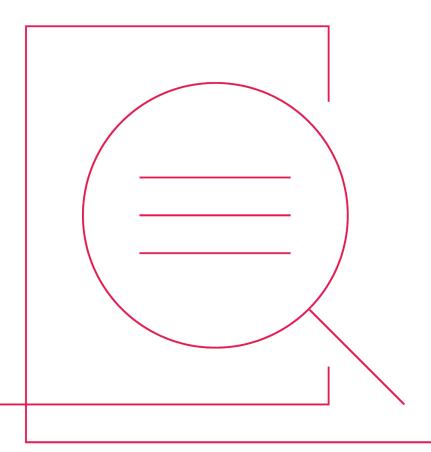
November / 2020

Evidence-Based Interventions List 2 Guidance





Evidence-Based Interventions

List 2: Guidance

First published: November 2020

Prepared by: Expert Advisory Committee to the Evidence-Based Interventions programme

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Foreword

Whether we are doctors or patients, we all know that medicine is constantly evolving and we must keep learning from the evidence as it emerges.

As a practising clinician I know there are many treatments and procedures I wouldn't contemplate prescribing or undertaking today that were commonplace perhaps just a few years ago. However, ensuring all doctors are up to date with the latest medical evidence about the effectiveness or otherwise of tests, treatments and procedures is no easy matter.

For this reason, I am delighted that the Academy has been able to host the Expert Advisory Committee (EAC) which has overseen the wave two of the Evidence-based Interventions (EBI) programme. As with wave one, it includes a list of tests, treatments and procedures which, the evidence tells us, are only appropriate for some patients, in certain circumstances when specific criteria are met. These recommendations – 31 in total – are set out in this document and will be formally adopted by NHS England in due course.

I am extremely grateful to my colleagues, Professor Martin Marshall and Professor Sir Terence Stephenson who co-chaired the EAC and who, along with specialist clinicians, patient groups and commissioners, sifted through extensive evidence relating to the interventions under review. In fact, this collaborative approach, with all groups coming together for a common purpose — and putting patients and their care at the heart of the conversation — is what makes the programme so effective in my view.

I must also say thank you to our dedicated colleagues at NHS England and the National Institute for Health and Care Excellence (NICE) for actively contributing to this work and providing much of the evidence base to help the EAC reach a set of conclusions that improves the quality of care for all.

It is important work and perhaps now, in the midst of COVID-19, never moreso. Because, as well as improving care and outcomes, it cannot be right that precious resources are invested in clinical activities which we know to be ineffective in some patients in some circumstances - and which in some cases can actually cause more harm than good.



It is equally important that patients have a choice in determining the treatments they are offered based on clear advice about the benefits, risks and alternatives to particular interventions. We should also be more open about what the evidence tells us will happen if we actively choose to 'do nothing'. Having the evidence to hand in one accessible format will, we hope, help doctors and the people they care for have this discussion in the most productive way.

This approach, of treating the whole patient, bearing in mind all the key issues in their lives, rather than just their specific condition, has to be at the heart of medical practice going forward and the EBI programme forms a central pillar of that. It is also a big part of the Academy's work around making the case for rethinking medicine and care more widely.

It is my firmly held view that regardless of COVID-19 this EBI work should never really reach an endpoint. The logic being that as medicine evolves, and more evidence emerges, we will always come up with new and better treatments for conditions, or in some cases just understand more about the condition itself. For this reason, I look forward to many more waves of EBI as the Academy have agreed to continue supporting the EAC in this work. This list is a great start, but it does not stop here.

Professor Helen Stokes-Lampard

Chair, Academy of Medical Royal Colleges



This guidance is produced by The Academy of Medical Royal Colleges (the Academy) as part of the Evidence-based interventions programme. It is based on recommendations from the Expert Advisory Committee and the National Institute for Health and Care Excellence (NICE).

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Background

Initially, NHSE/I led the EBI programme in partnership with the Academy, NICE and NHSCC. However, to ensure independent clinical leadership in the development of EBI guidance, the Expert Advisory Committee was established. To further bolster this clinical leadership, it feels the right time for the Academy to spearhead the continuation of this programme supported by NICE. NHSE/I will continue to support the implementation of EBI guidance while the strong clinical leadership ensures improving patient care is at the heart of the EBI programme.

Who is this guidance for?

This guidance sets out 31 tests, treatments and procedures where the evidence about their effectiveness or appropriateness has changed. It is set out in this document and is primarily directed at clinicians and other NHS staff who make decisions about patient care.

Why was the guidance developed?

There are two parallel and complementary objectives. First, to reduce the number of inappropriate interventions carried out by clinicians in the healthcare system. Second, to improve the quality of care patients receive. By reducing interventions which the evidence shows are less effective the EBI programme will:

- Free up valuable resources such as time, so that more effective interventions can be carried out. At a time when demand is exceeding available capacity and the COVID-19 pandemic is further stretching the system's finite resources, effective use of clinical time must be a priority
- Reduce harm or the risk of harm to patients. This is especially the case with surgical interventions which always carry the risk of complications or adverse reactions
- Help clinicians maintain professional practice. It is important that the
 evidence about which interventions are effective and which are not is
 disseminated to doctors in a clear, consistent and timely manner
- Create headroom for innovation. Care should always focus on improving quality and standards. We will only achieve this if we innovate

 Maximise value and avoid waste. Doctors should aim to be good stewards of scarce resources. Inappropriate care is not only potentially costly to patients, it also provides poor value for the taxpayer.

The Academy's ambition is to support clinicians improve outcomes for patients by ensuring they receive the highest possible standards of care. It follows therefore, that they only carry out interventions for which there is an established, high-quality evidence base.

How have the recommendations in this guidance been developed?

An independent Expert Advisory Committee [the EAC] was established in May 2019 to provide clinical leadership to the EBI programme. The Committee identified an initial long-list of interventions from clinical evidence including NICE guidance, Choosing Wisely recommendations,¹ academic studies and CCGs' policies on Procedures of Limited Clinical Effectiveness [PoLCE] collated through NHS Clinical Commissioners. At the same time, suggestions were taken from specialist clinicians, academics, commissioners, reflections from the EBI demonstrator community of 13 Sustainability and Transformation Partnerships [STPs] and Integrated Care Systems [ICSs].

The EAC considered each test, treatment and procedure before drafting guidance in collaboration with stakeholders including clinicians, commissioners and patients. It took particular note of:

- Advice from Medical Royal Colleges, specialist societies, clinicians, clinical commissioners, professional leaders and charities²
- Opinions from patients by liaising with patient advocates and patient representative groups, including the Strategic Co-Production Group at NHS England and NHS Improvement, the Academy of Medical Royal Colleges' Patient and Lay Committee and The Patients Association to test the proposals and understand patients' priorities
- The volume of interventions, geographical variation, strength of evidence and pace of change that could be applied to implement guidance relatively quickly and on a large scale

^{1.} Evidence includes NICE Cost Saving Guidance; NICE Technology Appraisal Guidance; Choosing Wisely UK http://www.choosingwisely.org/clinician-lists/
Choosing Wisely Canada http://choosingwisely.canada.org/recommendations/
Choosing Wisely Australia http://www.choosingwisely.org.au/recommendations/

^{2.} This refers to the Royal College of Anaesthetists (RCoA) including the Faculty of Pain Medicine; the Royal College of General Practitioners (RCGP); the Royal College of Pathologists (RCPath); the Royal College of Physicians (RCP) including British Gastroenterology Society (BSG), British Cardiovascular Society (BCS), British Society of Haematology (BSH); the Royal $\textbf{College of Paediatrics and Child Health (RCPCH) including British Association for Paediatric Otolaryngology (BAPO), British Ass$ Association of Perinatal Medicine (BAPM); the Royal College of Radiologists (RCR) including British Medical Ultrasound $Society \ [BMUS], British \ Society \ of \ Cardiovas cular \ Imaging \ [BSCI], British \ Society \ of \ Cardiovas cular \ Computed \ Tomography$ [BSCCT], British Society for Gastrointestinal and Abdominal Radiology [BSGAR], British Society of Thoracic Imaging [BSTI], British Society of Interventional Radiology (BSIR); the Royal College of Surgeons of England (RCSEng) and Federation of $Surgical Specialty Associations \ (FSSA) \ including \ Association \ of \ Anaesthetists, \ Association \ of \ Coloproctology \ of \ Great \ Britain$ and Ireland (ACPGBI), Association of Surgeons of Great Britain and Ireland (ASGBI), Association of Upper Gastrointestinal Surgery [AUGIS], Great Britain and Ireland Hepato Pancreato Biliary Association [GBIHPBA], Pancreatic Society of Great Britain and Ireland [PSGBI]; British Orthopaedic Association (BOA) including British Association for Surgery of the Knee [BASK], British Elbow and Shoulder Society [BESS], British Association of Spine Surgeons [BASS], British Hip Society [BHS]], British Association of Urological Surgeons (BAUS); British Association of Otolaryngology (ENTUK); British Blood Transfusion Society (BBTS); NHS Blood and Transplant (NHSBT); Craniofacial Society of Great Britain and Ireland (CFSGBI); Bladder Health UK, Versus Arthritis, Prostate Cancer UK; GUTS UK; Chartered Society of Physiotherapists [CSP]; British Heart Foundation (BHF)

- Reflections from commissioners and providers as well as partner teams in NHS England and Improvement such as Getting It Right First Time (GIRFT) and RightCare on the proportionality and levers that could be deployed to put guidance into practice
- The opportunity for shared decision making and self-care in which clinicians and patients work together to select treatments based on clinical evidence and patients' informed preferences.

It is important to note that the EAC did not consider the cost of the test, treatment or procedure or the amount of money that could be reallocated if the number of interventions was reduced.

Over the past year, and in collaboration with the stakeholders outlined above, evidence on each of the 31 interventions was reviewed thoroughly by the EAC and at least one appropriate clinical group, often comprising specialty specific experts.

It should also be noted that all of the clinical criteria consulted on were developed directly from existing NICE, NICE-accredited or specialist society guidance and local CCG policies, and the final set of wording used has been checked by the relevant Medical Royal Colleges, specialist societies, individual specialists, as well as clinical experts from within NHSE/I.

As the design principles were agreed through public consultation in 2018, engagement for the 31 interventions focused on refining the clinical criteria and supporting clinical codes. The Committee conducted a public engagement exercise between 13 July to 24 August 2020 to gain final consensus and support from the public, medical royal colleges, the appropriate specialist societies, clinicians and patients. While the number of interventions remains unchanged from those listed in the engagement document, there have been changes to the criteria and codes in response to feedback received. A detailed report on the Committee's proposal, including the engagement findings, can be found in 'Evidence-Based Interventions: List 2 Proposal'.3

The final set of criteria can be found in Appendix 1 and supporting clinical codes in Appendix 2.

This guidance supports the Clinical Prioritisation programme which is part of the third phase of the NHS response to COVID-19. The Clinical Prioritisation programme is designed to support the prioritisation of waiting lists as part of the recovery of elective activity. The priority is to ensure that all patients on an admitted patient care pathway have been reviewed and clinically prioritised to support discussions with patients and reach a decision about their planned care.⁴

To support health systems, implement the EBI guidance a digital solution has been developed. This is known as the EBIchecker which is a web-based system that incorporates the EBI guidance. It enables clinicians to access the EBI clinical criteria so they can use this evidence-based guidance to support them and the patient to reach a decision about what is appropriate care for their needs.⁵

 $^{3. \ \}underline{https://www.aomrc.org.uk/wp-content/uploads/2020/12/EBI_list2_proposals_1120.pdf}$

^{4.} https://www.england.nhs.uk/coronavirus/publication/validating-waiting-lists-framework/

 $^{5. \ \}underline{https://www.aomrc.org.uk/ebi/how-ebi-fits-with-the-national-clinical-validation-programme/$



Full clinical guidance for the 31 interventions

Clinical criteria for the 31 interventions

2A	
ZA	Diagnostic coronary angiography for low risk, stable chest pain
2B	Repair of minimally symptomatic inguinal hernia
2C	Surgical intervention for chronic rhinosinusitis
2D	Removal of adenoids for treatment of glue ear
2E	Arthroscopic surgery for meniscal tears
2F	Troponin test
2G	Surgical removal of kidney stones
2H	Cystoscopy for men with uncomplicated lower urinary tract symptoms
21	Surgical intervention for benign prostatic hyperplasia
2J	Lumbar Discectomy
2K	Lumbar radiofrequency facet joint denervation
2L	Exercise ECG for screening for coronary heart disease
2M	Upper GI endoscopy
2N	Appropriate colonoscopy in the management of hereditary colorectalcancer
20	Repeat Colonoscopy
2P	ERCP in acute gallstone pancreatitis without cholangitis
2Q	Cholecystectomy
2R	Appendicectomy without confirmation of appendicitis
2S	Low back pain imaging
2T	Knee MRI when symptoms are suggestive of osteoarthritis
2U	Knee MRI for suspected meniscal tears
2V	Vertebral augmentation (vertebroplasty or kyphoplasty) for painful osteoporotic vertebral fractures
2W	Shoulder Radiology: Scans for Shoulder Pain and Guided Injections
2X	MRI scan of the hip for arthritis
2Y	Fusion surgery for mechanical axial low back pain
2Z	Helmet therapy for treatment of positional plagiocephaly/brachycephaly in children
2AA	Pre-operative chest x-ray
2BB	Pre-operative ECG
2CC	Prostate-specific antigen (PSA) test
2DD	Liver function, creatinine kinase and lipid level tests – [Lipid loweringtherapy]
2EE	Blood transfusion



Summary of intervention

NICE guidelines recommend that where a diagnosis of chest pain cannot, by clinical assessment alone, exclude stable angina, 64-slice (or above) CT coronary angiography should be offered as first-line. Invasive coronary angiography should only be offered to patients with significant findings on CT coronary angiogram or with inconclusive further imaging.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

26.629

Proposal

When results of non-invasive functional imaging are inconclusive and patients are assessed as having low risk, stable cardiac pain, invasive coronary angiography (cardiac catheterisation) should be offered only as third-line investigation.

Patients who have chest pain that is not an Acute Coronary Syndrome (ACS), but there is concern that it is due to an ischemic cause (stable angina) should, in the first instance, be offered a CT Coronary angiography (64 slice or above). This is based on:

- Clinical assessment indicating typical or atypical angina; or
- Clinical assessment indicates non-anginal chest pain but the 12-lead resting ECG shows ST-T changes or Q waves.

Significant coronary artery disease (CAD) found during CT coronary angiography is $\geq 70\%$ diameter stenosis of at least one major epicardial artery segment or $\geq 50\%$ diameter stenosis in the left main coronary artery.

If the CT coronary angiography is inconclusive, non-invasive functional imaging for myocardial ischemia should be considered in the following forms:

- Stress echocardiography; or
- First-pass contrast-enhanced magnetic resonance (MR) stress perfusion; or
- MR imaging for stress-induced wall motion abnormalities; or
- Fractional flow reserve CT (FFR-CT); or
- Myocardial perfusion scintigraphy with single photon emission computed tomography (MPS with SPECT).

Invasive coronary angiography should only be offered as third-line investigation when the results of non-invasive functional imaging are inconclusive.

Rationale for Recommendation

NICE guidelines recommend that where a diagnosis of chest pain cannot, by clinical assessment alone, exclude stable angina, 64-slice [or above] CT coronary angiography should be offered as first-line investigation. Cardiac catheterisation and coronary angiography are generally considered to be safe procedures. However, as with all medical procedures, there are some associated risks. The main risks of coronary angiography include:

- **---**
- Haematoma or bruising in groin or arm
- Allergy to the contrast
- A very small risk including damage to the artery in the arm or leg where the catheter was inserted, heart attack, stroke, kidney damage and, very rarely, death (risk of a serious complication occurring is estimated to be less than 1 in 1,000. People with serious underlying heart problems are most at risk.)

References

- 1. NICE guidance: Chest pain of recent onset: assessment and diagnosis [clinical guideline CG95]: https://www.nice.org.uk/guidance/cg95
- 2. NICE Resource impact report: https://www.nice.org.uk/guidance/cg95/ resources/resource-impact-report-pdf-2726121709
- 3. NHS advice: https://www.nhs.uk/conditions/coronary-angiography/
- 4. NHS advice: https://www.nhs.uk/conditions/coronary-angiography/risks/
- 5. Guy's and St. Thomas' patient information: https://www.guysandstthomas.nhs.uk/resources/patient-information/cardiovascular/having-a-coronary-angiogram.pdf
- 6. NICE guidance: HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography [Medical technologies guidance MTG32]: https://www.nice.org.uk/guidance/mtg32
- 1.1.2 2B Repair of minimally symptomatic inguinal hernia

Summary of intervention

Watchful waiting is a safe option for people with minimally symptomatic inguinal hernias. Delaying and not doing surgical repair unless symptoms increase is acceptable because acute hernia incarcerations occur rarely. Many people with an inguinal hernia are asymptomatic or minimally symptomatic and may never need surgery.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

54,764

Proposal

Minimally symptomatic inguinal hernia can be managed safely with watchful waiting after assessment. Conservative management should therefore be considered in appropriately selected patients.

In women, all suspected groin hernias should be urgent referrals.

Rationale for Recommendation

Repair of minimally symptomatic inguinal hernia is a high cost and high frequency operation. A randomised control trial determined that watchful waiting was a safe and reasonable option for minimally symptomatic hernias. Up to one third of hernias give patients only mild pain that does not interfere with work or leisure activities.

The risks/potential harm of delaying surgery (which is a frequently cited

reason for repair) are rare. The incidence of hernia accident (i.e. acute hernia incarceration with bowel obstruction, strangulation of intraabdominal contents, or both) is very low (1.8 per 1'000 patients) and even in elderly, whom are at greater risk, the rate is 0 11% in patients aged over 65 years. Patients who develop symptoms have no greater risk of operative complications than those undergoing hernia repair for minimally symptomatic hernia. The rate of complications is similar for those undergo surgery for minimally symptomatic hernia and those who have surgery as a result of an increase in symptoms whilst under watchful waiting. The risks are infection, bleeding, perforation, and long-lasting significant pain after surgery as well as risks associated with sedation/anaesthetic. Although it is a generally safe and effective operation, procedures should be delayed where appropriate to avoid these associated risks.

In a male randomised clinical trial for two-year watchful waiting, for the instances that treatment escalated to surgery, the most common reason cited was increased hernia-related pain. The hernia repair can be safely delayed until increased pain or discomfort. Pain interfering with activities increased 5.1% for watchful waiting and 2.2% for surgical repair over this same time. The is confirmed by another trial looking at pain at 12 months that did not find statistically different values between surgery and watchful waiting groups. Those who had increased pain crossed over to have surgery where necessary. 23% of patients crossed over from watchful waiting to surgery within two years. Pain was decreased in both groups at two years.

Results of several randomised controlled and clinical trials agreed with these findings. It is safe to manage minimally symptomatic inguinal hernia with watchful waiting. Outcomes, pain and post-operative complications remained similar to hernia repair for minimally symptomatic hernia.

References

- 1. Royal College of Surgeons and British Hernia Society Commissioning Guide: Groin Hernia 2016: https://www.rcseng.ac.uk/-/media/files/rcs/standards-and-research/commissioning/groin-hernia-commissioning-guide_published-2016.pdf
- 2. Malik HT, Marti J, Darzi A, Mossialos E. Savings from reducing low-value general surgical interventions. Br J Surg. 2018 Jan;105[1]:13-25. doi:10.1002/bjs.10719. Epub 2017 Nov 8. Review. PubMed PMID: 29114846.
- 3. Fitzgibbons RJ Jr, Giobbie-Hurder A, Gibbs JO, Dunlop DD, Reda DJ, McCarthy M Jr et al. Watchful waiting vs repair of inguinal hernia in minimally symptomatic men: a randomized clinical trial. JAMA 2006; 295: 285 292.
- 4. O'Dwyer PJ, Norrie J, Alani A, Walker A, Duffy F, Horgan P. Observation or operation for patients with an asymptomatic inguinal hernia: a randomized clinical trial. Ann Surg 2006; 244: 167 173.
- 5. Fitzgibbons RJ Jr, Ramanan B, Arya S, Turner SA, Li X, Gibbs JO et al. Long-term results of a randomized controlled trial of a nonoperative strategy [watchful waiting] for men with minimally symptomatic inguinal hernias. Ann Surg 2013; 258: 508 515



Summary of intervention

Chronic rhinosinusitis (CRS) is defined as inflammation (swelling) of the nasal sinuses that lasts longer than 12 weeks. The sinuses are mucus secreting, air filled cavities in the face and head that drain into the nose; their normal function may be disrupted by environmental, infectious or inflammatory conditions which damage the epithelial lining and disturb the balance of the natural microbial community. Patients report a number of symptoms including nasal blockage, discharge, alteration to smell, and facial pressure or pain. They often have a relapsing course, with recurrence after treatment commonplace. Absenteeism and presenteeism are widespread.

It is a common chronic condition that affects approximately 11% of adults and has a significant detrimental effect on the quality of life of those affected, thus creating a significant disease burden.

CRS as a term encompasses a wide range of phenotypes but can broadly be divided into two main types. Chronic rhinosinusitis with Nasal Polyposis (CRSwNP) and Chronic Rhinosinusitis without Nasal Polyposis (CRSsNP).

First-line treatment is with appropriate medical therapy, which should include intranasal steroids and nasal saline irrigation. In the case of CRSwNP a trial of a short course of oral steroids should also be considered.

Where first-line medical treatment has failed patients should be referred for diagnostic confirmation and they then may be considered for endoscopic sinus surgery. This involves surgery using a telescope via the nasal cavity to open the sinuses and, if present, remove nasal polyps, both improving the effectiveness of ongoing medical therapy and relieving obstruction. The surgery is usually undertaken under general anaesthetic as a day-case procedure in otherwise healthy individuals.

This guidance applies to adults and children.

Number of interventions in 2018/19

12,610

Proposal

Patients are eligible to be referred for specialist secondary care assessment in any of the following circumstances:

 A clinical diagnosis of CRS has been made (as set out in RCS/ENT-UK Commissioning guidance) in primary care and patient still has moderate / severe symptoms after a 3-month trial of intranasal steroids and nasal saline irrigation.

AND

 In addition, for patients with bilateral nasal polyps there has been no improvement in symptoms 4 weeks after a trial of 5-10 days of oral steroids (0.5mg/kg to a max of 60 mg)

OR

Patient has nasal symptoms with an unclear diagnosis in primary care

OR

 Any patient with unilateral symptoms or clinical findings, orbital, or neurological features should be referred urgently / via 2-week wait depending on local pathways.

No investigations, apart from clinical assessment, should take place in primary care or be a pre-requisite for referral to secondary care (e.g. X-ray, CT scan). There is no role for prolonged courses of antibiotics in primary care.

Patients can be considered for endoscopic sinus surgery when the following criteria are met:

 A diagnosis of CRS has been confirmed from clinical history and nasal endoscopy and / or CT scan

AND

 Disease-specific symptom patient reported outcome measure confirms moderate to severe symptoms e.g. Sinonasal Outcome Test (SNOT-22) after trial of appropriate medical therapy (including counselling on technique and compliance) as outlined in RCS/ENT-UK commissioning guidance 'Recommended secondary care pathway'.

AND

 Pre-operative CT sinus scan has been performed and confirms presence of CRS. Note: a CT sinus scan does not necessarily need to be repeated if performed sooner in the patient's pathway.

AND

 Patient and clinician have undertaken appropriate shared decisionmaking consultation regarding undergoing surgery including discussion of risks and benefits of surgical intervention.

OR

 In patients with recurrent acute sinusitis, nasal examination is likely to be relatively normal. Ideally, the diagnosis should be confirmed during an acute attack if possible, by nasal endoscopy and/or a CT sinus scan.

There are a number of medical conditions whereby endoscopic sinus surgery may be required outside the above criteria and in these cases they should not be subjected to the above criteria and continue to be routinely funded:

- Any suspected or confirmed neoplasia
- Emergency presentations with complications of sinusitis (e.g. orbital abscess, subdural or intracranial abscess)
- Patients with immunodeficiency
- Fungal Sinusitis
- Patients with conditions such as Primary Ciliary Dyskinesia, Cystic Fibrosis or NSAID-Eosinophilic Respiratory Disease (NSAID-ERD, Samter's Triad Aspirin Sensitivity, Asthma, CRS)
- Treatment with topical and / or oral steroids contra-indicated.
- As part of surgical access or dissection to treat non-sinus disease (e.g. pituitary surgery, orbital decompression for eye disease, nasolacrimal surgery)

Rationale for Recommendation

There is a strong evidence base and expert consensus opinion to support the medical management of chronic rhinosinusitis with intranasal steroids and nasal saline irrigation as a first-line treatment. They are low cost and low risk, with newer generations of nasal steroids safe for long-term use owing to minimal systemic absorption.

There is also evidence to support the trial of oral steroids, but only when nasal polyposis is present. The benefits of oral steroids should be balanced against the risks when considering repeated courses. A Cochrane review has demonstrated the benefits of oral steroids can last up to three months; however the risks and side effects must be balanced against benefit for the patient with repeated courses.

There is evidence to support that when endoscopic sinus surgery is performed in appropriately selected patients (as outlined in the recommendation), it will lead to a significant and durable improvement in symptoms. There is also evidence that patients who undergo surgery early in their disease course will have a longer and more beneficial impact from the surgery. All national and international guidelines support consideration of endoscopic sinus surgery once appropriate medical therapy has failed.

It is important to note that there is currently a UK multidisciplinary randomised controlled trial [RCT] comparing medical therapy with surgery in the management of chronic rhinosinusitis [MACRO Trial: https://www.themacroprogramme.org.uk). he outcome of this trial may lead to modification of guidance for sinus surgery in due course.

