

1	<p>Treatment & Condition</p> <p>Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure</p>																													
2	<p>Associated appraisal body & Summary of ruling <i>(to include indication, restrictions, other relevant information)</i></p> <p>NICE Technology Appraisal Guidance 314 (June 2014)</p> <p>Implantable cardioverter defibrillators (ICDs) are recommended as options for:</p> <ol style="list-style-type: none"> 1) treating people with previous serious ventricular arrhythmia, that is, people who, without a treatable cause: <ul style="list-style-type: none"> • have survived a cardiac arrest caused by either ventricular tachycardia (VT) or ventricular fibrillation or • have spontaneous sustained VT causing syncope or significant haemodynamic compromise or • 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. 2) treating people who: <ul style="list-style-type: none"> • 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 or • have undergone surgical repair of congenital heart disease. <p>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.</p> <p>Table 1: Treatment options with ICD or CRT for people with heart failure who have left ventricular dysfunction with an LVEF of 35% or less (according to NYHA class, QRS duration and presence of LBBB)</p> <table border="1" data-bbox="244 1682 1437 2094"> <thead> <tr> <th rowspan="2">QRS Interval</th> <th colspan="4">NYHA class</th> </tr> <tr> <th>I</th> <th>II</th> <th>III</th> <th>IV</th> </tr> </thead> <tbody> <tr> <td><120 milliseconds</td> <td colspan="3">ICD if there is a high risk of sudden cardiac death</td> <td>ICD and CRT not clinically indicated</td> </tr> <tr> <td>120-149 milliseconds without LBBB</td> <td>ICD</td> <td>ICD</td> <td>ICD</td> <td>CRT-P</td> </tr> <tr> <td>120-149 milliseconds with LBBB</td> <td>ICD</td> <td>CRT-D</td> <td>CRT-P or CRT-D</td> <td>CRT-P</td> </tr> <tr> <td>≥150 milliseconds without LBBB</td> <td>CRT-D</td> <td>CRT-D</td> <td>CRT-P or CRT-D</td> <td>CRT-P</td> </tr> </tbody> </table> <p>LBBB, left bundle branch block; NYHA, New York Heart Association</p>	QRS Interval	NYHA class				I	II	III	IV	<120 milliseconds	ICD if there is a high risk of sudden cardiac death			ICD and CRT not clinically indicated	120-149 milliseconds without LBBB	ICD	ICD	ICD	CRT-P	120-149 milliseconds with LBBB	ICD	CRT-D	CRT-P or CRT-D	CRT-P	≥150 milliseconds without LBBB	CRT-D	CRT-D	CRT-P or CRT-D	CRT-P
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<p>3</p>	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>TA314 predicts a reduction in use of ICDs and a rise in use of CRT-D. The table below shows the NICE recommended future use of these complex devices, compared to BHSCT outturn for devices in 2013/14.</p> <table border="1" data-bbox="244 392 1050 779"> <thead> <tr> <th></th> <th colspan="2">NICE TA314 New Devices</th> <th colspan="2">BHSCT Outturn 2013/14</th> </tr> <tr> <th></th> <th>No.</th> <th>Rate pmp</th> <th>No.</th> <th>Rate pmp</th> </tr> </thead> <tbody> <tr> <td>ICD</td> <td>91</td> <td>50</td> <td>239</td> <td>131</td> </tr> <tr> <td>CRT-D</td> <td>237</td> <td>130</td> <td>71</td> <td>39</td> </tr> <tr> <td>CRT-P</td> <td>91</td> <td>50</td> <td>66</td> <td>36</td> </tr> <tr> <td></td> <td>419</td> <td></td> <td>376</td> <td></td> </tr> </tbody> </table> <p>The table indicates that current total use of new devices in 2013/14 appeared to be less than that recommended by NICE. However the mix of devices used in NI varies considerably from both NICE current assumptions as well as the recommended rates in the future, with higher ICD implantation and lower rates of CRT-D.</p> <p>Although not referred to in the NICE guidance for TA 314, the HSC also commissions replacement devices as clinically necessary, These are usually required approximately 5 years after initial implantation. This has cost implications.</p> <p>It has been agreed by the Regional Cardiology Implementation Group, in conjunction with the Cardiac Managed Clinical Network, that a regional audit will be undertaken to explore the reasons for variation in the balance between ICD and CRT-D device implantation.</p>		NICE TA314 New Devices		BHSCT Outturn 2013/14			No.	Rate pmp	No.	Rate pmp	ICD	91	50	239	131	CRT-D	237	130	71	39	CRT-P	91	50	66	36		419		376	
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<p>5.1</p>	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Not applicable</p>																														
<p>5.2</p>	<p>Infrastructure costs per patient per annum</p> <p>Catheterisation laboratory capacity is already in place to deliver significant numbers of complex device implants and replacements. To increase the total numbers of new cases annually by 43 will require less than one additional cath lab session weekly. This increase will be absorbed within the existing regional cath lab implementation process.</p>																														
<p>5.3</p>	<p>Current in year costs</p> <p>Device costs vary considerably by type, ranging from £13,980 to £3,049. Current</p>																														

	<p>clinical practice in NI varies from that predicted in NICE TA 314. This is not likely to change significantly in 2014/15 in advance of the proposed audit.</p> <p>BHSCT are currently forecasting an overspend of £620k on expensive devices; this includes replacements which are not covered in TA 314.</p> <p>Work is continuing with the Trust and NICE on the case mix of devices in use and the unit cost that can be achieved.</p>
<p>5.4</p>	<p>Recurrent overall costs per annum (<i>including additional costs</i>)</p> <p>The current CPC budget for all devices including replacements is £5.159m. The budget for new devices is approximately £4.26m. (but replacement numbers per annum can fluctuate)</p> <p>Belfast Trust procures devices through the Blackpool Consortium. This Consortium is designed to procure devices for its members at an advantageous rate. It is not clear why NICE costs, which were informed by advice from major GB Centres, indicate that the devices could be obtained at a much lower cost. If this is confirmed there may be an opportunity to secure potential savings, particularly on ICD costs. This would depend on the nature and length of the contractual commitment between BHSCT and the Consortium.</p> <p>NICE estimate that recurrent device costs for 419 new cases annually, in the proportions recommended in TA 314, will be £4.045m.</p> <p>At current BHSCT device costs this activity would cost £4.831m.</p> <p>If BHSCT can pursue device acquisition to match NICE estimates, implementation of NICE TA 314 can be achieved within existing resources.</p>
<p>5.5</p>	<p>Opportunities for cost savings and how these will be secured</p> <p>No cost savings are predicted, unless it is possible to obtain devices at a lower cost than is currently the case (see section 5.4).</p>
<p>6</p>	<p>Expected implementation period</p> <p>There is no cap on ICD or CRT implantation rates in NI, therefore there is no commissioning impediment to implementation of NICE TA 314 for new patients. However, the HSCB has requested Belfast Trust to explore as a matter of urgency the acquisition costs of these devices.</p> <p>It has also been agreed by the Regional Cardiology Implementation Group, in conjunction with the Cardiac Managed Clinical Network and SSCT, that a regional audit will be undertaken to explore the reasons for variation in the balance between ICD and CRT-D device implantation.</p>
<p>7</p>	<p>Commissioning arrangements</p> <p>These devices are commissioned via Specialist Services Commissioning Team on a cost per case basis.</p>

8	Monitoring arrangements The Trust will generate monthly reports on the cost per case returns which will be reviewed by SSCT.
9	DHSSPS Legislative/Policy Caveats This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.