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TERTIARY CARDIOLOGY

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- provides educational support to NHS staff in the application of the results of research;
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FOREWORD

Individuals or small groups in each District Health Authority in Trent have historically considered evidence on the likely effectiveness of new procedures or therapies in conjunction with their cost, making judgements on whether these should be supported. Since all or most Health Authorities face the same issues, there tends to be repetition in analysis and this can be wasteful of scarce professional expertise.

There are national attempts to remedy this situation by providing information on the effectiveness of interventions and these are welcomed. There remains, however, a significant gap between the results of research undertaken and their incorporation into contracts.

Following a request from purchasers, a network has been established in the Trent Region to allow purchasers to share research knowledge about the effectiveness of acute service interventions and to determine collectively their purchasing stance.

ScHARR, which houses the Sheffield Unit of the Trent Institute for Health Services Research, facilitates a Working Group on Acute Purchasing. A list of interventions for consideration is recommended by the purchasing authorities in Trent and approved by the Purchasing Authorities Chief Executives (PACE) and the Trent Development and Evaluation Committee (DEC). A public health consultant from a purchasing authority leads on each topic and is assisted, as necessary, by a support team from ScHARR which provides help including literature searching, health economics and modelling. A seminar is then led by the consultant on the particular intervention where purchasers and provider clinicians consider research evidence and agree provisional recommendations on purchasing policy. The guidance emanating from the seminars is reflected in this series of Guidance Notes.

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With an ageing population and new treatments, allowing treatment not previously possible, it is likely that an increase in resources will be required to meet clinical need. Resources are scarce and it will not be possible to meet all needs. The issue then, is how to allocate resources to be most effective.

It is important that resources are targeted in a sensible and agreed way, in order to maximise the benefit to the population. Further work on the appropriateness of current activity is required. Access to services should be equitable and evidence-based with more emphasis on agreed patient criteria reflecting need. Non-elective patients must remain a priority within this framework.

After briefly reviewing the pathology and epidemiology of Coronary Heart Disease, this paper discusses the evidence for the effectiveness, and where available, cost-effectiveness for the following Tertiary Cardiology interventions:

- Coronary angiogram/ coronary artery catheterisation;
- Percutaneous Transluminal Coronary Angioplasty and Stents;
- Coronary Artery Bypass Grafts;
- Pacemakers;
- Implantable Cardioverter Defibrillators; and
- Radiofrequency Catheter Ablation.

The paper then goes on to review the options for purchasers with regard to each intervention. The recommendations based upon the paper are then summarised in a matrix for each intervention.

1. INTRODUCTION

In response to 'The Health of the Nation'[1], all purchasers have to develop strategies to target Coronary Heart Disease (CHD), ranging from health promotion to disease management and rehabilitation.

Within such strategies, purchasers are under pressure to increase the funding of Tertiary Cardiology Services, often at the expense of complementary initiatives such as health promotion and rehabilitation.[2]

The aim of this paper is not intended to address the balance between these initiatives, but to assist purchasers with commissioning more appropriate Tertiary Cardiology Services.

With an ageing population and new treatments, allowing treatment previously not possible, it is likely that an increase in resources will be required to meet clinical need. Resources are scarce and it will not be possible to meet all needs. The issue then, is how to allocate resources to be most effective.

National targets for revascularisation rates have been set, but a study by the Clinical Standards Advisory Group has demonstrated wide clinical variations in the Coronary Artery Bypass Graft (CABG) rate which is unrelated to need,[3] as measured by the standardised mortality rate.

Many health authorities have been unable to purchase currently recommended target levels of activity within existing resources. This situation is unlikely to improve as there is now increasing pressure to set new higher targets .[4]

National 'blanket' targets unrelated to need are unhelpful, however, and research has found evidence of significant levels of inappropriate treatment. Further work on the appropriateness of current activity is required before higher levels of activity are promoted. [5]

Access to services should be equitable and evidence-based with more emphasis on agreed patient criteria reflecting need. Within this framework, non-elective patients will remain one of the priorities. This group should be defined clearly and receive appropriate care.

Resources must be targeted in a sensible and agreed way to maximise the benefit to the population.

This document contains:

(a) a brief review of the pathology and epidemiolgy of CHD;

(b) a brief discussion for each main Tertiary Cardiology intervention;

(c) possible options for purchasers;

(d) a matrix identifying patient criteria to warrant each intervention; likely activity levels, efficiency improvements and data items to monitor the quality of services.

Patient criteria are evidence-based where possible, but, in the absence of hard data, have been formed through broad agreement between all cardiologists in the Trent region who attended a regional seminar held by the Trent Institute for Health Services Research.

