NHS
National Institute for
Health and Clinical Excellence

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Audit criteria

Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids

NICE interventional procedure guidance 231

Interventional Procedure Implementation Tools

Audit criteria for NICE interventional procedure guidance 231

Magnetic resonance image-guided transcutaneous focused ultrasound for uterine fibroids

Objective of the audit
The aim of the audit is to assist individual clinicians and NHS trusts to determine whether the procedure being implemented is safe and efficacious, and follows the NICE guidance.

Patient group to be included in the audit
Patients undergoing magnetic resonance (MRI) image-guided focused ultrasound for uterine fibroids.

Sample for the audit
We encourage the audit of all cases where smaller numbers (less than 50 in a year) are being treated. In centres undertaking large numbers of treatments (more than 100) an audit which aims to provide a sample size that is likely to produce statistically significant results is encouraged.

Dataset required for the audit
Dataset items required for audit of this procedure are given in table 1 (overleaf). This dataset is intended to be collected for each woman by the clinical team providing the treatment. Some data items may already be available from hospital patient information systems. Table 2 provides the criteria proposed to audit the efficacy and safety of this procedure within the relevant department.

Frequency of review
When introducing this treatment, it is suggested that the efficacy of the procedure be reviewed every 30 patients or 12 months, whichever is sooner. Subsequently, the frequency of ongoing reviews should be considered alongside other pressures for audit within the specialty/trust.

Patient-reported outcomes
Because the procedure may be relatively new in some hospitals, it presents a clear opportunity to gather feedback from women on their views and experience of the outcomes of this treatment − in particular, unexpected patient reported outcomes. There are several general survey tools and disease-specific tools that could be administered to each patient on or after discharge to be returned to the trust on completion.

Adverse events
To ensure that any valuable insight regarding unexpected consequences of this procedure is shared among clinicians, each adverse event should be documented and details forwarded to the National Patient Safety Agency's (NPSA) National Reporting and Learning System.

Collation of audit results
The data should be collated using the definitions specified in the audit criteria in table 2.

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Table 1. Dataset: this defines the dataset items required within the audit criteria given in table 2

Dataset item ref.	Dataset required per patient	Data source − for example, data collection form, patient notes	Data variable type − for example, size in mm
	Baseline data − for example, size of tumour/problem		
A	Written information on procedure provided to patient and discussion with patient documented in notes	Data collection form or patient health record	Y/N
B	Written consent given by patient	Data collection form or patient health record	Y/N
C	Number, size and location of fibroids	Data collection form or patient health record	Number, size (cm), location
D	History of previous treatments	Data collection form or patient health record	Y/N; detail
E	Pre-procedural symptom assessment for example using Uterine Fibroid Symptom Quality of Life score (UFS-QOL)[1] to obtain symptom severity score (SSS)	UFS-QOL survey tool or other symptom assessment tool for pain and bleeding	Y/N; UFS-QOL scores
	Follow-up data (immediate postoperative period and long-term outcomes)		
F	Post-procedural symptom assessment using same tool as for baseline assessment e.g. UFS-QOL score at 6 months (and 12 months)	Tool used in baseline assessment	Y/N, Score; 6 months; Y/N Score; 12 months
G	Alternative treatment or repeat procedure undertaken within 2 years of original procedure	Data collection form or patient health record	Y/N; details and dates
	Adverse events (safety outcomes)		
H	Nerve paresis and or pain at any stage following the procedure, described by patient and documented in notes by clinician, which is still present 6 weeks following the procedure	Data collection form or patient health record	Y/N; details
I	Skin burns found after procedure – number & degree of burn(s)	Data collection form or patient health record	Y/N; number and degree of burns
	Aggregated data − for example, no. of patients with condition receiving treatment		
a	The number of patients receiving MRI-guided focused ultrasound for uterine fibroids in a given period	PAS or other administration system	Number

[1] Spies JB, Cyne K, Guaou Guaou N et al (2002)The UFS-QOL, a new disease-specific symptom and health-related quality of life questionnaire for leiomyomata. *Obstet Gynaecol* 99(2):290–300.

