

Commissioning Policy/Statement

Funding of Open/Standing MRI Scans

October 2015

This commissioning policy has been endorsed by and applies to patients within:
 NHS South Worcestershire Clinical Commissioning Group (CCG)
 NHS Redditch & Bromsgrove Clinical Commissioning Group (CCG)
 NHS Wyre Forest Clinical Commissioning Group (CCG)

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Ratified by (name and date of Committee):	NHS Redditch & Bromsgrove CCG Clinical Executive Team – 05/08/15 NHS South Worcestershire CCG Clinical Executive Team – 14/04/15 NHS Wyre Forest CCG Clinical Executive Team – 28/04/15
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Contribution list

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Review and Amendment Log

Version No	Type of Change	Date	Description of change
V1.1	Minor	30/10/15	Update to the referral proforma to clarify the process for requesters
V1.2	Minor	15/07/16	Update to the referral proforma and clarification of acceptance criteria

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SUMMARY

NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (also termed “the Commissioner” in this document) will fund referral for Open MRI scanning of greater than 0.5T as an alternative to conventional MRI in secondary care under the following circumstances only:

- The Patient has been recommended this diagnostic test by a specialist/Extended Scope Practitioner (referral pathways are noted in section 2 of this policy)

And

- Has failed standard MRI scanning and due to Claustrophobic reaction where an oral prescription sedative has not been effective

Or

- Has a condition that requires an Open MRI so as not to trigger an exacerbation of that condition

Or

- Has failed standard MRI scanning as they are considered obese and, therefore, cannot fit within a conventional MRI

Standing, upright, weight bearing or positional MRI will not be routinely commissioned

1. Definitions

- 1.1 **Exceptional clinical circumstances** are clinical circumstances pertaining to a particular patient, which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.
- 1.2 **A Similar Patient** refers to the existence of a patient within the patient population who is likely to be in the same or similar clinical circumstances as the requesting patient and who could reasonably be expected to benefit from the requested treatment to the same or a similar degree. When the treatment meets the regional criteria for supra-CCG policy making, then the similar patient may be in another CCG with which the Commissioner collaborates. The existence of one or more similar patients indicates that a policy position is required of the Commissioner.
- 1.3 An **individual funding request (IFR)** is a request received from a provider or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.
- 1.4 An **in-year service development** is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the Commissioner agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded

through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.

2. Scope of policy:

2.1 This policy should be considered in line with all other Worcestershire Commissioning Policies. Copies of these Commissioning Policies are available on the following website address:

<http://www.redditchandbromsgrovecg.nhs.uk/about-us/strategies-policies-and-procedures/commissioning-ifr/>

2.2 This policy applies to all patients that the Worcestershire CCGs have responsibility for including:

- People provided with primary medical services by GP practices who are members of one of the CCGs or
- People usually resident in the area covered by the CCG's and not provided with primary medical services by any CCG.

