NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: March 2020

Hyperlinks to the relevant NICE web page are included below.

NICE rapid COVID-19 guidelines

NICE has published some rapid guidelines on the care of people with suspected and confirmed COVID-19, and in patients without COVID-19.

These guidelines have been developed to maximise patient safety whilst making the best use of NHS resources and protecting staff from infection.

These have been developed using the interim process and methods for developing rapid guidelines on COVID-19 and based on evidence and expert opinion.

COVID-19 rapid guideline: delivery of radiotherapy NG162

The purpose of this guideline is to maximise the safety of patients who need radiotherapy and make the best use of NHS resources, while protecting staff from infection. It will also enable services to match the capacity for radiotherapy to patient needs if services become limited because of the COVID-19 pandemic.

COVID-19 rapid guideline: delivery of systemic anticancer treatments NG161

The purpose of this guideline is to maximise the safety of patients with cancer and make the best use of NHS resources, while protecting staff from infection. It will also enable services to match the capacity for cancer treatment to patient needs if services become limited because of the COVID-19 pandemic.

COVID-19 rapid guideline: dialysis service delivery NG160

The purpose of this guideline is to maximise the safety of patients on dialysis, while protecting staff from infection. It will also enable dialysis services to make the best use of NHS resources and match the capacity of dialysis services to patient needs if these become limited because of the COVID-19 pandemic.

COVID-19 rapid guideline: critical care NG159

The purpose of this guideline is to maximise the safety of patients who need critical care during the COVID-19 pandemic, while protecting staff from infection. It will also enable services to make the best use of NHS resources.

Technology Appraisals (TAs)

Recombinant human parathyroid hormone for treating hypoparathyroidism TA625 (terminated appraisal)

NICE is **unable to make a recommendation** on recombinant human parathyroid hormone for treating hypoparathyroidism because Shire Pharmaceuticals (now part of Takeda) did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Highly specialised technology guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Heavy menstrual bleeding: assessment and management NG88 (update)

This guideline covers assessing and managing heavy menstrual bleeding (menorrhagia). It aims to help healthcare professionals investigate the cause of heavy periods that are affecting a woman's quality of life and to offer the right treatments, taking into account the woman's priorities and preferences.

In March 2020, the MHRA updated their advice on the use of ulipristal acetate (Esmya) to say that healthcare professionals should contact patients currently taking Esmya for uterine fibroids as soon as possible and advise them to stop their treatment. The licence for Esmya has been suspended to protect public health while a safety review is conducted after a case of liver injury. The recommendations in this guideline covering ulipristal acetate have been amended or withdrawn accordingly.

Venous thromboembolic diseases: diagnosis, management and thrombophilia testing NG158

This guideline updates and replaces NICE guideline CG144 (June 2012).

This guideline covers diagnosing and managing venous thromboembolic diseases in adults. It aims to support rapid diagnosis and effective treatment for people who develop deep vein thrombosis (DVT) or pulmonary embolism (PE).

It also covers testing for conditions that can make a DVT or PE more likely, such as thrombophilia (a blood clotting disorder) and cancer.

The guideline does not cover pregnant women.

This guideline includes new and updated recommendations on:

- D-dimer testing
- pulmonary embolism rule-out criteria
- outpatient management of low-risk PE
- anticoagulation treatment for suspected and confirmed DVT or PE

- reviewing anticoagulation treatment
- inferior vena caval filters
- investigations for cancer

It also includes recommendations on:

- diagnosing and managing suspected DVT and PE
- information and support for people having anticoagulation treatment
- thrombolytic therapy
- thrombophilia testing

Abdominal aortic aneurysm: diagnosis and management NG156

This guideline updates and replaces NICE technology appraisal guidance 167 (published February 2009).

This guideline covers diagnosing and managing abdominal aortic aneurysms. It aims to improve care by helping people who are at risk to get tested, specifying how often to monitor asymptomatic aneurysms, and identifying when aneurysm repair is needed and which procedure will work best.

