GUIDELINES

Coronary angioplasty: guidelines for good practice and training

Joint Working Group on Coronary Angioplasty of the British Cardiac Society and British Cardiovascular Intervention Society

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Procedures involving the use of balloon dilatation catheters, stents, and other percutaneously delivered interventional devices are now commonly performed on selected patients with coronary heart disease (CHD). It is axiomatic that centres undertaking such procedures must be properly equipped and staffed, their operators competent, and the cases selected appropriate. Patients advised to undergo a coronary intervention procedure should have received sound professional advice, and their procedure should be undertaken with the outcome and their safety being the central focus of attention for all those involved with their care. Audit of the quality of care delivered should be undertaken, and its implementation and subsequent refinement should be with the wholehearted involvement and cooperation of interventional cardiologists. If centres and operators are to be assessed, and occasionally judged to be failing, such failings should be the result of their own shortcomings and not those of a system with wider inadequacies, for which others may more appropriately bear responsibility. The government's emphasis on clinical governance highlights the importance of this diverse responsibility.

In 1996 a previous British Cardiac Society (BCS)/British Cardiovascular Intervention Society (BCIS) working group published guidelines for the best practice of coronary angioplasty,[1], and these were subsequently endorsed in the Scottish intercollegiate document on coronary revascularisation.[2] The guidelines were based on a consensus of professional judgement, and placed some reliance on the volume of procedures undertaken by operators and institutions. It was recognised that numbers of procedures represented a poor surrogate for measures of quality, and that more meaningful indicators were required. The purpose of this paper is to define the indicators relevant to the delivery of a quality interventional cardiology service, the means by which these indicators might be assessed, and the training required for those who will become interventional cardiologists in the future.

Factors affecting the delivery of high quality care may be divided broadly into issues relating to: institutions; operators; case selection; audit (data collection and analysis, peer review, resources); and training. Each of these broad categories will be considered in turn.

Standards for institutions

CATHETER LABORATORIES

A centre undertaking percutaneous transluminal coronary angioplasty (PTCA) should have a cardiac catheter laboratory or laboratories, equipped with a physiological measurement system and full facilities for cardiopulmonary resuscitation, including an intra-aortic balloon pump. Sedation is often given during procedures so transcutaneous or an equivalent method of monitoring arterial oxygen saturation must be available. High quality radiographic imaging equipment, preferably digital and capable of imaging the coronary arteries from all directions, including cranial and caudal angulation, should be provided. Image manipulation including freeze frame, zoom, and playback should be immediately available and a "roadmapping" facility is desirable. An adequate system should be in place for the archiving and subsequent retrieval of image data, with images being retained for eight years. Radiation exposure should be kept to a minimum and good radiation protection should be provided for catheter laboratory staff as well as patients.[3] The need for particular items of angioplasty hardware, such as balloons, guide wires, guiding catheters, stents, and adjunctive pharmacology, often cannot be anticipated until a procedure is in progress; therefore it is vital that an adequate range of equipment and drugs are kept available at all times. Advances in technology and hardware have been very rapid in the field of interventional cardiology and the need to upgrade and extend the range of available equipment in the light of these advances should be anticipated.

STAFF AND FACILITIES

Centres undertaking angioplasty for acute coronary syndromes should create an infrastructure that ensures adequate facilities and staff are available to provide a 24 hour service seven days a week. Centres undertaking elective angioplasty procedures for stable coronary disease may undertake procedures only on certain days of the week; we still believe, however, that all centres should offer an unbroken service since some patients may require readmission

and urgent repeat angioplasty some days or even weeks after discharge from hospital. All centres should ensure that the intervention laboratory and its staff are fully operational within 60 minutes of being notified of need.

Staffing levels required to meet these institutional objectives will vary, depending on local circumstances, and it would be too inflexible to define a single arrangement that should be in place. Instead, the general environment and staffing levels provided in any institution should be sufficient to satisfy peer review that the service is acceptable. To ensure continuity of service provision each centre should have a minimum of three trained operators. An on-call cover of 1:3 in such an acute subspecialty puts unreasonable and unsustainable demands on the participating interventionists; centres with this minimum should make strenuous efforts to increase their number of operators to four and preferably five or six depending on local workload.

Where a patient's diagnostic coronary arteriography is carried out in a district general hospital it is important that a close liaison is developed between the cardiologist undertaking these diagnostic procedures and the centre to which those patients selected for revascularisation (PTCA or coronary artery bypass grafting (CABG)) would be referred. This is particularly relevant to coronary intervention where the indications for procedures, the range of technologies to undertake these procedures, and the management of patients subsequently, have changed so rapidly. A good liaison between the referring cardiologist and the interventionists and surgeons will help to ensure that the appropriate revascularisation procedure is chosen. There should be regular clinical meetings which involve the interventional cardiologist, cardiac surgeon, and diagnostic angiographer. Those undertaking revascularisation procedures should provide their audited results to their referring hospitals.

NUMBER OF PROCEDURES

Catheter laboratory nurses, technicians and radiographers, ward nurses and junior doctors, as well as interventional operators, all need to experience a sufficient number of cases in their centre to ensure institutional competence. Too few procedures results in inexperience, is potentially dangerous, and may not be cost effective. Some data have been reported to suggest that hospitals which perform more PTCA procedures have lower referral rates for emergency CABG and lower short term mortality rates after the procedure,[4–8] whereas others have not.[9] Overall, the results from these studies are far from conclusive and the data reported are open to differing interpretations.[10]

In 1996 the joint BCS/BCIS working group concluded that each centre in the UK should undertake at least 200 PTCA procedures a year.[1] This was felt to represent a minimum volume sufficient to help maintain the skills of all staff, both those involved in the catheter laboratory and those on the wards caring for the patient after the procedure. This recommendation was based on the supposition that too few procedures results in inadequate experience. Widely supported though this supposition may be, when applied to extremely low volumes (< 50 procedures per year[11]), creating a cut off figure above which a centre is felt to be satisfactory and below which it is not, is an arbitrary process which has an inadequate evidence base. In 1993, 10 of the 42 National Health Service (NHS) centres performing angioplasty undertook fewer than 200 procedures, but this had fallen to five in 1996.[12]

We believe that the results of audit and compliance with the standards highlighted in this document can both be assessed by peer review and should be used as indicators of quality for all centres, whether they are low volume (< 200 procedures per year) or higher volume institutions. A centre undertaking < 200 procedures annually but demonstrating good practice, as judged by peer review and against the criteria outlined in this document, should be supported and encouraged to increase its activity.