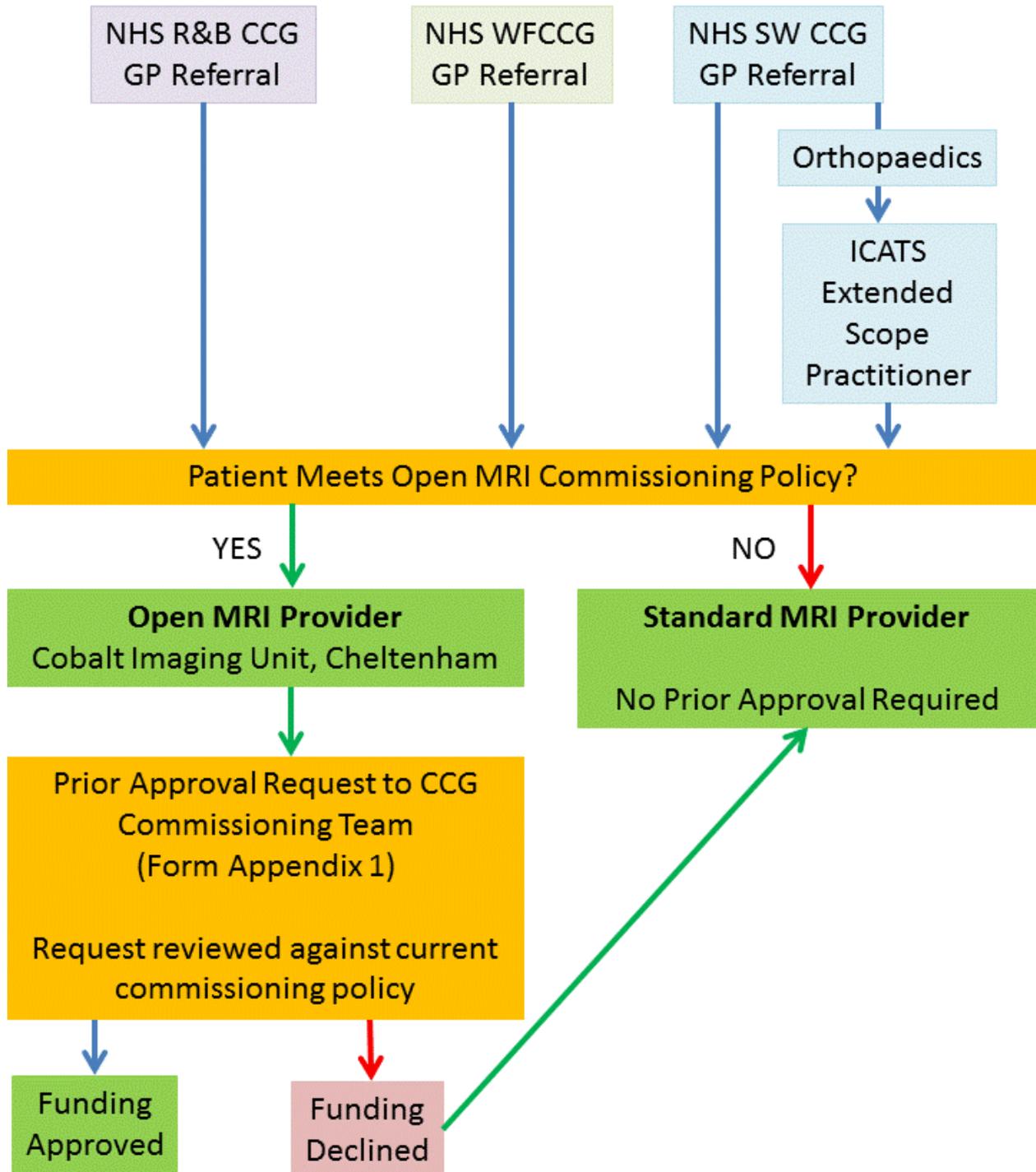
2.3 For patients who do not meet the policy and where there is demonstrable evidence that the patient has clinically exceptional circumstances, an Individual Funding Request may be considered. The referring clinician should consult the Commissioner's "Operational Policy for Individual Funding Requests" document for further guidance on this process.

For a definition of the term "clinically exceptional circumstances", please refer to the Definitions section of this document.

2.4 This policy applies to all patients for whom Open or Standing/Upright/Positional MRI is being considered.

2.5 Patients who meet the requirements for this policy should be referred to an appropriate service provider (for Worcestershire patients this is currently the Cobalt Imaging Unit based in Cheltenham). The current referral pathway is noted below:

