. baseline commissioning budgets and through the Ageing Well programme.

4. The introduction to the Report of Findings tells us "Long gone are the days when any one of the hospitals would cater exclusively for the needs of patients in their own distinct geographic area. Instead, patients are already used to visiting any one of the three city hospitals depending on the required specialism, clinical staff and bed availability." Do the CCGs have patient flows to back up this statement? Do Rutland & East Leicestershire patients (as a percentage of population) use proportionally more of the specialities delivered from the General Hospital site compared with the other sites?

Response

Outlined below are figures for Leicester Royal Infirmary (LRI), Leicester General Hospital (LGH) and Glenfield Hospital (GH):

LRI – Out of 480,011 patients, 21,078 were from Rutland and East Leicestershire which is 31.29% of the overall Rutland and East Leicestershire population.
LGH – Out of 238,694 patients, 11,780 were from Rutland and East Leicestershire which is 17.49% of the overall Rutland and East Leicestershire population.
GH – Out of 158,894 patients, 8,038 were from Rutland and East Leicestershire which is 11.93% of the overall Rutland and East Leicestershire population.

All the above are based on 20/21 data. Please note in defining Rutland and East Leicestershire, the data is based on the following postcodes LE13, LE14 and LE15.

From Lorraine Shilcock:

1. What is the meaning of the following statement on p25 of the Decision-Making Business Case? "However, work is ongoing with the New Hospital Programme to agree the scope of inclusion in the programme, and the potential sources of capital."

Response

Since the publication of the PCBC and the consultation, a 'New Hospitals Programme' has been established by NHS England and NHS Improvement to deliver the national programme of 40 new hospitals. This programme is in the middle of a process which will define the out-puts required within these new policy requirements, and the extent to which UHL, as one of the front running 8 new projects, will be required to deliver this policy change.

2. Which proposals/services do you plan to cut if the necessary finances are not forthcoming?

Response

We have been clear that the clinical model we consulted upon, which delivers future clinical sustainability, is our priority. Any additional policy requirements since the announcement of the £450m will need to attract additional funding from the centre. Without this, the additional policy requirements will not be possible to deliver since we do not plan to remove clinical scope from our programme.

From Sally Ruane:

"I wish to raise concerns about the use of an "impartiality clause" used by the CCGs during the consultation process which would have had the effect of stifling the expression of points of view at odds with those of the CCGs.

Via a Service level agreement with an impartiality clause, the CCGs commissioned and remunerated organisations to undertake engagement with people as "supporters" of the consultation exercise. However, the impartiality clause obstructed the ability of these organisations to inform their members (or those they engaged with) of any concerns they had about the proposals and it obstructed the ability of these organisations to draw on independent sources or their own body of knowledge in responding to members'/followers' questions.

The Impartiality clause (attached) stated "Organisations are not expected to express views or opinions on the consultation when engaging with their communities … and all queries and questions should be signposted to official literature or NHS leads".

It appears, therefore, that these organisations far from being impartial, could be said to be the voice of the CCGs, able only to point people to the official literature so providing them with a single, very particular narrative.

1. I would like to know if this practice is legal.
2. I would like to know if this is seen as good practice and what dangers were considered in deciding to proceed with these agreements.
3. Are the CCGs able to tell us what steps they took to ensure that organisations under contract informed their members/followers in any engagement they (the organisations) had with their members/followers that they were working under a service level agreement which contained an 'impartiality clause'.
4. How many of the 5,675 responses to the consultation were as a result of these contracts?
5. What changes have been made to the Building Better Hospitals for the Future proposals following public – not clinical- feedback?

Response

The impartiality clause included in the Service Level Agreement with voluntary and community organisations related to the promotion of the consultation only, and clearly stated that organisations were not being asked to encourage or promote support of the proposals or to support the proposals as organisations themselves.

The purpose of the clause was to protect the voluntary and community organisations that were agreeing to promote the consultation to their communities. The clause ensured that they could freely state the organisation's views on the proposals.

We also asked them as part of the clause to not edit or change the published consultation documents, thereby inadvertently misrepresenting what the proposals were to their communities.

The full clause read as follows:

"*We are asking local voluntary and community organisations to act as supporters for our consultation by promoting to targeted groups and communities.*

"Organisations will not be expected to promote support for the proposal itself, but rather support the consultation process by encouraging as many people as possible to give their feedback and have their say.

"In acting in the role of promoting the consultation to groups and communities it is important that supporters remain impartial. Organisations are not expected to express views or opinions on the consultation when engaging with their communities, should they be positive or negative, and all queries and questions should be signposted to official literature or NHS leads. However, we do appreciate that organisations in their own right, as registered charities or other entities, may wish to contribute to the consultation and express their views using the range of feedback mechanism open to them."

The Report of Findings includes the event feedback as both a separate and integrated section. We anticipate that around 600 responses to the consultation were made as a direct result of this partnership activity with the VCS.

The Decision Making Business Case includes a set of principles. The principles have been developed to address the key themes identified through the consultation, based on what matters most to people. They are commitments to the public in Leicester, Leicestershire and Rutland and will be used to support the implementation of the proposals.

In addition, one of the biggest changes based on feedback from the public has been the removal of the one-year trial period for the standalone midwifery led unit at Leicester General Hospital. The assessment of the viability of the standalone midwife led unit at the Leicester General Hospital campus will now take place over three years.

From Janet Underwood:

> The UHL reconfiguration plans were discussed and agreed at the CCG governing body meeting on 8th June 2021. However, the Chair of the CCG governing body noted the increased inequalities in accessing health care for those living in rural communities; especially in the east of the city.
>
> The UHL Travel Plan creates improved and environmentally sustainable travel around and within the city but no mention of improved travel facilities or better accommodation of the needs of those who live in rural areas.
>
> Healthwatch Rutland asks what plans, other than a trial park and ride for just 80 cars at Leicester General Hospital, UHL, working with partners in the Integrated Care System, have to mitigate these inequalities?

<u>Response</u>

Discussions are already well underway in Rutland to develop Place-Led Plans for what local health and care services should look like in the community These Place-led Plans, developed through the Health and Wellbeing Board for Rutland in partnership with the local authority, Healthwatch and a range of other stakeholders, include GP provision and the usage of local infrastructure, such as the community hospital, to deliver a greater range of services locally. We are committed to continuing these conversations over the coming months.

Progress is being made to improve travel to the UHL sites. In summary:

- *The introduction of the PlusBus ticket option on the Hospital Hopper in February 2021 providing seamless ticketing between train and bus.*
- *Plans are being progressed for a new Park & Ride facility at Leicester General Hospital in partnership with Leicester City Council, making it easier to travel to Leicester Royal Infirmary and Glenfield Hospital on the Hospital Hopper.*

- *UHL partnership with the authority with oversight for bus service provision in Rutland (Rutland County Council) to help improve the public awareness of existing travel options and consider opportunities to improve connectivity. The new National Bus Strategy will assist this partnership working.*
- *Introduction of ANPR (Automatic Number Plate Recognition) technology on the main patient car parks at the Leicester Royal Infirmary and Glenfield Hospital to assist with access issues at the Infirmary and remove the need for patients to estimate length of stay at the Glenfield Hospital.*

As part of these discussions it is important that we understand the current position in relation to the delivery of healthcare within Rutland. The below figures are approximate but set out the large amount of healthcare already delivered within the county.

- *c69% of patients accessing same day minor illness and injury NHS services are seen and treated in sites in Rutland*
- *89% of patients accessing an NHS community inpatient service are seen and treated at Rutland Memorial with a small proportion of these at Stamford*
- *100% of patients registered with Rutland practices can access joint NHS and County council in-home services following discharge via the Home First model of care*
- *50% of emergency low acuity NHS eye care is provided within Rutland and this will increase as we launch the new local service through 2 practices with 5 optometrists within Rutland*
- *40% of all NHS outpatient appointments accessed by patients registered with a Rutland practice are seen and treated either virtually or within Rutland*
- *100% of patients registered with Rutland practices have access to virtual IAPT services*
- *100% of patients registered with Rutland practices have access to clinical navigation services and 11 services from their own homes*

RESPONSES TO SUPPLEMENTARY QUESTIONS OR REQUESTS FROM SCRUTINY MEMBERS FOR WHICH ADDITIONAL INFORMATION OR ANSWERS WERE REQUIRED

Questions from Cllr Sam Harvey in relation to Rutlanders use of St Mary's Birthing Unit

Please confirm the following for the year 2019/2020:
(a)The number of Rutland residents who delivered at St Mary's Unit;

Response

St Marys Birth Centre	*14*

(b) The number of Rutland residents who received post partum inpatient care in the ward at St Mary's;

Response

No Rutland residents received post-partum inpatient care in the ward in St. Mary's.

(c) The number of Rutland Residents who delivered at either LGH or LRI;

Response

Leicester General Hospital	42
Leicester Royal Infirmary	37

(d) The number of Rutland residents who received post partum/ post natal care in Rutland, who delivered out of county, i.e. Peterborough, Kettering etc.

Response

For women having a first baby, there is a fairly high probability of transferring to an obstetric unit during labour or immediately after the birth

- *For nulliparous women, the peri-partum transfer rate was 45% for planned home births, 36% for planned FMU births and 40% for planned AMU births*

The figures for St. Mary's Birth Centre are below:

	2018/19			
	Women Booked for Delivery	**150**	of which:-	
Less:	Intrapartum Transfers	13	First time mothers	12
			Multiple pregnancies	1
	Women Recorded as Delivered	**137**		
Less:	Post Natal Transfers	9	First time mothers	5
			Multiple pregnancies	4
	Women Receiving Post Natal Care at St. Marys	**128**		
	Total Transfers	**22**	**Total Transfers of First Tme Mothers**	**11.3%**
	Total Transfers %	**14.7%**	**Total Transfers of Mothers Delivered Before**	**3.3%**
	2019/20			
	Women Booked for Delivery	**181**	of which:-	
Less:	Intrapartum Transfers	29	First time mothers	24
			Multiple pregnancies	5
	Women Recorded as Delivered	**152**		
Less:	Post Natal Transfers	19	First time mothers	10
			Multiple pregnancies	9
	Women Receiving Post Natal Care at St. Marys	**133**		
	Total Transfers	**48**	**Total Transfers of First Tme Mothers**	**18.8%**
	Total Transfers %	**26.5%**	**Total Transfers of Mothers Delivered Before**	**7.7%**

Where are qualitative comments from Rutland captured in the DMBC or Report of Findings?

Response

Healthwatch Rutland issued their own report before the consultation ended. That report was analysed as part of the overall consultation – but the numbers not included in the final count, as we felt that this may be double counting.

Specific mention of Rutland is included throughout the main report of findings. Specific areas include:

Summary:

- *Table 30, Page 87 Rutland demographics*
- *4.3.4.1 Page 28 reference to Rutland Report*

- *4.4.4.1 page 141 new technology*
- *4.6.4.1. page 194 stand alone birthing unit*

Main body of report

- *2.1.1.1 page 269 children's hospital*
- *2.1.1.2 page 279 access and transport*
- *2.1.1.3 page 294 other comments*

Question from Councillor Melissa March in relation to VCS partners

Officers agreed to provide breakdown VCS organisations and of cost to each organisation.

Response

During the acute consultation the CCGs strategically partnered with 17 VCS organisations to help reach out to and engage with traditionally overlooked or seldom heard communities. This includes representation across the protected characteristics as set out in the Equality Act. The amount of funding provided to each organisation depended on the size of the target audience and the plans set out by each organisation to reach these communities. The average level of funding was £1,566 per organisation. The full list of VCS partners is as follows:

- Adhar / South Asian Health Association
- Age UK
- Ashiedu Joel (target black heritage communities)
- Pamela Campbell Morris (targeting black heritage communities)
- Carer's Centre
- CommsPlus
- Council of Faiths
- Hashim Duale (targeting Somali community)
- Somali Development Services
- Healthwatch Rutland
- British Deaf Association
- LGBT Centre
- Project Polska
- Rutland Community Ventures
- Shama Women's Centre
- Voluntary Action LeicesterShire
- Vista

Question from Cllr Phil King in response to Hydrotherapy

Provision and location of hydrotherapy pools in the community.

Response

The Building Better Hospitals for the Future consultation undertaken at the end of 2020 included a proposal for the provision of hydrotherapy pools. The proposal outlined the use of hydrotherapy pools already located in community settings, enabling UHL to provide care closer to home. We asked people to tell us the extent to which they agreed or disagreed with this proposal and to explain the impact of the proposal on them, their family or groups they represented. This proposal received significant support.

The Report of Findings and the Decision Making Business Case for Building Better Hospitals for the Future was discussed in a meeting in public of the Clinical Commissioning Groups in Leicester, Leicestershire and Rutland and a decision made to go ahead with the planned £450 million transformation plans to improve Leicester's hospitals' acute hospital and maternity services. This decision includes the proposal for hydrotherapy pools. As a result, further work can now go ahead to identify appropriate pools that will implement this change in approximately 5 years. A mapping exercise has already identified the following hydrotherapy pools as possible locations:

Westgate School, Leicester
Stanford Hall, Loughborough
Inspire2tri Endless Pool Barn, Oakham

We are working with the Leisure Sub-group of the One Public Estate Leicester Group to continue to expand this offer over the next five years. We are keen to maximise the number of pools that we have available so we broaden the community offer for people across Leicester, Leicestershire and Rutland.

In moving to community based pools further assessments of suitability is being undertaken against clear criteria including temperature, it should be heated between 32.3C – 36.0C, and a depth of approximately 1.0 – 1.2m at its deepest, with steps down to each depth not a sloping floor. Venues will need to include the appropriate equipment such as a hoists and sessions will be led by appropriately trained staff from UHL.

This question was also raised by Cllr Terri Eynon, during the consultation, and was answered at a meeting of the Leicester, Leicestershire and Rutland Joint Health Overview and Scrutiny Committee on 14th December 2020. The response is published at http://politics.leics.gov.uk/mgAi.aspx?ID=66436.

	Population statistics				
	Total	Leicestershire	Leicester	Rutland	To
Population / consultation participants	1100306	706155	354224	39927	47
	100%	64%	32%	4%	10
Population/consultation participants not including those not providing a postcode or profile					
0-14	17.9%	16.8%	20.3%	15.5%	-
15-24	13.8%	11.9%	18.0%	9.9%	247
25-34	13.2%	11.8%	16.4%	10.4%	762
35-44	12.0%	12.1%	12.5%	11.1%	804
45-54	13.2%	14.4%	10.9%	14.1%	762
55-64	11.9%	12.9%	9.7%	13.6%	916
65+	18.0%	20.5%	12.2%	25.5%	1060
Prefer not to say	-	-	-	-	98
Base	-	-	-	-	*46*
Male	49.7%	49.4%	50.2%	50.9%	1331
Female	50.3%	50.6%	49.8%	49.1%	3101
Non-binary	-	-	-	-	8
Intersex	-	-	-	-	4
Other	-	-	-	-	4
Prefer not to say	-	-	-	-	166
Base	-	-	-	-	*46*
Day-to-day not limited	83.5%	83.8%	82.7%	84.5%	3354
Day-to-day limited	16.5%	16.2%	17.3%	15.5%	1226
Registered learning disability with a GP	-	0.4%	-	-	-
Base	-	-	-	-	*45*
White	78.4%	91.4%	50.5%	97.1%	3666
Asian/Asian British	16.1%	6.3%	37.1%	1.0%	590
Black/African/Caribbean/Black British	2.4%	0.6%	6.2%	0.7%	110
Mixed/Multiple Ethnic group	2.3%	1.7%	3.5%	1.0%	70
Other ethnic group	0.8%	-	2.6%	0.2%	84
Base	-	-	-	-	*45*
Christian	51.6%	60.3%	32.4%	68.2%	2232
No religion	25.6%	27.1%	22.8%	23.4%	1521

Muslim	**6.9%**	1.4%	18.6%	0.4%	**327**
Hindu	**6.7%**	2.8%	15.2%	0.2%	**214**
Sikh	**2.2%**	1.2%	4.4%	0.1%	**50**
Buddhist	**0.3%**	0.2%	0.4%	0.3%	**20**
Jewish	**0.1%**	0.1%	0.1%	0.1%	**11**
Other religion	**0.5%**	0.4%	0.6%	0.4%	**137**
Not stated	**6.2%**	6.5%	5.6%	7.0%	**-**
Base	**-**	-	-	-	***45***
Heterosexual	**-**	-	89%	-	**3924**
Bisexual	**-**	-	3%	-	**87**
Gay	**-**	-	1%	-	**67**
Lesbian	**-**	-	-	-	**40**
Other	**-**	-	-	-	**33**
Prefer not to say	**-**	-	-	-	**401**
Base	**-**	-	-	-	***45***

Consultation participants								
tal	Leicestershire		Leicester		Rutland		Other / postcode not provided or profiled	
22	2168		943		292		1319	
0%	46%		20%		6%		28%	
	63%		**29%**		**8%**			
Age								
-	-	-	-	-	-	-	-	-
5.3%	89	4.1%	83	8.9%	3	1.0%	72	5.6%
16.4%	382	17.8%	159	17.0%	33	11.5%	188	14.7%
17.3%	388	18.0%	164	17.6%	27	9.4%	225	17.6%
16.4%	350	16.3%	195	20.9%	26	9.1%	191	15.0%
19.7%	427	19.9%	180	19.3%	50	17.4%	259	20.3%
22.8%	490	22.8%	122	13.1%	141	49.1%	307	24.0%
2.1%	25	1.2%	31	3.3%	7	2.4%	35	2.7%
49	*2151*		*934*		*287*		*1277*	
Gender								
28.8%	535	24.9%	297	31.9%	81	28.1%	418	33.4%
67.2%	1549	72.2%	592	63.7%	200	69.4%	760	60.8%
0.2%		0.0%	4	0.4%		0.0%	4	0.3%
0.1%	2	0.1%		0.0%		0.0%	2	0.2%
0.1%	2	0.1%		0.0%		0.0%	2	0.2%
3.6%	58	2.7%	37	4.0%	7	2.4%	64	5.1%
14	*2146*		*930*		*288*		*1250*	
Disability								
73.2%	1613	75.8%	643	69.8%	199	70.3%	899	72.1%
26.8%	516	24.2%	278	30.2%	84	29.7%	348	27.9%
-	-	-	-	-	-	-	-	-
80	*2129*		*921*		*283*		*1247*	
Ethnicity								
81.1%	1956	92.4%	503	55.1%	280	98.6%	927	76.9%
13.1%	99	4.7%	327	35.8%	1	0.4%	163	13.5%
2.4%	11	0.5%	41	4.5%	-	-	58	4.8%
1.5%	25	1.2%	23	2.5%	2	0.7%	20	1.7%
1.9%	27	1.3%	19	2.1%	1	0.4%	37	3.1%
20	*2118*		*913*		*284*		*1205*	
Religion								
49.5%	1177	55.8%	296	32.5%	183	66.1%	576	47.4%
33.7%	782	37.1%	253	27.7%	90	32.5%	396	32.6%

7.2%	21	1.0%	186	20.4%		0.0%	120	9.9%
4.7%	50	2.4%	113	12.4%		0.0%	51	4.2%
1.1%	16	0.8%	20	2.2%		0.0%	14	1.2%
0.4%	8	0.4%	4	0.4%		0.0%	8	0.7%
0.2%	7	0.3%	1	0.1%		0.0%	3	0.2%
3.0%	48	2.3%	39	4.3%	4	1.4%	46	3.8%
-	-	-	-	-	-	-	-	-
12	*2109*		*912*		*277*		*1214*	
	Sexual Orientation							
86.2%	1877	88.7%	742	80.5%	258	90.2%	1047	85.2%
1.9%	31	1.5%	34	3.7%	3	1.0%	19	1.5%
1.5%	25	1.2%	22	2.4%	1	0.3%	19	1.5%
0.9%	17	0.8%	7	0.8%	1	0.3%	15	1.2%
0.7%	12	0.6%	11	1.2%	3	1.0%	7	0.6%
8.8%	153	7.2%	106	11.5%	20	7.0%	122	9.9%
52	*2115*		*922*		*286*		*1229*	

Analysis notes
Option not included in consultation survey
Consultation survey: age groups were 16-19, 20-24
Consultation survey: This is a combination of those stating day-to-day activities 'limited a little' and 'limited a lot'
Not captured in the consultation survey

Minute Item 13

Responses to Questions raised under Item 13 Any Other Urgent Business at the meeting on 6th July 2021

- **Do we have the information on the % of IUD procedures that are performed with a Local Anaesthetic?**

This data that is not routinely collected by our services but is reviewed as part of clinical audit. Some Fitters offer local anaesthetic routinely while some do not. The Faculty guideline (attached) does not support routine use of local anaesthetic for intra-uterine insertion procedure.

o Dr Louise Massey of the Faculty of Sexual and Reproductive Health Care of the Royal College of Obstetricians and Gynaecologists said on the BBC last week:
'the procedure can always be stopped if there is too much pain, discomfort or distress. It is always an option to abandon it; it can even be done under General anaesthetic if necessary and appropriate'

- **Do we offer and what % of IUD are fitted with a General anaesthetic across the Trust?**

The Integrated Sexual Health Service do not offer IUC fitting under general anaesthetic (GA). However, patients who choose for whatever reason to have fitting under GA would be asked to contact their GPs to refer them to Gynaecology dept.

- **What % of procedures are unsuccessful and are stopped from completion in Leicester, Leicestershire and Rutland?**
- **What % of IUD's need removing due to complications post procedure?**

We collect data routinely on the reasons for the removal of an IUD/S and the number of patients unable to cope with procedure due to pain or anxiety. The latest data we have available from the LARC audits from primary care providers in Leicestershire and Rutland relates to 2019/20. It reports the following findings:

- **The audits reported a total of 2279 devices fitted were in 2019/20, (1877 intrauterine systems and 402 intrauterine devices) in GP practices in Leicestershire and Rutland (as reported by practitioners).**
- **Practitioners reported 22 occasions of patients not able to cope with procedure due to pain or anxiety in 2019/20. For all instances the procedure was abandoned, and the following action was taken (breakdown can't be provided due to small numbers):**
  - **they were offered pain relief and was successful**
  - **procedure tried two weeks later and was successful**
  - **referred to gynae/family planning service/GP**
  - **patient took up an alternative form of contraception**
  - **data not provided**
- **The audit returns report a total of 1021 removals in 2019/20 for a variety of reasons, the most common being the device expired & needed a refit (56%), followed by no longer required (16%) and bleeding problems**

(9%). Pain accounted for 3% of all reasons for removal, affecting 38 individuals.

Regarding the change in policy question, all the practitioners who provide the service in GPs are linked to the LLR Fitters Forum and so will be provided with the expertise from Mr Oloto and Mr Kumar in this area. We cannot provide answers to "% of IUD procedures that are performed with a Local Anaesthetic?" and "Do we offer and what % of IUD are fitted with a General anaesthetic across the Trust?" as local anaesthetic is not provided in GP practices to undertake this procedure.

Liz Rodrigo may be able to help with City figures if needed.

- **If the data is not collected routinely is there any expected change in policy in light of the spotlight that has been placed on the procedure?**

We would always ensure our services follow the latest clinical guidelines and evidence base.

- **The anecdotal evidence that has been collected and published so far, has indicated that the procedure is far from routine for some. I note that the guidance on the procedure was recently updated on the national NHS website, but has there been any recent policy updates provided for those that fit IUD's in LLR? Particularly on pain management or device fitting triggering past trauma. If not, when will this be provided?**

'Reducing pain at IUC insertion' was extensively discussed in the last LLR IUC Fitters forum in October 2020, which was well evaluated (feedback attached). In the light of the recent spotlight, the Faculty issued a statement on the 30th June 2021 (attached), which was circulated to the IUC Fitters and other members of the sexual health team. Therefore, all provider are fully aware of the Faculty guidelines and how best to respond to patients who may have concern about pain relief. Local anaesthetic (topical or injectable) is readily available in the integrated sexual health service and all Fitters would be encouraged to discuss the pros and cons with the patients as part of the counselling. A further 'Fitters forum' for the wider LLR Fitters can be considered if necessary.

FSRH Statement: Pain associated with insertion of intrauterine contraception
30 June 2021

Recent media reports have highlighted cases of individuals who have experienced distressing intrauterine contraception (IUC) fitting. Some individuals do find IUC insertion anxiety-provoking and painful. However, studies suggest the majority of individuals report that pain during IUC fitting is mild (visual analogue score 1-3/10) or moderate (score 4-6/10) rather than severe (7-10/10)[1], even without use of analgesia[2,3]. By five minutes after insertion, reported mean pain scores are low.[4,5] In studies reporting both pain scores and a description of the experience, moderate pain scores correlate with descriptions of discomfort rather than pain.[1,6]

Can we identify individuals who might experience greater pain at IUC insertion?

Reported mean pain scores are generally higher amongst nulliparous individuals and those that have only had caesarean deliveries.[1,2,7,8] History of dysmenorrhoea is associated with higher pain scores.[8-11] Importantly, greater anxiety, greater anticipated pain and negative perceptions of intrauterine contraception prior to the procedure appear to correlate with higher experienced pain scores.[7,8,12] Previous experience of painful gynaecological/obstetric procedures may contribute to higher anticipated pain scores.[7]

For any individual it is, however, impossible to predict with certainty whether they will experience pain or discomfort during IUC fitting.

Interventions to manage pain associated with IUC insertion

Discomfort and pain may be experienced with any of the stages of IUC fitting: speculum insertion, tenaculum placement, and in particular, uterine sounding and device placement itself.[5,7] Technically difficult insertions may be associated with higher

reported pain scores.[2,3] It is noted that removal of IUC is a much more minor and usually well-tolerated procedure.

Numerous studies and systematic and narrative reviews have sought effective strategies are effective to reduce pain associated with IUC insertion.[3,13-18]

Oral analgesics (pre and post procedure)

Studies of prophylactic ibuprofen have not demonstrated reduced pain scores relative to placebo during IUC insertion. In a 2018 randomised controlled trial (RCT) Abbas[19] reported benefit relative to placebo with oral ketoprofen 150mg taken an hour prior to the procedure. In other RCTs, Karabayirli (2012)[20] reported lower mean overall pain scores compared to placebo amongst individuals using naproxen 550mg or tramadol 50mg one hour prior to the procedure (the effect was significantly greater with tramadol than with naproxen) and Ngo[21] demonstrated significantly reduced pain scores at five minutes after insertion with naproxen 550mg taken an hour pre-insertion compared with placebo. NSAIDs are effective to reactively treat post-insertion pain.[22]

Cervical priming

Misoprostol, a prostaglandin analogue, has been trialled in various regimens for cervical priming prior to IUC insertion. While some studies report significantly reduced insertion pain scores versus placebo, others do not, and prostaglandin side effects including cramping pain are an important consideration.[2-23]

Local anaesthetic

10% lidocaine spray 4 puffs (10mg per puff) applied to the surface of the cervix including the external os three minutes prior to the procedure has been demonstrated by three RCTs[5,24,25] to significantly reduce IUC insertion-related pain scores compared to placebo; one of these RCTs found lidocaine spray to be more effective than lidocaine injection and lidocaine cream.[25] Most participants in these studies were parous. Vaginal irritation was common[5], which could reflect the excipients, including flavourings, in the Xylocaine spray.[26] The FSRH CEU suggests that although the spray nozzles are disposable, the bottle delivers multiple doses and infection control must be carefully observed.

