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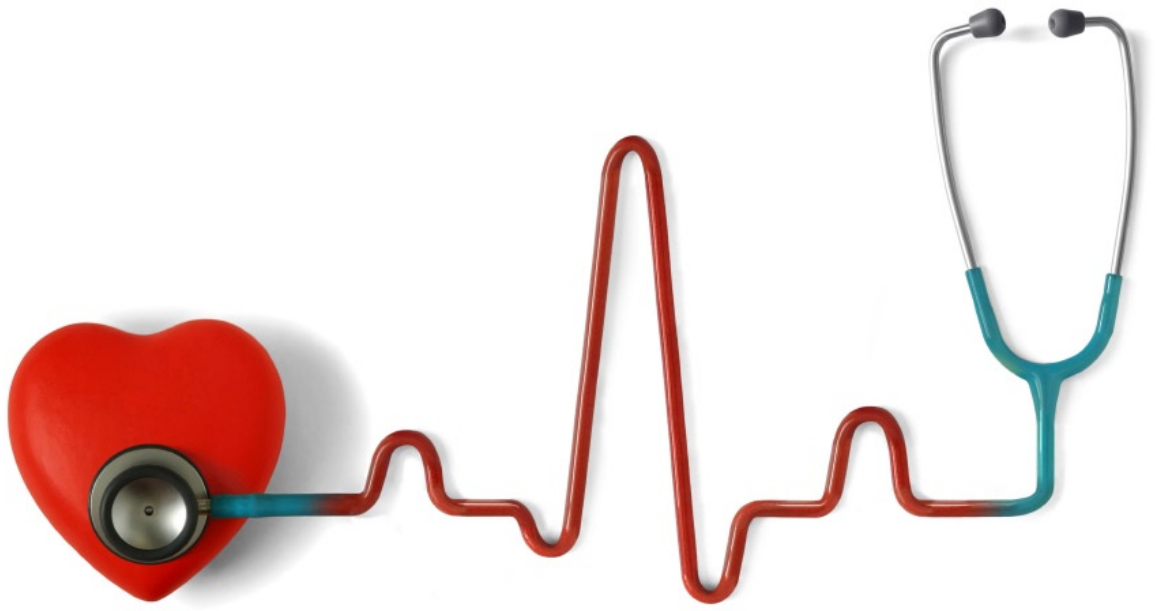
Angioplasty and Stents to treat Coronary Artery Disease.

The 2008 report of the National Audit of Percutaneous Coronary Intervention in the United Kingdom

Data from Jan 2007 to Dec 2007, Dr Peter F Ludman MA MD FRCP University Hospital Birmingham NHS Foundation Trust, Audit Lead for the British Cardiovascular Intervention Society (BCIS), On behalf of BCIS



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Angioplasty and Stents to treat Coronary Artery Disease. 2008 report of the National Audit of Percutaneous Coronary Intervention in the United Kingdom

The main objective of this audit is to improve the care of patients who undergo Percutaneous Coronary Intervention (PCI) procedures in the UK. The audit provides a mechanism to collect procedure-specific data based on the current minimum British Cardiovascular Interventional Society dataset. This audit project is being delivered in collaboration with the British Cardiovascular Interventional Society.

The audit described here allows clinicians to assess key aspects of the quality of their care when performing percutaneous coronary intervention (PCI). This is a United Kingdom wide audit performed by the Audit Lead of the British Cardiovascular Intervention Society (BCIS) with participation from hospitals performing PCI procedures.

The Angioplasty and Stents to treat Heart Disease 2008 report is available to download from:

Printed copies of this report can be ordered from The Information Centre for health and social care's (The IC) Contact Centre 0845 300 6016 or email: enquiries@ic.nhs.uk quoting document reference IC09020209.

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Foreword

The use of Percutaneous Coronary Intervention (PCI) continues to grow although at a slower rate than previous years. However, we still offer fewer treatments per head of population than most of our European partners. Within the UK Wales, in spite of growth, continues to lag behind.

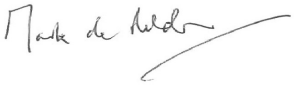
The biggest area of change over the next few years will be the widespread uptake of the use of PCI for the treatment of acute heart attacks. In this context it is referred to as "primary angioplasty" ("PPCI"). This treatment offers better outcomes for patients than the widespread use of clot-buster treatments (thrombolysis), but it requires the use of specialised teams available around the clock. Not all centres will have the infrastructure or staff to provide such a service, and so there is a need for designated centres to be identified as "Heart Attack Centres". A huge coordination is required between the ambulance teams, the angioplasty teams, hospital management as well as the clinical networks and commissioners.

We want to provide the best possible service with minimal time delays. In the past we have delivered one of the best thrombolysis services in the world, and it has been said that we do not want to replace a superb thrombolysis service with a sub-standard PPCI service. The Myocardial Ischaemia National Audit Project (MINAP) showed what a national audit exercise could do, with year on year improvements in minimising door-to-needle times with thrombolysis as well as measuring the uptake of secondary preventive medications and cardiac rehabilitation. Now, the British Cardiovascular Intervention Society (BCIS) and MINAP will work together to measure door-to-balloon and call-to-balloon times to ensure we provide efficient PPCI services. BCIS has already been working with the Central Cardiac Audit Database (CCAD) to develop systems of automatic feedback of such information so that units can continue to evaluate and improve their systems of care.

International studies have shown a link between the volume of PCI activity at an individual centre, as well as the case mix (the type of case treated), and the outcomes of the patients. Perhaps not surprisingly, the more patients treated, then the better the results. BCIS monitors the volume of activity and remains concerned that a few units are still doing far fewer cases than they originally planned, and fewer than the minimum numbers recommended in the national recommendations. More and more, commissioners will want to see evidence of the quality of care, and BCIS is working on methods of providing risk-adjusted data to individual units to show that short-term outcomes, at least, are to an acceptable standard.

As the evidence-base for our practice changes, with trials demonstrating the potential for improved outcomes with new technologies and new pharmacological agents, then it is essential that we audit these treatments, to measure how these advances are applied in the real world. This is essential if we want to demonstrate equity of access and monitor outcomes. BCIS is working with the newly formed National Institute for Clinical Outcomes Research (NICOR) to evaluate some of the new technologies. In some cases, this means the creation of new datasets and new ways of collecting data from across the country. We are also working with the National Institute for Clinical Effectiveness (NICE) and other national societies to aid the monitoring of new treatments such as transcatheter aortic valve implantation.

This requires coordinated activity from many people. Operators performing the treatments have to input data into databases at the clinical coalface and this requires hospital IT infrastructure and audit support for data verification and validation. Some hospitals still provide too little support to their clinical teams. The data are then collected and analysed within CCAD and now, NICOR. We continue to rely on the hugely energetic input from Peter Ludman, Audit Lead to BCIS, as well as David Cunningham, Nadeem Fazal, and their team within CCAD, especially Andrew Donald in particular has done some very impressive work. Without them, none of this work would be possible.



Mark de Belder
President, British Cardiovascular Society
8th February 2009

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Acknowledgements

The National Percutaneous Coronary Intervention Audit has been developed and run by the British Cardiovascular Intervention Society (BCIS) since 1988 and more recently has received support from The Information Centre for health and social care (The IC) and The Healthcare Quality Improvement Partnership (HQIP). The analysis on which this report is based was undertaken by the BCIS Audit Lead, Dr Peter Ludman.

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1.0 Executive Summary

Coronary heart disease accounts for about one in five deaths in men and one in six deaths in women. In addition, the British Heart Foundation estimate that there are over 1 million men living in the UK who have or have had angina (heart-related chest pain), and over 840,000 women.

Percutaneous coronary intervention (PCI) is a rapidly evolving technique used to treat patients whose coronary arteries – which supply the heart with blood – are narrowed or blocked. The procedure works by mechanically improving blood flow to the heart. First, the doctor uses x-ray images of the heart arteries to make the position and shape of any narrowing or blockages visible (a 'coronary angiogram'). If the clinical circumstances and the angiogram findings suggest that something needs to be done to physically modify the blood flow to the heart, then the majority of patients are treated by PCI.[1] A small balloon is inserted which, when inflated, squashes the fatty tissue out of the way and widens the artery. In most cases a 'stent' is then implanted - a stainless steel mesh tube that stays permanently in place to keep the artery wall open. Treatment thus aims to prevent the arteries blocking (which might cause a heart attack) and improve flow to the heart muscle to alleviate the symptoms of angina.

The audit described here allows clinicians to assess key aspects of the quality of their care when performing coronary angiogram and PCI. This is a United Kingdom wide audit performed by the Audit Lead of the British Cardiovascular Intervention Society (BCIS). This audit has recently been enhanced by the Central Cardiac Audit Database (CCAD) which allows electronic transfer of much more detailed information. This data collection and analysis for centres in England and Wales has project management and specialist IT support provided by the National Clinical Audit Support Programme (NCASP), which is part of the NHS Information Centre for health and social care (The IC). This portion of the audit is funded by the Healthcare Commission.

Key findings include:

- The number of PCIs in the UK was 1,269 per million population (pmp). These numbers are less than in most other developed European countries. The number of angiograms and PCI procedures are also less than that recommended by the British Cardiovascular Society (BCS), but both exceed the numbers expected by the National Service Framework (NSF) for Coronary Heart Disease. For PCIs, the NSF target in 2000 was 750 pmp, and the BCS 2003 target was 1,400 pmp, with expectations that the level might need to be 2-3,000 pmp.

- Although there has again been an increase in PCI activity in all the UK countries, there remain large differences between these countries, with the poorest provision in Wales at 1031 pmp compared with the highest in Northern Ireland at 1648 pmp.

- For the past 2 years the rate of increase in overall number of PCI procedures performed remains at the lowest level since records began in 1992.

- Centre size: there is evidence that suggests improved outcomes for patients being treated in higher volume PCI centres, particularly those that perform at least 400 procedures pa. This forms part of the recommendations of the Joint Working Group on PCI of BCIS and the British Cardiovascular Society.[2] In 2007 the majority of units were performing considerably more than the recommended minimum. Of the 29 units performing less than 400 cases pa, the majority were new units undertaking a gradually increasing volume of work. There are 5 NHS centres however with a persistently low volume of PCI activity over several years.

- The National Institue for Health and Clinical Excellence (NICE) recommend that "Stents should be used routinely where PCI is the clinically appropriate procedure for patients with either stable or unstable angina or with acute myocardial infarction".[3] The great majority of procedures do now involve stent insertion (95 per cent), suggesting that this aspect of good practice is being met.

1 Some patients are treated with a coronary artery bypass operation (CABG). Another audit describes outcomes for these patients, and a 'public portal' website allows patients to see the results for their local heart surgery centre [http://heartsurgery.healthcarecommission.org.uk]. The Healthcare Commission also funds audits of heart attacks, heart failure and other aspects of heart disease.

