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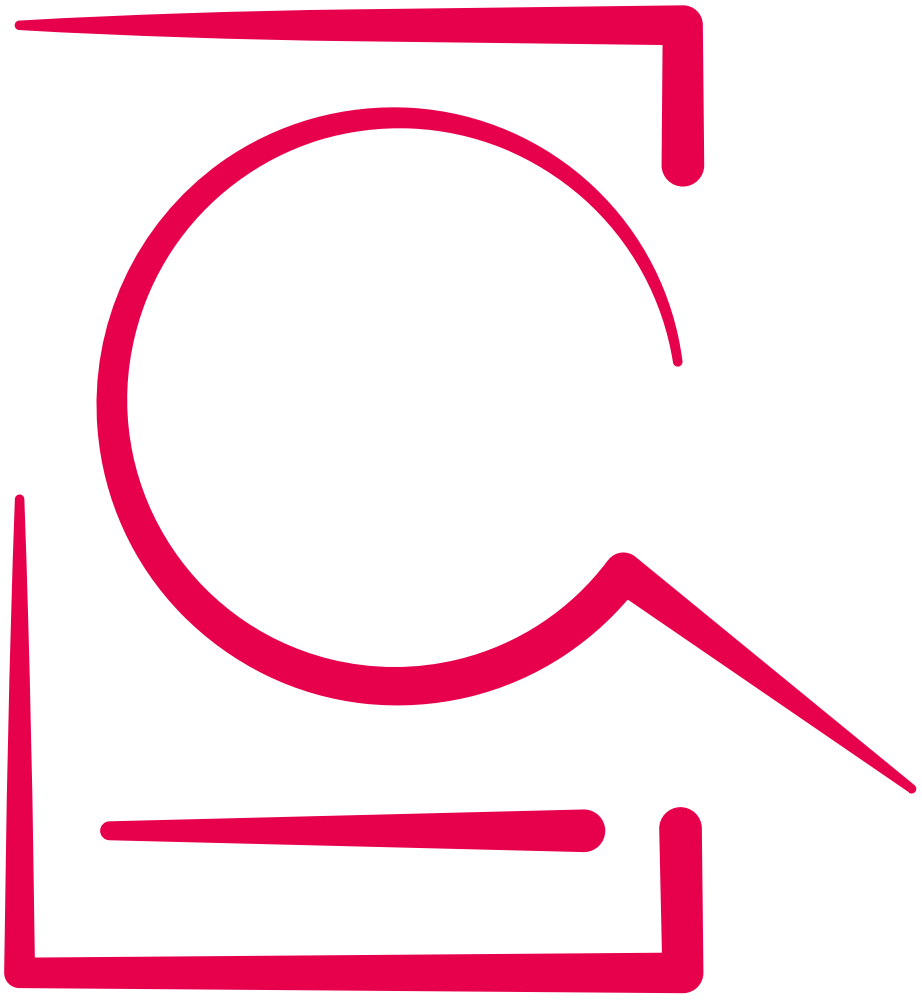
Academy of Medical Royal Colleges

Evidence based Interventions

List 3 Guidance



Evidence-based Interventions

List 3 clinical guidance.

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— Prepared by: The Academy of Medical Royal Colleges on behalf of the Evidence-based Interventions Programme Board.

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Foreword

Medicine is constantly evolving. The Evidence-based Interventions (EBI) Programme, now in its third phase (List 3) began in 2018. It's aim then, as it is now, is to capture that evolution and to ensure healthcare providers focus only on interventions which we know to be effective, based on the best available medical evidence. This approach is even more important as the NHS works to reduce the backlog in urgent and elective care.

This document sets out 10 interventions which have now been through an extensive consultation process to ensure:

- The evidence for their inclusion is up to date and sufficiently robust
- Medical experts agree on the precise wording of the guidance and are confident will only affect patients in certain circumstances where specific clinical criteria are met
- Patients, NHS commissioners and other interested groups have had a chance to review and shape the proposals.

I was pleased to see that, unlike in previous phases of the programme which focused on reducing or stopping tests, treatments and procedures, List 3 takes a more holistic approach and proposes that sometimes, the number of interventions should actually be increased. This is because, even with the pressures the NHS is under following the pandemic, it is right that we take a long-term view of a patient's care needs. If a relatively straightforward and low cost medical intervention can be made now which will alleviate or reduce the need for other potentially more expensive interventions further down the line, then we should take that opportunity.

I am grateful to colleagues on the EBI Programme Board for their time and expertise and to members of the independent Expert Advisory Committee (EAC) who have diligently examined the proposals from the numerous expert working groups (EWGs).

The specific recommendations have also been drafted in close collaboration with representatives drawn from specialist societies, medical royal colleges and colleagues from the Academy of Medical Royal Colleges (the Academy), NHS England and NHS Improvement, the National Institute for Health and Care Excellence (NICE), NHS Confederation and The Patients Association. Their obvious and enduring commitment to the EBI programme objectives over the last 24 months has been extraordinarily impressive.

Professor Dame Helen Stokes-Lampard
Chair, Academy Medical Royal Colleges

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Introduction

Why do we need the Evidence-based interventions programme?

By any measure, the NHS is an extraordinary organisation, treating well over a million people every single day in hospitals, GP surgeries, clinics, pharmacies and care centres across England. Free at the point of delivery and staffed by a dedicated workforce of over a million people who work round the clock caring for patients, it is a system we are rightly proud of.

But, as with any large organisation it cannot and should not stand still. As new and more effective treatments and interventions are developed, it is right that they should be adopted – replacing treatments which are less effective, have more side-effects or, in some cases, are more costly. But making this change happen in an organisation the size of the NHS is not easy.

The Evidence-based interventions (EBI) programme was developed in 2018 to help ensure a national approach to quality improvement takes place and that best practice is spread across the healthcare system. From the outset it had the following key principles:

— Improve the quality of care for everyone

— Reduce the risk of harm to patients

— Minimise unwarranted variation in service provision

— Optimise the use of finite resources and ensure any money saved is spent on other, more effective treatments.

These objectives have not changed and remain as central to List 3 as they did to Lists 1 and 2.

EBI and COVID-19

The COVID-19 outbreak has had a significant impact on the delivery of planned (elective) care, meaning that many patients are now waiting longer for treatment than they were before the pandemic. NHS services are working hard to recover elective services, such as planned, non-urgent operations, as quickly as possible. However, recovering and

transforming the way the NHS delivers this care requires a huge, collective effort from a range of key partners across health and social care.

In light of this, there has never been a more suitable time to review the use of clinically ineffective and inappropriate tests, treatments, pathways or procedures and, by extension, streamline waiting lists. Reducing clinically ineffective and inappropriate tests, treatments, pathways or procedures, will release resources which can be redirected to activities and interventions which are of higher clinical value for patients. Any time or money saved from the EBI programme must be redirected to other clinical activities.

However, the EBI programme also aims to reduce unwarranted variation in access to interventions that are clinically effective and appropriate, thereby reducing health inequalities. In reducing unwarranted variation, it is likely that there will be increases in the number of clinically effective and appropriate tests, treatments, pathways or procedures carried out. Therefore, there is a decision to be made at ICS level around both the long and short-term costs, benefits and health goals for the population and how they should be prioritised.

How did we select these recommendations and how did we analyse the evidence of their effectiveness?

In 2019, medical royal colleges and specialist societies were approached by the Academy of Medical Royal Colleges (the Academy), EBI clinical leads and members of the Expert Advisory Committee for their suggestions about which tests, treatments and procedures should be included on List 3.

This work was overseen by the Academy's clinical fellow and an original long list of around 34 potential tests, treatments, pathways and procedures was reduced to a short list of 17 where the Expert Advisory Committee felt the evidence was strongest. In parallel to this, a series of expert working groups (EWG) were formed to look in detail at the proposed changes to interventions, processes or care pathways. These expert working groups differed in size but comprised some of the most eminent specialist doctors in their field. It was their job to look at the evidence from:

- Clinical trials and data (global)
- Published studies (global)
- Other recommendations, from bodies such as the National Institute for Health and Clinical Excellence (NICE), the Medicines and Healthcare products Regulatory Agency (MHRA) and the Academy's Choosing Wisely programme
- Accepted real-world experience and their own clinical acumen.

This work was conducted through late 2019 and early 2020 but was suspended at the beginning of the COVID-19 outbreak so that clinicians could focus on supporting the NHS during the pandemic.

