

# NICE Update Bulletin June 2014 for guidance issued Wednesday 25<sup>th</sup> June 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>)

<b>Type</b>	<b>Guidance title and reference number</b>
<b>Technology Appraisals (TAs)</b>	<p data-bbox="395 434 1460 501"><a href="#"><u>Implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy for arrhythmias and heart failure (review of TA95 and TA120) TA314</u></a></p> <p data-bbox="395 528 555 562"><b><u>Background</u></b></p> <p data-bbox="395 573 1460 757">Ventricular arrhythmias most commonly occur in people with underlying heart disease. Approximately 75–80% of the 70,000 sudden cardiac deaths in England and Wales in 2010 could be attributed to ventricular arrhythmias. The average chance of survival of adults after an out-of-hospital episode of ventricular arrhythmia has been reported to be as low as 7%. However, with appropriate treatment, recent studies have reported 5-year survival of 69-100% in people who had survived a cardiac arrest.</p> <p data-bbox="395 775 639 808"><b><u>Recommendations</u></b></p> <p data-bbox="395 819 1369 853">1.1 Implantable cardioverter defibrillators (ICDs) are recommended as options for:</p> <ul style="list-style-type: none"> <li data-bbox="443 869 1460 936">• treating people with previous serious ventricular arrhythmia, that is, people who, without a treatable cause: <ul style="list-style-type: none"> <li data-bbox="544 947 1460 1014">○ have survived a cardiac arrest caused by either ventricular tachycardia (VT) or ventricular fibrillation <b>or</b></li> <li data-bbox="544 1025 1460 1093">○ have spontaneous sustained VT causing syncope or significant haemodynamic compromise <b>or</b></li> <li data-bbox="544 1104 1460 1227">○ have sustained VT without syncope or cardiac arrest, and also have an associated reduction in left ventricular ejection fraction (LVEF) of 35% or less but their symptoms are no worse than class III of the New York Heart Association (NYHA) functional classification of heart failure.</li> </ul> </li> <li data-bbox="443 1238 1460 1272">• treating people who: <ul style="list-style-type: none"> <li data-bbox="544 1283 1460 1384">○ have a familial cardiac condition with a high risk of sudden death, such as long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia <b>or</b></li> <li data-bbox="544 1395 1460 1429">○ have undergone surgical repair of congenital heart disease.</li> </ul> </li> </ul> <p data-bbox="395 1440 1460 1563">1.2 Implantable cardioverter defibrillators (ICDs), cardiac resynchronisation therapy (CRT) with defibrillator (CRT-D) or CRT with pacing (CRT-P) are recommended as treatment options for people with heart failure who have left ventricular dysfunction with a left ventricular ejection fraction (LVEF) of 35% or less as specified in table 1 (<a href="#">link here</a>)</p> <p data-bbox="395 1581 600 1615"><b><u>The technology</u></b></p> <p data-bbox="395 1626 1460 1839">Implantable cardioverter defibrillators (ICDs) are small, battery-powered devices that are implanted under the skin just below the collarbone, with leads inserted into the heart. The devices operate by sensing and analysing the electrical activity of the heart, thereby monitoring for arrhythmia, and delivering electrical pulses or shocks to restore normal rhythm if necessary. Based on average selling prices aggregated across all manufacturers of ICDs sold in the UK to the NHS in the financial year of 2011, the cost of a complete ICD system was estimated at £9,692.</p> <p data-bbox="395 1899 1305 1933"><a href="#"><u>Canagliflozin in combination therapy for treating type 2 diabetes TA315</u></a></p> <p data-bbox="395 1951 647 1984"><b><u>Recommendations</u></b></p> <p data-bbox="395 1995 1294 2051">1.1 Canagliflozin in a dual therapy regimen in combination with metformin is recommended as an option for treating type 2 diabetes, only if:</p>