Endoscopic sinus surgery is generally safe and low risk. Risks include bleeding, infection, scar tissue formation, and very rarely, orbital injury or cerebrospinal fluid leak (with associated risk of meningitis). Patients should be counselled that there is a risk of recurrent symptoms and that ongoing medical treatment is normally required to maintain symptom improvement after endoscopic sinus surgery.

References

- 1. RCS Commissioning Guide: Chronic Rhinosinusitis. 2016: https://www.rcseng.ac.uk/standards-and-research/commissioning/commissioning-guides/topics/
- 2. NICE Clinical Knowledge Summary Sinusitis: https://cks.nice.org.uk/sinusitis
- 3. Hastan D, Fokkens WJ, Bachert C, et al. Chronic rhinosinusitis in european underestimated disease. A GA[2]LEN study. Allergy. 2011;66[9]:1216-1223. doi: 10.1111/j.1398-9995.2011.02646.x [doi].
- 4. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: Rhinosinusitis. Int Forum Allergy Rhinol. 2016;6 Suppl 1:22. doi: 10.1002/alr.21695 [doi].
- 5. Fokkens WJ, Lund VJ, Mullol J, et al. EPOS 2012: European position paper on rhinosinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. Rhinology. 2012;50(1):1-12. doi: 10.4193/Rhino50E2 [doi].



Summary of intervention

Adenoids are lymphatic tissue that reside in the post nasal space and arise from the roof of the nasopharynx. Adenoids are only usually present in children and tend to grow from birth, reaching the largest size when a child is between 3 and 5 years of age, before slowly shrinking away by adulthood.

When the adenoids are enlarged or inflamed they may contribute to glue ear (otitis media with effusion), which can affect hearing. They can also cause symptoms of nasal blockage, mouth breathing, obstructive sleep and other upper respiratory tract symptoms (e.g. persistent runny nose).

When children have persistent glue ear that affects hearing, one option for treatment of the hearing loss is with grommet insertions (ventilation tubes) and guidance for this intervention is already set out in the EBI guidance published in November 2018 – 'grommets for glue ear in children'.

In some circumstances, when a child is undergoing surgery to insert grommets, the adenoids may also be partially resected at the same time. This is a short procedure performed via the mouth to remove excessive adenoidal tissue (adenoidectomy) and is most commonly performed either by electrocautery (monopolar suction diathermy), cold steel dissection (curettage), or coblation. The aim of adenoidectomy is to improve eustachian tube function and therefore reduce the recurrence of glue ear after grommets fall out.

This guidance applies to children aged 18 years and under.

Number of interventions in 2018/19

2,778

Proposal

Adjuvant adenoidectomy should not be routinely performed in children undergoing grommet insertion for the treatment of otitis media with effusion.

Adjuvant adenoidectomy for the treatment of glue ear should only be offered when one or more of the following clinical criteria are met:

- The child has persistent and / or frequent nasal obstruction which is contributed to by adenoidal hypertrophy (enlargement)
- The child is undergoing surgery for re-insertion of grommets due to recurrence of previously surgically treated otitis media with effusion
- The child is undergoing grommet surgery for treatment of recurrent acute otitis media.

This guidance only refers to children undergoing adenoidectomy for the treatment of glue ear and should not be applied to other conditions where adenoidectomy should continue to be routinely funded:

- As part of treatment for obstructive sleep apnoea or sleep disordered breathing in children (e.g. as part of adenotonsillectomy)
- As part of the treatment of chronic rhinosinusitis in children
- For persistent nasal obstruction in children and adults with adenoidal hypertrophy
- In preparation for speech surgery in conjunction with the cleft surgery team.

Rationale for Recommendation

NICE guidance recommends that adjuvant adenoidectomy should not be performed for the treatment of glue ear in the absence of persistent and / or frequent upper respiratory tract symptoms. A recent systemic review demonstrated that whilst adjuvant adenoidectomy resulted in an improvement in resolution of the glue ear at 6 and 12 months compared to grommets alone, the benefit in hearing compared to grommets alone was very limited.

Adjuvant adenoidectomy is considered a low risk procedure but does increase the length of surgery compared to inserting grommets alone. Risks include damage to teeth, lips or gums, bleeding (usually only minor and self-resolving), and rarely (around 1%) velopharyngeal insufficiency (VPI). VPI can result in speech problems such as hypernasal speech or audible escape of air out of the nose when talking and in some cases can cause nasal regurgitation.

If there is a history of cleft palate or palpable palate abnormality such as submucous cleft palate or a history of speech problems before the operation; full multidisciplinary assessment should be carried out before adenoidectomy.

References

- 1. NICE Guidance: https://www.nice.org.uk/Guidance/CG60.
- 2. Rosenfeld RM, Shin JJ, Schwartz SR, et al. Clinical practice guideline: Otitis media with effusion executive summary (update). Otolaryngol Head Neck Surg. 2016;154(2):201-214. https://doi.org/10.1177/0194599815624407. doi: 10.1177/0194599815624407.
- 3. Schilder AG, Marom T, Bhutta MF, et al. Panel 7: Otitis media: Treatment and complications. Otolaryngol Head Neck Surg. 2017;156(4_suppl):S88-S105. doi: 10.1177/0194599816633697 [doi].
- 4. Van dA, Schilder A, Herkert E, Boonacker C, Rovers MM. Adenoidectomy for otitis media in children. Cochrane Database of Systematic Reviews. 2010[1]. https://doi.org//10.1002/14651858.CD007810.pub2. doi: 10.1002/14651858. CD007810.pub2.

1.1.5 2E — Arthroscopic surgery for meniscal tears

Summary of intervention

Arthroscopy of the knee is a surgical technique where a camera and instruments are inserted into the knee through small incisions, usually under general anaesthesia. Following a detailed systematic assessment of the important structures within the knee joint a surgical procedure is performed which can involve repair or resection of meniscal tissue, with or without other associated procedures such as ligament reconstruction or repair of articular cartilage lesions. The British Association for surgery of the Knee [BASK] recently published guidelines for the use of arthroscopic surgery to treat degenerate meniscal tears.

This guidance applies to adults and children.

Number of interventions in 2018/19

38,088

Proposal

The use of arthroscopic surgery to treat degenerate meniscal tears should follow published BASK guidelines https://online.boneandjoint.org.uk/doi/pdf/10.1302/0301-620X.101B6.BJJ-2019-0126.R1.

Rationale for Recommendation

Meniscal tears in the knee are a common finding and in many cases are not related to any significant symptoms. They are often associated with degenerative articular cartilage change and osteoarthritis within the knee. A significant number of patients who present with persistent and often mechanical symptoms within the knee have a meniscal tear, which may be noted with an MRI scan.

The vast majority of patients with a meniscal tear should be initially treated non-operatively and should not have arthroscopic meniscectomy as a first-line treatment. Non-operative treatment is highly effective with patient education using verbal and written materials, physiotherapy and weight loss interventions. Exercise should comprise both local muscle strengthening and general aerobic fitness. Paracetamol and topical NSAIDs should be first-line pharmacological pain management strategies. Many patients treated this way will improve and do not require surgery.

There are a number of occasions when arthroscopic meniscal surgery can be considered as a first-line treatment. Firstly, patients who have a locked knee need urgent assessment. If a bucket handle tear of the meniscus is present, most cases need arthroscopic repair or resection of the meniscus. Secondly where the patient has had an acute injury and an MRI scan reveals a potentially repairable meniscus tear, an arthroscopic meniscal repair should be considered.

Where symptoms have not settled after three months of non-operative treatment an MRI scan should be considered. In these cases with an unstable meniscal tear on MRI, arthroscopic meniscal surgery may be indicated. Recent systematic review evidence has suggested that in these cases where there are persistent symptoms, there can be improvement with this procedure.

Patients considering arthroscopic knee surgery should go through a shared decision-making process and have a good understanding of the risks of surgery. The procedure is a relatively safe intervention but does carry a low a low risk of infection and deep vein thrombosis, both of which are serious complications

Routine use of arthroscopy for degenerative knee disease, where no specific target pathology has been identified [e.g. proven meniscal tear and persistent symptoms], is not recommended. Use of arthroscopy in patients with generic degenerative knee disease and no specific target pathology has not been found to be clinically beneficial and is unlikely to be cost-effective. Using agreed guidelines for employing arthroscopic surgery to treat meniscal tear pathology and avoiding indiscriminative use will reduce unwarranted variation in clinical care.

References

1. Kise NJ, Risberg MA, Stensrud S, Ranstam J, Engebretsen L, Roos EM. Exercise therapy versus arthroscopic partial meniscectomy for degenerative meniscal tear in middle aged patients: randomised controlled trial with two year follow up. BMJ2016;354:i3740. doi:10.1136/bmj.i3740 pmid:27440192

- ______
- 2. Khan M, Evaniew N, Bedi A, Ayeni OR, Bhandari M. Arthroscopic surgery for degenerative tears of the meniscus: a systematic review and meta-analysis. CMAJ2014;186:1057-64. doi:10.1503/cmaj.140433 pmid:25157057.
- 3. Thorlund JB, Juhl CB, Roos EM, Lohmander LS. Arthroscopic surgery for degenerative knee: systematic review and meta-analysis of benefits and harms. BMJ2015;350:h2747. doi:10.1136/bmj.h2747 pmid:26080045.
- 4. Devji T, Guyatt GH, Lytvyn L, et al. Application of minimal important differences in degenerative knee disease outcomes: a systematic review and case study to inform BMJ Rapid Recommendations. BMJ Open 2017;7:e015587. doi:doi:10.1136/bmjopen-2016-015587.
- 5. Brignardello-Peterson R, Guyatt GH, Schandelmaier S, et al. Knee arthroscopy versus conservative management in patients with degenerative knee disease: a systematic review. BMJ Open2017;7:e016114. doi:10.1136/bmjopen-2017-016114.
- 6. Marsh JD, Birmingham TB, Giffin JR, et al. Cost-effectiveness analysis of arthroscopic surgery compared with non-operative management for osteoarthritis of the knee. BMJ Open2016;6:e009949. doi:10.1136/bmjopen-2015-009949 pmid:26758265.
- 7. https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations
- 8. McGrory B, Weber K, Lynott JA, et al. American Academy of Orthopaedic Surgeons. The American Academy of Orthopaedic Surgeons evidence-based clinical practice guideline on surgical management of osteoarthritis of the knee. J Bone Joint Surg Am2016;98:688-92. doi:10.2106/JBJS.15.01311 pmid:27098328.
- 9. National Institute for Health and Clinical Excellence. Arthroscopic knee washout, with or without debridement, for the treatment of osteoarthritis [Interventional procedures guidance IPG230]. 200: http://www.nice.org.uk/guidance/ipg230/chapter/2-The-procedure.
- 10. Adelani MA, Harris AH, Bowe TR, Giori NJ. Arthroscopy for knee osteoarthritis has not decreased after a clinical trial. Clin Orthop Relat Res2016;474:489-94. doi:10.1007/s11999-015-4514-4 pmid:26290345.
- 11. Siemieniuk RAC, Harris IA, Agoritsas T, et al. Arthroscopic surgery for degenerative knee arthritis and meniscal tears: a clinical practice guideline. BMJ 2017;257:j1982. doi:10.1136/bmj.j1982.
- 12. Gauffin H, Tagesson S, Meunier A, Magnusson H, Kvist J. Knee arthroscopic surgery is beneficial to middle-aged patients with meniscal symptoms: a prospective, randomised, single-blinded study. Osteoarthritis Cartilage2014;22:1808-16. doi:10.1016/j.joca.2014.07.017 pmid:25086401.
- 13. Sihvonen R, Englund M, Turkiewicz A, Järvinen TL. Finnish Degenerative Meniscal Lesion Study Group. Mechanical symptoms and arthroscopic partial meniscectomy in patients with degenerative meniscus tear: a secondary analysis of a randomized trial. Ann Intern Med2016;164:449-55. doi:10.7326/M15-0899 pmid:26856620.

- ______
- 14. S. G. F. Abram, D. J. Beard, A. J. Price, BASK Meniscal Working Group. Bone Joint J 2019;101–B:652–659. Arthroscopic meniscal surgery a national society treatment guideline and consensus statement: https://doi.org/10.1302/0301-620X.101B6.BJJ-2019-0126.R1.
- 15. A. J. Price, F. S. Haddad, D. J. Beard. Bone Joint J 2019;101–B:625–626. New guidelines for the use of arthroscopic meniscal knee surgery. Published Online:1 Jun 2019: https://doi.org/10.1302/0301-620X.101B6.BJJ-2019-0550.
- 16. Abram SGF, Judge A, Beard DJ, Price AJ. Lancet. 2018 Nov 17;392[10160]:2194-2202. Adverse outcomes after arthroscopic partial meniscectomy: a study of 700 000 procedures in the national Hospital Episode Statistics database for England. doi: 10.1016/S0140-6736[18]31771-9. Epub 2018 Sep 24.
- 17. https://www.nice.org.uk/guidance/cg177.
- 18. https://online.boneandjoint.org.uk/doi/pdf/10.1302/0301-620X.101B6.BJJ-2019-0126.R1.
- 19. Arthroscopic partial meniscectomy for meniscal tears of the knee: a systematic review and meta-analysis http://dx.doi.org/10.1136/bjsports-2018-100223.
- 20. https://online.boneandjoint.org.uk/doi/full/10.1302/0301-620X.101B6.BJJ-2019-0126.R1.
- 21. https://www.sciencedirect.com/science/article/pii/S0968016018303934.
- 1.1.6 2F Troponin test

Summary of intervention

Troponin blood testing should be used to diagnose acute myocardial infarction. It should only be used in cases where a clinical diagnosis of acute coronary syndrome or myocarditis is suspected or for prognostic purposes when pulmonary embolism is confirmed.

Number of interventions in 2018/19

575.375

Proposal

In order to rule out suspected acute coronary syndrome (moderate or high risk of myocardial infarction) in people presenting with acute chest pain, NICE recommends early rule out using high-sensitivity troponin tests.

High-sensitivity troponin assays were developed to detect troponin in the blood at lower levels than non-high-sensitivity troponin assays. Using the high-sensitivity assays as part of an early rule-out protocol can reduce time to discharge. Guidance on early rule out of NSTEMI using high-sensitivity troponin assays recommends a 2-test strategy, typically on admission and at 3 hours. However, the committee concluded that there was insufficient evidence to recommend a specific test strategy and agreed that early rule-out protocols should be chosen according to local preference.

High-sensitivity troponin measurements should not be considered in isolation but interpreted alongside the clinical presentation, the time from onset of symptoms, the 12-lead resting ECG, pre-test probability of NSTEMI,

the possibility of chronically elevated troponin levels in some people and that 99th percentile thresholds for troponin I and T may differ between sexes.

If ACS is not suspected, high-sensitivity troponin test should not be used. For people at low risk of myocardial infarction only perform a second high-sensitivity troponin test if the first troponin test at presentation is positive.

Diagnosis of myocardial infarction is the detection of a rise and/or fall of cardiac troponin with at least one value above the 99th percentile of the upper reference limit and at least one of the following:

- symptoms suggesting myocardial ischaemia
- new / presumed new significant ST-segment-T wave (ST-T) changes or new left bundle branch block (LBBB)
- development of pathological Q waves on the ECG
- imaging evidence of new loss of viable myocardium or new regional wall motion abnormality
- identification of an intracoronary thrombus by angiography.

The appropriate use of high-sensitivity troponin testing should reduce the need for further investigation, result in shorter stays in hospital and overall result in cost-savings (if used in an early rule out clinical protocol). According to this recommendation, if acute coronary syndrome is suspected in a primary care setting, a referral should be made for prompt investigation and treatment.

This guidance applies to adults and children.

Rationale for Recommendation

NICE guidelines recommend that the initial assessment for a person presenting with chest pain and suspected acute coronary syndrome in hospital is a 12-lead resting ECG and a blood sample for high-sensitivity troponin I or T. NICE guidance considers high-sensitivity troponin tests to be those that have a coefficient of variation of 10% or less at the 99th percentile (the upper limit of the reference population), and are able to detect cardiac troponin in at least 50% of the reference population. Research suggests that troponin tests used for indications other than suspected acute coronary syndrome are rarely associated with cardiac disease, cause unnecessary investigations and increase length of hospital stay.

Troponin also has a role in the diagnosis of suspected myocarditis and for diagnosis and monitoring of chemotherapy related myocardial damage.

Troponin tests are useful prognostically but not diagnostically in cases of pulmonary embolism [PE] as markers of right ventricular dysfunction. Troponin levels are elevated in up to half of patients who have a moderate to large PE and are associated with clinical deterioration after PE. Troponin elevations usually resolve within 40 hours following PE, in contrast to the more prolonged elevation after acute myocardial injury.

References

1. NICE guidance: Myocardial infarction (acute): Early rule out using high-sensitivity troponin tests (Elecsys Troponin T high-sensitive, ARCHITECT STAT High Sensitive Troponin-I and AccuTnI+3 assays) https://www.nice.org.uk/guidance/dg15.

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- 2. NICE Guidance: Chest pain of recent onset: assessment and diagnosis ICG951, https://www.nice.org.uk/guidance/cg95.
- 3. NICE Costing Statement: https://www.nice.org.uk/guidance/dg15/resources/costing-statement-pdf-49213.
- 4. NICE adoption support resource: https://www.nice.org.uk/guidance/dg15/resources/adoption-support-resource-insights-from-the-nhs-6905227937/chapter/Introduction.
- 5. The Universal Definition of MI: Thygesen K, Alpert JS, Jaffe AS et al. [2012] https://www.ahajournals.org/doi/full/10.1161/CIR.0b013e31826e1058.
- 6. Al-Maskari M, Al-Makhdami M, Al-Lawati H, Al-Hadi H, Nadar SK. Troponin Testing in the Emergency Department: Real world experience. Sultan Qaboos Univ Med J. 2017;17(4):e398–e403. doi:10.18295/squmj.2017.17.04.004.
- 7. Cardiac troponin I elevation in acute pulmonary embolism is associated with right.
- 8. ventricular dysfunction. Meyer T, Binder L, Hruska N, Luthe H, Buchwald AB. J Am Coll Cardiol. 2000 Nov 1;36[5]:1632-6.
- 1.17 2G Surgical removal of kidney stones

Summary of intervention

Urinary tract stones are amongst the most common condition dealt with by urologists with an estimated 6,000 patients admitted to hospital per year with the condition. Shockwave lithotripsy (SWL) is a non-surgical technique for treating these stones in the kidney or ureter. The technique uses high energy shockwaves to break the stones into smaller fragments which can then pass spontaneously.

Stones can be observed to see if they pass spontaneously, or treated with shockwave lithotripsy, or surgical techniques such as ureteroscopy (URS) and percutaneous stone surgery (PCNL), both of which may involve placing a stent.

The optimal management depends on the type, size and location of the stone as well as patient factors such as co-morbidity and pregnancy. For appropriate stones SWL is advantageous as it is non-invasive and so has fewer major adverse events than surgery.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

14.456

Proposal

Please refer to NICE NG118 (recommendation 1.5) for full details on the assessment and management of renal and ureteric stones: https://www.nice.org.uk/guidance/ng118/chapter/Recommendations.

Adult renal stones

<5mm: If asymptomatic consider watchful waiting



5-10mm: If not suitable for watchful waiting offer SWL as first-line treatment [unless contra-indicated or not targetable]

10-20mm: Consider SWL as first-line treatment if treatment can be given in a timely fashion. URS can also be considered if SWL is contraindicated or ineffective

Over 20mm (including staghorn): Offer percutaneous nephrolithotomy (PCNL) as first-line treatment

Adult ureteric stones

<5mm: If asymptomatic consider watchful waiting with medical therapy e.g. Alpha blocker for use with distal ureteric stones

5-10mm: Offer SWL as first-line treatment where it can be given in a timely fashion (unless contra-indicated or not targetable)

10-20mm: Offer URS but consider SWL if local facilities allow stone clearance within 4 weeks.

Rationale for Recommendation

ESWL will not always be possible due to lack of access to a lithotripter or appropriately trained staff. As it is often the optimal treatment, hospitals should consider purchasing this equipment or liaising with neighbouring hospitals which do have these facilities.

Adult renal stones

Asymptomatic renal stones less than 5mm may pass spontaneously and so this carries less risk than intervention in the first instance. Watchful waiting for larger stones carries greater risk but in patients with co-morbidities should still be considered as these risks may be less than those of intervention.

For renal stones less than 10mmm SWL has shorter hospital stays, less pain and fewer major adverse events compared to URS, although URS normally needs fewer treatments. Overall as SWL is non-invasive with fewer major adverse events this should be considered first-line treatment.

For renal stones between 10mm and 20mm the optimal strategy depends on the stone but would be either SWL or URS. Because SWL is non-invasive with fewer major adverse events this could be considered before URS if treatments can be given in a timely fashion so minimising delay between treatments and SWL is not contraindicated.

Adult ureteric stones

For Ureteric stones less than 10mm SWL showed benefits in terms of readmission and fewer major adverse events although URS had lower retreatment rates. When a stent is used this is often only a temporary measure with additional surgery required to remove the stone. Therefore, SWL should be considered first-line when it is not contra-indicated and the stone is targetable.

For ureteric stones between 10mm and 20mm URS should be offered, though because SWL has been shown to result in shorter hospital stays, less pain and fewer adverse events, it could be considered if stone clearance is possible within four weeks.

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References

- 1. Renal and ureteric stones: assessment and management NG118: https://www.nice.org.uk/guidance/ng118.
- 2. Urology surgery Getting It Right First Time: https://www.gettingitrightfirsttime.co.uk/surgical-specialty/urology-surgery/.

1.1.8 2H — Cystoscopy for men with uncomplicated lower urinary tract symptoms

Summary of intervention

Cystoscopy is a diagnostic procedure used to examine the lining of the bladder and urethra. Either a rigid or flexible endoscope may be used, under general or local anaesthesia, respectively. Rigid cystoscopy is undertaken when flexible cystoscopy offers insufficiently clear views, or when biopsy is indicated.

Cystoscopy can cause temporary discomfort, occasionally pain and haematuria and is associated with a small risk of infection.

In the context of male lower urinary tract symptoms (LUTS), cystoscopy may offer indirect evidence regarding an underlying cause (commonly prostatic enlargement, for example).

This guidance applies to male adults aged 19 years and over.

Number of interventions in 2018/19

43,703

Proposal

Assessment of men with LUTS should focus initially on a thorough history and examination, complemented by use of a frequency – volume chart, urine dipstick analysis and International Prostate Symptom Score where appropriate. This assessment may be initiated in primary care settings.

Specialist assessment should also incorporate a measurement of flow rate and post void residual volume.

Cystoscopy should be offered to men with LUTS only when clinically indicated, for example, in the presence of the following features from their history:

- Recurrent infection
- Sterile pyuria
- Haematuria
- Profound symptoms
- Pain.

Additional contextual information may also inform clinical decision-making around the use of cystoscopy in men with LUTS. Such factors might include, but not be limited to:

- Smoking history
- Travel or occupational history suggesting a high risk of malignancy
- Previous surgery.

Other adjunct investigations may become necessary in specific circumstances and are dealt with in the NICE guideline. It may be reasonable to undertake flexible cystoscopy before doing some urological surgical interventions.

Rationale for Recommendation

In the context of male lower urinary tract symptoms (LUTS), cystoscopy may offer indirect evidence regarding an underlying cause (commonly prostatic enlargement, for example). However, no evidence was discovered in preparing NICE guideline CG97 to suggest any benefit, in terms of outcome, related to performing cystoscopy in men with uncomplicated LUTS (i.e. LUTS with no clinical evidence of underlying bladder pathology). The consensus opinion of the NICE guideline development group therefore aligned with the position that unless likely to uncover other pathology, cystoscopy should not be performed in men presenting with LUTS.

The European Association of Urology guideline on the management of non-neurogenic male LUTS summarises evidence demonstrating a lack of clear correlation between findings on cystoscopy and findings on investigations into bladder function (urodynamic assessment).

References

- 1. NICE clinical guideline 97. Lower urinary tract symptoms in men: management: https://www.nice.org.uk/guidance/cg97.
- 2. European Association of Urology guideline on the management of non-neurogenic male LUTS: https://uroweb.org/wp-content/uploads/EAU-Guidelines-on-the-Management-of-Non-neurogenic-Male-LUTS-2018-large-text.pdf.
- 3. Shoukry, I., et al. Role of uroflowmetry in the assessment of lower urinary tract obstruction in adult males. Br J Urol, 1975. 47: 559: https://pubmed.ncbi.nlm.nih.gov/1191927/.
- 4. Anikwe, R.M. Correlations between clinical findings and urinary flow rate in benign prostatic hypertrophy. Int Surg, 1976. 61: 39: https://pubmed.ncbi.nlm.nih.gov/61184/.
- 5. el Din, K.E., et al. The correlation between bladder outlet obstruction and lower urinary tract symptoms as measured by the international prostate symptom score. J Urol, 1996. 156: 1020: https://pubmed.ncbi.nlm.nih.gov/8583551/.
- 1.1.9 2I Surgical intervention for benign prostatic hyperplasia

Summary of intervention

Transurethral resection of prostate (TURP) is a therapeutic procedure involving removal of tissue from the inner aspect of the prostate using diathermy, via an endoscopic approach. It is commonly undertaken for voiding lower urinary tract symptoms (LUTS) presumed secondary to benign prostatic hyperplasia (BPH).