MRI Referral Pathway



3. Background:

- 3.1 NHS principles have been applied in the agreement of this policy.
- 3.2 NHS Redditch & Bromsgrove Clinical Commissioning Group, NHS South Worcestershire Clinical Commissioning Group and NHS Wyre Forest Clinical Commissioning Group (termed “the Commissioners”) consider all lives of all patients whom it serves to be of equal value and, in making decisions about funding treatment for patients, will seek not to discriminate on the grounds of sex, age, sexual orientation, ethnicity, educational level, employment, marital status, religion or disability except where a difference in the treatment options made available to patients is directly related to the patient’s clinical condition or is related to the anticipated benefits to be derived from a proposed form of treatment.
- 3.3 Where an NHS commissioned service is provided by the Independent Sector (a privately funded provider), any patient referred for NHS funded treatment MUST also comply with the Provider’s exclusion criteria for treatment; for example, at time of referral (and treatment) they must:
- Be aged 18 or over
 - Have a BMI of 40 or less
 - Not have an incapacitating disease which is a constant threat to life
 - Have had no previous adverse events or complications as a result of anaesthesia
 - Not have an unstable mental condition, receiving psychiatric treatment
- 3.4 Magnetic Resonance Imaging (MRI) is a widely used diagnostic imaging technology and is particularly useful in detecting soft tissue damage and disease. The patient undergoing imaging is placed in a gradient magnetic field delivering radiofrequency pulses to the patient and processing the electromagnetic signals emitted from the region being examined.¹ (CADTH)
- 3.5 The standard (Closed/high-field) method of MRI requires the patient to be horizontal and stationary. MRI uses a strong magnetic field and radio waves to produce detailed, usually 2-D, images of the inside of the body. MRI scans can show muscles, joints, bone marrow, blood vessels, nerves and other structures within the body and are commonly used to examine the brain, spine, abdomen and pelvis.
- 3.6 There are two main types of MRI. Open (or low-field) MRI has a typical magnetic field strength of around 1.0 tesla (T), while Closed (or high-field) MRI is the more powerful at around 1.5 or even 3T.
- 3.7 A Closed MRI scan often involves a cylinder-shaped scanner that is uncomfortable for larger patients and leaves some patients claustrophobic. For many patients Open MRI minimizes anxiety and claustrophobia because its ‘C’ shaped design offers a spacious environment in which patients lie between two plates. They are also used for intraoperative imaging or image guided interventions where easy access to the patient is required.¹
- 3.8 The main drawbacks of Open MRI are that the sequences needed (length of time to get an image) are longer, the signal-to-noise ratio is lower, and the spatial resolution is poorer. Consequently, for the analysis of small structures such as joints (wrists, fingers and toes), Closed MRI is always recommended because the quality and detail of the image will be superior. Also, the field strength of open magnets is significantly reduced and may be inadequate for some scanning purposes.

- 3.9 While it may have apparent limitations in terms of indications, there are situations that call for Open MRI, which as the name suggests is not reliant on having the patient lie in a long narrow tube. Open MRI can be used where there is the problem of claustrophobia, which affects about 10% of the population (Anxiety UK).
- 3.10 Furthermore, the increasing number of overweight and obese patients produces more problems for high-field MRI units. A third advantage of lowfield MRI is that the images obtained are affected to a much lesser degree by metallic structures that may be present in the body such as pins in the spine, implants or even shrapnel.
- 3.11 Musculo-skeletal Integrated Clinical Assessment and Treatment Service (MSK ICATS): MSK ICATS are primary care based services that provide GPs with the opportunity to refer to an accessible, specialist diagnosis service, which also provides, where clinically appropriate, medical treatment for adults (age 18 and above) with symptomatic musculoskeletal conditions who require additional orthopaedic assessment/treatment.
- 3.12 Whilst ICATS provision varies across the Clinical Commissioning Groups (CCGs), the primary aims of the ICATS service is to manage patients within primary and community based services rather than refer the patient into secondary care. ICATS will also be expected to take account of the provisions of this policy before considering making a referral into secondary care.
- 3.13 Current ICATS provision extends to NHS South Worcestershire CCG.

4. Relevant National Guidance and Facts

- 4.1. No National Guidance Found
- 4.2. The Technology:
The quality of MRI images is partly dependent on the field strength of the magnet which is measured in tesla (above 1 Tesla (T) is considered high).

