Consultation response from Patient Safety Learning

RCOG Green-top Guideline No. 59 Outpatient Hysteroscopy 2nd Edition Peer review (13 March 2023)

This is a submission by Patient Safety Learning to the consultation by the Royal College of Obstetricians and Gynaecologists seeking views on a draft Green-top Guideline on outpatient hysteroscopy.

Specific Comments

Section: 4.1 What are the requirements for running an effective outpatient hysteroscopy service?
Line: 83-85 "The same study demonstrated high and equivalent levels of patient satisfaction with outpatient hysteroscopy when compared to hysteroscopy under general anaesthesia".
In discussing the benefits of outpatient hysteroscopy, weighed against traditional day-case hysteroscopy under general anaesthesia, the guidance quotes the results of specific randomised controlled trial, noting the patient satisfaction rates drawn from this study. Patient Safety Learning believes that this guidance should also consider as part of its evidence the hundreds of personal accounts from women who have experienced very high levels of pain and associated trauma during and/or following outpatient hysteroscopy procedures in the NHS. You can find examples of these shared publicly on Patient Safety Learning's patient safety platform the hub and from survey work carried out by the Campaign Against Painful Hysteroscopy.[1] [2] We would suggest quoting one trial study as evidence that this has significantly higher rates of patient satisfaction than hysteroscopy under general anaesthesia does not effectively account for the full scope of patient experiences and the available evidence base in relation to this procedure. <u>References</u> 1. Patient Safety Learning's *the hub*, Community Forum, Painful Hysteroscopy. 2020. https://www.pslhub.org/forums/topic/68-painful-hysteroscopy/ 2. Hysteroscopy Action. CAPH Survey Results – Hysteroscopy Action. Accessed 27 February 2023. https://www.hysteroscopyaction.org.uk/caph-survey-results/

Section: 4.1 What are the requirements for running an effective outpatient hysteroscopy service?
Line: 95-98 "Music and the use of virtual reality headsets have been shown to reduce the pain and/or anxiety associated with outpatient hysteroscopy, however, if these are to be used then units must ensure that communication with healthcare staff is not affected and that such adjuncts may not be suitable for all women".

While it is acknowledged that there is evidence provided in this guidance to support this statement, patients have raised with us concerns about the inclusion of this in the guidance considering the absence of information about pain relief methods such as IV sedation in this. They have also highlighted that there are a lack of studies indicating that such music and virtual reality options for reducing pain associated with hysteroscopies are preferred by women when directly compared to pain-relief options such as IV sedation.

Section: 4.2 What information should be provided prior to outpatient hysteroscopy?

Line: 111

"Written information should be provided to the woman prior to their appointment. This should include details about the procedure, the benefits and risks, advice regarding pre-operative analgesia as well as alternative management options and contact details for the hysteroscopy unit."

We agree with the proposition that women should be provided with detailed written information prior to hysteroscopy procedures to help ensure they can make informed choices about this treatment.

We would note that we have had feedback from both patients and healthcare professionals who have suggested that the quality of information currently provided can be variable, particularly in terms of what is available through primary care via GPs. For this part of the guidance to be effectively implemented we believe there needs to be a more rigorous approach taken on the consistency of this information and its availability across the country.

When considering how this guidance can subsequently be implemented, we would suggest there may be particularly focus needed on how the provision of information about hysteroscopy procedures in primary care can be improved.

Section: 4.2 What information should be provided prior to outpatient hysteroscopy?

Line: 113-114

"Adequate, clear and simple, written information should be provided to the patient with the appointment letter, in the woman's preferred language where possible."

We concur with the need for adequate, clear, and simple written information to be provided prior to this procedure. We believe that this should extend to this information being available in a wide variety of formats, not necessarily limited to written information. The use of infographics and short explainer videos may also be beneficial. It would be useful if accompanying this guidance that good practice examples of this could be shared by RCOG.

The guidance notes that this should be provided "in the woman's preferred language where possible". While perhaps implied, we believe it should be made explicit that if this is not possible, another translation option should be sought to ensure the patient involved is able to receive the full information they require to make an informed decision about this procedure, regardless of any language barriers.

Section: 4.2 What information should be provided prior to outpatient hysteroscopy?
Line: 114-117 “This information should include the recommendation to take a simple oral non-steroidal anti-inflammatory drug (NSAID) such as ibuprofen, unless contraindicated (in which case alternative analgesics should be suggested– see section 5.1), 60 minutes before 117 their scheduled appointment.”
The guidance references using simple analgesia (ibuprofen and paracetamol) unless 'contraindications' but do not detail those contraindications are. We believe greater clarity about those relevant contraindications is required here, so that patients can have conversations that include their individual risk of pain and make informed decisions accordingly.

