NICE Update Bulletin January 2015 for guidance issued Wednesday 28th January 2015

Hyperlinks to the relevant NICE web page are included, to activate link left click on your mouse. Details are also available from the NICE website (**http://www.nice.org.uk**)

Type	Guidance title and reference number
Technology Appraisals (TAs)	**None published so far this month**
Highly specialized technology guidance (HSTs)	**Eculizumab for treating atypical haemolytic uraemic syndrome (HST1)** **Background** Atypical haemolytic uraemic syndrome (aHUS) is a chronic, rare, progressive condition that causes severe inflammation of blood vessels and the formation of blood clots in small blood vessels throughout the body, a process known as systemic thrombotic microangiopathy. In around 70% of patients, aHUS is associated with an underlying genetic or acquired abnormality of the proteins of the complement system, which is part of the body's defence against infection. The prognosis for people with aHUS is poor. Patients are at constant risk of sudden and progressive damage, and failure of vital organs. Mortality rates range from 10–15% in the acute phase of the disease and, within a year of diagnosis, up to 70% of patients progress to end-stage renal failure and need dialysis or die. One patient in 5 has aHUS affecting organs other than the kidneys, most commonly the brain or heart. aHUS can occur at any age. Onset occurs in childhood more frequently than in adulthood (around 60% and 40% of all cases respectively). Most children (70%) who develop aHUS will experience the disease for the first time before the age of 2 years. **Recommendations** 1.1 Eculizumab, within its marketing authorisation, is recommended for funding for treating atypical haemolytic uraemic syndrome, only if all the following arrangements are in place: • coordination of eculizumab use through an expert centre • monitoring systems to record the number of people with a diagnosis of atypical haemolytic uraemic syndrome and the number who have eculizumab, and the dose and duration of treatment • a national protocol for starting and stopping eculizumab for clinical reasons • a research programme with robust methods to evaluate when stopping treatment or dose adjustment might occur. 1.2 The long-term budget impact of eculizumab for treating atypical haemolytic uraemic syndrome is uncertain but will be considerable. NHS England and the company (Alexion Pharma UK) should consider what opportunities might exist to reduce the cost of eculizumab to the NHS. **The technology** Eculizumab (Soliris, Alexion Pharma UK) is a human monoclonal antibody that binds to complement C5 and blocks prothrombotic and pro-inflammatory processes. It is produced from murine myeloma cells by recombinant DNA technology. Eculizumab has a marketing authorisation in the UK 'in adults and children for the treatment of patients with atypical haemolytic uraemic syndrome (aHUS)'. It is also licensed for use in people with paroxysmal nocturnal haemoglobinuria. **Commissioning arrangements** Eculizumab is currently commissioned, through an interim commissioning policy, by NHS England in line with the Clinical Commissioning Policy Statement: Eculizumab for atypical haemolytic uraemic syndrome for:

	• new patients with aHUS (defined to include those with a functioning kidney), and • existing patients who are on dialysis and are suitable for a kidney transplant.

Note: The guideline below is the first to be produced using a new numbering system.

From January 2015 NICE has decided to use a single set of methods and processes to develop all NICE guidelines, whether they are clinical, public health, social care, safe staffing or medicines practice.

Technology appraisals, interventional procedures, medical technologies and diagnostics guidance; and quality standards and advice products, are unaffected by this change.

NICE Guidelines (NGs)	**Gastro-oesophageal reflux disease: recognition, diagnosis and management in children and young people (NG1)** **Background information** This NICE guideline offers evidence-based advice on the recognition, diagnosis and management of gastro-oesophageal reflux disease in children and young people. Gastro-oesophageal reflux (GOR) is a normal physiological process that usually happens after eating in healthy infants, children, young people and adults. In contrast, gastro-oesophageal reflux disease (GORD) occurs when the effect of GOR leads to symptoms severe enough to merit medical treatment. GOR is more common in infants than in older children and young people, and it is noticeable by the effortless regurgitation of feeds in young babies. **The recommendations in full cover** 1.1 Diagnosing and investigating GORD 1.2 Initial management of GOR and GORD 1.3 Pharmacological treatment of GORD 1.4 Enteral tube feeding for GORD 1.5 Surgery for GORD **Financial factors** NHS organisations are advised to assess the resource implications of this guidance locally. Potential areas for savings and benefits locally are: • Fewer prescriptions for medication to treat GOR. • More frequent medication reviews leading to optimised periods of treatment. • More appropriate use of GP appointments. • Better concentration of paediatric resources on those with GORD.
Interventional Procedures Guidance (IPGs)	**Hysteroscopic metroplasty of a uterine septum for primary infertility (IPG509)** **Recommendations** 1.1 Current evidence on the safety of hysteroscopic metroplasty of a uterine septum for primary infertility includes some serious but rare complications. Current evidence on efficacy is inadequate in quantity and quality. Therefore this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research. 1.2 Clinicians wishing to undertake hysteroscopic metroplasty of a uterine septum for primary infertility should take the following actions: • Inform the clinical governance leads in their NHS trust. • Ensure that women understand the uncertainty about the procedure's efficacy and its risks and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. • Audit and review clinical outcomes of all women having hysteroscopic metroplasty of a uterine septum for primary infertility.