2 Percutaneous Coronary Intervention: recommendations of good practice and training. KD Dawkins, T Gershlick, M de Belder, A Chauhan, G Venn, P Schofield, D Smith, J Watkins, HH Gray, Joint Working Group on Percutaneous Coronary Intervention of the British Cardiovascular Intervention Society and the British Cardiac Society. Heart 2005; 91 (Suppl VI): 1-27

3 Ischaemic Heart Disease- Coronary Artery Stents (TA 71)

- Following concerns about the safety of drug eluting stents in September 2006, there was a fall in their use to 55 per cent across the UK. These concerns have now been recognised to be mainly invalid and early indications are for a return to higher percentage use. The National Institute for Health and Clinical Excellence (NICE) has produced updated guidelines for the use of these stents, that are largely unchanged from its original guidance.[4] They again recommended that drug eluting stents should be used if "the target artery to be treated has less than a 3-mm calibre or the lesion is longer than 15 mm." Research suggests that compliance with the NICE guidance on use of such stents would result in about 70 to 80 per cent of patients being treated with a drug eluting stent,[5] which is in keeping with the rates observed in this audit prior to the down turn induced by concerns about possible long term safety. Early data from 2008 suggest a return to these sorts of levels now that safety issues are better understood.

- National and International guidelines recommend that in the emergency treatment of patients with ST elevation MI, angioplasty treatment should be performed within 90 minutes of arrival of the patient at the angioplasty site. Modifications to the BCIS-CCAD dataset have been made to allow more detailed analyses of the time delays in treatment by primary PCI. In 2007 the overall median door to balloon times for units delivering primary PCI instead of thrombolysis to treat STEMI was 61.7 minutes. Thirteen of the 21 units achieved this standard in more than three quarters of their patients and, conversely, eight failed to do so.

- The overall rate of death before discharge from hospital following PCI has gradually risen over the past few years. This is due to a change in case mix. There has been no evidence of a change in the outcomes when patients in similar clinical presentations are compared. For patients with unstable angina or NSTEMI, the in hospital mortality is less than 1 per cent. For patients with STEMI the mortality is higher at about 5 per cent.

- There has been a huge improvement in the number of centres sending data to CCAD for electronic collection and analysis. In 2007 all NHS units in England and Wales contributed to CCAD, as did all NHS Scottish units via an electronic link.

- There has been a marked improvement in the quality of data submitted.

The rest of this report contains more details and graphs of the audit findings. The complete set of data from the 2007 audit was presented at the British Cardiovascular Intervention Society's annual meeting (BCIS) in autumn 2008 and is available for download at the society's web site www.bcis.org.uk.

4 NICE Guidance TA 152 July 2008

5 S. N. Doshi, P. F. Ludman, J. N. Townend, N. P. Buller. Estimated annual requirement for drug eluting stents in a large tertiary referal centre, according to new NICE criteria. Heart 2004:90; suppl II A41

2.0 Introduction

The heart is a muscular pump which moves blood (containing the oxygen and food your body's organs need to function) around the body. To pump properly the heart muscle needs its own blood supply, and this is provided by vessels called the coronary arteries. If these arteries get narrowed or blocked, and the supply to a region of heart muscle is reduced, then this region may start to contract less well, and ultimately this region may die.

The sensation that many people experience when their heart muscle does not get enough blood supply is called angina, which is usually felt as a tight constricting feeling across the chest. If a region of heart muscle dies, this is called a 'heart attack' or 'myocardial infarction'.

Coronary Heart Disease (CHD), causes over 117,000 deaths a year in the United Kingdom, accounting for approximately one in five deaths in men and one in six deaths in women (www.heartstats.org). While death rates for CHD have been falling rapidly in the UK since the late 1970s they are still amongst the highest in Western Europe.

There is considerable variation in mortality from CHD across the UK. Death rates are higher in Scotland than the South of England, in manual workers than in non-manual workers and in certain ethnic groups.

In addition to being a leading cause of mortality, a large number of people suffer symptoms as a result coronary artery disease. The British Heart Foundation estimate that there are over 1 million men living in the UK who have or have had angina and over 840,000 women giving a total of just under 2 million.

Treatment of narrowed coronary arteries has two aims. The first is to try to prevent the coronary arteries blocking which might cause a myocardial infarction and lead to heart failure or death. The second is to improve flow to the heart muscle to alleviate symptoms of angina.

There are three aspects to most people's treatment. Medication is required in all cases. In addition many patients benefit from either:

a) percutaneous coronary intervention (PCI) or

b) coronary artery bypass surgery (CABG)

Both these procedures are ways of mechanically improving blood flow to the heart muscle, and are called 'revascularisation procedures'. There are many facts used to decide firstly whether any form of revascularisation procedure is necessary and, if so, which is most appropriate for an individual patient.

If either of these 2 procedures might be required, then it is first necessary to visualise the coronary arteries so that it is possible to see where the narrowings and blockages are. This is done by performing a 'coronary angiogram' which is essentially a special x-ray test.

2.1 The Coronary Angiogram procedure:

During this procedure, x-ray images are made of the heart arteries, while a special liquid is injected into them to make them visible. The procedure can be performed from the artery at the top of the leg, or in the wrist, and is performed under local anaesthetic. The area of skin is made numb using local anaesthetic and through this area a long thin tube (called a catheter) is fed into the artery. It is then guided under x-ray imaging control until the tip reaches the heart.

When the tip of the catheter is in position a special liquid is injected into the heart arteries so that they show up on the x-ray machine. The position and shape of any narrowings in these arteries can therefore be identified. This part of the procedure is called an angiogram, and usually takes about 30 minutes. It can be performed as a day case procedure, or as a prelude to a percutaneous coronary intervention (PCI), which would then occur immediately after the images are obtained.

As can be seen from the graphs below, if the clinical circumstances and the angiogram findings suggest that something needs to be done to physically modify the blood flow to the heart, then out of every 4 patients, 3 will need a PCI, and 1 will need a coronary artery bypass operation (CABG).

2.2 Percutaneous Coronary Intervention:

Procedure

A percutaneous coronary intervention (PCI) starts just like an angiogram. Then, once the images have been taken, a very thin wire is steered under x-ray image control, across the narrowed part of the coronary artery. Once in place, a balloon is fed over this wire and

so tracked across the narrowing. Inflating the balloon squashes the blockage (made of fatty tissue) out of the way and widens the artery. This may need to be done several times to be successful in fully widening the artery. In most cases a stent is then implanted. A stent is a small metal mesh in the shape of a tube which can be used to scaffold the artery wall in order to keep it open. The stent is supplied crimped over a balloon, which is used to deploy it against the inner wall of the artery. As the balloon inflates, so the stent is expanded, pressing out against the arterial wall, so helping to hold open the newly widened artery. The balloon is then deflated and withdrawn, leaving the stent in place. In the last few years we have seen the development of special stents called 'drug eluting' stents, which have a drug on their surface. This drug passes into the wall of the artery it is scaffolding to try to improve the longer term success rates of the procedure.

Following a PCI, most patients return home the next day, though some patients can be treated and discharged the same day. Generally, this is a very safe form of treatment. The potential complications can be broadly split into those that occur during or very shortly after angioplasty, and those that occur weeks or months later.

Potential Complications

At the time of PCI it is sometimes not possible to successfully open up the blocked vessel. Generally if the vessel was narrowed the success rates are very high (see audit below), but if the vessel was completely blocked before the procedure, the chances of re-opening it are rather lower. In addition, but very rarely, it is sometimes necessary to resort to emergency coronary artery bypass surgery to treat a complication (less than 0.2 per cent of cases, see audit below). Any treatments involving the coronary arteries may, rarely, be associated with complications such as stroke, heart attack or death (the risk is less than 1 per cent). As can be seen from the audit below, some patients are at higher risk of developing complications than others. For example, the treatment of a patient in a stable situation is associated with complication rates of less than 1 per cent, but in the context of an acute heart attack, this may rise to 10 per cent or more.

Potential later complications: After PCI, the symptoms of angina are usually much improved. There follows a period when the walls of the newly stretched arteries heal. If a simple metal stent has been deployed, then over the course of the first six months cells grow over this part of the artery wall, and form a new lining, embedding the stent within the artery wall. If the healing process is over exuberant this can lead to re-narrowing of the artery (so called 'restenosis'), and a recurrence of angina. If this is going to occur it usually does so within the first six months. If a drug eluting stent has been implanted, there is much less proliferation of cells around the stented site. This means that the chance of recurrent symptoms in the first few months is much lower. After both types of stent there is a small risk (less than 1 per cent per year) of the treated vessel blocking abruptly, usually due to clot formation. This risk is slightly higher for simple metal stents early after the angioplasty, and slightly higher for drug eluting stents later after the angioplasty.

3.0 Audit

From 1988, PCI activity across the UK has been gathered by the Audit Lead of the British Cardiovascular Intervention Society (BCIS) and presented to the society annually. Early data were published in the British Heart Journal, but data from 1992 onwards are available on the Society's web site (www.bcis.org.uk).

These audits have addressed a number of issues for the provision of care, to the outcome following procedures. The data have been gathered by asking all units that perform PCI to complete paper forms that summarised their year's activity.

3.1 Central Cardiac Audit Database

In order to improve a number of aspects of this audit, particularly to increase the amount of detailed information about each PCI procedure that can be collected and analysed, BCIS have been working with Central Cardiac Audit Database (CCAD) to role out electronic data collection for England and Wales. The CCAD project is described in detail at:

http://www.ic.nhs.uk/our-services/improving-patient-care/national-clinical-audit-support-programme-ncasp/heart-disease.

In brief, this project is funded by the Healthcare Commission, and infrastructure provided by the National Clinical Audit Support Programme (NCASP). The audits that concern PCI are under the clinical lead of the BCIS Audit Lead, Dr Peter Ludman.

Since 2005, the audit analysis has made extensive use of data that had been uploaded to CCAD, with the analyses presented being a combination of data from the usual paper forms (for all the United Kingdom), and also from the electronic data available on CCAD central servers. In 2007, 100 per cent of NHS units in England and Wales contributed to CCAD. Data from Scotland is collected electronically using a different system, but an interface and translation program was developed, and in 2007 we were able to combine these data with the England and Wales data. Thus data from all the UK PCI centres with the exception of Northern Ireland was available for procedures performed in 2007.

Presentations of the detailed audit data can be downloaded from the web at www.bcis.org.uk. Below is an overview of some of the key features of the 2007 audit, and how they pertain to national targets and the evolution of the provision of PCI.