1.1 Coronary Heart Disease: Incidence and Pathology

Approximately 25% of men show some evidence of heart disease, and one in five of this group is severely affected.[2]

CHD is caused by fatty deposits or plaques in the wall of the arteries of the heart. These deposits narrow the arteries, restricting the supply of blood carrying oxygen and other nutrients to the heart muscles. This restriction in the supply of oxygen results in pain on exertion (angina).

The plaque on the wall of the artery may split and become the site for the development of a clot. This may further narrow the artery, resulting in sudden onset of angina or worsening of existing angina (unstable angina). If the artery becomes blocked a myocardial infarction (MI) may occur, which may in turn cause sudden death.

Damage to a relatively small area of heart muscle following MI can cause abnormal electrical rhythms in the heart, e.g. ventricular fibrillation, preventing the heart pumping effectively.

Progressive damage to the heart muscle over a period of time may result in heart failure, resulting in breathlessness on effort or at rest, and swelling of the ankles and legs.[6]

1.2 Prognosis and Mortality

CHD is the single most common cause of death in England in both men and women. Although deaths attributable to CHD increase with age, there is a peak between the ages of 55 and 65 in men, after which they decrease. Mortality rates are approximately twice as high in men as in women. In the Trent region in 1991 CHD accounted for a total of 7,925 deaths among men, and 6,436 deaths among women.[6]

Since the late 1970s there has a been a decrease in CHD death rates in England and Wales, with the largest reduction occurring amongst middle-aged men and amongst middle-aged women. Trends in CHD death rates in different age groups of men and women in Trent are shown in Tables 1 and 2.[6]

Table 1: Trent CHD Death Rates 1983-90, Males by Age Group

	AGE 35-44 DEATH RATE PER 10,000	AGE 45-54 DEATH RATE PER 10,000	AGE 55-64 DEATH RATE PER 10,000	AGE 65-74 DEATH RATE PER 10,000
1983	4.74	24.87	73.27	159.88
1984	4.25	22.53	68.58	159.44
1985	4.27	22.60	68.76	155.40
1986	4.65	22.26	68.75	152.33
1987	4.02	19.88	64.64	151.61
1988	4.21	18.43	63.86	150.45
1989	3.83	17.54	57.99	142.78
1990	3.43	17.18	54.43	139.70

Table 2: Trent CHD Death Rates 1983-90, Females by Age Group

	AGE 35-44 DEATH RATE PER 10,000	AGE 45-54 DEATH RATE PER 10,000	AGE 55-64 DEATH RATE PER 10,000	AGE 65-74 DEATH RATE PER 10,000
1983	0.84	4.60	20.68	71.24
1984	0.59	5.63	22.88	72.01
1985	0.71	4.61	22.98	70.40
1986	0.82	4.76	21.10	70.48
1987	0.53	3.68	20.78	68.62
1988	0.87	3.93	18.89	68.33
1989	0.68	3.46	19.89	65.22
1990	0.56	3.47	19.97	64.61

2. TERTIARY CARDIOLOGY : SUMMARY OF EVIDENCE OF EFFECTIVENESS AND COSTS OF TERTIARY CARDIOLOGY PROCEDURES

There are a number of interventions used in the treatment of CHD. The more common procedures are Catheterisation; Percutaneous Transluminal Coronary Angioplasty (PTCA) with or without stents; CABG; and Pacemakers. It is recognised that Tertiary Cardiology covers a wider spectrum of activity than just these interventions. These interventions do represent, however, the vast majority of activity in Tertiary Cardiology.

The main body of this paper reviews the evidence on the effectiveness, and, where available, cost-effectiveness for each of these interventions.

2.1 Coronary Angiogram/ Coronary Artery Catheterisation

This is a radiological intervention requiring catheterisation of the heart and angiographic injection of the coronary arteries. Referral for catheterisation is the point where patients enter the Tertiary Cardiology intervention system. It is important, therefore, to ensure appropriate patient selection. Patient groups include stable/unstable angina, angina post acute MI, concomitant valve disease, catheters prior to surgery and post previous cardiac interventions/surgery. This is a diagnostic procedure and, therefore, does not produce a direct health benefit but rather aims to improve the quality and/or quantity of information on which the choice of treatment is based and, thereby, to improve the outcome of whichever procedure is subsequently adopted. There are, however, risks with this procedure including MI and death.

The delivery of coronary angiography is increasingly taking place in District General Hospitals (DGHs) and on a day case basis. This development raises two key concerns:

(i) often, there is no on-site surgical team available in case of emergencies;
(ii) the throughput at any one DGH is unlikely to be sufficient to take advantage of the well documented volume/outcome relationship in this procedure.[4]

Delivery of coronary angiography by DGHs was reviewed by the North Western Regional Health Authority in 1993. The report concluded that this 'should be discouraged on the grounds of: possible litigations in the absence of on-site surgery; service standard erosion; and sub-optimal use of an expensive facility'[7].