Given that technical skills are required for the safe performance of intervention, and that these skills require regular updating in the light of newly emerging technology, the UK should continue to concentrate interventional cardiology services in centres with relatively high volumes of procedures, using operators who maintain a high level of experience and offer a wide range of interventional techniques. If primary PTCA were to gain widespread acceptance as the treatment of choice for a significant number of patients with acute myocardial infarction then clearly angioplasty services will have to be expanded greatly. However, if this were to occur the potential numbers being undertaken would be considerable and so the volume of activity in almost any proposed new centre should be sufficient to contribute towards institutional and individual competence.

SURGICAL COVER

The issue of surgical cover for PTCA procedures remains an emotive one, with some regarding it as mandatory and requiring it to be on the same site as the angioplasty procedure, but others regarding it as unnecessary.[13] Of the 20 511 PTCA procedures undertaken in the UK in 1996 a total of 19 129 (93%) were performed in the 47 centres with on-site surgical cover and 1382 (7%) were undertaken in the six centres with off-site cover.[12] Emergency CABG within the first 24 hours following coronary angioplasty was required in only 1.5% of all reported procedures. Although this figure is relatively low, patients were referred for surgery in all of the subgroups analysed, including 2.0% of patients having undergone previous CABG and 0.6% of patients undergoing angioplasty for chronic occlusions—circumstances where the need for emergency bypass grafting would generally be anticipated to be very infrequent. With more detailed information on individual patients some cardiologists may have concluded that emergency CABG was unnecessary in some of these referrals. However, it is hard to conclude that there is any group of patients for whom surgical

standby is never potentially beneficial, except those in whom a preprocedure decision is made that the patient is unsuitable for emergency CABG. Such a decision should be made only after discussion between the interventional cardiologist, the cardiac surgeon, and the patient.

Some have argued that the need for surgical cover has restricted the development of angioplasty services and prevented non-surgical centres from undertaking these procedures. However, waiting lists for PTCA are generally much shorter than for CABG and most centres currently undertaking intervention could increase their activity significantly if additional funding were provided, suggesting that any limitation of service expansion is more likely to be because of financial constraints rather than the number of current institutions. It has also been suggested that when groups of patients can be shown to require emergency CABG sufficiently infrequently (< 1% of cases) its routine provision should be considered unnecessary; however, others argue that the need for emergency CABG is unpredictable and, even though required rarely, it may still be lifesaving. It is therefore hard to conclude that some patients should be deprived of a potentially lifesaving operation for the sake of an expansion in services that could be developed for the foreseeable future in existing centres, all of which have some form of surgical cover.

In 1992 a total of 2.0% of all angioplasty cases in the UK required emergency CABG compared to 1.5% in 1996, during which period the average number of cases involving the use of an intracoronary stent rose from 2.7% to 46%.[12] While intracoronary stenting has reduced the need for emergency CABG when abrupt or threatened coronary occlusion occurs during PTCA, operators are undertaking much more complex procedures with higher inherent risk of complications. This increase in risk and complexity probably explains why the overall referral rate for emergency CABG has fallen less than one might expect with the increase in use of stents.

While acknowledging that differences of opinion do exist, we believe that there is still a general consensus that access to emergency surgery, whether on-site or off-site, should be available for all patients undergoing PTCA, other than for those individuals who have been prospectively agreed not to require cover (as might occur in patients with severe comorbidity), or for groups of patients with clinical conditions which have been prospectively agreed locally not to require cover (for example, cardiogenic shock). The appropriateness of such agreements should satisfy peer review.

Most would accept that when emergency cardiac surgery is required for failed PTCA the earlier that cardiopulmonary bypass can be established the better the postoperative outcome is likely to be. Although defining an acceptable upper time limit must therefore be somewhat arbitrary we believe a guideline is required. We recommend that all centres, whether with on-site or off-site surgical cover, should be able to establish cardiopulmonary bypass within 90 minutes of the referral being made to the cardiac surgical service. For all patients requiring emergency cardiac surgery the time taken to establish cardiopulmonary bypass should be recorded and subsequently audited.

CENTRES WITH OFF-SITE SURGICAL COVER

A centre with off-site surgical cover, but meeting the general standards of care outlined in this paper, should ensure that reliable arrangements are in place to allow the prompt transfer of a patient to a suitable operating theatre, cardiac anaesthetist, and cardiac surgeon. The covering surgeon should know in advance that the PTCA procedure is being undertaken and an arrangement must exist with the local ambulance service for the immediate availability of an ambulance, fully equipped with resuscitation facilities, for emergency transfer of the patient when necessary. These arrangements should be explicit and agreed with purchasers and the ambulance service.