Closed MRIs have magnet field strengths of >1.5 tesla whereas Open MRIs have medium strengths magnets of 0.5-1.0T. The lower field strength of Open MRIs results in poorer quality images in comparison to Closed MRIs, with lower signal-to-noise ratios and more motion artefacts. The length of time required to obtain an image is also longer.¹

Generally low field strength is below 0.5T, mid-field strength is 0.5 T, up to 0.9 T or 1 T; and high-field strength is at/and or above 1 T.² High-field devices are usually closed-bore magnets because the stronger magnetic fields (1–3 T) require more robust shielding and gradient structure to maintain field homogeneity. The open magnet's field strength usually varies from 0.2–1.0 T.

5. Evidence Review

- 5.1 MRI studies reported in the literature are generally based on intermediate- or high-field MRI. There is insufficient evidence in the published peer-reviewed literature to support the use of low-field strength MRI for any diagnostic indication.^{3,4,5,6,7,8,9,10,11,12,13}

5.2 An evidence review performed by the Canadian Agency for Drugs and Technologies in Health (CADTH)¹ found several non-randomised trials which compared high and low field MRIs.

- In a prospective study comparing a 0.2 T open scanner and a 1.5 T high-field system were used to examine 401 patients.¹⁴ There was no significant difference in the diagnostic accuracy of the two types of scanners in examinations for patients with diseases of the kidney (n=78), shoulder (n=122), or spine (n=105), using surgical or clinical follow-up as the reference finding. In cerebral examinations (n=96), the high-field system had a statistically significant advantage in accuracy (p=0.01). The authors suggest that limitations due to field strength are relevant only in a small number of cases that warrant high-field examination.
- In a study on MRI arthrography of the shoulder, a 0.2 T Open MRI and a 1.5 T high-field system were used to examine 38 patients. Correlation of surgical and MRI findings was available for 27 patients (71%). The high-field MRI produced better image quality and fewer motion artefacts than the open low-field MRI, but diagnostic accuracy in the cases with surgical correlation was the same for both systems. The authors conclude that low-field MRI compares favourably to highfield MRI in detecting major abnormalities of the shoulder, but has disadvantages because of the duration of the examination, and the increased risk of reduced image quality due to motion artefacts.¹⁵
- Michel et al.¹⁶ compared patients' acceptance of MRI pelvimetry that was done using Open 0.5 T and Closed 1.5 T systems. Of 30 women referred for pelvimetry, 60% preferred the Open system, 7% the Closed system, and 33% had no preference. The image quality was adequate in both systems. In a British study, 47 of 50 patients (94%) who had failed to complete a scan in a conventional machine underwent successful MRI in a 0.5 T open system.¹⁷

5.3 **Standing, Weight-Bearing, Positional, or Upright MRI**

Washington State published a Health Technology Assessment on Standing, Weight-Bearing, Positional, or Upright MRI (2006). Conclusions included that:¹⁸

- there is limited scientific data available on the accuracy and diagnostic utility of standing, upright, weight-bearing or positional MRI
- there is no evidence from well-designed clinical trials demonstrating the accuracy or effectiveness of weight-bearing MRI for specific conditions or patient populations
- due to the lack of evidence addressing diagnostic accuracy or diagnostic utility, standing, weight-bearing, positional MRI is considered investigational and experimental

5.4 **Open-design**

Open MRI allows for imaging without the patient being placed within an enclosed space. Open MRI has become the standard of care when conventional design is contraindicated, as previously specified.

6. Patient Eligibility

6.1 Referral for Open MRI scanning of greater than 0.5T will be funded on the NHS as an alternative to conventional MRI in secondary care under the following circumstances only:

- The Patient has been recommended this diagnostic test by a specialist/Extended Scope Practitioner (referral pathways are noted in section 2 of this policy)

And

- Has failed standard MRI scanning and due to a claustrophobic reaction where an oral prescription sedative has not been effective

Or

- Has a condition that requires the use of an Open MRI to enable the positioning of the patient such that an exacerbation of that condition is not triggered

Or

- Has failed standard MRI scanning as they cannot fit within a conventional MRI

Please use the Open MRI Scan Proforma included within this policy (Appendix 1) when making a request for funding consideration.

