UNIVERSITY OF CAMBRIDGE
Winton Centre for
Risk and Evidence Communication

Decision Aid Supporting Document – Heavy Periods/Menorrhagia

Version 15.1 (Sept 2023) planned review (3 years)

This document is designed to give further information about how we made the Decision Support Tool (Decision Aid).

This supporting document and the decision aid were written and researched by Leila Finikarides and Dr Alexandra Freeman.

Each tool had an expert advisory group nominated by NHS England, who commissioned the tools, the involvement of relevant charities or support groups, and was designed through rounds of redesign and feedback from clinicians, patients and members of the public who might use it. These were one-on-one interviews, and the feedback was collated and acted on in multiple rounds.

EasyRead versions were then made through a similar process of iterative testing with experts and users.

Users (patients and the general public) are our focus, we include them from the beginning of the process and their views and feedback throughout are at the very heart of what we aim to do. The decision aids are for them.

Each tool is made to comply with the guidelines or criteria on decision aid development by IPDAS and NICE. Very often they go beyond what many might consider as a 'decision aid' because our work with patients and clinicians has emphasised how much patients want 'everything in one place' and clinicians find it helpful to have 'the perfect consultation' laid out to support them.

Patients particularly appreciated the help that the documents gave them in preparing for an appointment (knowing what might happen in advance, and helping prompt questions they might want to ask), pages that help them when they talk to their doctor, and those that remind them what's going on, what might happen, and what did just happen (what did the doctor tell me in the room). The extra information can make the documents seem long, but patients preferred this extra length, as long as the sections were easily navigable.

In this document you can find out more about who helped design the tool, some of the reasoning behind key decisions, and what reference sources were used. You can also see the answers to some of the questions we posed to the people we tested it with about how they might use the tool, which led to key decisions about its design. These are only examples designed to give you a sense of how they were made – the full process is too detailed to document.

In designing the graphical representations of the numbers, we use a large body of research into risk communication done over many years (some by us), plus the testing we do during the production of the tools. Graphic design was by the company Luna9.

Who was involved?

	number	
Expert Advisory Group Clinicians & Patient Reps & their Declarations of Conflicts of Interest (COI)	**x8**	**Prof Janice Rymer** Professor of Gynaecology Kings College London, Consultant Gynaecologist Guy's and St Thomas's Hospitals, National Specialty Advisor for Gynaecology for NHSE/I No COI to declare **Caroline Bell** (Nurse Hysteroscopist and Colposcopist, chair on British society gynaecology endoscopy) No COI do declare **Mr Andrew Kent** (Consultant Gynaecologist and Minimal Access Surgeon) No COI to declare **Katie Gore** (Clinical Academic in Pelvic Pain) No COI to declare **Dr Janet Barter** (Consultant in SRH and President of Faculty of Sexual and Reproductive Healthcare) No COI to declare **Dr Anne Connolly MBE** (GPSi gynae, Bevan Healthcare, Bradford. Chair PCWHF, RCGP clinical champion in women's health) Anne has provided education and consultancy on behalf of pharma – further details found on www.whopaysthisdoctor.org **Dr Ranee Thakar** (Subspecialist in Urogynaecology and Consultant Obstetrician and Gynaecologist, President Royal College of Obstetricians & Gynaecologists) PRESIDENT OF RCOG otherwise NONE **Dr Sam Finnikin** (GP and NHSE National Clinical Specialist Advisor in Personalised Care) No COI to declare.

Other clinicians (not part of the expert advisory group) who were interviewed or provided input or feedback	**x9**	5x GPs 2x nurse specialists 1x A&E registrar 1x midwife
Patients and public involved in 5 rounds of testing and feedback	**x20**	Range of ages, ethnicities, education levels 7 have experience of heavy periods 3 have neurodiversities, or different visual impairments or reading requirements 2 have English as not their native language 1 Equality & Inclusion professional
Who are the Winton Centre for Risk & Evidence Communication?		The Winton Centre was funded by a philanthropic donation from the David & Claudia Harding Foundation to help communicate evidence 'to inform, not persuade'. The team carried out research in how best to communicate numbers and uncertainty, created training courses to help professions who needed to communicate evidence in a balanced way, and produced tools to communicate evidence on different topics. They were commissioned, and funded, by NHS England to produce a series of printable decision support tools in 2022 and 2023. The funding for this work came from NHS England and the Winton Centre's own core funding.

