

NICE Update Bulletin November 2014 for guidance issued Wednesday 17th December 2014

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
<p>Technology Appraisals (TAs)</p>	<p><u>Dabigatran etexilate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism TA327</u></p> <p><u>Background</u></p> <p>Deep vein thrombosis is the formation of a thrombus in a deep vein, usually of the lower limbs. Dislodged thrombi may travel to the lungs (pulmonary embolism). Pulmonary embolism can cause sudden death and those who survive a pulmonary embolism occasionally require intensive care and recovery can take several weeks or months.</p> <p>Venous thromboembolism has an annual incidence of approximately 2 in 1,000 of the general population in the UK. This rate varies substantially with age - for people under 40 years the annual incidence of venous thromboembolism is 1 in 10,000, whereas for people over 80 years the incidence rises to 1 in 100. People who have had an episode of venous thromboembolism have a risk of recurrence within 8 years of approximately 30%. However, the risk of recurrence decreases substantially with time and may vary according to the treatment received.</p> <p><u>Recommendations</u></p> <p>Dabigatran etexilate is recommended, within its marketing authorisation, as an option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults.</p> <p><u>The technology</u></p> <p>Dabigatran etexilate is an oral direct thrombin inhibitor that specifically and reversibly inhibits thrombin, a key enzyme in blood clot formation. It is licensed for the treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. Dabigatran etexilate is contraindicated in people with severely reduced kidney function.</p> <p><u>Financial factors</u></p> <p>Dabigatran etexilate costs £65.90 for a 60-capsule pack of the 150 mg or 110 mg doses and costs £2.20 per day of treatment. Costs may vary in different settings because of negotiated procurement discounts.</p> <p>Dabigatran etexilate provides another option for treating and for preventing recurrent deep vein thrombosis and pulmonary embolism in adults. Because it is likely to be given as an alternative to rivaroxaban and the 2 drugs are similarly priced, NICE does not anticipate a significant impact on resources.</p> <p><u>Idelalisib for treating follicular lymphoma that is refractory to 2 prior treatments (terminated appraisal) TA328</u></p> <p>NICE is unable to make a recommendation about the use in the NHS of idelalisib for treating follicular lymphoma that is refractory to 2 prior lines of treatment because no evidence submission was received from Gilead Sciences for the technology.</p>
<p>Clinical Guidelines (CGs)</p>	<p><u>Postnatal care CG37</u></p> <p><u>Background information</u></p> <p>This guideline offers best practice advice on the care that every woman and her baby should receive in the first 6–8 weeks after birth. The advice on co-sleeping and sudden infant death syndrome covers the first year of an infant's life. Although for most women and babies the postnatal period is uncomplicated, care during this period needs to address any deviation from expected recovery after birth. This guideline gives advice on when additional care may be needed.</p>

The recommendations in full cover

- 1.1 Planning the content and delivery of care
- 1.2 Maternal health
- 1.3 Infant feeding
- 1.4 Maintaining infant health

Key priorities for implementation

Multiple recommendations were identified as priorities for implementation in the 2006 guideline and were not changed in this 2014 update.

Financial factors

NICE have not produced an updated costing statement for 2014 but in their 2006 costing statement predicted that full implementation of the guidance would result in a small net saving of approximately £1 Million for England by 2012-13.

[Colorectal cancer CG131](#)

Background information

Colorectal cancer is one of the most common cancers in the UK after breast and lung cancer, with approximately 40,000 new cases registered each year. Occurrence of colorectal cancer is strongly related to age, with almost three-quarters of cases occurring in people aged 65 or over. Colorectal cancer is the second most common cause of cancer death in the UK. Around half of people diagnosed with colorectal cancer survive for at least 5 years after diagnosis.

The recommendations in full cover

- 1.1 Investigation, diagnosis and staging
- 1.2 Management of local disease
- 1.3 Management of metastatic disease
- 1.4 Ongoing care and support

Key priorities for implementation

- Diagnostic investigations
- Staging of colorectal cancer
- Preoperative management of the primary tumour
- Colonic stents in acute large bowel obstruction
- Stage I colorectal cancer
- Imaging hepatic metastases
- Follow-up after apparently curative resection
- Information about bowel function

Financial factors

The NICE costing report states that because of insufficient data and variation in current practice, it is not possible to quantify the national cost impact of implementing the guidance.