TURP is undertaken on an in-patient basis, with a catheter left in-situ for 24-48 hours post-op for the purpose of irrigation. TURP may be undertaken under either general or spinal anaesthesia.

TURP causes temporary discomfort, occasionally pain, haematuria and is associated with small risks of infection and acute urinary retention after removal of the catheter. There is also a risk of sexual dysfunction following TURP. There are small but significant risks of significant harm, including severe fluid and electrolyte imbalances associated with absorption of large volumes of irrigating fluid (TUR syndrome). TUR syndrome can be avoided by

TURP is the longest established of a range of endoscopic surgical procedures for benign enlargement of the prostate, with varying indications and potential complications. These include, among others:

- Transurethral incision of the prostate (TUIP) or Bladder Neck Incision (BNI)
- Holmium LASER enucleation of the prostate
- 532 nm ('Greenlight') laser vaporisation of the prostate

using bipolar diathermy, a variant of the standard technology.

- UroLift
- Transurethral needle ablation of the prostate (TUNA)
- Transurethral vaporisation of the prostate (TUVP)
- Transurethral water vapour therapy (Rezum).

Open simple/benign prostatectomy is uncommonly undertaken in men with very large prostates and problematic symptoms. Newer ablative therapies are currently under evaluation and non-surgical procedures such as prostatic artery embolisation (PAE).

This guidance applies to male adults aged 19 years and over.

Number of interventions in 2018/19

14,561

Proposal

Only men with severe voiding symptoms, or in whom conservative management options and drug treatment have been unsuccessful, should be offered surgical intervention. Surgery is indicated (in healthy men) in complicated BPH i.e. chronic retention with renal impairment as evidenced by hydronephrosis and impaired GFR, and in most cases of acute retention secondary to BPH.

As such, a staged approach to managing voiding LUTS is recommended:

- 1. Conservative, or lifestyle interventions should be discussed.
- 2. Drug therapy should then be considered, in the context of more bothersome LUTS, or LUTS not responding to simple lifestyle interventions.
- 3. Where bothersome LUTS persist alongside high, or unchanged International Prostate Symptom Scores, or in the context of urinary tract infections, bladder stones or urinary retention, surgical intervention should be considered using a shared decision-making approach.

Men considering surgical intervention should be counselled thoroughly regarding alternatives to and outcomes from surgery. The quality of this counselling is deemed to be of major importance with respect to men's future experience and outcomes.

Following a discussion about whether to intervene surgically, men should be counselled about their preferred and most suitable surgical modality, incorporating reference to available evidence. Practical concerns, including the distance required to travel to pursue a given modality of surgical treatment are also important

Appropriate support shoulder be provided to make shared decisions pertinent to physical, emotional, psychological and sexual health. If appropriate, carers should be informed and involved.

With respect to surgical modality:

- The UroLift system relieves lower urinary tract symptoms while avoiding the risk to sexual function and should be considered as an alternative to current surgical procedures for use in a day-case setting in men who are aged 50 years and older and who have a prostate of less than 100 ml without an obstructing middle lobe
- TURP, TUVP (including laser prostatic vaporisation) or HoLEP should be offered to men with voiding LUTS presumed secondary to BPH
- HoLEP should be performed within centres specialising in the technique, or where mentorship arrangements are in place
- TUIP should be offered to men with a prostate estimated to be smaller than 30ml
- Open prostatectomy should only be offered as an alternative to endoscopic surgery, to men with prostates estimated to be larger than 80-100ml
- Transurethral needle ablation, transurethral microwave thermotherapy, high-intensity focused ultrasound, transurethral ethanol ablation of the prostate should not be offered as alternative surgical treatments for voiding LUTS presumed secondary to BPH.

Of note, some men with bothersome LUTS will have undergone multichannel cytometry, establishing clear evidence of bladder outlet obstruction. These men are the most likely to benefit from surgery, with guidance on when to undertake such assessment covered elsewhere in NICE and European guidelines.

Rationale for Recommendation

NICE guidance provides clear evidence, in clinical and cost-effectiveness terms, that patients voiding LUTS presumed secondary to BPH, should be offered surgical intervention, only when those symptoms are severe, or when conservative management options have been unsuccessful.

TURP has long been the mainstay of surgical treatment for voiding LUTS presumed secondary to BPH. The newer surgical modalities outlined above have therefore been evaluated in comparison with TURP, as well as conservative management. NICE CG97 accordingly incorporated a comprehensive matrix of comparative studies between treatment modalities within its evidence review. This reflects increasing complexity in decision-making around surgical intervention, increasingly involving 'which', as well as 'when' or 'whether' surgery should be offered.

The recommendation proposed here reflects the full breadth of comparative studies between surgical intervention and conservative management, as well as between different modalities of surgical intervention forming the basis of NICE CG97.

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References

- 1. NICE clinical guideline 97. Lower urinary tract symptoms in men: management: https://www.nice.org.uk/guidance/cg97.
- 2. NICE guidance UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia [Medical technologies guidance MTG 26]: https://www.nice.org.uk/guidance/mtg26/.
- 3. European Association of Urology guideline on the management of non-neurogenic male LUTS: https://uroweb.org/wp-content/uploads/EAU-Guidelines-on-the-Management-of-Non-neurogenic-Male-LUTS-2018-large-text.pdf.
- 4. GIRFT Urology Report: https://www.gettingitrightfirsttime.co.uk/surgical-specialty/urology-surgery/.

1.1.10 2J — Lumbar Discectomy

Summary of intervention

A discectomy is the surgical removal of intervertebral disc material to treat the symptoms resulting from compression of one or more spinal nerve roots. This loose material, which is part of the natural degeneration of the disc with age, is often described as bulging, prolapsed, herniated or slipped, resulting in pressure on usually one, but sometimes more nerve roots. The symptoms it causes are called radiculopathy or sciatica and can include pain, tingling, pins and needles, numbness, weakness, and rarely bowel and bladder problems. As more often than not, the symptoms will settle naturally, non-operative treatment is the preferred initial option.

Number of interventions in 2018/19

2,291

Proposal

Patients presenting with radiculopathy who show objective evidence of clinical improvement within six weeks (e.g. VAS pain scores, ODI), are more likely than not to continue improving with non-operative treatment as the natural history of most intervertebral disc herniations is favourable.

Primary care management typically includes reassurance, advice on continuation of activity with modification, weight-loss, analgesia, manual therapy and screening patients who are high risk of developing chronic pain (i.e. STaRT Back).

Persistent symptoms may warrant onward referral to spinal services for consideration of interventional pain management injections (e.g. nerve root blocks / caudal epidural injections) or surgery.

In the presence of concordant MRI changes, Discectomy may be offered to patients with compressive nerve root signs and symptoms lasting three months (except in severe cases) despite best efforts with non-operative management.

Please note: This guideline is not intended to cover patients who demonstrate a deterioration in neurological function (e.g. objective weakness, sexual dysfunction, cauda equina syndrome). These patients require an urgent

referral to an acute spinal centre for further evaluation and imaging, as nonoperative treatment may lead to irreversible harm.

This guidance applies to adults aged 19 years and over.

Rationale for Recommendation

There remains a reasonable body of evidence to show that in carefully selected patients, lumbar discectomy may lead to a greater and quicker improvement in pain scores than in non-operatively treated patients.

In other studies however, because of the irreversible degenerative changes, surgery has not shown a benefit over non-operative treatment in mid and long-term follow-up.

Lengthy periods of ineffective non-operative care may prompt repeated emergency department attendances, issues with chronic pain, significant neurological dysfunction and time off work.

References

- 1. NICE Low back pain and sciatica in over 16s: assessment and management (November 2016): https://www.nice.org.uk/guidance/ng59.
- 2. National Low Back and Radicular Pain Pathway 2017: https://www.ukssb.com/improving-spinal-care-project.
- 3. STarT Back: https://www.nice.org.uk/guidance/ng59/resources/endorsed-resource-start-back-screening-tool-with-matched-treatment-options-4906309933.
- 4. Back Skills Training (BeST): Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Prof Sarah E Lamb DPhil et al on behalf of the Back Skills Training Trial investigators: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736[09]62164-4/fulltext.
- 5. Surgical versus Non-Operative Treatment for Lumbar Disc Herniation: Four-Year Results for the Spine Patient Outcomes Research Trial (SPORT). Weinstein JN et al. Spine (Phila Pa 1976). 2008 Dec 1; 33(25): 2789–2800.doi: 10.1097/BRS.0b013e31818ed8f4.
- 6. Surgical versus Non-Operative Treatment for Lumbar Disc Herniation: Eight-Year Results for the Spine Patient Outcomes Research Trial (SPORT). Weinstein JN et al. Spine (Phila Pa 1976). 2014 January 1; 39(1): 3–16. doi:10.1097/BRS.00000000000000088
- 7. Surgical versus non-operative treatment for lumbar disc herniation: a systematic review and meta-analysis. Chen BL et al. Clin Rehabil. 2018 Feb;32(2):146-160. doi: 10.1177/0269215517719952.
- 8. Surgery versus prolonged conservative treatment for sciatica: 5-year results of a randomised controlled trial. Lequin MB et al. BMJ Open 2013;3:e002534. doi:10.1136/bmjopen-2012-002534.
- 9. Prolonged Physiotherapy versus Early Surgical Intervention in Patients with Lumbar Disk Herniation: Short-term Outcomes of Clinical Randomized Trial. Abou-Elroos DA et al. Asian Spin J 2017; 11[4]:531-537. doi:10.4184/asj.2017.11.4.531.



Summary of intervention

Radiofrequency denervation, also known as 'dorsal rhizotomy' or 'radiofrequency ablation,' is a non-surgical and minimally invasive procedure that uses heat to reduce or stop the transmission of pain signals arising from one or more spinal facet joints. It is only recommended when other alternatives have failed.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

1.612

Proposal

Lumbar radiofrequency facet joint denervation (RFD) should only be offered in accordance with NICE Guideline NG59 which recommends it as an adjunct in the management of chronic low back pain only when non-operative treatment has failed, and the main source of pain is thought to arise from one or more degenerate facet joints.

Rationale for Recommendation

The facet joints are pairs of joints that stabilise and guide motion in the lumbar spine. These joints are innervated by the medial branches of the dorsal rami. In current clinical practice, suitable patients are first offered one or more diagnostic injections to determine which facet joints are contributing to their symptoms. This particular type of injection is called a 'medial branch block,' and differs to facet joint injections, which are no longer recommended by NICE or GIRFT.

Manual therapy, with appropriate psychological therapies where necessary, should be considered as an early intervention to support the individual.

Medial branch blocks should be offered only in accordance with the low back pain pathway (https://www.boa.ac.uk/uploads/assets/e26cc007-74c3-4b22-94e408dd54ac79da/spinal%20pathfinder.pdf). Patients who experience a positive response to a medial branch block (i.e. a significant but short-term improvement in pain symptoms) may be offered a neurodestructive procedure called radiofrequency denervation in an attempt to achieve longer-term pain relief. Some patients may experience a prolonged response to medial branch blockade such that further interventional treatment is no longer required.

Radiofrequency energy is delivered along an insulated needle in contact with the target nerves. This focussed electrical energy heats and denatures the nerve. This process may allow axons to regenerate with time requiring the repetition of the radiofrequency procedure.

Research is ongoing to determine the optimum frequency of repeat radiofrequency denervation [https://www.nice.org.uk/researchrecommendation/radiofrequency-denervation-what-is-the-clinical-and-cost-effectiveness-of-radiofrequency-denervation-for-chronic-low-back-pain-in-the-long-term].

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References

- 1. NICE Low back pain and sciatica in over 16s: assessment and management (November 2016): https://www.nice.org.uk/guidance/ng59.
- 2. NICE: https://www.nice.org.uk/guidance/ng59/evidence/full-guideline-invasive-treatments-pdf-2726157998.
- 3. National Low Back and Radicular Pain Pathway 2017: https://www.boa.ac.uk/uploads/assets/e26cc007-74c3-4b22-94e408dd54ac79da/spinal%20 pathfinder.pdf.
- 4. Back Skills Training (BeST): Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Prof Sarah E Lamb DPhil et al on behalf of the Back Skills Training Trial investigators: https://doi.org/10.1016/S0140-6736[09]62164-4.
- 5. STarT Back: https://www.nice.org.uk/guidance/ng59/resources/ endorsed-resource-start-back-screening-tool-with-matched-treatment-options-4906309933.
- 6. Maas ET, Ostelo RWJG, Niemisto L, Jousimaa J, Hurri H, Malmivaara A, van Tulder MW. Radiofrequency denervation for chronic low back pain. Cochrane Database of Systematic Reviews 2015, Issue 10. Art. No.: CD008572. DOI: 10.1002/14651858.CD008572.pub2.
- 7. Faculty of Pain Management, Core Standards for Pain Management Services in the UK: https://fpm.ac.uk/standards-publications-workforce/core-standards.
- 1.1.12 2L Exercise ECG for screening for coronary heart disease

Summary of intervention

Exercise electrocardiogram (ECG) is a type of cardiac stress test that should no longer be used to screen for coronary heart disease (CHD).

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

45,745

Proposal

Exercise ECG has no role in the screening of asymptomatic and low risk patients for coronary heart disease because it has a very low pre-test probability of identifying pathology. Risk calculators, such as Systematic Coronary Risk Evaluation (SCORE), are instead recommended to identify patients who are at greater risk of CHD.

Under the guidance of cardiologists, the test has a limited role for diagnosis in selected patients with symptoms suggestive of CHD, and/or where CHD has been diagnosed to confirm functional capacity or severity.

Rationale for Recommendation

In randomised control trials, screening with exercise ECG in asymptomatic patients found no improvement in health outcomes, even when focussing on higher risk populations such as those with diabetes. There is no research



examining whether the addition of exercise ECG to traditional CHD risk factors results in accurate reclassification, however cohort studies looking at the role of resting ECG abnormalities found inconsistent impact on clinical decisions.

Reliability of exercise ECG testing varies based on many features including age, gender and known history of CHD, which significantly limits its utility as a screening tool. ECG sensitivity has been cited as 45-50% and specificity of 85-90%. Sensitivity and specificity data of exercise ECG testing is dependent upon the cohort of patients being studied: sensitivity is higher in patients with triple-vessel disease, and lower in patients with single-vessel disease. Gender differences mean that exercise ECG is only moderately specific for the diagnosis of CHD in women.

The European Society of Cardiology (ESC) recommend the use of a risk-estimation system i.e. SCORE to calculate total risk estimation for asymptomatic patients >40 years of age without evidence of diabetes, chronic kidney disease, cardiovascular disease, or familial hypercholesterolemia. The assessment of a family history of premature CVD is recommended. A validated clinical score should be used in patients <50 years of age who have a family history of premature CVD in a first-degree relative.

In asymptomatic but high-risk adults (with diabetes, a strong family history of CVD, or when previous risk-assessment tests suggest a high risk of CVD), functional imaging or coronary CTA may be considered for cardiovascular risk assessment.

For people at low risk of cardiovascular disease, the potential harms of screening with exercise ECG is thought by some (including the US Preventative Service Task Force) to be equal to or exceed the potential benefits. For people at intermediate to high risk, current evidence is thought to be insufficient to assess the balance of benefits and harms of screening. Therefore, the US Preventative Services Task Force recommends against screening for CHD with resting or exercise ECG in adults at low risk for CHD events.

Chou et al cite that exercise ECG screening has not been shown to improve patient outcomes and is instead associated with potential harms due to false-positive results leading to potentially unnecessary tests and procedures.

Overall in asymptomatic patients without a history of CHD, the potential harms of exercise ECG (which includes arrhythmias, acute MI, sudden cardiac death and harms of subsequent angiography or revascularisation procedures after abnormal test) are considered by many to exceed the screening benefit. However, literature examining the frequency of these harms is lacking.

References

- 1. NICE Guidance. Chest pain of recent onset: assessment and diagnosis. 2016: https://www.nice.org.uk/guidance/cg95.
- 2. Jonas D, Reddy S, Middleton J et al. Screening for cardiovascular disease risk with electrocardiography: an evidence review for the US preventative services task force. Rockville MD: Agency for healthcare research and quality. 2018.

- 3. Jin J. Screening for cardiovascular disease risk with ECG. JAMA, 2018; 319:22.
- 4. Koskinas K. Appropriate use of non-invasive testing for diagnosis of stable coronary artery disease. J Cardiology practice. 2014:12.

Chou R. et al. Cardiac screening with electrocardiography, stress echocardiography, or myocardial perfusion imaging: advice for high-value care from the American College of Physicians. Ann Intern Med. 2015 Mar 17;162[6]:438-47. doi: 10.7326/M14-1225.

5. Juhani Knuuti, et al. ESC Scientific Document Group, 2019. ESC Guidelines for the diagnosis and management of chronic coronary syndromes: The Task Force for the diagnosis and management of chronic coronary syndromes of the European Society of Cardiology (ESC), European Heart Journal: https://doi.org/10.1093/eurheartj/ehz425.

1.1.13 2M — Upper GI endoscopy

Summary of intervention

Endoscopy is an invasive procedure and is not always well tolerated. It carries significant risks and should not be used as a first-line indication in all patients.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

644,038

Proposal

Upper GI Endoscopy should only be performed if the patient meets the following criteria:

Urgent: (Within two weeks)

- Any dysphagia (difficulty in swallowing), to prioritise urgent assessment of dysphagia please refer to the Edinburgh Dysphagia Score OR
- Aged 55 and over with weight loss and any of the following:
 - Upper abdominal pain
 - Reflux
 - Dyspepsia (4 weeks of upper abdominal pain or discomfort)
 - Heartburn
 - Nausea or vomiting
- Those aged 55 or over who have one or more of the following:
 - Treatment resistant dyspepsia (as above), upper abdominal pain with low haemoglobin level (blood level) OR
 - Raised platelet count with any of the following: nausea, vomiting, weight loss, reflux, dyspepsia, upper abdominal pain OR
 - Nausea and vomiting with any of the following: weight loss, reflux, dyspepsia, upper abdominal pain.

For the assessment of Upper GI bleeding:

- For patients with haematemesis, calculate Glasgow Blatchford Score at presentation and any high-risk patients should be referred
- Endoscopy should be performed for unstable patients with severe acute upper gastrointestinal bleeding immediately after resuscitation
- Endoscopy should be performed within 24 hours of admission for all other patients with upper gastrointestinal bleeding.

For the investigation of symptoms:

- Clinicians should consider endoscopy:
 - Any age with gastro-oesophageal symptoms that are nonresponsive to treatment or unexplained
 - With suspected GORD who are thinking about surgery
 - With H pylori that has not responded to second- line eradication
 - Eradication can be confirmed with a urea breath test.

For management of specific cases

H pylori and associated peptic ulcer:

 Eradication can be confirmed with a urea breath test, however if peptic ulcer is present repeat endoscopy should be considered 6-8 weeks after beginning treatment for H pylori and the associated peptic ulcer.

Barrett's oesphagus:

- Where available the non-endoscopic test called Cytosponge can be used to identify those who have developed Barrett's oesophagus as a complication of long-term reflux and thus require long term surveillance for cancer risk
- Consider endoscopy to diagnose Barrett's Oesophagus if the person has GORD (endoscopically determined oesphagitis or endoscopy - negative reflux disease)
- Consider endoscopy surveillance if person is diagnosed with Barrett's Oesophagus.

Coeliac disease:

Patients aged 55 and under with suspected coeliac disease and anti-TTG >10x reference range should be treated for coeliac disease on the basis of positive serology and without endoscopy or biopsy.

Surveillance endoscopy:

 Surveillance endoscopy should only be offered in patients fit enough for subsequent endoscopic or surgical intervention, should neoplasia be found. Many of this patient group are elderly and/or have significant comorbidities. Senior clinician input is required before embarking on long term endoscopic surveillance

- ______
- Patients diagnosed with extensive gastric atrophy (GA) or gastric intestinal metaplasia, (GIM) (defined as affecting the antrum and the body) should have endoscopy surveillance every three years
- Patients diagnosed with GA or GIM just in the antrum with additional risk factors- such as strong family history of gastric cancer of persistent H pylori infection, should undergo endoscopy every three years.

Screening endoscopy can be considered in:

- European guidelines (2015) for patients with genetic risk factors / family history of gastric cancer recommend genetics referral first before embarking on long term screening. Screening is not appropriate for all patients and should be performed in keeping with European expert guidelines
- Patients where screening is appropriate, for individuals aged 50 and over, with multiple risk factors for gastric cancer (e.g. H. Pylori infection, family history of gastric cancer - particularly in first degree relative -, pernicious anaemia, male, smokers).

Post excision of adenoma:

 Following complete endoscopic excision of adenomas, gastroscopy should be performed at 12 months and then annually thereafter when appropriate.

Rationale for Recommendation

NICE and the British Society for Gastroenterology recommend the above criteria for use of endoscopy.

Endoscopy is a very invasive procedure for patients and is not always well tolerated. There are numerous risks associated with endoscopy, such as reaction to sedation, bleeding or perforation, the latter of which could lead to an emergency operation if serious enough. This is one of the reasons why endoscopy should not be a first-line of investigation in all patients.

For example, the first-line testing for H Pylori (and therefore associated dyspepsia) should be Urea breathe test or stool antigen test. This test is much less invasive for the patient.

In regard to the efficiency of services and value for money, endoscopy when used appropriately is of value. However, a literature review and meta-analysis have shown diagnostic overuse with significant resource implications. Of the meta-analyses results it found that 22% of OGDs were inappropriate indications. The aim of this rationale is not only to improve value, whilst still achieving high care for patients, and not submitting patients to unnecessary invasive endoscopies that can hold serious complications.

References

- 1. NHS Advice: https://www.nhs.uk/conditions/Endoscopy/.
- 2. NICE Guidance: https://www.nice.org.uk/guidance/ng12.
- 3. British Society of Gastroenterology guidelines: https://gut.bmj.com/content/68/9/1545.

- 4. BSG Interim Guidance: COVID-19 specific non-biopsy protocol for those with suspected coeliac disease: https://www.bsg.org.uk/covid-19-advice/covid-19-advice/covid-19-specific-non-biopsy-protocol-guidance-for-those-with-suspected-coeliac-disease/.
- 5. British Society of Gastroenterology-led multi-society consensus care bundle for the early clinical management of acute upper gastrointestinal bleeding: https://www.bsg.org.uk/wp-content/uploads/2019/11/flgastro-2019-101395.pdf.
- 6. NHS Advice: https://www.nhs.uk/conditions/gastroscopy/risks/.
- 7. Malik HT, Marti J, Darzi A, Mossialos E. Savings from reducing low-value general surgical interventions. Br J Surg. 2018 Jan;105[1]:13-25. doi:10.1002/bjs.10719.
- 8. Di Giulio E, Hassan C, Marmo R, Zullo A, Annibale.
- 9. B. Appropriateness of the indication for upper endoscopy: a meta-analysis. Dig Liver Dis 2010; 42: 122 126.
- 10. NICE guidance: Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management. September 2014. CG184.
- 11. NICE guidance: Acute upper gastrointestinal bleeding in over 16s management. June 2012. CG141.
- 12. Van der Post RS et al. <u>J Med Genet</u>. 2015 Jun; 52(6): 361–374. Published online 2015 May 15. doi: <u>10.1136/jmedgenet-2015-103094</u>.
- 13. BSG Guidance on recommending GI endoscopy. https://www.bsg.org.uk/covid-19-advice/bsg-guidance-on-recommencing-gi-endoscopy-in-the-deceleration-early-recovery-phases-of-the-covid-19-pandemic/.
- 14. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736[20]31099-0/fulltext.

Interventions including those in diagnostic and outpatient settings where data are available but further exploration of additional datasets is proposed to improvement robustness and establish national activity goals.⁶

^{6.} For these intervention data, procedure coding is available however diagnosis and indication coding is either partial or has limitations (see Appendix 2 tables for each intervention) therefore it was inappropriate to calculate goals for these interventions.

1.1.14 2N — Appropriate colonoscopy in the management of hereditary colorectal cancer

Summary of intervention

Colorectal carcinoma (CRC) is one of the most common cancers in the UK with more than 40,000 new cases diagnosed each year. An estimated 35% of CRC is due to heritable factors.

While colonoscopy is a safe procedure, there is a small risk of complications – including pain, intestinal perforation or major haemorrhage as well as issues related to any sedative used. Colonoscopy should therefore be used appropriately in the management of CRC in people who have been identified with an increased lifetime risk of CRC due to hereditary factors.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

415,262⁷

Proposal

Follow the British Society of Gastroenterology surveillance guidelines for colonoscopy in the management of hereditary colorectal cancer: https://www.bsg.org.uk/resource/guidelines-for-the-management-of-hereditary-colorectal-cancer.html.

Family history of CRC

For individuals with moderate familial CRC risk:

- Offer one-off colonoscopy at age 55 years
- Subsequent colonoscopic surveillance should be performed as determined by post-polypectomy surveillance guidelines.

For individuals with high familial CRC risk (a cluster of 3x FDRs with CRC across >1 generation):

Offer colonoscopy every 5 years from age 40 years to age 75 years.

Lynch Syndrome (LS) and Lynch-like Syndrome

For individuals with LS that are MLH1 and MSH2 mutation carriers:

Offer colonoscopic surveillance every 2 years from age 25 years to age 75 years.

For individuals with LS that are MSH6 and PMS2 mutation carriers:

Offer colonoscopic surveillance every 2 years from age 35 years to age 75 years.

^{7.} The number of interventions [415,262] represents colonoscopies for all indications, including those with symptoms and/or risk factors.

For individuals with Lynch-like Syndrome with deficient MMR tumours without hypermethylation/BRAF pathogenic variant and no pathogenic constitutional pathogenic variant in MMR genes (and their unaffected FDRs), and no evidence of biallelic somatic MMR gene inactivation:

Offer colonoscopic surveillance every 2 years from age 25 years to age 75 years.