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What questions do we ask of our expert group and user testers and why?

We interviewed the expert advisory group, regular patients and potential users of the decision aid and regular clinicians who might use the decision aid. We interviewed each tester (regular patients or users, and regular clinicians) via video call, usually for about an hour.

We need to understand which information to include and to what level of detail.

For users (patients):
We always first asked about their experience of the condition or the decision to be made. We asked them what did they want to know at the time and what would they have liked to have known. We asked them what they would tell someone now who was making the decision.

We then asked for their feedback on the decision aid.
We ask if they would like a clinician to go through the document with them.

Then we ask them:

- Whether they understood the purpose of the document (that it is a decision aid, not an information sheet).
- Whether they would read it, if they would find it useful, would it help them make a decision?
- Whether, if they were handed the document by a clinician, they would read it.
- Whether, if they saw this document on a table, for example in a clinic waiting room, they pick it up, and *want* to read it.

The aim of these decision aids is to help people make a decision. But in order to be useful and used, they need to be read. And in order to be read, they need to be picked up. We therefore amend and refine the documents and retest them (with a mix of the same and different testers) until the answers to these questions are “yes”.

If people want a clinician to go through the document with them, we make sure it’s clear in the document that this is what they can do and, on the front page, which pages are (most) useful to be used in a consultation with a healthcare professional.

For clinicians (both our expert group and regular clinicians):
We ask:

- What is the decision being made? (what are the treatment options that are available)
- At which point in a patient’s pathway/disease progression are they making the decision, and therefore what is the background knowledge of the potential user (what do they already know), and when and how would they physically receive this leaflet?

- Are there inclusion / exclusion criteria around the decision aid?
- How would the decision aid be used, e.g. by users 'on their own' before a consultation with a clinician, or always first with a clinician

The answers to these questions help us to understand which information to include in the leaflet, at what level of detail and language to use.

What is the decision? **And / or** **What are the treatment options available?**	We included treatment options guided by our expert group and NICE guidance ○ Do nothing ○ Medicines you take during your period ○ Hormone medicines (pills) ○ Hormone devices (IUS and vaginal ring) ○ Surgery (ablation, remove polyps / fibroids, hysterectomy) ○ Things you can do yourself The user wants to know whether or not they have heavy periods. They want to understand when or whether to seek help. They want to know whether to choose a treatment, and which treatment to choose and when. • Testers told us they sometimes didn't realise they had heavy periods until, for example, they were at university and started discussing it, or happened to visit their GP for something else. Definition of what heavy periods are was helpful. • Understanding whether to visit their GP or not, what information to take with them to make the appointment easier, and having a basic understanding of their options, testers told us would be helpful
When in the pathway will it be used? (clinician answer)	e.g. Pre-primary care, primary care, secondary care - clinicians all agree that the leaflet would be useful before a primary care visit, and at a primary care visit, and before referral to secondary care
When would it be useful? (patient answer)	The User - users all agreed they think this leaflet should be widely available to anyone who has periods. They thought that young girls just starting their periods should know about heavy periods and through to peri-menopausal women whose periods may change at that time of life and become heavy - users all agreed it would be useful before they see a clinician, and at that appointment and before a referral appointment to a specialist

	- Suggestions from users where they would like to find this leaflet include:
	  ○ Schools and libraries
	  ○ QR codes on shelves where period products are sold, eg in supermarkets
	  ○ Pharmacies
	  ○ Work places
	  ○ Social media

How would it be used?	e.g. patients to use it on their own before a consultation or always with a clinician? - this document has been designed to be used without the help of a clinician because so many users would use it to prepare for a first appointment and to understand if they should seek help or not (do they have heavy periods?) - there are pages (7, 8, 9, 10, 11 and 13) that can be completed by the user or show risks and benefits data, that are signposted as useful to use *with* a clinician
Are there any exclusion / inclusion criteria?	Who is the decision aid for? And who is it specifically not for? - Because this decision aid helps the user understand if they have heavy periods and whether to seek help, this leaflet is for anyone who has periods.
Would you prefer a printed version, online electronic version or both? (Patient answer)	We know from testing previous decision aids that most clinicians would prefer these were electronic online tools. NHS clinicians typically do say they have facilities to print (black and white only). Users: Of 12 patients and public who answered this question: - 8 wanted it as a printed piece of paper - 4 wanted it both online and printed - None wanted it online only
Any other comments?	
Were there any key decisions made when designing the document, and what was the	• Heavy periods and painful periods - Although these often go hand in hand, the decision was made to have clarity that this document was about flow, how heavy periods are. Pain is a different pathway with different treatments.