The recommendations that are likely to have the greatest resource impact are

- Diagnostic investigations
- Adjuvant chemotherapy for patients with high-risk stage II colon cancer
- Imaging for suspected metastases
- Chemotherapy for advanced and metastatic colorectal cancer

[Intrapartum care: care of healthy women and their babies during childbirth CG190](#)

Background information

This guideline updates and replaces NICE guideline CG55 (published September 2007). It offers evidence-based advice on the care of women and their babies during labour and

immediately after the birth. It covers healthy women with uncomplicated pregnancies entering labour at low risk of developing intrapartum complications.

New recommendations have been added in a number of areas, including choosing place of birth, care during the latent first stage of labour, transfer of care, fetal assessment and monitoring during labour (particularly cardiotocography compared with intermittent auscultation) and management of the third stage of labour.

The recommendations in full cover

- 1.1 Place of birth
- 1.2 Care throughout labour
- 1.3 Latent first stage of labour
- 1.4 Initial assessment
- 1.5 Ongoing assessment
- 1.6 General principles for transfer of care
- 1.7 Care in established labour
- 1.8 Pain relief in labour: non-regional
- 1.9 Pain relief in labour: regional analgesia
- 1.10 Monitoring during labour
- 1.11 Prelabour rupture of membranes at term
- 1.12 First stage of labour
- 1.13 Second stage of labour
- 1.14 Third stage of labour
- 1.15 Care of the newborn baby
- 1.16 Care of the woman after birth

Key priorities for implementation

- Place of birth
- Measuring fetal heart rate as part of initial assessment
- Interpretation of cardiotocograph traces
- First stage of labour
- Third stage of labour

Financial factors

The NICE costing statement advises NHS organisations to assess the resource implications of this guidance locally. Potential areas for additional costs locally are:

- training for staff who may move from 1 type of birth unit to another if services are reorganised
- promoting midwifery units and education for women about their choice of place of birth
- additional staff resource requirements in order to provide one-to-one care for women in labour
- capital cost of refurbishment of existing estate or, if required, identification of buildings or land for new midwifery units
- resource requirements for ambulance transfer services.

[Pneumonia CG191](#)

Background information

Every year between 0.5% and 1% of adults in the UK will have community-acquired pneumonia. It is diagnosed in 5–12% of adults who present to GPs with symptoms of lower respiratory tract infection, and 22–42% of these are admitted to hospital. At any time 1.5% of hospital inpatients in England have a hospital-acquired respiratory infection.

Variations in clinical management and outcome occur across the UK.

The recommendations in full cover

- 1.1 Presentation with lower respiratory tract infection
- 1.2 Community-acquired pneumonia
- 1.3 Hospital-acquired pneumonia

Key priorities for implementation

- Presentation with lower respiratory tract infection
- Community-acquired pneumonia

Financial factors

The NICE costing report advises NHS organisations to assess the resource implications of this guidance locally. Potential areas for additional costs locally are:

- C-reactive protein testing in primary care, including the one-off cost of analysers at £3.8 million for England, and recurring costs (such as reagents and maintenance costs) of around £13.50 per test.
- More timely diagnosis and targeted treatment of community-acquired pneumonia on presentation at hospital.

[Antenatal and postnatal mental health: clinical management and service guidance CG192](#)

Background information

This guideline updates and replaces NICE guideline CG45 (published February 2007) and replaces section 1.5.6 in NICE guideline CG62 (published March 2008). It offers evidence-based advice on the recognition, assessment, care and treatment of mental health problems in women during pregnancy and the postnatal period (up to 1 year after childbirth), and in women who are planning a pregnancy. New recommendations have been added in all sections except the section on the organisation of services.