Early Onset CRC (EOCRC)

For individuals diagnosed with CRC under age 50 years, where hereditary CRC symptoms have been excluded:

- Offer standard post-CRC colonoscopy surveillance after 3 years
- Then continue colonoscopic surveillance every 5 years until eligible for national screening.

Serrated Polyposis Syndrome (SPS)

For individuals with SPS:

- Offer colonoscopic surveillance every year from diagnosis once the colon has been cleared of all lesions >5mm in size
- If no polyps ≥ 10mm in size are identified at subsequent surveillance examinations, the interval can be extended to every 2 years.

For first degree relatives of patients with SPS:

- Offer an index colonoscopic screening examination at age 40 or ten years prior to the diagnosis of the index case
- Offer a surveillance colonoscopy every 5 years until age 75 years, unless polyp burden indicates an examination is required earlier according to post-polypectomy surveillance guidelines.

Multiple Colorectal Adenoma [MCRA]

For individuals with MCRA (defined as having 10 or more metachronous adenomas):

- Offer annual colonoscopic surveillance from diagnosis to age 75 years after the colon has been cleared of all lesions >5mm in size
- If no polyps 10mm or greater in size are identified at subsequent surveillance examinations, the interval can be extended to 2 yearly.

Familial Adenomatous Polyposis (FAP)

For individuals confirmed to have FAP on predictive genetic testing:

- Offer colonoscopic surveillance from 12-14 years
- Then offer surveillance colonoscopy every 1-3 years, personalised according to colonic phenotype.

For individuals who have a first degree relative with a clinical diagnosis of FAP (i.e. "at risk") and in whom a *APC* mutation has not been identified:

- Offer colorectal surveillance from 12-14 years
- Then offer every 5 years until either a clinical diagnosis is made and they are managed as FAP or the national screening age is reached.

MUTYH-associated Polyposis [MAP]

For individuals with MAP:

 Offer colorectal surveillance from 18-20 years, and if surgery is not undertaken, repeat annually.

For monoallelic MUTYH pathogenic variant carriers:

 The risk of colorectal cancer is not sufficiently different to population risk to meet thresholds for screening and routine colonoscopy is not recommended.

Peutz-Jeghers Syndrome (PJS)

For asymptomatic individuals with PSJ:

- Offer colorectal surveillance from 8 years
- If baseline colonoscopy is normal, deferred until 18 years, however if polyps are found at baseline examination, repeat every 3 years.

For symptomatic patients, investigate earlier.

Juvenile Polyposis Syndrome (JPS)

For asymptomatic individuals with JPS:

- Offer colorectal surveillance from 15 years
- Then offer a surveillance colonoscopy every 1-3 years, personalised according to colorectal phenotype.

For symptomatic patients, investigate earlier.

For some patients with multiple risk factors for CRC, for example those with Lynch Syndrome and inflammatory bowel disease/multiple polyps, more frequent colonoscopy may be indicated. This needs to be guided by clinicians but with a clear scientific rationale linked to risk management.

Rationale for Recommendation

This recommendation is based on the 2019 guidelines published by the British Society of Gastroenterology, the Association of Coloproctologists of Great British and Ireland and United Kingdom Cancer Genetics Group. The complete guidelines can be found here: https://www.bsg.org.uk/resource/guidelines-for-the-management-of-hereditary-colorectal-cancer.html.

Heritable factors account for approximately 35% of CRC risk, and almost 30% of the population in the UK have a family history of CRC. It is possible to stratify individuals to identify cohorts of patients with hereditary risk. This can help target management and determine who will benefit the most from colonoscopic surveillance and at what frequency.

References

- 1. Guidelines for the management of hereditary colorectal cancer from the British Society of Gastroenterology [BSG]/ Association of Coloproctologists of Great Britain and Ireland [ACPGBI]/ United Kingdom Cancer Genetics Group [UKCGG] https://www.bsg.org.uk/resource/guidelines-for-the-management-of-hereditary-colorectal-cancer.html.
- 2. NICE Colorectal cancer [NG151]: https://www.nice.org.uk/guidance/ng151.
- 3. NICE Colorectal cancer prevention: Colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas guideline [CG118]: https://www.nice.org.uk/guidance/cg118.
- 4. Cancer Research UK. Colonoscopy. Available from: https://www.cancerresearchuk.org/about-cancer/cancer-in-general/tests/colonoscopy.

1.1.15 20 — Repeat Colonoscopy

Summary of intervention

Colorectal carcinoma [CRC] is one of the most common cancers in the UK with more than 40,000 new cases diagnosed each year. Polyps are extremely common and certain types (colorectal adenomas and serrated lesions) have the potential to progress into CRC.

Colonoscopy can assist in the diagnosis of CRC and several other pathologies, including colonic polyps. Polyp removal [or polypectomy] can be performed endoscopically and is an effective way to treat pre-malignancy polyps [which includes both serrated polyps [excluding diminutive [1-5mm] rectal hyperplastic polyps] and adenomatous polyps. It does not include other polyps such as post inflammatory polyps] before they progress to cancer. Colonoscopy with or without polypectomy is a safe procedure however there is a small risk of complications - including pain, intestinal perforation or major haemorrhage as well as issues related to any sedative used.

Colorectal carcinoma is often treated by surgical resection, especially for people with potentially curative disease. Individuals who have had treatment for colorectal carcinoma and adenomas are known to be at high-risk of recurrence.

While reducing colorectal mortality is an important aim of colonoscopic surveillance, the main aim is to prevent colorectal cancer by resecting premalignant polyps. Many patients benefit from this alone and do not require subsequent surveillance.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19



Proposal

Follow the British Society of Gastroenterology surveillance guidelines for post-polypectomy and post-colorectal cancer resection: https://www.bsg.org.uk/resource/bsg-acpgbi-phe-post-polypectomy-and-post-colorectal-cancer-resection-surveillance-guidelines.html.

Risk Surveillance Criteria for Colonoscopy

Either of the following put individuals at high-risk for future colorectal cancer following polypectomy:

- 2 or more premalignant polyps including at least one advanced colorectal polyp (defined as a serrated polyp of at least 10mm in size or containing any grade of dysplasia, or an adenoma of at least 10mm in size or containing high-grade dysplasia); OR
- 5 or more premalignant polyps.

Surveillance colonoscopy after polypectomy

For individuals at **high-risk** and under the age of 75 **and** whose life-expectancy is greater than 10 years:

Offer one-off surveillance colonoscopy at 3 years.

For individuals with **no high-risk** findings:

- No colonoscopic surveillance should be undertaken
- Individuals should be strongly encouraged to participate in their national bowl screening programme when invited.

For individuals not at high-risk who are more than 10 years younger than the national bowel screening programme lower age-limit, consider for surveillance colonoscopy after 5 or 10 years, individual to age and other risk factors.

Surveillance colonoscopy after potentially curative CRC resection:

- Offer a clearance colonoscopy within a year after initial surgical resection.
- Then offer a surveillance colonoscopy after a further 3 years
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy high-risk criteria.

The number of interventions (415,262) represents colonoscopies for all indications, including those with symptoms and/or risk factors.

Surveillance after pathologically *en bloc* R0 EMR or ESD of LNPCPs or early polyp cancers:

- No site-checks are required
- Offer surveillance colonoscopy after 3 years
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy high-risk criteria.

Surveillance after piecemeal EMR or ESD of LNPCPs (large non-pedunculated colorectal polyps of at least 20mm in size):

- Site-checks at 2-6 months and 18 months from the original resection Once no recurrence is confirmed, patients should undergo postpolypectomy surveillance after 3 years
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy high-risk criteria.

Surveillance where histological completeness of excision cannot be determined in patients with: (i) a non-pedunculated polyps of 10-19mm in size, or (ii) an adenoma containing high-grade dysplasia, or (iii) a serrated polyp containing any dysplasia:

- Site-check should be considered within 2-6 months.
- Further surveillance colonoscopy to be determined in accordance with the post-polypectomy high-risk criteria

Ongoing colonoscopic surveillance:

- To be determined by the findings at each surveillance procedure, using the high-risk criteria to stratify risk
- Where there are no high-risk findings, colonoscopic surveillance should cease but individuals should be encouraged to participate in the national bowel screening programme when invited.

Rationale for Recommendation

This recommendation is based on the 2019 guidelines published by the British Society of Gastroenterology, the Association of Coloproctology of Great British and Ireland and Public Health England. The complete guidelines can be found here: https://www.bsg.org.uk/clinical-resource/bsg-acpgbi-phe-post-polypectomy-and-post-colorectal-cancer-resection-surveillance-guidelines/.

Premalignant polyps are common, occurring in a quarter to a half of all people of screening age, yet only about 5% of the population will develop CRC during their life. As such, only a minority of people with polyps will develop CRC, meaning that most people will not benefit from post-polypectomy surveillance.

It is an increasingly held view that the greatest benefit in terms of CRC prevention is derived from the initial polypectomy, rather than from subsequent surveillance. It is possible to stratify individuals according to future risk and identify cohorts of patients with persistently elevated CRC risk beyond index polypectomy, yet even with current risk stratification,

surveillance places a considerable burden on patients and endoscopy services: approximately 15% of the half a million colonoscopies performed each year in the UK are performed for polyp surveillance.

References

- 1. BSG/ACPGBI/PHE Post-polypectomy and post-colorectal cancer resection surveillance guidelines: https://www.bsg.org.uk/clinical-resource/bsg-acpgbi-phe-post-polypectomy-and-post-colorectal-cancer-resection-surveillance-guidelines/.
- 2. NICE Colorectal cancer: diagnosis and management Clinical guideline [CG131]: https://www.nice.org.uk/guidance/cg131/chapter/1-Recommendations#ongoing-care-and-support.
- 3. NICE Colorectal cancer prevention: Colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas guideline [CG118]: https://www.nice.org.uk/guidance/cg118.
- 4. Cancer Research UK. Colonoscopy: https://www.cancerresearchuk.org/about-cancer/cancer-in-general/tests/colonoscopy.

1.1.16 2P — ERCP in acute gallstone pancreatitis without cholangitis

Summary of intervention

Early endoscopic retrograde cholangiopancreatography (ERCP) for acute gallstone pancreatitis without cholangitis is not recommended.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

308

Proposal

Early ERCP in the treatment of acute gallstone pancreatitis, should only be performed if there is evidence of cholangitis or obstructive jaundice with imaging evidence of a stone in the common bile duct. Early ERCP refers to ERCP being performed on the same admission, ideally within 24 hours

Rationale for Recommendation

Gallstones are the most common cause of pancreatitis, causing up to 50% of cases. ERCP should be reserved for patients in whom therapeutic intervention is likely because ERCP is a very invasive procedure and carries a morbidity of 5-10% and a mortality rate of 0.1%- 0.5%. Risks associated with ERCP include risks of endoscopy and specific risks associated with ERCP, including pancreatitis, cholangitis, bleeding, and retroduodenal perforation.

ERCP is recommended for severe acute gallstone pancreatitis, dilatation of the common bile duct on imaging, jaundice, cholangitis or persistently abnormal and rising liver enzymes or if clinical deterioration occurs in patients with mild signs at presentation but who fail to improve after 48 hours.

Early ERCP for acute pancreatitis without cholangitis has been shown to have a higher mortality rate and is of little benefit in comparison to delayed ERCP. Many gallstones are passed spontaneously.

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References

- 1. Sages Patient Information: https://www.sages.org/publications/patient-information-for-ercp-endoscopic-retrograde-cholangio-pancreatography-from-sages/.
- 2. Tse F, YuanY. Early routine endoscopic retrograde cholangiopancreatography strategy versus early conservative management strategy in acute gallstone pancreatitis. Cochrane Database Syst Rev 2012: [5]CD009779.
- 3. NICE guideline [NG104]: https://www.nice.org.uk/guidance/ng104.
- 4. Schuster k, Holena D, salim A, savage S, crandall M, american association for the surgery of trauma emergency surgery guideline summaries: 2018, acute appendicitis, acute cholecystis, acute diveritculis, acute pancreatitis, and small bowel obstruction. Trauam surg acute care open. 2019; 4: e000281.
- 5. Uy MC, Daez ML,Sy PP,Banez VP,Espinosa WZ, Talingdan-Te MC. Early ERCP in acute gallstone pancreatitis without cholangitis: a meta-analysis. JOP 2009; 10: 299–305.
- 6. Michael F Byrne, Gallstone pancreatitis who really needs an ERCP? Can J Gastroenterol. 2006 Jan; 20(1): 15–17.PMCID: PMC2538962. PMID: 16432554.
- 7. Malik HT, Marti J, Darzi A, Mossialos E. Savings from reducing low-value general surgical interventions. Br J Surg. 2018 Jan;105[1]:13-25. doi:10.1002/bjs.10719.

1.1.17 2Q — Cholecystectomy

Summary of intervention

Cholecystectomy is a surgical procedure that removes the gallbladder. The gallbladder in an organ located just below the liver on the right side of the body. It is usually performed laparoscopically (keyhole), but can be performed open, which involves a large cut under the right rib cage. A cholecystectomy can be performed for numerous indications, two of which are gallstones or gallstone pancreatitis.

An interval cholecystectomy is one that is performed some weeks after the initial acute presentation, while an index cholecystectomy is one that is performed at the time of acute admission.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

2.056

Proposal

For patients who are admitted to hospital with acute cholecystitis or mild gallstone pancreatitis, index laparoscopic cholecystectomy should be performed within that admission. These patients should have their gallbladders removed, ideally before discharge, to avoid further delay and prevent further potentially fatal attacks. If the patient is fit enough for surgery and same admission cholecystectomy will be delayed for more than 24 hours, it may be reasonable to make use of a virtual ward, where the patient can return home under close monitoring prior to undergoing surgery as soon as possible.

Otherwise patients diagnosed with acute cholecystitis should have their laparoscopic cholecystectomy on the same admission within 72 hours [NICE guidelines published in October 2014 state one week, but 72 hours is preferable]. This guidance may not be applicable in patients with severe acute pancreatitis.

Surgery for these patients may be challenging and can be associated with a higher incidence of complications (particularly beyond 96 hours) and a higher conversion rate from laparoscopic surgery to open surgery. These patients should be operated on by surgeons with experience of operating on patients with acute cholecystitis, or if not available locally, transfer to a specialist unit should be considered. Timely intervention is preferable to a delayed procedure, and, if the operation cannot be performed during the index admission it should be performed within two weeks of discharge.

Rationale for Recommendation

Numerous studies and literature reviews have shown that index cholecystectomy for mild pancreatitis is preferable to interval cholecystectomy.

Compared with interval cholecystectomy, index cholecystectomy reduced the rate of recurrent gallstone-related complications in patients with mild gallstone pancreatitis, with a very low risk of cholecystectomy-related complications. In patients with mild biliary pancreatitis, same-admission cholecystectomy reduces the rate of recurrent gallstone-related complications significantly from 17% to 5%. The readmission rate for gallstone related complications (pancreatitis, cholangitis, cholecystitis, choledocholithiasis or gallstone colic) is reduced in index versus interval cholecystectomy. It is recognised that index cholecystectomy can be more technically challenging due to inflammation, however, the immediate complication rate of the surgery (i.e. bile leak, wound infection) has been shown to largely similar between index and interval cholecystectomy.

In patients with moderate to severe acute cholecystitis (using the Tokyo Guidelines 2018 definitions) there may be an increased risk of bile duct injury. In patients with severe acute biliary pancreatitis, surgical intervention may be required for other sequalae of the pancreatitis and therefore cholecystectomy should be undertaken once the patient has recovered from any organ failure and when it is clear if any other intervention is required, for example for acute fluid collections or pancreatic necrosis.

- 1. NICE. Gallstone disease: diagnosis and management. October 2014. CG188: https://www.nice.org.uk/guidance/cg188.
- 2. Malik HT, Marti J, Darzi A, Mossialos E. Savings from reducing low-value general surgical interventions. Br J Surg. 2018 Jan;105[1]:13-25. doi:10.1002/bjs.10719.
- 3. Schuster k, Holena D, salim A, savage S, crandall M, american association for the surgery of trauma emergency surgery guideline summaries: 2018, acute appendicitis, acute cholecystitis, acute diverticulitis, acute pancreatitis, and small bowel obstruction. Trauma surg acute care open. 2019; 4: e000281.

- ______
- 4. da Costa DW, Bouwense SA, Schepers NJ, Besselink MG, van Santvoort HC, van Brunschot S et al.; Dutch Pancreatitis Study Group. Same-admission versus interval cholecystectomy for mild gallstone pancreatitis (PONCHO): a multicentre randomised controlled trial. Lancet 2015; 386:1261 1268.
- 5. Association of Upper Gastrointestinal Surgeons of Great Britain and Ireland pathway for management of acute gallstone disease https://www.augis.org/wp-content/uploads/2014/05/Acute-Gallstones-Pathway-Final-Sept-2015.pdf.
- 6. Gutt CN, Encke J, Köninger J, Harnoss JC, Weigand K, Kipfmüller K et al. Acute cholecystitis: early versus delayed cholecystectomy, a multicenter randomized trial [ACDC study, NCT00447304]. Ann Surg 2013; 258: 385–393.
- 7. Ozardes A, Tokac M, dumlu EG, bozkurt B, ciftci B, yetisir F, kilic M. Early versus delayed laparoscopic cholecystectomy for acute cholecystitis: a prospective, randomise study. INt surg 2014;99: 56-61.
- 8. Tokyo Guidelines 2018: surgical management of acute cholecystitis: safe steps in laparoscopic cholecystectomy for acute cholecystitis. November 2017.

1.1.18 2R — Appendicectomy without confirmation of appendicitis

Summary of intervention

Appendicitis is the most common cause of abdominal pain requiring surgical intervention.

In children appendicitis can often be diagnosed clinically, if there is diagnostic uncertainty, an ultrasound can confirm appendicitis. CT is not recommended in children given the risks of ionising radiation; MRI can be used in centres with appropriate expertise.

In adults negative appendicectomy can occur in up to 30% of cases where appendicitis is suspected on clinical grounds but imaging is not performed. In patients with typical symptoms, diagnosis can generally be made based on history, physical examination and blood analysis. The 'triple-screen' [CRP <10, WCC <10.5 and a neutrophil percentage <75%] has a negative predictive value >99% in excluding appendicitis, and imaging for appendicitis is not recommended in this setting.

Recent studies have shown there is a potential role for non-operative management of acute appendicitis, imaging can help identify which patients could be managed conservatively.

Where patients present with atypical or equivocal symptoms, imaging should be sought to reduce the negative appendicectomy rate. While both ultrasound and computed tomography (CT) are effective, ultrasound is preferred as a first-line investigation. This is particularly important in young patients or in female patients when there is a significant incidence of a gynaecological differential diagnosis (where US is superior to CT). CT may be more appropriate in obese patients where ultrasound is more challenging, or for older patients in whom the differential diagnosis may be broad and where CT is usually of more value.

The diagnostic accuracy of MRI to diagnose appendicitis is similar to CT. Where specialist MRI is available it can be considered if CT is contraindicated, it is particularly useful for pregnant patients.

This guidance applies to adults and children.

Number of interventions in 2018/19

47.605

Proposal

Consider imaging of patients with the suspicion of acute appendicitis in a defined clinical pathway.

Where patients present with a high clinical suspicion of appendicitis, then imaging may not be necessary, but imaging can help identify which patients can be managed conservatively. If there is clinical doubt then imaging can reduce the negative appendicectomy rate. Most patients should have an ultrasound as the first-line investigation. If the diagnosis remains equivocal, a contrast-enhanced CT (CECT, preferably low dose) can be performed to give a definitive diagnosis prior to the patient returning to the surgical unit for a decision on management.

A pathway like this is dependent on the availability of an adequately skilled Radiologist (Consultant or Registrar) or Sonographer to perform the ultrasound assessment in a timely fashion. If this is not possible discretion should be used to proceed directly to limited dose CECT of the abdomen and pelvis.

Rationale for Recommendation

Appendicitis is a common surgical emergency. In many cases, typical history and physical examination are sufficient to reach a clinical diagnosis of appendicitis. However, patients can have a negative appendicectomy so there is a role for imaging if there is any diagnostic doubt (some reports suggest this is a more cost-effective way of managing suspected appendicitis), imaging can also help identify which patients can be managed conservatively. Where imaging is indicated, ultrasound is considered the preferred first-line diagnostic intervention followed by a conditional CECT after an inconclusive ultrasound. MRI, while having a comparable accuracy to CECT, has played a limited role in diagnosis of appendicitis due to scanner access. However, the lack of ionising radiation makes it a safer option for younger or pregnant patients with an inconclusive ultrasound (where there is appropriate access and expertise).

- 1. Royal College of Surgeons of England Commissioning Guide: Emergency general surgery (acute abdominal pain) 2014. NICE accredited.: https://www.rcseng.ac.uk/library-and-publications/rcs-publications/docs/emergency-general-guide/.
- 2. Bachur RG, Levy JA, Callahan MJ, Rangel SJ, Monuteaux MC. Effect of reduction in the use of computed tomography on clinical outcomes of appendicitis. JAMA Pediatr 2015; 169:755-760.
- 3. Frush DP, Frush KS, Oldham KT. Imaging of acute appendicitis in children: EU versus US ... or US versus CT? A North American perspective. Pediatr Radiol 2009; 39:500-505.

- 4. Garcia K, Hernanz Schulman M, Bennett DL, Morrow SE, Yu C, Kan JH. Suspected appendicitis in children: diagnostic importance of normal abdominopelvic CT findings with nonvisualized appendix. Radiology 2009; 250:531-537.
- 5. Kharbanda AB, Stevenson MD, Macias CG, Sinclair K, Dudley NC, Bennett J et al. Interrater reliability of clinical findings in children with possible appendicitis. Pediatrics 2012; 129:695-700.
- 6. Kotagal M, Richards MK, Chapman T, Finch L, McCann B, Ormazabal A et al. Improving ultrasound quality to reduce computed tomography use in pediatric appendicitis: The Safe and Sound campaign. Am J Surg 2015; 209:896-900.
- 7. Krishnamoorthi R, Ramarajan N, Wang NE, Newman B, Rubesova E, Mueller CM et al. Effectiveness of a staged US and CT protocol for the diagnosis of pediatric appendicitis: Reducing radiation exposure in the age of ALARA. Radiology 2011; 259: 231-239.
- 8. Malik HT, Marti J, Darzi A, Mossialos E. Savings from reducing low value general surgical interventions. Br J Surg 2018; 105[1]:13-25.
- 9. Schok T, Simons PC, Janssen Heijnen ML, Peters NA, Konsten JL. Prospective evaluation of the added value of imaging within the Dutch National Diagnostic Appendicitis Guideline do we forget our clinical eye? Dig Surg 2014; 31:436-4143.
- 10. Leeuwenburgh MM, Wiarda BM, Wiezer MJ, Vrouenraets BC, Gratama JW, Spilt A,Richir MC, Bossuyt PM, Stoker J, Boermeester MA; OPTIMAP Study Group. Comparison of imaging strategies with conditional contrast-enhanced CT and unenhanced MR imaging in patients suspected of having appendicitis: a multicenter diagnostic performance study. Radiology. 2013 Jul;268(1):135-43.
- 11. Ivan C, Al-Nowfal A, Hudson S, Osma A, Verma R Stephenson JÁ. Cost-effectiveness of imaging in the assessment of appendicitis. Insights Imaging. 2019; 10[2]:16.
- 12. Pickhardt PJ, Lawrence EM, Pooler BD, Bruce RJ. Diagnostic performance of multidetector computed tomography for suspected acute appendicitis. Ann Intern Med. 2011 Jun 21. 154(12):789-96.
- 13. Javanmard-Emamghissi, H., Boyd-Carson, H., Hollyman, M. et al. The management of adult appendicitis during the COVID-19 pandemic: an interim analysis of a UK cohort study. Tech Coloproctol [2020]: https://link.springer.com/article/10.1007/s10151-020-02297-4.
- 14. Mostbeck G, Adam EJ, Nielsen MB, et al. How to diagnose acute appendicitis: ultrasound first. Insights Imaging. 2016;7(2):255-263. doi:10.1007/s13244-016-0469-6.
- 15. Mushtaq R et al. First-line diagnostic evaluation with MRI of children suspected of having acute appendicitis. Radiology 2019 Feb 12; [e-pub]. [http://dx.doi.org/10.1148/radiol.2019181959].

16. James K, Duffy P, Kavanagh RG, Carey BW, Power S, Ryan D, Joyce S, Feeley A, Murphy P, Andrews E, McEntee MF, Moore M, Bogue C, Maher MM, O' Connor OJ. Fast acquisition abdominal MRI study for the investigation of suspected acute appendicitis in paediatric patients. Insights Imaging. 2020 Jun 16;11(1):78. doi: 10.1186/s13244-020-00882-7.

17. Mervak BM, Wilson SB, Handly BD, Altun E, Burke LM. MRI of acute appendicitis. J Magn Reson Imaging. 2019;50(5):1367-1376. doi:10.1002/jmri.26709.

1.1.19 2S — Low back pain imaging

Summary of intervention

The evaluation of low back pain by a medical provider should include a complete medical history and examination. It should be established if any "red flag" signs or symptoms are present that could indicate serious underlying pathology.

Serious underlying pathology includes but is not limited to:

- Infection
- Suspected cancer
- Spinal injury
- Spinal cord compression
- Inflammatory conditions
- Patients with cancer and symptoms suggestive of spinal metastases
- Spondyloarthritis in over 16s
- Cauda equina syndrome
- This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

253.956

Proposal

Do not routinely offer imaging in a non-specialist setting for people with low back pain with or without sciatica in the absence of red flags, or suspected serious underlying pathology following medical history and examination.