2.2 Percutaneous Transluminal Coronary Angioplasty and Stents

PTCA involves dilation of an occluded coronary artery (or arteries) by means of a balloon catheter to restore myocardial blood supply and may, where appropriate, include the insertion of a stent.

2.2.1 PTCA

PTCAs have recently been shown to increase survival[8] and are purely for symptom control.[9,10] Research indicates that PTCA is best used in patients presenting in an early stage of coronary artery disease involving one or two vessel disease[11,12,13,14] However, it is not confined to treating this patient group. It may be used to treat patients with long standing and wide-spread mural coronary disease, with still only one or two major stenoses for treatment.

Within 12 months post-PTCA, between 20% and 40% of patients re-stenose and require a repeat PTCA or CABG.[15,16,17] In Leicestershire, approximately 25% of cases are performed as an emergency, and an increasing number, around 10-15% at present, are in patients who have previously had a CABG.

Most patients have a 2-3 day hospital stay. Although day case PTCA may be a future consideration, the greatest saving will be in preventing re-stenosis and to a lesser extent in reducing the future need for CABG. Cardiac stents could resolve these problems.

The RITA trial[18] showed that the mean cost of PTCA is £6,916. It must be noted that this is considerably higher than the cost of PTCA in Leicestershire, where the average cost has been calculated to be £1,750.[19] This variation may be explained by the differences in the categories of cost that are included in each figure.

There is increasing use of PTCA as an acute phase treatment for MI management. It is likely, however, that 'any slight advantage is outweighted by the cost of making it available in all units'.[4]

2.2.2 Stents

Coronary artery stenting is a modification of the PTCA technique. A small metal tube mounted on a balloon is passed along the artery to a narrowing. The balloon is then inflated, the stent expanded against the wall of the artery, and the balloon deflated and withdrawn. Stents may be used to treat an unsatisfactory result or acute occlusion after PTCA. They may also be used electively to reduce restenosis.[16]

One main type is in use (Palmaz-Schatz). Others are being developed and refinements to simplify the medical regime and reduce the time required to perform the procedure may lead to reduced costs. **The precise criteria and cost benefits for stenting are not clear,** but with increasing experience the cost and benefits should become clearer. In addition, the costs are likely to fall in future with simplified anticoagulation regimes.

Five patient groups are appropriate for the use of PTCA with Stents[9];
a) Unsatisfactory result after PTCA;
b) Complex lesions with higher risk of dissection at PTCA;
c) Vein graft stenosis;
d) Restenosis lesion;
e) Elective use - larger (3mm or greater) artery to prevent restenosis.

Coronary artery stenting is associated with improved success rates[16], lower rates of emergency CABG[16], and lower re-stenosis rates (14-22% versus 32-40%)[16,17] when compared with PTCA. There is a risk, however, of thrombosis during the first month until the lumen of the stent becomes lined with endothelium.[16] In addition, intense anticoagulation is required over the first month with the associated risks of haemorrhage and groin complications.[17] Stents also require longer hospital stays; six days for an emergency procedure and three days for an elective procedure[16] and, indeed, may induce endothelial hyperplasia.[9] Although they have now been used for over 8 years, no data on long-term outcome or complications were found in the literature. At the present time stents are a costly

procedure[9], but the on-going development process may mean that the cost of stents will be reduced as a result of one or a combination of the following factors:

(a) Simplified deployment;
(b) Simplified anticoagulation;
(c) Cheaper stents;
(d) Shorter lengths of stay.

In addition, Heparin coated stents may reduce the need for anticoagulants and reduce reactive hyperplasia of the endothelium and restenosis.[20] There may also be a role for intra-coronary ultrasound in ensuring the accurate deployment of the stent.

2.3 Coronary Artery Bypass Graft

CABGs involve surgical therapy of ischaemic coronary artery disease achieved by grafting a section of saphenous vein, internal mammary artery, or other substitute between the aorta and the obstructed coronary artery distal to the obstructive lesion.

CABGs produce significant overall reductions in mortality compared with medical management, 26.4% vs 30.5% at 10 years. Significant differences have not been shown, however, for all patient groups.[4] Increased survival has been proven for patients with left main vessel stenosis; three vessel disease, especially in patients with poor left ventricular function, and two vessel disease with proximal left anterior descending stenosis.

CABGs are also performed for symptom control in patients with unstable angina, severe symptoms despite medical treatment and recurrent admissions for chest pain. In unstable angina, CABG has been reported to provide improved symptom relief and survival to those with three vessel disease and those with low ejection fractions (<0.5).[4]

The RITA Trial[18] reports the cost of a CABG as £8,739, Once again, this is considerably higher than the £3,000 reported cost in Leicestershire.[19] The Audit Commission identified a range of Extra Contractual Referral (ECR) prices from £2,250 to £8,008 with an average of £5,203.