Paracervical block using 1% lidocaine was reported by two RCTs to significantly reduce pain scores compared with placebo in nulliparous individuals, although there was pain associated with the local anaesthetic injection itself.[4,27] A third RCT using 10ml 2% lidocaine for paracervical block demonstrated benefit compared to placebo.[25]

In a recent RCT[28], **intracervical block** using 3.6ml of 2% lidocaine administered with a 27 gauge needle in divided doses at 3, 6, 9 and 12 o'clock prior to tenaculum placement significantly reduced both mean pain scores and occurrence of severe pain at tenaculum placement and device insertion compared with placebo and no intervention in nulliparous individuals. However, an earlier RCT[29] demonstrated no benefit with 1% lidocaine intracervical block compared to placebo.

2% lidocaine gel administered into the cervical canal and at the tenaculum site or self-administered to the vagina does not, in studies, significantly reduce insertion pain. However novel gel formulations could be more effective and may warrant further study.[3]

Parous individuals randomised to cervical application of **EMLA 5% lidocaine/prilocaine cream (**2ml to the anterior cervical lip with a cotton bud and 2ml into the cervical canal to the level of the internal os seven minutes prior to IUD insertion) reported significantly lower median pain scores than those randomised to placebo.[30] A 2019 systematic review and network meta-analysis by the same team suggested that application of EMLA cream could be the most effective option for pain reduction at tenaculum placement and device insertion.[16]

Summary

There is no clear "best" analgesic option. However,

paracervical block, intracervical local anaesthetic injection (see e-SRH Intrauterine Techniques module), 10% lidocaine spray applied to the surface of the cervix and external os three minutes prior to the procedure, or EMLA cream applied to the tenaculum site and into the cervical canal could all reduce insertion-related pain. Ketoprofen or naproxen taken an hour before the procedure could be beneficial for insertion and post-insertion pain. There is not evidence for routine prophylactic use of ibuprofen, although non-steroidal anti-inflammatory drugs are beneficial for treating established pain after insertion.

Non-pharmacological interventions

A 2019 systematic review highlighted the lack of evidence around non-pharmacological options for minimising anxiety and pain around IUC insertion.[14] The importance of creating an environment that affords privacy, reassuring professionalism and is sensitive to feelings of embarrassment is described.[31] It is noted that clinicians may underestimate the anxiety and pain experienced.[1] Healthcare practitioners regularly undertaking IUC insertion procedures know well the significant benefit of "vocal local" – an assistant present to provide support and distraction to the patient. No specific insertion equipment or inserter type is clearly associated with less pain at insertion, although narrower insertion devices could be associated with less difficult insertion and lower pain scores.

What does the FSRH recommend?

Insertion-related pain, both anticipated and experienced, and anxiety about the insertion procedure can be barriers to use of intrauterine contraception.

Work in partnership with users to establish the best strategies for reducing anxiety and the most effective interventions for minimising pain at IUC insertion needs to continue. FSRH considers it crucial that it is the patient's informed decision to use intrauterine contraception. The insertion procedure should be carried out by trained healthcare professionals who are mindful of the patient experience and understand that a minority of individuals do report severe pain associated with the

procedure. Healthcare professionals should create a reassuring, supportive environment, offer appropriate analgesia (and referral on to another provider if they cannot offer this) and ensure that the patient is aware that they can request that the procedure stops at any time.

Copper and hormonal intrauterine devices provide highly effective, convenient, reversible contraception. Hormonal devices offer the additional non-contraceptive benefit of management of heavy or painful menstrual bleeding, and copper IUDs afford an effective hormone-free contraceptive option. FSRH welcomes future studies, working with users to optimise the patient experience for individuals choosing intrauterine contraception.

References

1. Akintomide H, Brima N, Sewell RD, Stephenson JM. Patients' experiences and providers' observations on pain during intrauterine device insertion. *The European Journal of Contraception & Reproductive Health Care* 2015;20(4):319-26.
2. Chaves IA, Baêta T, Dolabella GB, et al. Pain scores at the insertion of the 52 MG levonorgestrel- releasing intrauterine system among nulligravidas and parous women. *The European Journal of Contraception & Reproductive Health Care* 2021:30:1-5.
3. Gemzell-Danielsson K, Jensen JT, Monteiro I, et al. Interventions

for the prevention of pain associated with the placement of intrauterine contraceptives: An updated review. *Acta obstetricia et gynecologica Scandinavica* 2019;98(12):1500-13.

4. Mody SK, Farala JP, Jimenez B, Nishikawa M, Ngo LL. Paracervical block for intrauterine device placement among nulliparous women: a randomized controlled trial. *Obstetrics and gynecology* 2018;132(3):575.

5. Panichyawat N, Mongkornthong T, Wongwananuruk T, Sirimai K. 10% lidocaine spray for pain control during intrauterine device insertion: a randomised, double-blind, placebo-controlled trial. *BMJ Sexual & Reproductive Health* 2020 Jun 25.
6. Castro TV, Franceschini SA, Poli-Neto O, et al. Effect of intracervical anesthesia on pain associated with the insertion of the levonorgestrel-releasing intrauterine system in women without previous vaginal delivery: a RCT. *Human Reproduction* 2014;29(11):2439-45.
7. Akdemir Y, Karadeniz M. The relationship between pain at IUD insertion and negative perceptions, anxiety and previous mode of delivery. *The European Journal of Contraception & Reproductive Health Care* 2019;24(3):240-5.
8. Dina B, Peipert LJ, Zhao Q, Peipert JF. Anticipated pain as a predictor of discomfort with intrauterine device placement. *American journal of obstetrics and gynecology* 2018;218(2):236-e1.
9. Allen R. Predicting Painful IUD Insertion. *Ob/gyn Clinical Alert* 2014;31(6):43-4.
10. Schneyer R, Lerma K, Conti J, Shaw K. Dysmenorrhoea as a risk factor for pain with intrauterine device insertion. *BMJ Sexual & Reproductive Health* 2021 Mar 30.
11. Ferreira LS, de Nadai MN, Poli-Neto OB, et al. Predictors of severe pain during insertion of the levonorgestrel 52 mg intrauterine system among nulligravid women. *Contraception* 2020;102(4):267-9.

12. Hunter TA, Sonalkar S, Schreiber CA, Perriera LK, Sammel MD, Akers AY. Anticipated pain during intrauterine device insertion. *Journal of pediatric and adolescent gynecology* 2020;33(1):27-32.
13. Lopez LM, Bernholc A, Zeng Y, et al. Interventions for pain with intrauterine device insertion. Cochrane Database of Systematic Reviews. 2015(7).
14. Nguyen L, Lamarche L, Lennox R, et al. Strategies to mitigate anxiety and pain in intrauterine device insertion: A systematic review. *Journal of Obstetrics and Gynaecology Canada* 2020;42(9):1138-46.
15. Anthoulakis C, Iordanidou E, Vatopoulou A. Pain perception during levonorgestrel-releasing intrauterine device insertion in nulliparous women: a systematic review. *Journal of pediatric and adolescent gynecology* 2018;31(6):549-56.
16. Samy A, Abbas AM, Mahmoud M, et al. Evaluating different pain lowering medications during intrauterine device insertion: a systematic review and network meta-analysis. *Fertility and sterility* 2019;111(3):553-61.
17. Perez-Lopez FR, Martinez-Dominguez SJ, Perez-Roncero GR, Hernandez AV. Uterine or paracervical lidocaine application for pain control during intrauterine contraceptive device insertion: a meta-analysis of randomised controlled trials. *The European Journal of Contraception & Reproductive Health Care* 2018;23(3):207-17.
18. Zapata LB, Jatlaoui TC, Marchbanks PA, Curtis KM. Medications to ease intrauterine device insertion: a

systematic review. *Contraception* 2016;94(6):739-59.

19. Abbas AM, Ali SS, Salem MN, Sabry M. Effect of oral ketoprofen on pain perception during copper IUD insertion among parous women: A randomized double-blind controlled trial. *Middle East Fertility Society Journal* 2018;23(4):491-5.
20. Karabayirli S, Ayrım AA, Muslu B. Comparison of the analgesic effects of oral tramadol and naproxen sodium on pain relief during IUD insertion. *Journal of minimally invasive gynecology* 2012;19(5):581-4.
21. Ngo L, Braaten K, Eichen E, Fortin J, Maurer R, Goldberg A. Naproxen sodium for pain control with intrauterine device insertion: a randomized controlled trial. *Contraception* 2016;94(4):404.

22. Grimes DA, Hubacher D, Lopez LM, Schulz KF, Van Vliet HA. Non-steroidal anti-inflammatory drugs for heavy bleeding associated with intrauterine contraception. Cochrane Database of Systematic Reviews. 2006(4).
23. Gemzell-Danielsson K, Mansour D, Fiala C, Kaunitz AM, Bahamondes L. Management of pain associated with the insertion of intrauterine contraceptives. *Human reproduction update* 2013;19(4):419-27.
24. Aksoy H, Aksoy Ü, Ozyurt S, Açmaz G, Babayigit M. Lidocaine 10% spray to the cervix reduces pain during intrauterine device insertion: a double-blind randomised controlled trial. *Journal of Family Planning and Reproductive Health Care* 2016;42(2):83-7.
25. Karasu Y, Cömert DK, Karadağ B, Ergün Y. Lidocaine for pain control during intrauterine device insertion. *Journal of Obstetrics and Gynaecology Research* 2017;43(6):1061-6.
26. emc .Aspen. Xylocaine 10mg Spray. Last updated on emc: 06 November 2018
27. Akers AY, Steinway C, Sonalkar S, Perriera LK, Schreiber C, Harding J, Garcia-Espana JF. Reducing pain during intrauterine device insertion: a randomized controlled trial in adolescents and young women. *Obstetrics & Gynecology* 2017;130(4):795-802.
28. De Nadai MN, Poli-Neto OB, Franceschini SA, et al. Intracervical block for levonorgestrel-releasing intrauterine system placement among nulligravid women: a randomized double-blind controlled trial. *American journal of obstetrics and gynecology* 2020;222(3):245-e1.
29. Elkhouly NI, Maher MA. Different analgesics prior to intrauterine device insertion: is there any evidence of

efficacy?. *The European Journal of Contraception & Reproductive Health Care* 2017;22(3):222-6.

30. Abbas AM, Abdellah MS, Khalaf M, et al. Effect of cervical lidocaine–prilocaine cream on pain perception during copper T380A intrauterine device insertion among parous women: a randomized double-blind controlled trial. *Contraception* 2017;95(3):251-6.
31. McCarthy C. Intrauterine contraception insertion pain: nursing interventions to improve patient experience. *Journal of clinical nursing* 2018;27(1-2):9-21.

The Clinical Effectiveness Unit (CEU) was formed to support the Clinical Effectiveness Committee of the Faculty of Sexual & Reproductive Healthcare (FSRH), the largest UK professional membership organisation working at the heart of sexual and reproductive healthcare. The FSRH CEU promotes evidence based clinical practice and it is fully funded by the FSRH through membership fees. It is based in Edinburgh and it provides a members' enquiry service, evidence-based guidance, new SRH product reviews and clinical audit/research. Find out more here.

FACULTY OF SEXUAL & REPRODUCTIVE HEALTHCARE

ROYAL COLLEGE OF OBSTETRICIANS & GYNAECOLOGISTS

Faculty of Sexual & Reproductive Healthcare Clinical Guidance

Intrauterine Contraception

Clinical Effectiveness Unit

April 2015 (Amended September 2019)

ISSN 1755-103X

Document reference number	02/FSRH/Intrauterine/2015
Title	Intrauterine Contraception
Author/publisher	Faculty of Sexual & Reproductive Healthcare (FSRH)
Publication date	April 2015 (Amended September 2019)
Description/descriptors	Intrauterine contraception, Cu-IUD, LNG-IUS, long-acting reversible contraception, LARC
Cross references	*United Kingdom Medical Eligibility Criteria (UKMEC) 2009* *FSRH New Product Review: Jaydess® Levonorgestrel Intrauterine System (LNG-IUS) 2014*
Superseded documents	FSRH CEU Intrauterine Contraception 2007
Update/amendment level	Full amendment – recommendations and practice changed
Review date	April 2020

DETAILS OF CHANGES TO ORIGINAL GUIDANCE DOCUMENT

Since this set of guidelines was first published the following changes have been made:

June 2015:

- Section 10.1 on page 19 has been reworded
- Table 5 on page 29, the fourth recommendation listed for removal/replacement outside the licensed duration of use has been expanded
- Reference 221 on page 39 has been revised

October 2015:

- Table 4 on page 7, the timing of IUC insertion for switching from Cu-IUD to LNG-IUS has been further defined.

September 2019:

- Throughout the guideline, where '52mg LNG-IUS' is used without clarification, it applies to any 52mg LNG-IUS. Where guidance applies only to a specific brand, the brand name is stated.
- Tables 3 (postpartum) and 4 (POP and Progestogen-only implant and progestogen-only injectable).

GRADING OF RECOMMENDATIONS

A Evidence based on randomised controlled trials

B Evidence based on other robust experimental or observational studies

C Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

✓ Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the guideline group

Published by the Faculty of Sexual & Reproductive Healthcare
Registered in England No. 2804213 and Registered Charity No. 1019969

First published in 2015 (Amended September 2019)

CONTENTS

ABBREVIATIONS USED

ALOs	actinomyces-like organisms
BASHH	British Association for Sexual Health and HIV
BMD	bone mineral density
BV	bacterial vaginosis
CEU	Clinical Effectiveness Unit
CHC	combined hormonal contraception/contraceptive
CI	confidence interval
COC	combined oral contraception/contraceptive
Cu-IUD	copper intrauterine device
DMPA	depot medroxyprogesterone acetate
EC	emergency contraception
EURAS	European Active Surveillance Study
FSRH	Faculty of Sexual & Reproductive Healthcare
GAS	group A streptococcus
GBS	group B streptococcus
HIV	human immunodeficiency virus
HMB	heavy menstrual bleeding
HPV	human papillomavirus
IM	intramuscular
IUC	intrauterine contraception
LA	local anaesthesia
LARC	long-acting reversible contraception/contraceptive
LNG	levonorgestrel
LNG-IUS	levonorgestrel intrauterine system
MI	myocardial infarction
NICE	National Institute for Health and Care Excellence
NSAID	non-steroidal anti-inflammatory drug
OR	odds ratio
PI	Pearl index
PID	pelvic inflammatory disease
RCT	randomised controlled trial
RR	relative risk
SC	subcutaneous
SPC	Summary of Product Characteristics
STI	sexually transmitted infection
UKMEC	*UK Medical Eligibility Criteria for Contraceptive Use*
UPA	ulipristal acetate
UPSI	unprotected sexual intercourse
USMEC	*US Medical Eligibility Criteria for Contraceptive Use*
VAS	Visual Analogue Scale
VTE	venous thromboembolism
VVC	vulvovaginal candida
WHO	World Health Organization
WHOMEC	*World Health Organization Medical Eligibility Criteria for Contraceptive Use*

SUMMARY OF KEY RECOMMENDATIONS

Eligibility

✓ Health professionals should be familiar with the UK Medical Eligibility Criteria for intrauterine methods.

Efficacy

B Women should be advised of the very low failure rates associated with use of intrauterine contraception (IUC).

A The most effective methods of IUC are the levonorgestrel intrauterine system (LNG-IUS) methods and T-shaped copper intrauterine devices (Cu-IUDs) with at least 380 mm^2 copper and copper bands on the transverse arms.

Insertion of IUC and duration of use

C A medical and sexual history should be carried out as part of the routine assessment for IUC to assess suitability for use of the method and need for STI testing.

✓ In asymptomatic women attending for insertion of IUC there is no need to wait for STI screening results or to provide antibiotic prophylaxis providing the woman can be contacted and treated promptly in the event of a positive result.

C Prophylactic antibiotics are not routinely required for the insertion or removal of IUC even in women with conditions where the risk of infective endocarditis may be increased.

B The Mirena 52 mg LNG-IUS can be used to provide endometrial protection in conjunction with estrogen therapy for up to 5 years (outside product licence).

Health benefits and risks

B Use of a Cu-IUD may be associated with a reduced risk of endometrial cancer and cervical cancer.

A The 52 mg LNG-IUS may reduce pain associated with primary dysmenorrhoea, endometriosis or adenomyosis.

A The 52 mg LNG-IUS is effective in reducing menstrual blood loss and can be used in the management of heavy menstrual bleeding.

C Women considering the LNG-IUS can be informed that systemic absorption of progestogen occurs with these devices. The 13.5 and 52 mg LNG-IUS have similar side-effect profiles (such as acne, breast tenderness/pain and headache) and hormonal side effects often settle with time. Rates of discontinuation due to side effects are not significantly different from Cu-IUD users.

B Women should be advised that existing evidence fails to support a negative effect on libido associated with IUC use.

B Weight gain has been observed with use of IUC. There is no significant difference between hormonal and non-hormonal intrauterine methods and evidence to support a causal association is lacking.

B In the 3-6 months following IUC insertion women may experience irregular, prolonged or frequent bleeding but menstrual bleeding patterns tend to improve with time.

B At 1 year infrequent bleeding is usual with the LNG-IUS and some women will experience amenorrhoea.

A Discontinuation due to bleeding and pain are similar for different types of framed and unframed Cu-IUDs.

B Evidence does not support a link between breast cancer and use of the LNG-IUS.

C Non-hormonal contraception is most appropriate for women with a history of breast cancer. Any consideration of the LNG-IUS should be carried out in consultation with the woman's cancer specialist.

B Evidence suggests there is little or no increased risk of venous thromboembolism or myocardial infarction associated with the use of a LNG-IUS.

Ectopic pregnancy

B The overall risk of ectopic pregnancy is reduced with use of IUC when compared to using no contraception.

B If pregnancy does occur with an intrauterine method *in situ*, the risk of an ectopic pregnancy occurring is increased and in some studies half of the pregnancies that occurred were ectopic.

C Data are insufficient to determine if the 13.5 mg LNG-IUS is associated with a greater risk of ectopic pregnancy than other IUC methods.

✓ IUC users should be informed about symptoms of ectopic pregnancy. The possibility of ectopic pregnancy should be considered in women with an intrauterine method who present with abdominal pain especially in connection with missed periods or if an amenorrhoeic woman starts bleeding. If a pregnancy test is positive an ultrasound scan is urgently required to locate the pregnancy.

Complications of IUC

B The risk of expulsion with IUC is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion.

B There is no need to delay insertion of an IUC post-abortion providing a woman has been informed of the small increased risk of expulsion.

B Although ovarian cysts may occur when using the LNG-IUS, most cysts are asymptomatic and resolve spontaneously.

B The rate of uterine perforation associated with IUC is up to 2 per 1000 insertions and is approximately six-fold higher in breastfeeding women.

B Return of fertility after IUC use is generally similar to fertility rates after discontinuation of oral contraceptives and barrier methods.

C Cu-IUD users with recurrent bacterial vaginosis or vulvovaginal candida may wish to consider an alternative method of contraception.

At the time of insertion

✓ Valid consent should be given by women prior to both pelvic examination and IUC insertion or removal.

✓ An appropriately trained assistant who can monitor the condition of the woman and assist in an emergency should be present during insertion of IUC.

A There is no evidence from current trials to support the use of topical lidocaine, misoprostol or non-steroidal inflammatory drugs (NSAIDs) for improving ease of insertion or reducing pain during insertion of intrauterine methods.

✓ Local anaesthetic block administered by cervical injection is not routinely required for IUC insertion but should be offered when cervical dilatation is required or difficult IUC insertion or removal is anticipated/experienced.

✓ NSAIDs can be offered to women who experience pain after insertion of an intrauterine method.

C A bimanual pelvic examination should be performed on all women before inserting IUC.

✓ There is no evidence to suggest that cervical cleansing prior to IUC insertion reduces subsequent pelvic infection.

Management of complications

✓ There is no evidence as to the most appropriate treatment option for women with unscheduled bleeding with the LNG-IUS. For women with unscheduled bleeding who wish to continue with the LNG-IUS and are medically eligible, a combined oral contraceptive could be tried for up to 3 months (this can be in the usual cyclic manner or continuously without a pill-free interval – unlicensed use).

A NSAIDS can be considered in the management of problematic bleeding with use of Cu-IUDs.

C Insertion or reinsertion of an intrauterine method can be carried out in asymptomatic women with actinomyces-like organisms (ALOs).

C There is no need to remove IUC in asymptomatic women with ALOs.

B IUC removal is not routinely required in women with pelvic inflammatory disease but it should be removed if there is no response to treatment (approximately 72 hours).

✓ Women should be offered instruction on how to check for the IUC and advised that if the threads cannot be felt the device may have perforated the uterus or been expelled. Additional contraception should be used until they seek medical advice.

C Women should be advised to seek medical assistance at any time if they develop symptoms of pelvic infection, pain, abnormal bleeding, late menstrual period (IUD), non-palpable threads or can feel the stem of the IUC.

Other issues to consider

✓ Women requesting intrauterine methods should be informed about the use of additional precautions for protection against STIs and advised about the appropriate timings of STI testing after an episode of unprotected sexual intercourse.

✓ Health professionals should inform women about the availability of EC and when it may be required with intrauterine methods.

✓ A routine follow-up visit can be advised after the first menses following insertion of IUC or 3–6 weeks later. However, it is not essential and it may be more important to advise women as to signs and symptoms of infection, perforation and expulsion, returning if they have any problems relating to their intrauterine method.

C Mooncups and tampons do not appear to be associated with an increased risk of IUC expulsion.

B Use of intrauterine methods should not be restricted based on parity or age alone.

✓ For women with cardiac disease the decision to use IUC should involve a cardiologist. The IUC should be fitted in a hospital setting if a vasovagal reaction presents a particularly high risk, for example, women with single ventricle circulation, Eisenmenger physiology, tachycardia or pre-existing bradycardia.

Faculty of Sexual & Reproductive Healthcare Clinical Effectiveness Unit

A unit funded by the FSRH and supported by NHS Greater Glasgow & Clyde to provide guidance on evidence-based practice

FSRH Guidance (April 2015)

Intrauterine Contraception

(Revision due by April 2020)

1 Purpose and Scope

This guidance provides evidence-based recommendations and good practice points for health professionals on the use of intrauterine contraception (IUC) currently available in the UK. Intrauterine methods include copper intrauterine devices (Cu-IUDs) and levonorgestrel intrauterine systems (LNG-IUS). This document updates previous Faculty of Sexual & Reproductive Healthcare (FSRH) guidance published in 2007.[1] The key changes include:

- Inclusion of the 13.5 mg LNG-IUS (Jaydess®); the 52 mg LNG-IUS Levosert and the 19.5 mg LNG-IUS (Kyleena) were not available at the time of publication of this guideline in 2015.
- Updated *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC)[2]
- Updated advice on sexually transmitted infection (STI) screening and timing of IUC insertion
- Updated advice on antibiotic prophylaxis for prevention of bacterial endocarditis
- Updated advice on interventions to ease IUC insertion
- New advice in relation to women presenting late for replacement of the 52 mg LNG-IUS (Mirena®)
- Advice on IUC use in women with cardiac disease.

This document focuses primarily on the use of intrauterine methods for contraception. A detailed analysis of non-contraceptive benefits is outside the scope of this guidance and is covered in other national guidelines.[3,4]

Recommendations are based on the available evidence and consensus opinion of experts. A key to the grading of recommendations, based on levels of evidence, is provided on the inside front cover of this document. Details of the methods used by the Clinical Effectiveness Unit (CEU) in developing this guidance are outlined in Appendix 1 and in the CEU section of the FSRH website (www.fsrh.org). The recommendations included in this document should be used to guide clinical practice but they are not intended to serve alone as a standard of medical care or to replace clinical judgment in the management of individual cases.

2 Background

IUC methods are long-acting reversible contraceptives (LARC) with licensed durations of use ranging between 3 and 10 years. IUC is more cost-effective than shorter-acting methods such as oral contraceptives because typical use failure rates of IUC methods are significantly lower,[5,6] and users need to visit contraceptive services less frequently.

The Cu-IUDs are non-hormonal and vary in size and shape. They consist of copper and plastic, with some types containing a core of silver or other noble metal, which helps to prevent corrosion by reducing copper fragmentation. In theory this may increase the longevity of the device, however no evidence was identified to confirm any clinical benefit over IUDs that only contain copper. Most of the Cu-IUDs licensed for use in the UK are radiopaque and contain barium.[7] In addition to ongoing contraception, the Cu-IUD can be used for emergency contraception (EC). Recommendations regarding the use of the Cu-IUD as EC are covered by separate FSRH guidance.[8]

The LNG-IUS is a T-shaped device with an elastomere core containing levonorgestrel (LNG). The 52 mg LNG-IUS (Mirena) releases approximately 20 µg LNG per day, reducing to approximately 10 µg per day after 5 years.[9] In addition to its use for contraception, the licensed indications for use of the Mirena LNG-IUS also include management of heavy menstrual bleeding (HMB) and endometrial protection during estrogen replacement therapy.[9] The 13.5 mg LNG-IUS (Jaydess) is licensed for contraception and has a release rate of approximately 14 µg per day for the first 24 days, decreasing to 5 µg per day after 3 years.[10] There is initially a faster release of LNG from the 13.5 mg LNG-IUS due to the open ends of its elastomer core. Despite this, the pharmacokinetic profile is similar to that of the 52 mg LNG-IUS and systemic exposure is not higher in the days following insertion.[10]

Note that the 52mg LNG-IUS Levosert and the 19.5mg LNG-IUS Kyleena were not available at the time of publication of this guideline in 2015.

3 UK Medical Eligibility Criteria for Contraceptive Use

UKME C[2]provides evidence-based recommendations on the use of contraceptive methods in the presence of different medical and social factors. Health professionals should ensure they are familiar with or refer to the most up-to-date version of this document when assessing a woman's eligibility to use intrauterine methods (www.fsrh.org). Unless specifically stated, UKMEC does not take account of multiple conditions. There is no agreed method for assessing multiple UKMEC categories. Assessing an individual's eligibility in the presence of multiple medical and social factors requires clinical judgement. UKMEC categories apply only to contraceptive use and are not applicable when use is solely for medical indications, such as HMB.

The definitions of the UKMEC categories used in this guidance document are shown in Table 1.

The Summary of Product Characteristics (SPC) for both the 52 mg Mirena[9] and 13.5 mg[11] LNG-IUS state that hypersensitivity to the active substance or any of the excipients is a contraindication to use. The CEU would suggest that such a contraindication would also apply to Cu-IUDs.

✓ Health professionals should be familiar with the UK Medical Eligibility Criteria for intrauterine methods.

4 Mode of Action

Both pre- and post-fertilisation effects contribute to the effectiveness of IUC.[12,13] Whilst there is potential for IUC to interfere with implantation, reduced rates of blastocyst formation have been observed in IUC users compared with non-users, suggesting that pre-fertilisation effects predominate in terms of mode of action for both Cu-IUDs and LNG-IUS.[12]

A Cu-IUD is effective immediately following insertion. With use of the Cu-IUD, fertilisation is inhibited through the effect of copper on the ovum and sperm. Alterations in the copper content of cervical mucus also inhibit sperm penetration.[14–16] If fertilisation has already occurred, the endometrial inflammatory reaction has been shown to have an anti-implantation effect.

A foreign body effect may be a contributing factor of the LNG-IUS,[17] as has been observed with other intrauterine methods.[16,18] The LNG-IUS has little effect on the hypothalamic-pituitary-ovarian axis,[19] serum estradiol concentrations are not reduced,[19] and the majority (>75%) of

Table 1 Summary of *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC) categories

UKMEC Category	Definition
1	A condition for which there is no restriction for the use of the contraceptive method.
2	A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
3	A condition for which the theoretical or proven risks usually outweigh the method. The provision of a method requires expert clinical judgement and contraceptive provider, since use of the method is not usually recommen appropriate methods are not available or not acceptable.
4	A condition which represents an unacceptable health risk if the method is used.