The arrangement whereby surgical cover is provided in another institution will impact on case selection in "off-site" centres. Cases should be selected on the basis of a lower anticipated overall risk and need for emergency CABG. Also, consideration should be given to the haemodynamic consequences and the patient's likely clinical stability, were abrupt occlusion of the target coronary lesion to occur and the patient require transfer by ambulance to another hospital. For instance, in centres with off-site surgical cover it would be inappropriate to undertake elective angioplasty for unprotected left main stem lesions or for lesions in a last remaining coronary vessel. Equally, where these procedures are undertaken in centres with surgical cover on-site, the surgical team should know in advance that the procedure is being undertaken so immediate surgical revascularisation can be achieved should the need arise.

POSTPROCEDURE CARE

The safety and success of angioplasty is not determined solely by the quality of the procedure itself. Appropriate case selection is an obvious example of an important preprocedure determinant of outcome, and postprocedure care is equally important. Centres undertaking PTCA should have a sufficient throughput to ensure that junior medical and ward nursing staff become experienced in the observation and treatment of patients, such that the management of postprocedure complications are well understood. Femoral artery sheath removal is associated with vasovagal and bleeding complications, both of which may potentially jeopardise the outcome of an angiographically successful PTCA procedure, and staff should have experience and be trained in the avoidance of complications and their management when they do occur. Facilities should be available for electrocardiographic and blood pressure monitoring for patients following angioplasty, and clear guidelines should exist for nursing and medical staff concerning the action to be undertaken in the event of

these being abnormal or the patient developing postprocedural chest pain. There should be immediate access to haematological, biochemical, and blood transfusion laboratories and vascular surgical advice; return to the catheter laboratory for further intervention should be possible immediately, throughout the patient's admission. If PTCA procedures are undertaken by an operator at a site remote from their normal base hospital the visiting operator should either be available personally for 24 hours after the procedure to offer immediate cover in the event of a postprocedure complication, or have ensured the same availability of another fully trained consultant who is based at the hospital where the procedure was performed.

Achieving high quality of care is the overriding objective, but in an increasingly litigious world the medicolegal implications for institutions and operators of failing to provide this comprehensive approach should also be carefully considered.

Standards for operators

NUMBER OF PROCEDURES

Coronary angioplasty is a skilled procedure with success and complication rates relating to the operator's expertise and judgement. It is obviously essential that those providing such a service to patients are properly trained and maintain their competence by continued practice. Intuitively, there must be a minimum number of procedures undertaken annually below which the necessary skills are not maintained.[14] Most would accept this but setting a value to this minimum number engenders heated debate, mainly because there are few data on which to base any recommendation. Low volume operators argue that by careful case selection and with a realistic appreciation of their own expertise they can achieve a high level of success with a low number of complications; far from being less safe they may have a lower absolute number of complications than higher volume more aggressive PTCA operators who undertake more complex procedures. By setting a minimum number of procedures which is above their current activity they are left with a difficult choice. Either they are forced to abandon interventional cardiology, which for the very low volume operator may be appropriate, or they may feel pressurised into undertaking procedures which they consider either inappropriate or ones which they may feel less comfortable performing. This may consequently increase rather than decrease the frequency of their complications. Others argue that lower volumes inevitably result in less experience and potential inability to deal with the complications of angioplasty, which inevitably occur even with selected cases that are anticipated to be low risk. Operators with greater experience argue that the lower volume operator who regards a case as complex will often refer the patient unnecessarily to a cardiac surgeon for CABG, rather than seek the opinion of a more experienced interventionist.

Attempts at setting a level for the absolute minimum number of procedures conducive to maintaining adequate skills is perhaps the most contentious of all issues relating to the setting of standards in interventional cardiology. In the USA a minimum number of 75 procedures a year has been recommended[10]; in 1996 the BCS/BCIS working group recommended a minimum of 60 per year and recommended that this minimum should be increased as UK centres increased their volume of procedures.[1] We recommend that the minimum for independent operators should now be **75 procedures per year**. We believe that those falling significantly below this level of activity are in danger of becoming deskilled and less able to respond appropriately and competently to unforeseen complications during an angioplasty procedure. It is our view that ideally all trained operators should undertake more than the minimum to maintain competence and that strenuous efforts should be made by those operators currently undertaking low volumes to increase their experience and level of activity. Anyone with an annual personal workload close to this recommended minimum should consider undertaking their procedures in a centre where other trained operators are available for help and advice if needed. At the end of each PTCA procedure a single person should be recorded as the primary operator, and this should be a person actively involved with the case and assuming principal responsibility for its outcome.

CONTINUING PROFESSIONAL DEVELOPMENT

The results of individual operators can be improved by sharing experiences with colleagues, and interventional centres should encourage discussions between operators, both informally and more formally, as part of departmental meetings. Operators should keep abreast of the literature and technological changes relating to coronary angioplasty and the rapidly changing field of adjunctive pharmacology. We recommend that trained operators spend at least four days per year attending national and international meetings relevant to their specialty and undertake their own personal audit of their interventional procedures. As a minimum this should consist of keeping a record of all the patients who have intervention procedures performed personally or under their auspices, their preprocedural and procedural details as outlined in the BCIS/CCAD minimum dataset (tables 1, 2, and 3), and their in hospital outcome including any postprocedural complications. Ideally this personal audit process should also include a record of any major adverse cardiac events which occur over the following 6 months after the procedure, although this should hopefully be undertaken as part of the audit undertaken at a departmental level. Operators should present their data locally to those involved with PTCA, such as interventional and non-interventional cardiologists, cardiac surgeons, and radiological, nursing, and technical staff, and the data should be available to purchasers.