reasoning behind them?	• Tests - Although tests are not always relevant to a decision about treatment, sometimes users find it useful to know what might happen when they go to see a clinician about their symptoms. Understanding that people can have treatment without an internal vaginal examination, for example, or that they can ask for a female clinician, was useful (vital) for some users to know. In this leaflet we decided to include fairly prominently the tests that might be offered. • Causes of heavy periods - We touch on, but don't go into details, causes of heavy periods (eg fibroids). We talk about treatment if your heavy periods are due to fibroids or polyps but we decided that to include detail around these would be too much for this document. • Treatments risks and side effects. Some of our clinical advisors found the risk of IUS falling out and side effects of tranexamic acid, mefenamic acid and ibuprofen, didn't correspond to their clinical experience, but no evidence was available to contradict the figures we have used. Nov 2023 Feedback from pharmacist re advice to take aspirin and paracetamol for period pain. We changed the wording in this bullet to "Pain medicines available from the pharmacy can help. Always tell your pharmacist or doctor if you are taking any other medicines or supplements. If you have severe pain that stops you doing normal activities talk to your doctor." (from pharmacist - I think your suggested re-focus on advice re 'pain medicines' is a really good solution. [If you're not naming medicines that increase the bleeding risk with anticoagulants there is no need to go into more detailed advice re risk.] These tools are a really good resource. I'll be using this one in particular. I end up speaking to women about peri-menopausal bleeding on a regular basis!
Some example answers from our patient and regular clinician testers and actions we took on the basis of them (organised by testing round)	
Round 1	- *Looks great, wish I had it when I was getting treated. Clear, easy to understand; like the colours, icons, layout and format - but it was a lot, and it seemed like the doc jumped around a lot.* - *I had been told that it was just something you were supposed to deal with - "suck it up"*

	- *The document is long so it needs to be divided up into stages - it would be helpful if the doc flowed the way treatment does in real life (self management, GP, Hospital)* - *Definitely need stats and flowcharts* - *Create a 1 page summary of the whole thing for a "quick read" - and more in depth information in this leaflet* - *Give it to pharmacists as women most likely to access them first for pain relief* - *It is long to read, so tell people they can skip sections if they are looking for specific things - flowcharts can help in this* - *I Like the empowering messaging. You can make it stronger - you don't have to put up with heavy periods if they are affecting your life* **In response to these, we made clearer sections and rearranged the document so it had a better flow.** - *I wanted to know is it normal to have SUCH heavy periods? I thought it was, that I had to put up with it – 'til a friend recommended a book and I realized it's not. I found it honest; liked that it would not sway someone either way, just up-front.* - *I like that you don't need any tests to get help* - (TESTS page) *Really loved this page; particularly helpful for autistic people! Great to know what's going to happen because often you turn up unprepared*
Round 2 – clinicians	- *It looks good. It's needed. How do you get it to the people who do have heaviest periods? For people where it's interfering with Quality of Life?* - *Include 'red flags'* - *Make the pages that your GP / clinician would use very clear* **In response to these, we included a tab on front page to specify which pages are useful for your GP or other clinician**