Chelsea
2019-08-01 09:52:04
Unmarked set by Chelsea

women continue to ovulate.[10,20,21] The incidence of anovulation is lower with the 13.5 mg LNG-IUS than with the 52 mg LNG-IUS, with data from a clinical trial reporting that in Years 1, 2 and 3, respectively, 97.1% (34/35), 96.2% (25/26) and 100% (26/26) of women ovulated.[10]

Progestogenic effects of the LNG-IUS on cervical mucus have been demonstrated[22–24] but it is not fully understood how quickly such changes are established. In a small descriptive study[25] cervical mucus remained penetrable by sperm for up to 5 days after mid-cycle insertion of a 52 mg LNG-IUS.

Prevention of implantation occurs via a progestogenic effect on the endometrium.[13,26] Within 1 month of insertion, high intrauterine concentrations of LNG induce endometrial atrophy.[17,18,27–29] In addition, distinct changes in the intercellular junctions between the endometrial epithelial and stromal cells[26] and an increase in endometrial phagocytic cells[26,28,30] may contribute to the contraceptive effect. The effects on the endometrium and cervical mucus are similar for the 13.5 and 52 mg LNG-IUS.

Contraceptive Efficacy and Duration of Use

5

A Cochrane Review concluded that the TCu380A® and TCu380S® were more effective than the other Cu-IUDs to which they were compared.[31] These IUDs are no longer available in the UK and have been replaced by the Copper T 380A®, TT 380 Slimline® and the T-Safe 380A® (Table 2). As there are now a number of similar devices available the CEU advise that the most effective Cu-IUDs are T-shaped IUDs containing 380 mm^2 copper with additional copper bands on the transverse arms (i.e. banded devices). Cumulative pregnancy rates for IUDs with copper content >300 mm^2 are noted as being between 0.1% and 1% after the first year of use and around 2.2% for the TCu380A after 12 years.[31] IUDs with the longest duration of use should ideally be used as they reduce the risk of infection, perforation and expulsion associated with reinsertion.

A Cochrane Review (including 23 000 woman-years of use) identified comparable failure rates for a framed (TCu380A) and a frameless device (GyneFix®).[32] The higher rates of expulsion associated with the frameless device (GyneFix) limit its effectiveness.[32–34]

A Cochrane Review from 2004 found insufficient evidence from randomised controlled trials (RCTs) to demonstrate any significant difference in pregnancy rates between 52 mg LNG-IUS users and users of IUDs containing >250 mm^2 copper.[35] However, the European Active Surveillance Study (EURAS) for Intrauterine Devices did find that the LNG-IUS was superior in terms of efficacy, although the failure rate was low with both types of device. This prospective cohort study in a typical population of over 61 000 users found an overall Pearl index (PI; pregnancies per 100 woman-years) of 0.06 [95% confidence interval (CI) 0.04–0.09)] in the LNG-IUS cohort and 0.52 (95% CI 0.42–0.64) in the Cu-IUD users. There was a markedly different age distribution between the cohorts in the study (with the LNG-IUS users being significantly older) but when stratified for age the LNG-IUS still remained superior at all ages, except for women aged between 40 and 50 years.[36]

The 52 mg LNG-IUS (Mirena) is licensed for 5 years of use but there is evidence[37–39] to suggest that it may provide effective contraception for longer than 5 years. For the Mirena, which initially release 20 µg LNG, studies have reported cumulative pregnancy rates of up to 1% at 5 years[40–42] and up to 1.1 at 7 years.[37,39] However, one study[43] used LNG-IUS devices that contained 60 mg LNG. The low pregnancy rates reported with long-term use could also be because of the small numbers of longer-term users who are likely to be relatively older and to have a well-positioned IUC.

Studies investigating serum levels of LNG with prolonged 52 mg LNG-IUS use have shown that serum levels are detectable beyond 5 years of use.[43,44] While systemic serum levels of LNG may be indicative of contraceptive effect, they cannot be relied upon as proof of efficacy, as much of the contraceptive action of the LNG-IUS is a local effect.[43,44] The fact that the release rate of the 52 mg LNG-IUS at 5 years is twice that of the new 13.5 mg LNG-IUS at 3 years suggests that it may be effective for some time beyond its 5 years' licensed indication.

An RCT reported a PI for the 13.5 mg LNG-IUS of 0.33 (95% CI 0.16–0.60) and a cumulative pregnancy rate of 0.9 per 100 women over 3 years.[45]

The CEU cannot specifically endorse use of IUC methods for longer than the durations stipulated in Table 2, although a review of the evidence does support extended use of many devices beyond the licensed duration.[46] The CEU does support extended use of a Cu-IUD fitted at age

40+ years or a Mirena 52 mg LNG-IUS inserted at the age of 45+ years.[6,47] Women should be advised to have their IUC removed when it is no longer effective or required.[47] Recommendations on the management of women who present late for IUC removal/replacement are detailed later (see Table 5 on page 29). As the risk of pregnancy remains low between 5 and 7 years after Mirena 52 mg LNG-IUS insertion, the FSRH advises that even if a woman has not been using additional contraception the device can be replaced immediately, providing a pregnancy test is negative. A further pregnancy test, no sooner than 3 weeks after the last episode of unprotected sexual intercourse (UPSI), should then be advised.

Not all women will continue to use their IUC for the totality of its permitted duration and may choose to discontinue the method. Reasons for 'early' discontinuation may relate to side effects.[48–50]

B Women should be advised of the very low failure rates associated with use of IUC.

A The most effective methods of IUC are the LNG-IUS methods and T-shaped devices with at least 380 mm^2 copper and copper bands on the transverse arms.

Table 2 provides examples of available methods of IUC. For more detailed information the CEU would advise checking the *British National Formulary* (BNF) and package insert. A number of generic IUC devices are available and the CEU supports their use. The insertion tube diameter and manufacturer's recommended uterocervical length are provided as a guide to the most appropriate device in each clinical situation. The information is not intended to mean that a device should never be used in a woman with a uterus that is shorter or longer than recommended.

Table 2 Examples of available methods of intrauterine contraception

Examples of devices available in the UK[a]	Copper surface area (mm^2)	Manufacturer's licensed duration of use (years)	Manufacturer's recommended uterocervical length[b] (cm)	Diameter of insertion tube (mm)
Levonorgestrel intrauterine system				
Mirena®	Not applicable	5 (contraception and idiopathic menorrhagia) 4 (endometrial protection)[c]	Not specified	4.40
Jaydess®	Not applicable	3 (contraception only)	Not specified	3.80
Copper devices (banded copper arms)				
Copper T 380A®	380	10	6.5–9.0	4.75
TT380 Slimline®	380	10	6.5–9.0	4.75
MiniTT 380 Slimline®	380	5	≥5	4.75
T-Safe 380A® Quickload	380	10	6.5–9.0	4.75
T-Safe 380A® Capped[d]	380	10	6.5–9.0	4.50
Flexi-T 380®	380	5	>6	4.75
Copper devices (copper in stem only)				
Nova-T 380®	380	5	6.5–9.0	3.60
UT 380®	380	5	6.5–9.0	
UT 380 short®	380	5	≥5	
Flexi-T 300®	300	5	>5	4.75
Multiload Cu375®	375	5	6–9	3.60
Multisafe 375 Short Stem®[d]	375	5	5–7	3.85
Copper device (frameless)				
GyneFix Viz 330®	330	5	Any	4.00

[a]List not exhaustive; generic versions of the above devices are also available; the 52mg LNG-IUS Levosert and the 19.5mg LNG-IUS Kyleena were not available at the time of publication of this guideline in 2015.
[b]Distance measured with uterine sound from upper limit of the endometrial cavity to external cervical os.
[c]FSRH guidance supports the use of the LNG-IUS (Mirena®) for 5 years for endometrial protection (see page 11).
[d]Product not currently on National Health Service Drug Tariff.

6 When Can IUC be Safely Inserted?

Health professionals should consider the woman's safety and convenience when considering the timing of IUC insertion. Recommendations for insertion of IUC in specific circumstances (for example, postpartum, post-abortion and when switching from other methods of contraception) are outlined in Tables 3 and 4.

As a Cu-IUD is effective immediately after insertion it can be inserted at any time in the menstrual cycle if it is reasonably certain the woman is not pregnant (Box 1). A systematic review was identified that examined the effect of inserting IUC on different days of the menstrual cycle specifically in relation to expulsion, pregnancy rates and pain.[51] No studies were identified for the LNG-IUS; eight Cu-IUD studies were included.[52–59] Although the review had some limitations, the authors found reasonable quality evidence that timing of insertion of a Cu-IUD did not have a significant effect on longer-term or short-term outcomes such as continuation, pregnancy rates, expulsion, bleeding at insertion or pain at insertion[51] (page 20). There is therefore no need to only insert IUDs during menses, providing the risk of pregnancy can be appropriately excluded.

If a woman has had UPSI, a Cu-IUD can be inserted as a means of EC providing it is inserted before the process of implantation begins (i.e. within 120 hours of the first episode of UPSI in a cycle, or up to 5 days after the earliest estimated day of ovulation). It is not always possible to know when a woman has ovulated, particularly if she has been using hormonal contraceptives or taken EC. A Cu-IUD can be fitted in good faith to act as EC, providing appropriate steps have been taken to try and establish a woman's earliest estimated date of ovulation. The Cu-IUD should not be inserted if there is a risk of pregnancy outside these circumstances or where there is uncertainty about the earliest date of ovulation.

For the purposes of excluding pregnancy, the CEU would advise that hormonal, intrauterine and barrier contraceptive methods can be considered reliable providing they have been used consistently and correctly on every incidence of intercourse. This should be assessed on an individual basis.

There are insufficient data to indicate precisely how soon after insertion of the LNG-IUS contraceptive protection is established.[51] A systematic review examining the effect of inserting IUDs on different days of the menstrual cycle found no studies for the 52 mg LNG-IUS.[51] A study observed no early pregnancies when the 52 mg LNG-IUS was inserted up to Day 10 of the menstrual cycle;[61] however, the authors did not provide information on sexual intercourse before or after insertion.

The SPCs for Mirena and Jaydess state that the LNG-IUS can be inserted up to Day 7 of the menstrual cycle.[9,11] No advice is given regarding avoidance of UPSI before insertion or use of additional contraception after insertion, and there is no information on starting the method at

Box 1 Criteria for excluding pregnancy (adapted from *UK Selected Practice Recommendations for Contraceptive Use*)[60]

Health professionals can be 'reasonably certain' that a woman is **not currently pregnant** if any one or more of the following criteria are met and there are no symptoms or signs of pregnancy:

- She has not had intercourse since last normal menses
- She has been correctly and consistently using a reliable method of contraception
- She is within the first 7 days of the onset of a normal menstrual period
- She is not breastfeeding and less than 4 weeks from giving birth
- She is fully or nearly fully breastfeeding, amenorrhoeic, and less than 6 months' postpartum
- She is within the first 7 days post-abortion or miscarriage.

A negative pregnancy test, if available, adds weight to the exclusion of pregnancy, but only if ≥3 weeks since the last episode of unprotected sexual intercourse (UPSI).

NB. In addition to the conditions mentioned above, health professionals should also consider whether a woman is **at risk of becoming pregnant** as a result of UPSI within the last 7 days.

any other time in the cycle. Thus, the SPCs suggest that the LNG-IUS can be safely inserted as late as Day 7 with no risk of pregnancy from UPSI earlier in the cycle or after insertion.

Advice from the FSRH and the World Health Organization (WHO) is consistent with that of the SPCs, stating that the LNG-IUS can be inserted up to Day 7 without the need for additional contraception, and that if an LNG-IUS is inserted later in the cycle additional contraceptive precautions are required for 7 days.[1,60,62,63]

An LNG-IUS can be inserted any time in the menstrual cycle if it is reasonably certain the woman is not pregnant or at risk of pregnancy (outside the terms of the product licence). The LNG-IUS should not be used for EC as unlike the Cu-IUD there is no evidence to demonstrate that it is effective immediately.

UKMEC indicates that postpartum insertion of an intrauterine method is UKMEC 3 between 48 hours and 4 weeks, after which time there is no restriction on use (UKMEC 1).[2] Updated UKMEC will include guidance on insertion during the first 48 hours postpartum as this is becoming more available in UK obstetric practice.[2] However, immediate postpartum insertion is undertaken in other countries[64,65] and WHO guidance[66] includes categories for the first 48 hours postpartum. In the first 48 hours insertion is a WHOMEC 1 for insertion of the Cu-IUD or LNG-IUS in non-breastfeeding women and insertion of the Cu-IUD in breastfeeding women. From birth until 4 weeks insertion of an LNG-IUS is a WHOMEC 3 in breastfeeding women.[66] More details on the timing of IUC insertion are outlined in Table 3.

Table 3 Faculty of Sexual & Reproductive Healthcare advice on starting intrauterine contraception

Circumstance	Method inserted	Timing of insertion	Additional contraceptive precautions required
All circumstances	Cu-IUD	Any time in menstrual cycle if reasonably certain the woman is not pregnant or at risk of pregnancy (unless qualifies for use as EC)	No
	LNG-IUS	Any time in menstrual cycle if reasonably certain the woman is not pregnant or at risk of pregnancy (outside terms of product licence after Day 7)	Yes, required for 7 days unless inserted in the first 7 days of the menstrual cycle
Postpartum (including post-Caesarean section and breastfeeding)	Cu-IUD	Within 48 hours of delivery or from 4 weeks after delivery if it is reasonably certain the woman is not pregnant or at risk of pregnancy (unless qualifies for use as EC	No
	LNG-IUS	Within 48 hours of delivery	No
		From 4 weeks after delivery if it is reasonably certain that the woman is not pregnant or at risk of pregnancy	Yes, required for 7 days unless inserted day 1-7 of cycle or LAM criteria are met
Following abortion (all induced or spontaneous abortions <24 weeks' gestation)	Cu-IUD	Post-surgical abortion IUC: ideally should be inserted at the end of the procedure	No
		Post-medical abortion IUC: can be fitted any time after completion of the second part of the abortion (i.e. passage of products of conception confirmed by clinical assessment and/or local protocols)	
	LNG-IUS	Post-surgical abortion IUC: ideally should be inserted at the end of the procedure	If an LNG-IUS is fitted after Day 7 post-abortion, additional precautions are required for 7 days
		Post-medical abortion IUC: can be fitted any time after completion of the second part of the abortion (i.e. passage of products of conception confirmed by clinical assessment and/or local protocols)	
Following administration of oral EC	Cu-IUD	Within the first 5 days (120 hours) following first UPSI in a cycle or within 5 days from the earliest estimated day of ovulation	No additional precautions required
		Outside of the above criteria Cu-IUD should not be inserted following administration of oral EC until pregnancy can be excluded by a pregnancy test no sooner than 3 weeks after the last episode of UPSI	Not applicable
	LNG-IUS	Should **not** be inserted following administration of oral EC until pregnancy can be excluded as above	Not applicable

Cu-IUD, copper intrauterine device; EC, emergency contraception; LAM, lactational amenorrhoea method; LNG-IUS levonorgestrel intrauterine system; UPSI, unprotected sexual intercourse.

Table 4 Faculty of Sexual & Reproductive Healthcare advice on switching to intrauterine contraception

IUC method switching to	Contraceptive method switching from	Timing of IUC insertion	Need for additional precautions	Additional information
Cu-IUD	All methods of contraception	Cu-IUD can be inserted at any time if another method of contraception has been used consistently and correctly and it is reasonably certain that the woman is not pregnant or at risk of pregnancy (except in those circumstances that would qualify for use as an EC)	No additional precautions required	Ideally if switching from an LNG-IUS to a Cu-IUD additional contraceptive precautions are advised in the 7 days before changing in case the new method cannot be inserted
LNG-IUS	CHC	Week 2 or 3 of CHC cycle or Day 1 of the hormone-free interval	No additional precautions required, providing CHC used correctly for 7 days prior to insertion	There is evidence to suggest that taking hormonally active pills for 7 consecutive days prevents ovulation[67]
		After Day 1 of the hormone-free interval or in Week 1 of CHC cycle	Continue CHC or use other additional contraception for 7 days	Advice for switching during the hormone-free interval may be overcautious but there is a theoretical risk that ovulation may occur as early as Day 10 after stopping CHC, before the LNG-IUS is fully effective[68]
	POP (traditional)	At any time	Yes, continue POP or use additional contraception for 7 days	
	POP (desogestrel)	At any time	No	
	Progestogen-only implant	Up to 3 years post-insertion	No	
		From 3 years post-insertion	Yes (7 days)	Exclude risk of pregnancy prior to insertion
	Progestogen-only injectable	≤14 weeks post-IM or SC injection	No	
		>14 weeks since last IM or SC injection	Yes (7 days)	IfExclude risk of pregnancy prior to insertion
	Barrier methods	Days 1–7 of the menstrual cycle	No	
		After Day 7 of the menstrual cycle	Yes, 7 days	If it is reasonably certain the woman is not pregnant or at risk of pregnancy
	Cu-IUD	Any time	Yes (7 days)	If sex has occurred in the last 7 days advise to leave Cu-IUD for a further 7 days from that episode and use extra precautions before change to LNG-IUS

CHC, combined hormonal contraception; Cu-IUD, copper intrauterine device; EC, emergency contraception; IM, intramuscular; IUC, intrauterine contraception; LNG-IUS levonorgestrel intrauterine system; POP, progestogen-only pill; SC, subcutaneous.

7 What Should Health Professionals Assess When a Woman is Considering IUC?

7.1 Clinical assessment

A full medical history should be taken and, if necessary, health professionals should check UKMEC to assess an individual woman's eligibility.[2] If a woman attends to discuss IUC in advance of the procedure, pelvic examination is not required unless indicated by the clinical history.

Additional investigations such as full blood count, pelvic ultrasound scan and endometrial biopsy may be indicated prior to or at the same time as IUC insertion in women with HMB, particularly if other treatments for HMB have not been effective or if a woman has risk factors for gynaecological disease. Clinicians should be guided by national[3] and local guidelines on management of HMB.

7.2 STI risk assessment

A sexual history must be taken in order to identify women at risk of STI.[62] The British Association for Sexual Health and HIV (BASHH) has guidance on sexual history taking.[69] Risk factors include:

- Being sexually active and aged <25 years
- Having a new sexual partner in the last 3 months
- Having more than one sexual partner in the last year
- Having a regular sexual partner who has other sexual partners
- A history of STIs
- Attending as a previous contact of STI
- Alcohol/substance abuse.

An STI screen should be offered to all women who are identified as being at risk of STIs when requesting IUC.[70,71] If STI testing is indicated *Chlamydia trachomatis* testing should be performed as a minimum requirement. In most settings a single vulvovaginal or endocervical swab can be sent for combined *C. trachomatis and Neisseria gonorrhoeae* testing by nucleic acid amplification techniques.[71–73] Vulvovaginal swabs may be self-taken if preferred. Urine specimens are no longer recommended for STI testing in women.[71–73] Syphilis and HIV testing should also be offered routinely.

There is no indication to screen for other lower genital tract organisms in asymptomatic women considering IUC. If bacterial vaginosis or candidal infection is diagnosed or suspected the infection should be treated and the method inserted without delay. A high vaginal swab is not routinely indicated in women with vaginal discharge and should only be taken in specific circumstances defined in FSRH guidance on *Management of Vaginal Discharge in Non-Genitourinary Medicine Settings*.[74]

8 When Should IUC Insertion be Delayed or Antibiotic Prophylaxis Given?

8.1 Women diagnosed with, or at risk of, STI

Where possible, screening for STIs in advance of IUC insertion will allow infection to be treated before or at the time of insertion. Following a positive chlamydia or gonorrhoea result, an intrauterine method can be inserted if the woman is asymptomatic and has completed antibiotic treatment. In a woman with asymptomatic chlamydia in an emergency situation, the IUC could be inserted on the same day as treatment was instituted.

There has been uncertainty with regard to insertion of IUC before STI results are available. A Cochrane Review[75] examined the effectiveness of prophylactic antibiotic administration, before IUD insertion, in reducing IUD-related complications and discontinuations within 3 months of insertion. It concluded that the risk of IUD-related infections was low, with or without antibiotic prophylaxis. There were possible benefits in terms of reducing unscheduled return visits but there was limited evidence to suggest such an intervention was cost-effective.

A large retrospective cohort study[76] compared the incidence of pelvic inflammatory disease (PID) in women who were and were not screened for gonorrhoea and chlamydia in advance of IUC insertion. In the 57 728 women undergoing IUC insertion the overall risk of PID within the first 90 days was 0.54% (95% CI 0.0048–0.0060). There was no association between screening and a reduced risk of PID. Same-day screening was associated with a similar risk to pre-screening even when age and race were taken into account.[76]

The CEU would therefore suggest that if a woman has been screened for STIs on or before the day of IUC insertion and the results are unavailable, an IUC can be inserted without prophylactic antibiotic treatment, providing the woman is asymptomatic and can be contacted and treated promptly when the results are known.

Women who have symptoms of possible STI infection and/or PID should ideally delay IUC insertion until test results are available, until PID or confirmed STI infection have been treated, and until symptoms have resolved. A bridging contraceptive method should be offered if necessary. Women diagnosed with an STI or PID should be advised to abstain from intercourse until they and any current sexual partner(s) have finished treatment or for 1 week after treatment with single-dose azithromycin.[77]

Antibiotic prophylaxis for chlamydia (and gonorrhoea if local prevalence or individual risk factors warrant) can be considered for women who require an emergency IUD and who are symptomatic or at high risk of STI (e.g. if their partner is known to be infected).

C A medical and sexual history should be carried out as part of the routine assessment for IUC to assess suitability for use of the method and need for STI testing.

✓ In asymptomatic women attending for insertion of IUC there is no need to wait for STI screening results or to provide antibiotic prophylaxis providing the woman can be contacted and treated promptly in the event of a positive result.

8.2 Streptococcal bacteria

In asymptomatic women routine screening for bacterial infection is not recommended prior to IUC insertion. However, cases of group A streptococcus (GAS) infection have been reported post-IUD insertion.[78–80] Such cases are rare but can include life-threatening septicaemia, invasive GAS (e.g. necrotising fasciitis) and streptococcal toxic shock syndrome.[81] Therefore, it is important that women found to be infected with GAS in the vagina are treated and IUC insertion delayed. In addition, women using IUC should be advised to seek medical advice if they experience signs or symptoms of infection. Guidance on the management of GAS infections in community and acute health care and maternity settings is available.[82,83]

Because GAS is a β-haemolytic streptococcus there is potential for it to be confused with group B streptococcus (GBS). GBS is a commensal organism which if detected does not usually require treatment except in pregnant or symptomatic women and neonates. There is no need to delay treatment or treat asymptomatic women who have been identified as having GBS.

8.3 Antibiotic prophylaxis for bacterial endocarditis

A review by the National Institute for Health and Care Excellence (NICE)[84] found no evidence to link level, frequency and duration of bacteraemia with the development of infective endocarditis. Risk factors for infective endocarditis are outlined in FSRH guidance on *Contraceptive Choices for Women with Cardiac Disease*.[85] NICE considered that for people who are at risk of infective endocarditis:

- There is insufficient evidence to determine whether antibiotic prophylaxis in those at risk of developing infective endocarditis reduces the incidence of infective endocarditis when given before a defined interventional procedure (both dental and non-dental).
- There is little evidence to support offering antibiotics routinely as a preventative measure to people at risk of infective endocarditis undergoing interventional procedures.

The NICE guideline[84] recommends that antibiotic prophylaxis is no longer offered routinely for defined interventional procedures. However, it should be noted that the NICE guideline does not exclude consideration of antibiotic prophylaxis on a case-by-case basis and states that if there is a suspected infection at a site of the genitourinary procedure, an antibiotic that covers organisms that cause infective endocarditis should be considered (see page 31 for more information on IUC use by women with cardiac disease).

C Prophylactic antibiotics are not routinely required for the insertion or removal of IUC even in women with conditions where the risk of infective endocarditis may be increased.

9 Health Benefits, Side Effects and Concerns/Risks

Choosing between a Cu-IUD and an LNG-IUS will likely be determined by any benefits for the individual, for example, changes to menstrual bleeding patterns, duration of use, any side effects or perceived concerns. The cost-effectiveness of LARC methods in the UK is affected by discontinuation rates;[5] therefore it is important that women are adequately informed before initiating their chosen method and offered appropriate information and management about any side effects or concerns during use.

9.1 Benefits

9.1.1 Endometrial and other cancer protection

The Mirena 52 mg LNG-IUS has been shown to provide endometrial protection from the stimulatory effects of estrogen[86–90] and is licensed in the UK for protection from endometrial hyperplasia during estrogen replacement therapy for up to 4 years.[9] Levosert is not licensed for this indication. The FSRH supports use of the Mirena 52mg LNG-IUS for up to 5 years (outside product licence) for this purpose.[47] A systematic review[91] that sought to review how effective the 52 mg LNG-IUS was at preventing endometrial pathology concluded that while in selected groups of women there was evidence that it counters endometrial proliferation and causes regression and prevention of endometrial hyperplasia, there is currently insufficient evidence to recommend its use as the treatment for endometrial hyperplasia or use solely as a preventative method in high-risk groups. However, other studies and reviews have suggested that the 52 mg LNG-IUS is no less effective than oral progestogens and indeed may actually provide more favourable outcomes in women with complex or atypical hyperplasia.[92,93]

Tamoxifen, used in the management of breast cancer, is known to stimulate the endometrium,[94] increasing the risk of endometrial hyperplasia and malignancy. A Cochrane Review reported that in breast cancer patients taking tamoxifen, use of the 52 mg LNG-IUS over 1 year reduced the risk of endometrial polyps.[95] However, the authors indicated that more studies are required to establish the effect of 52 mg LNG-IUS use on endometrial hyperplasia and cancer in such women.[95]

A systematic review, of case-control studies, reported that use of a Cu-IUD may be associated with a reduced risk of endometrial cancer [relative risk (RR) 0.51, 95% CI 0.3–0.8][96] and a meta-analysis of 10 studies suggested that there may be a decreased risk associated with IUD use.[97] A pooled analysis of 26 epidemiological studies reported that ever-use of IUDs was associated with a decreased risk of cervical cancer compared to never-users [odds ratio (OR) 0.55, 95% CI 0.42–0.70, $p<0.0001$]. This protective association was apparent for squamous-cell carcinoma (OR 0.56, 95% CI 0.43–0.72, $p<0.0001$), adenocarcinoma and adenosquamous carcinoma (OR 0.46, 95% CI 0.22–0.97, $p=0.035$). However, a protective effect was not observed amongst those women who were found to be human papillomavirus (HPV)-positive (OR 0.68, 95% CI 0.44–1.06, $p=0.11$). Amongst those without cervical cancer, IUD use was not reported to be associated with detection of cervical HPV DNA.[98] There are few data on risk of ovarian cancer and use of IUDs, but one cohort study reported a small increased risk,[99] while a large case-control study[100] observed that using the Cu-IUD for 4 years or less conferred a protective benefit against ovarian cancer.

B The Mirena 52 mg LNG-IUS can be used to provide endometrial protection in conjunction with estrogen therapy for up to 5 years (outside product licence).

B Use of a Cu-IUD may be associated with a reduced risk of endometrial cancer and cervical cancer.

9.1.2 Dysmenorrhoea/pelvic pain

One randomised[101] and two non-randomised trials[102,103] suggested that the 52 mg LNG-IUS reduced primary dysmenorrhoea. Available evidence also suggests that the 52 mg LNG-IUS reduces pain associated with endometriosis and adenomyosis.[104–112] A Cochrane Review[113] of three RCTs and a retrospective chart review, of adolescent women with endometriosis, suggested that insertion of a 52 mg LNG-IUS at the time of surgery reduced the recurrence of symptoms. The 52 mg LNG-IUS is a recommended treatment option for pain associated with endometriosis.[114]

A The 52 mg LNG-IUS may reduce pain associated with primary dysmenorrhoea, endometriosis or adenomyosis.