The recommendations in full cover

- 1.1 Using this guideline in conjunction with other NICE guidelines
- 1.2 Considerations for women of childbearing potential
- 1.3 Principles of care in pregnancy and the postnatal period
- 1.4 Treatment decisions, advice and monitoring for women who are planning a pregnancy, pregnant or in the postnatal period
- 1.5 Recognising mental health problems in pregnancy and the postnatal period and referral
- 1.6 Assessment and care planning in pregnancy and the postnatal period
- 1.7 Providing interventions in pregnancy and the postnatal period
- 1.8 Treating specific mental health problems in pregnancy and the postnatal period
- 1.9 Considerations for women and their babies in the postnatal period
- 1.10 The organisation of services

Key priorities for implementation

- Considerations for women of childbearing potential
- Principles of care in pregnancy and the postnatal period
- Treatment decisions, advice and monitoring for women who are planning a pregnancy, pregnant or in the postnatal period
- Recognising mental health problems in pregnancy and the postnatal period and referral
- Providing interventions in pregnancy and the postnatal period

	<ul style="list-style-type: none"> • Considerations for women and their babies in the postnatal period • The organisation of services <p><u>Financial factors</u></p> <p>The recommendations identified by the NICE costing report that have the most resource impact are shown below and estimated to be £10.8 million for England.</p> <ul style="list-style-type: none"> • Clinical networks should be established for perinatal mental health services [recommendation 1.10.3]. • Each managed perinatal mental health network should have designated specialist inpatient services [recommendation 1.10.5]. <p>Specialised perinatal mental health services, which include mother and baby units will be commissioned by NHS England under specialised commissioning arrangements. Perinatal networks will also be commissioned by NHS England, however some of the care provided for women during pregnancy and the first year after giving birth, will be commissioned by clinical commissioning groups (CCGs).</p>
Public Health Guidance	None published so far this month
Medical Technologies Guidance	None published so far this month
NICE Quality Standards	<p>Antibiotics for neonatal infection</p> <p>This quality standard covers the use of antibiotics to prevent and treat infection in newborn babies (both term and preterm) from birth to 28 days in primary (including community) and secondary care.</p>
Safe staffing guideline	None published so far this month
Interventional Procedures Guidance (IPGs)	<p>Insertion of a collagen plug to close an abdominal wall enterocutaneous fistula IPG507</p> <p><u>Recommendations</u></p> <p>1.1 Current evidence on the safety and efficacy of insertion of a collagen plug to close an abdominal wall enterocutaneous fistula is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.</p> <p>1.2 Clinicians wishing to insert a collagen plug to close an abdominal wall Enterocutaneous fistula should take the following actions.</p> <ul style="list-style-type: none"> • Inform the clinical governance leads in their NHS trust. • Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended. <p>Audit and review clinical outcomes of all patients having insertion of a collagen plug to close an abdominal wall enterocutaneous fistula.</p> <p>1.3 NICE encourages further research into insertion of a collagen plug to close an abdominal wall enterocutaneous fistula. Research should ideally take the form of prospective studies that compare the course of the enterocutaneous fistula (its natural history) with and without use of the procedure. Reports should record the conditions underlying all fistulas that are treated, their location, whether they are high or low output, and details of previous treatments. NICE may update the guidance on publication of further evidence.</p>