This guideline includes recommendations on:

- diagnosis
- monitoring and reducing the risk of rupture
- predicting and improving surgical outcomes
- repairing unruptured and ruptured aneurysms
- monitoring for complications after endovascular aneurysm repair
- managing endoleaks after endovascular aneurysm repair

Tinnitus: assessment and management NG155

This guideline covers the assessment, investigation and management of tinnitus in primary, community and secondary care. It offers advice to healthcare professionals on supporting people presenting with tinnitus and on when to refer for specialist assessment and management.

For adults with tinnitus and hearing loss, this guideline should be read together with the NICE guideline on hearing loss in adults.

This guideline includes recommendations on:

- Support and information for people with tinnitus
- Referring people with tinnitus
- Assessing the impact of tinnitus
- Investigations
- Management of tinnitus

Public Health Guidelines

None published this month.

Antimicrobial prescribing guidelines

None published this month.

Social Care guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

Selective internal radiation therapy for unresectable colorectal metastases in the liver IPG672

This replaces NICE interventional procedures guidance on selective internal radiation therapy for non-resectable colorectal metastases in the liver (IPG401).

Recommendations

Evidence on the safety of selective internal radiation therapy (SIRT) for unresectable colorectal metastases in the liver shows there can be serious complications, but these are well recognised and infrequent.

In people who cannot tolerate chemotherapy or have liver metastases that are refractory to chemotherapy, there is evidence of efficacy but this is limited, particularly for important outcomes such as quality of life. Therefore, in these people, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

In people who can have chemotherapy, evidence on overall survival and quality of life is inadequate in quality. Therefore, in these people, this procedure should only be used **in the context of research**.

Clinicians wishing to do SIRT for unresectable colorectal metastases in the liver, in people who cannot have chemotherapy or have liver metastases that are refractory to chemotherapy, should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these.
- Audit and review clinical outcomes of all patients having the procedure. Clinicians should enter details for all patients having SIRT for unresectable colorectal metastases in the liver onto a suitable register.

Patient selection should be done by a specialist hepatobiliary cancer multidisciplinary team that can offer the full range of treatment options for this condition.

This procedure should only be done by clinicians with specific training in SIRT including techniques to minimise the risk of damage to surrounding tissue.

Further research should report details of patient selection, whether the primary colorectal tumour arose in the left or right side of the colon, extrahepatic disease, and tumour-to-liver volume. Outcomes should include survival and quality of life.

NICE may update the guidance on publication of further evidence.

The condition

Around 30% to 50% of people with colorectal cancer have liver metastases at the time of presentation or develop them during the course of the disease.

Treatment of liver (hepatic) metastases depends on their extent and location. For unresectable tumours, treatment options include thermal ablation techniques, chemotherapy, different types of arterial embolisation therapy and external beam radiotherapy.

The procedure

Selective internal radiation therapy (SIRT; also known as radioembolisation) can be used as palliative treatment for unresectable colorectal metastases in the liver.

SIRT involves delivering microspheres containing radionuclides that emit beta radiation directly into the tumour. This aims to minimise the risk of radiation damage to surrounding healthy tissue. Using local anaesthesia and fluoroscopic guidance, the radioactive microspheres are injected into branches of the hepatic artery supplying the tumour. A percutaneous approach is used through the femoral or radial artery. The microspheres lodge in small arteries within and surrounding the tumour, releasing high doses of radiation directly into it. The procedure may be repeated depending on the response.

MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy IPG671

Recommendations

Evidence on the safety of MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy shows there are serious but well-recognised safety concerns. Evidence on its efficacy is limited in quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

Clinicians wishing to do MRI-guided laser interstitial thermal therapy for drug-resistant epilepsy should:

- Inform the clinical governance leads in their NHS trusts.
- Give patients and their parents or carers clear written information to support shared decision making, including NICE's information for the public.
- Ensure that patients and their parents or carers understand the procedure's safety and efficacy, as well as any uncertainties about these.