Table 1 BCIS dataset to be completed annually by each centre

	Description
Your centre	
Name of centre	
Hospital identifier	Code number only known to centre and BCIS
Your name	Name of person completing the form
Position	Position/grade of person completing the form
Contact telephone number	Telephone number of contact person
Contact fax number	Fax number of contact person
Contact email address	Email address of contact person
Surgical cover	0 = none, 1 = on-site, 2 = off-site
Your catheter laboratories	
Number of catheter laboratories	Number of labs in your centre
Number of adult catheter sessions per week	Session = half day in a single lab (includes mobile labs)
Do you have QCA?	Yes/no
Number of cine labs	Number (0–6)
Number of digital labs	Number (0–6)
Method of archiving	Video, CD, laser disk, optical disk, cine film (may use > 1 method)
Diagnostic catheter procedures	
Number of diagnostic catheterisers	Total number of diagnostic catheterisers
Consultant cardiologists (local)	Consultant employed principally in your centre
Consultant cardiologists (visiting)	Consultant employed principally in another hospital
Consultant radiologists	
Associate specialists	
Specialist registrars (cardiology)	
Other grade	
Total adult diagnostic procedures	Coronary and valve studies (excludes pacing, electrophysiology, paediatric and other work)
Intervention procedures	
Number of consultant interventionists	
Specialist registrars (radiology) cardiologists	Number
Radiologists	Number
Associate specialists	Number
Number of interventional trainees	Number (this refers to specialist registrars specifically being trained in intervention and not those just given exposure to PTCA)
Other staffing questions	
Number of catheter laboratory nurses	In your department
Number of cardiac technicians	In your department
Number of cardiac radiographers	In your department
Total number of specialist registrars (SpRs):	
In your centre	Number
Outside your centre	Refers to SpRs in other hospitals but rotating with your centre
Other catheter laboratories locally	List names of other hospitals undertaking catheterisation in your region/deanery and name possible contact person for each
Type of laboratories:	
Fixed dedicated cardiac	
Fixed shared	
Mobile	

QCA, quantitative coronary angiography.

Table 2 Breakdown of number of adult cardiac interventional procedures undertaken annually and submitted to the BCIS

Total coronary intervention procedures	*Number*
Breakdown of procedures	Number (include number of procedures involving use of any of these technologies)
Balloon alone	
Number of procedures involving stent insertion	
Directional atherectomy (DCA)	
Cutting balloon	
Rotational atherectomy	
Laser angioplasty	
TEC device	
Intravascular ultrasound	
Angioscopy	
Thrombus removal device	
Groin closure device	
Procedures when ReoPro used	
Other	Specify
Other interventional procedures	Number (include number of procedures involving use of any of these technologies)
Mitral valvoplasty	
Aortic valvoplasty	
Pulmonary valvoplasty	
Coarctation (native) dilatation	
Recoarctation dilatation	
Closure of PDA	
Closure of PFO	
Removal of foreign bodies	
Embolisations	
Other	Specify

PDA, patent ductus arteriosus; PFO, patent foramen ovale; ReoPro, abciximab; TEC, transluminal extraction catheter.

Case selection

Coronary angioplasty is undertaken in widely varying clinical circumstances and with very different risks. In the context of cardiogenic shock, a mortality rate following PTCA of 50% may be considered acceptable whereas a rate of 2% for stable angina and uncomplicated single vessel disease would be excessive. Sufficient patient and procedural data must be recorded to allow some form of risk stratification to be included in the audit process, and both centres and individual operators must take account of these factors when deciding the type of patients to accept for intervention. Risk may be related to patient specific factors, such as the presence of comorbid conditions (renal failure, diabetes) and clinical presentation (for example, stable angina, unstable angina, evolving myocardial infarction, etc), or lesion specific characteristics such as those suggested by the American College of Cardiology/American Heart Association task force[15] which classified stenoses into A, B1, B2, and C lesions. Anticipated outcome must take account of these factors. Where operators or centres have low volumes it would be wise to undertake procedures considered to be of lower risk, whereas for operators with higher volumes and wider experience, working in institutions

Table 3 Core dataset for individual patients and recorded for each intervention procedure. Submitted to BCIS/CCAD

General	
Patient surname	
Patient forename	
Date of birth	
Gender	Male/female/unknown
NHS number	
Post code	
Hospital identification number	
Hospital	
Indication for procedure	
Clinical syndrome (one choice only)	Stable angina Asymptomatic myocardial ischaemia Unstable angina (stabilised) Unstable angina (currently unstable) Reintervention Primary PTCA for acute MI Rescue (salvage) PTCA for acute MI Reinfarction (no thrombolysis) Reinfarction rescue ("salvage") Post MI unstable angina Post MI stable angina Other (specify) Unknown
If other, please specify	
Urgency	Urgency of procedure (elective, urgent, emergency, unknown)
Clinical factors	
Angina status	CCS class 1–4, or unknown
Dyspnoea status	NYHA class 1–4, or unknown
Previous MI	Yes/No, unknown/not applicable
Diabetes	None, non-IDDM, IDDM, unknown
Peripheral vascular disease	Yes/no/unknown
Cerebrovascular disease	Yes/no/unknown
Cardiogenic shock (preintervention)	Yes/no/unknown
Diagnostic catheter data	
Left ventricular function	Visual assessment (good, fair, poor, unknown)
Left ventricular ejection fraction (%)	If measured
Extent and severity of native coronary artery disease	Duke matrix (preprocedure)
Extent of coronary disease	Normal, 1 vessel, 2 vessel, 3 vessel, unknown
Left main stem disease	Yes/no/unknown
Previous CABG	Yes/no/unknown
Intervention procedure	
Date of procedure	
Name of operator 1	
Status of operator 1	1 = consultant cardiologist, 2 = consultant radiologist, 3 = specialist registrar, 9 = unknown
Number of vessels attempted	Number 1–5, 99 = unknown
Number of lesions attempted	Number 1–7, 99 = unknown
Restenosis lesion	No/yes (not in stent)/yes (in stent)/yes (location unknown)/unknown
Chronic occlusion	Yes/no/unknown
ReoPro used?	Yes/no/unknown
Stent(s) used	Yes/no/unknown
Devices used	Directional atherectomy (DCA) Rotational atherectomy Cutting balloon Laser angioplasty TEC device IVUS Angioscopy Thrombus removal device (specify) Groin closure device (specify) Intracoronary brachytherapy Other Unknown/not applicable
Specify device of hydrolyser/ thrombus removal or other device	Free text field
Postprocedure CAD score	Duke matrix 0–10, 99 = unknown
Laboratory outcome	Procedural success Partial success Failed procedure (no complication) Myocardial infarction Emergency CABG Death Unknown
Transfer to theatre?	N/A/cardiac massage/haemodynamically unstable/haemodynamically stable/unknown
Time to bypass	If applicable
Post AMI final TIMI coronary flow	TIMI 0–3, 9 = unknown (for AMI patients only)
In-hospital outcome	
Death	Yes/no/unknown
Date of death (if applicable)	
Q wave MI	Yes/no/unknown
Non-Q wave MI	Yes/no/unknown
Reinfarction	Yes/no/unknown
Reintervention (PCI)	Yes/no/unknown
Emergency CABG	Yes/no/unknown
Elective in-house CABG	Yes/no/unknown
Was post-PCI CK measured?	Yes/no/unknown