2.4 Pacemakers

A pacemaker is a device designed to stimulate, by electric impulses, contraction of the heart muscles. It may be temporary (external) or permanent (internal or internal-external). These devices are lifesaving in patients with heart block and improve the quality of life in others. Before the era of pacemakers, patients with high grade atrioventricular (AV) block had a poor prognosis, 50% dying within 1 year and 75-90% within 5 years.[21] Pacing dramatically restores this to a similar rate to the age matched general population.[22]

AV block comprises approximately 45% of the paced population. Sinus node disease makes up the other 45% with pacing in this group largely to improve symptoms of syncope and pre syncope. There are six commonly used pacing modes; **AAI** fixed rate atrial pacing suitable for patients with AV node conduction and sinus bradycardia; **VVI** fixed rate ventricular pacing which is the commonest used pacing mode; **AAIR/VVIR** single chamber rate responsive pacing; **DDD** dual chamber pacing and **DDDR** dual chamber rate responsive pacing.

Pacing can involve either one or two chambers of the heart. Although dual chamber pacemakers are superior in improving quality of life, they are considerably more expensive. Pacemakers presently have a life span of 8-9 years and, therefore, need replacing. The costs of each type of pacemaker are given in Table 3.

Table 3: Cost of Pacemakers

TYPE OF PACEMAKER	COST (£)
AAI fixed rate atrial pacing	1,104.50
VVI fixed rate ventricular pacing	1,104.50
AAIR single chamber rate responsive pacing	1,997.50
VVIR single chamber rate resonsive pacing	1,997.50
DDD dual chamber pacing	2,226.63
DDDR dual chamber rate responsive pacing	2,467.50

Source: Glenfield General Hospital, Leicester

Single chamber pacemakers give 70 beats per minute and are used for patients who suffer infrequent bradycardia, atrial fibrillation (AF), or who are immobile for other reasons.

A dual chamber pacemaker gives a variable rate with exercise, improves cardiac output, prevents the development of AF, and is appropriate for patients with constant heart block. Evidence on the use of dual chamber pacemakers in the elderly (i.e. 70+) is unclear and a trial is underway.

Pacemakers should be implanted according to guidelines, for example, the recommendations of the British Pacing and Electrophysiology Group.[22] Patient groups for whom pacemakers are recommended include:

Patients with heart block
- Complete;
- Second-degree AV;
- Alternating Bundle Branch Block;
- After myocardial infarction.

Patients with sick sinus syndrome and hypersensitive carotid sinus syndrome.

The implantation of a pacemaker has been shown to relieve symptoms, improve quality of life and increase life expectancy. In addition, pacemakers reduce the cost for anti-arrythmic drugs. Problems with pacemakers requiring readmission to hospital are rare and, generally, pacemakers provide good value for money when guidelines for appropriate pacing are followed.[23,24] VVI pacing improves survival in patients with AV block.

When dual chamber pacing (DDD) is compared with VVI pacing, DDD pacing is associated with:

(a) an increased survival in both complete heart block[25] and sinus node disease;[26,27]

(b) increased cardiac output both at rest and on exercise, as well as increased exercise tolerance; [28]

(c) decreased incidence of AF,[29] stroke and congestive cardiac failure.[30,31]

Disadvantages of pacemakers include, pacemaker syndrome, which affects 7-25% of VVI patients.[32,33] Symptoms include frank syncope to breathlessness on exertion. A cure requires that the pacemaker be upgraded to DDD. Recent work has suggested a subclinical form can affect up to 64% of the population.[34] Following publication of these data, the British Pacing and Electrophysiological Group published guidelines recommending a trial pacing for all those patients with P-wave activity.[22] This is expensive, however, and if all

patients were to receive an optimal pacemaker unit this would lead to a 75% increase in expenditure.[23,24,35]

There is no difference in cardiac output and exercise tolerance between DDD and VVIR pacemakers,[36,37] although longer-term studies have shown relative improvements in quality of life with VVIR pacing.[36] VVIR, DDD and DDDR pacemakers, because of their increased complexity, take longer to programme both initially and at follow up.

General complications of pacemakers include pneumothorax, haematoma and infection. The latter requires removal of the pacemaker and lead, which may require thoracotomy, systemic antibiotics and a new pacemaker system. More specific complications include lead dislodgement. Atrial electrodes have a greater displacement rate. Reintervention rates of up to 2% can be anticipated for atrial electrodes. Longer-term problems vary from, crush between the first rib and the clavicle, to exit block caused by excessive fibrosis around the electrode tip.