Imaging in low back pain should be offered if serious underlying pathology is suspected. Serious underlying pathology includes but is not limited to: cancer, infection, trauma, spinal cord injury (full or partial loss of sensation and/or movement of part(s) of the body) or inflammatory disease.

Further information can be accessed at the relevant NICE guideline for these conditions.

Patients presenting with low back pain and sciatica should be reviewed in accordance with the low back pain and sciatica guidance (https://www.nice.org.uk/guidance/ng59). Patients presenting with low back pain without sciatica should be reviewed and if none of the above serious underlying pathology are suspected, primary care management typically includes reassurance, advice on continuation of activity with modification, weightloss, analgesia, manual therapy and reviewing patients who are high risk of



developing chronic pain (i.e. STaRT Back).

NICE guidelines recommend using a risk assessment and stratification tool, [e.g. STaRT Back], and following a pathway such as the National Back and Radicular Pain Pathway, to inform shared decision making and create a management plan.

Consider a combined physical and psychological programme for management of sub-acute and chronic low back pain (greater than 3 to 6 months duration) e.g. Back Skills Training (BeST).

Consider referral to a specialist centre for further assessment and management if required. Imaging within specialist centres is indicated only if the result will change management.

For further information please see the following NICE guidance:

- Low back pain and sciatica in over 16s: assessment and management [November 2016] https://www.nice.org.uk/guidance/ng59
- Low back pain and sciatica in over 16s: assessment and management [November 2016] - Quality statement 2: Referrals for imaging https://www.nice.org.uk/guidance/qs155/chapter/Quality-statement-2-Referrals-for-imaging
- National Pathway of Care for Low Back and Radicular Pain https://www.nice.org.uk/guidance/ng59/resources/endorsed-resource-national-pathway-of-care-for-low-back-and-radicular-pain-4486348909.

Rationale for Recommendation

NICE recommends imaging does not often change the initial management and outcomes of someone with back pain. This is because the reported imaging findings are usually common and not necessarily related to the person's symptoms. Many of the imaging findings [for example, disc and joint degeneration] are frequently found in asymptomatic people. Requests for imaging by non-specialist clinicians, where there is no suspicion of serious underlying pathology, can cause unnecessary distress and lead to further referrals for findings that are not clinically relevant.

Undertaking imaging when it is not indicated can lead to further additional and unnecessary investigations and treatment, including surgery, increasing the risk of harm to patients and driving up costs.

There is evidence that most patients in whom a serious underlying pathology is not suspected and without red flag symptoms will recover from low back pain within six weeks.

In patients with symptoms suggestive of cauda equina syndrome, imaging should not be delayed. The spinal surgery GIRFT report has recommended there should be a low threshold for investigation and, following urgent referral by a senior clinician, an MRI should be undertaken as an emergency. The decision to perform an MRI does not require discussion with the local spinal services. The MRI must be undertaken as an emergency in the patient's local hospital and a diagnosis achieved prior to any discussion with the spinal services. The MRI must take precedence over routine cases and any reasons for a delay or a decision not to perform an emergency scan should be clearly documented. Hospitals with MRI facilities that are not providing a 24/7 service (usually due to a lack of radiographer out of hours support) are being encouraged to provide this service.

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- 1. Low back pain and sciatica in over 16s: assessment and management [November 2016] Quality statement 2: Referrals for imaging: https://www.nice.org.uk/guidance/qs155/chapter/Quality-statement-2-Referrals-for-imaging.
- 2. NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings (2014): https://www.nice.org.uk/guidance/cg173.
- 3. Spondylarthritis in over 16: diagnosis and management: https://www.nice.org.uk/guidance/ng65.
- 4. Royal College of Radiologists iRefer: Making the best use of clinical radiology. Eighth edition. 2017: http://guidelines.irefer.org.uk/adult/#Tpc90.
- 5. STarT Back: https://www.nice.org.uk/guidance/ng59/resources/endorsed-resource-start-back-screening-tool-with-matched-treatment-options-4906309933.
- 6. Back Skills Training (BeST): Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Prof Sarah E Lamb DPhil et al on behalf of the Back Skills Training Trial investigators: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736[09]62164-4/fulltext.
- 7. Williams CM, Maher CG, Hancock MJ, et al. Low Back Pain and Best Practice Care: A Survey of General Practice Physicians. Arch Intern Med. February 8, 2010 2010;170(3):271-277.
- 8. Chou R, Fu R, Carrino JA, Deyo RA. Imaging strategies for low back pain: systematic review and meta-analysis. Lancet. Feb 7 2009;373(9662):463-472.
- 9. Kendrick D, Fielding K, Bentley E, Miller P et al. The role of radiography in primary care patients with low back pain of at least 6 weeks duration: a randomised (unblinded) controlled trial. Health Technol Assess. 2001; 5 (30):1-69. [UK].
- 10. Kerry S, Hilton S, Patel S, Dundas D et al. Routine referral for radiography of patients presenting with low back pain: Is patients' outcome influenced by GPs' referral for plain radiography? Health Technol Assess. 2000; 4 [20]:1-129. [UK]. National Low Back and Radicular Pain Pathway 2017.
- 11. Lemmeres GPG, <u>van Lankveld W</u>, <u>Westert GP et al</u>, Imaging versus no imaging for low back pain: a systematic review, measuring costs, healthcare utilization and absence from work, European Spine Journal, May 2019, 28[5]:937-950.
- 12. Low back pain and sciatica in over 16s: assessment and management [November 2016]: https://www.nice.org.uk/guidance/ng59.
- 13. Savigny P, Kuntze S, Watson P, et al. Low Back Pain: early management of persistent non-specific low back pain. London: National Collaborating Centre for Primary Care and Royal College of General Practitioners.



Summary of intervention

Osteoarthritis (OA), the most common form of arthritis, is characterised by joint pain accompanied by a varying degree of functional limitation and reduced quality of life. The most commonly affected joints are the knees, hips and small hand joints with a poor link between changes visible on a radiograph and symptoms of osteoarthritis.

An initial diagnosis of OA can be made when clinical assessment is suggestive of this pathology. If imaging is required to confirm the diagnosis, then weight bearing radiographs are the first-line of investigation. Magnetic resonance imaging [MRI] for knees is not usually needed.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

80,315 9

Proposal

In primary care, where clinical assessment is suggestive of knee OA, imaging is not usually necessary. If imaging is required than weight bearing radiographs are the first-line of investigation.

Patients with persistent symptoms should, after three to four months, be referred to secondary care and should have imaging of the knee to investigate for OA and/or other pathology.

Where imaging is necessary, in secondary care the first-line investigation of potential knee OA is weight bearing plain radiography. If the patient has a pattern of disease that allows surgical treatment to be adequately planned with plain radiographs, then MRI is not required.

However, there are a number of situations where MRI of the osteoarthritic knee can be useful:

- Patients who have severe symptoms but relatively mild OA on standard X-rays. In this situation the MRI offers more detail and can show much more advanced OA or Osteonecrosis within the knee
- In working up a patient for possible HTO or partial knee replacement an MRI can be a very useful investigation focusing on the state of the anterior cruciate ligament and state of the retained compartments.

In summary an MRI scan can be a useful investigation in the contemporary surgical management of osteoarthritis, giving critical information on the pattern of disease and state of the soft tissues. However, requesting an MRI scan when it is not indicated potentially prolongs further waiting times for patients, can cause unnecessary anxiety while waiting for specialist consultation and can delay MRI scans for appropriate patients.

^{9.} Currently there is no diagnostic data in outpatients so indication for knee MRI is not clear, therefore the number of interventions [80,315] represents the total number of knee MRIs [T - Knee MRI when symptoms are suggestive of osteoarthritis and U - Knee MRI for suspected meniscal tears].

Rationale for Recommendation

The diagnosis of knee OA can be effectively made in primary care based upon the patient's history and physical examination. In particular, NICE recommends diagnosing osteoarthritis clinically, and without investigations, in patients who:

- Are 45 or over AND
- Have activity-related joint pain AND
- Has either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.

It is important to exclude other diagnoses in some cases where there may be atypical features which may indicate alternative or additional diagnoses such as:

- A history of trauma
- History of cancer or corresponding risk factors
- Prolonged morning joint-related stiffness
- Rapid worsening of symptoms
- The presence of a hot swollen joint.

Important differential diagnoses include gout, other inflammatory arthritides (for example, rheumatoid arthritis), septic arthritis and malignancy (bone pain).

In secondary care when surgical intervention for OA is being considered an MRI scan can offer valuable information about the pattern of disease within the knee. This includes planning for osteotomy around the knee for OA and for partial knee replacement, where in both cases information about the state of the preserved compartments and the anterior cruciate ligament are critical to the surgical plan

A meta-analysis published in 2017 assessing the role of MRI in OA assessed 16 studies, which included 1220 patients. It found that MRI can detect OA with an overall high specificity and moderate sensitivity so better used to exclude OA than to confirm it. The study recommended that standard clinical algorithm for OA diagnosis, aided by radiographs is the most effective method for diagnosing OA.

The European League Against Rheumatism (EULAR) conducted a systematic review including 390 studies leading to seven recommendations concerning the use of imaging in peripheral joint 0A as below:

- Imaging is not required to make the diagnosis in patients with typical presentation of OA. Level of evidence: III-IV. LOA [95% CI] 8.7 [7.9 to 9.4]
- In atypical presentations, imaging is recommended to help confirm the diagnosis of OA and/or make alternative or additional diagnoses. Level of evidence: IV. LOA (95% CI) 9.6 (9.1 to 10)
- Routine imaging in OA follow-up is not recommended. However, imaging is recommended if there is unexpected rapid progression of symptoms or change in clinical characteristics to determine if this relates to OA severity or an additional diagnosis. Level of evidence: III–IV. LOA [mean, 95% CI] 8.8 [7.9 to 9.7]

- If imaging is needed, conventional (plain) radiography should be used before other modalities. To make additional diagnoses, soft tissues are best imaged by US or MRI and bone by CT or MRI. Level of evidence: III–IV. LOA (95% CI) 8.7 (7.9 to 9.6).
- Consideration of radiographic views is important for optimising detection of OA features; in particular for the knee, weightbearing and patellofemoral views are recommended. Level of evidence: III. LOA (95% CI) 9.4 (8.7 to 9.9)
- According to current evidence, imaging features do not predict nonsurgical treatment response and imaging cannot be recommended for this purpose. Level of evidence: II-III. LOA [95% CI] 8.7 [7.5 to 9.7]
- The accuracy of intra-articular injection depends on the joint and on the skills of the practitioner and imaging may improve accuracy. Imaging is particularly recommended for joints that are difficult to access due to factors including site (e.g., hip), degree of deformity and obesity. Level of evidence: III-IV. LOA (95% CI) 9.4 (8.9 to 9.9).

References

- 1. Osteoarthritis: care and management NICE Guidelines Clinical guideline [CG177] Published date February 2014 https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#diagnosis-2.
- 2. Menashe L, et al. The diagnostic performance of MRI in osteoarthritis: a systematic review and meta-analysis. Osteoarthritis Cartilage. 2012 Jan;20[1]:13-21. PMID: 22044841.
- 3. Sakellariou G, et al. EULAR recommendations for the use of imaging in the clinical management of peripheral joint osteoarthritis. Ann Rheum Dis. 2017 Sep;76[9]:1484-1494. PMID: 28389554.

1.1.21 2U — Knee MRI for suspected meniscal tears

Summary of intervention

Patients who have knee pain with persistent mechanical symptoms (locking, catching and intermittent sudden pain on movement) that has not responded to three months of initial non-operative care may have a symptomatic meniscal tear. These patients are referred to intermediate or secondary care and in these circumstances an MRI scan is the best investigation to determine the cause of symptoms.

Patients who have a clear history of a significant acute knee injury and mechanical symptoms or who have a locked knee require referral to intermediate or secondary care and should undergo MRI investigation.

The majority of patients who present to primary care with knee pain do not require initial investigation with an MRI scan once red flag symptoms and signs have been excluded.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19



Proposal

Patients with a clear history of a significant acute knee injury and mechanical symptoms or who have a locked knee may have a repairable meniscal tear and should undergo referral to intermediate or secondary care and have MRI investigation.

The majority of patients who initially present in primary care with knee symptoms, no red flags and no history of acute knee injury or a locked knee do not need an MRI investigation and can be treated with non-operative supportive measures.

Patients with persistent mechanical knee symptoms should be referred to secondary care and should have an MRI scan of the knee to investigate for a meniscal tear and/or other pathology.

Rationale for Recommendation

Degenerate meniscal tears and OA are extremely common in the general population. MRI is not recommended for a suspected degenerative meniscal tear unless there are mechanical symptoms [e.g. locking] or lack of improvement with conservative treatment [e.g. exercise/therapy, weight loss, bracing, topical or oral analgesia]. Acute knee injury can result in meniscal pathology that may require surgical intervention such as meniscal repair and an MRI scan is the investigation of choice in these cases. A locked knee requires urgent assessment and an MRI scan is the investigation of choice to define the cause.

- 1. Choosing Wisely Canada: https://choosingwiselycanada.org/wp-content/uploads/2017/05/Sport-and-exercise-medicine.pdf.
- 2. Arthritis Alliance of Canada. The Impact of Arthritis in Canada: Today and Over the Next 30 Years [Internet]. 2011 [cited 2017 May 5].
- 3. Buchbinder R, et al. Management of degenerative meniscal tears and the role of surgery. BMJ. 2015;350:h2212. PMID: 26044448.
- 4. Englund M. The role of the meniscus in osteoarthritis genesis. Rheum Dis Clin North Am. 2008;34:573-9. PMID: 18687273.
- 5. Englund M. Meniscal tear a common finding with often troublesome consequences. J Rheumatol. 2009;36:1362-4. PMID: 19567632.
- 6. Englund M, et al. Incidental meniscal findings on knee MRI in middle-aged and elderly persons. N Engl J Med. 2008;359:1108-15. PMID: 18784100.
- 7. Strobel MJ. Manual of Arthroscopic Surgery. Springer: Verlag Berlin Heidelberg; 2002;1:99-200. US Department of Veteran Affairs. VA/DoD Clinical Practice Guidelines: The Non-Surgical Management of Hip & Knee Osteoarthritis (OA) [Internet]. 2014 [cited 2017 May 5].
- 8. S. G. F. Abram, D. J. Beard, A. J. Price, BASK Meniscal Working Group. Bone Joint J 2019;101-B:652-659. Arthroscopic meniscal surgery a national society treatment guideline and consensus statement: https://doi.org/10.1302/0301-620X.101B6.BJJ-2019-0126.R1.

^{10.} Currently there is no diagnostic data in outpatients so indication for knee MRI is not clear, therefore the number of interventions [80,315] represents the total number of knee MRIs [T - Knee MRI when symptoms are suggestive of osteoarthritis and U - Knee MRI for suspected meniscal tears].



1.1.22 2V — Vertebral augmentation (vertebroplasty or kyphoplasty) for painful osteoporotic vertebral fractures

Summary of intervention

Osteoporotic bones are of reduced density and are more susceptible to fractures. Vertebral compression fractures are a break in a bone of the spinal column that results in a reduction in height of that bone. Osteoporotic vertebral fractures can cause pain and potentially an associated reduction in mobility. The pain can often improve as healing occurs. Deformity and respiratory or gastrointestinal disturbance as a result of fractures may be permanent.

Vertebral augmentation, including vertebroplasty (VP) and kyphoplasty (KP), refers to spinal procedures which involve the injection of bone cement (typically polymethylmethacrylate (PMMA)) into the fractured vertebral body via a needle inserted through the skin, using image guidance). These procedures aim to increase stability and strengthen the bone with the intention of reducing pain and further collapse. The procedure can be performed under local anaesthetic with sedation, or general anaesthesia interventional radiologist, spinal surgeon or pain specialist. Decisions regarding the need for vertebral augmentation are made by the operator, in conjunction with metabolic and pain specialists, geriatricians and the patient.

The alternative to vertebral augmentation is conservative management. This consists of pain relief, bracing, and manual therapy, although the evidence for bracing and manual therapy has shown to be of no benefit. Bone healing can take place over 2-12 weeks. Hospitalisation, immobility and opioid pain medication often have significant side effects, particularly in older patients. The majority of older hospitalised patients treated conservatively still have significant pain at three months and over one third at six months.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

303

Proposal

Vertebroplasty (VP) or kyphoplasty (KP) should be offered as a treatment for painful osteoporotic vertebral fractures on a case-by-case basis.

As per advice in the NICE Technology Appraisal Guidance 279 (TAG 279), VP or KP may be considered:

- In cases where patients have 'severe (7/10 or greater on VAS scale) ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management' and in particular hospitalised older people
- Where the acute vertebral fracture has been proven on imaging and correlates with the site of maximal pain on clinical examination
- The decision to treat should be taken after multidisciplinary team discussion
- The procedure should take place at a facility with access to spinal surgery services
- Processes for audit and clinical governance should be in place
- VP/KP must be performed in conjunction with additional measures to improve bone health.

NICE TAG 279 (https://www.nice.org.uk/guidance/ta279) delegates the eligible timeframe for intervention to the clinician. However, evidence from a 2016 randomised controlled trial (RCT) offers evidence that older patients (>60 years old) with fractures at most 6 weeks old and severe pain despite optimal

pain management that benefit most from the procedure.

Rationale for Recommendation

The evidence for VP in the management of vertebral compression is heterogeneous in population, comparators and outcomes. In 2013 and 2016 NICE TAG 279 reviewed the available evidence. NICE stated that the available open label randomised controlled trials comparing VP with conservative management better reflected the clinical reality. These studies demonstrated improvement in pain post VP. NICE acknowledged double blind RCTs which had demonstrated no significant improvement post VP but felt these to be less relevant.

Since 2016, two further double blind RCTs assessing VP compared to sham procedure have been completed. A 2016 RCT with more specific inclusion criteria (including patients over 60 years old, with fractures less than 6 weeks old and severe pain despite medication). compared VP with subcutaneous local anaesthetic. It demonstrated improved pain management in VP. A 2018 RCT, which included fractures up to 9 weeks old demonstrated no difference between VP and periosteal injection of local anaesthetic.

A 2018 Cochrane systematic review stated that there was no evidence to support the use of VP in painful osteoporotic fractures. However, this review has been subject to criticism.

NICE TAG 279 and a number of publications since 2016 have shown a reduction in mortality in those treated with VA as opposed to conservative management.

Currently, there is no convincing body of evidence to alter the stance of the NICE TAG 279. There is general agreement that further adequately powered trials are needed for further assessments of subgroups, particularly hospitalised older people.

VAPOUR (2016) showed a significant reduction in length of stay for their inpatient cohort.

Risk of serious adverse event following VA is rare.

VA has not shown to cause an increase in additional/adjacent vertebral fractures.

It is clear that aggressive treatment of the underlying osteoporosis is paramount.

- 1. Nice Technology Appraisal Guidance 279. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures, https://www.nice.org.uk/guidance/ta279.
- 2. Clark W, Bird P, Gonski P, Diamond TH, Smerdely P, McNeil HP, Schlaphoff G, Bryant C, Barnes E, Gebski V. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures [VAPOUR]: a multicentre, randomised, doubleblind, placebo-controlled trial. The Lancet. 2016 Oct 1;388[10052]:1408-16.

- 3. Farrokhi MR, Alibai E, Maghami Z. Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. Journal of Neurosurgery: Spine. 2011 May 1;14[5]:561-9.
- 4. Voormolen MH, Mali WP, Lohle PN, Fransen H, Lampmann LE, Van der Graaf Y, Juttmann JR, Jansssens X, Verhaar HJ. Percutaneous vertebroplasty compared with optimal pain medication treatment: short-term clinical outcome of patients with subacute or chronic painful osteoporotic vertebral compression fractures. The VERTOS study. American Journal of Neuroradiology. 2007 Mar 1;28(3):555-60.
- 5. Klazen CA, Lohle PN, de Vries J, Jansen FH, Tielbeek AV, Blonk MC, Venmans A, van Rooij WJ, Schoemaker MC, Juttmann JR, Lo TH. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. The Lancet. 2010 Sep 25;376(9746):1085-92.
- 6. Blasco J, Martinez Ferrer A, Macho J, San Roman L, Pomés J, Carrasco J, Monegal A, Guanabens N, Peris P. Effect of vertebroplasty on pain relief, quality of life, and the incidence of new vertebral fractures: a 12 month randomized follow up, controlled trial. Journal of Bone and Mineral Research. 2012 May;27(5):1159-66.
- 7. Rousing R, Andersen MO, Jespersen SM, Thomsen K, Lauritsen J. Percutaneous vertebroplasty compared to conservative treatment in patients with painful acute or subacute osteoporotic vertebral fractures: three-months follow-up in a clinical randomized study. Spine. 2009 Jun 1;34[13]:1349-54.
- 8. Buchbinder R, Osborne RH, Ebeling PR, Wark JD, Mitchell P, Wriedt C, Graves S, Staples MP, Murphy B. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. New England Journal of Medicine. 2009 Aug 6;361[6]:557-68.
- 9. Kallmes DF, Comstock BA, Heagerty PJ, Turner JA, Wilson DJ, Diamond TH, Edwards R, Gray LA, Stout L, Owen S, Hollingworth W. A randomized trial of vertebroplasty for osteoporotic spinal fractures. New England Journal of Medicine. 2009 Aug 6;361(6):569-79.
- 10. Firanescu CE, de Vries J, Lodder P, Venmans A, Schoemaker MC, Smeet AJ, Donga E, Juttmann JR, Klazen CA, Elgersma OE, Jansen FH. Vertebroplasty versus sham procedure for painful acute osteoporotic vertebral compression fractures (VERTOS IV): randomised sham controlled clinical trial. bmj. 2018 May 9;361:k1551.
- 11. Buchbinder R, Johnston RV, Rischin KJ, Homik J, Jones CA, Golmohammadi K, Kallmes DF. Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. Cochrane Database of Systematic Reviews. 2018[11].
- 12. Clark W, Bird P, Diamond T, Gonski P, Gebski V. Cochrane vertebroplasty review misrepresented evidence for vertebroplasty with early intervention in severely affected patients. BMJ evidence-based medicine. 2019 Mar 9:bmjebm-2019.

- 13. Tsoumakidou G, Too CW, Koch G, Caudrelier J, Cazzato RL, Garnon J, Gangi A. CIRSE guidelines on percutaneous vertebral augmentation. Cardiovascular and interventional radiology. 2017 Mar 1;40(3):331-42
- 14. Position Statement on Percutaneous Vertebral Augmentation John D. Barr, MD et al.
- 15. Firanescu C, de Vries J, P Lodder, Venmans A, Schoemaker M, Smeets M, Donga E, Juttmann J, Klazen C, Elgersma O, Jansen F, Tielbeek A, Boukrab I, Schonenberg K, van Rooij WJ, Hirsch J, Lohle P. Vertebroplasty versus sham procedure for painful acute osteoporotic vertebral compression fractures [VERTOS IV]: randomised sham controlled clinical trial. 2018 May 9: 361:k1551.
- 16. Orthosis in Thoracolumbar Fractures A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Daniela Linhares Bernardo Sousa Pinto, Manuel Ribeiro da Silva, Nuno Neves, João A Fonseca Spine (Phila Pa 1976) 2020 Aug 26.
- 17. Exercise or manual physiotherapy compared with a single session of physiotherapy for osteoporotic vertebral fracture: three-arm PROVE RCT. Barker KL, Newman M, Stallard N, Leal J, Minns Lowe C, Javaid MK, Noufaily A, Adhikari A, Hughes T, Smith DJ, Gandhi V, Cooper C, Lamb SE. Health Technol Assess. 2019 Aug;23[44]:1-318. doi: 10.3310/hta23440.
- 18. The Nottingham Spinal Health (NoSH) Study: a cohort study of patients hospitalised with vertebral fragility fractures. T. Ong, O. Sahota & J. R. F. Gladman. Osteoporosis International volume 31, pages 363–370 (2020).

1.1.23 2W — Shoulder Radiology: Scans for Shoulder Pain and Guided Injections

Summary of intervention

W(i) Scans for Shoulder Pain

X-rays should be used routinely as the first line of radiological investigation for the diagnosis of most routine shoulder pathology. This practice should be followed in primary, intermediate and secondary care.

The use of Ultrasound, MRI and CT scanning should be restricted to those secondary care services that are responsible for the definitive treatment of such patients. The use of these investigations outside secondary care should only be allowed if referral pathways have been developed with the local secondary care specialist shoulder service.

Primary care patients that are deemed urgent or have red flags should be referred urgently to the appropriate secondary care team.

W(ii) Image Guided Injections for Shoulder Pain

Image guided subacromial injections are not recommended in primary, intermediate or secondary care.

Evidence does not support the use of guided subacromial injections over unguided subacromial injections in the treatment of subacromial shoulder pain.

Other image guided shoulder injections should only be offered under the guidance of a secondary care shoulder service.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

W(i) - scans for shoulder pain: 128,809

W(ii) - image guided injections for shoulder pain: 2,934

Proposal

For patients who initially present with shoulder pain in primary or intermediate care, the first line of radiological investigation should be a plain x-ray. X-rays diagnose most routine shoulder problems such as osteoarthritis, calcium deposits, rotator cuff arthropathy, impingement, fractures and primary and secondary tumours.