As health and care systems began to recover in the summer of 2021 the work picked up again and by late 2021 the Expert Advisory Committee had sanctioned all 17 proposals, moving to the public engagement stage of the process for further scrutiny, check and challenge.

Who was consulted, when and why?

The NHS is a public service, funded by taxpayers. Therefore, it is important that, as far as is practicable, as many people as possible have an opportunity to make their views known about possible changes to the way care is delivered.

For this reason, the EBI team worked closely with a range of key stakeholders during the engagement process. These included:

- National patient groups including the Patients Association and Healthwatch
- Special interest groups such as Prostate Cancer UK
- Healthcare providers and commissioners
- Specialist clinicians and subject matter experts who weren't part of the Expert Working Groups

In all, more than a dozen online public engagement events took place throughout February and March of 2022. Members of the EWGs discussed feedback and, wherever possible and practical, took good account of the views being expressed. Many of these sessions were well attended, with some attracting an audience of well over a hundred people. For most of the intervention specific engagement sessions, it is fair to say that the majority of attendees were either clinicians or clinical commissioners. To ensure patient and lay input, the Academy worked specifically with the Patients Association, which arranged a series of panel discussions. On top of this, the team welcomed feedback via the EBI inbox and an online survey on the Academy's website over the course of a 10 week period.

Once all feedback had been collated and discussed by the Expert Working Group and the guidance updated accordingly, the recommendations were passed back to the Expert Advisory Committee for final sign-off. It is those recommendations which are set out in the guidance below.

It should be noted, however, that this guidance contains only 10 interventions, seven less than the original 17. This is for a range of reasons. In some cases, it is because the evidence has evolved since the time of drafting. In others, the programme became aware that new

national guidance is being drawn up and, rather than risk a conflict, the EBI team have elected to pause its recommendations so that guidance can be aligned later.

Who is this guidance for?

This guidance is designed for patients, doctors and health service managers in England. It is threshold guidance and has been developed to apply to the general population with the intention of reducing unwarranted variation across the country.

We expect that where treatment criteria (the *threshold*) are met, the procedures or pathways in question would be routinely funded, without any need to apply for prior approval. However, there will always be exceptions. If a patient does not fully meet these criteria, but something about their personal clinical situation means that the general rule should not apply, the option to apply for an Individual Funding Request (IFR) remains available. Clinical acumen and discretion should remain central to the diagnosis and treatment process.

There are a number of instances where precise criteria for inclusion or exclusion have not been defined. Such terms include:

- Psychological distress
- Routine and conservative medical management
- Functional impairment.

This is because it must be recognised that all patients are different and, again, this guidance does not preclude clinical judgement on these issues. It should also be noted that there will likely be variation in the way terms such as those above are defined.

EBI is part of the NHS Standard Contract, which is mandated by NHS England for use by commissioners for all contracts for healthcare services other than primary care. It should be noted that EBI recommendations are guidance and not a statutory requirement.

To ensure inclusivity, we have intentionally used gender-neutral language throughout this guidance and have only specified sex (male/ female) where necessary and appropriate. Where gendered terms are used (men/ women), this is typically due to limitations of the evidence base or because we are directly referencing another source. Wherever possible, it is written with the non-specialist reader in mind, although some sections are, of necessity, highly technical in nature.

Measuring the impact of these recommendations

We are currently in the process of exploring possible approaches to the development of clinical coding for List 3 to enable data capture and ongoing evaluation of the impact of these recommendations. However, given the more holistic approach taken for List 3, we do anticipate greater complexity in identifying these codes. As a result, tracking the implementation of the guidance will not be possible in the short term while this coding is being developed. We will share further information in due course as work on List 3 coding progresses.

Therefore, to support the future measurement of EBI impact at a national and local level, we have developed a data framework. This includes actions on identifying EBI metrics for measurement, elements around data capture, and the development and roll-out of a monitoring tool to support implementation and continuous improvement within local systems.

Health inequalities and unwarranted variation

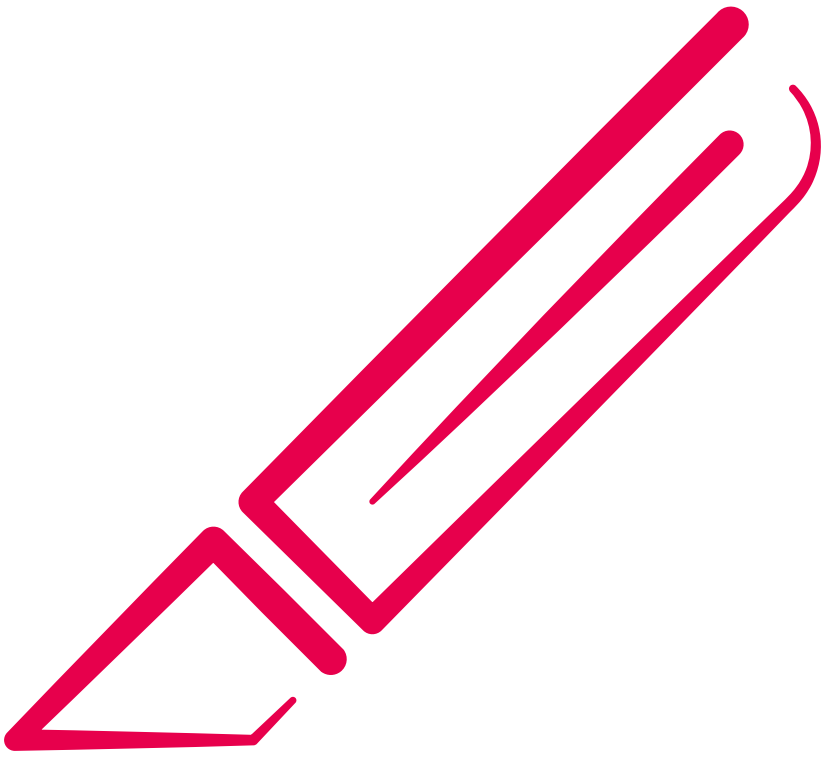
Health inequalities are the preventable, unfair and unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental and economic conditions within societies, which determine the risk of people getting ill, their ability to prevent sickness, or opportunities to take action and access treatment when ill health occurs (NHS England, Reducing health inequalities resources).

Tackling health inequalities is a key priority for NHS England, as has been emphasised in the NHS Long Term Plan. Unwarranted variation – a closely related concept - is defined as variation that cannot be explained by need or by the preferences of populations [ref Gray, Muir, 'Value based healthcare' BMJ 2017; 356 (27 January 2017)].

One of the primary aims of the EBI programme is to minimise unwarranted variation, ensuring that tests, treatments and procedures are carried out more uniformly across the country. In this way, the EBI programme actively seeks to reduce geographic health inequalities.

Health inequalities more generally have also been a central consideration throughout the development of the List 3 guidance. As part of the List 3 engagement process, we specifically requested feedback regarding any potential impacts on health inequalities and received many valuable responses. We have considered this feedback in detail and, where possible, amended the guidance accordingly. We have also produced an Equality and Health Inequalities Impact Assessment (EHIA).

Breast surgery



Breast prosthesis removal

Surgery to remove breast implants is only carried out by the NHS in specific situations when criteria are met. All patients should be aware when having implant surgery that due to capsular contracture and less frequently rupture they will need to be replaced at some point.

Clinical overview

Breast implants may be inserted during reconstructive surgery for treatment or prevention of breast cancer or for cosmetic purposes. Surgery to remove a breast implant may be used to treat the complications of breast implants inserted for reconstructive or cosmetic purposes.

Guidance

This guidance applies to those 18 years and over.

This proposal does not cover the following:

— Gender reassignment surgery

— Implants inserted following surgery for breast cancer or breast cancer prevention performed under the NHS. In these cases, please refer to the Association of Breast Surgery (ABS) Guidance for the Commissioning of Oncoplastic Breast Surgery.

Surgery to remove breast implants should only be considered for the following clinical indications:

— After implant leakage or rupture

OR

— There is severe capsular contracture (grade III/IV on the Baker classification). This will need to be confirmed by a specialist opinion.

OR

— Implants are complicated by recurrent implant infection or seroma

OR

— The patient develops Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).

Pre and postoperative photographs MUST be recorded for audit purposes. All eligible patients MUST be entered into the Breast and Cosmetic Implant Registry (BCIR) for audit purposes.