2.5 Implantable Cardioverter Defibrillators

Implantable Cardioverter Defibrillators (ICDs) are devices which continuously monitor the electrical activity of the heart and automatically detect and terminate ventricular tachycardia and ventricular fibrillation. They consist of an impulse generator, batteries and electrodes. These devices are used in the treatment of patients with sustained ventricular tachyarrhythmias (VT) and survivors of sudden cardiac arrest.[38]

The first ICD was implanted in 1980. Since that time the numbers implanted have doubled every year worldwide.[39] In 1991, over 20,000 ICDs were implanted worldwide (80% in the USA).[39] This represents a dramatic explosion in use before conclusive evidence of efficacy has become available. This is mostly due to the limitations of alternative treatments and their possibly harmful characteristics.[40]

Patients at risk of sudden cardiac death have an estimated life expectancy of 11.1 years with ICD and 6.7 years with amiodarone.[41] Several trials are presently underway comparing amiodarone v ICDs.[40]

Four main patient groups are suitable for ICD:

(a) Victims of cardiac arrest (excluding acute MI);

(b) Rapid (>150 bpm) or poorly tolerated VT inducible at Electrophysiological (EP) study despite sotalol or amiodarone therapy;

(c) Slow (150 bpm) and well tolerated VT despite drug therapy;

(d) Prophylactic indications.

The advantages of ICDs are that they provide reliable defibrillation and reduce mortality from sudden cardiac arrest.[38,42,8] The disadvantages of ICDs are the risk of infection (in the region of 2%), their efficacy in prophylactic use is unproven, long-term outcomes are not known and the cost is high. ICDs have a lifespan of approximately 5 years at present, before a replacement is required, which also adds to the cost.

2.6 Radiofrequency Catheter Ablation

This procedure involves the destruction of tissue with electrical current delivered via electrodes positioned at the distal end of a catheter. Energy sources are commonly direct current (DC-shock) or alternating current at radiofrequencies (usually 750 kHz). The technique is used most often to ablate the AV junction and/or accessory pathways in order to interrupt AV conduction and produce AV block in the treatment of various tachyarrhythmias.

Radio Frequency Catheter Ablation (RFA) eliminates or improves specific arrythmias resulting in a better quality of life, and either removes or reduces the need for drug treatment.[8] Evidence in the USA[43] suggests that there is an initial surge in the activity levels for RFA which eventually plateaux or even reduce. The introduction of RFA in the UK is still relatively recent and an upward trend in activity is likely to continue in the short-term.

RFA is appropriate for the following patient categories:

(a) Symptomatic Wollf Parkinson-White (WPW) syndrome;[8]

(b) AF or flutter with ventricular rate uncontrolled by medical therapy;

(c) AV nodal tachycardia with symptoms uncontrolled by first-line antiarrhythmic drugs or drugs not tolerated;

(d) Idiopathic ventricular tachycardia with symptoms uncontrolled by first-line antiarrhythmic drugs or drugs not tolerated.

RFA eliminates or improves tachycardia.[48] Its use 'avoids the need for electropharmacological testing, long-term antiarrhythmic drug therapy and surgical therapy in the majority of patients with WPW syndrome or with symptomatic tachycardias involving accessory AV connections'.[8] It is one of the most effective therapies available in any sphere of medicine, and is a curative procedure with 90% success rate, and a very low complication rate of 4% for WPW syndrome.[8] In addition, RFA 'pays for itself' in a short time when used appropriately, principally, by eliminating recurrent hospital admissions.[44]

The disadvantages of RFA treatment are that AF patients may develop complete heart block and require a pacemaker for life. In addition, the duration of the treatment may lead to excessive radiation exposure of both patients and staff. [45] Also, long-term outcomes are mostly unknown.

3. OPTIONS FOR PURCHASERS AND PROVIDERS

3.1 Catheterisation and Percutaneous Transluminal Coronary Angioplasty

(i) *Accept progressive increase in activity with catheters used as a routine investigation for CHD.*

This would allow the coronary anatomy of individual patients to be studied. However, equity and inappropriate activity would not be addressed. This would also entail some patients developing complications following an inappropriate investigation.

(ii) *Target catheters at patients who meet agreed patient criteria to maximise effective and efficient use of resources and ensure equity of access to services. Compliance with patient criteria to be 90% of all patients to allow for clinical flexibility.*

This would address equity and reduce inappropriate activity. A compliance target of 100% would not allow for clinical flexibility in a minority of patients. These strict criteria may also prevent access for a few patients who would benefit from further tertiary care.

(iii) *Catheter to proceed to PTCA during same procedure where appropriate.*

This is not an alternative to (i) or (ii), but additional. Catheter proceeding to PTCA during the same procedure would improve efficiency and reduce the need for a second admission. However, it may encourage clinicians to offer PTCA less appropriately.

3.2 Percutaneous Transluminal Coronary Angioplasty with Stents

(i) *Stop stenting*

This would save resources which could be allocated to other interventions, but it would possibly be unacceptable and unethical with current knowledge.