3.2 Data completeness

There has been a big improvement in the completeness of the fields for each of the procedures entered into CCAD for the 2007 data compared with 2006. Healthcare Commission's Healthcheck for 2007/2008 asked trusts to try to achieve more than 90 per cent completeness of the key fields required for risk adjusted outcome. The actual percentage completeness for hospitals in England and Wales is listed overleaf:

	Hospital	Date of Birth	Sex	Medical History	Pre-procedure shock	Procedure urgency	Vessels treated	Renal disease	Diabetes	Discharge date	Discharge status	PCI hospital outcome	NHS number
NHS	CGH. Conquest Hospital	100	100	100	100	100	100	100	100	100	100	100	100
NHS	FRM. Frimley Park Hospital	100	100	100	100	100	100	100	100	100	100	100	100
NHS	SEH. Southend Hospital	100	100	100	100	100	100	100	100	100	100	100	100
NHS	SPH. St Peter's Hospital	100	100	100	100	100	100	100	100	100	100	100	100
NHS	BHR. Royal Berkshire and Battle Hospital	100	100	100	100	100	100	100	100	100	100	100	99.8
NHS	MOR. Morriston Hospital	100	100	100	100	100	100	100	100	100	100	100	99.8
NHS	BHL. Cardiothoracic Centre Liverpool	100	100	99.8	100	100	100	100	100	100	100	100	99.8
NHS	SCM. James Cook University Hospital	100	100	99.6	100	100	100	99.9	99.9	100	100	100	100
NHS	DGE. Eastbourne DGH	100	100	100	100	100	100	100	100	100	100	100	99
NHS	GRL. Glenfield Hospital	100	100	99.9	100	100	100	98.7	99.8	100	100	100	99.7
NHS	CHN. Nottingham City Hospital	100	100	100	100	100	100	100	100	100	98.8	100	99.1
NHS	QEB. Queen Elizabeth Hospital, Edgbaston	100	100	100	100	100	98.6	99.7	99.8	99.7	99.7	99.8	98.9
NHS	CHH. Castle Hill Hospital	100	100	97.4	100	100	100	100	100	100	99.8	99.6	99.3
NHS	NGS. Northern General Hospital	99.9	99.9	99.7	99.9	100	100	99.9	99.7	99.4	99.4	99.5	98.5
NHS	RCH. Royal Cornwall Hospital	100	100	100	100	100	100	96.8	99.5	99.8	99.8	100	99.4
NHS	SAN. Sandwell District General Hospital	100	100	100	100	100	97.7	98.7	99.5	99.5	100	100	99.7
NHS	TOR. Torbay Hospital	100	100	98.7	100	100	100	97.7	99.3	100	100	100	99.3
NHS	DUD. City Hospital	100	100	100	100	100	97.4	98.9	99.3	100	100	99.6	98.5
NHS	AEI. Royal Albert Edward Infirmary	100	100	100	100	100	97.1	97.1	98.6	100	100	100	100
NHS	RFH. Royal Free Hospital	100	100	99.4	100	100	96.2	100	99.7	100	99.8	99.7	97.5
NHS	SGH. Southampton General Hospital	100	99.9	100	100	100	97.8	97.4	98.8	99.1	99.1	99.1	99.9
NHS	RDE. Royal Devon & Exeter Hospital	100	99.4	100	100	100	93.6	98.7	98.8	100	100	100	99.3
NHS	SUN. Sunderland Royal Hospital	100	100	99.3	100	100	100	100	100	96.6	96.6	97	100
NHS	GEO. St George's Hospital	100	100	99.2	100	100	100	99.6	99.8	99.9	99.8	100	90.9
NHS	DER. Derby Royal Infirmary	100	97.6	99.1	97.2	100	100	99.4	99.4	97.3	98.8	100	100
NHS	MRI. Manchester Royal Infirmary	100	100	100	100	100	99.4	99.8	99.2	100	100	91.7	98.7
NHS	WRG. Worthing Hospital	100	100	100	100	100	100	97.9	98.2	97.6	97.9	100	94.9
NHS	WAL. Walsgrave Hospital	100	100	94.8	100	100	100	97.9	95.8	100	99.9	99.9	98.1

	Hospital	Date of Birth	Sex	Medical History	Pre-procedure shock	Procedure urgency	Vessels treated	Renal disease	Diabetes	Discharge date	Discharge status	PCI hospital outcome	NHS number
NHS	FRE. Freeman Hospital	100	99.9	97.8	99.3	100	97.2	97.7	96.9	99.9	100	98.7	98.8
NHS	NHB. Royal Brompton Hospital	100	100	97.5	99.2	100	100	97.7	98.4	99.8	99.8	99.9	90.9
NHS	BRD. Bradford Royal Infirmary	100	100	99.6	100	100	92.3	96.4	97.2	99.6	99.6	99.6	97.6
NHS	LGI. Yorkshire Heart Centre	99.9	99.9	94.2	100	100	99.9	94.9	97	99.5	99.6	97.7	99.1
NHS	RSC. Royal Sussex County Hospital	100	99.8	89.8	100	100	98.6	100	100	100	99.6	96.9	96.4
NHS	QAP. Queen Alexandra Hospital	100	100	91.8	100	100	93	100	99.4	99.8	99.8	94.2	99.8
NHS	EBH. Birmingham Heartlands Hospital	99.4	98.5	99.9	100	100	96	93.5	97.4	98.9	98.5	100	94.9
NHS	NCR. New Cross Hospital	100	99.9	96.3	98.2	100	99.9	97	97.5	97.4	99.2	97.6	93.7
NHS	STH. St Thomas' Hospital	100	100	99.4	100	100	100	90.2	91.3	100	100	100	94.6
NHS	WYT. Wythenshawe Hospital	100	100	100	91.8	99.8	99.5	92.1	92.7	100	99.9	100	99.2
NHS	BRI. Bristol Royal Infirmary	100	100	78.7	100	100	96.8	100	100	100	100	99.9	99.1
NHS	PMS. The Great Western Hospital	100	100	97.9	100	95.5	100	90	94.1	99.6	99.6	97.3	100
NHS	UHW. University Hospital of Wales	100	100	93	97.1	99.9	99.7	95.6	97.3	96.5	98.7	99.4	95.7
NHS	CHG. Cheltenham General Hospital	100	99.8	76.4	100	100	98.6	98.9	99.8	99.8	99.4	100	99.8
NHS	HRI. Hull Royal Infirmary	100	100	91.9	97.1	100	100	94.8	94.8	100	98.2	96.9	97.6
NHS	BAL. Barts and the London	100	100	91.6	99.8	100	99.4	92.4	98.5	92.6	100	98.5	96
NHS	VIC. Victoria Hospital	100	99.2	91.5	100	100	98.9	92.3	92.6	99.2	100	100	94.1
NHS	HH. Harefield Hospital	100	99.8	87.6	97.8	99.9	99.4	87.7	96.7	99.9	99.9	99.9	96.1
NHS	AMG. Wycombe General Hospital	100	99.5	68.9	100	100	100	97.9	89.1	93.3	93.3	100	100
NHS	UCL. University College Hospital	100	100	87	100	100	100	76.5	83.6	98.5	99.5	100	93.6
NHS	WEX. Wexham Park Hospital	100	100	86.1	100	100	94.2	86.9	73	98.4	99.2	100	100
NHS	BOU. Royal Bournemouth General Hospital	100	100	90.2	100	100	100	96.3	96.1	49.3	100	100	99.6
NHS	WHC. Whipps Cross University Hospital	100	100	61.1	100	100	100	100	67.9	99.5	100	100	94.8
NHS	STO. North Staffordshire Hospital	99.3	90.7	99.8	100	99.8	97.1	97.6	98.3	98.4	97	45.2	99.8
Private	LBH. London Bridge Hospital	100	100	100	100	100	100	100	100	100	100	100	0

	Hospital	Date of Birth	Sex	Medical History	Pre-procedure shock	Procedure urgency	Vessels treated	Renal disease	Diabetes	Discharge date	Discharge status	PCI hospital outcome	NHS number
Private	HSC. Harley Street Clinic	100	100	100	100	100	100	98.7	100	100	100	100	0
Private	HHW. Wellington Hospital	100	100	100	100	100	100	99	99	100	100	100	0
Private	PHB. BMI Priory Hospital	100	100	100	100	100	94.9	89.6	100	100	100	100	8.3
NHS	RAD. John Radcliffe Hospital	100	100	100	85.1	100	98.7	37.4	67.6	100	98.9	100	98.9
NHS	HHH. Hemel Hempstead General Hospital	99.6	100	80.5	100	100	93.1	94.1	100	59.4	59	93.5	99.2
NHS	BHH. Rochdale Infirmary	100	100	27.3	66.9	100	99.7	83.8	93.6	100	100	100	99.5
Private	ANT. St Anthony's Hospital	100	99.3	78.3	100	100	99.3	44.1	89.5	99.3	97.9	100	60.8
NHS	MPH. Taunton & Somerset	99.4	99.8	95.9	100	100	98.4	99.6	100	38.4	38.2	98.4	92.7
NHS	KCH. King's College Hospital	100	99.3	97.1	99.1	99.9	96.1	96.3	99.6	28.4	87.4	97.6	58.1
NHS	PLY. Derriford Hospital	100	100	48.3	99.8	100	99.3	99.4	99.9	99.3	99	3.3	99.6
NHS	NOR. Norfolk & Norwich Hospital	100	100	48.9	100	100	100	51.6	53.2	70.6	99.8	92.4	100
NHS	ESU. New East Surrey Hospital	100	96.8	100	64.3	100	100	29	30.6	100	96.8	100	89.5
NHS	NPH. Northwick Park Hospital	100	99.7	94.4	62.5	99.7	92.1	65.6	74.8	98.7	99.3	92.8	25.6
Private	CRO. Cromwell Hospital	100	100	64.7	100	100	100	64.7	100	17.6	88.2	88.2	70.6
NHS	HAM. Hammersmith Hospital	99.9	99.8	100	43.9	100	99.4	35.5	41.8	100	99.2	100	72
NHS	LIS. Lister Hospital	100	99.7	64.9	96.8	100	99.1	87	87	34.8	47	39.6	100
NHS	WHH. William Harvey Hospital	100	100	33.1	70.3	100	96.6	39.9	37.2	74.3	98	99.3	95.9
NHS	NHH. North Hampshire Hospital	100	100	100	3.7	100	100	0.3	21.4	100	100	100	93.7
NHS	BAT. Royal United Hospital Bath	100	100	36.7	100	100	100	96.3	74.3	40.7	42	100	0.3
NHS	MAY. Mayday University Hospital	99.5	99.5	0	100	100	0	92.2	95.1	100	98.1	0	97.8
NHS	PAP. Papworth Hospital	100	100	3.8	4.7	99.9	3.3	66	62.2	100	100	100	97.9
NHS	STM. St Mary's Hospital	100	99.7	77	100	100	0	4.4	100	4.7	100	100	0.1

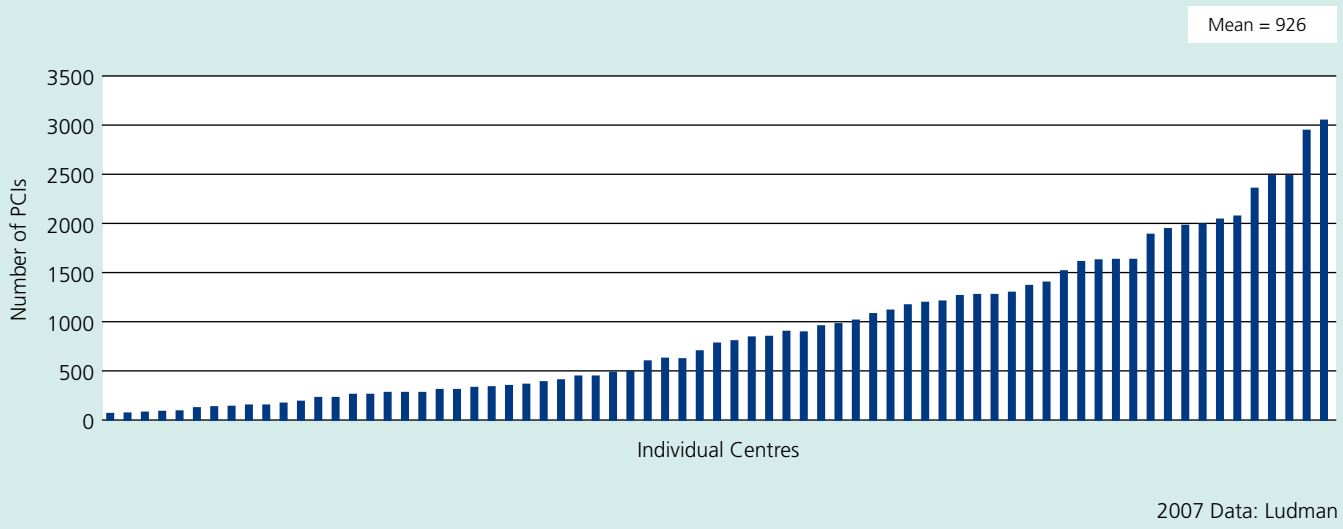
Table 1: Data completeness for PCI units in England and Wales 2007

3.3 Infrastructure

There was a further expansion in the number of sites performing percutaneous coronary intervention, and because this is partly driven by angiography only centres starting PCI, there was a fall in the number of sites performing angiography only. Thus in the United Kingdom there were a total of 98 PCI centres, and 85 angiography only centres in 2007. There are data from many countries that suggest improved outcomes for patients being treated in higher volume centres, particularly those that perform at least 400 procedures per annum. This recommendation therefore forms part of the report by the Joint Working Group on Percutaneous Coronary Intervention of the British Cardiovascular Intervention Society and the British Cardiovascular Society entitled 'Recommendations for good practice and training'[6].