Standing, upright, weight bearing or positional MRI will not be routinely commissioned

7. Supporting Documents

1. CADTH. Open Magnetic Resonance Scanner. Issue 92. November 2006
2. CIGNA. Magnetic Resonance Imaging- low field. CIGNA coverage policy 0444
3. Paakko E, Reinikainen H, Lindholm EL, Rissanen T. Low-field versus high-field MRI in diagnosing breast disorders. *Eur Radiol.* 2005 Jul;15(7):1361-8. Epub 2005 Feb 12.
4. Klein HM, Meyners W, Neeb B, Labenz J, Truümmeler KH. Cardiac magnetic resonance imaging using an open 0.35 T system. *J Comput Assist Tomogr.* 2007 May-Jun;31(3):430-4.
5. Rupprecht T, Nitz W, Wagner M, Kreissler P, Rascher W, et al. Determination of the pressure gradient in children with coarctation of the aorta by low-field magnetic resonance imaging. *Pediatr Cardiol.* 2002 Mar-Apr;23(2):127-31. Epub 2002 Feb 19.
6. Terada H, Gomi T, Harada H, Chiba T, Nakamura T, Iwabuchi S, et al. Development of diffusion-weighted image using a 0.3T open MRI. *J Neuroradiol.* 2006 Feb;33(1):57-61.
7. Mehdizade A, Somon T, Wetzel S, Kelekis A, Martin JB, Scheidegger JR, et al. Diffusion weighted MR imaging on a low-field open magnet. Comparison with findings at 1.5T in 18 patients with cerebral ischemia. *J Neuroradiol.* 2003 Jan;30(1):25-30.
8. Abolmaali ND, Schmitt J, Krauss S, Bretz F, Deimling M, Jacobi V, et al. MRI of lung parenchyma at 0.2 T: evaluation of imaging techniques, comparative study with chest radiography and interobserver analysis. *Eur Radiol.* 2004 Apr;14(4):703-8. Epub 2004 Feb 10.
9. Wagner M, Bowing B, Kuth R, Deimling M, Rascher W, Rupprecht T. Low field thoracic MRI- a fast and radiation free routine imaging modality in children. *Magn Reson Imaging.* 2001 Sep;19(7):975-83

10. Stecco A, Oronzo P, Armienti F, Borraccino C, Fossaceca R, Canalis L, et al. Contrastbolus - MR angiography of the transplanted kidney with a low-field (0.5-T) scanner: diagnostic accuracy, sensitivity and specificity of images and reconstructions in the evaluation of vascular complications. *Radiol Med (Torino)*. 2007 Oct;112(7):1026-35. Epub 2007 Oct 21.
11. Kajander S, Kallio T, Alanen A, Komu M, Forsstrom J. Imaging end-stage kidney disease in adults. Low-field MRI with magnetization transfer vs. ultrasonography. *Acta Radiol*. 2000 Jul;41(4):357-60.
12. Ertl-Wagner BB, Reith W, Sartor K. Low field-low cost: can low-field magnetic resonance systems replace high-field magnetic resonance systems in the diagnostic assessment of multiple sclerosis patients? *Eur Radiol*. 2001;11(8):1490-4.
13. Dubrulle F, Delomez J, Kiaei A, Berger P, Vincent C, Vaneecloo FM, et al. Mass screening for retrocochlear disorders: low-field-strength (0.2-T) versus high-field-strength (1.5-T) MRI. *AJNR Am J Neuroradiol*. 2002 Jun-Jul;23(6):918-23.
14. Merl T, et al. *Eur J Radiol* 1999;30(1):43-53.
15. Loew R, et al. *Eur Radiol* 2000;10(6):989-96.
16. Michel SC, et al. *Eur Radiol* 2002;12(12):2898-905.
17. Spouse E, et al. *Br J Radiol* 2000;73(866):146-51.
18. Washington State Department of Labor and Industries, Office of the Medical Director. Standing, weight-bearing, positional or upright MRI. Health Technology Assessment. Olympia Washington State Department of Labor and Industries; May 31 2006
19. Worcestershire CCGs: Operational Policy for Individual Funding Requests
20. Worcestershire CCGs: Prioritisation Framework for the Commissioning of Healthcare Services
21. West Midlands Strategic Group Commissioning Policy 1: Guiding principles and considerations to underpin priority setting and resource allocation within collaborative commissioning arrangements
22. West Midlands Strategic Group Commissioning Policy 4: Use of cost-effectiveness, value for money and cost effectiveness thresholds
23. West Midlands Strategic Group Commissioning Policy 16: Prior Approval
24. West Midlands Strategic Group Commissioning Policy 9: Individual funding requests