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Table 2. Audit criteria: these are the audit criteria developed by NICE to support the implementation of this guidance. Users can cut and paste these into their own programmes or they can use this template

Criterion no.	Numerator (dataset item ref.)	Denominator (dataset item ref.)	Definition of terms and/or general guidance (dataset item ref.)	Audit criterion and standard (dataset item refs and calculation)	Exceptions
	The number of women receiving MRI-guided focused ultrasound for uterine fibroids within a given period:	The number of women receiving MR image-guided focused ultrasound for uterine fibroids within a given period (a)		The proportion of women receiving MR image-guided focused ultrasound for uterine fibroids within a given period:	
1	– who have (i) received written information on the procedure, (ii) had a discussion with the doctor which is documented in the notes and (iii) given written consent (or have a completed and signed Consent Form 4) (A & B)	As above (a)	The DH 'Good practice in consent' initiative produced formal processes and documents for full and informed consent. The correct documents should be used to support the consent process for all investigations and treatments. Consent Form 4 is for adults who are unable to consent to investigation or treatment	– who have (i) received written information on the procedure, (ii) had a discussion with the clinician which is documented in the notes and (iii) given written consent [Where A & B = Yes/a x 100] (Standard = 100%)	None
2	– who have had a symptom assessment at (i) baseline, (ii) 6 months and (iii) 12 months following the procedure (E & F)	As above	Follow-up of symptom relief resulting from the procedure among these patients should be encouraged as part of routine practice	– who have had a symptom assessment at (i) baseline, (ii) 6 months and (iii) 12 months following the procedure (i) [where a score exists for E/a x 100] (ii & iii) [where scores exists for F at 6 months/a x 100 and F at 12 months/a x 100] (Standard = 100%)	Those lost to follow up within the period. This figure should be reported alongside the results
3	– who achieved a 10 point reduction in their pre-procedural symptom severity score, 6 months	As above	The success of the treatment may be affected by the size of the fibroid therefore the results should be analysed by size and number of	– who achieved a ten point reduction in their pre-procedural symptom severity score, 6 months (and 12 months) after the procedure	Those lost to follow up within period. This figure should be reported

[2] Fennessy FM, Tempany CM, McDonnald NJ et al (2007) Uterine Leiomyomas: MR Imaging-guided Focused Ultrasound surgery – Results of different treatment protocols. *Radiology* 10. 1148/ radiol.243 (3): 885-893.l

	(and 12 months) after the procedure (E & F)		tumour (C). Previous treatments should also be considered (D) A 10-point improvement is consistent with a clinical improvement[2]	[where E – F ≥ 10 points/ a x 100] (Rates in literature = 71-79.2% at 6 months and 51- 78% at 1 year therefore suggested standard = 75% at 6 months and 65%)	separately and considered with the results
4	– who suffer a skin burn as a result of the procedure (I)	As above	The results should be presented in terms of the number and the degree of the burn	– who suffered a skin burn as a result of the procedure [I/a x 100] (Rate in literature = 4–5% so suggested standard = max. 5% of all burns)	None
5	– who are suffering nerve paresis or pain 6 weeks following the procedure (H)	As above	The success of the treatment may be affected by the size of the fibroid therefore the results should be analysed by size and number of tumour (C). Previous treatments should also be considered (D).	– who are suffering nerve paresis or pain 6 weeks following the procedure [H / a x 100] (Insufficient evidence in literature to set a standard)	Those lost to follow up within period. This figure should be reported separately and considered with the results
6	– who have an alternative treatment or a repeat procedure within 2 years of the original procedure (G)	As above	The success of the treatment may be affected by the size of the fibroid therefore the results of this audit should consider the size and number of fibroid tumours (C). Previous treatments should also be considered (D)	- who have alternative treatment or a repeat procedure within 2 years of the original procedure [G/a x 100] (Rate in literature = 12–28% so suggested standard = 20% in those less than 20cm)	Those lost to follow up within the period. This figure should be reported alongside the results
No. of criterion replaced	***Local alternatives to above criteria (to be used where other data addressing the same issue are more available) and examples of patient-reported outcome tools***				

Appendix: Using the audit criteria to audit implementation of the guidance

The following paragraphs are provided to assist clinicians and NHS trusts in setting up special arrangements for audit of NICE interventional procedure guidance. They represent current good practice in audit, but additional guidance can be found in 'Principles for best practice in clinical audit'.

Auditing implementation of NICE guidance
Following dissemination of the guidance to all relevant parties, clinicians are encouraged to undertake a baseline audit to determine whether practice is in accordance with the guidance. Where practicable, the audit should be repeated on a regular basis to enable comparisons of practice and results over time.

Audit rationale and planning
The Healthcare Commission assesses the performance of NHS organisations in meeting core and developmental standards set by the Department of Health (DH) in 'Standards for better health'. The implementation of NICE guidance will help organisations meet developmental standard D13. Standard C5(d) states that 'Healthcare organisations ensure that clinicians participate in regular clinical audit and reviews of clinical services'. Standard C3 states that healthcare organisations protect patients by following NICE interventional procedures guidance. In order to sign off annual declarations to the Healthcare Commission, NHS trust boards need to receive regular reports on the implementation of NICE guidance, highlighting areas of non-compliance and risk.

The audit of this guidance needs to be planned alongside audits of other NICE guidance, in order to feed into the appropriate reporting cycle.