Round 2 – patients	- *Not very reassuring language, Quite male and strident language used. Not very feminine, doesn't reach out and reassure.* **We looked carefully at the tone and language used and amended until testers were happy**
Round 4	- *The colours are great; it is not sad or stressful. Good.* - *Great work! I like the way you explain the percents which is usually very boring and hard to illustrate. I also like the fact that one part is black and the ' fill-in' part is purple.*
Round 5	- *I must say that it is very nice and interesting to read. A lot of information and lovely layout (fresh, colourful, precise and clear)* - *Front page - Image – like it – love diversity - Nice to see that - Better than a uterus which would be more medical and daunting – this is approachable and friendly. Language is good.* - *Icon array – not clear enough. Struggled with the colour code the numbers with the – took me a minute to understand it. Writing the colour of the blobs?* **In response to this, we labelled the icon array and made the colours more distinct** - *Loved the diagrams, loved the colours, loved the signposting through the document* - Risks and benefits pages – *I like that it's showing the range – arrows and the slope works and shows the range. Easy to understand the figures underneath* - Risks and benefits pages – *It's useful to understand the risks. Nausea – I got nausea and no one knew why – I take naproxen and tranexamic acid! This is helpful here for sure. I raised nausea as an issue – and now I know it's that. Reassuring to have it there.* - *FILL IN BEFORE YOU SEE YOUR DOCTOR pages - WRITE DOWN EVERYTHING beforehand – what kinds of questions your doctor will ask – it's great! Under pressure my mind goes blank. I'm armed with the information* - *It will help me and my GP – not wasting anyone's time. From a doctor's point of view it's helping them get to the nitty gritty*

Reading age range	Using https://readabilityformulas.com/readability-scoring-system.php Average Reading Age Consensus Calculator Average reading 10-11

Easy Read development	
Heavy Periods was the first decision aid for which we created an Easy Read version. In testing and creating this topic we were able to create a basic structure and set of illustrations for the other Easy Read decision aids. **Heavy Periods - Tested in 5 rounds of testing with x 31 people in total**	
Number of Rounds of testing	x 5 rounds of testing
Professionals	x 8 professionals - A speech therapist - Writers of easy reads and groups for those with learning difficulties including; Inspired Services, People First, Speaking up Together, Change - Women's health clinicians
People who use Easy Read versions	23 Easy Read users in groups from: - Speaking up Together - Tameside People First - People First - Camden People First 2 x Individual Easy Read users
Notes and lessons learned	To our knowledge there were no other decision aids / decision support tools in Easy Read format (i.e. documents helping readers make a treatment decision informed by evidence). Usually Easy Read users would be using the leaflets with a carer or clinician. We aimed for the language and illustrations to be as simple as possible but in some instances need to rely on carers or others to explain some concept. If users have profound disability such that they need help to understand they would always have someone with them to advocate for them or explain to them. Some feedback about images came from clinicians, for example, we initially showed a GP in a white coat. GPs

	(and other clinicians) pointed out that they do not wear white coats. We tested with the Easy Read users and asked 'what we could draw to show a doctor?' They suggested a desk, a monitor and a stethoscope. We developed and tested ways of expressing the concept of a 'choice' and presenting different options and outcomes in a way that the readers could make a decision (by themselves, if necessary). - Easy Read users preferred photographs when a specific kind of medication or treatment was being referred to and they wanted to know what it looked like. Otherwise, cartoons were OK. There were several poses that they were used to seeing. - If using a colour key (e.g. purple is always medicine in the leaflet), they asked us to explain this. For example, say clearly "medicines are aways purple in this leaflet" - explaining what we were doing instead of assuming a key, colour code, shape etc would 'speak for itself'. - Because the leaflets are long, we clearly split them into sections, explaining at the start that you might not want to read it all at once. And that you don't need to. Risks and benefit visualisations - We experimented with ways of showing the potential risks and benefits of the different options. In the standard versions of the same tools these are generally expressed as expected frequencies (number out of 100 expected to show each outcome), plus a bar to show the number visually; e.g. 20 in every 100 who have this treatment have this effect. - We usually present ranges around the numbers to encompass the quantified uncertainty in the data available. - We also usually present the evidence in the past tense (out of 100 people who HAD/CHOSE…) to

	emphasise that the numbers are not a prediction but are a summary of past numbers. For Easy Read users - For the Easy Read audience, these bars were not clear, and nor were the ranges. They also found the past tense more difficult than present tense. - We also could not present outcomes 'out of 100' because this high number wasn't so easily imagined by the audience. - Testing revealed that 'out of 10' outcomes were understandable for the audience, and generally provided as precise a number as they needed to inform their decision. So we present the risks and benefits out of 10. - This of course means 'rounding' - sometimes in quite an extreme way. However, our testers felt that it gave them enough information to make comparisons. - Easy Read users told us they were used to 'faces' as icons, to help them know which represented positive and which represented negative outcomes without having to check. This was useful on the 'amount of bleeding' outcome on heavy periods (even though we are describing a continuous outcome, not a frequency). For most other outcomes (frequencies), anthropomorphic icons were fine. - They also told us that they were used to having the number that had a 'positive' outcome on the right hand side, and those that had a 'negative' outcome on the left hand side of an icon array, and to be consistent with that (rather than putting the number that 'had' the described outcome always on the left). - Testers were very happy to see the information and have it presented so clearly. They were very engaged and happy to have been consulted.