1.3 Patient selection and treatment should be done by a multidisciplinary team including specialists in reproductive medicine, uterine imaging and hysteroscopic surgery.

1.4 Clinicians undertaking hysteroscopic metroplasty of a uterine septum for primary infertility should be trained in hysteroscopic surgery in accordance with the Royal College of Obstetricians and Gynaecologists training module.

1.5 Further research should include clear documentation of patient selection and of all complications. Outcomes should include pregnancy rates, live birth rates and instances of preterm delivery. Comparative studies would be helpful. NICE may update the guidance on publication of further evidence.

The procedure

Hysteroscopic metroplasty of a uterine septum for primary infertility aims to create a normal uterine cavity by removing the uterine septum, which may help implantation of pregnancy.

Hysteroscopic metroplasty is usually done with the patient under general or spinal anaesthesia. After cervical dilation, a hysteroscope is inserted into the uterus through the cervix. The uterine cavity is distended with fluid; fluid control must be carefully monitored to avoid overload. The septum is excised, most commonly using microscissors, electrosurgery or laser. The procedure may be done using ultrasound or laparoscopic guidance.

Hysteroscopic metroplasty of a uterine septum for recurrent miscarriage (IPG510)

Recommendations

1.1 Current evidence on the safety of hysteroscopic metroplasty of a uterine septum for recurrent miscarriage includes some serious but rare complications. Current evidence on efficacy is adequate to support the use of this procedure provided that **normal arrangements** are in place for clinical governance, consent and audit.

1.2 Patient selection and treatment should be done by a multidisciplinary team including specialists in reproductive medicine, uterine imaging and hysteroscopic surgery.

1.3 Clinicians undertaking hysteroscopic metroplasty of a uterine septum for recurrent miscarriage should be trained in hysteroscopic surgery in accordance with the Royal College of Obstetricians and Gynaecologists training module.

The procedure

Hysteroscopic metroplasty of a uterine septum for recurrent miscarriage aims to create a normal uterine cavity by removing the septum, and consequently reduce the risk of miscarriage.

Hysteroscopic metroplasty is usually done with the patient under general or spinal anaesthesia. After cervical dilation, a hysteroscope is inserted into the uterus through the cervix. The uterine cavity is distended with fluid; fluid control must be carefully monitored to avoid overload. The septum is excised, most commonly using microscissors, electrosurgery or laser. The procedure may be done using ultrasound or laparoscopic guidance.

After a miscarriage, an interval of at least 6 weeks is left before doing a hysteroscopic metroplasty.

Open reduction of slipped capital femoral epiphysis (IPG511)

Recommendations

1.1 The evidence on efficacy of open reduction of slipped capital femoral epiphysis is adequate. With regard to safety, there is a risk of avascular necrosis. Therefore this procedure should only be used with **special arrangements** for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake open reduction of slipped capital femoral epiphysis should take the following actions:

- Inform the clinical governance leads in their NHS trusts. Specifically, local

governance arrangements should ensure that the procedure is done only by clinicians with appropriate training and experience.

- Ensure that patients and their parents or carers understand the potential outcomes of having or not having the procedure, in particular the risk of avascular necrosis and its consequences. In addition, the use of NICE's information for the public is recommended.

1.3 Clinicians should enter details about all patients having open reduction of slipped capital femoral epiphysis onto the British Society for Children's Orthopaedic Surgery (BSCOS) register, which is scheduled to go live in early 2015 and will be available at: bscosregistry.org.uk. Clinical outcomes should also be reviewed locally.

1.4 Training and experience are important in preserving the blood supply to the femoral head. When the procedure is done with surgical dislocation of the hip, clinicians should undertake their initial procedures with an experienced mentor.

1.5 Patient selection may be complex and specialists should consider, discuss with clinical colleagues, and record the balance between the potential benefits and risks of this procedure for each patient.

1.6 Further research into open reduction of slipped capital femoral epiphysis should clearly describe details of clinical presentation (for example, Loder classification), the degree of slip, its stability, and the surgical technique used; including whether surgical dislocation of the hip was done. Outcomes from 2 years onwards should include degree of correction, occurrence of avascular necrosis and need for subsequent hip surgery (and its timing).

The procedure

Open reduction of slipped capital femoral epiphysis aims to relocate the capital femoral epiphysis and centre its position in the acetabulum, while minimising the risk of avascular necrosis by preserving blood vessels to the epiphysis.

The procedure can be done in a variety of ways (some with eponymous names such as the Dunn, Bernese and Ganz approaches). Most involve a cuneiform (wedge-shaped) osteotomy of the femoral neck. An important point of the technique is whether or not the hip is surgically dislocated during the procedure. This is done to create an extended retinacular flap, to provide extensive subperiosteal exposure of the circumference of the femoral neck, and so protect the blood supply to the epiphysis, minimising the risk of avascular necrosis.