If following an x-ray and clinical assessment, the diagnosis is still in doubt then a referral to the secondary care shoulder service is indicated where further specialist assessment and appropriate investigations including USS, CT scans and MRI scans can be arranged. The British Elbow and Shoulder Society (BESS) have produced treatment and referral guidelines for routine shoulder conditions (https://bess.ac.uk/patient-care-pathways-and-guidelines/).

If shoulder RED FLAGS are present, an urgent referral to secondary care should be arranged for further investigation and management:

- Any history or suspicion of malignancy
- Any mass or swelling
- Suggestions of infection, e.g. red skin, fever or systemically unwell
- Trauma, pain and weakness
- Trauma, epileptic fit or electric shock leading to loss of rotation and abnormal shape.

Injections for shoulder pain are often indicated as a first line of treatment. The common areas injected are the subacromial space, the glenohumeral joint and the acromioclavicular joint. The most common injection is a subacromial injection. Guided injections (usually utilising ultrasound) are more expensive than unguided injections.

Evidence now indicates there is no additional benefit from a guided subacromial injection over an unguided landmark injection and so these are no longer recommended in primary, intermediate and Secondary care during routine management of patients with subacromial shoulder pain.

The use of other guided injections for glenohumeral joint and acromioclavicular joint problems should only be offered under the guidance of a secondary care shoulder service responsible for definitive treatment of these patients.

Rationale for Recommendation

There is now a very significant burden on radiology departments from an expanding list of investigations and interventional treatments being offered to a variety of services in primary, intermediate and secondary care.

While there is no obvious harm directly caused by these investigations, the waiting times are becoming excessive and such delays may cause harm. It appears that a large number of these investigations may add little clinical value to the treatment pathway but cause unnecessary delay to those patients in need and so adversely affecting their outcome. Practices vary but overall there are large volumes of referrals for X-rays, MRIs, CTs and ultrasounds.

With little evidence to support the escalating use of shoulder scans by all, a restriction of these investigations to the secondary care services directly responsible for the definitive treatment of such patients is recommended. Any primary or intermediate care services requesting such scans should be under local referral guidelines developed with the local specialist shoulder service. This will likely decrease unnecessary referrals and improve patient experience and waiting times.

The burden of referrals for guided shoulder injections, particularly subacromial injections in secondary care has also expanded significantly in recent years and is compounded further by the need for a radiologist to perform or supervise the scan/injection. While the offer and provision of such injections by intermediate care providers may seem attractive, evidence now suggests no additional benefit to be had from more expensive guided subacromial injections over standard unguided ones.

The restriction of guided subacromial injections will lead to more immediate unguided injection treatments for patients by their consulting clinician and will improve radiology waiting times for other patients in need of other interventional radiology treatments further improving patient experience and waiting times.

References

- 1. NICE Clinical Knowledge Summary on Shoulder Pain Management (2017) https://cks.nice.org.uk/shoulder-pain#!scenario.
- 2. BESS/BOA Patient Care Pathways Subacromial shoulder pain R Kulkarni, J Gibson, P Brownson, M Thomas, A Rangan, A Carr and J Rees. Shoulder & Elbow 2015, Vol. 7(2) 135–143.
- 3. https://www.ouh.nhs.uk/shoulderandelbow/information/documents/ JRFinal2010poster.pdf.

The British Shoulder and Elbow Society (BESS) and the British Orthopaedic Association (BOA) have produced updated Shoulder Diagnosis, Treatment and Referral Guidelines for Primary, Community and Intermediate Care. These can be found in Appendix 3 and have been produced in response to comments from clinicians and patients during the EBI consultations, to assist with education and safe implementation of the EBI W1 and W2 shoulder radiology recommendations.

4. Optimising outcomes of exercise and corticosteroid injection in patients with subacromial pain (impingement) syndrome: a factorial randomised trial. Roddy E, Ogollah RO, Oppong R, Zwierska I, Datta P, Hall A, Hay E, Jackson S, Jowett S, Lewis M Shufflebotham J, Stevenson K, van der Windt DA, Young J, Foster NE. Br Journal of Sports Medicine (in press.)



Summary of intervention

When clinical assessment is suggestive of osteoarthritis (OA) and plain radiographs demonstrate typical OA features, the use of MRI for the investigation of hip pain is not usually needed.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

13,352

Proposal

Do not request a hip MRI when the clinical presentation (history and examination) and X-rays demonstrate typical features of OA. MRI scans rarely add useful information to guide diagnosis or treatment.

Requesting MRI scans further prolongs waiting times for patients. Importantly it can cause unnecessary anxiety while waiting for specialist consultation and can delay MRI scans for patients with diagnoses other than OA of the hip.

The diagnosis of hip OA can be effectively made based upon the patient's history and physical examination. NICE recommends diagnosing osteoarthritis clinically without investigations in patients who:

- Are 45 or over AND
- Have activity-related joint pain AND
- Have either no morning joint-related stiffness or morning stiffness that lasts no longer than 30 minutes.

It is important to exclude other diagnoses, especially when red flags are present. If imaging is necessary, the first-line investigation should be plain x-ray.

An MRI or urgent onward referral may be warranted in some circumstances. These include:

- Suggestions of infection, e.g. pyrexia, swollen and red joint, significant irritability, other risk factors of septic arthritis
- Trauma
- History or family history of an inflammatory arthropathy
- Mechanical, impingement type symptoms
- Prolonged and morning stiffness
- History of cancer or corresponding risk factors
- Suspected Osteonecrosis / Avascular necrosis of the hip
- Suspected transient osteoporosis
- Suspected periarticular soft tissue pathology e.g. abductor tendinopathy

Important differential diagnoses include inflammatory arthritis (for example, rheumatoid arthritis), femoro-acetabular impingement, septic arthritis and malignancy (bone pain).

Rationale for Recommendation

A meta-analysis published in 2017 assessing the role of MRI in OA, assessed 16 studies which included 1220 patients. It concluded that MRI is more useful in excluding OA rather than diagnosing it. The study recommended that standard clinical algorithm for OA diagnosis, aided by radiographs is the most effective method for diagnosing OA.

The European League Against Rheumatism (EULAR) conducted a systematic review including 390 studies leading to seven recommendations concerning the use of imaging in peripheral joint OA as below:

- Imaging is not required to make the diagnosis in patients with typical presentation of OA. Level of evidence: III-IV. LOA (95% CI) 8.7 (7.9 to 9.4)
- In atypical presentations, imaging is recommended to help confirm the diagnosis of OA and/or make alternative or additional diagnoses. Level of evidence: IV. LOA (95% CI) 9.6 (9.1 to 10)
- Routine imaging in OA follow-up is not recommended. However, imaging
 is recommended if there is unexpected rapid progression of symptoms
 or change in clinical characteristics to determine if this relates to OA
 severity or an additional diagnosis. Level of evidence: III-IV. LOA [mean,
 95% CI] 8.8 [7.9 to 9.7]
- If imaging is needed, conventional (plain) radiography should be used before other modalities. To make additional diagnoses, soft tissues are best imaged by US or MRI and bone by CT or MRI. Level of evidence: III–IV. LOA (95% CI) 8.7 (7.9 to 9.6)
- Consideration of radiographic views is important for optimising detection of OA features; in particular for the knee, weightbearing and patellofemoral views are recommended. Level of evidence: III. LOA [95% CI] 9.4 [8.7 to 9.9]
- According to current evidence, imaging features do not predict nonsurgical treatment response and imaging cannot be recommended for this purpose. Level of evidence: II-III. LOA [95% CI] 8.7 [7.5 to 9.7]
- The accuracy of intra-articular injection depends on the joint and on the skills of the practitioner and imaging may improve accuracy. Imaging is particularly recommended for joints that are difficult to access due to factors including site (eg, hip), degree of deformity and obesity. Level of evidence: III-IV. LOA [95% CI] 9.4 [8.9 to 9.9].

- 1. Osteoarthritis: care and management NICE Guidelines Clinical guideline [CG177] Published date February 2014: https://www.nice.org.uk/guidance/cg177/chapter/1-Recommendations#diagnosis-2.
- 2. Menashe L, et al. The diagnostic performance of MRI in osteoarthritis: a systematic review and meta-analysis. Osteoarthritis Cartilage. 2012 Jan;20[1]:13-21. PMID: 22044841.
- 3. Sakellariou G, et al. EULAR recommendations for the use of imaging in the clinical management of peripheral joint osteoarthritis. Ann Rheum Dis. 2017 Sep;76[9]:1484-1494. PMID: 28389554.



Summary of intervention

Spinal fusion is when two individual spinal vertebrae become joined together by bone formed as a result of surgery. This may involve the use of bone graft and/or surgical implants. The aim of the surgery is to stop motion at that joint in order to stabilise the joint. Spinal fusion is not recommended for patients with non-specific, mechanical back pain.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

41

Proposal

Spinal fusion is not indicated for the treatment of non-specific, mechanical back pain. The NICE exclusion criteria are:

- Conditions of a non-mechanical nature, including:
 - inflammatory causes of back pain (for example, ankylosing spondylitis or diseases of the viscera)
 - serious spinal pathology (for example, neoplasms, infections or osteoporotic collapse)
 - scoliosis
- Pregnancy-related back pain
- Sacroiliac joint dysfunction
- Adjacent-segment disease
- Failed back surgery syndrome
- Spondylolisthesis.

Instead, spinal fusion is usually reserved for,

- Patients with a symptomatic spinal deformity (e.g. scoliosis)
- Instability (e.g. spondylolisthesis; trauma)
- An adjunct during spinal decompression surgery, where a more extensive exposure of the affected neurological structures is required and would otherwise render the spine unstable.

Primary care management typically includes reassurance, advice on continuation of activity with modification, weight-loss, analgesia, manual therapy and screening patients who are high risk of developing chronic pain (i.e. STaRT Back). Use combined physical and psychological programme for management of sub-acute and chronic low back pain e.g. Back Skills Training [BeST].

Rationale for Recommendation

Mechanical low-back pain is common, often multifactorial and amenable to multimodal non-operative treatment (e.g. lifestyle modifications, weight loss, analgesia, manual therapy, exercise).

Imaging [e.g. plain film radiographs, MRI] in the absence of focal neurology [e.g. sciatica] or 'red-flags' may identify incidental, if not trivial, findings of age-related 'wear and tear' which can unnecessarily create a health-anxiety for some patients, where simple reassurance would otherwise usually suffice.

By the nature of the description 'non-specific low back pain,' a focal site of pathology is usually never found. In many cases, symptoms may be underpinned by a centralised pain disorder that exists outside the spine.

In the absence of a focal structural pathology (see above) and concordant mechanical or neurological symptoms, there remains a distinct lack of high-quality evidence to support fusion of the spine as a treatment of mechanical axial back pain. NICE Guideline NG59 established formal, multi-disciplinary consensus on the management of back pain, with which is implemented through the National Back Pain Pathway. This NICE-endorsed pathway offers all patients timely, evidence-based care for back pain.

References

- 1. NICE Low back pain and sciatica in over 16s: assessment and management (November 2016): https://www.nice.org.uk/guidance/ng59.
- 2. National Low Back and Radicular Pain Pathway 2017: https://www.ukssb.com/improving-spinal-care-project.
- 3. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. Chau R et al. Spine (Phila Pa 1976). 2009 May 1;34(10):1094-109. doi: 10.1097/BRS.0b013e3181a105fc.
- 4. STarT Back: https://www.nice.org.uk/guidance/ng59/resources/endorsed-resource-start-back-screening-tool-with-matched-treatment-options-4906309933.
- 5. Back Skills Training (BeST): Group cognitive behavioural treatment for low-back pain in primary care: a randomised controlled trial and cost-effectiveness analysis. Prof Sarah E Lamb DPhil et al on behalf of the Back Skills Training Trial investigators: https://doi.org/10.1016/S0140-6736[09]62164-4.
- 6. Evidence for surgery in degenerative lumbar spine disorders. Jacobs WC et al. Best Pract Res Clin Rheumatol. 2013 Oct;27(5):673-84. doi: 10.1016/j. berh.2013.09.009. Epub 2013 Oct 5.
- 7. https://choosingwiselycanada.org/spine/.
- 8. NICE CG173 Neuropathic pain in adults: pharmacological management in non-specialist settings (2014): https://www.nice.org.uk/guidance/cg173.
- 9. Transaxial interbody lumbosacral fusion IPG 387: https://www.nice.org.uk/guidance/ipg387.

Interventions where data are sufficiently robust to determine rates of variation and set national activity goals using the same methodology as used in the initial list of 17 interventions.

1.1.26 2Z — Helmet therapy for treatment of positional plagiocephaly/brachycephaly in children

Summary of intervention

Non-synostotic/positional plagiocephaly and brachycephaly are distortions of the skull (flattening to the side or the back of the head) that most commonly become apparent in the first few months of life as a result of the amount of time a baby spends lying on their back. Non-synostotic/positional

plagiocephaly and brachycephaly are very common, affecting up to 40% of infants (as opposed to synostotic conditions which are rare).

Cranial Moulding Orthosis – or 'helmet therapy' – is an intervention that claims to correct the shape of the head. A specially moulded solid helmet is created (with space to allow the flattened area to re-mould) that must be worn 23 hours a day. This helmet requires repeated adjustments as the baby grows.

This guidance applies to children aged 2 years and under.

Number of interventions in 2018/19

Data are not currently available

Proposal

As clinically evidenced by the four major designated supraregional craniofacial services in the UK (prior to the availability of Helmet therapy), the flattened area of the head usually self-corrects naturally, as a baby grows, develops and becomes more mobile with increased muscle strength, and spends less time lying in one position.

There is clear evidence and expert consensus that a helmet does not affect the natural course of skull growth and should not be used.

Helmets may be associated with significant risks such as pain, pressure sores and may adversely affect the bond between baby and parents. They are also expensive.

To reduce pressure on the flattened part of the head and encourage remoulding, the following simple interventions are suggested:

- 'Tummy time' Allow baby to spend time lying on their front while awake, supervised and playing.
- Change the position of toys / mobiles / cot in the room to encourage baby to move their head away from the flattened side
- Use a sling or a front carrier to reduce the amount of time baby spends lying on a firm flat surface
- Modify Parental lap "nursing" position to promote contact with less flattened side to parental chest.

All babies including those with non-synostotic/positional plagiocephaly or brachycephaly must be laid to sleep on their back. Sleeping in positions other than this is associated with an increased risk of Sudden Infant Death Syndrome or SIDS (formerly known as Cot Death). For the same reason, no pillows or props should be used to change a baby's sleeping position.

Rationale for Recommendation

Non-synostotic/positional plagiocephaly is a mechanical distortion that corrects itself as the child grows. Studies have shown that helmet therapy is no more effective than leaving the head to remould naturally as the baby grows. Choosing Wisely UK and Choosing Wisely Canada have both advised against helmet therapy as an intervention for positional plagiocephaly and brachycephaly. In the guideline NG127 Suspected neurological conditions: recognition and referral published in May 2019 NICE does not refer to helmet therapy and recommends:

For babies aged under 1 year whose head is flattened on one side [plagiocephaly]:

- Be aware that positional plagiocephaly (plagiocephaly caused by pressure outside the skull before or after birth) is the most common cause of asymmetric head shape
- Advise parents or carers of babies with positional plagiocephaly that it is usually caused by the baby sleeping in one position and can be improved by changing the baby's position when they are lying, encouraging the baby to sit up when awake, and giving the baby time on their tummy.

The NICE committee discussed how measuring the distance between the tragus of the ear and the outer canthus of the eye is a useful adjunct to clinical inspection of the head shape of a child under one age and would help a clinician reassure parents that this was a benign condition. However, the committee acknowledged that this was not an absolute discriminator and that if there was uncertainty, referral for specialist assessment was appropriate.

In terms of positional plagiocephaly, the NICE committee recommend that once the flat area at the back of the head is relieved of pressure with changing position, and the child is spending more time sitting, natural growth of the head will reduce the flattening. The committee does not recommend referral for investigations or management for a condition that has an excellent prognosis over time. The committee recommends referral for assessment of developmental disorders if there is concern that delay in meeting early motor milestones – rolling, sitting – is contributing to degree or maintenance of plagiocephaly. The referral would be for diagnostic assessment as well as assessing the need for therapy and provision of equipment such as adapted seating.

Consider referral to physiotherapy if there is concern of neck muscle pathology.

- 1. NHS: Plagiocephaly and brachycephaly (flat head syndrome): https://www.nhs.uk/conditions/plagiocephaly-brachycephaly/.
- 2. NHS: Reduce the risk of sudden infant death syndrome (SIDS): https://www.nhs.uk/conditions/pregnancy-and-baby/reducing-risk-cot-death/.
- 3. NICE guidance NG127 Suspected neurological conditions: recognition and referral: https://www.nice.org.uk/guidance/ng127.
- 4. Wilbrand J-F et al. Complications of Helmet Therapy. Journal of Cranio-Maxillofacial Surgery Volume 40, Issue 4, June 2012, Pages 341-346.
- 5. Expensive helmets do not correct skull flattening in babies. BMJ. 2014 May 1;348:g3066. PMID: 24791750: https://www.bmj.com/content/348/bmj.g3066.
- 6. Tamber MS, et al. Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline on the Role of Cranial Molding Orthosis [Helmet] Therapy for Patients With Positional Plagiocephaly. Neurosurgery. 2016 Nov;79[5]:E632-E633. PMID: 27776089: https://www.cns.org/guidelines/browse-guidelines-detail/5-role-of-cranial-molding-orthosis-helmet-therapy.
- 7. van Wijk RM, et al. Helmet therapy in infants with positional skull deformation: Randomised controlled trial. BMJ. 2014 May 1;348:g2741. PMID: 24784879: https://www.bmj.com/content/348/bmj.g2741.

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- 8. Choosing Wisely UK: Helmet therapy is not effective in the treatment of positional Plagiocephaly in children, other treatment options should be considered and discussed with your patient.
- 9. Choosing Wisely Canada https://choosingwiselycanada.org/pediatric-neurosurgery/.
- 10. PURLs: Helmets for positional skull deformities: A good idea, or not? https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4294410/.

1.1.27 2AA — Pre-operative chest x-ray

Summary of intervention

Chest radiographs in the pre-operative assessment of adult, elective surgical patients prior to routine surgery is not recommended.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

Data are not currently available

Proposal

Pre-operative chest radiographs should not be routinely performed in adult elective surgical patients. However, they may be appropriate in specific cohorts of patients, including when the following criteria apply:

- Patients undergoing cardiac or thoracic surgery
- Patients undergoing organ transplantation or live organ donation
- At the request of the anaesthetist in:
 - Those with suspected or established cardio-respiratory disease, who have not had a chest radiograph in the previous 12 months, and who are likely to go to critical care after surgery
 - Those with a recent history of chest trauma
 - Patients with a significant smoking history who have not had a chest radiograph in the previous 12 months, or those with malignancy and possible lung metastases
 - Those undergoing a major abdominal operation, who are at high risk of respiratory complications.

Rationale for Recommendation

In the UK, most patients are seen up to 12 weeks before surgery in preoperative assessment clinics, where a structured history and examination is performed by a nurse. Relevant preoperative investigations may also be taken according to locally developed protocols.

Routine preoperative investigations are expensive, labour intensive, and of questionable value. Excessive pre-operative testing may cause anxiety for patients, delays in treatment due to spurious results, and further unnecessary investigation or treatment, without changing outcomes or influencing perioperative management of the patient. In addition, some investigations can be associated with increased patient morbidity, for example the small dose of ionising radiation (0.2mSv) that every patient is subjected to during a chest radiograph. A more structured approach is therefore required.

In general, patients who are healthy or having relatively non-invasive surgery may require few. if any, pre-operative tests.

In the case of imaging, national guidelines agree that routine use of preoperative chest radiographs is not indicated in adult elective surgical patients, but that it may be appropriate in specific cohorts of patients. NICE recommend that chest radiographs should not be routinely offered before elective surgery.

References

- 1. O'Neill F, Carter E, Pink N, Smith I. Routine preoperative tests for elective surgery: summary of updated NICE guidance. BMJ 2016; 354: doi: https://doi.org/10.1136/bmj.i3292.
- 2. NICE Guidelines. Routine preoperative tests for elective surgery. NICE Guidelines (NG45); 2016. https://www.nice.org.uk/guidance/NG45.
- 3. RCR iRefer: Making the best use of clinical radiology. Eighth edition. 2017. Royal College of Radiologists. http://guidelines.irefer.org.uk/adult/#Tpc90.
- 4. Puddy E, Hill C. Interpretation of the chest radiograph. CEACCP 2007; 7: 71-75.
- 5. Klein AA, Arrowsmith JE. Should routine preoperative testing be abandoned? Anaesthesia 2010; 65: 974-76.
- 6. Association of Anaesthetists of Great Britain and Ireland. Pre-operative assessment and patient preparation: the role of the anaesthetist 2. AAGBI 2010. www.aagbi.org/sites/default/files/preop2010.pdf.

1.1.28 2BB — Pre-operative ECG

Summary of intervention

Performance of a resting electrocardiogram (ECG) in asymptomatic adult patients undergoing low-risk, non-cardiac elective surgery during the preoperative assessment is not necessary.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

Data are not currently available

Proposal

Pre-operative electrocardiograms should not be routinely performed in low-risk, non-cardiac, adult elective surgical patients.

However, they may be appropriately performed when the following criteria apply:

- Patients with an American Society of Anaesthesiologists (ASA) physical classification status of 3 or greater and no ECG results available for review in the last 12 months
- Patients with a history of cardiovascular or renal disease, or diabetes
- Patients with any history of potential cardiac symptoms (e.g. cardiac chest pain, palpitations, unexplained syncope or breathlessness) or a new murmur, that has not previously been investigated

Patients over the age of 65 attending for major surgery.

Where pre-operative tests are completed outside the centre in which surgery will be completed, avoid unnecessarily repeating these tests on admission and ensure appropriate transfer of images takes place.

Rationale for Recommendation

In the UK, most patients are seen in preoperative assessment clinics within 12 weeks of elective surgery, where a structured history and examination is performed by a nurse. Relevant preoperative investigations may also be taken according to locally developed protocols.

Routine preoperative investigations are expensive, labour intensive, and of questionable value unless shown to affect quality of care or clinical outcomes. Tests which have not been shown to change outcomes or influence perioperative management may cause anxiety for patients, delays in treatment due to results of uncertain relevance, and referral for further investigations or treatment. In addition, some investigations can be associated with increased patient morbidity. A more structured approach is therefore required.

In general, patients who are otherwise healthy or having relatively non-invasive surgery may require few, if any, pre-operative tests.

NICE recommend that ECGs should not be routinely offered before low risk, non-cardiac elective surgery. Low risk surgery includes minor or intermediate procedures, such as excision of skin lesions, abscess drainage, knee arthroscopy or hernia repair.

However, some patient groups should have ECG pre-operatively. This can include patients who have a history of cardiovascular disease (such as heart attack, stroke, heart failure, peripheral arterial disease), palpitations or comorbidities that would predispose them to cardiovascular disease such as diabetes or renal disease. In addition, patients who are assessed as higher risk, and therefore scored as an ASA physical classification status of 3 or more (patient has severe systemic disease), with no ECG in the preceding 12 months, would benefit from further investigation.

Finally, an ECG would be prudent in patients over the age of 65 attending for major surgery.

- 1. O'Neill F, Carter E, Pink N, Smith I. Routine preoperative tests for elective surgery: summary of updated NICE guidance. BMJ 2016; 354: doi: https://doi.org/10.1136/bmj.i3292.
- 2. NICE Guidelines. Routine preoperative tests for elective surgery. NICE Guidelines (NG45); 2016: https://www.nice.org.uk/guidance/NG45.
- 3. Klein AA, Arrowsmith JE. Should routine preoperative testing be abandoned? Anaesthesia 2010; 65: 974-76.
- 4. Association of Anaesthetists of Great Britain and Ireland. Pre-operative assessment and patient preparation: the role of the anaesthetist 2. AAGBI 2010: www.aagbi.org/sites/default/files/preop2010.pdf.
- 5. ASA Physical Status Classification System: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system.



Summary of intervention

Prostate-specific antigen (PSA) is a protein produced by the prostate gland. Blood PSA levels can be elevated in prostate cancer as well as a number of other conditions including benign prostatic hypertrophy, prostatitis and urinary tract infection. The PSA test is the most commonly used test that can lead to the diagnosis of localised prostate cancer for which potentially curative treatment can be offered. Increased PSA levels may be associated with a raised probability of prostate cancer. However, many men have raised PSA levels without having prostate cancer and many men with prostate cancer don't have raised PSA levels.

Typically, men with persistently raised PSA levels are referred on for further evaluation and may be offered histological assessment by trans-rectal or trans-perineal biopsy. Some centres are now using multi-parametric MRI scans to further assess people before taking biopsies. MRI is less likely than biopsy to detect clinically insignificant cancers and therefore reduces over-diagnosis. MRI also enables a more accurate diagnosis of clinically significant cancers because the MRI image can be used to target the biopsy.

Biopsies help to confirm the presence of cancer and allows an assessment of the cancer grade and stage. It is possible that biopsies not guided by MRI imaging can miss smaller areas of cancer or detect indolent disease of unclear clinical significance (which may subsequently require further investigation or treatment). There are a number of potential adverse effects of biopsies including pain, bleeding, urinary retention, infection (which may become serious sepsis) and sexual problems. It is also recognised this process has a significant psychological burden.

This guidance applies to male adults aged 19 years and over.