Patients whose initial procedure was privately funded should seek assurance from their private provider in the first instance.

If, however, the patient meets one of the above clinical indications, and the private provider is unable to offer the patient surgery, the patient can be offered an NHS referral for breast implant removal but not for replacement.

Where a patient is eligible for implant removal due to a problem associated with a single implant, bilateral implant removal should be offered.

Only implant removal should be performed, and no other subsequent cosmetic procedure e.g. mastopexy.

The removal of breast implants due to symptoms termed as Breast Implant Illness (BII) or Autoimmune Syndrome Induced by Adjuvants (ASIA) on social media, or due to the risk of developing Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is not currently recommended.

Only patients whose initial procedure was funded by the NHS should be considered for both implant removal and replacement. In line with current guidance, patients eligible to have their implant replaced must be informed of the potential risk of BIA-ALCL.

As per guidance NG180 from the National Institute for Health and Care Excellence (NICE), discuss lifestyle modifications with people having surgery — for example stopping smoking and reducing alcohol consumption — in order to reduce the risk of post-operative complications. See NICE guidance NG180 on Perioperative care in adults for more information.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

Patients should be informed at the time of initial surgery that implants are likely to need replacement and further surgery may be required.

In the case of implant rupture, severe capsular contracture, recurrent infection, breast disease and BIA-ALCL the benefit of removing an implant outweighs the risk of keeping the implant in place.

It is accepted that the NHS has a duty of care to patients who require their implant to be removed for a listed clinical indication, but only if their private provider is unable to offer this care. As the NHS does not routinely commission breast implants for cosmetic reasons, removal but not replacement is considered appropriate in these cases.

Concerns have been expressed about the potential side effects of breast implants including the development of BIA-ALCL and BII or Autoimmune Syndrome Induced by Adjuvants (ASIA).

The BIA-ALCL is uncommon and in the UK is currently estimated to be 1 per 15,000 implants sold. The most recent guidance from the Medicines and Healthcare products Regulatory Agency (MHRA) states that based on the current available evidence people with breast implants do not need to have them removed in the absence of symptoms of ALCL. The MHRA states this position is consistent with international regulators and they will continue to collect data on ALCL in patients with breast implants and review the guidance in light of any new evidence.

BII/ASIA is used by some to describe a constellation of symptoms felt to be associated with their breast implants. However, BII/ASIA is not a World Health Organization recognised disease. The MHRA states there is no single disease which could explain the reported symptoms and it is currently unknown whether there is a link between breast implants and the reported health problems.

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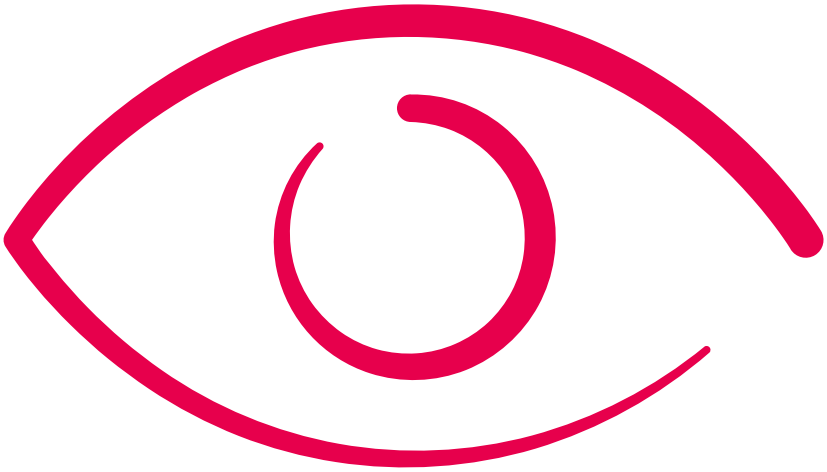
Ophthalmology



Optical coherence tomography (OCT) use in diabetic retinopathy referral

Diabetes can affect the eyes and can cause blindness. People with diabetes have their eyes checked each year through a nationally funded screening programme separate from the optometrist sight test service. 2D digital pictures of the retina at the back of the eye are used to check for any retina problems, however these are not accurate in showing the amount of treatable change (fluid build-up known as oedema) present in the central part of the retina, called the macula. Approximately 50% of patients referred for macular problems on the basis of the 2D pictures do not need hospital treatment.

There is an additional tool called Optical Coherence Tomography (OCT) which uses light waves to take 3D pictures. The detailed images from OCT are much more sensitive and accurate at detecting treatable oedema and so the use of OCT 3D pictures, before attendance at a hospital clinic for macular treatment, can reduce unnecessary referrals.

Currently, diabetic eye screening contracts in England do not include the use of OCT. The EBI programme recommends that the referral pathway for diabetic patients to be seen by hospital eye services is updated across England to include locally commissioned OCT assessments to supplement the NHS England-commissioned diabetic eye screening services.

Clinical overview

Diabetic macular oedema (DMO) is the leading cause of blindness in young adults in developed countries. The best way of preventing visual loss in patients with diabetes is early detection and treatment. Every diabetic person in the UK is required to attend (at minimum) an annual Diabetic Eye Screening (DES) where a 2D colour fundus (retina) image is taken. DES services are commonly held in the community or primary care with agreed criteria for referral to HES. Referrals to HES are made if there is a grade of R2 (pre-proliferative diabetic retinopathy) or R3 (proliferative retinopathy) and/or M1 (diabetic macular oedema/DMO) on the 2D colour fundus image. However, in DMO, leaked fluid builds up at the macula (the central part of the retina) causing swelling/elevation which is difficult to detect on a 2D image. OCT is a non-invasive imaging tool, using light waves to take high resolution cross-sectional 3D images of the retina. It allows accurate detection of DMO and quantification of the degree of oedema through the measure of the central retinal thickness (CRT).

Thresholds for treatment are based on OCT measures of CRT. NICE recommends active treatment of DMO with licensed intravitreal injections in eyes with CRT of 400 µm or more. Individuals with non-central DMO or CRT <400µm may also be suitable for macular laser treatment. As retinal thickness is essential to make a clinical decision on treatment but cannot be accurately judged with 2D colour fundus image, an OCT is required to decide on treatment.

Current protocols in DES are significantly variable by geography with regards to OCT use. NHS Scotland introduced the inclusion of OCT surveillance in DES in January 2021. However, these changes have not been adopted in England at present.

Therefore, the use of OCT in diabetic maculopathy referral refinement pathways would reduce unnecessary referrals to HES.

Guidance

This guidance applies to those 18 years and over.

The proposed guidance uses best available evidence to propose patients with DES diabetic retinopathy grading M1 or above should have integration of OCT within the DES pathways or as part of a referral refinement protocol prior to assessment in secondary care treatment clinics, in addition to the current fundus photography. Where possible, OCT should be made available within the same appointment as the diabetic screening assessment for efficiency, patient convenience and to reduce patient anxiety.

Referral to / assessment in secondary care face to face treatment clinics should NOT be accepted for any patient with diabetic maculopathy grading of M1 or above without an OCT scan and assessment of images to filter referrals. The OCT scan can be performed at either:

— Diabetic eye screening (DES)

OR

— Local referral refinement.

In addition, patients with low-risk maculopathy below treatment levels should be monitored in OCT-supported assessments outside of routine medically led secondary care clinics.

Integration of OCT imaging into patient pathways can be directly made into the screening programme itself, ideally within the same appointment as the screening assessment, which is the most patient-centred pathway. Alternatively, it can take the form of an asynchronous virtual clinic after undertaking a non-medical (usually technician-led) OCT

diagnostic assessment. If not available within the DES setting, the right 'place' for OCT capture will depend on local arrangements and availability of resources, such as the imaging equipment, connectivity and commissioning arrangements. It could be conducted at a diagnostic clinic in the hospital eye service, at a diagnostic hub or mobile unit in the community or in primary care optometry enhanced services. If undertaken outside the DES, appropriate failsafe and recall arrangements need to be incorporated. There will need to be local agreements, based on available multidisciplinary clinical decision making expertise and experience, as to where decisions are taken on OCT images and how non-consultant decision makers can access virtual decision support from consultant-led hospital teams. It offers an obvious opportunity to reduce the workload and delays in access to the core hospital eye service and avoid unnecessary referrals of patients with diabetic maculopathy to face to face treatment clinics who do not require treatment.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

Recent data suggests that DES referral criteria with photographic data in the UK is highly successful at detecting diabetic retinopathy and preventing blindness. Using OCT imaging to view retinal layer structures with precision, along with fundal photography, increases sensitivity of detecting DMO and identifies progression earlier, and therefore facilitates earlier intervention and improved outcomes.