Acknowledgements:

- NHS Wandsworth Open MRI imaging commissioning policy
- NHS North London Open MRI commissioning policy
- NHS Cornwall & Isles of Scilly Open MRI commissioning policy

OPEN MRI SCAN PRIOR APPROVAL PROFORMA

About The Requester:			
Provider Name			
Contact Name			
Contact Email			
Contact Telephone			
Date of Request			
About The Patient:			
Patient Name/Initials			
Patient Date of Birth			
NHS Number			
GP Practice			
About The Requested Treatment:			
Condition to be Scanned			
Type of Scan Required			
Proposed Cost of Scan			
Date of Treatment			
Adherence to Policy:			
Has the Patient has been recommended this diagnostic test by a specialist/Extended Scope Practitioner*	Yes	No	Details
If Yes			
Has the Patient received a standard MRI using a prescribed oral sedative	Yes	No	Details
If Yes			
Was the prescribed oral sedative effective (i.e. standard MRI achieved)?	Yes	No	Details
OR			
Does the patient have a condition that requires an open MRI in order not to trigger an exacerbation of the condition	Yes	No	Details
OR			
Has the Patient failed standard MRI scanning as they are considered obese and, therefore, cannot fit within a conventional MRI	Yes	No	Details
<p>Please complete in full and send to The Open MRI Provider with your referral</p> <p>The Open MRI Provider will send to: The Individual Funding Request Panel Email: nhsworcs.fundingrequests@nhs.net Core Hours: 09:00 – 17:00 Monday to Friday</p>			

* For NHS South Worcestershire CCG patients with Orthopaedic issues requiring investigation, referral for an Open MRI must be made by a specialist or ICATS extended scope practitioner.

Equality Impact Assessment

Department Name of person completing EIA

Date of EIA Accountable CCG Lead

CCG Sign off and date

Piece of work being assessed

Aims of this piece of work

Other partners/stakeholders involved

Who will be affected by this piece of work?

Single Equality Scheme Strand	Baseline data and research on the population that this piece of work will affect. What is available? Eg population data, service user data. What does it show? Are there any gaps? Use both quantitative data and qualitative data where possible. Include consultation with service users wherever possible	Is there likely to be a differential impact? Yes, no, unknown
Gender	No differential impact as treatment will be provided based on clinical presentation	No
Race	No differential impact as treatment will be provided based on clinical presentation	No
Disability	No differential impact as treatment will be provided based on clinical presentation	No
Religion/ belief	No differential impact as treatment will be provided based on clinical presentation	No
Sexual orientation	No differential impact as treatment will be provided based on clinical presentation	No
Age	No differential impact as treatment will be provided based on clinical presentation	No
Social deprivation	No differential impact as treatment will be provided based on clinical presentation	No
Carers	No differential impact as treatment will be provided based on clinical presentation	No
Human rights	Will this piece of work affect anyone's human rights?	No