MI, myocardial infarction; AMI, acute MI; CCS, Canadian Cardiovascular Society, NYHA, New York Heart Association; IDDM, insulin dependent diabetes mellitus; IVUS, intravascular ultrasound; CAD, coronary artery disease; CK, creatine kinase; PCI, percutaneous intervention; TEC, thrombus extraction catheter.

with a wider range of interventional equipment, more complex procedures may be appropriate.

Although angioplasty has yet to become widely used in the management of acute myocardial infarction, circumstances may arise where angioplasty would justifiably be regarded as the treatment of choice and potentially life saving, but the patient might be either too unwell to be transferred to an angioplasty centre or the delay in making such a transfer may be considered to be clinically unacceptable. We accept that in such circumstances it may be appropriate for so called "salvage" angioplasty to be undertaken by a trained operator in a centre not routinely undertaking PTCA procedures. With the anticipated future increase in the use of angioplasty for patients with acute infarction, recommendations regarding best practice in this area will need to be reviewed and modified.

Audit

Audit of practice and outcome is a necessary means of creating a climate of confidence in which patients, operators, and those involved in the purchase and provision of care can see that quality care is being delivered. It is an integral part of providing an angioplasty service and cannot be regarded as an optional extra. If the audit process is to work in interventional cardiology standards must be defined in all relevant areas that impact on the quality of care. Performance must then be assessed against these standards and conclusions drawn from these assessments used to implement appropriate changes. The assessment process should then be repeated to determine whether quality of care has been improved. It is unacceptable to assess only one part of the process, such as the mortality rate for a single operator, without taking account of other relevant factors such as case selection, postprocedural care, and clinical support infrastructure. Government, purchasers of health care, hospital management, medical and other staff all bear a responsibility for ensuring that these objectives are achieved.

Purchasers of health care increasingly request guidelines so that clauses relating to quality can be built into their contracts with providers. If those involved in interventional cardiology do not help to define these standards, however much they may be based at present on professional judgement rather than scientific fact, then purchasers will draw up their own criteria. It is our view that these may be less well informed and may be restrictive because they are influenced unduly by factors relating to cost containment. Also, attempting to set standards and emphasising the importance of audit should encourage all involved in interventional cardiology to audit their activities; through national data collection the audit information may assist centres in the process of bidding for appropriate local facilities, funding for clinical audit, and an appropriate workload. Additionally, a process of continuous audit will allow individual operators or a unit as a whole to recognise early when standards need local review.

In the following sections we discuss the audit process and its constituents (data collection and analysis, peer review, resources) and the application of conclusions drawn from audit into clinical practice.

DATA COLLECTION AND ANALYSIS

The central cardiac audit database (CCAD) project, funded by the Department of Health, set out to investigate the feasibility of collecting data on patients undergoing a variety of invasive cardiological and cardiac surgical procedures, transmitting these data to a central computer server, electronically encrypted to ensure data security, and tracking subsequent mortality after discharge from hospital. The pilot phase of this project has been completed and showed the practical possibility of similar data collection being undertaken in all centres. As part of its development during this three year pilot phase, a minimum dataset was defined for interventional cardiology (tables 1, 2, and 3) and we recommend that all centres ensure the collection of this "core" dataset. Collecting a limited and well defined amount of data on every patient has the advantages that data collection can realistically be expected to be 100%, true measurements of mortality and complication rates can be made, allowance is made for basic risk stratification, and comparisons can be made between operators, and between individual centres and a national mean. Such a process allows individual operators to assess their results and where significant variance occurs, either for an operator or centre, early corrective action can be taken. BCIS has defined a "desirable" dataset, containing information which is additional to the "core" dataset, and have circulated this to all intervention centres with the request that this also be collected wherever possible. All centres should submit these audit returns to the BCIS, which in turn reports annually to the BCS.

PEER REVIEW

Interventional centres have historically worked somewhat in isolation. Individual operators have presented data at meetings and may have occasionally discussed the management of individual patients with colleagues, but a more systematic appraisal of the practice of angioplasty in interventional centres has never been undertaken. This has been at least partly because of the constraints of time, funding, and lack of staff. In the vast majority of centres angioplasty procedures are undertaken to a high standard but a formal peer review process is now needed to reinforce public and professional confidence. By improving existing systems of internal audit within centres, and establishing a process of periodic external audit, patients can be given the reassurance that individuals and centres meet acceptable standards. Operators and centres can either be reassured by external peer approval or gain from constructive criticism aimed at improving standards.