The majority of units perform considerably greater numbers that 400 pa (Figure 1).

Figure 1: The number of PCI procedures performed by all UK NHS centres in 2007



The units performing less than the recommended number of 400 pa are shown in figures 2 and 3 below. In the majority of cases this is because the unit is new, and undertaking a gradually increasing volume of work. The start date for the unit's PCI program can be seen in the figures.

6 Dawkins KD Heart 2005;91(Suppl VI):vi1–vi27

Figure 2: Centres performing less than 200 PCI procedures in 2007, and the start year of the PCI program.

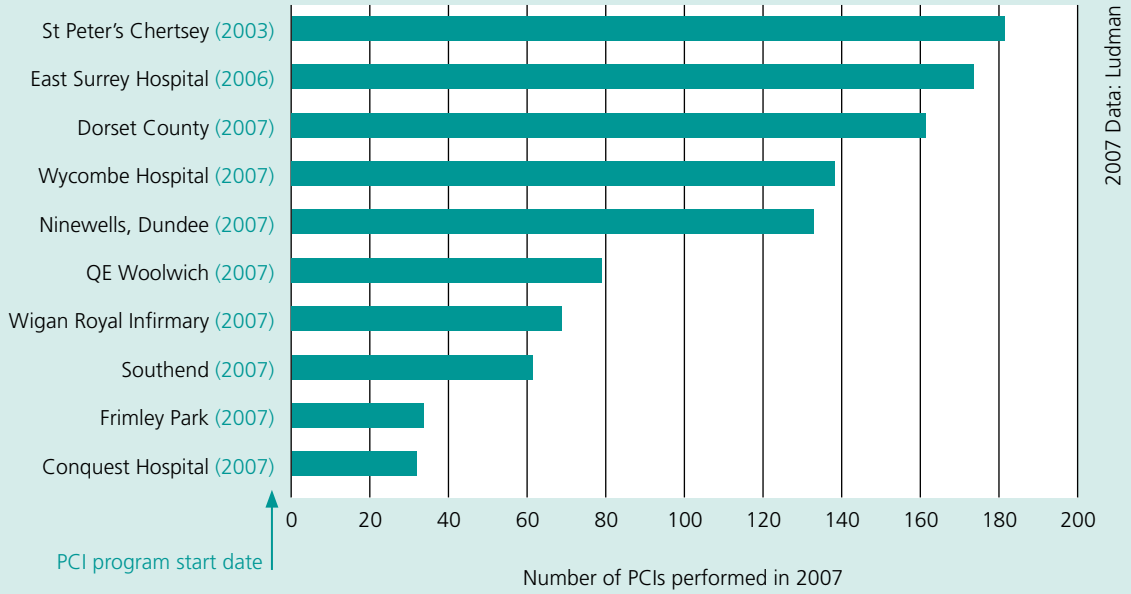
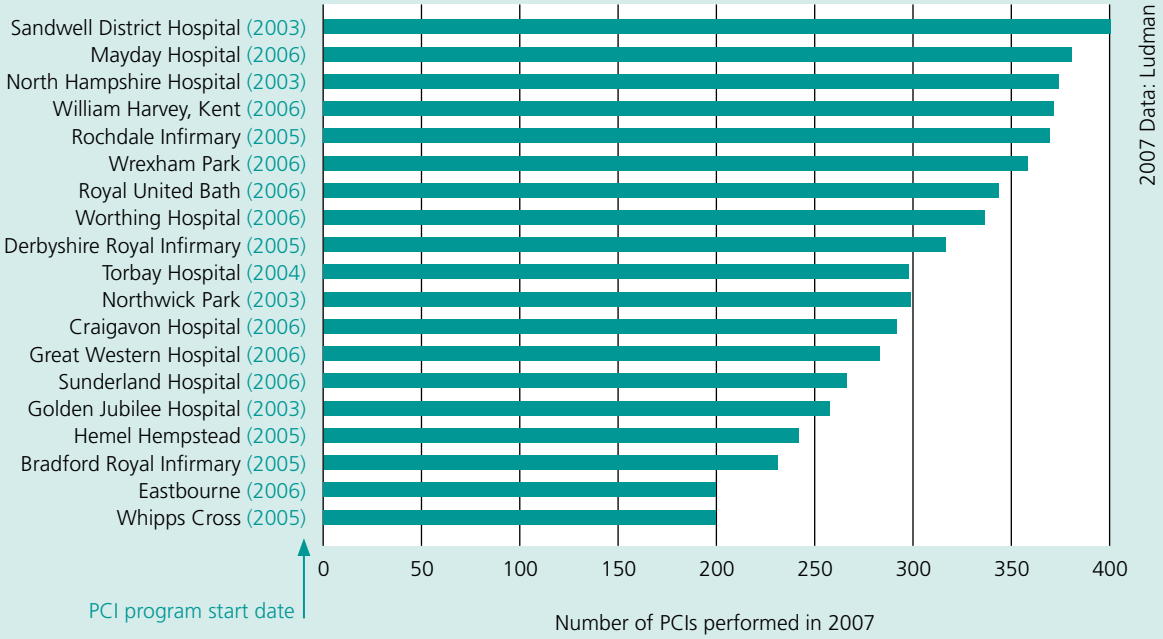


Figure 3: Centres performing 200 to 400 PCI procedures in 2007, and the start year of the PCI program.



3.4 Revascularisation rates in the United Kingdom

3.4.1 Coronary angiography

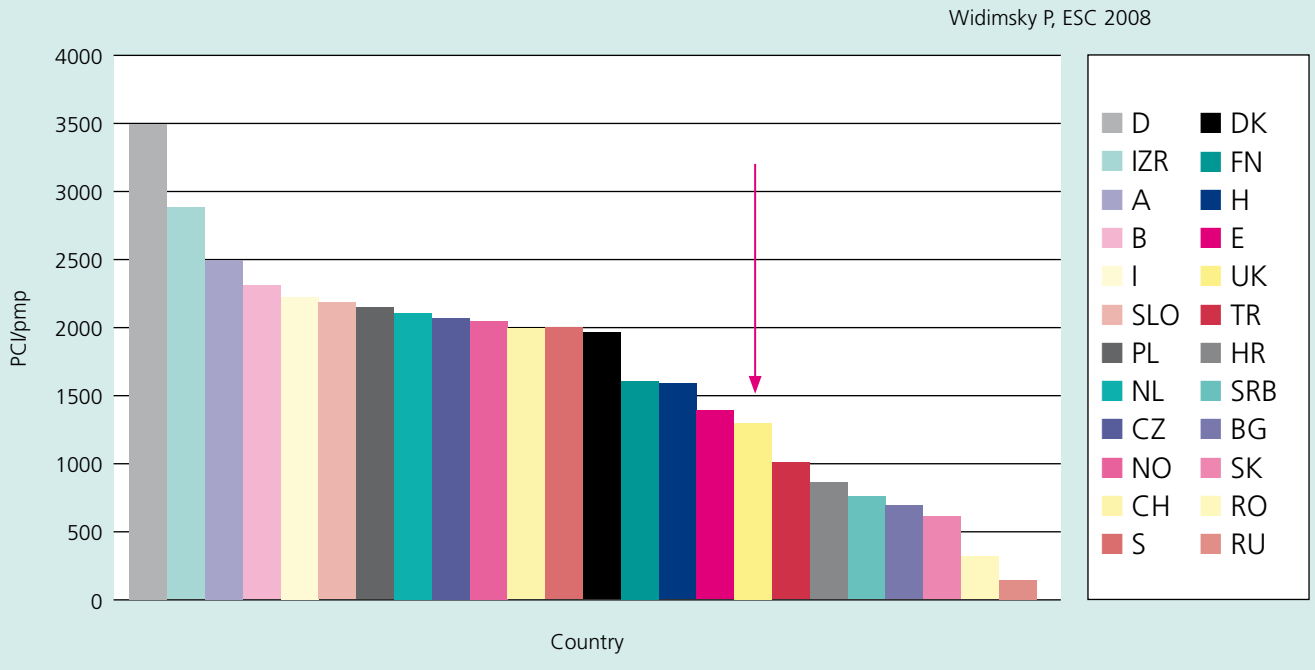
In 2007, 223,638 diagnostic coronary angiograms were performed. This represents a rate of 3668 angiograms pmp. There is no government target for coronary angiograms, but the National Service Framework (NSF) for Coronary Heart Disease targets for revascularisation (published in 2000) would be expected to lead to a rate of about 3000 angiograms pmp. The British Cardiovascular Society made recommendations in 2002 that would be expected to lead to over 5000 angiograms pmp (Hackett D, BCS Working Group on Cardiology Workforce Requirements 2003).

3.4.2 Percutaneous coronary angioplasty

There was a total of 77,373 PCIs performed in the calendar year 2007. With an estimated UK population of 61.0 million in mid 2007, this represents a rate of 1269 PCI pmp.

The National Service Framework for Coronary Heart Disease, published in 2000, set a number of targets. While this document is now 8 years old, it gives an idea of how the service provision in the UK has improved. The NSF target for PCI was 750 pmp. The British Cardiovascular Society published a workforce planning document in 2003 suggesting an immediate increase in the target to 1400 pmp, but with expectations that the required level might be 2000 to 3000 pmp. Comparisons with provision in Europe remain interesting, and can be seen in the figure below:

Figure 4: Rates of PCI pmp in Europe in 2007



While the most appropriate rate of PCI pmp is difficult to judge, and will depend on many factors including the varying demographic profiles of populations in different countries, the UK has a lower rate than most of the rest of the developed European countries. In spite of this, the rate of increase in PCI in the UK over the last 2 years remains at its lowest level that at any time since records began in 1992 (Figure 5 and 6).