With the patient under general anaesthesia, an anterior or anterolateral approach is used to expose the hip and a capsulotomy is done; at this stage, the hip may be dislocated surgically. A section of bone is then removed from the metaphysis of the femoral neck. Reduction is done by adducting and rotating the limb, realigning the epiphysis in its normal position in the acetabulum. The realigned femoral neck is then secured with 1 or 2 cannulated screws or Kirschner wires.

Implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis (IPG512)

Recommendations

1.1 Current evidence on the safety and efficacy of implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis is inadequate in quantity and quality. Therefore, this procedure should only be used **in the context of research**.

1.2 Further research into implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis should include comparative studies against existing forms of management. Studies should record patient selection, functional outcomes, quality of life and complications. They should also report the nature and timing of any further surgery on the knee and the effect of removing the device. A minimum follow-up period of 2–3 years is needed. NICE may update the guidance on publication of further evidence.

The procedure

The aim of this procedure is to lighten the load on the knee when the person is standing by inserting a load absorber. This reduces pain and potentially delays the

	need for further surgery. The device is implanted subcutaneously outside the knee joint, along its medial aspect. It is secured to the femur and tibia. It is intended to keep surrounding structures including bone, muscle and ligaments intact, allowing subsequent surgery to be performed if necessary. The device can be removed at a later date. The procedure is performed with the patient under general anaesthesia and supine. Fluoroscopy is used to confirm alignment of the knee joint. Two incisions, over the medial aspects of the femoral and tibial condyles, are made. A femoral base plate is inserted through the proximal incision and attached to the medial femoral cortex using surgical screws; a tibial base plate is similarly attached to the medial tibial cortex. A tunnel is created between the 2 incisions beneath the skin using blunt dissection and the load absorber is implanted in this tunnel. The load absorber is attached to the 2 base plates. Its function is checked and the wounds are closed.
Medical Technologies Guidance	**None published so far this month**
Diagnostics Guidance	**None published so far this month**
NICE Quality Standards	**Urinary incontinence in women (QS77)** This quality standard covers the management of urinary incontinence in women aged 18 years and over. It does not cover urinary incontinence in women with neurological disease. **Sarcoma (QS78)** This quality standard covers the diagnosis, treatment, support and follow-up of sarcoma in children, young people and adults. **Idiopathic pulmonary fibrosis (QS79)** This quality standard covers the diagnosis and management of idiopathic pulmonary fibrosis in adults, from the initial suspicion of the disease to referral, supportive care and treatment.
NICE Pathways	These pathways are not guidance in themselves but a way of displaying online the various guidance that exists around a subject.
Commissioning Guides	**None published so far this month**
Public health briefings for local government	**Tobacco (LGB24)** This briefing summarises NICE's recommendations for local authorities and partner organisations on tobacco. It is particularly aimed at health and wellbeing boards. It is an update of NICE's local government briefing on tobacco published in July 2012. The recommendations cover: how to prevent people from taking up smoking and helping them to stop; reducing tobacco use in the community; reducing the harm caused by smoking; and helping South Asian communities to stop using smokeless tobacco.

Current NICE consultations with links and start and finish dates for stakeholders to make contribution

Title / link	Start date of consultation	End date of consultation
Diabetes in children and young people: guideline consultation	10/12/2014	04/03/2015
Type 1 Diabetes (update): guideline consultation	10/12/2014	04/03/2015
Sunlight exposure - benefits and risks: guideline consultation	23/12/2014	10/12/2015
Diabetic foot problems: guideline consultation	07/01/2015	04/03/2015
Type 2 Diabetes: guideline consultation	07/01/2015	04/03/2015
Increasing the uptake of HIV testing among people at higher risk of exposure: scope consultation	13/01/2015	10/02/2015
Accident and emergency departments - guideline consultation	16/01/2015	12/02/2015
Severe mental illness and substance misuse (dual diagnosis) - community health and social care services: call for evidence	22/01/2015	19/02/2015
Electrotherapy for the treatment of haemorrhoids: consultation	26/01/2015	19/02/2015
Asthma - diagnosis and monitoring: guideline consultation	28/01/2015	11/03/2015
Implantation of a sphenopalatine ganglion stimulation device for chronic cluster headache: consultation	29/01/2015	25/02/2015
Implanting a baroreceptor stimulation device for resistant hypertension: consultation	29/01/2015	25/02/2015
Homes - preventing accident and unintentional injury among children and young people under 15: topic engagement exercise	30/01/2015	13/02/2015
Melanoma: guideline consultation	30/01/2015	13/03/2015
Safe staffing - Mental health in-patient settings: call for evidence	30/01/2015	13/02/2015
Eating disorders (update): scope consultation	02/02/2015	02/03/2015
Lower urinary tract symptoms (update SC): addendum consultation	03/02/2015	03/03/2015
Smoking - harm reduction: quality standard consultation	05/02/2015	05/03/2015
Intrapartum care: topic engagement exercise	10/02/2015	24/02/2015

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