Section: 4.2 What information should be provided prior to outpatient hysteroscopy?
Line: 121-126 “In addition, the provided information should make women aware that there are alternative types of pain management (e.g. intravenous sedation, regional and general anaesthesia) that they can choose if they have concerns about undergoing hysteroscopy in the setting or if the procedure needs to be abandoned at the patient’s request. Women should be aware that these alternative options can be discussed at their clinic appointment and that their hysteroscopy can be rescheduled to accommodate the preferred model of care and pain management as necessary.”
We welcome the emphasis on ensuring women are provided with information about alternative types of pain management and the option to re-schedule appointments. Too many patients have shared with us experiences of this not being the case and therefore we would expect to see clear plans to address this in the implementation of this guidance. We would also note in relation to this part of the guidance that the Campaign Against Painful Hysteroscopy has highlighted that this does not cover all options for hysteroscopy, including IV sedation with analgesia, procedural sedation analgesia, spinal anaesthesia, and light general anaesthetic. We believe the guidance would benefit from being updated to also cover these options.

Section: 4.3 How should consent be obtained prior to outpatient hysteroscopy?
Line: 147-148 “The hysteroscopist must inform the woman that they are likely to experience period-like cramping and lower abdominal pain during and/or after the procedure.”
While we appreciate pain is a complex issue, we would note that this is quite an imprecise description and that some women may not find this helpful in making an informed decision

about their care. Many women experience pain differently, experiences of period pain can vary significantly, and some post-menopausal women may have not experienced period pain for years prior to undergoing this procedure.

We believe there needs to be significantly greater research undertaken into the extent of pain around these procedures and better ways of sharing what pain might be like without referring to such general terms.

We would also note that some patients have raised concerns that describing pain as 'period-like', intentionally or unintentionally, can be viewed as minimising its importance, or even this being viewed as an acceptable form of pain.

Section: 4.3 How should consent be obtained prior to outpatient hysteroscopy?

Line: 148-150

"The woman or person with a cervix or a womb should be advised that if they find the procedure too painful or distressing at any point, then they must alert the clinical team who will stop the procedure immediately."

We welcome the emphasis on the importance of patients being able to stop this procedure at any point.

We believe this could be strengthened by including in the guidance a reference to the concept of a 'two-step stop' to the woman during the consent.[1] This being where a patient can ask for the procedure to be paused at any time and is then told what part of the procedure they are at/time left to complete this. They are then asked if they would like the entire procedure to stop based on this information. It is also important as part of this to note that the patient is told this information in a factual way, without making them feel coerced or pressured by the clinicians opinion.

Taking a 'two-step stop' approach could help to ensure that the intent of this part of the guidance, ensuring women can stop this procedure at any time, is satisfactorily fulfilled in practice.

We would also note in relation to this point that in describing their negative experiences of hysteroscopy procedures in the NHS, some women have shared with us that during the procedure as a result of the pain they have felt frozen and unable to speak. We believe the guidance therefore should also account for this possibility when considering obtaining and maintaining consent, as this may provide a barrier to raising such concerns mid-procedure.

Related to this, the way this part of the guidance is phrased appears to put the onus on this solely on the patient. While their role is obviously key here, we believe it would be beneficial to acknowledge that clinicians too should be alert to the possibility of pain and should be monitoring for signs of this. This may prove particularly important in cases as mentioned above where shock may hinder the patient from making their concerns known.

References

1. Saira Sundar, Through the hysteroscope: Reflections of a gynaecologist, 26 January 2021. https://www.pslhub.org/learn/patient-safety-in-health-and-

care/womens-health/through-the-hysteroscope-reflections-of-a-gynaecologist-r3907/

Section: 4.4 Should a pre-procedural safety checklist be performed prior to outpatient hysteroscopy?

Line: 162-165

"Units should consider using a checklist (e.g. a specifically adapted World Health Organisation [WHO] surgical safety checklist or a locally developed outpatient procedure safety standard checklist) to make sure essential elements such as patient identity checks, allergy status and exclusion of pregnancy are recorded where appropriate."

We would note that while use of a pre-procedural safety checklist may be beneficial prior to these procedures, there is a need for good practice examples to be shared to illustrate and support this. This may not be within the scope of the guideline itself, but in ensuring this is implemented effectively by healthcare professionals it would be helpful if RCOG could publicly share such a checklist, specifically adapted to hysteroscopy procedures.

Section: 4.5 How should care after outpatient hysteroscopy be provided?

Line: 208-211

"The woman's condition, comfort and pain control should be assessed, monitored and analgesia be provided when necessary. Access should be available to a longer duration recovery area when pain cannot be easily managed or complications have arisen during the procedure."

While we welcome this explicit reference to assessing a patient's condition immediately after the procedure, we believe it would also benefit from adding advice for a follow up phone call/appointment a few days after the procedure to help assess this. We have heard from many women who have had a painful hysteroscopy who have felt an initial sense of shock immediately following the procedure and as a result would not have been easily able to feedback about their experience at that point.