Referrals from diabetic eye screening for suspected maculopathy (M1) has a high false positive rate of referrals, with 50% of referrals for diabetic maculopathy not requiring treatment. Therefore, incorporating OCT within the referral pathway can improve the sensitivity and specificity, preventing patients who do not need treatment from the anxiety and burden of unnecessary hospital visits.

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Available at: https://future.nhs.uk/NationalEyeCareHub/grouphome

Shared decision making for cataract surgery

Cataracts are when the focusing lens inside your eye develops cloudy patches. Over time, these can cause blurriness, mistiness and deterioration of vision and, if untreated, cause blindness, although this is normally reversible with surgery. Cataract surgery replaces the lens in your eye with an artificial one. People who are referred for cataract surgery need to be fit enough to undergo the surgery, as well as understand the process and want to have it done. Currently, across England the number of people referred who go onto have the surgery varies between 40-92%: this is known as the conversion rate. It is thought this variation is because of how patients are identified, counselled and referred, with many patients who do not want surgery being referred. Conversely, in some areas NICE guidance is not being respected and access to surgery is being inappropriately restricted based on visual acuity.

To improve the conversion rate, and therefore reduce unnecessary referrals for patients who do not want cataract surgery, evidence suggests that clinicians should always use resources to help support patients in making an informed decision as to whether surgery is the best option for them. Decisions to refer for surgery should not be based on visual acuity alone, but instead on the effect the cataract is having on the patient's visual function and quality of life, and their willingness to have surgery once they understand the risks and benefits.

The EBI programme proposes that the pathway for patients with cataracts to be referred for surgery is updated across England to include shared decision making and not restrict access based on visual acuity.

Clinical overview

Currently, cataract referral guidelines and processes are agreed locally between hospital ophthalmology services, general practitioners, and primary care eye service providers such as optometrists. There is a wide variation across England between the number of patients referred for surgery and those who undergo surgery, with rates ranging from 40-92%. Ideally, for patients, this conversion rate should be more than 80%, which can be achieved if following referral guidance as recommended by the Royal College of Ophthalmologists. Much of the improvement to patient experience and clinical outcome is due to shared decision making. This empowers the patient to be better informed and agreeable to treatment before they are referred to secondary care and protects patients who do not wish to consider surgery, once they are properly informed of the risks and

benefits, from needing to go to hospital. This will naturally filter the number of referrals to secondary care to be only those who wish to have the procedure, reducing unnecessary referrals and saving clinician time. Therefore, all referral pathways for cataract surgery should include shared decision making tools.

Guidance

This guidance applies to those 18 years and over.

Cataract referrals should not be accepted unless a formally documented shared decision making process has been performed by their referring primary care optometrist with the patient (and their family members or carers, as appropriate) as part of a referral. This includes but is not limited to:

- How the cataract affects the person's vision and quality of life
- Whether one or both eyes are affected
- What cataract surgery involves, including possible risks and benefits
- How the person's quality of life may be affected if they choose not to have cataract surgery
- Whether the person wants to have cataract surgery.

In line with NICE guidance, do not restrict access to cataract surgery on the basis of visual acuity.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

Cataract surgery represents 6% of all surgery performed in the UK (over 400,000 procedures a year) with a pre-pandemic predicted growth of 25% in the next 10 years. Patients who are referred need to be reasonable candidates for surgery and have a desire to undergo the operative procedure. Current referral processes often refer patients who, when they have had an informed discussion, do not wish to undergo surgery, which has produced huge variability in conversion rates (from direct cataract referral to undergoing surgery) nationwide, with rates ranging from 40-92%. The reason for poor conversion rates can be due to many factors including commissioning of services, incomplete training, and lack of engagement of primary care staff on shared decision making. The ideal conversion rate to cataract surgery is not agreed, but rates of more than 80% can be achieved by referral guidelines and efficient forms, as recommended by the Royal College of Ophthalmologists.

Shared decision making tools have been proven to improve conversion rates and lead to better patient experience and clinical outcomes. Their use is endorsed by the Department of Health policy 'Equity and Excellence: liberating the NHS' highlighting the importance of the patient's opinion and choice with regards to their care. This guidance uses evidence to propose that all referral pathways for cataract surgery should include shared decision making tools.

NICE guidance has clearly stated since 2017 that referrals for cataract surgery should not be restricted purely on the basis of a measure of visual acuity, and this is strongly endorsed by the Royal College of Ophthalmologists.

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Glaucoma referral criteria

Currently, glaucoma (a common eye condition where the optic nerve, which connects the eye to the brain, becomes damaged, leading to sight loss) is usually found in people during routine sight tests by optometrists (opticians). The optometrist will then refer them to a hospital. However, the accuracy of sight tests for ruling out glaucoma is poor. This can create unnecessary anxiety for patients and unwarranted referrals. Evidence shows that additional clinical assessment by optometrists will improve the accuracy of referrals.

The EBI programme proposes that the pathway for the referral of glaucoma and related conditions (such as ocular hypertension [OHT] which is raised eye pressure without optic nerve damage) to a hospital eye service is consistent across England to include additional clinical assessments and repeat measurements performed by optometrists, as recommended by NICE NG81 These services are outside of the sight test and need to be locally commissioned.

Clinical overview

Glaucoma is a leading cause of irreversible blindness worldwide. In England, new glaucoma cases are detected in primary care via routine optometric sight tests. These are then referred to HES for monitoring and treatment. However, these sight tests have accuracy limitations for detecting or ruling out glaucoma and glaucoma-related conditions, resulting in a high percentage of false positive referrals to secondary care (up to 40% in certain cases). This causes unnecessary anxiety for patients who do not need referral and potential delays for those who do, risking avoidable blindness.

Guidance

This guidance applies to those 18 years and over.

Before referral for further investigation and diagnosis of glaucoma and related conditions, offer all of the following tests, which are separate from a sight test:

- Central visual field assessment using standard automated perimetry (full threshold or supra-threshold)
- Optic nerve assessment and fundus examination using stereoscopic slit lamp biomicroscopy (with pupil dilatation if necessary) and optical coherence tomography (OCT) or optic nerve head image if available.

— Intraocular pressure (IOP) measurement using Goldmann-type applanation tonometry

— Peripheral anterior chamber configuration and depth assessments or, if not available, or the person prefers, the van Herick test or Optical Coherence Tomography (OCT).

Before deciding to refer, consider repeating visual field assessment and IOP measurement on another occasion (repeat measures) to confirm a visual field defect or IOP of 24mmHg or more, unless clinical circumstances indicate urgent or emergency referral is needed.

Refer for further secondary care investigation and diagnosis of glaucoma and related conditions, after considering repeat measures, if:

— There is optic nerve head damage on stereoscopic slit lamp biomicroscopy

OR

— There is a visual field defect consistent with glaucoma

OR

— IOP is 24 mmHg or more using Goldmann-type applanation tonometry.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

Ophthalmology is the busiest outpatient speciality in UK secondary care, with demand increasingly surpassing capacity. Monitoring and treating patients with glaucoma accounts for 20% of current ophthalmology outpatient activity. Over the next 10 (20) years glaucoma cases are predicted to rise exponentially; confirmed glaucoma diagnoses by 22% (44%), suspected glaucoma cases by 10% (18%) and OHT by 9% (16%).

Currently, new glaucoma cases are referred via routine optometric sight tests. However, evidence suggests there is poor sensitivity and specificity for detecting glaucoma and glaucoma-related conditions, resulting in a high percentage of false positive referrals to secondary care (up to 40% in certain cases). A variety of enhanced primary eye care services and referral filtering models have been developed to improve the accuracy of referrals. Referral filtering models range from 1) 'repeat measurement' schemes in which IOP measurement or visual field assessments, or both, are repeated at a separate visit by the referring optometrist to 2) enhanced case finding (more extensive tests than IOP

measurements) undertaken by another optometrist, to 3) referral refinement, in which another optometrist who is specifically trained undertakes a more comprehensive set of tests defined by NICE NG81.