(ii) *Allow stent developments as part of Multi-Centre Research only.*

This would restrict the use of stents within a trial and ensure that activity generated additional data on which to base future policy decisions. Coronary artery stents have passed the stage of research, however, and are now in active clinical use.

(iii) *Consider stents for unsatisfactory results, complex lesions, higher risk cases and vein graft patients.*

This would restrict the use of stents to patients who are likely to benefit more, but would not necessarily offer further research information.

(iv) *Accept that an increasing percentage (rising to 40%) of PTCAs will be stent procedures.*

This would allow stents to realise their full potential. However, precise patient criteria are uncertain and this option would be very expensive.

3.3 Coronary Artery Bypass Graft

(i) *Restrict CABGs to those patients where improved mortality has been demonstrated.*

This would maximise benefits. When patients are no longer responding to medication, however, a CABG will significantly improve their quality of life.

(ii) *Allow CABGs also for patient criteria where improved symptom control has been demonstrated and the patient is unsuitable for PTCA.*

This will enable improved symptom control, but reduce overall benefit.

(iii) *Introduce a protocol to assess patient risk and prioritise patients on the waiting list.*

This is not an alternative to options (i) or (ii), but would enable more appropriate clinical prioritisation for patients on the waiting list and potentially reduce the risk of litigation.

3.4 Pacemakers

(i) *Single chamber pacing for patients with AV block and chronic AF 15-20% patients.*

(ii) *Dual chamber pacing for all patients with an indication for pacing and intact sinus node function:80-85% patients.*

This is the most expensive option but it would allow services to fully meet the clinical need.

(iii) *Single chamber (AAI or AAIR) devices for patients with sinus node disease with no evidence of AV block on ECG, 24 hour tape or incremental atrial pacing: 25% of patients.*

Single chamber (VVI of VVIR) devices for patients with chronic (>6 months) AF and AV block, very infrequent periods of AV block, or activity limited by other disease: 20% of patients.

Dual chamber devices (DDD or DDDR) for all patients with AV block and intact sinus node function: 50% of patients.

This reduces the ability to meet all clinical need, but is potentially more cost effective.

(iii) *As for option (ii) but all patients over 70-75 years would get a single chamber device, irrespective of indication for pacing.*

With a 70 year cut-off: 30% dual-chamber, 70% single chamber.

With a 75 year cut-off: 40% dual-chamber, 60% single chamber.

This enables resources to be saved, but is openly ageist and, therefore, may not be ethically defensible.

(iv) Single chamber pacemakers for all patients with an indication for pacing: 100% patients.

This enables the maximum amount of resources to be saved. Many patients, however, would not be offered appropriate care.

4. DISCUSSION AND CONCLUSION

Although shown to be effective, most established Tertiary Cardiology procedures have little evidence to indicate their cost-effectiveness.[4]

In the absence of such information, purchasers should encourage appropriate cost-effectiveness research and, where possible, ensure that current activity conforms to best practice according to evidence-based guidelines.

The focus should move away from 'blanket' activity targets to equity of access and patient criteria based on ability to benefit. Purchasers should encourage clinicians to monitor compliance with agreed patient criteria (See Matrix on next page) to justify additional resources in the future.

5. INDICATIONS AND AUDIT OF CARDIAC PROCEDURES AND OPERATIONS: SUMMARY MATRIX

PROCEDURE	PATIENT CRITERIA	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVING	AUDIT POINTS
A. Coronary Angiography I) Stable Angina	1. Have symptoms of angina uncontrolled by adequate medical treatments. 2. In absence of this to have previous history of MI/unstable angina within 2 years 3. On at least one anti-anginal drug (excluding GTN or Aspirin) 4. Patient unable to complete Stage 3 of standard Bruce protocol (equivalent to 9 METS) due to symptoms or abnormal ECG.	This will form the bulk of catheterisations.	1. Increase day case work. 2. Use cheaper contrast agent. 3. Catheter proceeds to angioplasty during same procedure admission.	1. Aim for 100% but accept 70-80% of cases on waiting list should meet the patient criteria. 2. Audit complications 3. No. & % patients where catheter and angioplasty could be performed during same admission. 4. Quality assurance of interpretation of angiogram.
II) Unstable Angina	1. Non elective/urgent cases. 2. Recurrent or prolonged chest pain at rest despite I.V. nitrates, and at least one oral anti-anginal drug (betablocker, calcium antagonist, oral nitrate) 3. Recurrent non-elective admission for chest pain.	Approximately one third of catheterisations.	1. Prompt catheterisation. 2. Catheter proceeds to angioplasty - same procedure, or sheath left in and angioplasty performed during same admission. 3. Hospital discharge - if pain settles with consideration of early exercise test and catheterisation if patient meets stable angina criteria .	1. Audit complications. 2. Audit of later course - i.e. M. I. revascularization. 3. No. & % patients where catheter and angioplasty could be performed during same admission. 4. Quality assurance of radiologist interpretation of angiogram.
III) Valve Disease	1. Symptoms of Dyspnoea, Angina, Syncope. 2. Previous or current CCF. 3. Infective Endocarditis. Worsening objective criteria- heart size on CXR, LV dimension on Echo , significant valve gradient on doppler.	15% catheterisations (but possibly higher).	1. Increase day case work. 2. Patients who clearly need surgery placed immediately onto surgery waiting list and receive pre-operative catheter on admission for surgery.	1. Complications 2. Outcome