Figure 5: Graph of absolute number of PCIs and rates pmp

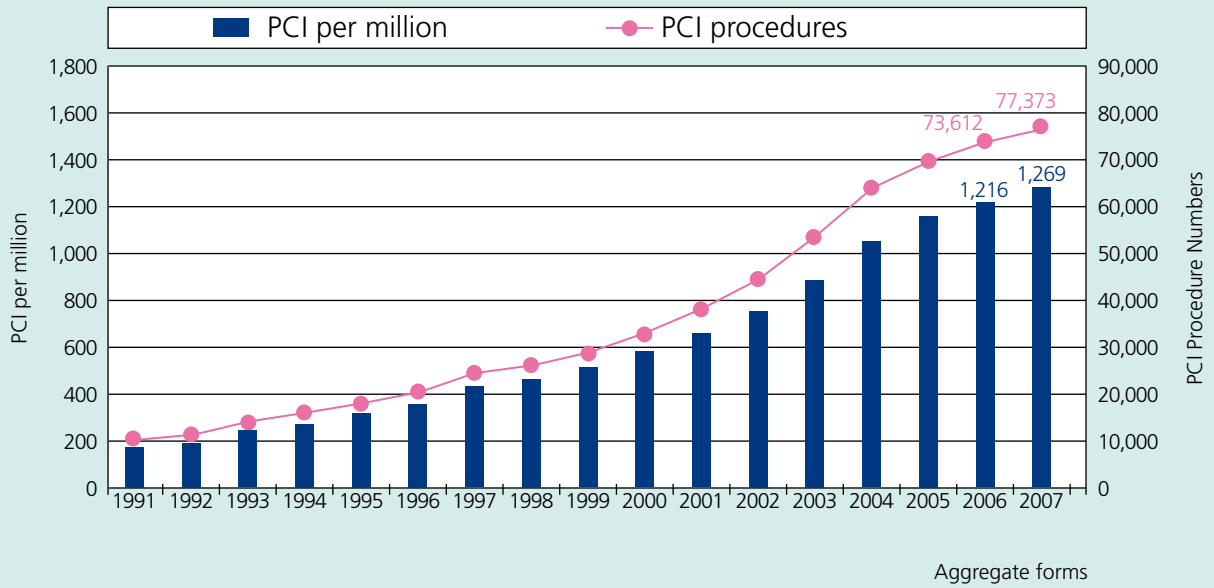
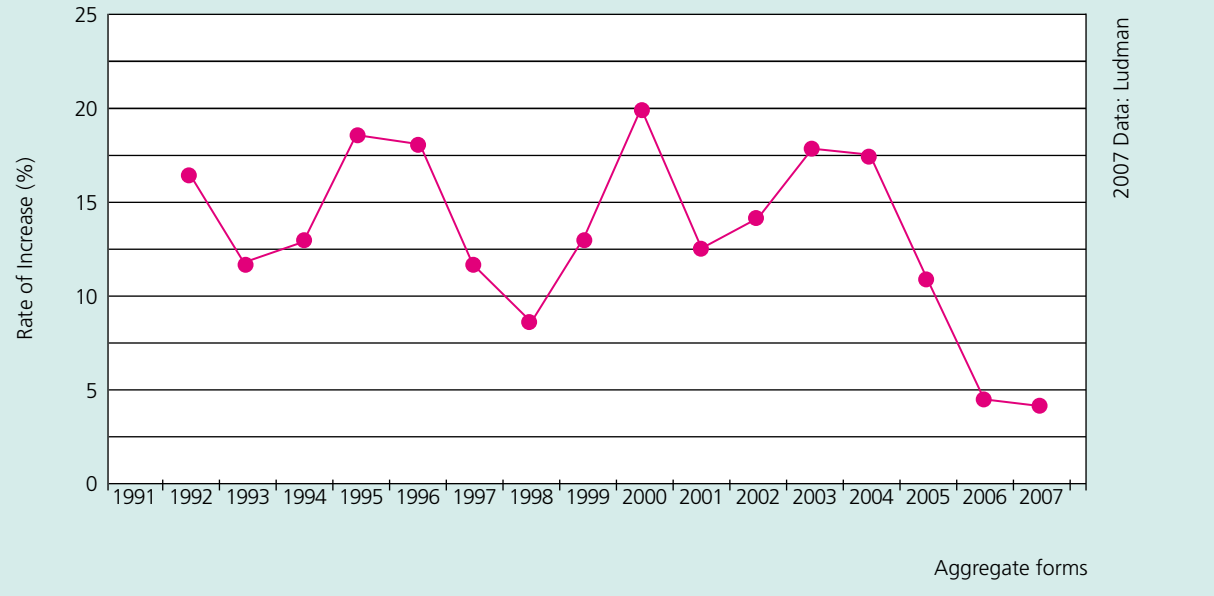
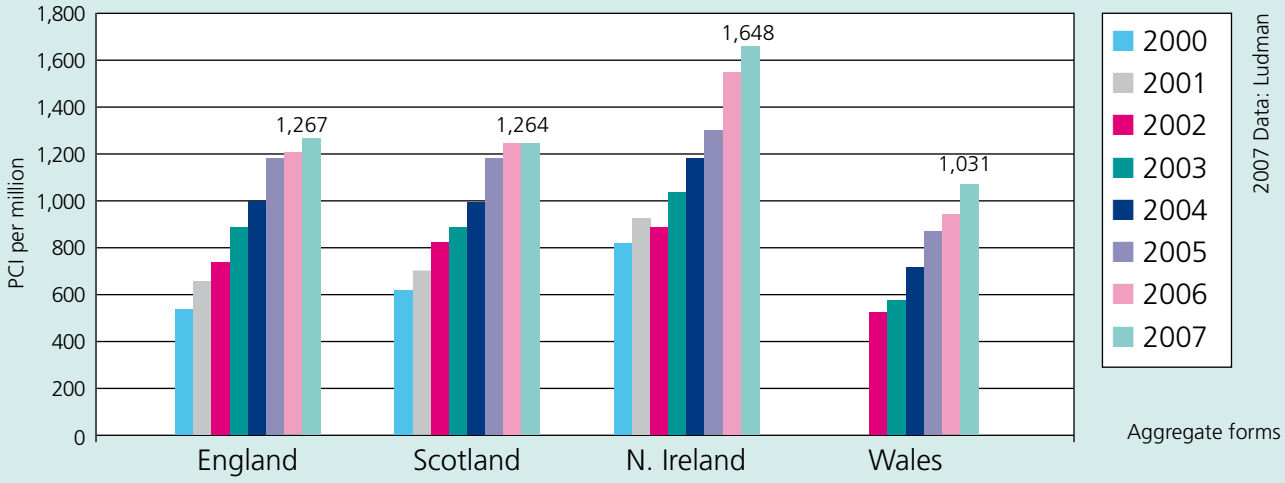


Figure 6: Rate of increase in PCI numbers pmp in the UK since 1992



While the increase in PCI activity has occurred in all the countries in the UK, there remain large differences between these countries, with the poorest provision still in Wales at 1031 pmp compared with the highest in Northern Ireland at 1648 pmp. The rates in Scotland have remained virtually unchanged over the last 2 years (Figure 7).

Figure 7: PCI activity per million population in the UK countries.



The majority of patients who need mechanical revascularisation can be treated by PCI rather than requiring bypass surgery (Figure 8). In 2007, there was not much change in this ratio, which is running at about 3:1 (Figure 9).

Figure 8: PCI vs Isolated CABG Numbers (UK) 1991 to 2007

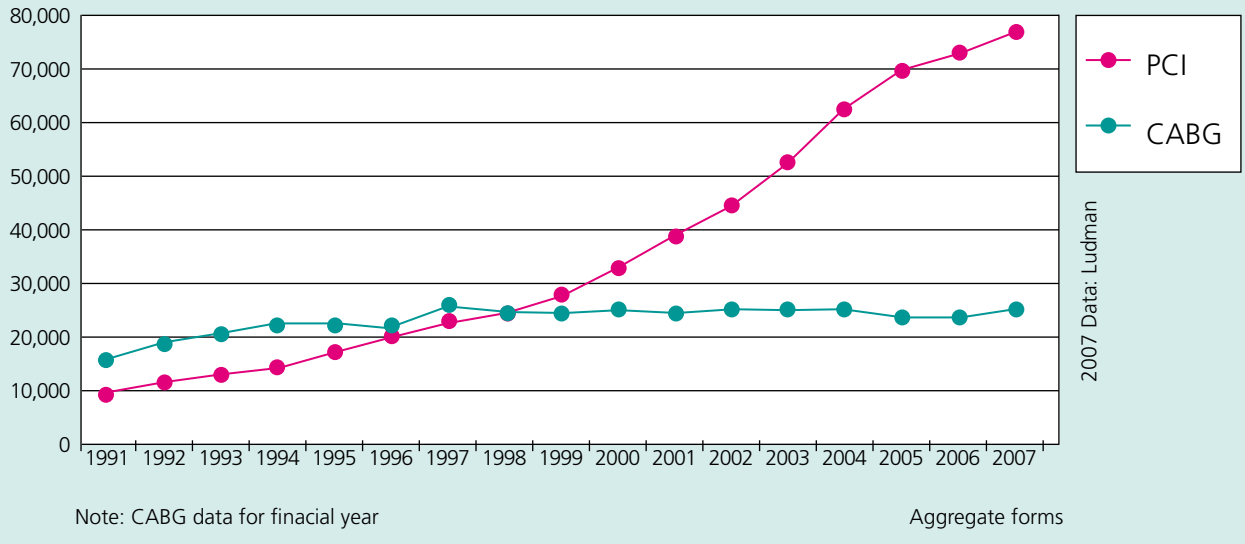
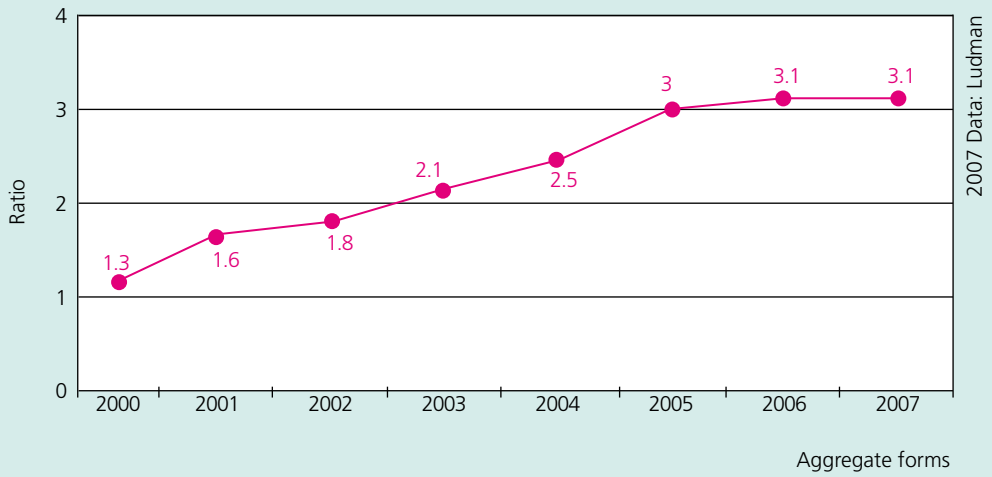