	<p><u>The procedure</u></p> <p>The fistula track is visualised using fluoroscopy, a guide wire is inserted from the skin surface through the track into the bowel lumen and a delivery sheath is put in place. A collagen plug is passed through the track under fluoroscopic guidance. The collagen plug fills the fistula track and acts as a scaffold for tissue growth, allowing the fistula to become filled with tissue and to heal. The patient is usually kept in hospital for a few days of strict bed rest, to prevent displacement of the plug and to encourage its incorporation.</p> <p><u>Single-incision laparoscopic cholecystectomy IPG508</u></p> <p><u>Recommendations</u></p> <p>This document replaces previous guidance on single-incision laparoscopic cholecystectomy (interventional procedure guidance 346).</p> <p>1.1 Current evidence on the safety and efficacy of single-incision laparoscopic cholecystectomy is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.</p> <p>1.2 Single-incision laparoscopic cholecystectomy is technically challenging and should only be carried out by experienced laparoscopic surgeons who have had specific training in the procedure.</p> <p><u>The procedure</u></p> <p>Single-incision laparoscopic cholecystectomy aims to remove the gallbladder through a single incision which is usually made near the umbilicus. The claimed benefits of this procedure over standard laparoscopic cholecystectomy include less pain, shorter recovery time, fewer wound complications and improved cosmesis.</p>
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
Diagnostics Guidance	<p><u>Fluorouracil chemotherapy DG16</u></p> <p><u>Recommendations</u></p> <p>The My5-FU assay is only recommended for use in research for guiding dose adjustment in people having fluorouracil chemotherapy by continuous infusion. The My5-FU assay shows promise and the development of robust evidence is recommended to demonstrate its utility in clinical practice).</p> <p><u>The Technology</u></p> <p>The My5 FU assay can be used to guide pharmacokinetic dose adjustment and to monitor the levels of 5 fluorouracil (5 FU) in the blood (therapeutic drug monitoring) in people having 5 FU chemotherapy by continuous infusion. The aim is to achieve an optimal plasma level of the drug. Increasing the number of people with plasma levels within the therapeutic range may result in increased therapeutic effect without additional toxicity.</p>
Public health briefings for local government	None published so far this month

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

Title / link	Start date of consultation	Finish date of consultation
Cystic fibrosis: scope consultation	20/11/2014	18/12/2014
Implantation of Left Ventricular Assist Device (LVAD) for destination therapy: consultation	20/11/2014	18/12/2014
Insertion of a balloon device to disimpact an engaged fetal head prior to emergency caesarean section: consultation	20/11/2014	18/12/2014
Radiofrequency ablation for gastric antral vascular ectasia: consultation	20/11/2014	18/12/2014
Transanal total mesorectal excision of the rectum: consultation	20/11/2014	18/12/2014
Ultrasound enhanced catheter-directed thrombolysis for deep vein thrombosis: consultation	20/11/2014	18/12/2014
Ultrasound enhanced catheter-directed thrombolysis for pulmonary embolism: consultation	20/11/2014	18/12/2014
Osteoarthritis: quality standard consultation	21/11/2014	19/12/2014
Personality disorders (borderline and antisocial): quality standard consultation	21/11/2014	19/12/2014
Depression in children and young people (update): addendum consultation	24/11/2014	22/12/2014
Mental health in-patient settings: scope consultation	01/12/2014	31/12/2014
Preventing unintentional injury: topic engagement exercise	10/12/2014	05/01/2015
Bronchiolitis in children: guideline consultation	17/11/2014	05/01/2015
Leukaemia (chronic lymphocytic) - obinutuzumab (with chlorambucil, 1st line) [ID650]: appraisal consultation 2	02/12/2014	06/01/2015
Psoriatic arthritis (active) - ustekinumab (Rapid Rev TA313): appraisal consultation	09/12/2014	07/01/2015
Bipolar disorder, psychosis and schizophrenia in children and young people: topic engagement exercise	15/12/2014	08/01/2015
Anaemia management in chronic kidney disease (update): guideline consultation	17/11/2014	08/01/2015
Prostate cancer (hormone relapsed, bone metastases) - radium-223 dichloride [ID576]: appraisal consultation 2	15/12/2015	09/01/2015
Violence and aggression (update): guideline consultation	19/11/2014	14/01/2015
Pressure ulcers: quality standard consultation	12/12/2014	20/01/2015
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
Suspected cancer (update): guideline consultation	20/11/2014	09/11/2015

Produced by

**Andrew Williams (Clinical Effectiveness Technical Support
Officer) NEW Devon CCG Clinical Effectiveness and Medicines
Optimisation Team**

**For distribution Northern, Eastern and Western Devon CCG &
South Devon and Torbay CCG**

County Hall, Topsham Road, Exeter, EX2 4QL

Tel: 01392 26 7771

Email: andrew.williams6@nhs.net