We recommend that the BCIS, the specialist affiliated group of the BCS, establish an

advisory group to which centres concerned about their practice can turn for advice, and with the remit to set up a system of peer review whereby each interventional centre receives a site visit and formal external review every three years. Following each review the advisors will provide a report to the centre and offer advice regarding ways in which the local service might be improved. Centres developing an interventional programme should be visited in the planning phase to offer help to clinicians and management in developing an appropriate infrastructure and to give advice regarding audit. Such a centre should be revisited at the end of its first year, and then every three years thereafter if a satisfactory service is in place. The advisors would be free to recommend an earlier review than every three years if any centre was felt to have significant problems. We anticipate that the Department of Health and the National Institute for Clinical Excellence would support these proposals and therefore it is our recommendation that such a peer review process should become obligatory. Centres having been assessed satisfactorily could use this endorsement as an indicator of quality care.

The peer review process should assess a centre's facilities, staffing arrangements, preprocedural, procedural, and postprocedural standards of care, and patient in-hospital outcome following intervention. These assessments should be based on comparison with standards set out in this paper, information in peer reviewed scientific journals, and available national data such as that from BCIS and CCAD. We acknowledge that this document does not define precisely all the standards against which a centre's intervention service should be assessed, tending more towards a description of broader guidelines. This is deliberate since we anticipate that as part of the development of peer review a clearer picture will emerge of the variety of interventional practice around the UK. By assessing and discussing local practice those delegated to undertake the pilot phase of peer review will be able to help define and refine standards of care which carry broad peer acceptance, and in turn this will benefit the process as a whole.

RESOURCES

The BCIS has collected basic data of procedural outcome since 1988,[16] but despite strenuous attempts to improve data collection a number of centres still fail to provide even simple information. Of the 53 centres undertaking PTCA in the UK in 1996, 16 (30%) were unable to report their mortality.[12] We believe that the poor response of some centres is usually not caused by an inherent reluctance to share data but by the lack of a system in place for the prospective collection of information, hence the dependence on retrospective data collection at the end of each year. With current data recording depending mostly on medical and nursing case notes this task of retrospective data collection is difficult, time consuming and potentially inaccurate. For centres, operators, and purchasers to know more accurately what actually happens to patients undergoing PTCA, much better internal audit processes are required. For this to develop, additional funds will be required in order to appoint sufficient staff and establish an adequate infrastructure so that data can be reliably collected. This can only be developed if there is sufficient will on the part of government and management. Additional funding is unlikely to come from central budgets and so audit will probably have to compete with other deserving causes for allocation of funds from existing resources. The local audit process needs to be costed and could be built into contracts with purchasers. The participation of purchasers in such audit should be welcomed and some may consider it appropriate to include its performance as a requirement in contracts.

Training and accreditation

TRAINEES

Specialist registrar clinical training, introduced following the Calman recommendations, takes six years.[17] In the first four years the trainee is expected to have assisted at 25 PTCA procedures, but training in angioplasty as a specialty does not start formally until the last two years. The likelihood is that there will continue to be only a limited number of consultant interventionist posts falling vacant each year, so only a minority of specialist trainees will be required to undertake specialist angioplasty training. So far it has been left to individual trainees to decide whether the training in PTCA in their particular centre would be of sufficient quality, and the possibility of a consultant vacancy in future sufficiently high, to commit themselves to specialist training, and it has been left to educational supervisors and angioplasty trainers to undertake local selection. It is inevitable that selection will continue to occur, so that those individuals most naturally suited to undertaking interventional procedures are offered the limited training available. For planning purposes training posts should not be counted as providing any service commitment.

Defining the minimum number of PTCA procedures that constitutes an acceptable training in angioplasty is difficult because individuals learn at different rates and case selection and available facilities will differ between centres. Previous recommendations for specialist training restricted angioplasty training only to the final year, concluding that the trainee must undertake at least 100 PTCA procedures in this year, 50 of which were to be as principal (first) operator.[1] Experience in previous years could not be aggregated with those in the advanced year. This figure of 100 procedures was previously regarded as being too few but was the maximum that was felt to be achievable given the one year time scale. With specialty training now potentially undertaken over the last two years of the six year programme,[18] we believe the minimum should now be set at **200 cases, with 125 as first operator**.

It is not uncommon for more than one operator to be involved in PTCA procedures and it can sometimes be difficult to define

clearly the principal operator. However, for the purposes of training it should be left to the trainer to determine when a trainee has been the principal, as opposed to assistant (second), operator. The trainee must be familiar with the catheter laboratory and angioplasty equipment and understand the radiation implications of PTCA procedures and the means by which radiation exposure can be minimised. In addition to performing PTCA effectively the trainee should be directly involved in the subsequent care of patients on the ward and after discharge from hospital, and the auditing of results for the centre as a whole. The individual should be involved in discussions concerning case and equipment selection and must keep abreast of the literature on PTCA. The trainee is expected to maintain a log book of all catheter laboratory procedures throughout training and should spend at least four days each year attending appropriate educational meetings, which in the case of an advanced trainee in PTCA would be at meetings involving interventional cardiology.

TRAINERS

Operators undertaking training should themselves undertake a minimum of **125 procedures personally** each year, of which 50 must involve the direct supervision of a trainee during a procedure. Trainers should be experienced angioplasty operators, having undertaken at least 500 cases personally, and should work in centres offering as wide a range of interventional procedures as possible. Each centre should designate one trainer to be organisationally responsible for interventional trainees, and for ensuring their appraisal and assessment, and the content of the training programme. This designated trainer would be responsible for confirming that the trainee has completed their interventional training year satisfactorily, and the specialist advisory committee in cardiology of the Royal College of Physicians should consider establishing a formal accreditation procedure to mark satisfactory completion of angioplasty training.