	It would not have been possible to make these Easy Read versions without multiple testing rounds. We consistently found language or images that we felt were clear, but did not make sense at all to the groups.
Example feedback and decisions specific to Heavy Periods	*"It would definitely help you make a decision especially if you didn't want painful treatment"* *V3.5* What is missing? *"feelings! Moods, I'm always grumpy, chocolate! We want to eat chocolate"* *"A perfect example of an easy read document"* *v3.5 then v5.0* *"Colour coding is better"* *"Much easier to understand"* *V5.0* *"It's amazing - love the layout and imagery used as clear and easy to understand. Beautifully formatted and colour scheme layout is not affecting my reading flow."* *"As for the wording and content - looks fab. The only thing I would change is to include imagery and where to i.e image of school/morrisons? If that's possible"*

Where did we get our numbers from?

This section explains what sources we used, and why.

How many people have the condition?

Where possible we try to use the most recent UK registry/audit data for the prevalence of a condition, or (if many who have the condition may not be diagnosed and hence recorded as having it), survey or other relevant methods of determining prevalence.

In this case, we used data from a national audit on heavy menstrual bleeding, from 2014. (HQIP Table 4.1 in https://www.hqip.org.uk/wp-content/uploads/2018/02/HwNYNM.pdf)

Potential benefits & harms of different treatment options

For this section of each decision aid, we try to find the absolute risks (the number out of every 100 people who would have experienced the outcome) for each of the things that patients and clinicians tell us is important. Numbers can come from observational studies (where people choose their treatment and the outcomes are recorded), or from clinical trials (where people are assigned to a treatment at random). Which is more useful depends on the circumstances, but in some clinical trials some people assigned to one treatment ends up taking another (for different reasons). Some academic studies report the outcomes as if they had taken the treatment they were originally assigned (called 'intention to treat' data), and some studies report the outcomes depending on the treatment that they actually took (called 'per protocol' or 'per treatment' data). We always try to find 'per protocol' data as this is more useful for an individual wanting to know what might happen if they have one treatment or another.

We usually start by looking at trustworthy summaries of evidence, such as those done by NICE or by the Cochrane collaboration.

If these summaries give us all the numbers that we need, and are considered up to date by the expert group, we would use those. If not, we would look for any large trial in a population that is relevant to the UK and use the findings of that. If there are many trials, we would collate them all and tend to cite a range based on the lowest and highest number for each outcome found across those studies (rounding the numbers to give an appropriate sense of the degree of certainty). Where there is consensus that there is 'no significant difference' between different outcomes, we will ensure this is reflected in the ranges we give.

The expert group will agree all the numbers, and suggest better sources for them, throughout the development process.

Unfortunately the Cochrane review on this topic did not give absolute risks (for the benefits). So, we sourced all the studies mentioned by NICE (NICE Evidence Review in 2018: https://www.nice.org.uk/guidance/ng88) and by Cochrane, and extracted the absolute risks data from those. We had to do additional literature searches using Google Scholar to help fill in blanks (such as data on amenorrhoea).

The Health Quality Ontario review from 2016 was helpful, and Battacharya 2011 was useful for the IUS and surgical options.