Audit reporting template
As part of this guidance, NICE has developed recommended audit criteria and has included these within an audit reporting template. It is recognised that some trusts will have their own well-developed systems for reporting audit results within the organisation and for retaining results to allow progress over time to be monitored. Where this is the case, NICE would not wish to alter current approaches − the reporting template is provided for those trusts that might find it useful.

Calculation of compliance
Where compliance (%) with the guidance should be calculated as a measure, this is calculated as follows:

$$\frac{\text{Number within the population group whose care is consistent with the criterion}}{\text{Number within the population group to whom the measure applies (that is, the total population group less any exceptions)}} \times 100\%$$

As well as reporting the percentage compliance, it will often be useful to report the actual numerator and denominator figures (to give an idea of scale).

Review of audit findings
NICE encourages the local discussion of audit findings and, where there is an identified lack of compliance with the guidance, the development of an action plan. See 'How to put NICE guidance into practice: a guide to implementation for organisations'. Progress against the plan can then be monitored and reported to the trust board to show that progress towards desired improvements is being achieved.

Definitions used within the audit criteria and audit reporting template	
Criterion	Measurable element derived from the key priorities for implementation of each piece of guidance. The numerator and denominator which make up the criterion are defined separately. By definition, new interventional procedures have a limited evidence base, and for this reason suggested event rates (either for efficacy or safety) from the literature are included where available.
Exceptions	Where implementation of guidance is not appropriate for a particular subgroup of the population, this is clearly stated. Where there are no exceptions, this is also stated.
Definition of terms and/or general guidance	Unambiguous definitions of any terms used in the audit criteria to promote consistency of approach and measurement and reduce the risk of non-comparable findings. This may include general guidance specific to that criterion. These definitions do not include any interpretation (or other clarification) of the NICE guidance. Should there be a need to include any such clarification, this will be inserted as a footnote to the audit template. The desired standard is shown in parentheses.
Dataset	Data to be gathered or used as evidence of implementation.
Data source	Source(s) of data specified within the dataset. This may simply refer to a data collection form or point to patient information systems where this information is already compiled and available.
Compliance	Percentage compliance within the audited sample (see previous section for calculation).
Findings	Usually, this will provide added detail around the basic compliance figure − such as showing variation by age, ethnic group − to ensure that an aggregate compliance figure does not mask difficulties being experienced by particular subgroups of the population.
Comments	This allows free text for comment on audit findings and the local context in which they exist. It can provide the reference to other, more detailed documents including, if necessary, an action plan for improvement.

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Audit report: This report is designed to be completed for each audit to record compliance, findings and comments

Date audit completed:	
Audit lead/manager:	
Number of audit:	
Summary of previous audit results: (where applicable)	

To be completed by service during audit					
Criterion no.	**Criterion**	**Data source**	**Compliance**	**Findings**	**Comments**
	The proportion of women receiving MR image-guided focused ultrasound for uterine fibroids within a given period:				
1	– who have (i) received written information on the procedure, (ii) had a discussion with the clinician which is documented in the notes and (iii) given written consent				
2	– who have had a symptom assessment at (i) baseline, (ii) 6 months and (iii) 12 months following the procedure				
3	– who achieved a ten point reduction in their pre-procedural symptom severity score, 6 months (and 12 months) after the procedure				
4	– who suffered a skin burn as a result of the procedure				
5	– who are suffering nerve paresis or pain 6 weeks following the procedure				
6	– who have alternative treatment or a repeat procedure within 2 years of the original procedure				

Date audit completed:	
Audit lead/manager:	
Number of audit:	
Summary of previous audit results: (where applicable)	

To be completed by service during audit					
Criterion no.	**Criterion**	**Data source**	**Compliance**	**Findings**	**Comments**
No. of criterion	**Local alternatives to above criteria (to be used where other data addressing the same issue are more readily available)**				

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History of audits: This is designed for the recording the results of consecutive audits, to demonstrate progress over time

		Compliance			Other findings		
Number of audit:		**Initial**	**2**	**3**	**Initial**	**2**	**3**
Date audit completed:							
Audit lead/manager:							
Criterion no.	**Criterion**						
	The proportion of women receiving MR image-guided focused ultrasound for uterine fibroids within a given period:						
1	– who have (i) received written information on the procedure, (ii) had a discussion with the clinician which is documented in the notes and (iii) given written consent						
2	– who have had a symptom assessment at (i) baseline, (ii) 6 months and (iii) 12 months following the procedure						
3	– who achieved a ten point reduction in their pre-procedural symptom severity score, 6 months (and 12 months) after the procedure						
4	– who suffered a skin burn as a result of the procedure						
5	– who are suffering nerve paresis or pain 6 weeks following the procedure						
6	– who have alternative treatment or a repeat procedure within 2 years of the original procedure						
No. of criterion replaced	**Local alternatives to above criteria (to be used where other data addressing the same issue are more readily available)**						