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Vascular

Asymptomatic carotid artery stenosis screening

The carotid arteries (major blood vessels in the neck) can become narrowed by deposition of fatty substances in the arterial wall (atherosclerotic plaque build-up). Narrowing can cause symptoms, such as a Transient Ischaemic Attack (TIA) or ischaemic stroke (where blood supply to the brain is reduced). However, only 8% of all ischaemic strokes are caused by narrowed carotid arteries. Often the narrowing (stenosis) causes no symptoms.

The EBI programme looked at the evidence for and against imaging (screening) the carotid arteries of patients who had no symptoms. Based on the evidence, the EBI programme proposes that patients without symptoms should not be referred for imaging. If a patient is found to have narrowed arteries, they do not require follow up if they continue to have no symptoms. However, if a patient does have symptoms or evidence of an ischaemic event in the brain, they should be referred for a duplex ultrasound of the arteries as the first-line investigation.

The EBI programme proposes clear, evidence-based criteria for use across England.

Clinical overview

Extracranial internal carotid stenosis, narrowing of the lumen of the internal carotid arteries, is most commonly attributed to atherosclerotic plaque formation and may present symptomatically as a Transient Ischaemic Attack (TIA) or ischaemic stroke. Carotid artery stenosis is thought to be the cause of approximately 8% of all ischaemic strokes. However, in some cases asymptomatic carotid artery stenosis may be identified as either an incidental finding on imaging or in individuals with known vascular disease, such as coronary atherosclerosis, peripheral arterial disease, abdominal aortic aneurysm or contralateral carotid stenosis. Asymptomatic carotid artery stenosis is defined as luminal narrowing in the absence of a history of TIA, ischaemic stroke, or other neurological signs or symptoms attributable to carotid artery disease.

Investigation of carotid artery stenosis may involve use of carotid duplex ultrasound, CT angiography and MR angiography. However, the increased risks of ionising radiation and adverse reactions to intravenous contrast mean CT and MR-based imaging would be more suitable for second line imaging to define the anatomy in more detail, rather than as a screening method. Carotid duplex ultrasound is a non-invasive method used to measure blood flow through the carotid arteries. It enables quantification of the degree of luminal

narrowing with atherosclerotic disease, based on the North American Symptomatic Carotid Endarterectomy Trial (NASCET) measurements. A meta-analysis identified that duplex ultrasound in the detection of greater than 50% angiographic stenosis of the internal carotid arteries has a sensitivity and specificity of 98% and 88% respectively compared to angiography.

Guidance

This guidance applies to those 18 years and over.

- Screening for carotid artery stenosis should **NOT** be performed in asymptomatic individuals
- There is no indication for asymptomatic screening even in patients with known peripheral vascular disease
- Other than to risk stratify patients for coronary intervention, there is no indication for asymptomatic screening of the carotid arteries in patients undergoing other forms of cardiac surgery
- There is no routine indication for follow up for asymptomatic patients with carotid artery stenosis.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

The Royal College of Physicians' 5th National Clinical Guideline for Stroke (2016) recommended against screening for asymptomatic carotid artery disease and recommended that surgery or angioplasty/stenting for asymptomatic coronary artery disease should not be routinely performed unless as part of a clinical trial.

The United States Preventative Services Task Force in 2014 recommended against screening for asymptomatic carotid artery stenosis amongst the general population. This guidance was reaffirmed in 2021 following a comprehensive review which identified that, within the general population, the risks of harm from screening for asymptomatic carotid artery stenosis outweigh the benefits.

In a general population, duplex ultrasound screening may yield many false-positive results. This is also supported by The European Society for Vascular Surgery guidelines. These guidelines note that an unselected screening of patients aged >80 years for severe stenosis (>70%) would be <2%, which is not clinically effective. This yield would be even less in a younger screened population.

Additionally, there is no evidence that patients diagnosed with peripheral vascular disease benefit from undergoing carotid artery stenosis screening for this indication only. There is no clear evidence for being able to risk stratify an asymptomatic patient population for carotid artery stenosis screening.

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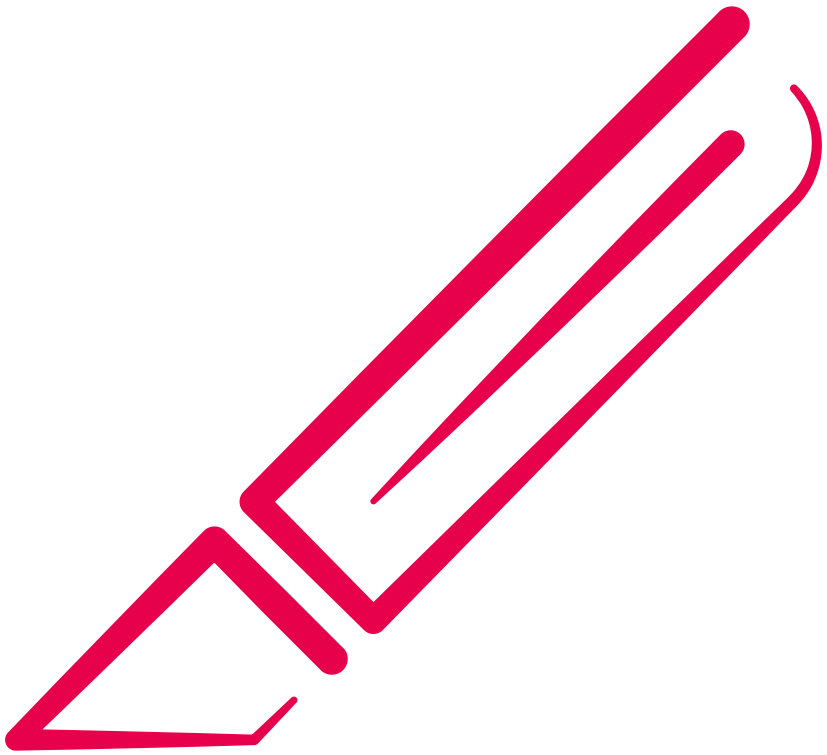
Upper gastrointestinal surgery



Referral for bariatric surgery

There are a variety of minimally invasive surgical options to help weight loss (bariatric surgery) and improve health. These include Roux-en-Y gastric bypass, one anastomosis (mini) gastric bypass, vertical sleeve gastrectomy and adjustable gastric banding. NICE guideline CG189 states that surgery for obesity is an option if specific criteria are met, balancing the risk of surgery with the long-term benefits of alleviating ill health caused by obesity.

Evidence shows that when commissioned as recommended, surgery is highly effective in causing weight loss, reduces the long-term impact of poor health and reduces the risk of premature death from obesity-related conditions. Despite this, the UK has one of the lowest rates of bariatric surgery in the developed world.

The EBI programme proposes clear, evidence-based criteria for use across England.

Clinical overview

There are a variety of surgical options available for promoting weight loss. These bariatric procedures include Roux-en-Y gastric bypass, one anastomosis (mini) gastric bypass, vertical sleeve gastrectomy and adjustable gastric banding. The specific type of procedure should be decided as part of a shared decision making conversation between the patient and the surgeon, during which risks and possible outcomes are discussed.

Bariatric procedures aim to promote weight loss and improve other metabolic complications of obesity. This proposed guidance establishes criteria for referral of a patient to a bariatric surgical centre for consideration of performing a bariatric surgical procedure.

Guidance

This guidance applies to those aged 18 years and over.

For patients with a BMI of 50 or more, surgery should be considered as a first-line treatment intervention.

Patients with a BMI less than 50 should be referred for consideration of bariatric surgery if they meet the following criteria:

— The patient has a BMI of 40 kg/m2 or more, or between 35 kg/m2 and 40 kg/m with significant obesity-related complications likely to improve with weight loss (for example, type 2 diabetes, sleep apnoea or hypertension)

OR

— The patient has a BMI of 30 kg/m2 or more with type 2 diabetes of less than 10 years duration. This BMI threshold should be reduced to 27.5 kg/m2 if the patient is of Asian family origin.

All patients being considered for bariatric surgery must also meet the following criteria:

— Appropriate non-surgical measures have been tried but the patient has not achieved or maintained adequate, clinically beneficial weight loss

AND

— The patient has been receiving or will receive intensive management in a tier 3 service or equivalent. For more information on tier 3 services, please refer to NHS England's report of the working group into joined up clinical pathways for obesity and The Royal College of Surgeon's Weight Assessment and Management Tier Services Commissioning Guide.

AND

— The patient is otherwise fit for anaesthesia and surgery

AND

— The patient commits to long-term follow-up

AND

— The patient and clinician have undertaken appropriate shared decision-making consultation regarding undergoing surgery including discussion of risks and benefits of surgical intervention.