The future

UK DEMAND FOR PTCA

It is difficult to define the true needs of the population for coronary revascularisation procedures because of a lack of good epidemiological data. An assessment of need can be calculated from standardised mortality ratios for CHD, although these correlate poorly with the referral rates for PTCA and CABG in the UK. Quite distinct geographical variations exist in the UK for both the prevalence of CHD and the provision of revascularisation procedures.[19] Unmet demand for intervention procedures, as measured by waiting lists, may be used as a surrogate indicator of population need but is likely to underestimate the true need considerably. If long waiting lists were an indicator merely of a backlog of unmet demand rather than continuing need, then the number of patients on waiting lists should gradually fall as the provision of services improves. Far from doing this, the number of patients waiting for intervention is actually increasing, despite an average annual increase in the number of angioplasty procedures undertaken in the UK of 13–18%,[12] which strongly suggests a continuing population need.

The mortality from CHD is gradually falling[20] and this may reflect, in part, a decline in its incidence. However, more patients are surviving acute myocardial infarction, a proportion of whom will subsequently require PTCA, and PTCA is increasingly being undertaken in the older population, for whom the benefits have been shown to be similar to younger patients. Also, more patients who have previously undergone a revascularisation procedure now undergo repeat revascularisation. Hence, even though the incidence of CHD may be falling in the population as a whole, the number of patients requiring PTCA is likely to rise for the foreseeable future. The UK undertakes relatively few revascularisation procedures compared to other European countries and to the USA[21] and this would tend to support the conclusion that the UK does not meet the true needs of its population.

In 1998 the UK government set up a national services framework (NSF) committee to review a wide range of issues relating to the national provision of cardiac services. From provisional data reviewed by the NSF (P Doyle, personal communication, 1999) the 10% of health authorities which commissioned the most coronary angioplasty procedures in 1997–98 had an annual average number of procedures equating to 550 per million of their local population. The burden of CHD, as measured by CHD mortality rates, in this top decile of purchasing authorities was close to the national average. Given that there is no evidence of over commissioning, especially by comparison with other European countries, the NSF committee is likely to recommend that the target figure for the average annual number of coronary angioplasty procedures for England and Wales should be 550 per million. However, the burden of CHD varies significantly between different parts of the country. With improvements in the means of assessing local needs it is likely that a range of commissioning rates for PTCA will emerge, with around 400–450 per million being undertaken for those populations with the lowest incidence of CHD, and 800–850 per million for those with the highest. Achieving national equality of access to coronary revascularisation, related to local need, is a stated high priority of the NSF committee.

It should be stressed that the results of clinical trials, changing technologies, and the provision of angioplasty to more patients with acute myocardial infarction and unstable angina would considerably increase the overall need for these procedures. Approximately 200 000 patients with acute myocardial infarction reach hospital alive in the UK each year, and conservative estimates suggest at least as many additional admissions for unstable angina.[22] If one errs towards the conservative and estimates that 25% of these patients may be suitable for early angioplasty, one can see that at least

Table 4 Data on number of angioplasties and consultant operators in the UK in 1996

Total UK angioplasty procedures	20511
Rate per million UK population	359
Mean number of consultant operators per centre	5.0
Calculated total number of consultant operators in the UK	210
Mean number of procedures per consultant operation	98

100 000 of these patients with acute coronary syndromes might be considered for PTCA. This compares to approximately 4000–5000 of such cases undertaken in 1996[12] out of a total of 20 511 procedures performed in the UK that year.

FUTURE NEED FOR INTERVENTIONAL CENTRES

There has been an absence of strategic planning in the development of angioplasty services in the UK and this is regrettable. Many district hospitals now undertake diagnostic cardiac catheterisation, but a situation in which there is unplanned proliferation of PTCA undertaken in low volumes in these centres is one that is likely to be associated with suboptimal results, a higher frequency of complications, and possibly higher unit costs. We consider such development to be undesirable. However, where centres can show a local need for the development of an angioplasty service (as might occur in more remote parts of the UK where distance from an existing centre may be a disadvantage), sufficient funding, and the likelihood of satisfying the recommendations contained in this document, then they should be encouraged to develop. As a guideline for future planning we recommend one interventional centre for every 0.5–1.0 million population, and waiting times of < 6 weeks for diagnostic catheterisation and < 8 weeks for coronary angioplasty. The UK requires a further increase in PTCA activity if it is to meet the target of 550 procedures per million population.

In 1996 the majority (90%) of units undertaking PTCA in the UK were in cardiac surgical centres, each serving populations of around 1.5–3.0 million people, and these surgical centres undertook 92% of all the PTCA procedures.[12] These centres would have to perform 825–1650 PTCA procedures per year if all suitable patients were referred to them and the target figure of 550 per million were to be achieved. The number of surgical centres is increasing but only very slowly. Therefore, as the number of PTCA procedures rises surgical centres will have to decide how many procedures they can undertake, perhaps achieving some increase by reducing the number of diagnostic catheters undertaken; non-surgical centres may also need to increase their activity. Such alterations with time are likely to be dictated principally by available levels of funding and hence will be determined by local contractual arrangements.

Table 5 Number of consultant operators required to meet annual targets of 400, 500, and 600 PTCA procedures per million population

Annual number of PTCA procedures undertaken per consultant	*Number of consultant operators required (400 PTCA/million)*	*Number of consultant operators required (500 PTCA/million)*	*Number of consultant operators required (600 PTCA/million)*
100	228	285	342
125	182	228	274
150	152	190	228

FUTURE NEED FOR INTERVENTIONAL CARDIOLOGISTS

For the purposes of achieving appropriate training numbers it is obviously important to estimate the likely future need of the UK for trained angioplasty operators. However, such calculations depend on a number of factors such as the number of procedures likely to be funded and the mean number of procedures likely to be undertaken per operator. The more widespread use of angioplasty for acute myocardial infarction and unstable angina would considerably alter the anticipated future need for operators.