- Audit and review clinical outcomes of all patients having the procedure. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

Patient selection should be done by a multidisciplinary team experienced in managing drug-resistant epilepsy. This may include a neurologist, neurosurgeon, neurophysiologist, neuroradiologist and psychiatrist.

The procedure should only be done in specialist centres by clinicians with experience and specific training.

Further research could be in the form of randomised controlled trials, large case series or collaborative registries. It should report details of patient selection, including the size and site of the lesions being created, patient-reported outcomes and long-term follow up, particularly neurodevelopmental outcomes in children.

The condition

Epilepsy is a neurological condition characterised by episodes of abnormal electrical activity in the brain (recurrent seizures). The seizures can be focal or generalised.

The main treatment for epilepsy is antiepileptic drugs taken to prevent or reduce the occurrence of seizures. However, many people with epilepsy have drug-resistant epilepsy, which is refractory to drug treatment (estimates vary between 20% and 40% of people with epilepsy). They have frequent seizures and are at risk of status epilepticus and sudden unexpected death in epilepsy. If drug treatment fails to control the epilepsy adequately, surgery may be considered. Surgical options include open surgical resection (such as lesionectomy, anterior temporal lobectomy or hemispherectomy) or disconnection (such as multiple subpial transection or corpus callosotomy), neuroablation (for example, with stereotactic radiosurgery, radiofrequency thermocoagulation or MRI-guided focused ultrasound) or neuromodulation (such as cranial nerve stimulation, deep-brain stimulation or closed-loop stimulation).

The procedure

Preoperatively, an MRI scan is done to identify the part of the brain causing the seizures and to identify the entry location for the laser catheter. The procedure is usually done under general anaesthesia with the patient lying on an MRI couch. A small burr hole is made in the skull and a fine fibreoptic laser catheter is inserted into the target area under stereotactic guidance. Continuous real-time MRI scanning is done to allow visualisation of the exact target area to be ablated and the surrounding tissue, and to monitor the temperature in the brain during the procedure. Under computer guidance, laser energy is applied to the target area. The laser is switched off and removed when temperatures have reached levels sufficient to cause coagulation necrosis (usually 46°C to 60°C) and the target tissue has been ablated. After the procedure, an MRI is done to verify the location and volume of the tissue ablated. The aim is to precisely ablate the target tissue and to minimise damage to the surrounding area. MRI-guided laser interstitial thermal therapy has most commonly been used for patients with a well-defined epileptogenic focus, especially in the temporal lobe, but it can be used elsewhere in the brain.

Cyanoacrylate glue occlusion for varicose veins IPG670

This replaces NICE interventional procedures guidance on cyanoacrylate glue occlusion for varicose veins (IPG526).

Recommendations

Evidence on the safety and efficacy of cyanoacrylate glue occlusion for varicose veins is adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.

The procedure should only be done by clinicians with appropriate training in this procedure and experience in the use of venous ultrasound.

The condition

Varicose veins are a sign of underlying venous insufficiency. Primary valvular incompetence is the most common underlying cause of varicose veins. The saphenous veins are the most frequently affected vessels. Most people with varicose veins have no symptoms, but venous insufficiency may cause fatigue, heaviness, aching, throbbing, itching and cramps in the legs. Chronic venous insufficiency can lead to skin discoloration, inflammatory dermatitis and ulceration.

NICE's guideline describes the diagnosis and management of varicose veins. Interventional treatment options include endothermal ablation (such as radiofrequency ablation and endovenous laser ablation therapy), foam sclerotherapy, mechanochemical ablation and surgery (usually stripping and ligation of the great and small saphenous veins, and phlebectomies).

The procedure

Cyanoacrylate glue occlusion for varicose veins aims to close the veins by adherence then fibrosis of the lumen, without the need for tumescent anaesthesia and with reduced need for postoperative compression therapy.