PROCEDURE	PATIENT CRITERIA	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVING	AUDIT POINTS
IV) Prior to Surgery	1. Clinical event e.g. unstable angina or MI whilst on waiting list for CABG or valve surgery 2. Unsuspected or new clinical finding on patient to have cardiac surgery. 3. Elective CABG delayed longer than 12 months.	Small number of cases. Less than 5% of catheters.	Catheter procedure during same admission as that for surgery.	Catheter complications. No. & % of non-elective admissions of patients on waiting list.
V) Post Previous Cardiac Interventions/Surgery	1. Recurrent symptoms e.g angina, SOB 2. Objective evidence confirming ischaemia. 3. Uncertain or inadequate operation result	10% of catheter procedures.	Seamless service - repeat PTCA/surgery during same procedure or admission. Increase day case work.	Complications of procedure.
VI) Catheterisation Waiting list	<u>Elective Routine</u> 1. Any of the above criteria I, III-V. 2. To be admitted in less than 3 months. <u>Non-elective patients</u> 1. Hospital in-patients 2. Unstable angina or heart failure or infective endocarditis with valvular problems. <u>Elective urgent</u> 1. To be admitted in less than one month. 2. Recent hospital admission for unstable angina. 3. Strongly positive exercise test (i.e. unable to complete stage 1 of standard Bruce protocol, equivalent to 5 METS, due to chest pain, arrhythmia or ST depression).			<u>Elective Routine</u> No. & % who presently wait under & over 3 months <u>Elective Urgent</u> No. & % patients who presently wait under & over 1 month.

PROCEDURE	PATIENT CRITERIA	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVINGS	AUDIT POINTS
Catherisation Waiting List / Continued.	4. Recent MI and recurrent rest pain. 5. Recent CCF. 6. High Valve Gradient.			
B. PTCA I) first PTCA	<u>Previous Coronary Angiogram with suitable anatomy</u> 1. Patients will already meet criteria for stable or unstable angina. 2. Coronary anatomy is suitable for angioplasty.	Total PTCA 300-400/million 40% Non elective	1. More than 1 vessel PTCA at same procedure i.e. during same procedure or admission clinician could deal with 2 (or occasionally 3) vessels, rather than readmitting for second PTCA to the second vessel. 2. Cheaper contrast agent. 3. Seamless service - PTCA during same admission as catheter (especially for repeat PTCA). 4. Day case PTCA.	1. Audit of immediate results and during admission, (deaths, emergency CABG, MI). 2. Audit of longer-term (1-5 years) results. 3. Audit of restenosis and re-intervention. 4. No. & % catheters on patients who could have angioplasty during same admission. 5. No. & % patients with more than 1 vessel who presently have more than one admission who could have all angioplasties on one admission.
II) Repeat PTCA	Recurrent angina less than 6 months post previous PTCA.	20% of total PTCAs	1. Seamless service - catheter proceeds to PTCA during same admission. 2. Day Case PTCA.	As for First PTCA.

PROCEDURE	PATIENT CRITERIA	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVINGS	AUDIT POINTS
III) First PTCA with stent	1. Acute closure at PTCA. 2. Unsatisfactory result at PTCA. 3. Elective stent - higher risk lesion - to reduce incidence of restenosis. - saphenous vein grafts. 4. Coronary artery diameter should be greater than or equal to 3mm.	Estimated to be 15-20% of PTCA procedures but could possibly be as high as 30%.	1. Palmaz-Schatz stent reduces restenosis. Two trials (Stress and Benestent have shown the elective use of stent in suitable vessels can approximately halve restenosis (from 40% to 20%). Elective stents can reduce need for emergency surgery. 2. Pre-procedure anticoagulation. Establish Warfarin control over 1-2 weeks before PTCA procedure. Will lower hospital stay from 7-10 days to 3-4 days. 3. Stent without anticoagulation - For large calibre vessels - Hospital stay same as routine PTCA	As for first PTCA. For elective stents emphasis on need, emergency CABG and restenosis and re-intervention.
IV) Repeat PTCA with stent	1. Same as Repeat PTCA II	Uncertain, could be 40% of repeat PTCA procedures (same vessel/alternative vessel)	Same as first PTCA with stent III.	As for first PTCA I, and first PTCA with stent III.
V) Waiting List - PTCA with or without Stent Procedures	Elective - Routine 1. Maximum wait 2 months from time patient's name placed on waiting list. After this time there is risk of disease progression and vessel may no longer be suitable for PTCA. Non-elective 1. Unstable angina. 2. Recurrent pain after Acute MI 3. Acute MI (about 3% PTCAs) - less than 2 hours from onset of large anterior MI or contra-indication to thrombolytic drug. 4. Acute MI complications - cardiogenic shock.	Elective and non-elective PTCAs should be performed in centres with emergency cardiac surgery back-up on site by specialists who perform at least 50 procedures per year (BCIS recommendation)		Elective No. & % who presently wait under & over 3 months.