Figure 9: Ratio of PCI to isolated CABG

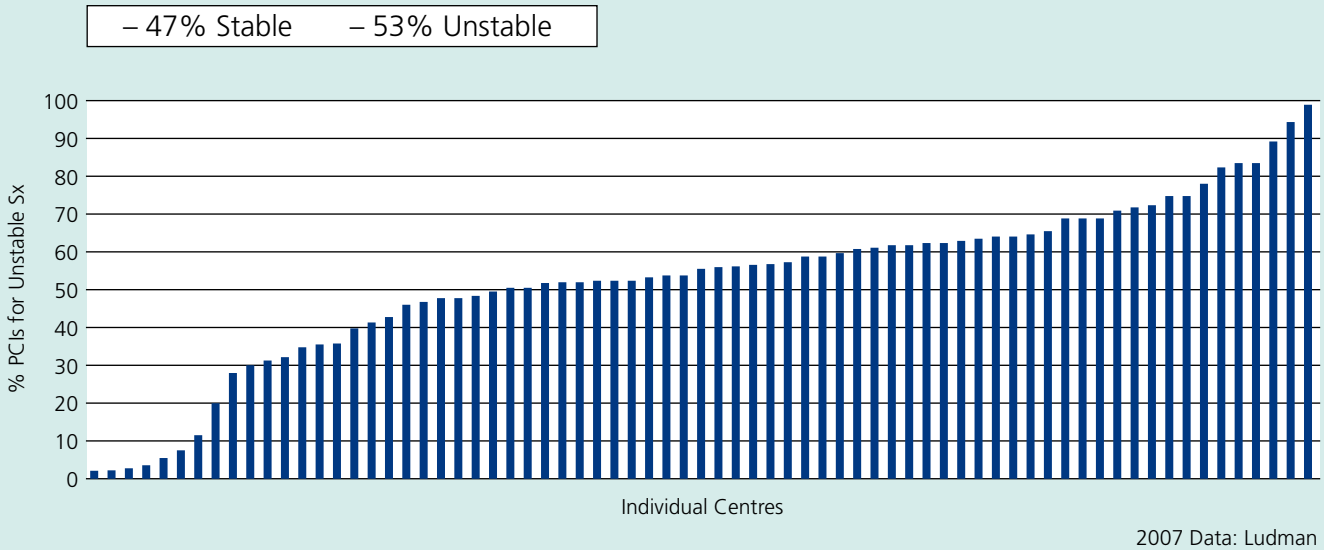


3.5 Clinical Presentation

Patients can develop symptoms of coronary disease in a number of ways. They may for example notice a gradual onset of chest pain on exertion. If they are being treated as an outpatient, then such a patient is usually described as having 'stable angina'. Alternatively a patient may present with sudden onset of symptoms that leads to a hospital admission. Such a presentation would be described as being an acute coronary syndrome, which may include unstable angina or a myocardial infarction. Myocardial infarction is further subdivided into 2 different electrocardiographic presentations – ST elevation myocardial infarction (STEMI) and non ST elevation myocardial infarction (NSTEMI).

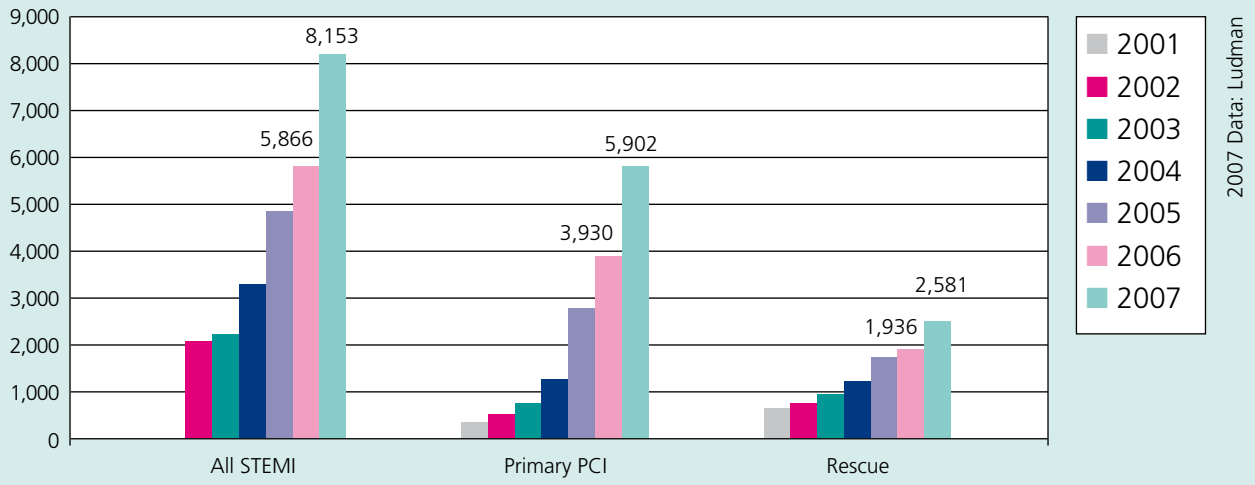
It can be seen that there is a fairly even split between those being treated for stable symptoms and for acute coronary syndromes, but with quite a lot of individual variation between different units (Figure 10).

Figure 10: Clinical Syndrome



Currently the commonest treatment for STEMI is thrombolysis, and this therapy, which must be delivered very quickly, is the subject of the Myocardial Ischaemia National Audit Project (MINAP) audit. Primary PCI is an alternative treatment for STEMI, where the occluded blood vessel causing the heart attack is opened mechanically by emergency angioplasty techniques rather then with lytic drugs. When delivered promptly by an experienced team, treatment by primary PCI can be associated with better short and long term outcomes than treatment with thombolysis. As a result many centres across the UK are introducing emergency PCI in place of thrombolysis to treat patients presenting with STEMI. Some aspects of the feasability and cost effectiveness of this approach have been assessed by the department of Health, and are described in detail in the recently published final report of the National Infarct Angioplasty Project (NIAP) (ref – 290911/Treatment of heart attack national guidance). The large increase in the use of primary PCI is shown in figure 11. Rescue PCI describes the use of PCI in patients who have been treated by thrombolysis, but in whom this has failed to work. This has also increased significantly in 2007.

Figure 11: PCI for STEMI



3.6 Process

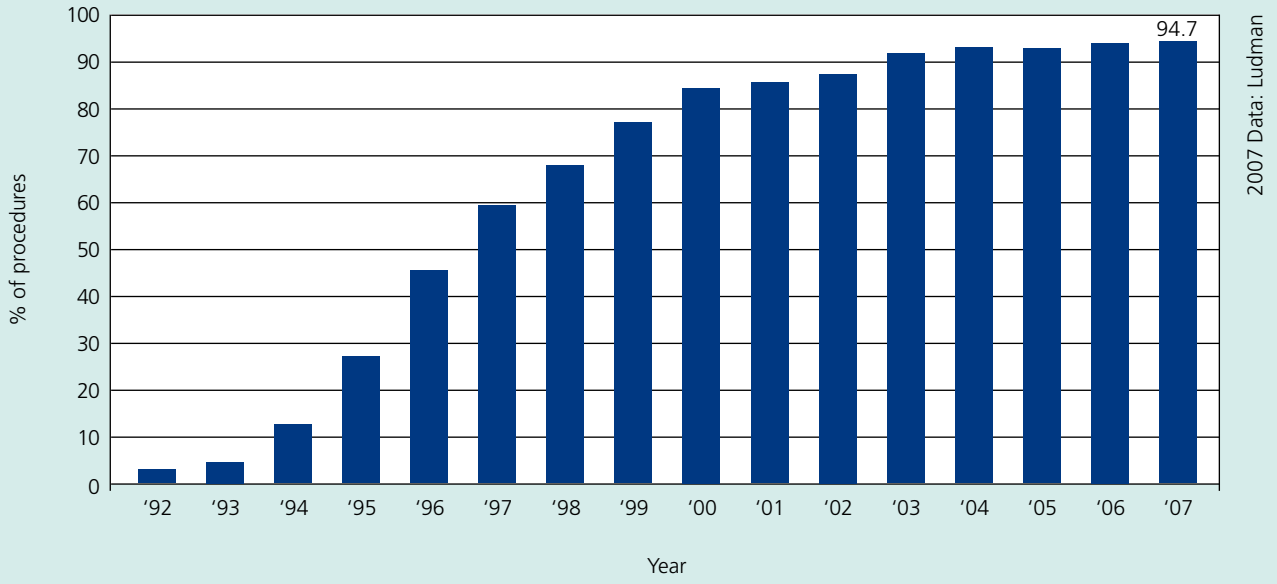
3.6.1 Stents

During angioplasty, after the vessel has been dilated, there is increasing evidence that where possible, a stent should be inserted, as it is associated with a better outcome. There are technical reasons why this is not always possible, but the issue of stent implantation has been the subject of the National Institute of Clinic Excellence recommendation "Stents should be used routinely where PCI is the clinically appropriate procedure for patients with either stable or unstable angina or with acute myocardial infarction".[7]

It can be seen that the use of stents has increased in line with these recommendations, so that stents are now used in more than 90 per cent of procedures (Figure 12).

7 Ischaemic Heart Disease- Coronary Artery Stents (TA 71)

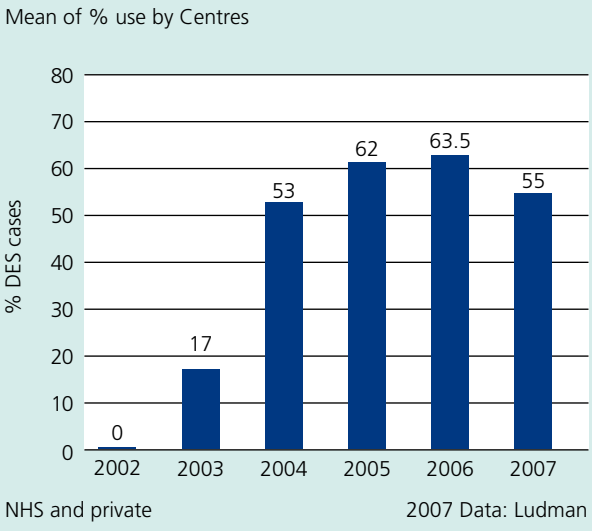
Figure 12: Procedures using Stents



An over-exuberant healing process following stent implantation can lead to renarrowing of the vessel, usually 4 to 6 months after the procedure. Drug eluting stents have been developed to reduce this problem. The initial enthusiasm for these stents was slightly dampened by some data presented in September 2006 that their use might be associated with later complications. Further research has shown that many of these anxieties were unfounded, but the reduction in use of drug eluting stents following the identification of potential problems with the techonlogy can be seen in figure 13.

The National Institute for Health and Clinical Excellence (NICE) has produced updated guidelines for the use of these stents, that are largely unchanged from its original guidance.[8] They again recommended that drug eluting stents should be used if "the target artery to be treated has less than a 3-mm calibre or the lesion is longer than 15 mm." Research suggests that compliance with the NICE guidance on use of such stents would result in about 70 to 80 per cent of patients being treated with a drug eluting stent,[9] which is in keeping with the rates observed in this audit prior to the down turn induced by concerns about possible long term safety. Early data from 2008 suggest a return to these sorts of levels now that safety issues are better understood.