	<ul style="list-style-type: none"> <li>• a sulfonylurea is contraindicated or not tolerated <b>or</b></li> <li>• the person is at significant risk of hypoglycaemia or its consequences.</li> </ul> <p>1.2 Canagliflozin in a triple therapy regimen is recommended as an option for treating type 2 diabetes in combination with:</p> <ul style="list-style-type: none"> <li>• metformin and a sulfonylurea <b>or</b></li> <li>• metformin and a thiazolidinedione.</li> </ul> <p>1.3 Canagliflozin in combination with insulin with or without other antidiabetic drugs is recommended as an option for treating type 2 diabetes.</p> <p>1.4 People currently receiving treatment initiated within the NHS with canagliflozin that is not recommended for them by NICE in this guidance should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.</p> <p><b><u>The technology</u></b></p> <p>Canagliflozin is an orally administered selective sodium–glucose cotransporter-2 (SGLT-2) inhibitor. It lowers blood glucose in people with type 2 diabetes by blocking the reabsorption of glucose in the kidneys and promoting excretion of excess glucose in the urine. The expected annual cost of canagliflozin is £476.93 for the 100 mg daily dosage and £608.21 for the 300 mg daily dosage. Costs may vary in different settings because of negotiated procurement discounts.</p>
<p><b>Clinical Guidelines (CGs)</b></p>	<p><b><u><a href="#">Atrial fibrillation: the management of atrial fibrillation – CG180</a></u></b></p> <p>This guideline updates and replaces 'Atrial fibrillation' (NICE clinical guideline 36).</p> <p><b><u>Background information</u></b></p> <p>Atrial fibrillation is the most common sustained cardiac arrhythmia, and estimates suggest its prevalence is increasing. If left untreated atrial fibrillation is a significant risk factor for stroke and other morbidities. Men are more commonly affected than women and the prevalence increases with age.</p> <p>The aim of treatment is to prevent complications, particularly stroke, and alleviate symptoms. Drug treatments include anticoagulants to reduce the risk of stroke and antiarrhythmics to restore or maintain the normal heart rhythm or to slow the heart rate in people who remain in atrial fibrillation. Non-pharmacological management includes electrical cardioversion, which may be used to 'shock' the heart back to its normal rhythm, and catheter or surgical ablation to create lesions to stop the abnormal electrical impulses that cause atrial fibrillation.</p> <p>This updated guideline addresses several clinical areas in which new evidence has become available, including stroke and bleeding risk stratification, the role of new antithrombotic agents and ablation strategies.</p> <p>The recommendations apply to adults (18 years or older) with atrial fibrillation, including paroxysmal (recurrent), persistent and permanent atrial fibrillation, and atrial flutter. They do not apply to people with congenital heart disease precipitating atrial fibrillation.</p> <p><b><u>The key priorities for implementation are</u></b></p> <ul style="list-style-type: none"> <li>• Personalised package of care and information</li> <li>• Referral for specialised management</li> <li>• Assessment of stroke and bleeding risks</li> <li>• Interventions to prevent stroke</li> <li>• Rate and rhythm control</li> </ul> <p><b><u>The recommendations in full cover</u></b></p> <ol style="list-style-type: none"> <li>1.1 Diagnosis and assessment</li> <li>1.2 Personalised package of care and information</li> <li>1.3 Referral for specialised management</li> <li>1.4 Assessment of stroke and bleeding risks</li> </ol>