Doing nothing
We used data from:
Khjehei 2013: a randomised study in 93 women:
https://doi.org/10.7196/SAJOG.587
Preston 1995: a randomised study in 46 women:
https://doi.org/10.1111/j.1471-0528.1995.tb11293.x
Fraser 2011: A randomised study in 231 women:
https://doi.org/10.1093/humrep/der224

IUS
For the benefits, we used data from:
A summary of data in the existing literature from Gupta 2022:
https://doi.org/10.3399/bjgp.2022.0260
Kaunitz 2010 (145 women):
https://doi.org/10.1097/AOG.0b013e3181ec622b
Kiseli 2016 (62 women):
https://doi.org/10.1159/000443393
Ghazizadeh 2014 (110 women):
https://doi.org/10.1089/gyn.2012.0041
Reid 2005 (51 women):
https://doi.org/10.1111/j.1471-0528.2005.00642.x
Shabaan 2011 (112 women):
https://doi.org/0.1016/j.contraception.2010.06.011
Ghazizadeh 2011 (110 women):
https://doi.org/10.2147/IJWH.S20999
Irvine 1998 (44 women):
https://doi.org/10.1111/j.1471-0528.1998.tb10172.x
Heliovaara-Peippo 2013 (236 women)
Ergun 2011 (58 women)
Bhattacharya 2011 – a Health Technology Review meta-analysis of data from 2,814 women who had either had the LNG-IUS, endometrial ablation or hysterectomy:
https://doi.org/10.3310/hta15190
A review of all the evidence in 2016 by Health Quality Ontario:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5159479/

Combined pill
We used data from:
Fraser 1991: A study in 45 women: https://doi.org/10.1111/j.1479-828X.1991.tb02769.x
Shabaan 2011: A randomised study in 112 women:
https://doi.org/10.1016/j.contraception.2010.06.011

Endrikat 2009: A randomised study of 40 women:
https://doi.org/10.1016/S1701-2163(16)34151-2

Number whose periods stopped completely was taken from a study of 1,103 women in 2000: https://doi.org/10.1016/S0010-7824(00)00183-9

Vaginal ring
We used information from:
A randomised study in 50 women in
2016: http://dx.doi.org/10.1016/j.ejogrb.2016.05.009
Which described it as 'similar effectiveness' to combined pill.

Progestogen-Only Pill
We used data from:
Kiseli 2016: A randomised study in 62 women:
https://doi.org/10.1159/000443393
Irvine 1998: A randomised study in 44 women:
https://doi.org/10.1111/j.1471-0528.1998.tb10172.x
Cooper 1997: A study in 197 women:
https://doi.org/10.1111/j.1471-0528.1997.tb11004.x

Number whose periods stopped completely taken from a study of 1,320 women reported in 2003: https://doi.org/10.1196/annals.1290.019

medroxyprogesterone acetate
We used data from:
Kriplani 2006: A randomised study in 94 women:
https://doi.org/10.1080/01443610600913932
Goshtasebi 2013: A randomised study in 90 women:
https://doi.org/10.1007/s00404-013-2839-3
Kaunitz 2010: A randomised study in 145 women:
https://doi.org/10.1097/AOG.0b013e3181ec622b

Tranexamic acid
We used data from:
Kiseli 2016: A randomised study in 62 women:
https://doi.org/10.1159/000443393
Kriplani 2006: A randomised study in 94 women:
https://doi.org/10.1080/01443610600913932
Goshtasebi 2013: A randomised study in 90 women:
https://doi.org/10.1007/s00404-013-2839-3
Preston 1995: A randomised study in 46 women:
https://doi.org/10.1111/j.1471-0528.1995.tb11293.x

NSAIDs
We used data from:

Khajehei 2013: a randomised study in 93 women:
https://doi.org/10.7196/SAJOG.587
Reid 2005: A randomised study in 51 women:
https://doi.org/10.1111/j.1471-0528.2005.00642.x
Grover 1990: A randomised study in 80 women:
https://doi.org/10.1111/j.1447-0756.1990.tb00235.x
Fraser 1991: A study in 45 women:
https://doi.org/10.1111/j.1479-828X.1991.tb02769.x

Ablation
We sourced data from:
Ergun 2011 (58 women):
https://doi.org/10.5505/tjod.2011.75768
Ghazizadeh 2014 (104 women):
https://doi.org/10.1089/gyn.2012.0041
Vihko 2003 (31 women):
https://doi.org/10.1080/j.1600-0412.2003.00110.x
Silva-Filho 2013 (84 women)
Bhattacharya 2011 – an analysis of data from 2,814 women who had either had the LNG-IUS, endometrial ablation or hysterectomy:
https://doi.org/10.3310/hta15190

Hysterectomy:
We sourced data from:
Dwyer 1993 (194 women):
https://doi.org/10.1111/j.1471-0528.1993.tb15237.x
O'Connor 1997 (172 women):
https://doi.org/10.1016/S0140-6736(96)07285-6
Bhattacharya 2011 – an analysis of data from 2,814 women who had either had the LNG-IUS, endometrial ablation or hysterectomy:
https://doi.org/10.3310/hta15190

For the risks, it was difficult to choose which particular risks to state. We chose nausea and headaches because they were common across a lot of the hormone-based treatments, and then also cited significant common other risks for each of the treatment options. The expert group commented on these until everyone was happy.