9.1.3 Heavy menstrual bleeding

The 52 mg LNG-IUS is very effective in reducing menstrual blood loss[115–120] and has been shown to be more effective at improving quality of life than other medical treatments for HMB.[121] The 52 mg LNG-IUS is licensed for the management of HMB and is one of the recommended pharmaceutical treatments within NICE guidelines.[6]

The 13.5 mg LNG-IUS (Jaydess) is not licensed for treatment of HMB. The 13.5 mg LNG-IUS does reduce menstrual bleeding and there is a significant increase in the number of women who experience amenorrhoea with time. However, the proportion of women experiencing amenorrhoea at the end of 3 years in an RCT was less amongst those who used the 13.5 mg LNG-IUS compared to the 52 mg LNG-IUS (12.7% vs 23.6%).[123]

A The 52 mg LNG-IUS is effective in reducing menstrual blood loss and can be used in the management of HMB.

9.2 Hormonal side effects

Undesirable effects are more prevalent in the first few months after insertion of the LNG-IUS but decrease with prolonged use.[9] Side-effect profiles for the 13.5 and 52 mg LNG-IUS have been reported as being similar.[123]

9.2.1 Acne, breast tenderness/pain, headaches and mood changes

The SPC[9] for the 52 and 13.5 mg LNG-IUS[11] lists acne, breast tenderness/pain, headache and mood changes as common (≥1/100 to <1/10) undesirable effects reported by users. A systematic review[124] identified no significant differences in overall side effects between using a 52 mg LNG-IUS or an IUD.

C Women considering the LNG-IUS can be informed that systemic absorption of progestogen occurs with these devices. The 13.5 and 52 mg LNG-IUS have similar side-effect profiles (such as acne, breast tenderness/pain and headache) and hormonal side effects often settle with time. Rates of discontinuation due to side effects are not significantly different from Cu-IUD users.

9.2.2 *Libido*

Identifying a causal relationship between use of contraceptives and libido is difficult due to the impact of other potential influences, such as psychological and/or partner problems. Due to the limitations of observational research, an effect on libido with IUC use cannot be completely excluded, however existing evidence fails to support a negative association.[125–129]

B Women should be advised that existing evidence fails to support a negative effect on libido associated with IUC use.

9.2.3 *Weight*

It is difficult to assess the 'true' impact of contraceptives on body weight due to a number of potential confounding factors.

Weight gain has been observed with use of both Cu-IUDs and the 52 mg LNG-IUS.[40,111,130] A 5-year RCT of a 46 mg LNG-IUS with the Nova T (200 mm^2 Cu) reported that at 5 years the mean weight in both groups had increased to 64.4 kg from a baseline of 62.0 kg and 61.9 kg, respectively.[40] A small prospective study[130] evaluating body weight and composition in users of the 52 mg LNG-IUS and the TCu380A observed an increase of body weight in both groups 1 year after insertion. Although the mean gain body weight among the 52 mg LNG-IUS users was significantly increased, there was no significant difference when comparing 52 mg LNG-IUS and Cu-IUD users. The 52 mg LNG-IUS users also demonstrated a significant increase in fat mass, whilst Cu-IUD users demonstrated a non-significant loss. There were no significant differences in body composition between the two groups at 12 months. There is no known biological mechanism for weight gain with a Cu-IUD, suggesting that weight gain with IUC use is likely to be a consequence of confounding factors such as increasing age.

B Weight gain has been observed with use of IUC. There is no significant difference between hormonal and non-hormonal intrauterine methods and evidence to support a causal association is lacking.

9.3 Health concerns/risks

Altered menstrual bleeding patterns are a common reason for discontinuation of Cu-IUDs and the 52 mg LNG-IUS.[6,41,49,131,132] Discontinuation rates for the 52 mg LNG-IUS and Cu-IUD are similar,[35] as are discontinuation rates due to bleeding for different types of framed devices.[31]

The aetiology of bleeding associated with the 52 mg LNG-IUS is complex.[18,133,134] Infrequent bleeding is common after the first year of 52 mg LNG-IUS use.[135] Amenorrhoea is more common with the 52 mg LNG-IUS than a Cu-IUD.[135]

Some women will have normal bleeding patterns after insertion of an intrauterine method, however some will experience longer and more frequent bleeding.[136]

There is some evidence to suggest that bleeding patterns in IUD and LNG-IUS users tend to improve/settle with time after insertion (>3 months);[135,136] however, irregular bleeding may be present in around 20% of women at 1 year of use of intrauterine methods.[135] One study[137] reported that although improvements with menstrual bleeding and dysmenorrhoea were generally observed over a 12-month period, there were no changes in complaints of other pelvic pain and spotting episodes. Similar trends in patterns of bleeding have been observed with insertion following an abortion.[135]

Postpartum bleeding patterns have been studied following the immediate fitting of IUC during elective Caesarean sections.[138] In one study, women fitted with a Cu-IUD compared to controls with no IUC had a significantly longer duration of postpartum bleeding but the heaviness of bleeding was comparable. Insertion of an 52 mg LNG-IUS was associated with significantly

shorter and lighter puerperal bleeding, longer duration of amenorrhoea, and shorter and lighter menstrual periods than women in the control or Cu-IUD group.[138]

During the first year of 52 mg LNG-IUS use infrequent bleeding and amenorrhoea become more common. Studies of women who had a replacement 52 mg LNG-IUS, after approximately 5 years of use, have found that there is an initial slight increase in bleeding/spotting after replacement but that there is an overall decrease in bleeding episodes and increase in amenorrhoea during use of a second 52 mg LNG-IUS.[38,139] Data from trials suggest that users of the 13.5 mg LNG-IUS have a lower rate of amenorrhoea than users of the 52 mg LNG-IUS, although there is still a trend towards less bleeding with time (i.e. a temporal relationship).[123] While less amenorrhoea may appeal to some woman, it may equally be perceived as a disadvantage by others (see page 23 for management of bleeding).

B In the 3–6 months following IUC insertion women may experience irregular, prolonged or frequent bleeding but menstrual bleeding patterns tend to improve with time.

B At 1 year infrequent bleeding is usual with the LNG-IUS and some women will experience amenorrhoea.

A Discontinuation due to bleeding and pain are similar for different types of framed and unframed Cu-IUDs.

9.3.1 *Bone mineral density*

Studies investigating bone mineral density (BMD) with use of IUC have found no significant differences in BMD at the mid-shaft of the ulna[140,141] or the distal radius[141] when comparing 52 mg LNG-IUS users and Cu-IUD users. In a comparative trial of two low-dose LNG-IUS devices, no effect on BMD was observed and no reduction in estradiol levels was reported in a pooled pharmacokinetic and pharmacodynamic analysis of Phase II and III studies.[10]

9.3.2 *Breast cancer*

The Collaborative Group on Hormonal Factors in Breast Cancer undertook a re-analysis of 54 studies to investigate the relationship between breast cancer and hormonal contraceptives.[142] Progestogen-only methods (oral and injectable) were used by less than 3% of the women studied. The quantity of information available was therefore limited but for oral progestogens the results were broadly similar to those found for combined oral contraceptives (COCs). The study reported a slightly increased risk of breast cancer associated with current or recent use of hormonal contraceptives and found there was no evidence of an increased risk 10 or more years after stopping use.[142]

A limited number of studies have examined the risk specifically associated with the 52 mg LNG-IUS.[143–145] Two of these studies[144,145] reported no increased risk of breast cancer, although both acknowledged that an increased risk could not be excluded because of the methodological limitations of observational research. A case-control study[143] evaluating the association between postmenopausal hormone therapy and the risk of breast cancer, in recently postmenopausal Finnish women, reported an increased risk of breast cancer in women who used the 52 mg LNG-IUS on its own or in conjunction with estradiol. The authors themselves stated that this was a surprising finding and that bias and confounding could not be excluded.

There is limited evidence of the effect of 52 mg LNG-IUS on breast cancer recurrence. A retrospective case-controlled cohort study[146] that compared 79 breast cancer patients using the 52 mg LNG-IUS to a control group of 120 breast cancer patients with no history of 52 mg LNG-IUS use was identified. Overall the authors did not observe an increased risk of breast cancer recurrence associated with use of the 52 mg LNG-IUS. A subgroup analysis was carried out in which women who developed breast cancer and continued to use the 52 mg LNG-IUS were shown to have a higher risk of recurrence; however, it was of borderline statistical

significance.[146] This study was again limited by its retrospective design, and potential confounding factors were identified by the authors.

In women with current breast cancer, UKMEC[2] advises that it is a condition which represents an unacceptable health risk if the method is used (UKMEC 4). For those with a past history and no evidence of disease recurrence for 5 years or more, UKMEC advises that the theoretical or proven risks of using the LNG-IUS generally outweigh the advantages. The provision of the LNG-IUS to women with a history of breast cancer requires expert clinical judgement and/or referral to a specialist contraceptive provider, since use of the method is not usually recommended unless other more appropriate methods are not available or not acceptable (UKMEC 3). Currently these categories apply to all breast cancer cases irrespective of receptor status.

B Evidence does not support a link between breast cancer and use of the LNG-IUS.

C Non-hormonal contraception is most appropriate for women with a history of breast cancer. Any consideration of the LNG-IUS should be carried out in consultation with the woman's cancer specialist.

9.3.3 *Cardiovascular health*

Few studies have been large enough to evaluate the risk of venous thromboembolism (VTE) with progestogen-only contraception. Data have thus far generally suggested that there is little or no risk of VTE associated with progestogen-only contraception.[147–150]

No increased risk of myocardial infarction (MI) (OR 1.07, 95% CI 0.62–1.84) was reported with use of progestogen-only contraception by a meta-analysis[151] of six case-control studies. The results were similar regardless of the route of administration (i.e. implant, injectable or oral). The authors felt further research was required, especially among women at high risk of MI.

Specific studies[152–154] examining the effect of 52 mg LNG-IUS on cardiovascular risk factors, such as lipids, are reassuring although more research is required; particularly in higher-risk populations. For women with either multiple risk factors for cardiovascular disease, stroke, current or history of ischaemic heart disease, or a history or current VTE there is no restriction for the use of the Cu-IUD (UKMEC 1).[2] The advantages of initiating a LNG-IUS in women with any of these conditions generally outweigh the risks (UKMEC 2). Continuing to use the LNG-IUS in a woman who develops ischaemic heart disease or has a stroke is a UKMEC 3.

Women with systemic lupus erythematosus are at increased risk of a number of cardiovascular conditions such as ischaemic heart disease, stroke and VTE. It is for this reason that greater caution is advised amongst women with positive or unknown antiphospholipid antibodies compared to women who have a history of VTE.[2] A UKMEC Category 3 does not exclude use of the method, but the provision requires expert clinical judgement and/or referral to a specialist contraceptive provider since use is not usually recommended unless other more appropriate methods are not available or not acceptable (also see section on cardiac disease on page 31).

B Evidence suggests there is little or no increased risk of VTE or MI associated with the use of a LNG-IUS.

9.3.4 *Ectopic pregnancy*

In users of IUC the absolute risk of ectopic pregnancy is reduced because they are such effective methods of contraception overall. The absolute risk of ectopic pregnancy is lower than among women not using any contraception.[155–157] A meta-analysis of case-control studies reported no increased risk of ectopic pregnancy with current IUD use when cases were compared to non-pregnant controls with past IUD use (pooled OR 1.06, 95% CI 0.91–1.59).[158] NICE[6] recommends that women are informed that the overall risk of ectopic pregnancy when

using an IUC is very low, at about 1 in 1000 at 5 years. The EURAS-IUD study reported an ectopic pregnancy rate for the 52 mg LNG-IUS of 0.02 per 100 woman-years (95% CI 0.01–0.003) and for the Cu-IUD a rate of 0.08 per 100 woman-years (95% CI0.04–0.13).[36]

While the absolute risk of ectopic pregnancy is not increased by use of IUC, should a pregnancy occur with an intrauterine method *in situ*, the likelihood of it being ectopic is greater than if a pregnancy were to occur with no IUC *in situ*. An early prospective study from the UK reported that among 90 unintended pregnancies in women using IUC, 8.9% were ectopic.[159] In a cross-sectional study[160] of 52 mg LNG-IUS users (17 360 users, totalling 58 600 woman-years) there were 64 pregnancies reported with a 52 mg LNG-IUS *in situ*. The risk of pregnancy was therefore low (5-year cumulative pregnancy rate of 0.5 per 100 users). However, of the 64 pregnancies, approximately half (53%) were ectopic. In the more recently reported EURAS-IUD study, 52 mg LNG-IUS users appeared to experience fewer ectopic pregnancies than Cu-IUD users, but when pregnancy did occur, 5/13 (38.6%) were ectopic compared with 10/56 (17.9%) in Cu-IUD users.[36]

Data from a meta-analysis[158] of case-control studies also suggested that a past history of IUC use is a risk factor for ectopic pregnancy (OR 1.4, 95% CI 1.23–1.59). The strength of association is small and may be the result of confounding or bias.

As with other intrauterine methods, the absolute risk of an ectopic pregnancy is reduced with use of the 13.5 mg LNG-IUS. In a phase III study the absolute ectopic pregnancy rate for the 13.5 mg LNG-IUS was reported as 0.10 per 100 woman-years (95% CI 0.02–0.29).[45] However, as with other intrauterine methods, when pregnancy does occur it is more likely to be ectopic. There was one ectopic pregnancy out of two pregnancies in phase II studies of the 13.5 mg LNG-IUS,[123] and three ectopic pregnancies out of seven failures in a phase III study.[45] It is difficult to compare ectopic pregnancy rates for the 13.5 and 52 mg LNG-IUS due to the small number of studies involving the 13.5 mg LNG-IUS.[45,161] Furthermore, the ectopic pregnancy rates for the 13.5 mg LNG-IUS are expressed as woman-years, preventing direct comparison with the rates quoted in the literature for 52 mg LNG-IUS (1 in 1000 at 5 years and 0.1% per year).[9]

A previous ectopic pregnancy is not a contraindication to use of intrauterine methods of contraception (UKMEC 1).[2]

B The overall risk of ectopic pregnancy is reduced with use of IUC when compared to using no contraception.

B If pregnancy does occur with an intrauterine method *in situ*, the risk of an ectopic pregnancy occurring is increased and in some studies half of the pregnancies that occurred were ectopic.

C Data are insufficient to determine if the 13.5 mg LNG-IUS is associated with a greater risk of ectopic pregnancy than other IUC methods.

✓ IUC users should be informed about symptoms of ectopic pregnancy. The possibility of ectopic pregnancy should be considered in women with an intrauterine method who present with abdominal pain especially in connection with missed periods or if an amenorrhoeic woman starts bleeding. If a pregnancy test is positive, an ultrasound scan is urgently required to locate the pregnancy.

9.3.5 Expulsion

A Cochrane systematic review[31] observed little difference in expulsion rates between the devices studied. The review reported a small significant excess in expulsions with Multiload Cu375® compared to TCu380A in the fourth and subsequent years. In Years 1 and 4, the TCu380S was reported as being associated with more expulsions than the TCu380A. Fewer partial expulsions were observed with the NovaT380 in comparison to the TCu380S, but no significant difference was observed in the overall expulsion rate.

Problems with early expulsion have been reported in trials of the frameless device (GyneFix).[162–164] A subsequent study[165] using a modified inserter observed no significant difference in expulsion rates between the frameless device and the TCu380A at 1 year. However, a Cochrane Review[32] examining whether or not the frameless IUD GyneFix reduced the risk of expulsion, pregnancy, problems of bleeding and pain necessitating early removal concluded that there was insufficient evidence to suggest that the modified inserter had helped to overcome problems of early expulsion.

A Cochrane Review[31] has indicated that the 52 mg LNG-IUS has a statistically significantly higher rate of expulsion at 5 years than for users of IUDs containing >250 mm^2 copper. However, a multicentre retrospective chart review,[166] that included data for 2138 women aged 13–35 years, reported more expulsions in women using a Cu-IUD than a 52 mg LNG-IUS (hazard ratio 1.62, 95% CI 1.06–2.50).

It has been estimated that expulsion of IUC occurs in approximately 1 in 20 women and is most common in the first 3 months after insertion and often occurs during menstruation.[61,167] Anecdotal evidence suggests that a past history of IUC expulsion increases the risk of future/subsequent expulsions.

B The risk of expulsion with IUC is around 1 in 20 and is most common in the first year of use, particularly within 3 months of insertion.

9.3.6 *Post-abortion insertion*

Royal College of Obstetricians and Gynaecologists guidance on *The Care of Women Requesting Induced Abortion*[168] recommends that any chosen method of contraception may be initiated immediately after abortion. WHO guidance on *Safe Abortion: Technical and Policy Guidance for Health Systems*[169] states that for medical abortion, hormonal contraception can be started by the woman after taking the first pill of a medical abortion regimen, but confirmation that the abortion is complete should precede insertion of an IUD or sterilisation.

There is consensus in the literature that offering LARC concomitantly with first-trimester abortion increases insertion rates[170–173] and reduces the number of subsequent unwanted pregnancies and repeat abortions.[172–174] There is consistent evidence reporting high non-attendance rates for follow-up appointments for interval insertion of IUC or the initiation of other LARC methods.[170,173,175–177]

An RCT[177] sought to assess the expulsion rate of IUC following insertion soon after medical abortion (5–9 days after the procedure) and delayed insertion (3–4 weeks after the procedure). The study reported that there was no difference in the expulsion rate between early (9.7%) and delayed (7.4%) intrauterine contraceptive insertion or in adverse other events.

A cohort study that examined the safety and adverse reactions associated with the immediate insertion of a Cu-IUD, following surgical abortion, compared to interval insertion (after the next menstrual bleed) reported that there was no difference in terms of either contraceptive efficacy or side effects between the two groups.[178] A multicentre RCT[179] randomised participants to receive one of three difference IUDs (two copper, UCu200 or TCu380A, and one LNG-IUS) following vacuum aspiration and followed up participants for 1 year. The study reported that no pregnancies were observed during follow-up. The expulsion rate for the UCu200 was 4.13 per 100 women (95% CI 0.83–5.75), 5.16 per 100 women (95% CI 0.92–6.96) for the TCu380A and 2.73 per 100 women (95% CI 0.67–4.05) for the LNG-IUS.[179] Another RCT[173] randomised participants to either immediate IUD insertion or delayed insertion (2–6 weeks) following aspiration for induced or spontaneous abortion. The study reported that the 6-month expulsion rate for immediate insertion was 5% (13/258 women) and 2.7% (6/226 women) for delayed insertion (absolute difference 2.3%, 95% CI 1.0–5.8). The RCT reported that no pregnancies were observed at 6 months' follow-up for the immediate treatment arm and that five pregnancies were observed in the delayed treatment arm (p=0.07). A retrospective cohort study[175] reported that there was no difference in complications between a group comprised of participants with immediate IUC insertion in comparison to a group with delayed insertion following surgical abortion.

Individual studies suggest a trend towards higher expulsion rates with immediate or early insertion in comparison to interval insertion following both medical and surgical abortion. A systematic review[180] concluded that the insertion of IUC immediately after abortion is not associated with an increased risk of adverse outcomes when compared to other contraceptive methods or no contraception. Furthermore, the review stated that IUD expulsions were low but are higher for later first-trimester abortions in comparison to early first-trimester abortions. A meta-analysis[171] of three RCTs concluded that following sub-analysis, higher expulsion rates were observed for post-abortion insertions when compared to interval insertions. Despite this, the authors concluded that the insertion of IUC immediately after abortion is safe and practical but expulsion rates appear to be higher when compared to interval insertions.

B There is no need to delay insertion of an IUC post-abortion providing a woman has been informed of the small increased risk of expulsion.

9.3.7 *Postpartum insertion*

The evidence comparing immediate postpartum insertion (within 10 minutes of placental delivery) with other insertion times following birth is limited but appears to suggest that it is associated with higher expulsion rates than with interval (6–8 weeks after birth) insertion.[181] A prospective cohort study[65] examining immediately post-placental placement of a CuT380A at Caesarean delivery found no self-reported expulsions in the 48% of women who returned for 6-week follow-up. The study was limited by high attrition rates. Larger studies, which also include insertion of the 52 mg LNG-IUS, are required. A systematic review[182] of 26 articles on event rates in interval and post-placental IUD insertion following Caesarean section reported expulsion rates of 5–15 per 100 woman-years of use. At 6+ weeks (interval insertion) following Caesarean section, insertion of an IUD was associated with a higher expulsion rate (≥5%) predominantly with use of older-type devices.

9.3.8 *Ovarian cysts and use in women with ovarian cancer*

Cu-IUDs have not been found to be associated with the development of functional ovarian cysts.[183]

An increased incidence of benign functional ovarian cysts has been observed in 52 mg LNG-IUS users.[184] No correlation has been identified between the presence of ovarian cysts and age or bleeding pattern. The majority of cysts occurring in LNG-IUS users are asymptomatic and resolve spontaneously. In an RCT comparing different dose LNG-IUS devices, ovarian cysts were observed more frequently with the 52 mg LNG-IUS than with a 19.5 mg LNG-IUS or the 13.5 mg LNG-IUS.[123]

Women should be informed that functional ovarian cysts are reported to be a common (1/100 to <1/10) possible undesirable effect of LNG-IUS use.[9] Ovarian pathology should be considered in the differential diagnosis of abdominal pain in LNG-IUS users.[185] There is no restriction on the use of IUC (LNG-IUS or Cu-IUD) in women with a history of ovarian cysts (UKMEC 1)[2] and there is no need to remove the method unless requested by the woman.

No data have been identified on the safety of using IUC in women with ovarian cancer.[186] UKMEC guidance on initiation and continuation of IUC in the presence of ovarian cancer is being updated. The Centres for Disease Control's *US Medical Eligibility Criteria for Contraceptive Use* (USMEC)[187] gives use of IUC in women with ovarian cancer a Category 1 (i.e. no restrictions). This decision was taken in the light of new treatments that can preserve the ovaries and fertility, whereas previously the ovaries would have been removed. In addition, the American group was unable to identify any evidence or theoretical concerns that insertion of IUC could worsen the condition.

B Although ovarian cysts may occur when using the LNG-IUS, most cysts are asymptomatic and resolve spontaneously.

9.3.9 *Pelvic pain*

In a large cohort study[49] of LARC users, pelvic pain or cramping was the most commonly reported reason for discontinuation of IUC at 6 months' follow-up. Of the 200 women who had discontinued IUC, and for whom data was available, 28% of 52 mg LNG-IUS discontinuers and 35% of Cu-IUD discontinuers reported pain/cramping as the reason for discontinuation; the difference was not statistically significant (p=0.38).

9.3.10 *Pelvic inflammatory disease*

Evidence examining a link between IUC use and PID is subject to limitations, confounding and bias, and good evidence is lacking.[188]

A large retrospective cohort study[76] of 57 728 insertions found an overall risk of PID within the first 90 days of 0.54% (95% CI 0.0048–0.0060); the study included women who were and were not screened for gonorrhoea and chlamydia in advance of insertion.

In IUC users, PID appears to be most strongly related to the insertion procedure and to the background risk of STIs. A review of 12 randomised and one non-randomised trial (22 908 insertions and more than 51 399 woman-years of follow-up) identified low rates of PID (1.6 per 1000 woman-years).[189] A six-fold increase in the risk of PID was reported in the 20 days after insertion, after adjusting for confounding factors, but the overall risk was low. After this time the risk was low and remained low unless there was exposure to STIs. A systematic review[190] designed to establish timeframes for appropriate follow-up following initiation of specific contraceptive methods, including intrauterine methods, found that compared to women starting depot medroxyprogesterone acetate (DMPA) and 52 mg LNG-IUS or COCs, the incidence of PID was similar for women starting a Cu-IUD. The findings are somewhat restricted by the limitations of the included studies.

One multicentre RCT[191] reported that the cumulative rate of PID was higher after 36 months of use amongst women using a Cu-IUD (Nova T 200 mm^2) as compared with women using the 52 mg LNG-IUS. Differences were also observed after 60 months of use amongst the youngest women in a 5-year study.[40] However, in another RCT[192] that compared a 52 mg LNG-IUS to the Copper T 380Ag IUD, cumulative PID rates did not differ between the two methods. No significant differences in discontinuation rates due to PID were observed between different Cu-IUDs or when the 52 mg LNG-IUS has been compared to Cu-IUDs in randomised trials.[191,192]

9.3.11 *Perforation*

The rate of uterine perforation associated with IUC use is very low.[6,193–195] No significant differences were identified in the perforation rates with differed framed Cu-IUDs.[31] A Cochrane Review has indicated that it is not known if the perforation rate for framed devices differs from frameless devices but only one perforation was noted with GyneFix in the studies reviewed (approximately 3000 insertions) compared to none with the framed device.[32]

The rate of perforation reported with the 52 mg LNG-IUS in a large observational cohort study was 0.9 per 1000 insertions.[196] A randomised trial comparing the 52 mg LNG-IUS and a TCu380A IUD reported similarly low perforation rates at 7 years.[192]

Findings from observational studies suggest an association between IUD perforation rates and breastfeeding.[195,197,198] Findings from the large EURAS comparative prospective cohort study[199] suggest that while perforation rates with use of IUC are low, around 1 in 1000 insertions, there was an increased relative risk of total uterine perforation amongst breastfeeding women (RR 6.1, 95% CI 3.6–10.1). Summaries of product information for Mirena[9] and Jaydess[11] highlight that the risk of perforation is increased in breastfeeding women and may be increased in postpartum insertions (see page 26 for management of suspected perforation and page 25 for management of pregnancy).

B The rate of uterine perforation associated with IUC is up to 2 per 1000 insertions and is approximately six-fold higher in breastfeeding women.

9.3.12 Return to fertility

Concerns about IUC affecting fertility have been cited as a reason for discontinuation of IUC[200] and women's wariness of long-acting contraception.[201] Many reports show no delay in return of fertility among mainly parous women using the Cu-IUD.[202–204] One study of nulliparous women in the UK suggested that longer-term Cu-IUD use for 78 months or more was associated with lower fertility rates after discontinuation than use of oral contraceptives or barrier methods.[205] The difference in fertility remained after adjusting for age and history of gynaecological illness. The authors advise caution extrapolating these findings to current-day practice because of improvements in STI screening since the time of the study.

There are fewer data available on return of fertility after use of the 52 mg LNG-IUS. Reviews of the evidence suggest no delay.[6,206]

B Return of fertility after IUC use is generally similar to fertility rates after discontinuation of oral contraceptives and barrier methods.

9.4 Vasovagal reaction

Cervical stimulation during the insertion of intrauterine methods can cause a vasovagal reaction, bradycardia and other arrhythmias.[207–209] In healthy women vasovagal incidents usually resolve with simple resuscitation measures; rarely bradycardia persists and requires treatment with intravenous or intramuscular atropine[85,210,211] (see page 22).

9.5 Vulvovaginal candida and bacterial vaginosis

The Cu-IUD has been identified as a possible risk factor for acute or recurrent vulvovaginal candida (VVC).[212] There is some evidence to demonstrate that yeasts adhere to IUDs and produce biofilm[213,214] that could possibly facilitate recurrent VVC by protecting yeasts from antifungal agents. There is, however, no consistent evidence of an association between use of a Cu-IUD and VVC, and although cervical cytology slides from LNG-IUS users have shown increased presence of candida with time from insertion, rates of symptomatic infection are not significantly changed.[215,216]

Bacterial vaginosis (BV) is associated with use of the Cu-IUD[217] and FSRH guidance recommends that women with a Cu-IUD who experience recurrent BV may wish to consider switching to an alternative method of contraception.[74] The association between BV and use of the LNG-IUS is unclear. Advice on the management of vaginal discharge is available from the FSRH[74] and guidance on the management of BV[218] and VVC[219] is available from BASHH.