After surgery, the host bariatric surgery unit should follow up with the patient for two years. Thereafter, responsibility for follow up should be handed over to the either the local non-surgical Tier 3 service OR the patient's GP, who should conduct yearly appointments. These appointments should include weight measurement and a request for nutritional blood tests. See British Obesity & Metabolic Surgery Society (BOMSS) guidance for more details.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

According to NICE guideline CG189 surgery for the treatment of obesity is recommended if specific criteria are met, relating to the patient's body mass index and the presence of obesity-related complications. This balances the risk of surgery with its potential positive long-term impact on the patient. When commissioned appropriately, obesity surgery is highly effective in promoting weight loss, and more importantly, reducing mortality and morbidity burden. It is also one of the most cost-effective treatments in the field of surgery. The penetrance of obesity surgery remains very low even though thousands of eligible patients stand to benefit from this life-saving intervention with the associated health benefits it provides.

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Cardiology

Angioplasty for PCI (percutaneous coronary intervention) in stable angina

Stable angina is typically chest discomfort which comes on with exertion and is relieved by rest. NICE guidance (CG126) indicates that medical management should be optimised in such patients. This includes lifestyle interventions, medications to reduce risk and appropriate medications to improve angina.

Clinical trials looking at the role of revascularisation (widening of blocked or narrowed coronary arteries) by percutaneous coronary intervention (PCI) in patients with stable angina showed that PCI did not improve mortality (death rate). However, longer-term follow up is needed to see if differences emerge over time. The current primary aim of PCI in stable angina is to improve angina symptoms.

The EBI programme proposes clear, evidence-based criteria for the use of PCI across England. PCI should only be performed in patients with stable angina that fulfil these criteria, after optimisation of medication. Patients should be properly consented with documented shared decision making.

Clinical overview

Stable angina is typically defined as exertional chest discomfort that is relieved by rest. However, there is a variation to the presentation of stable angina, and this is beyond the scope of this document. The European Society of Cardiology (ESC) and American Heart Association/ American College of Cardiology (AHA/ACC) guidelines recommend that in most patients with stable angina, percutaneous coronary intervention (PCI) should be considered for symptom relief. Ideally medical therapy, which should include therapies for the reduction of cardiovascular risk as well as anti-anginal therapies, should be optimised prior to PCI being considered.

Guidance

This guidance applies to those 18 years and over.

This guidance does not apply to:

— Patients presenting with ST-elevation myocardial infarction, non ST-elevation myocardial infarction or staged procedures after acute coronary syndrome

— Patients presenting with unstable angina defined as myocardial ischaemia at rest or on minimal exertion in the absence of acute cardiomyocyte injury/necrosis

— Patients presenting with crescendo (rapidly worsening) stable angina

— Patients who may be best treated with coronary artery bypass graft surgery .

PCI should only be performed in patients with stable angina if patients:

— Have ongoing anginal symptoms despite optimal anti-anginal medication*

OR

— Have ongoing angina symptoms with intolerance of anti-anginal medications*

OR

— Are participating in clinical research in stable coronary artery disease

In addition, if agreed at an appropriately constituted myocardial revascularisation cardiac multidisciplinary meeting (MDM)**, PCI may also be performed in patients with stable angina in the following cases:

— In patients with impaired left ventricular systolic function

OR

— In patients with left main stem disease

OR

— In patients with significant ischemic burden

OR

— Where PCI is otherwise considered appropriate by the MDM.**

All patients being considered for elective revascularisation should have documented evidence that a formal shared decision-making process has taken place with informed patient choice.

*Optimal medical management should be offered and include:

Lifestyle interventions:

- Weight management
- Smoking cessation
- Adherence to a cardioprotective diet
- Regular physical activity.

Risk reduction management:

- Antiplatelet therapy or anticoagulant in line with current guidelines
- Adequate lipid lowering therapy
- ACE Inhibitor or alternative to optimal dose
- Anti-hypertensive therapy to guideline-directed targets
- Appropriate glycaemic control in patients with diabetes.

Anti-anginal medication in line with current guidelines:

- Preferably two anti-anginal agents at recommended daily dose.
- Symptoms should ideally be reassessed after an appropriate period of optimal anti-anginal medication uptitration and assessment of side effects.

**** Patients without ongoing angina should be discussed at an appropriate multidisciplinary meeting (MDM) before being offered PCI. This could include patients that are not within these criteria, for example, patients undergoing transcutaneous aortic valve implantation, asymptomatic patients with evidence of significant ischaemia, occupational indications, or patient preference.

An appropriately constituted myocardial revascularisation MDM would typically include:

- MDM coordinator
- Interventional cardiologist – at least one (the norm should be two or more)
- Non-interventional cardiologists – at least one (the norm should be two or more)
- Cardiac surgical consultant – at least one (the norm should be two or more)
- Other attendees including cardiac anaesthetists / intensivists may be required for some cases.

See references for guidance on the conduct of myocardial revascularisation MDMs.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

The results of multiple trials in stable coronary artery disease (CAD), including COURAGE and ISCHEMIA have shown that revascularization does not improve mid-term mortality. However, revascularisation did significantly reduce spontaneous myocardial infarction in ISCHEMIA, therefore longer term follow up will be important.

Furthermore, it is important to note that around one third of the patients allocated to medical therapy in both COURAGE and ISCHEMIA had to undergo revascularisation within their primary follow up periods because of ongoing angina. There are selected subgroups where PCI can be offered at an earlier stage: patients with impaired left ventricular systolic function and significant left main stem disease. A multidisciplinary heart team approach** and shared decision making with the patient is key.

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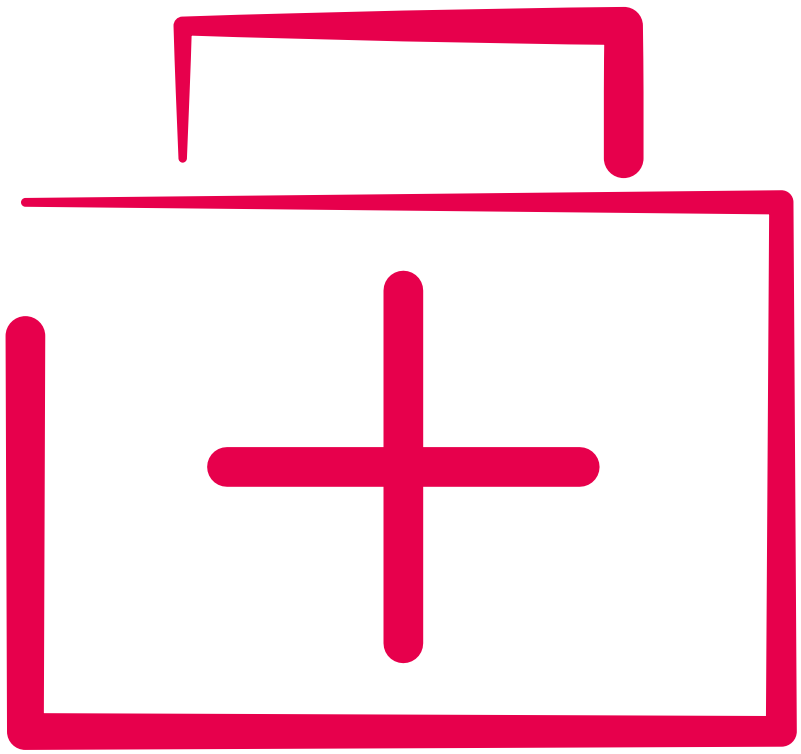
Urology



Non-visible haematuria

Non-visible haematuria is blood that is present but not visible in urine. It is usually found on the dipstick test and can indicate cancer (between 3- 9% of people with non-visible haematuria go on to be shown to have cancer). It is also common in other, benign conditions such as infections or bladder / kidney stones. There is guidance on how to manage and refer people with non-visible haematuria in primary care but no evidence-based guidance on how this should be investigated in hospitals. Due to this, there is a marked difference in how this is done across England.

The EBI programme proposes clear, evidence-based criteria for use across England.

Clinical overview

Non-visible haematuria (blood in the urine) can be present in people with a urological cancer, in particular bladder cancer. However, it can also be present in a number of benign urological conditions, such as urinary tract infection, renal or ureteric stones or an enlarged prostate, as well as in the presence of kidney disease. Non-visible haematuria is common and the majority of people, if investigated, will not turn out to have a cancer or any other urological cause found for their symptoms.