For the data for each risk we used:

IUS:
Hurskainen 2001 (236 women)
https://doi.org/10.1016/S0140-6736(00)03615-1
A review of all the evidence in 2016 by Health Quality Ontario:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5159479/
Shabaan 2011 (112 women):
https://doi.org/0.1016/j.contraception.2010.06.011

Ghazizadeh 2011 (110 women):
https://doi.org/10.2147/IJWH.S20999
Reid 2005 (51 women):
https://doi.org/10.1111/j.1471-0528.2005.00642.x
Kaunitz 2010 (145 women):
https://doi.org/10.1097/AOG.0b013e3181ec622b
Kiseli 2016 (62 women):
https://doi.org/10.1159/000443393

There was some discussion amongst the expert group about the proportion of IUS expulsions/partial expulsions. We decided to go with the 5% figure given in the FSRH guidelines:
FSRH Clinical Guideline: Intrauterine contraception (March 2023, Amended July 2023) - Faculty of Sexual and Reproductive Healthcare (p97).

Combined pill
Fraser 1991: A study in 45 women: https://doi.org/10.1111/j.1479-828X.1991.tb02769.x

Progesterone only pill
Kiseli 2016: A randomised study in 62 women:
https://doi.org/10.1159/000443393

medroxyprogesterone acetate
Kriplani 2006: A randomised study in 94 women:
https://doi.org/10.1080/01443610600913932
Kaunitz 2010: A randomised study in 145 women:
https://doi.org/10.1097/AOG.0b013e3181ec622b

Tranexamic acid
Kiseli 2016: A randomised study in 62 women:
https://doi.org/10.1159/000443393
Kriplani 2006: A randomised study in 94 women:
https://doi.org/10.1080/01443610600913932

NSAIDs
Khajehei 2013: a randomised study in 93 women:
https://doi.org/10.7196/SAJOG.587
Reid 2005: A randomised study in 51 women:
https://doi.org/10.1111/j.1471-0528.2005.00642.x

Ablation
Pellicano 2002 (82 women):
https://doi.org/0.1067/mob.2002.124958
Vihko 2003 (31 women):
https://doi.org/10.1080/j.1600-0412.2003.00110.x

Bhattacharya 2011 – an analysis of data from 2,814 women who had either had the LNG-IUS, endometrial ablation or hysterectomy:
https://doi.org/10.3310/hta15190

Hysterectomy
O'Connor 1997 (172 women):
https://doi.org/10.1016/S0140-6736(96)07285-6
Hurskainen 2001 (236 women):
https://doi.org/10.1016/S0140-6736(00)03615-1

We added blood clot risks from different sources:

Risks of blood clots from:
Faculty of Sexual & Reproductive Healthcare (FSRH)
For combined oral contraceptives:
https://www.fsrh.org/standards-and-guidance/documents/combined-hormonal-contraception/
For progestogen-only pill:
https://www.fsrh.org/documents/cec-guideline-pop/

For Provera:
Federal Drug Administration data
https://www.accessdata.fda.gov/drugsatfda_docs/label/2007/011839s071lbl.pdf

The Provera blood clot risks were particularly difficult to find. The FSRH guidance had no increased risk for progestogen-only pills, but Provera's own FDA declaration had an increased risk of about 2x. We decided to err on the cautious side and include this, even though we had to apply the relative risk to baseline risk from the 'do nothing' column ourselves. The absolute risks are all low.

The cancer risks were also difficult. We used the latest Oxford study (Fitzpatrick et al, 2023 https://doi.org/10.1371/journal.pmed.1004188) for breast cancer risks, and contacted the authors to confirm that we were using the numbers correctly. Good data on other cancer risks was not easily available so we did not give numbers.