C Cu-IUD users with recurrent BV or VVC may wish to consider an alternative method of contraception.

10 How Can Safe Insertion of IUC be Facilitated?

10.1 Training

Health professionals offering IUC should hold the appropriate FSRH Letter of Competence in Intrauterine Techniques or have achieved equivalent recognised competencies and show evidence of recertification/reaccreditation.[220] The risk of perforation is related to the competence of the health care professional. In one study, doctors who performed fewer than 10 IUD insertions in a 10-year period reported significantly more perforations than doctors fitting between 10 and 99 devices in the same study period.[221] To ensure health professionals are able to maintain competence they should be able to show evidence of at least two continuing professional development (CPD) credits relevant to intrauterine techniques, completion of

e-SRH Module 18 or other approved distance-learning course, basic life support and anaphylaxis update, and a minimum of 12 insertions with at least two different types of intrauterine method in conscious women undertaken during a 12-month period within 24 months of recertification. The FSRH website (www.fsrh.org) contains information about training requirements and recertification. No formal training as such is required for removal of IUDs but health professionals should have basic gynaecological skills and sufficient contraceptive knowledge to identify and appropriately manage any risk of pregnancy at the time of IUC removal, and to advise on ongoing contraceptive needs.

10.2 Valid consent

Valid consent should be obtained before examining, taking an STI screen, or starting treatment for a patient.[220,222] Detailed information can be found in the *FSRH Service Standards for Sexual and Reproductive Healthcare*.[220] Women should be given appropriate information about the contraceptive method and the procedure in order to give valid consent. Oral consent is sufficient for a non-anaesthetised woman.

✓ Valid consent should be given by women prior to both pelvic examination and IUC insertion or removal.

10.3 Assistants and chaperones

All women should be offered a chaperone. An appropriately trained assistant should be present during cervical instrumentation procedures. This person may be required to call for additional assistance, monitor the condition of the woman, or perform basic life support.[210]

✓ An appropriately trained assistant who can monitor the condition of the woman and assist in an emergency should be present during insertion of IUC.

10.4 Interventions to ease IUC insertion

Factors that predict pain during insertion of intrauterine methods include nulliparity or no history of vaginal delivery, anxiety, and length of time since last pregnancy or last menses.[57,223–225] In a non-randomised prospective study[226] of nulligravid women undergoing IUC insertion, severe dysmenorrhoea was identified as a predictor of painful insertion, and shorter uterine length and steeper flexion angle were associated with difficult insertion. However, the majority of fittings were uneventful irrespective of individual anatomy.[226]

10.4.1 Cervical priming agents

Various agents have been investigated for their potential to prime (soften) the cervix. The cervical priming agent misoprostol has been extensively studied with regard to ease of insertion and pain.[227–230] A Cochrane Review[231] concluded that none of the cervical priming agents investigated reduced IUC insertion pain. Side effects associated with using misoprostol were reported in several of the studies.

Gels containing the smooth muscle dilating drugs nitroprusside[232] and nitroglycerin[233] have also been used to ripen the cervix prior to IUC insertion but have had no effect on ease of insertion or pain.

10.4.2 Prophylactic oral analgesia

Oral ibuprofen administered at doses up to 600 mg and at different intervals before insertion has not been shown to reduce pain at the time of IUC insertion.[59,224,234–238] There is limited evidence suggesting that other non-steroidal anti-inflammatory drugs (NSAIDs) (e.g. naproxen and mefenamic acid) may relieve post-insertion pain.

10.4.3 Bladder filling

A study of 200 women reported no difference in ease of insertion between groups randomised to IUD insertion with the woman's bladder filled or when emptied immediately prior to the procedure.[239]

10.4.4 IUC design

Ease of insertion and pain may vary with the insertion of different devices. A Cochrane Review[31] reported that RCTs found no difference between the framed Cu-IUDs studied in relation to ease of insertion or pain during insertion. In a placebo-controlled study[225] examining the effects of lidocaine gel, insertion of a 52 mg LNG-IUS was associated with greater pain than insertion of a Cu-IUD (Paragard®). In a clinical trial of the smaller-framed 13.5 mg LNG-IUS[123] health professionals were significantly more likely to report placement as 'easy' compared with insertion of a 52 mg LNG-IUS. Clinical trials of the 13.5 mg LNG-IUS failed to use a validated measure of pain.[45,123] Subjects were asked to rate pain during placement as 'none', 'mild', 'moderate' or 'severe'. Pain relief and cervical dilation were provided at the physician's discretion with no randomisation. A significantly higher proportion of women using lower-dose LNG-IUS devices (13.5 and 19.5 mg) reported no or mild pain compared with those in the 52 mg LNG-IUS group.[123] However, subsequent to these studies, a narrower, more ergonomic inserter has been introduced to aid insertion of the 52 mg LNG-IUS Mirena, and therefore the observed difference may no longer exist.

10.4.5 Tissue forceps

Application of tissue forceps (volsellum) to the cervix facilitates IUC insertion by stabilising the cervix and reducing the flexion angle of the uterus. Forceps are available with a single-tooth (tenaculum) or multi-tooth design. Some multi-tooth forceps are termed 'atraumatic' because they grasp only the superficial tissue layers. Slow application of forceps over a few seconds and distraction techniques are commonly practised to reduce pain. There is insufficient evidence to recommend any particular type of forceps or application technique.

10.4.6 Local anaesthetic

There is wide variation in clinical practice with regard to administration of local anaesthetic prior to IUC insertion. A survey of UK clinicians reported that approximately one-quarter (*n*=129) of health professionals who undertook the survey routinely used local anaesthetic for IUC insertion, with around one-quarter of health professionals never, or rarely, offering it, and the remainder doing so sometimes.[240]

A Cochrane Review[231] concluded that none of the included trials showed an effect of topical local anaesthetic on insertion pain, although the authors acknowledged that there may be a case for further investigation of topical lidocaine. However, further RCTs have not shown any benefit, even when applied and left for 3 minutes prior to insertion.[225,241,242]

The two main techniques for cervical local anaesthesia (LA) are paracervical and intracervical block using a dental syringe and fine-gauge needle. The local anaesthetic drugs prilocaine, lidocaine or mepivicaine may be used with or without a vasoconstrictor. Use of the mepivicaine product Scandonest® is outside the product licence as it is currently licensed for dental use only. There is wide variation in how cervical block techniques are described in the literature. Further information is available via the FSRH e-learning Module 18 on Intrauterine Techniques.

There is evidence that cervical LA block effectively reduces the pain associated with gynaecology procedures,[243–246] and it is generally advised for any procedure that requires dilatation of the cervix. There is limited evidence regarding the routine use of cervical block for IUC insertion. In a small randomised trial[247] using 1% lidocaine paracervical block, perceived pain during IUC insertion was less in the paracervical block group [median Visual Analogue Scale (VAS) score 24.0 mm] than women receiving no anaesthetic (median VAS score 62.0 mm). The median VAS score associated with the LA block itself was 40.0 mm. Another small randomised study[248] with a placebo injection arm reported that paracervical block with 1%

lidocaine was associated with significantly lower pain scores at tenaculum placement, IUC insertion, and 5 minutes after the procedure when compared to placebo saline injection or no injection. Pain experienced during injection was not reported. Further studies are required to fully evaluate the use of LA cervical block for straightforward IUC insertion.

A There is no evidence from current trials to support the use of topical lidocaine, misoprostol or NSAIDS for improving ease of insertion or reducing pain during insertion of intrauterine methods.

✓ Local anaesthetic block administered by cervical injection is not routinely required for IUC insertion but should be offered when cervical dilatation is required or difficult IUC insertion or removal is anticipated/experienced.

10.5 Post-procedure analgesia

NSAIDs such as ibuprofen effectively reduce pain after IUC insertion, although evidence suggests that treatment is unlikely to improve discontinuation rates in women who cite pain as a reason for removal.[59,249]

✓ NSAIDs can be offered to women who experience pain after insertion of an intrauterine method.

10.6 Emergency management for problems at IUD insertion

Any invasive procedure in a non-anaesthetised woman, including IUC fitting, can trigger a vasovagal response. It is recommended that all staff involved with IUC insertion should undergo training and regular updates in resuscitation. For further information health professionals should refer to the FSRH *Service Standards for Sexual and Reproductive Health Services*[220] and *Service Standards for Resuscitation*.[210]

All significant adverse clinical events should be recorded and reported according to local policies, and should be discussed with individuals and a process put in place for the whole team to learn from them.

10.7 Practical procedures for intrauterine insertions

10.7.1 Bimanual examination

A bimanual pelvic examination should be performed prior to inserting IUC to allow health professionals to assess the position, size, shape and mobility of the uterus.

C A bimanual pelvic examination should be performed on all women before inserting IUC.

10.7.2 Measurement of pulse rate and blood pressure

Practice in the UK varies around the measurement of pulse rate and blood pressure before and after insertion of IUC. The clinical picture should guide clinicians in the appropriate measurement and documentation of pulse rate and blood pressure before, during and/or after inserting IUC.

10.7.3 Cervical cleansing

Although a study found that a high number of doctors reported cleaning the cervix prior to insertion of IUC,[250] no studies were identified that suggested such practice reduced post-insertion pelvic infection. None of the standard cleansing agents are effective bacteriocidally against chlamydia or gonorrhoea. Health professionals may choose to remove any mucus or debris from the cervix prior to insertion.

✓ There is no evidence to suggest that cervical cleansing prior to IUC insertion reduces subsequent pelvic infection.

10.7.4 Sterile gloves

Gloves should be worn on both hands for pelvic examination.[251] There is no recommendation regarding the use of sterile gloves when fitting IUC particularly if a 'no touch' or aseptic technique is used (i.e. one whereby anything that is to be inserted into the uterine cavity remains sterile). Gloves should be changed after the pelvic examination and before proceeding to uterine instrumentation to avoid cross-contamination.

10.7.5 Use of forceps and assessment of the uterine cavity

Application of tissue forceps to the cervix has been recommended to ease insertion and reduce the risk of perforation. Evidence for the routine application of tissue forceps is lacking but use of forceps is advised in IUC manufacturers' instructions. In individual clinical circumstances an experienced clinician may choose not to use tissue forceps if the risks (e.g. from bleeding) are judged to outweigh the benefits. A uterine sound should be used to assess the length of the uterine cavity, reducing the risk of perforation and facilitating fundal placement of the device.[251,252]

10.8 Documentation

Recommendations for record-keeping specific to intrauterine insertion are available within FSRH *Service Standards for Record Keeping*.[253]

11 Managing Problems Associated with IUC

11.1 Unscheduled bleeding

While bleeding patterns can be irregular with IUC, STIs represent a common cause of problematic bleeding in women of reproductive age. Women with intermenstrual, postcoital or unscheduled bleeding while using these methods should be assessed to identify their individual risk of STI. Consideration should also be given to other causes of bleeding, such as concurrent gynaecological pathology, pregnancy, and other infections. Details are provided in *The Management of Unscheduled Bleeding in Women Using Hormonal Contraception*.[254]

Bleeding is common in the initial months of using any progestogen-only method and often settles without treatment. If treatment encourages women to continue with the method, it may be considered. Evidence for appropriate treatment options is lacking with regard to the LNG-IUS. An RCT[255] of 187 women who received a 52 mg LNG-IUS and were then randomised to receive tranexamic acid (500 mg), mefenamic acid (500 mg) or placebo three times daily during episodes of bleeding or spotting found that compared with placebo neither of these options was effective at 'treating' nuisance bleeding. A double-blind placebo-controlled trial,[256] designed to evaluate the effect of intermittent ulipristal acetate (UPA) on unscheduled bleeding in the first 4 months following insertion, found that although initially beneficial (first 28 days after treatment) the effect then reversed. In the absence of evidence, the FSRH recommend that as a short-term empirical treatment, a COC (30–35 µg ethinylestradiol with LNG or norethisterone) may be considered for up to 3 months continuously or in the usual cyclical regimen (outside product licence) in eligible women experiencing unscheduled bleeding with the 52 mg LNG-IUS. This may help settle bleeding in some women.[254]

A Cochrane Review[249] of RCTs reported that NSAIDs can reduce the pain and bleeding associated with IUDs and that if ineffective, antifibrinolytics (tranexamic acid) can be considered for bleeding issues. A systematic review,[257] which included 17 studies of varying quality, similarly reported that there may be some benefit associated with the use of NSAIDs.

✓ There is no evidence as to the most appropriate treatment option for women with unscheduled bleeding with the LNG-IUS. For women with unscheduled bleeding who wish to continue with the LNG-IUS and are medically eligible, a COC could be tried for up to 3 months (this can be in the usual cyclic manner or continuously without a pill-free interval – unlicensed use).

A NSAIDS can be considered in the management of problematic bleeding with use of Cu-IUDs.

11.2 Non-visible threads

IUC threads may not be visible in the vagina as a consequence of IUD expulsion, perforation or pregnancy, but often the cause is retraction of the threads into the cervical canal or uterus. If no threads are visible on speculum examination pregnancy should be excluded, additional precautions advised, and an ultrasound scan undertaken to locate the device (Figure 1).

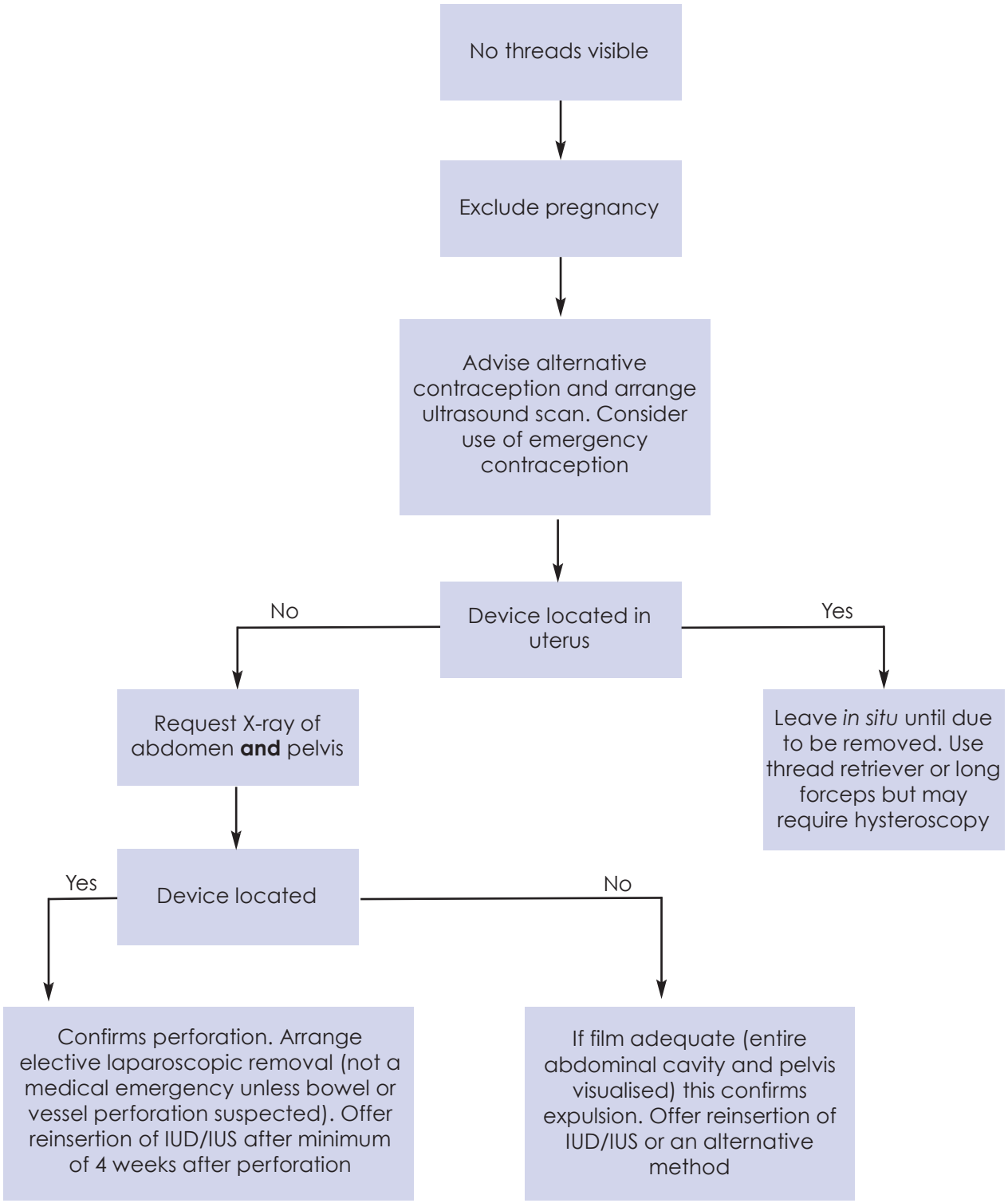

Figure 1 Management of women with no intrauterine contraceptive threads visible on speculum examination. IUD, intrauterine device; IUS, intrauterine system.

If the IUC device is confirmed to be within the uterine cavity, the woman can be reassured and the device left *in situ*. If the device is to be removed, then thread retrievers (such as Retrievette® or Emmett) or Spencer Wells forceps can be used to facilitate this process.[258]

It is not advisable to use a thread retriever or forceps blindly without first confirming the intrauterine location of the device and excluding pregnancy.

If the IUC device cannot be removed easily, individuals should be referred for specialist review and then for removal using IUD removal forceps under local anaesthetic. Ultrasound guidance may be helpful and hysteroscopic removal is occasionally required.

When an IUC device is due to be removed or replaced, in general it should not be left *in situ* because of 'lost threads'. Cases of actinomyces-like organisms (ALOs) and pyometra have very occasionally occurred in postmenopausal women with IUDs. Careful discussion is required to balance the risks of surgical removal against the risks of infection from retained IUC, or if the woman refuses to have the IUC removed.

11.3 Non-fundally placed IUC

There is limited evidence to allow recommendations to be made about management of non-fundally placed intrauterine methods. It is believed that correct IUC insertion to the fundus may be necessary for maximum efficacy and that incorrect placement may increase the risk of expulsion.

In theory the efficacy of the LNG-IUS may be less affected by its position in the uterine cavity, because of the local release of progestogen hormone. However, one study[259] suggested that intracervical placement of a specially designed intracervical IUS was associated with less uniform endometrial suppression and more days of bleeding and spotting than fundal placement of a standard IUS. Another study[260] (*n*=298) comparing the small intracervical IUS with an intrauterine IUS showed that there was no difference in the number of pregnancies in the two groups. However, it was not clear whether this study was powered to demonstrate equivalence. There is currently insufficient evidence to confirm whether efficacy is reduced or maintained when intrauterine methods are non-fundally placed. Repositioning of malpositioned 52 mg LNG-IUS devices was attempted in a small study[261] of 18 women. At follow-up 2–3 months later, the 52 mg LNG-IUS was still in place in 14/17 cases in which repositioning was possible.

Overall, the guideline group were of the opinion that contraceptive efficacy of a non-fundally placed IUC cannot be guaranteed, especially if it is more than 2 cm from the fundus on ultrasound measurement. The decision to remove and replace a device is a matter of individual clinical judgement following discussion with the woman and consideration of her individual circumstances (e.g. history of expulsion, age and type of device). Timing of removal may be dictated by recent sexual intercourse. EC may need to be considered in certain circumstances. If removed, immediate replacement or an alternative contraception should be initiated

11.4 Pregnancy

A systematic review[262] of observational studies concluded that compared to women who conceive without an IUC *in situ*, those who do are at greater risk of adverse pregnancy outcomes such as spontaneous abortion, preterm delivery, septic abortion and chorioamnionitis. From the limited available evidence it appears that removal of the IUC early in pregnancy may help to improve outcomes, although it will not necessarily eliminate the risks.

If a woman does become pregnant while using IUC, the site of the pregnancy should be determined by ultrasound scan and advice given regarding appropriate removal of the intrauterine method, where possible, before 12 weeks' gestation. The SPC for the 52 mg LNG-IUS[9] suggests that in case of an accidental pregnancy with the device *in situ*, ectopic pregnancy should be excluded and the IUS must be removed and termination of the pregnancy should be considered. There is limited evidence of pregnancy outcomes with a 52 mg LNG-IUS *in situ* but to date there is no evidence of birth defects.[9]

If it has not been possible to remove an IUD or confirm its location during pregnancy and the IUD is not found at the time of delivery or abortion, it is important to exclude uterine perforation by arranging an abdominal X-ray (see page 24).

11.5 Presence of actinomyces-like organisms

Actinomyces israelii is a commensal of the female genital tract.[263–265] Actinomyces-like organisms (ALOs) have been identified in women with and without IUC,[267–271] although it is acknowledged that the level is thought to be low and that actinomycosis is rare.[272] The role of ALOs in infection in women using IUC is unclear.[273,274] No evidence was identified as to whether or not an IUD should be inserted in women who have ALOs identified prior to IUD use.

If ALOs are identified and the woman presents with symptoms of pelvic pain, then removal of IUC may be considered. Treatment involves high-does antibiotics for at least 8 weeks and health professionals should consult with a microbiologist. Other more common causes of pain (including STIs) should be excluded. It has been suggested that asymptomatic women with positive ALOs on a cervical smear are more likely to be colonised by ALOs than infected,[272] with the IUD potentially providing a good surface for the development of biofilm *in vivo*.[275] There is no need to remove IUC in asymptomatic women with ALOs. For women who require a replacement device but have ALOs identified there is some evidence to suggest that immediate reinsertion or a short delay of 3–5 days is safe.[276]

C Insertion or reinsertion of an intrauterine method can be carried out in asymptomatic women with ALOs.

C There is no need to remove IUC in asymptomatic women with ALOs.

11.6 Suspected pelvic infection

If a woman diagnosed with pelvic infection wishes to continue to use IUC there is no need for routine removal and appropriate antibiotic treatment can be initiated.[62] BASHH guidance[77] suggests that there may be better short-term clinical outcomes from IUD removal, and that the decision to remove an IUD in women PID needs to be balanced against the risk of pregnancy in those women who may have had sex in the preceding 7 days. A systematic review[277] of three studies, two RCTs and one prospective cohort suggested that there was no advantage to Cu-IUD removal and that clinical or laboratory outcomes for women who were hospitalised for PID tended to be similar or better for those who retained their device. No studies examining the LNG-IUS were identified by the systematic review. Oral EC may need to be considered in women requesting or having their IUC removed and advice should be provided about avoidance of sex/additional precautions. The CEU supports the continued use of IUC and appropriate antibiotic treatment if PID is suspected.

Follow-up of women with pelvic infection is advised 72 hours after starting treatment.[77] Further follow-up may be warranted 2–4 weeks after treatment.[77]

B IUC removal is not routinely required in women with PID but it should be removed if there is no response to treatment (approximately 72 hours).

11.7 Suspected uterine perforation

Although some uterine perforations are identified at the time of insertion, there can be a delay before perforation is identified.[194,198,278] For those women in whom perforation is identified at the time of insertion, the procedure should be stopped, the IUC removed, and vital signs (blood pressure and pulse rate) and level of discomfort monitored until stable.

Mild lower abdominal pain, 'lost threads', changes in bleeding (LNG-IUS) and a history of pain at the time of insertion may indicate uterine perforation.[197,198,278,279] The threads may remain in the vagina and may break off at attempted removal if an IUC has become embedded in the uterine wall or has perforated the cervix.

If there is any possibility of perforation at the time of insertion or later, an ultrasound scan and then, if indicated, a plain abdominal and pelvic X-ray should be arranged as soon as possible in order to locate the device. Women should be advised to use additional contraceptive precautions in the interim (see Figure 1).

12 What Information Should be Given to Women About Ongoing Use of IUC and Follow-up?

12.1 Information about the device

Women should be informed about what device has been inserted and when it needs to be removed and/or replaced. In addition to oral information, women should be given/directed to appropriate sources of information (e.g. leaflets, websites and apps).

12.2 Checking threads and device

Information should be offered on how to check for the threads of the IUC after each menstruation (or alternatively at regular intervals). If a woman's bleeding pattern changes from what might be expected with their chosen method (e.g. amenorrhoea to bleeding) or a period is missed when using the Cu-IUD, women should consider returning to have their IUC checked. If threads are present and menstruation has not been missed or has not changed from the usual pattern, an IUC can be assumed to be normally placed. If threads are not present women should be advised to use condoms or abstain from intercourse until the location of the IUC can be confirmed. Hormonal EC may be indicated if there is a risk of pregnancy.

Women should be advised to seek medical advice if the IUC causes discomfort to her or her partner during sexual intercourse. The threads can be cut shorter or flush within the cervical os if they cause irritation to a partner's penis.

✓ Women should be offered instruction on how to check for the IUC and advised that if the threads cannot be felt the device may have perforated the uterus or been expelled. Additional contraception should be used until they seek medical advice.

12.3 Symptoms requiring medical attention

Women should be advised that the risk of pelvic infection is greatest in the first few weeks following IUC insertion and to look out for symptoms of pelvic infection as well as symptoms associated with pregnancy or uterine perforation.

C Women should be advised to seek medical assistance at any time if they develop symptoms of pelvic infection, pain, abnormal bleeding, late menstrual period (IUD), non-palpable threads or can feel the stem of the IUC.

12.4 Sexually transmitted infections

IUC methods do not provide protection against STIs. Women requesting these methods should be informed about safer sex and that the consistent and correct use of condoms provides an effective means of protecting against STIs including the human immunodeficiency virus (HIV).[280]

Individuals with concerns about STIs, HIV or other blood-borne viruses, whether symptomatic or

not, should have a risk assessment and an appropriate medical and sexual history taken.[71] The minimum tests that in combination constitute an STI check (often called an STI screen) are those for chlamydia, gonorrhoea, syphilis and HIV.[70,71]

Although an STI screen can be offered immediately following sexual activity, this may only identify pre-existing infection. An STI screen 2 weeks after sexual activity is recommended to detect chlamydia and gonorrhoea acquired at the time of potential risk exposure. Serological tests for HIV, hepatitis and syphilis will require individuals to wait longer to allow for seroconversion.

✓ Women requesting intrauterine methods should be informed about the use of additional precautions for protection against STIs and advised about the appropriate timings of STI testing after an episode of UPSI.

12.5 Emergency contraception

EC may need to be considered if recent intercourse has occurred and the IUC is to be removed or in those who do not take additional precautions, when indicated, after an LNG-IUS is fitted. Additionally, EC may be required if the IUC is used for longer than its licensed duration.

The Cu-IUD can be used for EC and for ongoing contraception thereafter. All eligible women presenting between 0 and 120 hours of UPSI or within 5 days of expected ovulation should be offered a Cu-IUD because of the low documented failure rate.[8] Women requesting a Cu-IUD for EC and ongoing contraception should ideally be fitted with a device with at least 380 mm^2 copper and banded copper on the arms of the device.[8]

It is not appropriate to 'quick start' a LNG-IUS following administration of oral EC.[281] The Cu-IUD can be inserted after administration of oral LNG or UPA only if it is within 5 days of UPSI orwithin 5 days after the earliest expected ovulation.

✓ Health professionals should inform women about the availability of EC and when it may be required with intrauterine methods.