	<p>1.5 Interventions to prevent stroke</p> <p>1.6 Rate and rhythm control</p> <p>1.7 Management for people presenting acutely with atrial fibrillation</p> <p>1.8 Initial management of stroke and atrial fibrillation</p> <p>1.9 Prevention and management of postoperative atrial fibrillation</p>
<p><b>Public Health Guidance</b></p>	<p><b>None published so far this month</b></p>
<p><b>Medical Technologies Guidance</b></p>	<p><a href="#"><u>The MAGEC system for spinal lengthening in children with scoliosis MTG 18</u></a></p> <p><b><u>Recommendations</u></b></p> <p>1.1 The case for adopting the MAGEC system for spinal lengthening in children with scoliosis is supported by the evidence. Using the MAGEC system would avoid repeated surgical procedures for growth rod lengthening. This could reduce complications and have other physical and psychological benefits for affected children and their families.</p> <p>1.2 The MAGEC system should be considered for use in children with scoliosis aged 2 years and over who need surgery to correct their spinal curvature, for example when conservative methods such as bracing or casting have failed.</p> <p>1.3 Findings from cost modelling estimate that using the MAGEC system is cost saving compared with conventional growth rods from about 3 years after first insertion. The estimated cost saving per child after 6 years is around £12,077. The cost savings remained robust in sensitivity analyses. Further savings could be made by avoiding the need for spinal cord monitoring, which is sometimes used during conventional growth rod lengthening but is not needed when lengthening the MAGEC growth rods.</p> <p><b><u>The technology</u></b></p> <p>The MAGEC system comprises 1 or 2 sterile titanium implantable growth rods and an external remote control for non-invasive lengthening. The diameter of the rods used depends on the child's body weight. Lengthening is achieved by using an external portable remote control which uses permanent magnets to rotate the fixed magnet within the rod turning an internal screw-thread.</p> <p><a href="#"><u>The geko device for reducing the risk of venous thromboembolism MTG19</u></a></p> <p><b><u>Recommendations</u></b></p> <p>1.1 The case for adopting the geko device is supported for use in people who have a high risk of venous thromboembolism and for whom other mechanical and pharmacological methods of prophylaxis are impractical or contraindicated. Although clinical evidence is limited, the case is supported because of the plausibility that the geko device may reduce the high risk of venous thromboembolism in patients who cannot use other forms of prophylaxis, and the low risk of the device causing harm.</p> <p>1.2 In patients at high risk of venous thromboembolism who would otherwise receive no prophylaxis, using the geko device is estimated to be cost saving. The amount saved depends on the level of reduction in relative risk of deep vein thrombosis associated with geko treatment compared with no treatment. There is no direct evidence on the size of this reduction, but when values obtained with other mechanical methods of prophylaxis were used in cost modelling, the estimated cost saving for the geko device in patients at high risk of venous thromboembolism compared with no prophylaxis was £197 per patient.</p> <p><b><u>The technology</u></b></p> <p>The geko device is a portable, compact, light (weight 16g) and resembles a small wristwatch. It is applied via a self-adhesive strip to the skin over the fibular head (or other application site) below the crease of the knee. The device uses a patented electrical impulse delivery system. The impulses stimulate the common peroneal nerve, which causes muscular contractions in the lower leg and foot. The muscular action drives the venous muscle pump of the lower leg, facilitating the emptying of veins and increasing</p>

	<p>the return of blood to the heart. The list price stated in the sponsor's submission is £22 (excluding VAT) per pair of geko devices.</p>
<p><b>NICE Quality Standards</b></p>	<p>None published so far this month</p>
<p><b>Interventional Procedures Guidance (IPGs)</b></p>	<p><a href="#"><u>Arthroscopic radiofrequency chondroplasty for discrete chondral defects of the knee IPG 493</u></a></p> <p><b>Recommendations</b></p> <p>1.1 Evidence on the efficacy of arthroscopic radiofrequency chondroplasty for discrete chondral defects of the knee is limited but shows benefit in the short term, and there are no major safety concerns. <b>Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.</b></p> <p>1.2 The procedure should only be carried out by clinicians with specific training in the use of arthroscopic radiofrequency ablation and with particular attention to the avoidance of thermal injury.</p> <p>1.3 Further research into arthroscopic radiofrequency chondroplasty of the knee should clearly document patient selection and the types of chondral defects being treated. More evidence on long-term outcomes would be useful.</p> <p><b>The procedure</b></p> <p>Radiofrequency chondroplasty aims to slow the progression of discrete chondral defects by removing the unstable edges of the defect, producing a smooth, stable articular cartilage surface. An arthroscope is inserted into the knee and large chondral defects are trimmed from the weight-bearing surfaces of the femoral condyles, using instruments such as a blunt hook or an electric shaver. Under arthroscopic guidance, a radiofrequency probe is then used to smooth the edge of the chondral defect using irrigation to stabilise temperature and flush any debris.</p> <p><a href="#"><u>Endoscopic saphenous vein harvest for coronary artery bypass grafting IPG494</u></a></p> <p><b>Recommendations</b></p> <p>1.1 Current evidence on the efficacy and safety of endoscopic saphenous vein harvest for coronary artery bypass grafting (CABG) is <b>adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.</b></p> <p>1.2 Clinicians should enter details of all patients undergoing endoscopic saphenous vein harvest for CABG onto the UK Central Cardiac Audit Database.</p> <p><b>The procedure</b></p> <p>The procedure is carried out with the patient under general anaesthesia, at the same time as coronary artery bypass grafting. An endoscope is usually inserted through a short incision near the knee, to visualise the subcutaneous plane in which the great saphenous vein lies. Carbon dioxide insufflation may be used to open this space. The vein is mobilised by blunt dissection and its tributaries are clipped and divided before removing the dissected segment of vein.</p> <p><a href="#"><u>Radiofrequency tissue reduction for turbinate hypertrophy IPG495</u></a></p> <p><b>Recommendations</b></p> <p>1.1 Current evidence on the safety of radiofrequency tissue reduction for turbinate hypertrophy is adequate. Evidence on efficacy in the short and medium term (to about 2 years) is also adequate. <b>Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.</b></p> <p>1.2 During the consent process patients should be informed about alternative treatment options. They should be warned about the risk of recurrence of symptoms and the possible need for further treatments.</p> <p><b>The procedure</b></p> <p>Inferior turbinates are ridges inside the nose, covered by mucous membrane, which</p>