The procedure is done using local anaesthesia. An introducer sheath is inserted into the distal great saphenous vein and, using ultrasound guidance, a delivery catheter is advanced into position before the saphenofemoral junction. The proximal vein is compressed, and medical glue is delivered in measured doses through the tip of the catheter to seal the vein.

This is repeated at different positions as the catheter is withdrawn, using ultrasound imaging to monitor the procedure. The procedure may also be done in a similar way for the small saphenous vein.

Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse IPG669

Recommendations

Evidence on the safety and efficacy of bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse is inadequate in quantity and quality. Therefore, this procedure should only be used **in the context of research**.

Further research should include randomised controlled trials, and report details of patient selection, technique, improvement in the prolapse, procedure-related adverse events and patient-reported outcome measures.

In July 2018, the Government announced a period of 'high vigilance restriction' on the use of a group of procedures, including this procedure, to treat stress urinary incontinence and pelvic organ prolapse, in England. This followed a recommendation by Baroness Cumberlege, who is chairing an independent review of surgical mesh procedures and has heard from women and families affected by them. For details, see the letter from NHS England and NHS Improvement to trust medical directors. The high vigilance restriction period was extended in March 2019.

In April 2019, NICE updated their guideline on urinary incontinence and pelvic organ prolapse and published patient decision aids to support people to make informed decisions about surgery for stress urinary incontinence, uterine prolapse and vaginal vault prolapse.

The condition

Pelvic organ prolapse is defined as symptomatic descent of 1 or more of: the anterior vaginal wall, the posterior vaginal wall, the cervix or uterus, or the apex of the vagina (vault or cuff). Symptoms include a vaginal bulge or sensation of something coming down, urinary, bowel and sexual symptoms, and pelvic and back pain. These symptoms affect women's quality of life.

NICE's guideline on urinary incontinence and pelvic organ prolapse describes its management. Non-surgical management options include lifestyle modification, such as losing weight and minimising heavy lifting, topical oestrogen, pelvic floor muscle training and vaginal pessaries. Surgery may be needed when the prolapse is severe. Different surgical procedures are available using vaginal or abdominal (open, laparoscopic or robotic) approaches. Some procedures involve using mesh, the aim being to provide additional support.

The procedure

Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) for pelvic organ prolapse are mesh procedures, done through open or laparoscopic approaches using general anaesthesia. If the uterus is still in place, the first step of the procedure is a hysterectomy. A polyvinylidene fluoride (PVDF) mesh ligament-replacement structure is then placed within the peritoneal fold of both the left and right uterosacral ligaments. Anterior fixation of each PVDF structure is done by centrally suturing it to the cervix or vaginal vault with 3 or 4 interrupted, nonabsorbable polyester sutures. For posterior fixation, the PVDF structures are fixed to the left and right prevertebral fascia of the sacral vertebra at the level of S1 and S2, using a fixation device or sutures. The peritoneum above the cervix or vaginal vault is then closed to cover the PVDF structure. The aim is to support the pelvic organs in their correct position, and to improve symptoms associated with the prolapse.

Medical Technologies Guidance (MTGs)

None published this month.

Diagnostics Guidance (DGs)

None published this month.

NICE Quality Standards

None published this month.

Changes to ways of working in response to COVID-19

NICE is supporting the NHS and social care to respond quickly to the challenges of the coronavirus pandemic. Their guidance is produced by advisory committees that include a lot of frontline NHS staff. During this crisis they do not want to take them away from their work caring for patients.

NICE are reviewing all the guidance they have in development and prioritising:

- therapeutically critical topics
- diagnosis of COVID-19
- treatment of COVID-19.

NICE is working on revised timelines for all other guidance that is not related to COVID-19 or therapeutically critical. They will continue with development work on guidance where they can; there is some work they can do without committee engagement.