12.6 Routine follow-up

Following IUC fitting a follow-up visit after the first menses (or 3–6 weeks) has traditionally been advised to exclude infection, perforation or expulsion;[62] however, many women do not return for such appointments. The CEU would therefore suggest greater emphasis is placed on ensuring women are informed about how to check their own threads and to be aware of problems that might occur with IUC such as side effects, infection or irregular bleeding. Women should be advised to return at any time if they have any concerns, cannot locate their threads, or if they want to change their contraceptive method.[62]

✓ A routine follow-up visit can be advised after the first menses following insertion of IUC or 3-6 weeks later. However, it is not essential and it may be more important to advise women as to signs and symptoms of infection, perforation and expulsion, returning if they have any problems relating to their intrauterine method.

12.7 Timing of removal/replacement

Advice for removal and replacement of IUC is given in Table 5. If a device is inadvertently inserted after the expiry date stated on the packaging the woman should be advised that if the device has only recently expired this is unlikely to affect contraceptive efficacy. The risk of infection from loss of microbiological sterility is likely to be lower than the risk of infection from replacement of the device; consequently the device does not necessarily need to be removed unless requested by the woman. The error should be managed according to local clinical governance policies.

Table 5 Recommendations for removal/replacement of intrauterine contraception

Reason for removal	Recommendation for removal
For a planned pregnancy	Offer pre-pregnancy advice regarding lifestyle, diet, folic acid, rubella immunity, vitamin D, then remove at any time in the menstrual cycle when the woman is ready to conceive
When removal is within the licensed duration of use and an alternative method is chosen	Women using Cu-IUDs can have their method removed up to Day 3 after the onset of menstruation without the need for additional precautions Women having a Cu-IUD removed after Day 3 and women having an LNG-IUS removed at any time should be advised to avoid intercourse or use another method of contraception for at least 7 days before removal. Advise contraception thereafter
When replacement is within the licensed duration of use	Advise condoms for at least 7 days before the procedure in case reinsertion is not possible
When removal/replacement are outside the licensed duration of use	A Cu-IUD (containing ≥300 mm^2 copper) inserted at or after the age of 40 years can be retained until 1 year after the last menstrual period if this occurs when the woman is over the age of 50 years (2 years if under 50 years) Women who wish replacement of a Cu-IUD outwith the licensed duration of use (excluding those detailed above) should have pregnancy reliably excluded prior to the replacement or fit the criteria for an emergency IUD Women who had their 52 mg LNG-IUS inserted for contraception and/or heavy menstrual bleeding at the age of 45 years or over can use the device for 7 years or if amenorrhoeic until the menopause,* after which the device should be removed Women who were under the age of 45 years at the time of 52 mg LNG-IUS insertion and who present for replacement of the device between 5 and 7 years after insertion may have immediate replacement if a pregnancy test is negative and another pregnancy test is advised no sooner than 3 weeks after the last episode of UPSI If a woman is under 45 years at the time of 52 mg LNG-IUS insertion and more than 7 years have elapsed since insertion, replacement should be delayed until the woman has a negative pregnancy test at least 3 weeks after the last UPSI Women who retain their 13.5 mg LNG-IUS for more than 3 years should be advised to use additional precautions until pregnancy can be excluded, after which time a replacement device can be inserted

*See FSRH guidance on *Contraception for Women Aged Over 40 Years*.[47]
Cu-IUD, copper intrauterine device; LNG-IUS levonorgestrel intrauterine system; UPSI, unprotected sexual intercourse.

12.8 Vibrating gym plates

Some gym product information advises that women using IUC consult a health professional before using vibrating gym plates. This is because of theoretical concerns about an increased risk of expulsion caused by the vibrations and contractions that occur during use. The CEU found no evidence of any adverse effect; however, precautionary advice has been to avoid such activity in the first few weeks following insertion. Women should be reminded about how to check threads and to use additional precautions if they have any concerns until a device can be checked.

12.9 Magnetic resonance imaging

Most Cu-IUDs are composed of plastic with copper wire or fitted with copper bands, while some also have a central core of silver to prevent copper fragmentation. Theoretically as none of these materials are magnetic, no magnetic force should be experienced with magnetic resonance imaging (MRI).

An *in vitro* study[282] was conducted to determine if MRI using a Signa 1.5T system would create movement, torque or heating of a Copper T 380A IUD placed within the magnetic field. No

significant temperature changes were seen and, additionally, there was no static deflection of the IUD and no turning motion with different gradient pulses of MRI. The authors concluded that these findings were to be expected because the IUD has no magnetic or magnetisable components. They recommended that screening women for the presence of an IUD prior to an MRI scan is unnecessary, and that removal of the device before the scan is unjustified.

The safety of using some Cu-IUDs has been shown at static magnetic field strengths of 1.5[283] and 3 Tesla[284] under test conditions. Nevertheless, most diagnostic centres ask women to inform them if they have any metallic object in their body, including an IUD. Some have policies stating that the IUD should be removed prior to an MRI scan and the CEU suggests checking with the local radiology department. However, the CEU would suggest that IUD removal is not required when a static magnetic field of up to 3 Tesla is used.

There is no reason for either the 13.5 or 52 mg LNG-IUS to be removed at any strength of magnetic field.

12.10 Mooncups and tampons

The manufacturer of the Moon Cup® recommends waiting for 6 weeks following the insertion of IUC before using the menstrual cup.[285] They also state that the Moon Cup should be placed low in the vagina with an adequate seal, which should be broken before the cup is removed. The manufacturer also recommends checking for IUC threads after each menses. If the threads cannot be located, or if a woman thinks her Cu-IUD has moved or if a woman experiences pain, the manufacturer recommends using additional contraception and consulting with an appropriate health care professional.[285]

A retrospective chart review[286] was identified which examined the risk of IUC device expulsion associated with the use of tampons, menstrual cups and sanitary towels. The study retrospectively reviewed the medical records of 1050 women with 743 meeting the eligibility criteria. A total of 135 women used a menstrual cup, 469 used tampons and 293 used sanitary towels. The study reported that at between 6 and 8 weeks' post-insertion that there were five expulsions (3.7%, 95% CI 1.6–8.4) in the menstrual cup cohort, 11 expulsions (2.4%, 95% CI 1.3–4.2) in the tampon cohort and 11 expulsions (3.8%, 95% CI 2.1–6.6) in the sanitary towel cohort. As the confidence intervals overlap, the authors concluded that there was no evidence to suggest that the use of menstrual cups or tampons was associated with increased early IUC expulsion.

C Mooncups and tampons do not appear to be associated with an increased risk of IUC expulsion.

13 IUC in Specific Populations

13.1 Nulliparous and adolescent women

Health professionals may present a possible barrier to the use of IUC in nulliparous women due to their own misconceptions about the difficulties associated with insertion and risks.[287]

A systematic review[288] of six cohort studies and seven case-series indicated that there is a lack of data on the use of IUC in young people but that existing data are generally reassuring. A retrospective cohort study conducted using health insurance claims reported that serious complications occurred in less than 1% of women regardless of age or IUD type.[289]

To date there is no evidence from RCTs to suggest that any of the IUC devices available in the UK is better for nulliparous women.[31,290]

UKMEC would suggest that the advantages of using IUC in women under the age of 20 years generally outweigh any theoretical or proven risks providing there are no other factors that would affect use. The CEU further suggests that there is no restriction on the use of IUC in young women based on parity.[2]

B Use of intrauterine methods should not be restricted based on parity or age alone.

13.2 Perimenopausal women

In women using the LNG-IUS, bleeding patterns cannot be used to determine menopausal status. Guidance on the menopause and stopping contraception in women using IUC can be found in FSRH guidance on *Contraception for Women Aged Over 40 Years*.[47] The 52 mg LNG-IUS Mirena offers protection against the stimulatory effects of estrogen as part of hormone replacement therapy (see page 10). The 52 mg LNG-IUS is also helpful in reducing HMB (see page 11), which women may experience during the perimenopause. In women over the age of 45 years for whom medical treatment such as the LNG-IUS has failed, an endometrial biopsy should be considered.[3]

13.3 Women with cardiac disease

Vasovagal reaction represents a particularly serious risk for women with cardiac conditions such as single ventricle (e.g. Fontan circulation) or Eisenmenger physiology. These women may also be at particularly high risk if they become pregnant, therefore the risk of IUD/IUS insertion must be balanced against the risks associated with pregnancy. Women with arrhythmias can also experience vasovagal collapse because the heart rate is too fast to allow ventricular filling or too slow to facilitate adequate outflow.

Women with cardiac disease may not respond to standard treatment measures in the same way. Therefore, those at increased risk from vasovagal reaction should have IUC fitted in a hospital setting. More detailed guidance on contraception for women with cardiac disease can be found in separate FSRH guidance.[85]

✓ For women with cardiac disease the decision to use IUC should involve a cardiologist. The IUC should be fitted in a hospital setting if a vasovagal reaction presents a particularly high risk, for example, women with single ventricle circulation, Eisenmenger physiology, tachycardia or pre-existing bradycardia.

13.4 Women who are immunosuppressed/taking immunosuppressants

No evidence was identified on the risk of infection with IUC for women immunocompromised due to the use of drugs that affect the immune system. Any inflammatory changes in the endometrium as a result of a Cu-IUD may possibly be attenuated by immunosuppressant drugs. In theory this could reduce the efficacy of the Cu-IUD. Use of NSAIDs does not reduce the efficacy of the Cu-IUD.[291] The CEU would advise there is no evidence to support a reduction in IUC efficacy with immunosuppressant drugs.

A small retrospective case review investigating use of the 52 mg LNG-IUS in renal transplant patients found no documented cases of pelvic infection. Prospective data have suggested comparable rates of pelvic infection among HIV-positive and HIV-negative women using the Cu-IUD.[293] A conference poster abstract[294] outlining a small 5-year follow-up study reported that long-term use of the 52 mg LNG-IUS was safe in women with HIV and no cases of pelvic infection occurred among users. When compared to hormonal contraceptives IUC has not been shown to adversely affect progression of HIV,[295] increase significant genital shedding of HIV[296,297] or increase risk of transmission to sexual partners.[298,299]

13.5 Long-term corticosteroid users

Long-term corticosteroid treatment suppresses the adrenal response to stress. Consequently, women on steroid replacement therapy for Addison's disease or on long-term corticosteroids for other indications may be at greater risk of cardiovascular collapse during IUC insertion. Advice should be sought from the woman's physician regarding the need for increased steroid treatment prior to IUC insertion.

References

1 Faculty of Sexual & Reproductive Healthcare. *Intrauterine Contraception*. 2007. http://www.fsrh.org/pdfs/CEUGuidanceIntrauterineContraceptionNov07.pdf [Accessed 23 March 2015].

2 Faculty of Sexual & Reproductive Healthcare. *UK Medical Eligibility Criteria for Contraceptive Use* (UKMEC 2009). 2009. http://www.fsrh.org/pdfs/UKMEC2009.pdf [Accessed 23 March 2015].

3 National Institute for Clinical Excellence (NICE). *Heavy Menstrual Bleeding*. 2007. https://www.nice.org.uk/guidance/cg44 [Accessed 23 March 2015].

4 Dunselman GAJ, Vermeulen N, Becker C, *et al*. ESHRE guideline: management of women with endometriosis. *Hum Reprod* 2014; ePub 15 January 2014; doi:10.1093/humrep/det457.

5 Mavranezouli I, LARC Guideline Development Group. The cost-effectiveness of long-acting reversible contraceptive methods in the UK: analysis based on a decision-analytic model developed for a NICE clinical practice guideline. *Hum Reprod* 2008; **23**: 1338–1345.

6 National Institute for Clinical Excellence (NICE). *Long-acting Reversible Contraception*: *The Effective and Appropriate Use of Long-acting Reversible Contraception*. 2014. https://www.nice.org.uk/guidance/cg30 [Accessed 23 March 2015].

7 Joint Formulary Committee. British National Formulary. *British National Formulary: (BNF) 67*. London, UK: British Medical Association and Royal Pharmaceutical Society, 2014.

8 Faculty of Sexual & Reproductive Healthcare. *Emergency Contraception*. 2011 (Updated January 2012). http://www.fsrh.org/pdfs/CEUguidanceEmergencyContraception11.pdf [Accessed 23 March 2015].

9 Bayer plc. Mirena: Summary of Product Characteristics. 2013. https://www.medicines.org.uk/emc/medicine/1829 [Accessed 23 March 2015].

10 Apter D, Gemzell-Danielsson K, Hauck B, *et al*. Pharmacokinetics of two low-dose levonorgestrel-releasing intrauterine systems and effects on ovulation rate and cervical function: pooled analyses of phase II and III studies. *Fertil Steril* 2014; **101**: 1656–1662.

11 Bayer plc. Jaydess 13.5 mg intrauterine delivery system: Summary of Product Characteristics. https://www.medicines.org.uk/emc/medicine/28672/SPC/Jaydess+13.5+mg+intrauterine+delivery+system [Accessed 23 March 2015].

12 Ortiz ME, Croxatto HB. Copper-T intrauterine device and levonorgestrel intrauterine system: biological bases of their mechanism of action. *Contraception* 2007; **75(6 Suppl.)**: S16–S30.

13 Stanford JB, Mikolajczyk RT. Mechanisms of action of intrauterine devices: update and estimation of postfertilization effects. *Am J Obstet Gynecol* 2002; **187**: 1699–1708.

14 Jonsson B, Landgren BM, Eneroth P. Effects of various IUDs on the composition of cervical mucus. *Contraception* 1991; **43**: 447–458.

15 Hagenfeldt K. Intrauterine contraception with the Copper-T-Device: effect on trace elements in the endometrium, cervical mucus and plasma. *Contraception* 1972; **6**: 37–54.

16 Ortiz ME, Croxatto MB. The mode of action of IUDs. *Contraception* 1987; **36**: 37–53.

17 Silverberg SG, Haukkamaa M, Arko H. Endometrial morphology during long-term use of the levonorgestrel-releasing intrauterine devices. *Int J Gynaecol Pathol* 1986; **5**: 235–241.

18 Jones RL, Critchley HOD. Morphological and functional changes in human endometrium following intrauterine levonorgestrel delivery. *Hum Reprod* 2000; **15(Suppl.)**:162–172.

19 Kurunmäki H, Toivonen J, Lähteenmäki PL, *et al*. Pituitary and ovarian function and clinical performance during the use of a levonorgestrel-releasing intracervical contraceptive device. *Contraception* 1984; **29**: 31–43.

20 Nilsson CG, Lähteenmäki PL, Luukkainen T. Ovarian function in amenorrheic and menstruating users of a levonorgestrel-releasing intrauterine device. *Fertil Steril* 1984; **41**: 52–55.

21 Ratsula K, Toivonen J, Lähteenmäki PL, *et al*. Plasma levonorgestrel levels and ovarian function during the use of a levonorgestrel-releasing intracervical conrtaceptive device. *Contraception* 1989; **39**: 195–204.

22 Barbosa I, Bakos O, Olsson S, *et al*. Ovarian function during use of a levonorgestrel-releasing IUD. *Contraception* 1990; **42**: 51–66.

23 Barbosa I, Olsson SE, Odlind V, *et al*. Ovarian function after seven years' use of a levonorgestrel IUD. *Adv Contracept* 1995; **11**: 85–95.

24 Lewis RA, Taylor D, Natavio MF, *et al*. Effects of the levonorgestrel-releasing intrauterine system on cervical mucus quality and sperm penetrability. *Contraception* 2010; **82**: 491–496.

25 Natavio MF, Taylor D, Lewis RA, *et al*. Temporal changes in cervical mucus after insertion of the levonorgestrel-releasing intrauterine system. *Contraception* 2013; **87**: 426–431.

26 Pakarinen PI, Lähteenmäki PL, Lehtonen E, *et al*. The ultrastructure of human endometrium is altered by administration of intrauterine levonorgestrel. *Hum Reprod* 1998; **13**: 1846–1853.

27 Nilsson CG, Haukkamaa M, Vierola H, *et al*. Tissue concentrations of levonorgestrel in women using a levonorgestrel-releasing IUD. *Clin Endocrinol (Oxf)* 1982; **17**: 529–536.

28 Critchley HOD, Wang H, Jones RL, *et al*. Morphological and functional features of endometrial decidualization following long-term intrauterine levonorgestrel delivery. *Hum Reprod* 1998; **13**: 1218–1224.

29 Pekonen F, Nyman T, Lähteenmaki P. Intrauterine progestin induces continuous insulin-like growth factor-binding protein production in humans. *J Clin Endocrinol Metab* 1992; **75**: 660–664.

30 Yin M, Zhu P, Luo H, *et al*. The presence of mast cells in the human endometrium pre- and post-insertion of intrauterine devices. *Contraception* 1993; **48**: 245–254.

31 Kulier R, Helmerhorst FM, O'Brien P, *et al*. Copper containing framed intra-uterine devices for contraception. *Cochrane Database Syst Rev* 2007; **4**: CD005347.

32 O'Brien PA, Marfleet C. Frameless versus classical intrauterine device for contraception. *Cochrane Database Syst Rev* 2005; **1**: CD003282.

33 Meirik O, Rowe PJ, Peregoudov A, *et al*. The frameless copper IUD (GyneFix) and the TCu380A IUD: results of an 8-year multicenter randomized comparative trial. *Contraception* 2009; **80**: 133–141.

34 Dennis J, Webb A, Kishen M. Introduction of the GyneFix intra-uterine device into the UK: client satisfaction survey and case notes review. *J Fam Plann Reprod Health Care* 2001; **27**: 139–144.

35 French R, Sorhaindo AM, Van-Vliet-Huib AAM, *et al*. Progestogen-releasing intrauterine systems versus other forms of reversible contraceptives for contraception. *Cochrane Database Syst Rev* 2004; **3**: CD001776.

36 Heinemann K, Reed S, Moehner S, *et al*. Comparative contraceptive effectiveness of levonorgestrel-releasing and copper intrauterine devices: the European Active Surveillance Study for Intrauterine Devices. Contraception 2015; **91**: 280–283.

37 Diaz J, Bahamondes L, Monteiro I, *et al*. Acceptability and performance of the levonorgestrel-releasing intrauterine system (Mirena) in Campinas, Brazil. *Contraception* 2000; **62**: 59–61.

38 Ronnerdag M, Odlind V. Health effects of long-term use of the intrauterine levonorgestrel -releasing system: a follow-up study over 12 years of continuous use. *Acta Obstet Gynecol Scand* 1999; **78**: 716–721.

39 Sivin I, Coutinho E, Mattos S, *et al*. Prolonged intrauterine contraception: a seven-year randomized study of the levonorgestrel 20mcg/day (LNg 20) and the Copper T380 Ag IUDS. *Contraception* 1991; **44**: 473–480.

40 Andersson K, Odlind V, Rybo G. Levonorgestrel-releasing and copper-releasing (Nova T) IUDs during five years of use: a randomized comparative trial. *Contraception* 1994; **49**: 56–72.

41 Cox M, Tripp J, Blacksell S. Clinical performance of the Nova T380 intrauterine device in routine use by the UK Family Planning and Reproductive Health Research Network: 5-year report. *J Fam Plann Reprod Health Care* 2002; **28**: 69–72.

42 Nilsson CG, Allonen H, Diaz J, *et al*. Two years' experience with two levonorgestrel-releasing intrauterine devices and one copper-releasing intrauterine device: a randomized comparative performance study. *Fertil Steril* 1983; **39**: 187–192.

43 Hidalgo MM, Hidalgo-Regina C, Bahamondes MV, *et al*. Serum levonorgestrel levels and endometrial thickness during extended use of the levonorgestrel-releasing intrauterine system. *Contraception* 2009; **80**: 84–89.

44 Seeber B, Ziehr SC, Gschlieber A, *et al*. Quantitative levonorgestrel plasma level measurements in patients with regular and prolonged use of the levonorgestrel-releasing intrauterine system. *Contraception* 2012; **86**: 345–349.

45 Nelson A, Apter D, Hauck B, *et al*. Two low-dose levonorgestrel intrauterine contraceptive systems: a randomized controlled trial. *Obstet Gynecol* 2013; **122**: 1205–1213.

46 Wu S, Pickle S. Extended use of the intrauterine device: a literature review and recommendations for clinical practice. *Contraception* 2014; **89**: 495–503.

47 Faculty of Sexual & Reproductive Healthcare. *Contraception for Women Aged Over 40 Years*. 2010. http://www.fsrh.org/pdfs/ContraceptionOver40July10.pdf [Accessed 23 March 2015].

48 Weisberg E, Bateson D, McGeechan K, *et al*. A three-year comparative study of continuation rates, bleeding patterns and satisfaction in Australian women using a subdermal contraceptive implant or progestogen releasing-intrauterine system. *Eur J Contracept Reprod Health Care* 2014; **19**: 5–14.

49 Grunloh DS, Casner T, Secura GM, *et al*. Characteristics associated with discontinuation of long-acting reversible contraception within the first 6 months of use. *Obstet Gynecol* 2013; **122**: 1214–1221.

50 Short M, Dallay D, Omokanye S, *et al*. Acceptability of long-acting progestin-only contraception in Europe: a two-year prospective, non-interventional study. *Eur J Contracept Reprod Health Care* 2014; **19**: 29–38.

51 Whiteman MK, Tyler CP, Folger SG, *et al*. When can a woman have an intrauterine device inserted? A systematic review. *Contraception* 2013; **87**: 666–673.

52 Akinla O, Luukkainen T, Timonen H. Important factors in the use-effectiveness of the copper-T-200 IUD. *Contraception* 1975; **12**: 697–707.

53 White MK, Ory HW, Rooks JB, *et al*. Intrauterine device termination rates and the menstrual cycle day of insertion. *Obstet Gynecol* 1980; **55**: 220–224.

54 Edelman DA, Zipper J, Rivera M, *et al*. Timing of the IUD insertion. *Contraception* 1979; **19**: 449–454.

55 Kokonya DA, Sinei SK, Sekadde-Kigondu CB, *et al*. Experience with IUCD insertion outside of menses in Kenya. *East Afr Med J* 2000; **77**: 369–373.

56 Zhang J, Feldblum PJ, Chi IC, *et al*. Risk factors for copper T IUD expulsion: an epidemiologic analysis. *Contraception* 1992; **46**: 427–433.

57 Goldstuck ND, Mathews ML. A comparison of the actual and expected pain response following insertion of an intrauterine contraceptive device. *Clin Reprod Fertil* 1985; **3**: 65–71.

58 Goldstuck ND. Pain response following insertion of a Gravigard (Copper-7) intrauterine contraceptive device in nulliparous women. *Int J Fertil* 1981; **26**: 53–56.

59 Hubacher D, Reyes V, Lillo S, *et al*. Preventing copper intrauterine device removals due to side effects among first-time users: randomized trial to study the effect of prophylactic ibuprofen. *Hum Reprod* 2006; **21**: 1467–1472.

60 Faculty of Sexual & Reproductive Healthcare. *UK Selected Practice Recommendations for Contraceptive Use*. 2002. http://www.fsrh.org/pdfs/archive/SelectedPracticeRecommendations2002.pdf [Accessed 23 March 2015].

61 Luukkainen T, Allonen H, Haukkamaa M, *et al*. Effective contraception with the levonorgestrel-releasing intrauterine devices: 12-month report of a European multicenter study. *Contraception* 1987; **36**: 169–179.

62 World Health Organization. *Selected Practice Recommendations for Contraceptive Use* (2nd edn). 2004. http://whqlibdoc.who.int/publications/2004/9241562846.pdf [Accessed 23 March 2015].

63 World Health Organization. *Selected Practice Recommendations for Contraceptive Use*: 2008 Update. 2008. http://whqlibdoc.who.int/hq/2008/WHO_RHR_08.17_eng.pdf?ua=1 [Accessed 23 March 2015].

64 Grimes DA, Lopez LM, Schulz KF, *et al*. Immediate post-partum insertion of intrauterine devices. *Cochrane Database Syst Rev* 2010; **5**: CD003036.

65 Levi E, Cantillo E, Ades V, *et al*. Immediate postplacental IUD insertion at cesarean delivery: a prospective cohort study. *Contraception* 2012; **86**: 102–105.

66 World Health Organization. *Medical Eligibility Criteria for Contraceptive Use* (4th edn, 2009). 2010. http://whqlibdoc.who.int/publications/2010/9789241563888_eng.pdf?ua=1 [Accessed 23 March 2015].

67 Curtis KM, Chrisman CE, Mohllajee AP, *et al*. Effective use of hormonal contraceptives: Part I: combined oral contraceptive pills. *Contraception* 2006; **73**: 115–124.

68 Faculty of Sexual & Reproductive Healthcare. *Statement: Missed Pill Recommendations*. 2011. http://www.fsrh.org/pdfs/CEUStatementMissedPills.pdf [Accessed 23 March 2015].

69 Brook G, Bacon L, Evans C, *et al*. 2013 national guideline for consultations requiring sexual history taking. *Int J STD AIDS* 2014; **25**: 391–404.

70 British Association for Sexual Health and HIV CEG. *Sexually Transmitted Infections: UK National Testing and Screening Guidelines*. 2006. http://www.bashh.org/documents/59/59.pdf [Accessed 23 March 2015].

71 Medical Foundation for HIV & Sexual Health, British Association for Sexual Health and HIV. *Standards for the Management of Sexually Transmitted Infections (STIs)*. Revised and updated January 2014. http://www.medfash.org.uk/uploads/files/p18dtqli8116261rv19i61rh9n2k4.pdf [Accessed 23 March 2015].

72 British Association for Sexual Health and HIV. *Chlamydia trachomatis*: *UK Testing Guidelines*. 2010. http://www.guideline.gov/content.aspx?id=36066 [Accessed 23 March 2015].

73 British Association for Sexual Health and HIV Clinical Effectiveness Group. *United Kingdom National Guideline for Gonorrhoea Testing* 2012. 2013. http://www.bashh.org/documents/4490.pdf [Accessed 23 March 2015].

74 Faculty of Sexual & Reproductive Healthcare. *Management of Vaginal Discharge in Non-Genitourinary Medicine Settings*. 2012. http://www.fsrh.org/pdfs/CEUGuidanceVaginalDischarge.pdf [Accessed 23 March 2015].

75 Grimes DA, Lopez LM, Schulz KF. Antibiotic prophylaxis for intrauterine contraceptive device insertion. *Cochrane Database Syst Rev* 1999; **3**: CD001327.

76 Sufrin CB, Postlethwaite D, Armstrong MA, *et al*. *Neisseria gonorrhea and Chlamydia trachomatis* screening at intrauterine device insertion and pelvic inflammatory disease. *Obstet Gynecol* 2012; **120**: 1314–1321.

77 British Association for Sexual Health and HIV. *UK National Guideline for the Management of Pelvic Inflammatory Disease*. 2011. http://www.guideline.gov/content.aspx?id=36068 [Accessed 23 March 2015].

78 Gisser JM, Fields MC, Pick N, *et al*. Invasive group A streptococcus associated with an intrauterine device and oral sex. *Sex Transm Dis* 2002; **29**: 483–485.

79 Saleh S, Ahmad G, Majumdar A. Group A streptococcus necrotising fasciitis from a levonorgestrel-containing intrauterine system ('Mirena' coil). *J Obstet Gynaecol* 2011; **31**: 192–194.

80 Venkataramanasetty R, Aburawi A, Phillip H. Streptococcal toxic shock syndrome following insertion of an intrauterine device – a case report. *Eur J Contracept Reprod Health Care* 2009; **14**: 379–382.

81 Public Health England. *Group A Streptococcal Infections: Guidance and Data*. 2014. https://www.gov.uk/government/collections/group-a-streptococcal-infections-guidance-and-data [Accessed 23 March 2015].