The typical initial investigation of people with non-visible haematuria who are referred to secondary care involves imaging and cystoscopy. Further investigations may be indicated depending on the findings of these.

Imaging practice varies, with most centres using ultrasound as their first line modality. While computed tomography (CT) urography has higher sensitivity for upper tract cancers than ultrasound, it carries a high dose of ionising radiation.

Cystoscopy is a diagnostic procedure used to examine the lining of the bladder and urethra. Either a flexible or rigid endoscope may be used, under local or general anaesthesia, respectively. Typically, flexible cystoscopy under local anaesthesia is used as first line to investigate non-visible haematuria.

Guidance

This guidance applies to those 18 years and over.

Patients should be referred from primary care to secondary care for investigation of non-visible haematuria in line with guideline NG12 from the National Institute for Health and Care Excellence (NICE).

Refer people to secondary care using a suspected cancer pathway referral (for an appointment within 2 weeks) for bladder cancer if they are:

- Aged 60 and over

AND

- Have unexplained non-visible haematuria

AND

- Either dysuria OR a raised white cell count on a blood test.

Consider non-urgent referral for bladder cancer in people aged 60 and over with recurrent or persistent unexplained urinary tract infection.

The NICE guidance also includes recommendations on patient information and support, safety netting and the diagnostic process which are applicable both to patients who do and who do not meet the above referral criteria.

Secondary care urological investigation of non-visible haematuria should consist of:

- Imaging
    - Ultrasound scan (USS) should be first line imaging modality
    - **DO NOT** routinely perform CT urography if USS is normal

AND

- Cystoscopy
    - Flexible cystoscopy under local anaesthesia should be the preferred approach unless patient choice or other factors make this inappropriate

AND

- A discussion regarding the rationale, risks, benefits and likely outcomes of investigation with patients as part of a shared decision making process.

Where, following investigation with imaging and cystoscopy, no cause for non-visible haematuria is found, patients should be discharged from secondary care follow up. They should not be referred or investigated again for future episodes of non-visible haematuria unless there is a change in their symptoms or signs (most notably the development of visible haematuria in the absence of urinary tract infection).

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

There is no existing national evidence-based guidance on the investigation of non-visible haematuria referred to secondary care according to NICE NG12 criteria and there is evidence of significant variation in practice. There is marked variation in the recommendations made in international guidelines.

The NICE guidance on primary care management (NG12) recognises the importance of striking a balance between minimising the number of people without bladder cancer who get inappropriately referred and maximising the number of people with bladder cancer who get appropriately referred. It therefore recommends referral to secondary care for those symptoms with a positive predictive value of 3% or above.

A similar balance of advantages and disadvantages applies to secondary care investigations. Given that between 3.04% and 6.38% of patients referred to secondary care with non-visible haematuria will be diagnosed with a urological cancer as a result, it is important that the approach to investigation be both proportionate and appropriately discussed with the patient.

CT urogram has similar sensitivity to ultrasound for the detection of renal tumours but superior sensitivity for upper tract urothelial cancers (UTUC). However, the incidence of upper tract tumours (renal and UTUC) in non-visible haematuria is low (0.4%) with UTUC extremely rare and CT urogram carries a high dose of ionising radiation as well as potential for harms associated with administration of intravenous contrast medium and investigation of incidental imaging findings.

Several recent studies have used modelling to compare ultrasound to CT urogram in patients with non-visible haematuria and suggested that the harms associated with radiation exposure, with only small increases in cancer detection, make CT urogram an inappropriate first line imaging modality. Ultrasound imaging is also likely to be less resource-intensive than CT urogram. It is important to note that older age, male sex, and, in particular, current or previous smoking history are associated with increased risk

of cancer in people with non-visible haematuria. Non-visible haematuria is common, with prevalence estimated at 2.5% of the population, rising to 18% in males of 70 years and older. The vast majority of patients (93.6-97%) will have no urological cancer found following secondary care investigation of non-visible haematuria.

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Needle biopsy of prostate

Prostate cancer is the second most common cause of cancer death in people assigned male at birth. It is important that cancer pathways give equal access to care across England. Traditionally needle biopsies would have been taken for diagnosis of prostate cancer. However, studies now show that multiparametric magnetic resonance imaging (mpMRI) scans, which produce a detailed picture of the prostate gland, can more accurately detect clinically significant prostate cancer compared to biopsy alone.

The EBI programme proposes clear, evidence-based criteria for use across England. This details who should be referred, how they should be triaged, over what time period, and how they should be managed, including the type of imaging, how to report, the need for biopsy and how this should be performed.

Clinical overview

Prostate cancer is the commonest non-cutaneous cancer in people assigned male at birth in the UK and Europe. Approximately 48,500 new cases of prostate cancer are diagnosed within the UK each year. In the UK among people assigned male at birth, prostate cancer is the second most common cause of cancer death.

Prostate biopsy is a minimally invasive procedure where a small sample of prostatic tissue is obtained using a spring-loaded biopsy gun to assess for the presence of cancer. Generally prostatic biopsies are obtained by either a transperineal (TP) or transrectal (TR) route. There are different techniques to perform prostate biopsy – systematic or targeted. Targeted biopsy refers to image-guided biopsy of a specific target/lesion within the prostate, whereas in systematic biopsy the whole prostate is biopsied in a systematic way. Biopsies may be performed under general or local anaesthetic.

Guidance

This guidance applies to those 18 years and over.

Triage or one-stop clinic

— All patients with suspected prostate cancer, based on clinical examination and/or Prostate Specific Antigen (PSA) level, should be offered urgent clinical triage by a

suitable member of the clinical team (within two weeks), preferably via remote triage consultation (either video or telephone). Offer face-to-face consultations where remote consultations are not considered appropriate

- Following initial triage, mpMRI should be considered to enable a fully informed discussion regarding the role of prostate biopsy based on clinical examination, mpMRI findings and other risk factors. One-stop clinics could be considered, where feasible
- In addition to PSA, digital rectal examination and mpMRI findings, other risk factors such as PSA density, should be considered for clinically suspected cases of prostate cancer.

Pre-biopsy mpMRI

- Offer mpMRI as the first line investigation for people with suspected non-metastatic prostate cancer. mpMRI should not routinely be offered to people with prostate cancer who are not suitable for radical treatment
    - Consider omitting a prostate biopsy for people whose mpMRI Likert or Prostate Imaging and Data System (PI-RADS) v2.1 interpretation score is 1 or 2, and the PSA density is less than 0.15, but only after discussing the risks and benefits with the person and reaching a shared decision. If a person opts to have a biopsy, offer a systematic prostate biopsy
- Prostate biopsy should be offered for patients with PSA density >0.15 on mpMRI specified volume assessment, a strong family history of prostate cancer (e.g. multiple relatives at a young age) or an abnormal prostate on examination, even if Likert or PI-RADS v2.1 score is 1 or 2
- Patients with a Likert or PI-RADS v2.1 score of 3 should be considered for prostate biopsy. This should be following consideration of clinical assessment, PSA density and prostate cancer risk factors, and after discussing the risks and benefits with the patient and reaching a shared decision
- Offer prostate biopsy to all patients with a Likert or PI-RADS v2.1 score of 4 or 5, unless otherwise clinically contraindicated.

Biopsy route and setting

- Biopsies may be performed by transperineal (TP) or transrectal (TR) routes
- Preferably offer transperineal biopsy under local anaesthetic (LATP) as a first line investigation.

All centres involved in the diagnosis and management of prostate cancer should aim to offer LATP as an option.

If LATP is not appropriate, then offer alternative options such as general anaesthetic transperineal biopsy or local anaesthetic transrectal ultrasound scan (TRUS) biopsy, based on patient specific factors.

The use of general anaesthetic should be minimised. However, indications may include:

- Patient is unable to tolerate biopsy under local anaesthetic
- Biopsy involves multiple entry points — Repeat biopsy (e.g. following an inconclusive result)
- Prostatic anatomical variation

Visible lesions should be targeted. If there is a lesion, both targeted and systematic biopsies should be offered. Target biopsies should be performed initially, followed by systematic biopsies and sent separately for histological analysis.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

Standardised cancer care pathways are required to facilitate equitable access to care. The NHS urgent cancer diagnostic services during COVID-19 (v 2.0) recommends that patients with suspected prostate cancer undergo virtual triage as initial assessment.