Funding is probably the major factor which influences the rate of expansion of an angioplasty service, but if this is ignored for the purpose of calculating future need for angioplasty operators, two other determinants are relevant. The total number of angioplasty procedures undertaken in the UK annually can be increased either by each trained operator performing more procedures, or by each operator maintaining their present workload and additional trained operators being appointed. In 1996 a total of 20 511 angioplasty procedures were undertaken, 92% being performed in NHS hospitals.[12] The remaining 8% of procedures were undertaken in private hospitals, but almost all of these were performed by consultant operators who also undertook procedures in NHS centres. Very few consultant operators practise solely in the private sector. In NHS centres angioplasty procedures were also undertaken by junior medical staff, some of whom were in training and others who had undertaken the minimum of 100 angioplasty procedures previously required to be termed "trained". However, since all procedures undertaken by junior staff are performed under the auspices of a consultant, usually with supervision, these procedures have been regarded as undertaken by a consultant operator for the purposes of manpower calculations. In 1996 a total of 42 NHS centres undertook PTCA procedures in the UK, each with a mean of 5.0 consultant operators,[12] either employed at the centre or visiting from another hospital. Therefore, the calculated total number of consultant operators in the UK in 1996 was 210, with a mean annual personal (NHS and private) and training workload of 98 cases per consultant (table 4), having risen from a mean of 72 per consultant in 1993.[1]

If all these 210 existing consultant operators performed a minimum of 100 procedures per year at least 21 000 procedures could be performed annually. If this minimum were 125 or 150 per year the potential totals would be at least 26 250 and 31 500, respectively. Table 5 shows the number of consultant operators required to meet annual targets of 400, 500, and 600 PTCA procedures per million population, related to a mean annual number of procedures per operator of 100, 125, and 150, respectively.

From the above calculations it can be seen that a significant increase in the total number of angioplasty procedures undertaken in the UK could be achieved with little or no increase in the number of operators over the next few years, assuming existing operators increased their personal workloads to > 100 procedures per year. Since existing consultant interventionists already have full timetables any expansion in their workload would have to be at the expense of some other professional activity, such as a reduction in outpatient clinics, ward rounds, teaching or administration. The probability that there will be few new consultant appointments over the next few years should be considered by those in training, 44% of whom, when surveyed, listed interventional cardiology as a career "preference" (see appendix).

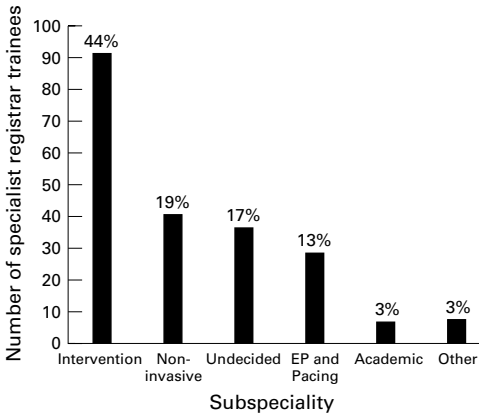
Where multiple visiting operators undertake angioplasty procedures at a single centre available laboratory time may eventually limit further increases in a centre's activity and in turn "cap" the potential maximum for individual operators. However, it seems likely that a continuing gradual transfer of diagnostic catheterisation away from surgical centres to district hospitals should allow additional laboratory time to be allocated to intervention for the immediate future. However, it should be stressed again that these calculations are based on current angioplasty practice; they should be regarded as potentially a considerable underestimate of true need if more angioplasty were undertaken in future for patients with acute coronary syndromes.

Conclusions

1. Interventional centres should equip their coronary angioplasty service with adequate staff and facilities to perform safe and effective procedures.
2. The angioplasty service should provide a 24 hour service seven days a week, and catheter laboratories should be capable of being fully functional within 60 minutes of being needed.
3. All interventional centres should audit their activity against the standards set out in this paper, present the results of this audit locally, and submit their data to BCIS/CCAD for national statistics to be produced.
4. Surgical cover, whether on-site or off-site, is still recommended for all coronary angioplasty procedures other than those few cases prospectively agreed not to be suitable for emergency CABG. All interventional centres should be able to establish cardiopulmonary bypass within 90 minutes of the decision being made to refer the patient for surgery.
5. An independent angioplasty operator should undertake a minimum of 75 coronary procedures annually, and those performing close to this minimum should ideally increase their workload to nearer 100 procedures.
6. Angioplasty operators should ensure they undertake continuous professional development and audit their own procedures and outcome, including those performed by others under their auspices.
7. The BCIS should establish a peer review system and each centre should undergo review at least every three years.
8. Centres undertaking < 200 procedures per year should be encouraged to increase their activity, so as to improve the experience and skills of all staff involved with providing the coronary angioplasty service.
9. Specialist registrars in training should perform 200 PTCA procedures in their last two years of training, 125 of which should be as first operator, before being considered for accreditation as an independent operator.
10. Trainers should perform at least 125 procedures per year, at least 50 of which should involve the direct supervision of a trainee.
11. The BCS, BCIS, interventional centres, and individual operators should continue to press for an expansion in the availability of coronary angioplasty services in the UK, aiming for 550 procedures per million population to be undertaken annually by the financial year 2000/2001.
12. A further BCS/BCIS working group should be established in three years' time to review the recommendations made in this report and the response to their publication.

Appendix

Questionnaires were sent to all 340 cardiology specialist registrar trainees in the UK holding national training numbers, requesting information about their career intentions. The results from the 208 replies (61%) are shown in the figure below.



Results of a postal survey of the career intentions of all cardiology specialist registrar trainees in the UK in 1998. EP, electrophysiology.

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