82 Health Protection Agency Group A. Streptococcus Working Group. Interim UK guidelines for management of close community contacts of invasive group A streptococcal disease. *Commun Dis Public Health* 2004; **7**: 354–361.

83 Steer JA, Lamagni T, Healy B, *et al*. Guidelines for prevention and control of group A streptococcal infection in acute healthcare and maternity settings in the UK. *J Infect* 2012; **64**: 1–18.

84 National Institute for Clinical Excellence (NICE). *Prophylaxis Against Infective Endocarditis: Antimicrobial Prophylaxis Against Infective Endocarditis in Adults and Children Undergoing Interventional Procedures*. 2008. https://www.nice.org.uk/guidance/cg64 [Accessed 23 March 2015].

85 Faculty of Sexual & Reproductive Healthcare. *Contraceptive Choices for Women with Cardiac Disease*. 2014. http://www.fsrh.org/pdfs/CEUGuidanceContraceptiveChoicesWomenCardiacDisease.pdf [Accessed 23 March 2015].

86 Andersson K, Mattsson L, Rybo G, *et al*. Intrauterine release of levonorgestrel – a new way of adding progestogen in hormone replacement therapy. *Obstet Gynecol* 1992; **79**: 963–967.

87 Boon J, Scholten PC, Oldenhave A, *et al*. Continuous intrauterine compared with cyclic oral progestin administration in perimenopausal HRT. *Maturitas* 2003; **46**: 69–77.

88 Raudaskoski T, Tapanainen J, Tomás E, *et al*. Intrauterine 10µg and 20µg levonorgestrel systems in postmenopausal women receiving oral oestrogen replacement therapy: clinical, endometrial and metabolic response. *Br J Obstet Gynaecol* 2002; **109**: 136–144.

89 Varila E, Wahlstrom T, Rauramo I. A 5-year follow-up study on the use of a levonorgestrel intrauterine system in women receiving hormone replacement therapy. *Fertil Steril* 2001; **76**: 969–973.

90 Wollter-Svensson L, Stadberg E, Andersson K, *et al*. Intrauterine administration of levonorgestrel 5 and 10 mg/24 hours in perimenopausal hormone replacement therapy. *Acta Obstet Gynecol Scand* 1997; **76**: 449–454.

91 Wan YL, Holland C. The efficacy of levonorgestrel intrauterine systems for endometrial protection: a systematic review. *Climacteric* 2011; **14**: 622–632.

92 Gallos ID, Shehmar M, Thangaratinam S, *et al*. Oral progestogens vs levonorgestrel-releasing intrauterine system for endometrial hyperplasia: a systematic review and metaanalysis. *Am J Obstet Gynecol* 2010; **203**: 547–510.

93 Gallos ID, Krishan P, Shehmar M, *et al*. LNG-IUS versus oral progestogen treatment for endometrial hyperplasia: a long-term comparative cohort study. *Hum Reprod* 2013; **28**: 2966–2971.

94 Daniel Y, Inbar M, Bar-Am A, *et al*. The effects of tamoxifen treatment of the endometrium. *Fertil Steril* 1996; **65**: 1083–1089.

95 Chin J, Konje JC, Hickey M. Levonorgestrel intrauterine system for endometrial protection in women with breast cancer on adjuvant tamoxifen. *Cochrane Database Syst Rev* 2009; **4**: CD007245.

96 Hubacher D, Grimes DA. Noncontraceptive health benefits of intrauterine devices: a systematic review. *Obstet Gynecol Surv* 2002; **57**: 120–128.

97 Beining RM, Dennis LK, Smith EM, *et al*. Meta-analysis of intrauterine device use and risk of endometrial cancer. *Ann Epidemiol* 2008; **18**: 492–499.

98 Castellsague X, Diaz M, Vaccarella S, *et al*. Intrauterine device use, cervical infection with human papillomavirus, and risk of cervical cancer: a pooled analysis of 26 epidemiological studies. *Lancet Oncol* 2011; **12**: 1023–1031.

99 Tworoger SS, Fairfiled KM, Colditz GA, *et al*. Association of oral contraceptive use, other contraceptive methods, and infertility with ovarian cancer risk. *Am J Epidemiol* 2007; **166**: 894–901.

100 Ness RB, Dodge RC, Edwards RP, *et al*. Contraception methods beyond oral contraceptives and tubal ligation, and risk of ovarian cancer. *Ann Epidemiol* 2011; **21**: 188–196.

101 Nilsson CG, Luukkainen T, Diaz J, *et al*. Clinical performance of a new levonorgestrel-releasing intrauterine device. A randomized comparison with a Nova-T-Copper device. *Contraception* 1982; **25**: 345–356.

102 Kelekci S, Kelekci KH, Yilmaz B. Effects of levonorgestrel-releasing intrauterine system and T380A intrauterine copper device on dysmenorrhea and days of bleeding in women with and without adenomyosis. *Contraception* 2012; **86**: 458–463.

103 Lindh I, Milsom I. The influence of intrauterine contraception on the prevalence and severity of dysmenorrhea: a longitudinal population study. *Hum Reprod* 2013; **28**: 1953–1960.

104 Bayoglu TY, Dilbaz B, Altinbas SK, *et al*. Postoperative medical treatment of chronic pelvic pain related to severe endometriosis: levonorgestrel-releasing intrauterine system versus gonadotropin-releasing hormone analogue. *Fertil Steril* 2011; **95**: 492–496.

105 Cho S, Nam A, Kim H, *et al*. Clinical effects of the levonogestrel-releasing intrauterine device in patients with adenomyosis. *Am J Obstet Gynecol* 2008; **198**: 373 e1–e7.

106 Crosignani PG, Vercellini P, Mosconi P, *et al*. Levonorgestrel-releasing intrauterine device versus hysteroscopic endometrial resection in the treatment of dysfunctional uterine bleeding. *Obstet Gynecol* 1997; **90**: 257–263.

107 Fedele L, Bianchi S, Raffaelli R, *et al*. Treatment of adenomyosis-associated menorrhagia with a levonorgestrel-releasing intrauterine device. *Fertil Steril* 1997; **68**: 426–429.

108 Lockhat FB, Emembolu JO, Konje JC. The efficacy, side-effects and continuation rates in women with symptomatic endometriosis undergoing treatment with an intra-uterine administered progestogen (levonorgestrel): a 3 year follow-up. *Hum Reprod* 2005; **20**: 789–793.

109 Ozdegirmenci O, Kayikcioglu F, Akgul MA, *et al*. Comparison of levonorgestrel intrauterine system versus hysterectomy on efficacy and quality of life in patients with adenomyosis. *Fertil Steril* 2011; **95**: 497–502.

110 Petta CA, Ferriani RA, Abaro MS, *et al*. Randomized clinical trial of a levonorgestrel-releasing intrauterine system and a depot GnRH analogue for the treatment of chronic pelvic pain in women with endometriosis. *Hum Reprod* 2005; **20**: 1993–1998.

111 Sheng J, Zhang WY, Zhang JP, *et al*. The LNG-IUS study on adenomyosis: a 3-year follow-up study on the efficacy and side effects of the use of the levonorgestrel intrauterine system for the treatment of dysmenorrhoea associated with adenomyosis. *Contraception* 2009; **79**: 189–193.

112 Tanmahasamut P, Rattanachaiyanont M, Angsuwathana S, *et al*. Postoperative levonorgestrel-releasing intrauterine system for pelvic endometriosis-related pain: a randomized controlled trial. *Obstet Gynecol* 2012; **119**: 519–526.

113 Abou-Setta AM, Houston B, Al-Inany HG, *et al*. Levonorgestrel-releasing intrauterine device (LNG-IUD) for symptomatic endometriosis following surgery. *Cochrane Database Syst Rev* 2013; **1**: CD005072.

114 European Society of Human Reproduction and Embryology (ESHRE). *Guideline on the Management of Women with Endometriosis*. 2013. http://www.eshre.eu/Guidelines-and-Legal/Guidelines/Endometriosis-guideline.aspx [Accessed 23 March 2015].

115 Andersson JK, Rybo G. Levonorgestrel-releasing intrauterine device in the treatment of menorrhagia. *Br J Obstet Gynaecol* 1990; **97**: 690–694.

116 Grigorieva V, Chen-Mok M, Tarasova M, *et al*. Use of a levonorgestrel-releasing intrauterine system to treat bleeding related to uterine leiomyomas. *Fertil Steril* 2003; **79**: 1194–1198.

117 Irvine G. A., Campbell-Brown MB, Lumsden MA, *et al*. Randomised comparative trial of the levonorgestrel intrauterine system and norethisterone for treatment of idiopathic menorrhagia. *Br J Obstet Gynaecol* 1998; **105**: 592–598.

118 Lethaby AE, Cooke I, Rees M. Progesterone or progestogen-releasing intrauterine systems for heavy menstrual bleeding. *Cochrane Database Syst Rev* 2005; **3**: CD002126.

119 Matteson KA, Rahn DD, Wheeler TL, *et al*. Nonsurgical management of heavy menstrual bleeding: a systematic review. *Obstet Gynecol* 2013; **121**: 632–643.

120 Mercorio F, De Simone R, Di Spiezio Sardo A, *et al*. The effect of a levonorgestrel-releasing intrauterine device in the treatment of myoma-related menorrhagia. *Contraception* 2003; **67**: 277–280.

121 Gupta J, Kai J, Middleton L, *et al*. Levonorgestrel intrauterine system versus medical therapy for menorrhagia. *N Engl J Med* 2013; **368**: 128–137.

122 Mithra Pharmaceuticals. Tresovelle 20 micrograms/24 hours Intrauterine Delivery System: Summary of Product Characteristics. 2014. http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con395240.pdf [Accessed 23 March 2015].

123 Gemzell-Danielsson K, Schellschmidt I, Apter DA. A randomized phase II study describing the efficacy, bleeding profile, and safety of two low-dose levonorgestrel-releasing intrauterine contraceptive systems and Mirena. *Fertil Steril* 2012; **97**: 616–622.

124 French RS, Cowan FM, Mansour DJA, *et al*. Implantable contraceptives (subdermal implants and hormonally impregnated intrauterine systems) versus other forms of reversible contraceptives: two systematic reviews to assess relative effectiveness, acceptability, tolerability and cost-effectiveness. *Health Technol Assess* 2000; **4**: i–iv, 1–107.

125 Bastianelli C, Farris M, Benagiano G. Use of the levonorgestrel-releasing intrauterine system, quality of life and sexuality. Experience in an Italian family planning center. *Contraception* 2011; **84**: 402–408.

126 Enzlin P, Weyers S, Janssens D, *et al*. Sexual functioning in women using levonorgestrel-releasing intrauterine systems as compared to copper intrauterine devices. *J Sex Med* 2012; **9**: 1065–1073.

127 Halmesmaki K, Hurskainen R, Teperi J, *et al*. The effect of hysterectomy or levonorgestrel-releasing intrauterine system on sexual functioning among women with menorrhagia: a 5-year randomised controlled trial. *Br J Obstet Gynaecol* 2007; **114**: 563–568.

128 Li RH, Lo SS, Teh DK, *et al*. Impact of common contraceptive methods on quality of life and sexual function in Hong Kong Chinese women. *Contraception* 2004; **70**: 474–482.

129 Martin-Loeches M, Ortí RM, Monfort M, *et al*. A comparative analysis of the modification of sexual desire of users of oral hormonal contraceptives and intrauterine contraceptive devices. *Eur J Contracept Reprod Health Care* 2003; **8**: 129–134.

130 Dal'Ava N, Bahamondes L, Bahamondes MV, *et al*. Body weight and composition in users of levonorgestrel-releasing intrauterine system. *Contraception* 2012; **86**: 350–353.

131 Jenabi E, Alizade SM, Baga RI. Continuation rates and reasons for discontinuing TCu380A IUD use in Tabriz, Iran. *Contraception* 2006; **74**: 483–486.

132 Wong RC, Bell RJ, Thunuguntla K, *et al*. Implanon users are less likely to be satisfied with their contraception after 6 months than IUD users. *Contraception* 2009; **80**: 452–456.

133 McGavigan CJ, Dockery P, Metaxa-Mariatou V, *et al*. Hormonally mediated disturbance of angiogenesis in the human endometrium after exposure to intrauterine levonorgestrel. *Hum Reprod* 2003; **18**: 77–84.

134 Skinner JL, Riley SR, Gebbie AE, *et al*. Regulation of matrix metalloproteinase-9 in endometrium during the menstrual cycle and following administration of intrauterine levonorgestrel. *Hum Reprod* 1999; **14**: 793–799.

135 Suvisaari J, Lahteenmaki P. Detailed analysis of menstrual bleeding patterns after postmenstrual and postabortal insertion of a copper IUD or a levonorgestrel-releasing intrauterine system. *Contraception* 1996; **54**: 201–208.

136 Datey S, Gaur LN, Saxena BN. Vaginal bleeding patterns of women using different contraceptive methods (implants, injectables, IUDs, oral pills): an Indian experience. *Contraception* 1995; **51**: 155–165.

137 Hubacher D, Chen PL, Park S. Side effects from the copper IUD: do they decrease over time? *Contraception* 2009; **79**: 356–362.

138 Elsedeek MS. Puerperal and menstrual bleeding patterns with different types of contraceptive device fitted during elective cesarean delivery. *Int J Gynaecol Obstet* 2012; **116**: 31–34.

139 Gemzell-Danielsson K, Inki P, Boubli L, *et al*. Bleeding pattern and safety of consecutive use of the levonorgestrel-releasing intrauterine system (LNG-IUS) – a multicentre prospective study. *Hum Reprod* 2010; **25**: 354–359.

140 Bahamondes L, Espejo-arce X, Hidalgo MM, *et al*. A cross-sectional study of the forearm bone density of long-term users of levonorgestrel-releasing intrauterine system. *Hum Reprod* 2006; **21**: 1316–1319.

141 Bahamondes MV, Monteiro I, Castro S, *et al*. Prospective study of the forearm bone mineral density of long-term users of the levonorgestrel-releasing intrauterine system. *Hum Reprod* 2010; **25**: 1158–1164.

142 Collaborative Group on Hormonal Factors in Breast Cancer. Breast cancer and hormonal contraceptives: collaborative reanalysis of individual data on 53 297 women with breast cancer and 100 239 women without breast cancer from 54 epidemiological studies. *Lancet* 1996; **347**: 1713–1727.

143 Lyytinen HK, Dyba T, Ylikorkala O, *et al*. A case-control study on hormone therapy as a risk factor for breast cancer in Finland: intrauterine system carries a risk as well. *Int J Cancer* 2010; **126**: 483–489.

144 Dinger J, Bardenheuer K, Minh TD. Levonorgestrel-releasing and copper intrauterine devices and the risk of breast cancer. *Contraception* 2011; **83**: 211–217.

145 Backman T, Rauramo I, Jaakola K, *et al*. Use of the levonorgestrel-releasing intrauterine system and breast cancer. *Obstet Gynecol* 2005; **106**: 813–817.

146 Trinh XB, Tjalma WAA, Makar AP, *et al*. Use of the levonorgestrel-releasing intrauterine system in breast cancer patients. *Contraception* 2008; **90**: 17–22.

147 Lidegaard O, Nielson L, Skovlund CW, *et al*. Venous thrombosis in users of non-oral hormonal contraception: follow-up study, Denmark 2001–10. *BMJ* 2012; **344**: e2990.

148 Lidegaard O, Nielson LH, Skovlund CW, *et al*. Risk of venous thromboembolism from use of oral contraceptives containing different progestogens and oestrogen doses: Danish cohort study, 2001–9. *BMJ* 2011; **343**: d6423.

149 Mantha S, Karp R, Raghavan V, *et al*. Assessing the risk of venous thromboembolic events in women taking progestin-only contraception: a meta-analysis. *BMJ* 2012; **345**: e4944.

150 World Health Organization. Cardiovascular disease and use of oral and injectable progestogen-only contraceptives and combined injectable contraceptives. *Contraception* 1998; **57**: 315–324.

151 Chakhtoura Z, Canonico M, Gompel A, *et al*. Progestogen-only contraceptives and the risk of acute myocardial infarction: a meta-analysis. *J Clin Endocrinol Metab* 2011; **96**: 1169–1174.

152 Morin-Papunen L, Martikainen H, McCarthy MI, *et al*. Comparison of metabolic and inflammatory outcomes in women who used oral contraceptives and the levonorgestrel-releasing intrauterine device in a general population. *Am J Obstet Gynecol* 2008; **199**: 529.e1–529.e10.

153 Ng YW, Liang S, Singh K. Effects of Mirena (levonorgestrel-releasing intrauterine system) and Ortho Gynae T380 intrauterine copper device on lipid metabolism – a randomized comparative study. *Contraception* 2009; **79**: 24–28.

154 Selim MF, Hussein AF. Endothelial function in women using levonorgestrel-releasing intrauterine system (LNG-IUS). *Contraception* 2013; **87**: 396–403.

155 Ory HW. Ectopic pregnancy and intrauterine contraceptive devices: new perspectives. The Women's Health Study. *Obstet Gynecol* 1981; **57**: 137–144.

156 Rossing MA, Daling JR, Voigt LF, *et al*. Current use of an intrauterine device and risk of tubal pregnancy. *Epidemiology* 1993; **4**: 252–258.

157 World Health Organization. A multinational case-control study of ectopic pregnancy. *Clin Reprod Fertil* 1985; **3**: 131–143.

158 Xiong X, Buekens P, Wollast E. IUD use and the risk of ectopic pregnancy: a meta-analysis of case-control studies. *Contraception* 1995;**52**: 23–34.

159 Vessey M, Meisler L, Flavel R, *et al*. Outcome of pregnancy in women using different methods of contraception. *Br J Obstet Gynaecol* 1979; **86**: 548–556.

160 Backman T, Rauramo I, Huhtala S, *et al*. Pregnancy during the use of levonorgestrel intrauterine system. *Am J Obstet Gynecol* 2004; **190**: 50–54.

161 Melvin L, Scott J, Craik J. Jaydess® levonorgestrel intrauterine system. *J Fam Plann Reprod Health Care* 2014; **40**: 165–169.

162 Rosenberg MJ, Foldesy R, Mishell DR Jr, *et al*. Performance of the TCu380A and Cu-Fix IUDs in an international randomized trial. *Contraception* 1996; **53**: 197–203.

163 D'Souza RE, Master T, Bounds W, *et al*. Randomised controlled trial assessing the acceptability of GyneFix versus Gyne-T380S for emergency contraception. *J Fam Plann Reprod Health Care* 2003; **29**: 23–29.

164 Rowe PJ, Reinprayoon D, Koetswang S, *et al*. The TCu 380A IUD and the frameless IUD "the Flexigard": interim three-year data from an international multicenter trial. *Contraception* 1995; **52**: 77–83.

165 Wu S, Hu J, Wildemeersch D. Performance of the frameless GyneFix and the TCu380A IUDs in a 3-year multicenter, randomized, comparative trial in parous women. *Contraception* 2000; **61**: 91–98.

166 Aoun J, Dines VA, Stovall DW, *et al*. Effects of age, parity, and device type on complications and discontinuation of intrauterine devices. *Obstet Gynecol* 2014; **123**: 585–592.

167 World Health Organization (WHO). *Mechanism of Action, Safety and Efficacy of Intrauterine Devices*. 1987. http://whqlibdoc.who.int/trs/WHO_TRS_753.pdf [Accessed 23 March 2015].

168 Royal College of Obstetricians and Gynaecologists (RCOG). *The Care of Women Requesting Induced Abortion* (Evidence-based Guideline No. 7). London, UK: RCOG, 2011.

169 World Health Organization (WHO). *Safe Abortion: Technical and Policy Guidance for Health Systems* (2nd edn). Geneva, Switzerland: WHO, 2012.

170 McNicholas C, Hotchkiss T, Madden T, *et al*. Immediate postabortion intrauterine device insertion: continuation and satisfaction. *Womens Health Issues* 2012; **22**: e365–e369.

171 Grimes DA, Lopez LM, Schulz KF, et al. Immediate postabortal insertion of intrauterine devices. *Cochrane Database Syst Rev* 2010; **6**: CD001777.

172 Langston AM, Joslin-Roher SL, Westhoff CL. Immediate postabortion access to IUDs, implants and DMPA reduces repeat pregnancy within 1 year in a New York City practice. *Contraception* 2014; **89**: 103–108.

173 Bednarek PH, Creinin MD, Reeves MF, *et al*. Immediate versus delayed IUD insertion after uterine aspiration. *N Engl J Med* 2011; **364**: 2208–2217.

174 Ames CM, Norman WV. Preventing repeat abortion in Canada: is the immediate insertion of intrauterine devices postabortion a cost-effective option associated with fewer repeat abortions? *Contraception* 2012; **85**: 51–55.

175 Fox MC, Oat-Judge J, Severson K, *et al*. Immediate placement of intrauterine devices after first and second trimester pregnancy termination. *Contraception* 2011; **83**: 34–40.

176 Cameron ST, Berugoda N, Johnstone A, *et al*. Assessment of a "fast-track" referral service for intrauterine contraception following early medical abortion. *J Fam Plann Reprod Health Care* 2012; **38**: 175–178.

177 Saav I, Stephansson O, Gemzell-Danielsson K. Early versus delayed insertion of intrauterine contraception after medical abortion – a randomized controlled trial. *PLoS One* 2012; **7**: e48948.

178 Tsikouras P, Vrachnis N, Grapsa A, *et al*. IUD in first-trimester abortion: immediate intrauterine contraceptive devices insertion vs delayed insertion following the next menstruation bleeding. *Arch Gynecol Obstet* 2014; **290**: 99–105.

179 Hu X, Li L, Zou Y, *et al*. A multicenter comparative study of UCu200, TCu380A, and medicated-IUD devices inserted immediately after vacuum aspiration. *Int J Gynaecol Obstet* 2013; **122**: 65–69.

180 Steenland MW, Tepper NK, Curtis KM, *et al*. Intrauterine contraceptive insertion postabortion: a systematic review. *Contraception* 2011; **84**: 447–464.

181 Kapp N, Curtis KM. Intrauterine device insertion during the postpartum period: a systematic review. *Contraception* 2009; **80**: 327–336.

182 Goldstuck ND, Steyn PS. Intrauterine contraception after cesarean section and during lactation: a systematic review. *Int J Womens Health* 2013; **5**: 811–818.

183 Christensen JT, Boldsen JL, Westergaard JG. Functional ovarian cysts in premenopausal and gynecologically healthy women. *Contraception* 2002; **66**: 153–157.

184 Inki P, Hurskainen R, Palo P, *et al*. Comparison of ovarian cyst formation in women using the levonorgestrel-releasing intrauterine system vs. hysterectomy. *Ultrasound Obstet Gynecol* 2002; **20**: 381–385.

185 Robinson GE, Bounds W, Kubba AA, *et al*. Functional ovarian cysts associated with the levonorgestrel releasing intrauterine device. *Br J Fam Plann* 1989; **14**: 131–132.

186 Zapata LB, Whiteman MK, Marchbanks PA, *et al*. Intrauterine device use among women with ovarian cancer: a systematic review. *Contraception* 2010; **82**: 38–40.

187 Centres for Disease Control and Prevention. *US Medical Eligibility Criteria for Contraceptive Use. MMWR Morb Mortal Wkly Rep* 2010; **59**: 1–85.

188 Hubacher D, Grimes DA, Gemzell-Danielsson K. Pitfalls of research linking the intrauterine device to pelvic inflammatory disease. *Obstet Gynecol* 2013; **121**: 1091–1098.

189 Farley TNM, Rosenberg M, Rowe PJ, *et al*. Intrauterine contraceptive devices and pelvic inflammatory disease: an international perspective. *Lancet* 1992; **339**: 785–788.

190 Steenland MW, Zapata LB, Brahmi D, *et al*. Appropriate follow up to detect potential adverse events after initiation of select contraceptive methods: a systematic review. *Contraception* 2013; **87**: 611–624.

191 Toivonen J, Luukkainen T, Allonen H. Protective effect of intrauterine release of levonorgestrel on pelvic infection: three years' experience of levonorgestrel- and copper-releasing intrauterine devices. *Obstet Gynecol* 1991; **77**: 261–264.

192 Sivin I, Stern J. Health during prolonged use of levonorgestrel 20 mg/d and the Copper TCu 380Ag intrauterine contraceptive devices: a multicenter study. *Fertil Steril* 1994; **61**: 70–77.

193 Caliskan E, Oztürk N, Dilbaz B, *et al*. Analysis of risk factors associated with uterine perforation by intrauterine devices. *Eur J Contracept Reprod Health Care* 2003; **155**: 150.

194 Harrison-Woolrych M, Ashton J, Coulter D. Uterine perforation on intrauterine device insertion: is the incidence higher than previously reported? *Contraception* 2003; **67**: 53–56.

195 Kaislasuo J, Suhonen S, Gissler M, *et al*. Intrauterine contraception: incidence and factors associated with uterine perforation – a population-based study. *Hum Reprod* 2012; **27**: 2658–2663.

196 Zhou L, Harrison-Woolrych M, Coulter DM. Use of the New Zealand Intensives Medicines Monitoring Programme to study the levonorgestrel-releasing intrauterine device (Mirena). *Pharmacoepidemiol Drug Saf* 2003; **12**: 371–377.

197 Andersson K, Ryde-Blomqvist E, Lindell K, *et al*. Perforations with intrauterine devices: report from a Swedish survey. *Contraception* 1998; **57**: 251–255.

198 Van Grootheest K, Sachs B, Harrison-Woolrych M, *et al*. Uterine perforation with the levonorgestrel-releasing intrauterine device: analysis of reports from four national pharmacovigilance centres. *Drug Saf* 2011; **34**: 83–88.

199 Heinemann K, Reed S, Moehner S, *et al*. Risk of uterine perforation with levonorgestrel-releasing and copper intrauterine devices in the European Active Surveillance Study on Intrauterine Devices. *Contraception* 2015; **91**: 274–297.

200 Alnakash AH. Influence of IUD perceptions on method discontinuation. *Contraception* 2008; **78**: 290–293.

201 Glasier A, Scorer J, Bigrigg A. Attitudes of women in Scotland to contraception: a qualitative study to explore the acceptability of long-acting methods. *J Fam Plann Reprod Health Care* 2008; **34**: 213–217.

202 Wilson JC. A prospective New Zealand study of fertility after removal of copper intrauterine contraceptive devices for conception and because of complications: a four year study. *Am J Obstet Gynecol* 1989; **160**: 391–396.

203 Hov GG, Skjeldestad FE, Hilstad T. Use of IUD and subsequent fertility – follow-up after participation in a randomized clinical trial. *Contraception* 2007; **75**: 88–92.

204 Vessey MP, Lawless M, McPherson K, *et al*. Fertility after stopping use of intrauterine contraceptive device. *BMJ* 1983; **286**: 106.

205 Doll H, Vessey M, Painter R. Return of fertility in nulliparous women after discontinuation of the intrauterine device: comparison with women discontinuing other methods of contraception. *Br J Obstet Gynaecol* 2001; **108**: 304–314.

206 Mansour D, Gemzell-Danielsson K, Inki P, *et al*. Fertility after discontinuation of contraception: a comprehensive review of the literature. *Contraception* 2011; **84**: 465–477.

207 Farmer M, Webb A. Intrauterine device insertion-related complications: can they be predicted? *J Fam Plann Reprod Health Care* 2003; **29**: 227–231.

208 Acker D, Boehm FH, Askew DE, *et al*. Electrocardiogram changes with intrauterine contraceptive device insertion. *Am J Obstet Gynecol* 1973; **15**: 458–461.

209 Anzar R, Reynoso L, Eligio L, *et al*. Electrocardiographic changes induced by insertion of an intrauterine device and other uterine manipulations. *Fertil Steril* 1976; **27**: 92–96.