Performance of high quality mpMRI before prostate biopsy is important to ensure best outcomes for patients with prostate cancer. The PROMIS (Prostate MRI Imaging Study) demonstrated that mpMRI is a highly sensitive test (93% sensitivity) for the detection of clinically significant prostate cancer if performed before biopsy. In addition, approximately 25% of patients who undergo mpMRI can potentially avoid biopsy. A subsequent cost effectiveness analysis demonstrated that mpMRI prior to prostate biopsy is highly cost-effective. The PRECISON (Prostate Evaluation for Clinically Important Disease: Sampling Using Image Guidance or Not?) found that one third of patients who underwent mpMRI did not require prostate biopsy. MpMRI influenced biopsy was significantly better at detecting prostate cancer than transrectal ultrasound (TRUS) biopsy alone, and reduced the detection of clinically insignificant disease. Of note, PRECISON compared MRI guided target biopsy with TRUS (without MRI), and current NHS practice is to perform MRI influenced biopsy, TRUS or transperineal biopsy. As a result of this study, the 2019 European Association of Urology (EUA) and 2019 NICE guideline NG131, now recommend mpMRI as the initial diagnostic test in biopsy naïve patients referred with suspected prostate cancer.

It should be noted that between 11 and 28 of 100 people with a low-risk MRI actually have clinically significant cancer. Shared decision making should be involved in all cases of suspected prostate cancer.

We note that biparametric MRI (bpMRI), which differs from mpMRI – in that dynamic contrast enhanced sequences are not performed – is used in some centres. We recommend the use of mpMRI over bpMRI given current PI-RADS, EUA, NICE and UK Consensus guidelines.

NICE NG131 recommends the reporting of mpMRI using the Likert scale, however, these recommendations also support the use of PI-RADS system, which has been widely adopted around the world. Both systems demonstrate high cancer detection rates – a recent study comparing the clinical validity and utility of the two scoring systems has demonstrated that both result in similar rates of biopsy.

Overall, the Likert scale was superior at detecting clinically significant prostate cancer in expert centres. Authors do comment that PI-RADS may play a valuable role in the reporting of mpMRI, particularly in less experienced centres. It is also worth noting that this study assessed PI-RADS v2.0 and not the most recent v2.1 and there is currently no evidence on how this updated scoring system directly compares to the Likert scale.

We acknowledge that the literature currently is lacking in high quality evidence comparing transrectal versus transperineal prostate biopsy and that this remains an ongoing area of research. High quality research in this area is strongly recommended and to be encouraged. LATP biopsy is associated with a lower risk of post-procedure infection and rectal bleeding. Furthermore, as LATP biopsy may avoid the use of prophylactic antibiotics, this will also facilitate antibiotic stewardship.

There is currently notable variation in practice between NHS trusts offering transperineal versus transrectal biopsy, with an increasing trend towards the utilisation of the transperineal route. Current clinical consensus supports the use of LATP over transrectal biopsy and we therefore recommend this be considered as first line investigation, where feasible.

Also, this guidance aims to standardise practice and reduce variation between NHS trusts. Reducing the proportion of biopsies performed under general anaesthetic would enable more patients to undergo work up for prostate cancer in community based diagnostic hubs, reduce the risks associated with general anaesthetic and improve resource allocation.

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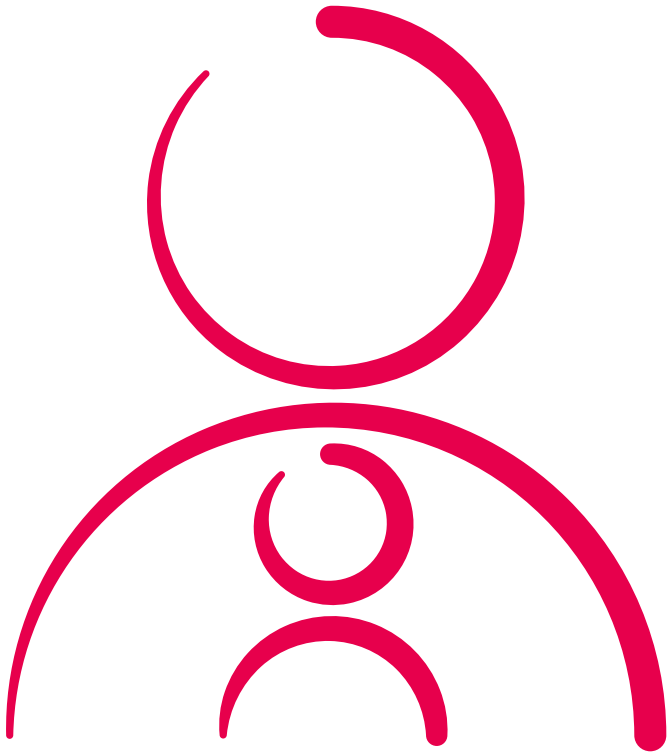
Paediatric urology



Penile circumcision

Penile circumcision is the removal of the foreskin from the penis. This guidance does not focus on religious or cultural reasons for penile circumcision. It refers only to the medical indications for penile circumcision in children and young people under 16 years of age. Phimosis (where the foreskin is too tight to be pulled back over the head of the penis) is normal in babies and young children. The percentage that can fully retract the foreskin increases with age.

Evidence shows that there is a wide variation in numbers of penile circumcision performed across the England. It is important to note that young children may be unable to give informed consent to penile circumcision, therefore clinicians should carefully consider the evidence-base and alternative options available.

The EBI programme proposes clear, evidence-based criteria for use across England.

Clinical overview

Penile circumcision is the surgical removal of the foreskin. It is performed as a day case procedure and requires general anaesthetic. While penile circumcision may be undertaken for religious, cultural, or medical reasons, the focus of this guideline is on the medical indications for penile circumcision.

Most foreskin conditions can be managed with simple advice and reassurance. There are a range of treatment options available for foreskin conditions and it's important that children and their parents are informed of these options prior to the decision to perform a penile circumcision, which cannot be reversed once performed.

While major morbidity and mortality following medical penile circumcision is very rare, these could be reduced and potentially avoided if surgical indications were more stringently applied.

Guidance

Medical penile circumcision is rarely indicated as a primary treatment. Most children and young people presenting with penile problems require no intervention other than reassurance.

This guidance applies to children and young people under 16 years.

This guidance excludes children and young people with congenital penile conditions such as hypospadias.

Penile circumcision should only be performed for:

— Prevention of urinary tract infection (UTI) in patients with recurrent UTIs or at high risk of UTI

OR

— Pathological phimosis (balanitis xerotica obliterans /lichen sclerosus)

OR

— For persistent phimosis in children approaching puberty, following an attempted a trial of non-operative interventions e.g. a six-week course of high-dose topical steroid. A prescription of this would not normally exceed three months and should have achieved maximal therapeutic benefit within this time. A topical steroid such as Betamethasone (0.025-0.1%) is commonly prescribed.

OR

— Acquired trauma where reconstruction is not feasible, for example, following zipper trauma or dorsal slit for paraphimosis

ALL patients must have a formally documented discussion of the risks and benefits of foreskin preserving surgery versus penile circumcision using a shared decision making framework.

Please note that this guidance is intended as a standard threshold for access. However, if you/ your patient falls outside of these criteria, the option to apply for an Individual Funding Request is still available to you.

Rationale for recommendation

The diagnostic code most often used for medical penile circumcision is phimosis. Phimosis is normal in babies and young children as the foreskin and glans of the penis are initially fused.

The percentage of children with full retraction of the foreskin increases with age. By the age of six years, approximately 8/100 cannot retract their foreskin at all, and 63/100 have adhesions which prevent the foreskin from being fully retracted. Since 99% of all children

with a penis have full retraction of the foreskin by age 17 years, this leaves only one in 100 requiring medical penile circumcision for phimosis by their 17th birthday.

The GIRFT Paediatric General Surgery and Urology National Report reviewed medical penile circumcisions performed in hospital trusts in England and found variation in volumes and activity:

— 17.5% of penile circumcisions are in children aged under five years old

— In some trusts, as many as 50% of children are under the age of five years at the time of their procedure.

It is important to note that young children, especially those aged under five years are unable to give informed consent or assent and therefore it is especially important that surgeons and parents consider the evidence base and consider less radical options when making the decision to perform penile circumcision, which cannot be reversed once performed.

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