Figure 13: Percentage of patients treated with drug eluting stents



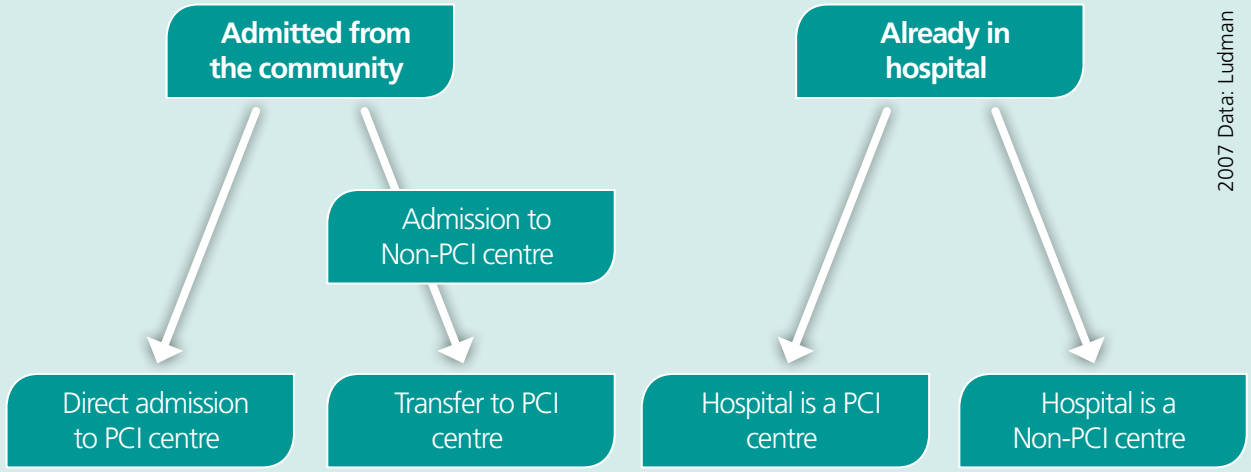
3.6.2 Time Delays to Treatment

In the treament of STEMI, speed is of the essence, because delays increase the risk of a patient not surviving the heart attack. When treatment is with thrombolytic therapy, the time delay between a patient presenting with chest pain, and being given the correct intravenous drug treatment is measured (known as the 'door to needle' time). The Myocardial Ischaemia National Audit Project (MINAP), was set up to help measure and minimise these time delays, and so improve patient outcome. MINAP is supported by The NHS Information Centre's National Clinical Audit Support Programme (NCASP) and CCAD. The MINAP report can be downloaded from the Royal College of Physicians website as a PDF.

When PCI is used instead of drug treatment, speed is also essential in maximising patient benefit. For primary PCI, one of the key time delays in the process of care is the time between a patient presenting to a hospital with chest pain, and the time the first device is used to re-open the blocked coronary artery. This is known as the 'door to balloon' time. Guidelines from the both the European Cardiology Society and the American College of Cardiology[10] recommend that this delay is less than 90 minutes.

There are a number of different ways in which a patient can present with chest pain and require primary PCI. They may develop pain in the community, and be taken straight to a centre performing primary PCI, or be taken to a non-PCI centre and need to be transferred as an emergency to a centre for PCI. Alternatively they may present with chest pain while already in hospital. This hospital might be one in which primary PCI can be performed, or the patient may need transfer to another hospital for PCI. This is summarised in figure 14:

Figure 14: Admission scenarios for primary PCI



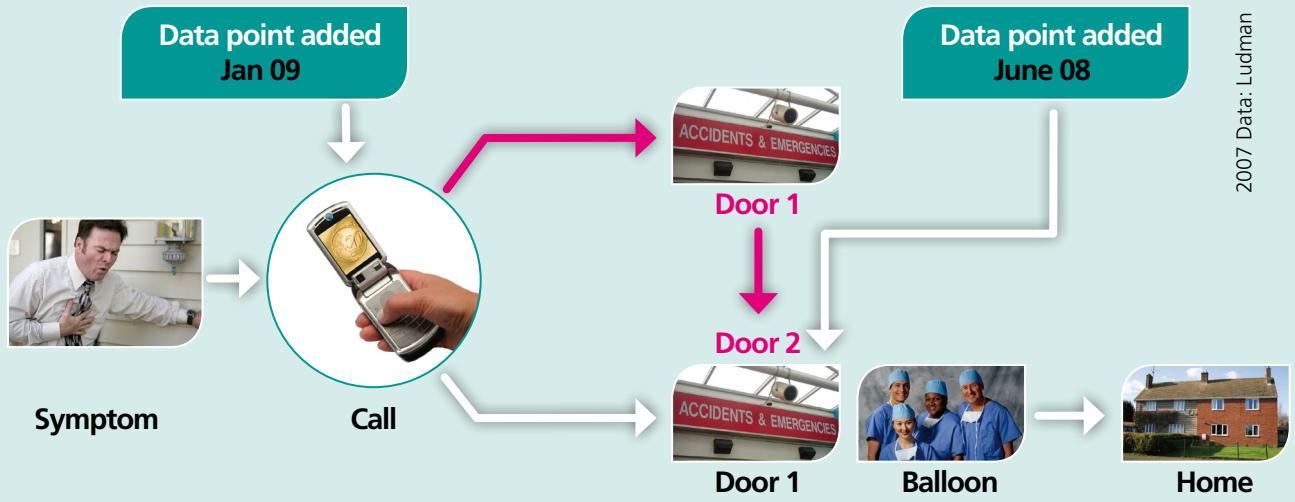
8 NICE Guidance TA 152 July 2008

9 S. N. Doshi, P. F. Ludman, J. N. Townend, N. P. Buller. Estimated annual requirement for drug eluting stents in a large tertiary referal centre, according to new NICE criteria. Heart 2004:90; suppl II A41

10 2007 Focused Update of the ACC/AHA 2004 Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines:
Circulation, Jan 2008; 117: 296 - 329

During 2008 the BCIS-CCAD dataset was been modifed to allow measurement of all the time delays in the provision of primary PCI, in all the above scenarios. The time points are summarized in figure 15

Figure 15: updates to BCIS-CCAD dataset time points



For 2007, only limited data are available, but by 2008 the modifications to the dataset described above will allow a much more detailed analysis.

Figure 16 below shows data for those units whose default strategy for the treatment of STEMI is PCI rather than thrombolysis. It also looks only at those patients who were admitted directly to that PCI centre (not those who were transferred to that centre from another hospital), The median door to balloon times compare favourably to the audit standard of less than 90 minutes.

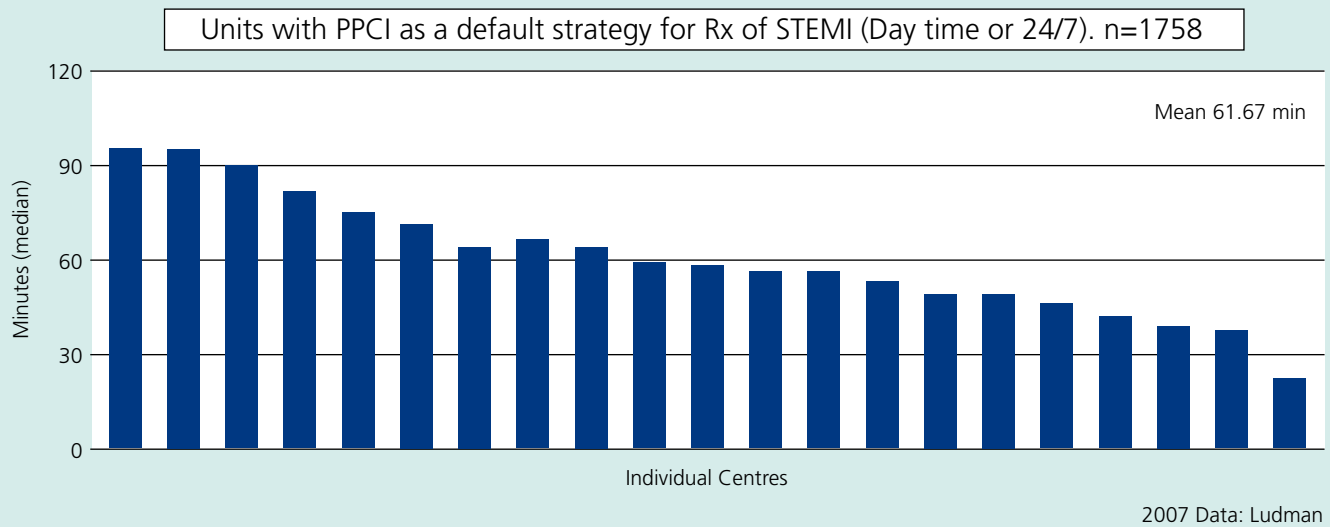
Figure 16: Time intervals for patients treated for STEMI by primary PCI

	Time Mean of units' median times	**Units**	
Symptom to arrival	2.46	Hours	n=1792
Door to Balloon	61.7	Min	n=1758
PCI to discharge	3.15	Days	n=2197
Length of Stay	3.28	Days	n=1821

2007 Data: Ludman

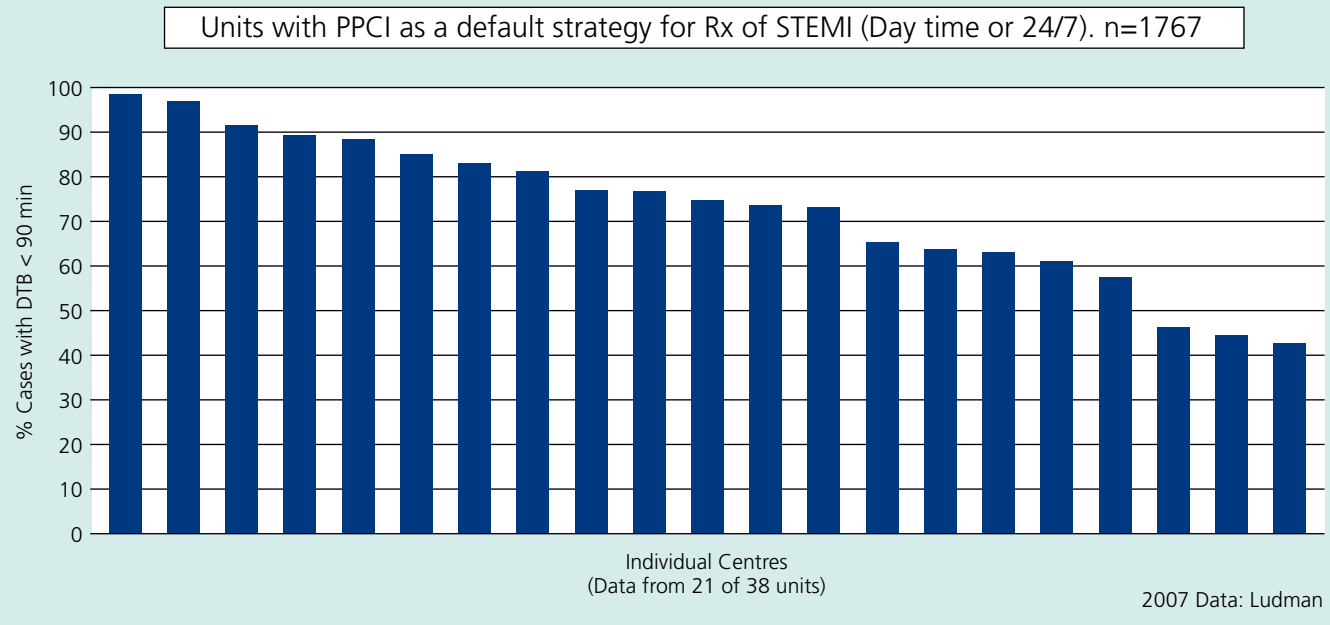
The median time delays for each of the 21 units are shown in figure 17

Figure 17: median door to balloon times for each unit



There are 3 units with a median door to ballooon time of about 90 minutes, which means that they will be failing to meet the audit standard in about half of their patients. The same data can also be presented as the percentage of cases for whom the door to balloon time met or exceeded the audit standard of 90 minutes (figure 18). Thirteen of the 21 units achieved this standard in more than three quarters of their patients and, conversely, eight failed to do so.