210 Faculty of Sexual & Reproductive Healthcare. *Service Standards for Resuscitation in Sexual and Reproductive Health Services*. 2013. http://www.fsrh.org/pdfs/Resucitation_January_2013.pdf [Accessed 23 March 2015].

211 Faculty of Sexual & Reproductive Healthcare. *Statement on the Management of Persistent Bradycardia During the Fitting of Intrauterine Contraceptives*. 2009. http://www.fsrh.org/pdfs/StatementBradycardia.pdf [Accessed 23 March 2015].

212 Guzel AB, Ilkit M, Akar T, *et al*. Evaluation of risk factors in patients with vulvovaginal candidiasis and the value of chromID Candida agar versus CHROMagar Candida for recovery and presumptive identification of vaginal yeast species. *Med Mycol* 2011; **49**: 16–25.

213 Auler ME, Morreira D, Rodrigues FF, *et al*. Biofilm formation on intrauterine devices in patients with recurrent vulvovaginal candidiasis. *Med Mycol* 2010; **48**: 211–216.

214 Chassot F, Negri M, Svidzinski A, *et al*. Can intrauterine contraceptive devices be a Candida albicans reservoir. *Contraception* 2008; **77**: 359.

215 Donders GGG, Berger J, Heuninckx H, *et al*. Vaginal flora changes on Pap smears after insertion of levonorgestrel-releasing intrauterine device. *Contraception* 2011; **83**: 352–356.

216 Lessard T, Simoes JA, Discacciati MG, *et al*. Cytological evaluation and investigation of the vaginal flora of long-term users of the levonorgestrel-releasing intrauterine system (LNG-IUS). *Contraception* 2008; **77**: 30–33.

217 Joesoef MR, Karundeng A, Runtupalit C, *et al*. High rate of bacterial vaginosis among women with intrauterine devices in Mando, Indonesia. *Contraception* 2001; **64**: 169–172.

218 British Association for Sexual Health and HIV. *UK National Guideline on the Management of Bacterial Vaginosis*. 2012. http://www.bashh.org/documents/4413.pdf [Accessed 23 March 2015].

219 British Association for Sexual Health and HIV Clinical Effectiveness Group. *United Kingdom National Guideline on the Management of Vulvovaginal Candidiasis*. 2007. http://www.bashh.org/documents/1798.pdf [Accessed 23 March 2015].

220 Faculty of Sexual & Reproductive Healthcare. *Service Standards for Sexual and Reproductive Healthcare*. 2013. http://www.fsrh.org/pdfs/All_Service_standards_January_2013.pdf [Accessed 23 March 2015].

221 Harrison-Woolrych M, Ashton J, Coulter D. Uterine perforation on intrauterine device insertion: is the incidence higher than previously reported? *Contraception* 2003; **67**: 53–56.

222 Faculty of Sexual & Reproductive Healthcare. *Service Standards on Obtaining Valid Consent in Sexual Health Services*. 2011. http://www.fsrh.org/pdfs/ServiceStandardsObtainingValidConsent.pdf [Accessed 23 March 2015].

223 Allen RH, Carey MS, Raker C, *et al*. A prospective cohort study of pain with intrauterine device insertion among women with and without vaginal deliveries. *J Obstet Gynaecol* 2014; **34**: 263–267.

224 Hubacher D, Reyes V, Lillo S, *et al*. Pain from copper intrauterine device insertion: randomized trial of prophylactic ibuprofen. *Am J Obstet Gynecol* 2006; **195**: 1272–1277.

225 Maguire K, Davis A, Rosario Tejeda L, *et al*. Intracervical lidocaine gel for intrauterine device insertion: a randomized controlled trial. *Contraception* 2012; **86**: 214–219.

226 Kaislasuo J, Heikinheimo O, Lahteenmaki P, *et al*. Predicting painful or difficult intrauterine device insertion in nulligravid women. *Obstet Gynecol* 2014; **124**: 345–353.

227 Edelman AB, Schaefer E, Olson A, *et al*. Effects of prophylactic misoprostol administration prior to intrauterine device insertion in nulliparous women. *Contraception* 2011; **84**: 234–239.

228 Heikinheimo O, Inki P, Kunz M, *et al*. Double-blind randomized, placebo-controlled study on the effect of misoprostol on ease of consecutive insertion of the levonorgestrel-releasing intrauterine system. *Contraception* 2010; **81**: 481–486.

229 Li YT, Kuo TC, Kuan LC, *et al*. Cervical softening with vaginal misoprostol before intrauterine device insertion. *Int J Gynaecol Obstet* 2005; **89**: 67–68.

230 Saav I, Aronsson A, Marions L, *et al*. Cervical priming with sublingual misoprostol prior to insertion of an intrauterine device in nulliparous women: a randomized controlled trial. *Hum Reprod* 2007; **22**: 2647–2652.

231 Allen RH, Bartz D, Grimes DA, *et al*. Interventions for pain with intrauterine device insertion. *Cochrane Database Syst Rev* 2009; **3**: CD007373.

232 Bednarek PH, Micks EA, Edelman AB, *et al*. The effect of nitroprusside on IUD insertion experience in nulliparous women: a pilot study. *Contraception* 2013; **87**: 421–425.

233 Micks EA, Jensen JT, Bednarek PH. The effect of nitroglycerin on the IUD insertion experience in nulliparous women: a pilot study. *Contraception* 2014; **90**: 60–65.

234 Pergialiotis V, Vlachos DG, Protopappas A, *et al*. Analgesic options for placement of an intrauterine contraceptive: a meta-analysis. *Eur J Contracept Reprod Health Care* 2014; **19**: 149–160.

235 Bednarek PH, Creinin MD, Reeves MF, *et al*. Pain with IUD insertion following prophylactic ibuprofen: a randomized trial. *Contraception* 2010; **82**: 194–195.

236 Chor J, Bregand-White J, Golobof A, *et al*. Ibuprofen prophylaxis for levonorgestrel-releasing intrauterine system insertion: a randomized controlled trial. *Contraception* 2012; **85**: 558–562.

237 Chor J, Harwood B, Cowett A. Ibuprofen prophylaxis for levonorgestrel-releasing intrauterine system insertion: a randomized controlled trial. *Contraception* 2010; **82**: 201–202.

238 Jensen HH, Blaabjerg J, Lyndrup J. Prophylactic use of prostaglandin synthesis inhibitors in connection with IUD insertion [in Danish]. *Ugeskr Laeger* 1998; **160**: 6958–6961.

239 Cameron ST, Glasier A, Cooper A, *et al*. Does a full bladder assist insertion of intrauterine contraception? A randomised trial. *J Fam Plann Reprod Health Care* 2013; **39**: 207–210.

240 Akintomide H, Sewell RDE, Stephenson JM. The use of local anaesthesia for intrauterine device insertion by health professionals in the UK. *J Fam Plann Reprod Health Care* 2013; **39**: 276–280.

241 Allen RH, Raker C, Goyal V. Higher dose cervical 2% lidocaine gel for IUD insertion: a randomized controlled trial. *Contraception* 2013; **88**: 730–736.

242 McNicholas CP, Madden T, Zhao Q, *et al*. Cervical lidocaine for IUD insertional pain: a randomized controlled trial. *Am J Obstet Gynecol* 2012; **207**: 384–386.

243 Duncan I, McKinley C, Pinion S, *et al*. A double-blind, randomized, placebo-controlled trial of prilocaine and felypressin (Citanest and Octapressin) for the relief of pain associated with cervical biopsy and treatment with the Semm coagulator. *J Low Genital Tract Dis* 2005; **9**: 171–175.

244 Harper D. Paracervical block diminishes cramping associated with cryosurgery. *J Fam Pract* 1997; **44**: 71–75.

245 Lee E, Ozumba E, Bevan J. A randomized trial of Citanest with Octapressin for relief of pain associated with laser vaporization of the cervix. *Br J Obstet Gynaecol* 1986; **93**: 967–969.

246 Readman E, Maher P. Pain relief and outpatient hysteroscopy: a literature review. *J Am Assoc Gynaecol Laparoscopists* 2004; **11**: 315–319.

247 Mody SK, Kiley J, Rademaker A, *et al*. Pain control for intrauterine device insertion: a randomized trial of 1% lidocaine paracervical block. *Contraception* 2012; **86**: 704–709.

248 Cirik DA, Taskin EA, Tuglu A, *et al*. Paracervical block with 1% lidocaine for pain control during intrauterine device insertion: a prospective, single-blinded, controlled study. *Int J Reprod Contracept Obstet Gynecol* 2013; **2**: 263–267.

249 Grimes D, Hubacher D, Lopez LM, *et al*. Non-steroidal anti-inflammatory drugs for heavy bleeding or pain associated with intrauterine-device use. *Cochrane Database Syst Rev* 2006; **4**: CD006034.

250 Tolcher R. Intrauterine techniques: contentious or consensus opinion. *J Fam Plann Reprod Health Care* 2003; **29**: 21–24.

251 The International Planned Parenthood Foundation International Medical Advisory Panel (IMAP). Statement on intrauterine devices. *IPPF Med Bull* 1995; **29**: 1–4.

252 Kasliwal AP, Webb A. Intrauterine device insertions: setting our standards. *J Fam Plann Reprod Health Care* 2002; **28**: 157–158.

253 Faculty of Sexual & Reproductive Healthcare. *Service Standards for Record Keeping.* 2010. http://www.fsrh.org/pdfs/ServiceStandardsRecordKeeping.pdf [Accessed 23 March 2015].

254 Faculty of Sexual & Reproductive Healthcare. *The Management of Unscheduled Bleeding in Women Using Hormonal Contraception*. 2009. http://www.fsrh.org/pdfs/UnscheduledBleedingMay09.pdf [Accessed 23 March 2015].

255 Sordal T, Inki P, Draeby J, *et al*. Management of initial bleeding or spotting after levonorgestrel-releasing intrauterine system placement: a randomized controlled trial. *Obstet Gynecol* 2013; **121**: 934–941.

256 Warner P, Guttinger A, Glasier AF, *et al*. Randomized placebo-controlled trial of CDB-2914 in new users of a levonorgestrel-releasing intrauterine system shows only short-lived amelioration of unscheduled bleeding. *Hum Reprod* 2010; **25**: 345–353.

257 Gemzell-Danielsson K, Mansour D, Fiala C, *et al*. Management of pain associated with the insertion of intrauterine contraceptives. *Hum Reprod Update* 2013; **19**: 419–427.

258 Bounds W, Hutt S, Kubba A, *et al*. Randomised comparative study in 217 women of three disposable plastic IUCD thread retrievers. *Br J Obstet Gynaecol* 1992; **99**: 915–919.

259 Pakarinen PI, Suvisaari J, Luukkainen T, *et al*. Intracervical and fundal administration of levonorgestrel for contraception: endometrial thickness, patterns of bleeding, and persisting ovarian follicles. *Fertil Steril* 1997; **68**: 59–64.

260 Pakarinen P, Luukkainen T. Five years' experience with a small intracervical/intrauterine levonorgestrel-releasing device. *Contraception* 2005; **72**: 342–345.

261 Ber A, Seidman DS. Management of the malpositioned levonorgestrel-releasing intrauterine system. *Contraception* 2012; **85**: 369–373.

262 Brahmi D, Steenland MW, Renner RM, *et al*. Pregnancy outcomes with an IUD in situ: a systematic review. *Contraception* 2012; **85**: 131–139.

263 Burkman RT, Damewood M. Actinomyces and the intrauterine contraceptive device. In: Zatuchin GI, Goldsmith A, Sciarra JJ (eds), *Intrauterine Contraception – Advances and Future Prospects (Parfr Series on Fertility Regulation)*. Philadelphia, PA: Harper and Row, 1985.

264 Gupta PK. Intrauterine contraceptive devices: vaginal cytology pathologic changes and clinical implications. *Acta Cytol* 1982; **26**: 571–613.

265 Lippes J. Pelvic actinomycosis: a review and preliminary look at prevalence. *Am J Obstet Gynecol* 1999; **180**: 265–269.

266 Valincenti JF, Pappas AA, Graber CD, *et al*. Detection and prevalence of IUD-associated Actinomyces colonization and related morbidity: a prospective study of 69,925 cervical smears. *JAMA* 1982; **247**: 1149–1152.

267 Austoker J. Cancer prevention in primary care: screening for cervical cancer. *BMJ* 1994; **309**: 241–248.

268 Curtis EM, Pine L. Actinomyces in the vaginas of women with and without intrauterine contraceptive devices. *Am J Obstet Gynecol* 1981; **152**: 287–290.

269 Fiorino AS. Intrauterine contraceptive device-associated actinomycotic abscess and Actinomyces detection on cervical smear. *Obstet Gynecol* 1996; **87**: 142–149.

270 Persson E, Holmberg K, Dahlgren S, *et al*. *Actinomyces israelli* in the genital tract of women with and without intrauterine contraceptive devices. *Acta Obstet Gynecol Scand* 1983; **62**: 563–568.

271 Persson E, Holmberg K. A longitudinal study of *Actinomyces israelii in the female genital tract. Acta Obstet Gynecol Scand* 1984; **63**: 207–216.

272 Westhoff C. IUDs and colonization or infection with Actinomyces. *Contraception* 2007; **75**: S48–S50.

273 Burkman RT. Intrauterine devices and pelvic inflammatory disease: evolving perspectives on the data. *Obstet Gynecol Surv* 1996; **51**: S35–S41.

274 Thiery M, Claeys G, Mrozowski B, *et al*. Significance of colonization of the lower female genital tract with *Actinomyces israelii*. *RCS Med Sci* 1986; **14**: 292–293.

275 Carrillo M, Valdez B, Vargas L, *et al*. In vitro *Actinomyces israelii* biofilm development on IUD copper surfaces. *Contraception* 2010; **81**: 261–264.

276 Merki-Feld GS, Rosselli M, Imthurn B. Comparison of two procedures for routine IUD exchange in women with positive PAP smears for actinomyces-like organisms. *Contraception* 2008; **77**: 177–180.

277 Tepper NK, Steenland MW, Gaffield ME, *et al*. Retention of intrauterine devices in women who acquire pelvic inflammatory disease: a systematic review. *Contraception* 2013; **87**: 655–660.

278 Kaislasuo J, Suhonen S, Gissler M, *et al*. Uterine perforation caused by intrauterine devices: clinical course and treatment. *Hum Reprod* 2013; **28**: 1546–1551.

279 Van Houdenhoven K, van Kaam KJ, van Grootheest AC, *et al*. Uterine perforation in women using a levonorgestrel-releasing intrauterine system. *Contraception* 2006; **73**: 257–260.

280 Faculty of Sexual & Reproductive Healthcare. *Barrier Methods: Contraception and STI Prevention*. 2012. http://www.fsrh.org/pdfs/CEUGuidanceBarrierMethodsAug12.pdf [Accessed 23 March 2015].

281 Faculty of Sexual & Reproductive Healthcare. *Quick Starting Contraception*. 2010. http://www.fsrh.org/pdfs/CEUGuidanceQuickStartingContraception.pdf [Accessed 23 March 2015].

282 Pasquale SA, Russer TJ, Foldesy R, *et al*. Lack of interaction between magnetic resonance imaging and the copper-T380A IUD. *Contraception* 1997; **55**: 169–173.

283 Mark AS, Hricak H. Intrauterine contraceptive devices: MR imaging. *Radiology* 1987; **162**: 311–314.

284 Hess T, Stepanow B, Knopp MV. Safety of intrauterine contraceptive devices during MR imaging. *Eur J Radiol* 1996; **6**: 66–68.

285 Mooncup Limited. FAQs: IUD/coil. http://www.mooncup.co.uk/advice-centre/faqs/all-questions/mooncup-and-iud-ius-coil.html [Accessed 23 March 2015].

286 Wiebe ER, Trouton KJ. Does using tampons or menstrual cups increase early IUD expulsion rates? *Contraception* 2012; **86**: 119–121.

287 Black K, Lotke P, Buhling KJ, *et al*. A review of barriers and myths preventing the more widespread use of intrauterine contraception in nulliparous women. *Eur J Contracept Reprod Health Care* 2012; **17**: 340–350.

288 Deans EI, Grimes DA. Intrauterine devices for adolescents: a systematic review. *Contraception* 2009; **79**: 418–423.

289 Berenson AB, Tan A, Hirth JM, *et al*. Complications and continuation of intrauterine device use among commercially insured teenagers. *Obstet Gynecol* 2013; **121**: 951–958.

290 O'Brien PA, Kulier R, Helmerhorst FM, *et al*. Copper-containing framed intrauterine devices for contraception: a systematic review of randomized controlled trials. *Contraception* 2008; **77**: 318–327.

291 Thonneau P, Almont T, de La Rochebrochard E, *et al*. Risk factors for IUD failure: results of a large multicentre case-control study. *Hum Reprod* 2006; **21**: 2612–2616.

292 Ramhendar T, Byrne P. Use of the levonorgestrel-releasing intrauterine system in renal transplant recipients: a retrospective case review. *Contraception* 2012; **86**: 288–289.

293 Morrison CS, Sekadde-Kigondu C, Sinei SK, *et al*. Is the intrauterine device appropriate contraception for HIV-1-infected women? *Br J Obstet Gynaecol* 2001; **108**: 784–790.

294 Heikinheimo O, Lehtovirta P, Aho I, *et al*. The levonorgestrel-releasing intrauterine system in human immunodeficiency virus-infected women: a 5-year follow-up study. *Am J Obstet Gynecol* 2011; **204**: 126.e1–126.e4.

295 Stringer EM, Kaseba C, Levy J, *et al*. A randomized trial of the intrauterine contraceptive device vs hormonal contraception in women who are infected with the human immunodeficiency virus. *Am J Obstet Gynecol* 2007; **197**: 144–148.

296 Richardson BA, Morrison CS, Sekadde-Kigondu C, *et al*. Effect of intrauterine device use on cervical shedding of HIV-1 DNA. *AIDS* 1999; **13**: 2091–2097.

297 Heikinheimo O, Lehtovirta P, Suni J, *et al*. The levonorgestrel-releasing intrauterine system (LNG-IUS) in HIV-infected women – effects on bleeding patterns, ovarian function and genital shedding of HIV. *Hum Reprod* 2006; **21**: 2857–2861.

298 European Study Group on Heterosexual Transmission of HIV. Comparison of female to male and male to female transmission of HIV in 563 stable couples. *BMJ* 1992; **304**: 809–813.

299 Sinei SK, Morrison CS, Sekadde-Kigondu C, *et al*. Complications of use of intrauterine devices among HIV-1 infected women. *Lancet* 1998; **351**: 1238–1241.

APPENDIX 1: DEVELOPMENT OF CEU GUIDANCE

GUIDELINE DEVELOPMENT GROUP

Dr Louise Melvin – Director, Clinical Effectiveness Unit

Ms Julie Craik – Researcher, Clinical Effectiveness Unit

Mr John Scott – Researcher, Clinical Effectiveness Unit

Dr Oluseye Arikawe – General Practitioner, Audley Mills Surgery, Rayleigh, Essex

Dr Najia Aziz – FSRH Meetings Committee representative; Specialty Trainee, Community Sexual and Reproductive Healthcare, Sexual Health Services, Portsmouth

Dr Michelle Cooper – Specialty Trainee, Obstetrics and Gynaecology, NHS Tayside, Dundee

Dr Lesley Craig – FSRH Clinical Effectiveness Committee representative; Associate Specialist, Sexual and Reproductive Health, NHS Grampian

Dr Jo Dennis – Clinical Lead for Contraception, East Cheshire Centre for Sexual Health, Macclesfield District General Hospital, Chester

Dr Susanna Hall – Specialty Trainee, Community Sexual and Reproductive Health, University Hospitals Bristol NHS Foundation Trust

Ms Lynn Hearton – Former Clinical and Information Lead, Family Planning Association (FPA), London

Dr Anja Guttinger – Consultant in Sexual and Reproductive Health, Sandyford, NHS Greater Glasgow and Clyde, Glasgow

Dr Praveen Jayadeva – FSRH Clinical Standards Committee representative; Specialty Trainee, Community Sexual and Reproductive Healthcare, Mersey Deanery, Central Abacus, Liverpool Community NHS Trust, Liverpool

Ms Sally Kelsey – Lead Nurse, Sexual Health and Contraception, Barking, Havering and Redbridge University Hospitals, Essex

Ms Sarah Kipps – Reproductive Sexual Health Nurse Specialist, Tooting Health Centre, London

Dr Kerry Parton – Associate Specialist Clinical Lead RSH, Tooting Health Centre, London

Dr Karin Piegsa – Consultant in Sexual and Reproductive Health, Whyteman's Brae Hospital, Kirkcaldy

Dr Debbie Smith – General Practitioner, Leeds Student Medical Practice, Leeds

Dr Dawn Wilkinson – Consultant in Genitourinary Medicine, St Mary's Hospital, London

INDEPENDENT PEER REVIEWERS

Professor Pekka Lähteenmäki – Faculty of Medicine, University of Helsinki, Helsinki, Finland

Professor Ian Milsom – Chief Physician, Department of Obstetrics and Gynaecology, University of Göteborg, Gothenburg, Sweden

Declared Interests

Dr Karin Piegsa has received lecture fees for delivering non-promotional update sessions to general practice. Her department has received payment from Bayer and Merck, Sharp and Dohme towards training fees for subdermal implant training.

Administrative support to the CEU team was provided by **Mr John Matthews**.

Patient Consultation

A questionnaire on the proposed guidance content was completed by a sample of potential users.

Clinical Effectiveness Unit (CEU) guidance is developed in collaboration with the Clinical Effectiveness Committee (CEC) of the Faculty of Sexual & Reproductive Healthcare (FSRH). The CEU guidance development process employs standard methodology and makes use of systematic literature review and a multidisciplinary group of professionals. The multidisciplinary group is identified by the CEU for their expertise in the topic area and typically includes clinicians working in family planning, sexual and reproductive health care, general practice, other allied specialities, and user representation. In addition, the aim is to include a representative from the FSRH CEC, the FSRH Meetings Committee and FSRH Council in the multidisciplinary group.

Evidence is identified using a systematic literature review and electronic searches are performed for: MEDLINE (1996–2014); EMBASE (1996–2014); PubMed (1996–2014); The Cochrane Library (to 2014) and the US National Guideline Clearing House. The Cochrane Library is searched for relevant systematic reviews, meta-analyses and controlled trials relevant to intrauterine contraception. Previously existing guidelines from the FSRH (formerly the Faculty of Family Planning and Reproductive Health Care), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and the British Association for Sexual Health and HIV (BASHH), and reference lists of identified publications, are also searched. Summary evidence tables are available on request from the CEU. The process for development of CEU guidance is detailed in the CEU section of the FSRH website (www.fsrh.org). The methods used in development of this guidance (CEU Process Manual Version 2.0) have been accredited by NHS Evidence.

Questions for Continuing Professional Development

The following questions have been developed for continuing professional development (CPD).

The answers to the questions and information on claiming CPD points can be found in the 'members-only section' of the FSRH website (www.fsrh.org), which is accessible to all Diplomates, Members, Associate Members and Fellows of the FSRH.

1 Intrauterine contraception (IUC) works primarily by:

a. Destroying developing embryos
b. Inhibiting ovulation
c. Preventing fertilisation
d. Preventing implantation

2 The daily release rate of the 52 mg levonorgestrel intrauterine system (LNG-IUS) is:

a. 5 µg
b. 14 µg
c. 20 µg
d. 52 µg

3 In women aged over 45 years, the CEU recommends use of the 13.5 µg LNG-IUS for:

a. 3 years
b. 4 years
c. 7 years
d. Until the menopause

4 A woman presents with heavy menstrual bleeding (HMB). What is the single most appropriate advice to give in relation to use of an LNG-IUS?

a. The LNG-IUS is not recommended for HMB
b. The LNG-IUS has no effect on HMB
c. The 13.5 mg LNG-IUS is licensed to manage HMB
d. The 52 mg LNG-IUS is licensed to manage HMB

5 A woman who wishes to use IUC for long-term contraception presents reporting multiple episodes of unprotected sexual intercourse (UPSI) since her last period. The earliest episode was 10 days ago and the most recent 3 days ago. She is on Day 18 of a regular 28-day cycle. What is the single most appropriate advice to offer her from the list below?

a. Advise that it is too late to use emergency contraception (EC) and to return when she has her period
b. Advise that it is too late to use EC and offer a bridging method
c. Advise that she can have a copper intrauterine device (Cu-IUD) inserted for EC and ongoing contraception
d. Advise that she can have an LNG-IUS inserted for EC and ongoing contraception

6 A woman presents requesting to start the LNG-IUS. She is on Day 19 of a 28-day cycle. She received ulipristal acetate 5 days ago for a single episode of UPSI. She has had no further episodes. What is the single most appropriate management from the list below?

a. Do not insert the LNG-IUS, advise her to return when her period starts
b. Insert the LNG-IUS and advise a pregnancy test if she has no period
c. Insert the LNG-IUS and advise additional precautions for 7 days
d. Offer a bridging method until pregnancy can be excluded

7 A woman presents enquiring about the risk of ectopic pregnancy associated with IUC. What is the single most appropriate advice to offer her?

a. Compared to no contraception, IUC increases the risk of ectopic pregnancy
b. Copper intrauterine devices (Cu-IUDs) decrease the risk of ectopic pregnancy when a pregnancy occurs
c. The LNG-IUS decreases the risk of ectopic pregnancy when a pregnancy occurs
d. Overall the risk is decreased with IUC but the risk is increased if a pregnancy occurs

8 A woman presents enquiring about use of the LNG-IUS for contraception. She is keen to know how it will affect her bleeding patterns. What is the single most appropriate piece of information to give her?

a. Bleeding patterns can be irregular but by 1 year infrequent bleeding is usual
b. Following insertion, bleeding patterns will remain regular throughout use
c. Following insertion, bleeding patterns are likely to regular and heavy
d. Following insertion, infrequent bleeding is usual until the last year of use

9 A woman with a Cu-IUD *in situ* presents with pelvic inflammatory disease. She wants to know if she should have the device removed. What is the single most appropriate advice according to CEU guidance?

a. Clinical outcomes are much worse if the device is removed
b. She can choose to keep her IUD whilst receiving treatment
c. Long-term clinical outcomes are better if the device is removed
d. Removal is recommended unless sex has occurred in the last 7 days

10 A woman presents requesting an LNG-IUS. She is currently using a norethisterone progestogen-only pill (POP). What is the single most appropriate advice to offer her in relation to switching?

a. She can start immediately with no additional precautions required
b. She can start immediately and should continue the POP for 2 days
c. She should delay starting until her next menstrual bleed
d. She can start immediately and should continue the POP for 7 days

What learning needs did this guidance address and how will it change your practice? (Please write below)

Auditable Outcomes for Intrauterine Contraception

The following auditable outcomes have been suggested by the FSRH Clinical Standards Committee.

Auditable Outcomes

1 The proportion of sexually active women offered sexually transmitted infection screening requesting intrauterine contraception (IUC). [Auditable standard 97%]

2 The proportion of women who had a pelvic assessment either by bimanual examination or ultrasound scan before insertion of IUC. [Auditable standard 97%]

3 An appropriately trained assistant should be present during insertion of IUC. [Auditable standard 97%]

COMMENTS AND FEEDBACK ON PUBLISHED GUIDANCE

All comments on published guidance can be sent directly to the Faculty of Sexual & Reproductive Healthcare (FSRH) at **mail@fsrh.org**.

The FSRH is unable to respond individually to all feedback. However, the FSRH will review all comments and provide an anonymised summary of comments and responses, which are reviewed by the Clinical Effectiveness Committee and any necessary amendments made.