	<p>increase the surface area within the nose and help to filter and humidify inspired air. Radiofrequency tissue reduction is usually performed using local anaesthesia in an outpatient setting. A radiofrequency probe is inserted submucosally radiofrequency energy is applied for a number of seconds to the anterior, middle and posterior third of each inferior turbinate, heating the submucosal tissue around the probe and causing coagulation. Small blood vessels responsible for the enlargement of the turbinate are also ablated during the procedure, limiting their ability to swell and expand. The submucosal tissue shrinks during healing, thereby reducing excess tissue volume.</p>
<b>NICE Pathways</b>	<p>These pathways are not guidance in themselves but a way of displaying online the various guidance that exists around a subject.</p>
<b>Commissioning Guides</b>	<p><b>None published so far this month</b></p>
<b>Diagnostics Guidance</b>	<p><b>None published so far this month</b></p>
<b>Public health briefings for local government</b>	<p>These briefings will be relevant to local authority officers and councillors, directors of public health, and commissioners and directors of adult social care and children's services. It will also be relevant to members of local authority scrutiny committees.</p> <p><a href="#"><u>Looked-after children and young people LGB19</u></a></p> <p><a href="#"><u>Domestic violence and abuse: how services can respond effectively LGB20</u></a></p> <p><a href="#"><u>HIV testing LGB21</u></a></p>

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

<b>Title / link</b>	<b>Start date of consultation</b>	<b>Finish date of consultation</b>
<a href="#">Constipation in children and young people: surveillance review proposal</a>	16/06/2014	27/06/2014
<a href="#">Renal replacement therapy services: quality standard consultation</a>	12/06/2014	27/06/2014
<a href="#">Acute Kidney Injury: quality standard consultation</a>	30/05/2014	27/06/2014
<a href="#">Key Therapeutics Topics - 2014 update</a>	02/06/2014	30/06/2014
<a href="#">Developing NICE guidelines - the manual</a>	01/04/2014	30/06/2014
<a href="#">Oral health - in nursing and residential care: consultation on the draft scope</a>	03/06/2014	01/07/2014
<a href="#">Sofosbuvir for treating chronic hepatitis C: appraisal consultation</a>	16/06/2014	04/07/2014
<a href="#">Behaviour change: consultation on the review proposal</a>	23/06/2014	07/07/2014
<a href="#">Community engagement: call for evidence</a>	17/06/2014	08/07/2014
<a href="#">Long acting reversible contraception: addendum consultation</a>	11/06/2014	09/07/2014
<a href="#">Parafricta Bootees and Undergarments to reduce skin breakdown in people with or at risk of pressure ulcers: guidance consultation</a>	12/06/2014	10/07/2014
<a href="#">Mental health problems in people with learning disability: scope consultation</a>	12/06/2014	10/07/2014
<a href="#">Workplace health - older employees: call for evidence</a>	11/06/2014	10/07/2014
<a href="#">Gallstone disease: guideline consultation</a>	05/06/2014	17/07/2014
<a href="#">Insertion of an annular disc implant at lumbar discectomy: interventional procedures consultation</a>	20/06/2014	18/07/2014
<a href="#">Telemetric adjustable pulmonary artery banding for reducing pulmonary hypertension in infants with congenital heart defects: interventional procedures consultation</a>	20/06/2014	18/07/2014
<a href="#">Open reduction of slipped capital femoral epiphysis: interventional procedures consultation</a>	20/06/2014	18/07/2014
<a href="#">Cyanoacrylate glue ablation for the treatment of varicose veins: interventional procedures consultation</a>	20/06/2014	18/07/2014
<a href="#">Excess winter deaths and illnesses: guideline consultation</a>	13/06/2014	25/07/2014
<a href="#">Pneumonia: guideline consultation</a>	18/06/2014	30/07/2014
<a href="#">Accreditation process manual update consultation</a>	02/06/2014	26/08/2014
<a href="#">Quality standards process guide consultation (update)</a>	10/06/2014	03/09/2014

**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](mailto:andrew.williams6@nhs.net)**