It would be useful if there could be a standard process around this when collecting information for Patient Reported Outcome Measures so that patient experiences can be used to inform future practice and ongoing improvements.

Section: 4.6 How should training and standards in outpatient hysteroscopy be provided and assessed?

Line: 214-239

"A hysteroscopic training programme should include knowledge and understanding of both basic and advanced skills relevant to hysteroscopic procedures alongside aspects of clinical governance in hysteroscopy."

We believe it is important that staff who undertake these services should receive standardised and regulated training. This should include the risks of severe pain, clinical factors that make someone more susceptible, the limitations of clinician perception to assess pain, the importance of listening to women throughout and the application of consent guidelines. Skills are clearly important but also are the behaviours that support women's decision making and their confidence in being able to say 'no' if there are uncomfortable, in pain and /or anxious.

We would suggest there would be significant value in ensuring that any training programme takes account of and draws on the many experiences of painful hysteroscopies highlighted by organisations such as the Campaign Against Painful Hysteroscopy as part of this. One approach to doing so could be to co-design parts if this training with harmed patients or patient groups so that their experiences can help to inform and improve future hysteroscopy care.

General comments

In addition to our specific comments about this guidance, we also have the following general comments:

Triage

Although it is difficult to predict who will experience severe pain during a hysteroscopy, conversations between the patient and the clinician around medical history could help to identify who might be more susceptible. For example, women who have experience sexual trauma, found gynaecological procedures very painful in the past and those who have not given birth may be more at risk.

We believe there is a significant gap in the guidance in this area. There is a lack of detail about triaging women for susceptibility to severe pain and providing advice accordingly. Information on this is crucial for women to be able to make informed decisions accordingly.

There appears to be no criteria, or associated evidence, including in this guidance concerning the likelihood of some patients experience severe pain as a result of this procedure. If there is no available data to support this, we believe the guidance should be making it clear how healthcare professionals should capture this within the patient reported outcomes process.

Patient reported outcomes

Patient-reported outcome data is routinely collected after these procedures to identify any emerging patient safety concerns and made publicly available. We believe this should be mandated for all hysteroscopy procedures and make this data publicly available.

Patient safety incidents

We believe that severe pain during hysteroscopy procedures, as reported by patients, should be recorded by healthcare professionals as a patient safety incident.

Research into pain

We believe that research should be commissioned to identify the factors that lead to patients being at greater risk of experiencing high levels of pain during outpatient

hysteroscopy. This should then be used by NHS England and RCOG to create evidence-based guidance to support clinicians in identifying patients most at risk of severe pain during hysteroscopy.

Long-term consequences of harm

In raising concerns with us around this consultation, a patient has highlighted that although in the initial press release announcing this consultation RCOG have sited the potentially 'traumatic' experiences of these procedures that some patients experience, this does not translate into the guidance.[4] They have pointed out that the potential of psychological trauma from these procedures is not referenced in this guidance.

We have heard an number of patient experiences, both directly shared with us on *the hub* and by patient groups such as the Campaign Against Painful Hysteroscopy, citing such issues. In our view the guidance should acknowledge and consider this.

Implementation

How the positive elements of this guidance are implemented in practice will be key to its effectiveness. From hearing from patients with safety concerns relating to hysteroscopy, we know that all too often they can experience a variable approach to the information that they receive prior to the procedure, information on pain management options.[1] [2] [3]

To successfully implement this guidance we believe greater clarity is needed on:

- Who is monitoring and reporting on its implementation?
- How is this being communication/translated into practice?
- Will there be an audit around whether people have the right skills, training, staff and equipment that is highlighted as needed for best practice in the guidance?
- Where is the national collection of data using a standardised patient outcome form that captures all of the information needed to make this procedure as safe as possible and provide evidence for future clinical guidance?

We believe there needs to be timeframes for implementation, measures of success, plans for working with patients and other key stakeholders, details of associated staff requirements and training, and information on how progress will be reviewed, monitored and reported on.

References

1. Patient Safety Learning, Improving hysteroscopy safety, 6 November 2020. https://www.patientsafetylearning.org/blog/improving-hysteroscopy-safety
2. Patient Safety Learning, Guidance for outpatient hysteroscopy: Consultation Response, 16 March 2022. https://www.patientsafetylearning.org/blog/guidance-for-outpatient-hysteroscopy-consultation-response
3. Patient Safety Learning, Hysteroscopy: 6 calls for action to prevent avoidable harm, 1 March 2023. https://www.patientsafetylearning.org/blog/hysteroscopy-6-calls-for-action-to-prevent-avoidable-harm
4. RCOG, Draft guideline on Outpatient Hysteroscopy opens for consultation, 13 February 2023. https://www.rcog.org.uk/news/draft-guideline-on-outpatient-hysteroscopy-opens-for-consultation/