Number of interventions in 2018/19

Data are not currently available

Proposal

Where PSA testing is clinically indicated (see below), or requested by the man aged 50 and over, he should have a careful discussion about the potential risks and benefits of PSA testing which allows for shared decision making before a PSA test. Various tools are available to assist with shared decision making (see below)

PSA testing should be considered in asymptomatic men over age 40 who are at higher risk of prostate cancer due if they are Black and/or have a family history of prostate cancer

PSA testing should be considered when clinically indicated (ideally after counselling on the potential risks and benefits of testing) in men when there is clinical suspicion of prostate cancer, which may include the following symptoms:

- Lower urinary tract symptoms (LUTS), such nocturia, urinary frequency, hesitancy, reduced flow, urgency or retention.
- Erectile dysfunction.
- Visible haematuria.
- Unexplained symptoms that could be due to advanced prostate cancer (for example lower back pain, bone pain, weight loss).

PSA testing for prostate cancer is not recommended in asymptomatic men [unless they are at high risk of prostate cancer i.e. Black and/or family history] is not recommended. This is because the benefits have not been shown to clearly outweigh the harms. In particular, there is concern about the high risk of false positive results.

Where PSA test results are mildly raised above the age specific range for an individual patient, it may be appropriate to repeat the test within two to three months to monitor the trend.

Note: PSA testing for prostate cancer should be avoided if the man has:

- An active or recent urinary infection (PSA may remain raised for many months).
- Had a prostate biopsy in the previous 6 weeks

both of which are likely to raise PSA and give a false positive result.

Relevant Resources

Public Health England (PHE) patient information sheet - <u>PSA testing and</u> prostate cancer: advice for well men aged 50 and over.

Prostate Cancer Research Foundation - SWOP Risk Calculator.

Choosing Wisely UK - <u>Patient education and shared decision-making</u> resources.

Prostate Cancer UK - <u>Patient education and shared decision-making</u> resources.

Rationale for Recommendation

PSA testing for prostate cancer in asymptomatic men remains controversial. Testing probably increases the diagnosis of prostate cancer but there is little or no evidence this has an effect on cancer related mortality. Testing is also known to be associated with potential harms including overdiagnosis, infection and complications of treatment for indolent disease. Evidence suggests that people at high risker of prostate cancer may benefit more from PSA testing.

Recently published UK guidance, based on an updated systematic review, made a weak recommendation against offering systematic PSA testing. This was because of the small and uncertain benefits of testing on prostate cancer mortality and the large variability in men's values and preferences. Given the lack of clear benefits, the group highlighted the importance of shared decision making in deciding whether to proceed with PSA testing which, is supported by other evidence.

It is worth considering, that the USA Preventive Services Task Force [USPSTF] has previously recommended against prostate cancer screening using PSA testing in men aged 75 years and above. The European Randomised study of Screening for Prostate Cancer [ERSPC] suggests that screening may reduce the long term risk of prostate cancer-specific mortality by at least 9% [relative reduction].

NICE guidance stresses the importance of considering symptoms when proposing a PSA test and offering PSA to symptomatic men with lower

urinary tract symptoms (LUTS), such as nocturia, urinary frequency, hesitancy, urgency or retention, erectile dysfunction, visible haematuria, or symptoms that could be due to advanced prostate cancer (for example lower back pain, bone pain, weight loss). It also advises on the use of tools to aid shared decision making between clinician and patient when deciding on PSA testing.

- 1. NHS advice: https://www.nhs.uk/conditions/prostate-cancer/should-i-have-psa-test/.
- 2. Tikkinen KAO, Dahm P, Lytvyn L, et al. Prostate cancer screening with prostate-specific antigen (PSA) test: a clinical practice guideline. BMJ 2018:362:k3581. doi:10.1136/bmj.k3581.
- 3. Prostate Cancer UK: https://prostatecanceruk.org/prostate-information/prostate-biopsy.
- 4. Ilic D, Djulbegovic M, Jung JH, et al. Prostate cancer screening with prostate-specific antigen (PSA) test: a systematic review and meta-analysis. BMJ 2018:362:k3519. doi:10.1136/bmj.k3519.
- 5. Vernooij RWM, Lytvyn L, Pardo-Hernandez H, et al. Values and preferences of men for undergoing prostate-specific antigen screening for prostate cancer: a systematic review. BMJ Open 2018;0:e025470. doi:10.1136/bmjopen-2018-025470.
- 6. Martin RM, Donovan JL, Turner EL, et al., CAP Trial Group Effect of a low-intensity PSA-based screening intervention on prostate cancer mortality: The CAP Randomized Clinical Trial. JAMA2018;319:883-95.
- 7. Young GJ, Harrison S, Turner EL, et al Prostate-specific antigen (PSA) testing of men in UK general practice: a 10-year longitudinal cohort study. BMJ Open2017;7:e017729. doi:10.1136/bmjopen-2017-017729. pmid:29084797.
- 8. Jemal A, Fedewa SA, Ma J, et al. Prostate cancer incidence and PSA testing patterns in relation to USPSTF screening recommendations. JAMA2015;314:2054-61. doi:10.1001/jama.2015.14905. pmid:26575061.
- 9. Van der Meer S, Kollen BJ, Hirdes WH, et al. Impact of the European Randomized Study of Screening for Prostate Cancer (ERSPC) on prostate-specific antigen (PSA) testing by Dutch general practitioners. BJU Int2013;112:26-31. doi:10.1111/bju.12029. pmid:2346517.
- 10. NICE Clinical Knowledge Summary Prostate Cancer https://cks.nice.org.uk/prostate-cancer#!diagnosisSub:2.
- 11. Schröder FH et al. Screening and prostate-cancer mortality in a randomized European study. N Engl J Med. 2009 Mar 26;360[13]:1320–8.
- 12. Thompson IM et al. Prevalence of prostate cancer among men with a prostate-specific antigen level < or =4.0 ng per milliliter. N Engl J Med. 2004 May 27;350(22):2239–46.
- 13. Promis Study: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736[16]32401-1/fulltext.
- 14. Precision Study: https://www.nejm.org/doi/full/10.1056/NEJMoa1801993.

1.1.30 2DD — Liver function, creatinine kinase and lipid level tests – (Lipid lowering therapy)

Summary of intervention

Lipid modification therapies are a group of medicines which help to lower the level of low-density lipoprotein (LDL) cholesterol in the blood. High levels of LDL cholesterol are linked to the development of cardiovascular disease (CVD) which includes ischaemic heart disease and stroke. There is strong evidence that lipid modification therapy improves the mortality for people at high risk of cardiovascular diseases as well as those with established disease. Clinically significant side effects associated with lipid modification therapy include skeletal muscle and liver and toxicity.

Skeletal muscle toxicity related to lipid modification treatment may result in myopathy, myositis and rhabdomyolysis. Whilst these conditions are potentially serious, they occur rarely. The likelihood of muscle toxicity increases with higher lipid modification therapy doses and in patients with predisposing co-morbidities. Creatine kinase is a blood marker which becomes elevated in various skeletal muscle pathologies and is used, alongside signs and symptoms, to diagnose muscle toxicity related to lipid lowering treatment.

Adverse effects on the liver related to lipid modification treatment are very rare and include transaminitis (raised transaminase liver enzymes in the blood) as well as jaundice and liver failure. Liver function testing is used alongside signs and symptoms to diagnose liver toxicity.

This guidance applies to adults aged 19 years and over.

Number of interventions in 2018/19

Data are not currently available

Proposal

Creatine Kinase Testing

- Creatine kinase should not be routinely monitored in asymptomatic people who are taking lipid modification therapy
- Creatine kinase measurement is indicated:
 - Prior to lipid modification therapy initiation in patients who have experienced generalised, unexplained muscle pains or weakness [whether or not associated with previous lipid-monitoring therapy]
 - If a patient develops muscle pains or weakness whilst on lipid modification therapy.

Liver Function Testing

- Baseline liver function should be measured before starting lipid modification therapy
- Liver function should be measured within 3 months of starting treatment and at 12 months, but not again unless clinically indicated
- Routine monitoring of liver function tests in asymptomatic people is not indicated after 12 months of initiating lipid lowering therapy
- ALT can be used as a measure of liver function.

Lipid Testing

- Measure full lipid profile by taking at least one lipid sample before starting lipid modification therapy. This should include measurement of total cholesterol, HDL cholesterol, non-HDL cholesterol and triglyceride concentrations. A fasting sample is not needed.
- Total cholesterol, HDL cholesterol and non-HDL cholesterol should be measured in all people who have been started on high-intensity statin treatment (both primary and secondary prevention, including atorvastatin 20 mg for primary prevention) at 3 months of treatment and aim for a greater than 40% reduction in non-HDL cholesterol.
- Consider an annual non-fasting blood test for non-HDL cholesterol to inform discussion at annual medication reviews.

Further details on creatine kinase, liver function and lipid testing during lipid lowering treatment are outlined in NICE guidance and ECS guidance for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk

Rationale for Recommendation

Creatine Kinase

In order to identify people with pre-existing skeletal muscle disorders, NICE guidance recommends that people are asked about symptoms of persistent, generalised, unexplained muscle pain prior to lipid lowering therapy initiation. If these symptoms are present, creatine kinase levels should be measured before starting treatment.

People taking lipid lowering therapy have an increased incidence of develop muscle disorders and there is consensus that patients should be advised to seek medical advice if they develop significant muscle symptoms (such as pain, tenderness or weakness) so that creatine kinase levels can be measured.

There is no evidence to support routine monitoring of creatine kinase in asymptomatic people on lipid lowering treatment.

Liver Function Testing

Baseline liver function testing is performed before lipid lowering treatment initiation to identify patients with pre-existing liver dysfunction or secondary causes of dyslipidaemia.

Product literature states that lipid lowering treatment is contraindicated in people with active liver disease or persistently raised serum transaminases (>3 times the upper limit of normal, ULN). It also states that lipid modification therapy should be initiated with caution for people with known hepatic impairment.

NICE guidance suggests that liver function is measured within 3 months of starting treatment and at 12 months. This is consistent with product literature which states that moderate elevations of serum transaminases (< 3 x ULN) have been reported following therapy with simvastatin. These changes appeared soon after initiation of therapy, were often transient, were not accompanied by any symptoms and interruption of treatment was not required.

There is no evidence to support routine monitoring of liver function testing in asymptomatic people after 12 months on lipid lowering treatment.

Lipid Testing

There is no evidence to support routine monitoring of lipid levels in asymptomatic people after 3 months on lipid lowering treatment. Consider an annual non-fasting blood test for non-HDL cholesterol to inform the discussion in annual medication reviews.

- 1. NHS Digital. Statins. Available at: https://www.nhs.uk/conditions/statins/.
- 2. Collins R, Reith C, Emberson J, Armitage J, Baigent C, Blackwell L, Blumenthal R, Danesh J, Davey Smith G, DeMets D, et al. Interpretation of the evidence for the efficacy and safety of statin therapy. Lancet. 2016 Sep 8: S0140-6736[16]31357-5. Published online 2016 Sep 8. doi: 10.1016/S0140-6736[16]31357-5.
- 3. Yusuf S, Bosch J, Dagenais G, Zhu J, Xavier D, Liu L, Pais P, López-Jaramillo P, Leiter L, Dans A, et al. Cholesterol Lowering in Intermediate-Risk Persons without Cardiovascular Disease. N Engl J Med. 2016 May 26; 374[21]: 2021–2031. Published online 2016 Apr 2. doi: 10.1056/NEJMoa1600176.
- 4. Joint Formulary Committee. British National Formulary (online) London: BMJ Group and Pharmaceutical Press. Atorvastatin. Available at: [Accessed on 7 Aug 19]: https://bnf.nice.org.uk/drug/atorvastatin.html.
- 5. C Cooper A, Nherera L, Calvert N, O'Flynn N, Turnbull N, Robson J, Camosso- Stefinovic J, Rule C, Browne N, Ritchie G, Stokes T, Mannan R, Brindle P, Gill P, Gujral R, Hogg M, Marshall T, Minhas R, Pavitt L, Reckless J, Rutherford A, Thorogood M, Wood D[2008] Clinical Guidelines and Evidence Review for Lipid Modification: cardiovascular risk assessment and the primary and secondary prevention of cardiovascular disease London: National Collaborating Centre for Primary Care and Royal College of General Practitioners.
- 6. NICE (2013). Cardiovascular disease: risk assessment and reduction, including lipid modification Clinical guideline [CG181]. Published date: July 2014 Last updated: September 2016 . Available at: https://www.nice.org.uk/guidance/cg18.
- 7. Electronic Medicines Compendium [2014] Simvastatin 40 mg tablets: summary of product characteristics, Available from: <a href="https://www.medicines.com/https://www.medici
- 8. Electronic Medicines Compendium (2013) Atorvastatin 10 mg film-coated tablets: summary of product characteristics: https://www.medicines.org.uk/emc/medicine/26431 (accessed 17 Jan 2017).

- ______
- 9. Smith CC, Bernstein LI, Davis RB, Rind DM, Shmerling RH. Screening for statin-related toxicity: the yield of transaminase and creatine kinase measurements in a primary care setting. Arch Intern Med. Mar 24 2003;163[6]:688-692.
- 10. Sniderman AD. Is there value in liver function test and creatine phosphokinase monitoring with statin use? Am J Cardiol. Nov 4 2004;94[9A]:30F-34F.
- 11. European Society of Cardiology/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk: The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS), European Heart Journal (2020) 41, 111 188 doi:10.1093/eurheartj/ehz455

1.1.31 2EE — Blood transfusion

Summary of intervention

A blood transfusion may be indicated if a patient has a shortage of red blood cells (RBC) causing haemodynamic instability or impeding oxygen delivery to tissues and organs. This can be for a variety of reasons including severe bleeding, cancer or a blood disorder. However, blood transfusion carries risks and only the minimum number of units should be transfused to avoid harm. It is recommended to use restrictive thresholds for transfusion, and to give only a single unit at a time, except where the patient has active bleeding.

This guidance applies to adults (or equivalent based on body weight for children or adults with low body weight) only.

Number of interventions in 2018/19

Data are not currently available

Proposal

This guidance focuses on RBC transfusions for adults (or equivalent based on body weight for children or adults with low body weight) only.

Do not give RBC transfusions to patients with B12, folate or iron deficiency anaemia unless there is haemodynamic instability. If haemodynamic instability is present, treat this with transfusion of appropriate blood components (do not delay emergency transfusions).

Where, however, severe acute anaemia (Hb <70g/litre) exists that is symptomatic and prevents rehabilitation or mobilisation, those patients may benefit from a single unit of blood.

For adult patients (or equivalent based on body weight for children or adults with low body weight) needing RBC transfusion, suggest restrictive thresholds and giving a single unit at a time except in case of exceptions below.

Restrictive RBC transfusion thresholds are for patients who need RBC transfusions and who do not:

- Have major haemorrhage or
- Have acute coronary syndrome or
- Need regular blood transfusions for chronic anaemia.

While transfusions are given to replace deficient red blood cells, they will not correct the underlying cause of the anaemia. RBC transfusions will only provide temporary improvement. It is important to investigate why patients are anaemic and treat the cause as well as the symptoms.

Note: Consider whether a dramatic fall in haemoglobin could be due to a severe haemolytic episode and not associated with any of the 3 exceptions. This would also be a possible indication to transfuse more than one unit at a time.

When using a restrictive RBC transfusion threshold, consider a threshold of 70 g/litre and a haemoglobin concentration target of 70–90 g/litre after transfusion.

For patients with acute coronary syndrome, a RBC transfusion threshold of 80 g/litre should be considered and a haemoglobin concentration target of 80–100 g/litre after transfusion.

For patients requiring regular transfusion for chronic anaemia, NICE advise defining thresholds and haemoglobin concentration targets for each individual.

Rationale for Recommendation

NICE guidelines recommend single-unit RBC transfusion for adults [or equivalent based on body weight for children or adults with low body weight] who are not actively bleeding, do not have acute coronary syndrome or need regular blood transfusions for chronic anaemia. This decision should be based on a clinical assessment of each individual patient including their underlying cause of anaemia. They also recommend that after each single-unit RBC transfusion the patient should be reassessed clinically, and have their haemoglobin levels checked and be given further transfusions if required.

Several randomised control trials (RCTs) have proven that it is safe to give single-unit RBC transfusions with a restrictive transfusion trigger (pretransfusion haemoglobin level or symptoms of anaemia). After receiving a single-unit RBC transfusion, symptoms may be alleviated enough to make it possible to give alternative anaemia treatment and postpone the need for further blood transfusions.

There is high quality evidence that demonstrates a lack of benefit and, in some cases, harm to patients transfused to achieve an arbitrary transfusion level. If necessary, transfuse only the minimum number of units required instead of a liberal transfusion strategy. Potential risks and harms associated with RBC transfusions include:

- Pulmonary complications: transfusion of two or more RBC units in succession is associated with an increase in pulmonary oedema or transfusion-associated circulatory overload
- Volume overload
- Haemolysis, in particular for those with sickle cell disease
- Acute transfusion reaction due to allergy
- Transmission of infection

To monitor for transfusion reactions, observe and monitor the patient's condition and vital signs before, during and after blood transfusions.

This guidance is in line with the work of the Serious Hazards of Transfusion organisation

- 1. NICE guidance: Blood transfusion [NG24]: https://www.nice.org.uk/guidance/ng24.
- 2. NICE 2016 Blood transfusion Quality Standard (QS138.)
- 3. Cochrane Review: Transfusion thresholds and other strategies for guiding allogenic red blood cell transfusion.
- 4. NHS Advice: https://www.nhs.uk/conditions/blood-transfusion/.
- 5. Choosing Wisely UK Recommendations for blood transfusion: https://www.choosingwisely.co.uk/i-am-a-clinician/recommendations/#1528715344800-ce240876-45ec.
- 6. British Blood Transfusion Society: https://www.bbts.org.uk/blog/choosingwisely_time_to_act_/.
- 7. Choosing Wisely Canada: https://choosingwiselycanada.org/transfusion-medicine/.
- 8. Choosing Wisely Canada Toolkit: Why give two when one will do: https://choosingwiselycanada.org/perspective/transfusion-toolkit/.
- 9. JPAC Transfusion in surgery: https://www.transfusionguidelines.org/transfusion-handbook/7-effective-transfusion-in-surgery-and-critical-care/7-1-transfusion-in-surgery.
- 10. International Society of Blood Transfusion: Single unit transfusion: https://www.isbtweb.org/working-parties/clinical-transfusion/6-single-unit-transfusion/.
- 11. NHS Blood and Transplant Single unit blood transfusions (pilot study King's College hospital): https://hospital.blood.co.uk/patient-services/ patient-blood-management/single-unit-blood-transfusions/.
- 12. Markus M Mueller, MS; Hans Van Remoortel, PhD; Patrick Meybhn, MS, PhD; et al. Recommendations from the 2018 Frankfurt Consensus Conference. https://jamanetwork.com/journals/jama/article-abstract/2727453.
- 13. Jeffrey L Carson; Simon J Stanworth; John H Alexander; Nareg Roubinian; Dean A Fergusson; Darrell J Triulzi; Shaun G Goodman; Sunil V. Rao; Carolyn Doree; Paul C Hebert. Clinical trials evaluating red blood cell transfusion thresholds: An updated systematic review and with additional focus on patients with cardiovascular disease: https://www.sciencedirect.com/science/article/abs/pii/S0002870318301169?via%3Dihub.
- 14. https://www.shotuk.org/.

Appendix 1 Clinical glossary

A

Adenoma — Adenomas are a type of non-cancerous tumor or benign that may affect various organs.

Angina — Angina is chest pain caused by reduced blood flow to the heart muscles. It's not usually life threatening, but it's a warning sign that you could be at risk of a heart attack or stroke.

Angiogram / Angiography — Angiography is a type of X-ray used to check the health of your blood vessels and how blood flows through them.

Acute gallstone pancreatitis without cholangitis - Cholangitis is an inflammation in the bile duct. Gallstones are small stones that form in your gallbladder. They can sometimes trigger acute pancreatitis if they move out of the gallbladder and block the opening of the pancreas.

Appendicitis — Appendicitis is a painful swelling of the appendix.

Adenoids — Adenoids are small lumps of tissue at the back of the nose, above the roof of the mouth. These can become swollen after a bacterial or viral infection, or after a substance triggers an allergic reaction.

Arthritis — Arthritis is a common condition that causes pain and inflammation in a joint.

Arrhythmias — Arrhythmias are abnormal heart rhythms.

Arthroscopic surgery — is a procedure usually performed under general anaesthesia. A fibreoptic telescope (arthroscope) attached to a video camera is inserted through a small incision near the knee joint, and saline is introduced via a cannula in a further incision near the joint.

Acute Myocardial Infarction (MI) — Acute myocardial infarction is the medical name for a heart attack.

Acute Coronary Syndrome (ACS) — A significant blockage in the coronary arteries, the term covers MI and unstable angina comprise ACS.

В

Barrett's Oesphagus — Barrett's oesophagus is when the cells lining the lower part of your oesophagus (gullet) get damaged by acid and bile



repeatedly coming up from your stomach. Over time, the cells may become abnormal and there's a small risk that cancer will develop.

Benign Prostatic Hypertrophy (Benign prostate enlargement (BPE) — Benign prostate enlargement (BPE) is the medical term to describe an enlarged prostate, a condition that can affect how you pass urine.

Brachycephaly (Flat head syndrome) — Flat head syndrome in babies where the back of the head becomes flattened, causing the head to widen, and occasionally the forehead bulges out.

Blood transfusion — A blood transfusion is when you're given blood from someone else [a donor].

Brittle bones (Osteoporosis) — Osteoporosis is a health condition that weakens bones, making them fragile and more likely to break. It develops slowly over several years and is often only diagnosed when a fall or sudden impact causes a bone to break [fracture].

C

Cholecystectomy — A surgical procedure that removes the gallbladder.

Choledocholithisis — The presence of a gallstone in the common bile duct.

Chronic rhinosinusitis with Nasal Polyposis (CRSwNP) — Chronic rhinosinusitis with nasal polyps is diagnosed by the presence of both subjective and objective evidence of chronic sinonasal inflammation.

Computerised Tomography (CT) scan — uses X-rays and a computer to create detailed images of the inside of the body.

Creatinine Kinase tests (Lipid lowering therapy) — Creatine Kinase levels are the clinical measure of muscle damage (rhabdomyolysis) and are widely used to monitor the safe use of lipid lowering therapy.

Cystoscopy — A cystoscopy is a procedure to look inside the bladder using a thin camera called a cystoscope.

Cranial Moulding Orthosis — Helmet moulding therapy, or cranial orthosis, is a type of treatment in which a baby is fitted with a special helmet to correct the shape of the skull.

Coronary angiography — Invasive diagnostic procedure that provides information about the structure and function of the heart. It is considered the best method for diagnosing coronary artery disease.

Coronary heart disease [CHD] — Coronary heart disease is the term that describes what happens when your heart's blood supply is blocked or interrupted by a build-up of fatty substances in the coronary arteries.

Cardiomyopathy — A general term for diseases of the heart muscle, where the walls of the heart chambers have become stretched, thickened or stiff.

Coronary revascularization — In medical and surgical therapy, revascularization is the restoration of perfusion to a body part or organ that has suffered ischemia. It is typically accomplished by surgical means.

Cardiovascular disease (CVD) — Cardiovascular disease is a general term for conditions affecting the heart or blood vessels.

Chest radiograph — Another term for a chest x-ray.

Cardiothoracic surgery — Cardiothoracic surgery (also known as thoracic surgery) is the field of medicine involved in surgical treatment of organs inside the thorax (the chest), generally treatment of conditions of the heart (heart disease) and lungs (lung disease).

Cardiopulmonary exercise testing (CPET) — Cardiopulmonary exercise testing is a non-invasive method used to assess the performance of the heart and lungs at rest and during exercise.

D

Discectomy — A discectomy is a surgical treatment of pain caused by a prolapsed disc in your back. It is the surgical removal of the disc material that is irritating the nerve root.

Dural tear — Where the thin covering over the spinal cord is damaged.

Dyspepsia — Indigestion.

Е

Electrocardiogram (ECG) — An electrocardiogram is a simple test that can be used to check your heart's rhythm and electrical activity.

Endoscopic retrograde cholangio — pancreatography (ERCP) - An invasive procedure that involves a small camera (endoscope) being placed into your mouth and fed through to look at the area around your small intestine, pancreas and biliary tree.

F

Flat head syndrome (plagiocephaly and brachycephaly) — Babies sometimes develop a flattened head when they're a few months old, usually as a result of them spending a lot of time lying on their back.

Fusion surgery — Spinal fusion surgery involves the use of surgical implants and/or bone graft to obliterate motion between vertebrae.

н

Haematoma — When the blood vessels under your skin are damaged and blood leaks out and pools, resulting in a bruise.

Haemothorax — A collection of blood between the chest wall and the lung cavity.

Heart tracing (ECG) — A simple test that can be used to check your heart's rhythm and electrical activity

Hernia — A hernia occurs when an internal part of the body pushes through a weakness in the muscle or surrounding tissue wall.

Indolent disease — A disease that causes no pain or other symptoms and is not causing immediate health effects.

Interval cholecystectomy — The removal of a diseased gallbladder after drainage for acute infection.

Intermediate care — Care provided to patients who are medically stable but too unstable to be treated in alternative healthcare settings such as home, ambulatory, or a nursing home and need some rehabilitation or step-down care until they are stable enough to go home or elsewhere. (NIHR)

Inguinal hernia — The most common type of hernia which occurs when an internal part of the body pushes through a weakness in the muscle or surrounding tissue wall.

Ischaemia — Ischemia or ischaemia is a restriction in blood supply to tissues, causing a shortage of oxygen that is needed for cellular metabolism (to keep tissue alive).

K

Knee arthroscopy — Knee arthroscopy is a surgical technique that can diagnose and treat problems in the knee joint.