PROCEDURE	PATIENT CRITERIA	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVINGS	AUDIT POINTS
	Elective Urgent 1. Maximum wait 1 month 2. Recurrent unstable angina or 3. Recurrent pain Post MI 4. Strongly positive exercise test.			Urgent No. & % patients presently waiting under/over 1 month. All PTCAs No. of procedures per provider. No. of procedures per consultant.
C. CABG I) CABG for improved survival and symptom control	1. Patient will already meet criteria for catheter. 2. Angiogram shows left main vessel stenosis of greater than 50% or three vessel disease especially with poor LV function or two vessel disease with proximal LAD stenosis especially with poor LV function.	60 - 70% of CABG cases.	1. Seamless service - angiogaphy and CABG during same admission. 2. Replace Warfarin with Aspirin. 3. Early discharge - 3-4th day homecare by district nurse. 4. Reduced waiting time will reduce non-elective CABG admission, AMI, repeat catheters	Complications and result of operation. Audit risk stratification/proforma
II) CABG for Symptom control only	1. Patients will already meet criteria for catheter. 2. Angiogram shows CAD not suitable for PTCA and suitable for CABG (i.e. later stage, non focal).	30-40% of CABG cases,	Same as CABG I	Same as CABG I.

PROCEDURE	PATIENT CRITERIA	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVINGS	AUDIT POINTS
III) CABG procedures waiting times	Elective Routine 4 months from placing patient on waiting list for surgery. Non-elective Emergency - less than 24 hours Urgent - within 72 hours from decision that patient needs operation. Elective - urgent Maximum waiting 1 month from time placed on waiting list. Recent unstable angina. CABG for increased survival especially L main stem stenosis. Recurrent pain post recent MI. Strongly positive exercise test.	Total CABG - 400/million is a conservative estimate for the Leicestershire population.		Elective 1. No. and % patients who presently wait under and over 4 months. 2. No. and % elective patients on waiting list who require non-elective admission. Non-Elective No. and % who receive CABG within 24 and 72 hours. Urgent 1. No. and % who presently wait under and over 1 month.
D. Pacemakers **(new or replacement)**	Single chamber devices 1. Single chamber (AAI or AAIR) devices for patients with sinus node disease with no evidence of AV block on ECG, 24hr tape or incremental pacing. 2. Single chamber (VVI or VVIR) devices for patients with chronic (>6 months) AF and AV block, very infrequent periods of AV block, or activity limited by other disease. Dual chamber devices Dual chamber devices (DDD or DDDR) for all patients with AV block and intact sinus node function other than those indicated above.	New - 300-350 / million. Replacement - 50-70 / million. 25% of total. 10-15% of total. 60% of total.	Increase day cases. Increase day cases.	1. Audit of adherence to criteria. 2. Audit of complications. 1. Audit of adherence to criteria. 2. Audit of complications.

PROCEDURE	PATIENT CRITERIA	ESTIMATED FUTURE ACTIVITY	OPPORTUNITY FOR COST SAVINGS	AUDIT POINTS
E. ICD (new or replacement)	1. Survivors of cardiac arrest (excluding acute MI). 2. Rapid (>150 bpm) or poorly tolerated VT inducible at EP study despite sotalol or amiodarone therapy.	15 per million population (about 25 cases per year for total population covered by General Glenfield Hospital).	Future use of pectoral devices similar to pacemakers. Earlier discharge. Negotiate with hardware manufacturers (e.g. consortium approach).	1. Audit of criteria above, and of complications. 2. Long-term follow up.
F. RFA	1. Symptomatic WPW syndrome. 2. AF or flutter with ventricular rate uncontrolled by medical therapy. 3. AV nodal re-entrant tachycardia with symptoms uncontrolled by first-line antiarrhythmic drugs or drugs not tolerated.	Incidence rate of 30-35 patients/ million population (150 cases per year for total population served by Glenfield General Hospital). Backlog - unknown (possibly at least 50 / year for a number of years).	Catheter reuse.	1. Audit of adherence to criteria above. 2. Success and complications rates.

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