Kidney stones — Waste products in the blood can occasionally form crystals that collect inside the kidneys. Over time, the crystals may build up to form a hard stone-like lump.

L

Left bundle branch block (LBBB) — Left bundle branch block is a blockage of electrical impulses to the heart's left ventricle.

Lower urinary tract symptoms (LUTS) — Lower urinary tract symptoms

comprise of storage, voiding and post-micturition symptoms affecting the lower urinary tract.

Lung metastases — Lung metastasis is cancer that started in another part of the body and spread to the lungs.

M

Magnetic resonance imaging (MRI) scan — Magnetic resonance imaging is a type of scan that uses strong magnetic fields and radio waves to produce detailed images of the inside of the body.

Mechanical axial low back pain — A variety of structures in the low back can cause axial or mechanical lower back pain, such as a degenerated disc, facet joint problems, and damage to soft tissues – muscles, ligaments, and tendons.

Malignant — A term for diseases in which abnormal cells divide without control and can invade nearby tissues. Malignant cells can also spread to other parts of the body through the blood and lymph systems.

Myocardial infarction (MI) — Also known as a heart attack, occurs when blood flow decreases or stops to a part of the heart, causing damage to the heart muscle.

Ν

Non-cardiac — Refers to any procedure not involving the heart or major blood vessels.

0

Osteoarthritis (OA) — The commonest form of arthritis, characterised by joint pain accompanied by a varying degree of functional limitation and reduced quality of life.

Osteonecrosis — When the bone tissue doesn't get enough blood supply and dies.

Osteoporotic vertebral fractures — Osteoporotic vertebral fractures cause pain and an associated reduction in mobility. Osteoporotic bones are of reduced density and are more susceptible to fractures.

Overdiagnosis — Making people patients unnecessarily, by identifying problems that were never going to cause harm or by medicalising ordinary life experiences through expanded definitions of diseases. [BMJ]

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P

Paced ventricular rhythm — An electrocardiographic finding in which the ventricular rhythm is controlled by an electrical impulse from an artificial cardiac pacemaker.

Patient body habitus - Physique / Build.

Pancreatitis — Pancreatitis is a condition where the pancreas is inflamed and is not working properly as a result. It can be acute or chronic.

Percutaneous — Through the skin.

Plagiocephaly (Flat head syndrome) — Flat head syndrome in babies where the head is flattened on 1 side, causing it to look asymmetrical; the ears may be misaligned, and the head looks like a parallelogram when seen from above, and sometimes the forehead and face may bulge a little on the flat side.

 ${f Pneumothorax}$ — A collapsed lung where air leaks into the space between the chest wall and the lung cavity.

Primary care services — Provide the first point of contact in the healthcare system, acting as the 'front door' of the NHS. Primary care includes general practice, community pharmacy, dental, and optometry (eye health) services. [NHS England]

Prognosticate Coronary Heart Disease (CHD) — Where a person is predicted to be at significant risk of coronary heart disease.

Prostate-specific antigen (PSA) — Is a protein produced by the prostate gland. Blood PSA levels can be elevated in prostate cancer as well as a number of other conditions including benign prostatic hypertrophy, prostatitis and urinary tract infection.

Pulmonary oedema — A condition caused by excess fluid on the lungs.

R

Radiofrequency facet joint denervation — Facet joint radiofrequency denervation is a procedure in which nerve fibres supplying the painful facet joints are selectively destroyed by heat produced by radio waves and delivered through a needle.

Radionucleotide myocardial perfusion imaging — Used to assess the heart condition, it involves taking pictures of the heart in action and the flow of blood within the heart.

Revascularisation — The restoration of perfusion to a body part or organ that has suffered ischemia

Renal disease — The name for a disease or condition that mainly affects the kidneys.

S

Secondary care — Sometimes referred to as 'hospital and community care', can either be planned (elective) care such as a cataract operation, or urgent and emergency care such as treatment for a fracture. (NHS Providers)

Sepsis — A serious infection that causes your immune system to attack your body.

Shock wave lithotripsy (SWL) — A non-invasive fragmentation of kidney stones or gallstones with shock waves generated outside the body

Spinal fusion surgery — Involves the use of surgical implants and/or bone graft to obliterate motion between vertebrae.

Sound wave therapy — Can be used for removing kidney stones.

Stress echocardiograms — Stress echocardiography is a test that uses ultrasound imaging to show how well your heart muscle is working to pump blood to your body.

Т

Transurethral incision of the prostate (TUIP) — Surgical treatment to reduce the size of an enlarged prostrate by making incision.

Transurethral needle ablation of the prostate [TUNA] — Is a technique that uses low energy radio frequency delivered through two needles to ablate excess prostate tissue.

Transurethral resection of prostate (TURP) — Is a therapeutic procedure involving removal of tissue from the inner aspect of the prostate using diathermy, via an endoscopic approach. It is commonly undertaken for voiding LUTS presumed secondary to BPE.

Transurethral vaporisation of the prostate (TUVP) — Utilises the heat from high-voltage electric current which ablates obstructive prostatic tissue and seals the surrounding blood vessels

U

Upper GI endoscopy — A procedure that allows your doctor to look at the inside lining of your esophagus, your stomach, and the first part of your small intestine [duodenum].

 $\label{lem:ureteroscopy} \mbox{ [URS]} - \mbox{A procedure to examine in the inside of your urinary tract using a small lighted viewing scope}$

Urology — The branch of medicine that focuses on surgical and medical diseases of the male and female urinary tract system

√_ |

V

Valvular heart disease — Occurs when the valves of the heart become diseased or damaged, affecting the blood flow through the body and putting extra strain on the heart.

Ventricular pre-excitation — An abnormality in the electrical functioning of the heart which may cause rapid heart rates. The abnormality affects the electrical signal between the atria and ventricles.

Vertebroplasty (VP) — A procedure which involves the injection of cement (typically polymethylmethacrylate (PMMA)) into the fractured vertebral body via a needle inserted through the skin, using image guidance.

Vertebral compression fractures — A break in a bone of the spinal column that results in a reduction in height of that bone.



Appendix 2 Coding methodology summary tables

The coding for the interventions in this guidance has been updated since publication. To avoid any confusion it has been removed from this copy of the guidance.

Please refer to the EBI website for a <u>complete list of coding</u> for all Evidence-based Interventions, or to the <u>individual</u> intervention you are interested in.



Appendix 3 Shoulder pain Diagnosis, Treatment and Referral Guidelines for Primary, Community and Intermediate Care



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.





SHOULDER PAIN

Diagnosis, Treatment and Referral Guidelines for Primary, Community and Intermediate Care

Jonathan L Rees, Rohit Kulkarni, Amar Rangan. Anju Jaggi, Peter Brownson, Michael Thomas, David Clark, Paul Jenkins, Jaime Candal-Couto, Shantanu, Shahane, Christopher Peach, Mark Falworth, Stephen Drew, Julia Trusler, Phillip Turner, Aoife Molloy.

These care pathway guidelines for the shoulder have been written in collaboration with the NHS Evidence Based Interventions (EBI) programme. The EBI programme is a partnership between the Academy of Medical Royal Colleges, NHS Clinical Commissioners, the National Institute for Health and Care Excellence, as well as NHS England and Improvement

This is a summary document of the published BESS/BOA Patient Care Pathways series. These shoulder guidelines align with the new NHS England primary and community musculoskeletal adult services restoration principles and align with the new NHS England Evidence Based Interventions (EBI) Programme on shoulder imaging and injections. They also support the NICE 2017 Clinical Knowledge Summary for Shoulder Pain Management.

BESS/BOA Patient Care Pathways cover common shoulder conditions seen in primary, community and intermediate care (see <u>Full BESS PCPs</u>). They are evidence and consensus based <u>best practice recommendations</u> aimed at standardising treatment and referral pathways to ensure equal access for all and to drive quality improvement to achieve the best possible outcomes for UK patients.

Acknowledgements:

The authors would like to acknowledge Professor Martin Marshall, Chair of RCGP and Professor of Healthcare Improvement, UCL and Professor Sir Terence Stephenson, Chair of the Health Research Authority for England and Nuffield Professor of Child Health at the Great Ormond Street Institute of Child Health, UCL. Professor Marshall and Professor Sir Stephenson are co-chairs of the Evidence Based Interventions Expert Advisory Committee. They support the guidance and pathway published here. The work by BESS is incorporated in EBI guidance for implementation to improve patient care.



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.

A commitment to shared decision making and an awareness of shoulder RED Flags for urgent referral are highly important messages common to all the BESS patient care pathways (PCPs).

Shared Decision Making

The General Medical Council's 'Good Medical Practice duties of a doctor' guide clearly states in the section on working in partnership with patients that doctors' should:

- Listen to patients and respond to their concerns and preferences.
- Give patients the information they want or need in a way they can understand.
- Respect patients' right to reach decisions with the doctor about their treatment and care.
- Support patients in caring for themselves to improve and maintain their health.

This can only be achieved by direct consultation between the patient and their treating clinician. Decisions about treatment taken without such direct consultation between patient and treating clinician are not appropriate, as they do not adhere to principles of good medical practice.

Urgent Red Flag referrals for the Shoulder

Acute severe shoulder pain needs proper and competent diagnosis. Any shoulder 'Red Flags' identified during primary, community and intermediate care assessment need urgent secondary care referral.

- A suspected infected joint needs same day emergency referral.
- An unreduced traumatic shoulder dislocation needs same day emergency referral.
- Suspected tumour and malignancy will need urgent referral following the local two-week cancer referral pathway.
- An acute cuff tear as a result of a traumatic event needs urgent referral and ideally should be seen in the next available outpatient clinic.

While acute calcific tendinopathy is not a red flag, it is severely painful, often mimicking malignant pain and usually necessitates an early secondary care referral for more interventional treatment. It should also be noted that patients with shoulder pain in which the symptoms and signs suggest a more systemic inflammatory joint disease or polymyalgia rheumatica, should be considered as a 'rheumatological red flag'. Any new inflammatory oligo or polyarthritis, with symptoms of inflammation in several joints, should be referred urgently (following local rheumatology referral pathways), as time is of the essence with these diseases and a prompt diagnosis with early commencement of disease modifying drugs where appropriate is essential.

Contents - Shoulder Conditions

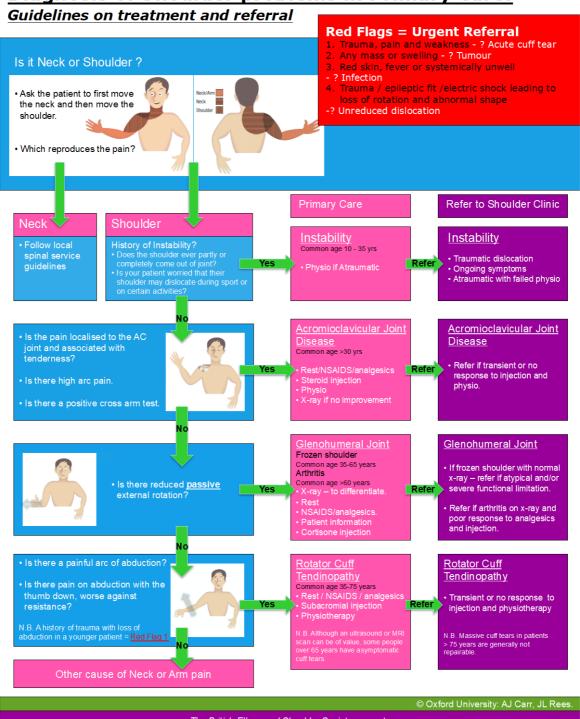
- 1. Primary, Community and Intermediate Care Diagnosis Aid
- 2. Subacromial Pain
- 3. Frozen Shoulder
- 4. Glenohumeral Arthritis
- 5. Traumatic Anterior Instability (caused by trauma)
- 6. Instability without trauma (Atraumatic instability)

Summary guidelines for each of these conditions is now presented with links to the full guidelines which include the entire patient pathway.



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.

Diagnosis of Shoulder problems in Primary Care:



The British Elbow and Shoulder Society supports
Patient Care Pathways for the Shoulder



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.

Subacromial Shoulder Pain

(Link to Full Guidelines)

Definition

Subacromial shoulder pain originates from the subacromial space of the shoulder and is mainly caused by rotator cuff tendinopathy. There are a number terms that describe the same condition (supraspinatus tendinopathy, tendinitis, bursitis, impingement).

Primary Care/Community Triage and Intermediate Services.

Diagnosis

- Diagnosis is based on History and Examination
- Making the correct diagnosis will ensure an efficient and optimum treatment experience for the patient. Primary, community and intermediate care clinicians can work through the Shoulder Diagnosis Poster (click to download diagnosis poster)
- The poster emphasises the importance of passive external rotation in differentiating between subacromial pain and other causes of shoulder pain when making a diagnosis.
- Features of importance include patient expectation, hand dominance, occupation and level of activity or sports, location, radiation and onset of pain, duration of symptoms, exacerbating and relieving factors, history of trauma, involvement of other joints, systemic illnesses and comorbidities and any Red Flags.
- Shoulder X-rays with two views (true anteroposterior view and axillary view) in primary and intermediate care can be useful in patients not improving with conservative treatment and are recommended.
- Imaging with Ultrasound or MRI is rarely indicated in primary, community and intermediate care. The NHS England EBI programme now **recommends against** shoulder ultrasound or MRI unless an agreed specific treatment pathway exists with the local specialist shoulder service.

Treatment in Primary Care/Community Triage and Intermediate Services

- The NHS England EBI programme recommends treatment to follow the BESS/BOA patient care pathway on subacromial pain.
- Conservative treatment should, in general, include rest, exercise, physiotherapy, analgesics.
- Physiotherapy rehabilitation is usually for 6 weeks initially unless physiotherapists identify a reason for earlier referral to secondary care. If there is patient improvement in the first 6 weeks of physiotherapy, then at least another 6 weeks therapy is justified.
- Online patient information and shoulder rehabilitation videos are available from the BESS website (Patient rehab videos).
- No more than 2 subacromial corticosteroid injections should be given (evidence suggests repeated frequent corticosteroid injections may cause tendon damage).
- Image guided subacromial injections should **NOT** be used. Trial evidence has now demonstrated that image guided injections offer no added benefit. The NHS England EBI Programme now **recommends against** <u>image guided subacromial injection</u>.

Referral to Secondary Care

• Failure of these primary care and community treatments will prompt secondary care hospital referral for specialist imaging, assessment and treatment.

- 1. NICE Clinical Knowledge Summary NICE CKS Rotator Cuff Disorders
- 2. BESS/BOA Patient Care Pathway <u>Subacromial Pain PCP</u>
- 3. NHS England EBI Programme
- 4. NHS England primary and community musculoskeletal adult services restoration principles



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.

Frozen Shoulder

(Link to Full Guidelines)

Definition

Frozen shoulder is an extremely painful and debilitating condition leading to stiffness and disability. It typically occurs in the fifth and sixth decades of life affecting individuals of working age. The disability resulting from this condition has considerable economic impact on affected individuals and society.

Primary Care/Community Triage and Intermediate Services.

Diagnosis

- Diagnosis is based on History and Examination
- Making the correct diagnosis will ensure an efficient and optimum treatment experience for the patient. Primary, community and intermediate care clinicians can work through the Shoulder Diagnosis Poster (click to download diagnosis poster).
- The poster emphasises the importance of assessing passive external rotation in making a diagnosis of Frozen Shoulder.
- Features of importance include associated conditions like diabetes and cardiovascular disease, patient expectation, hand dominance, occupation, level of activity or sports, location, radiation and onset of pain, duration of symptoms, exacerbating and relieving factors, history of trauma, involvement of other joints, systemic illnesses, and any Red Flags.
- Normal X-rays (true anteroposterior view and axillary view are recommended) to rule out bony mechanical causes such as arthritis, avascular necrosis or dislocation, is critical in confirming a correct diagnosis of Frozen shoulder.
- Imaging with Ultrasound or MRI is not indicated in primary, community and intermediate care. The NHS England EBI programme now **recommends against** shoulder ultrasound or MRI unless an agreed specific treatment pathway exists with the local specialist shoulder service.

Treatment in Primary Care/Community Triage and Intermediate Services

- Treatment depends on the phase of the disease, severity of symptoms and degree of restriction of work, domestic and leisure activities. The aims of treatment are pain relief, improving range of motion, reducing duration of symptoms, return to normal activities
- This is a painful and debilitating condition, where the pain is often severe, mimicking malignant disease (e.g. night pain) so beware of red flags. Treatment should be tailored to individual patient needs depending on response and severity of symptoms.
- The following interventions are suitable for primary, community and intermediate care: analgesics/nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injection (<u>intra-articular</u>), domestic exercise programme, supervised physiotherapy/manual therapy.
- The NHS England EBI programme recommends image guided injections only be used if part of an agreed specific treatment pathway with the local specialist shoulder service.
- A proportion of patients with frozen shoulder will respond to conservative treatment.
- Physiotherapy rehabilitation is usually for 6 weeks unless patients are unable to tolerate, or physiotherapists identify a reason for earlier referral to secondary care. If there is patient improvement in the first 6 weeks of physiotherapy, then a further 6 weeks of therapy is justified.

Referral to Secondary Care

- Refer if symptoms of up to 3 months with failure of conservative treatment measures.
- Refer if severe symptoms necessitate; it is not appropriate to persist with ineffective treatments and delay referral of patients who experience severe pain and restriction.

- 1. NICE Clinical Knowledge Summary Frozen Shoulder CKS
- 2. BESS/BOA Patient Care Pathway Frozen Shoulder PCP
- 3. NHS England EBI Programme
- 4. NHS England primary and community musculoskeletal adult services restoration principles



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.

Glenohumeral (Shoulder) Arthritis (Link to Full Guidelines)

Definition

Degenerative shoulder (glenohumeral) osteoarthritis is characterized by degeneration of articular cartilage and subchondral bone with narrowing of the glenohumeral joint. It causes significant pain, functional limitation and disability with an estimated prevalence of between 4% and 26%.

Primary Care/Community Triage and Intermediate Services.

Diagnosis

- Diagnosis is based on History and Examination.
- Making the correct diagnosis will ensure an efficient and optimum treatment experience for the patient. Primary, community and intermediate care clinicians can work through the Shoulder Diagnosis Poster (click to download diagnosis poster).
- This is a painful and debilitating condition, where the pain is often severe. The onset of stiffness is usually progressive over many years and will cause significant functional deficit, typically presenting in patients over 60 years of age.
- Features of importance are hand dominance, occupation, level of activity, location and onset of pain, duration of symptoms, global reduction in range of motion (especially marked loss of passive external rotation), and history of multiple joint involvement or systemic manifestations.
- Plain radiographs (x-rays) of the shoulder are essential for confirming the diagnosis especially with a history of previous trauma. True anteroposterior view (in scapular plane) and axillary view are recommended.
- Imaging with Ultrasound or MRI is not indicated in primary, community and intermediate care. The NHS England EBI programme now **recommends against** shoulder ultrasound or MRI unless an agreed specific treatment pathway exists with the local specialist shoulder service.

Treatment in Primary Care/Community Triage and Intermediate Services

- Treatment depends on the severity of symptoms, degree of restriction of work, domestic and leisure activities. The aims of treatment is pain relief, improving range of motion and return to normal activities
- Treatment should be tailored to individual patients' needs depending on response and severity of symptoms.
- The following interventions are suitable for primary, community and intermediate care: analgesics/non-steroidalanti-inflammatory drugs (NSAIDs), intra-articular injection, acupuncture, physical therapy.
- The NHS England EBI programme recommends image guided injections only be used if part of an agreed specific treatment pathway with the local specialist shoulder service.
- Most patients with established osteoarthritis will respond poorly to conservative treatment. The most frequent indications for invasive treatments are pain and persistent and severe functional restrictions that are resistant to conservative measures.

Referral to Secondary Care

- Refer if there is doubt about the diagnosis.
- Refer if there is a failure of conservative treatment and patient wishes to consider shoulder replacement surgery. There are limited other surgical options.

- 1. NICE Clinical Knowledge Summary NICE CKS Glenohumeral arthritis
- 2. BESS/BOA Patient Care Pathway Glenohumeral OA PCP
- 3. NHS England EBI Programme
- 4. NHS England primary and community musculoskeletal adult services restoration principles



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.

Traumatic Anterior Instability (Link to Full Guideline)

Definition

Anterior traumatic shoulder instability can be defined as excessive anterior translation of the humeral head on the glenoid fossa caused primarily by a traumatic event. This results in symptoms including pain, discomfort, subluxation or dislocation.

Risk of recurrence

The risk of recurrent dislocation with this type of instability is inversely proportional to the age of the patient at the time of first dislocation. Therefore, the younger the patient, the more likely the risk of recurrence. Almost 90% of recurrent dislocations occur within 2 years of primary dislocation. Males under the age of 20 years have approximately 72% chance of recurrent instability.

Primary Care/Community Triage and Intermediate Services.Diagnosis

- Diagnosis is based on History and Examination.
- Making the correct diagnosis will ensure an efficient and optimum treatment experience for the patient. Primary, community and intermediate care clinicians can work through the Shoulder Diagnosis Poster (click to download diagnosis poster).
- Features of importance are, patient expectation, hand dominance, occupation and level of activity or sports, age at primary dislocation, sex of patient, symptoms of on-going instability, number of dislocations, systemic illnesses and comorbidities.
- While in younger patients there tends to be a glenoid labral injury, older patients can suffer an acute rotator cuff tear and an awareness of this is very important and should not be missed.
- Although shoulder X-rays (true anteroposterior view and axillary view are recommended) in primary
 care can be useful in patients not improving with conservative treatment, imaging with Ultrasound or
 MRI is not indicated in primary, community and intermediate care. The NHS England EBI programme
 now recommends against shoulder ultrasound or MRI unless an agreed specific treatment pathway
 exists with the local specialist shoulder service.

Treatment in Primary Care/Community Triage and Intermediate Services

- While most patients will be managed following an acute traumatic anterior dislocation through the accident services and fracture clinic in secondary care, this is not always the case. Consider referral to the fracture clinic if problems exist after a recent acute traumatic injury especially if any red flags present.
- Otherwise adopt shared decision-making and define treatment goals, taking into account personal circumstances.
- Conservative treatment following dislocation should focus on early mobilization. The risk of recurrence is not reduced with prolonged immobilization of greater than 1 week.
- Physiotherapy rehabilitation is usually for 4 weeks to 12 weeks depending on patient response unless patients are unable to tolerate the exercises, or physiotherapists identify a reason for earlier referral to secondary care.

Referral to Secondary Care

- Refer to secondary care if conservative treatments fail to improve instability or dislocation symptoms.
- Refer to secondary care if acute rotator cuff tear (Red Flag) suspected
- Refer to secondary care if patient remains symptomatic and is requesting surgery

- 1. NICE Clinical Knowledge Summary <u>NICE CKS Instability Disorders</u>
- 2. BESS/BOA Patient Care Pathway Traumatic Instability PCP
- 3. NHS England EBI Programme
- 4. NHS England primary and community musculoskeletal adult services restoration principles



Standardising Referral Guidelines and Optimising Outcomes for Shoulder patients.

Instability without trauma (Atraumatic Instability) (Link to Full Guideline)

Definition

Atraumatic shoulder instability is best defined as abnormal motion or position of the shoulder that leads to pain, subluxations, dislocations and functional impairment, but importantly it happens without any history of a significant preceding injury

Background

There are multiple causes of atraumatics houlder instability. The majority of patients will have a combination of underlying laxity with an associated loss of muscle control. There is, however, a wide spectrum of patients with this problem and while successful outcomes can be achieved following non-operative treatment in 50–80% of cases, some patients often require amore multidisciplinary team approach with consideration of psychosocial factors and other barriers to recovery if they are to be treated successfully.

Primary Care/Community Triage and Intermediate Services.

Diagnosis

- Diagnosis is based on History and Examination.
- Making the correct diagnosis will ensure an efficient and optimum treatment experience for the patient. Primary, community and intermediate care clinicians can work through the Shoulder Diagnosis Poster (click to download diagnosis poster).
- Atraumatic shoulder instability predominantly affects young patients under the age of 25.
- This group more commonly experience subluxations of the shoulder rather than dislocations
- Some will initially voluntarily displace their shoulder, often termed a 'party trick', however this can develop into an uncontrolled event
- Some will have significant functional disruption with associated pain and muscle spasms that may make relocation difficult, leading to frequent attendances to the A&E.
- MRI or other specialist imaging is only appropriate in the secondary care setting after specialist assessment. The NHS England EBI programme now **recommends against** shoulder ultrasound or MRI unless an agreed specific treatment pathway exists with the local specialist shoulder service.

Treatment in Primary Care/Community Triage and Intermediate Services

- Patients presenting with symptoms of instability as described above with no history of trauma should initially be referred in primary care for physiotherapy.
- It is important to reassure such patients early on that the vast majority of patients will respond to treatment but that symptoms may take up to six months to resolve.
- Corticosteroid injections should not be used for pain relief.
- Physiotherapy should include education, reassurance and appropriate exercise prescription.

Referral to Secondary Care

- Refer to secondary care if community physiotherapy fails to improve instability or dislocation symptoms.
- A subgroup of patients are best served by early referral to a tertiary shoulder unit with experience in managing these complex patients. Look out for frequent attendance at A&E for relocation, persistent displacement or shoulder dislocation/ subluxation. If under 18 years of age, absence from school (>20%) or work (>3 months).

- 1. NICE Clinical Knowledge Summary NICE CKS Instability Disorders
- 2. BESS/BOA Patient Care Pathway Atraumatic Instability PCP
- 3. NHS England EBI Programme
- 4. NHS England primary and community musculoskeletal adult services restoration principles

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1056565

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