Figure 18: Percentage of cases treated within 90 minutes by unit

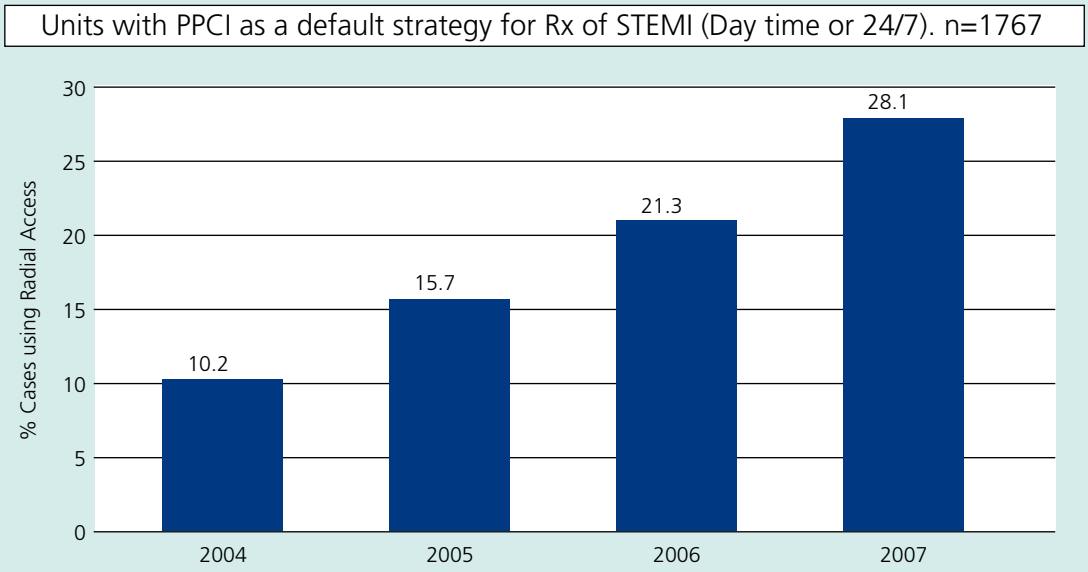


The MINAP audit has demonstrated that treatment of STEMI by lysis has been very well organised in the UK, with very short delays between arrival at A&E and thrombolysis (short door to needle times). While there is enthusiasm to move towards a PCI based reperfusion strategy, it is essential that primary PCI is delivered promptly or the potential benefits of that treatment strategy will be lost. We must be careful to avoid replacing a prompt lytic service with a poor (slow) primary PCI service.

3.6.3 Arterial Access

Traditionally, the femoral artery has been used to gain access to the circulation, and so PCI has involved inserting tubes into this artery at the top of the leg. There has been increasing use of the radial artery (at the wrist) as this approach can be associated with fewer complications at the puncture site. This route was used in over 28% of cases in 2007 as seen in figure 19.

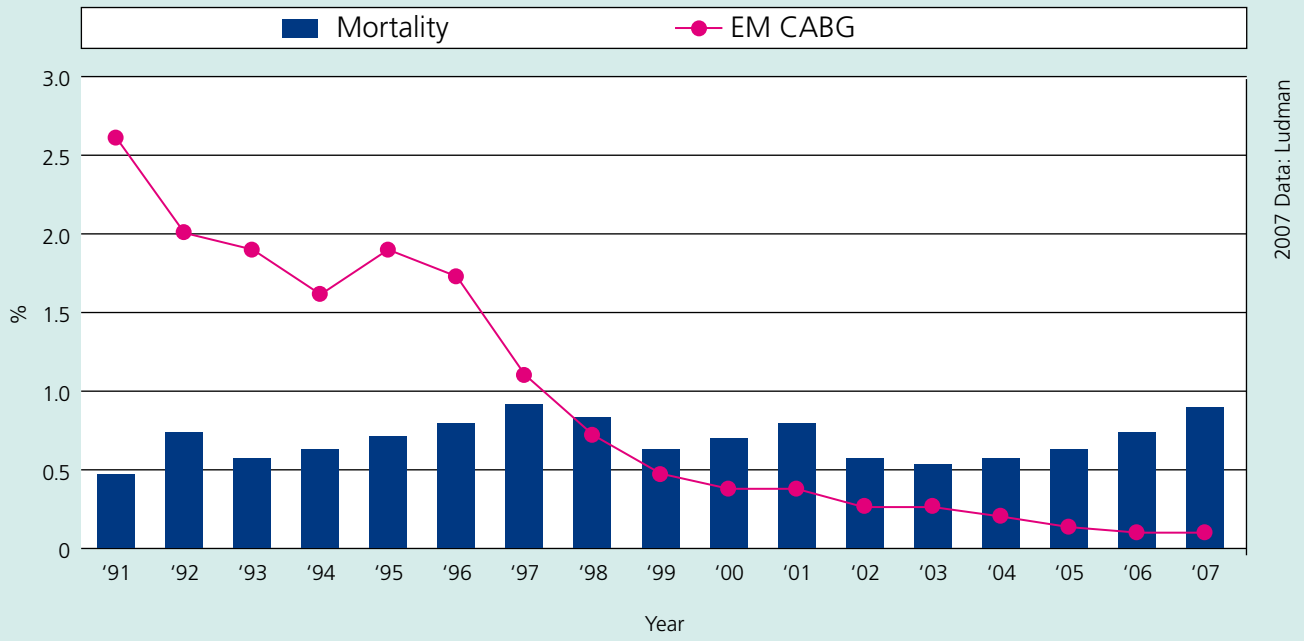
Figure 19: Radial Artery Access



3.7 Outcome

The complications from PCI have fallen progressively as techniques have evolved. Nevertheless this has also meant that the procedure can be offered to patients who are considerably sicker, and in whom a higher risk of complications is expected. The rate of requirement for emergency CABG remains very low at less than 1% (figure 20). The overall rate of death before discharge from hospital following PCI has, however, gradually increased over the past few years. The explanation for this increase could be that PCI is being performed less well, or that the case mix is changing. This is examined below.

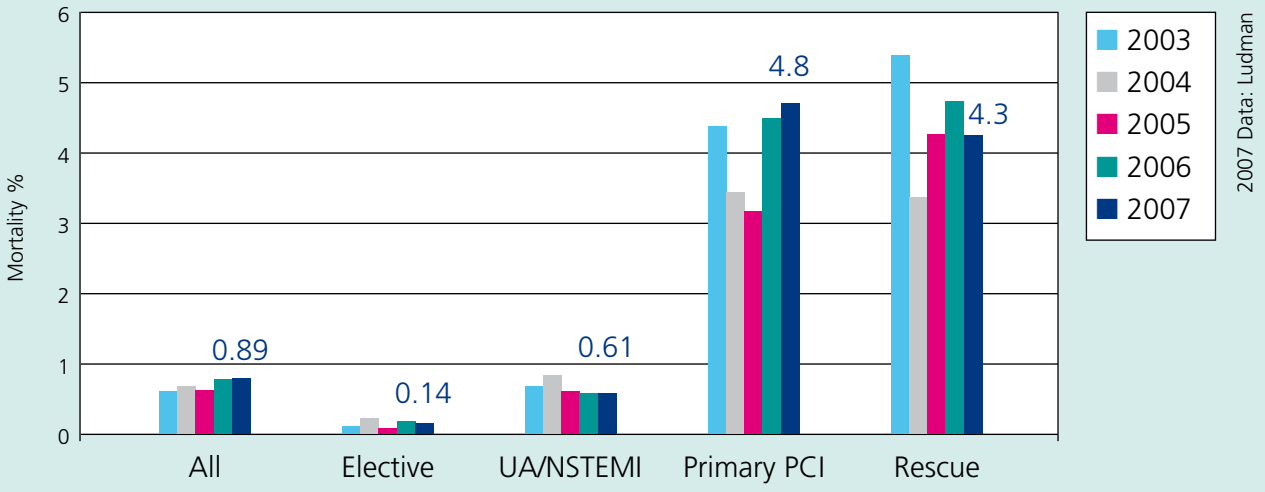
Figure 20: Overall outcome



It is important to understand that the risk of dying when presenting with coronary disease is largely dependent on the clinical scenario. Some patients have a very high risk of dying from their disease (whether or not a PCI is performed). A PCI may well offer a big reduction in that risk, but nevertheless the overall mortality risk will still be higher than patients who have little chance of succumbing to their disease in the first place. 'Elective' describes patients who are placed on a waiting list and are therefore admitted routinely from home. The remainder have all been treated during an emergency admission to hospital brought about by unexpected angina. Those with 'UA / NSTEMI' are usually treated urgently, within a few days of admission. Those presenting and treated for primary PCI or Rescue, are much sicker, and need to be treated much more quickly.

By looking at mortality for each of these major presenting syndromes it can be seen that the outcomes for each of these groups have remained stable (figure 21). Thus the increase in overall mortality is due to an increasing proportion of sicker patients being treated by PCI, in other words a gradual change in case mix towards treating sicker patients. This change is exemplified by an increase in the number of patients being treated for STEMI as seen in figure 11

Figure 21: Outcome by syndrome



This analysis clearly demonstrates the importance of risk adjustment in the assessment of outcome to help avoid misleading conclusions. To this end we have started to create analyses of each PCI unit's performance, comparing the observed outcomes with those that would be expected using a risk model.

All models have limitations and results must be interpreted with caution. The model we are currently using is that derived from the North West Quality Improvement Program (NQWIP)[11], which has recently been validated in a contemporary series[12]. Each PCI procedure is assessed and a predicted risk of a major adverse cardiac or cerebrovascular event (MACCE) is calculated. MACCE is defined as in hospital death, Q wave myocardial infarction, stroke or the need for emergency CABG. A cummulative plot is then constructed, with expected MACCE for each successive case, compared with the 2 and 3 sigma probability lines. These lines approximately equate to 95% and 99% confidence intervals. A similar line can be plotted for the actual (observed) outcomes. If the observed outcomes lie within the 3 sigma confidence lines of the predicted, then the unit's outcomes are in line with the predictions of the model. Conclusions from these plots must be reached with care. If a unit's outcomes are better or worse than predicted, there are a variety of possible explanations. It may be that the unit is performing PCI better or worse than expected. But equally it may be that the model is inaccurate for that unit's population and demographic mix. Clearly the conclusions are also dependant on accurate reporting of demographic and procedural risk factors and of observed outcomes.

11 Multivariate prediction of major adverse cardiac events after 9914 percutaneous coronary interventions in the north west of England A D Grayson, R K Moore, M Jackson, S Rathore, S Sastry, T P Gray, I Schofield, A Chauhan, F F Ordoubadi, B Prendergast, R H Stables, on behalf of the North West Quality Improvement Programme in Cardiac Interventions (NWQIP) Heart 2006;92:658

12 External validation of established risk adjustment models for procedural complications after percutaneous coronary intervention B Kunadian, J Dunning, R Das, A P Roberts, R Morley, A J Turley, D Twomey, J A Hall, R A Wright, A G C Sutton, D F Muir, M A de Belder. Heart 2008;94:1012 - 1018

An example of one unit's activity is shown in figure 22 below.

Figure 22: Percentage actual and predicted MACCE outcome

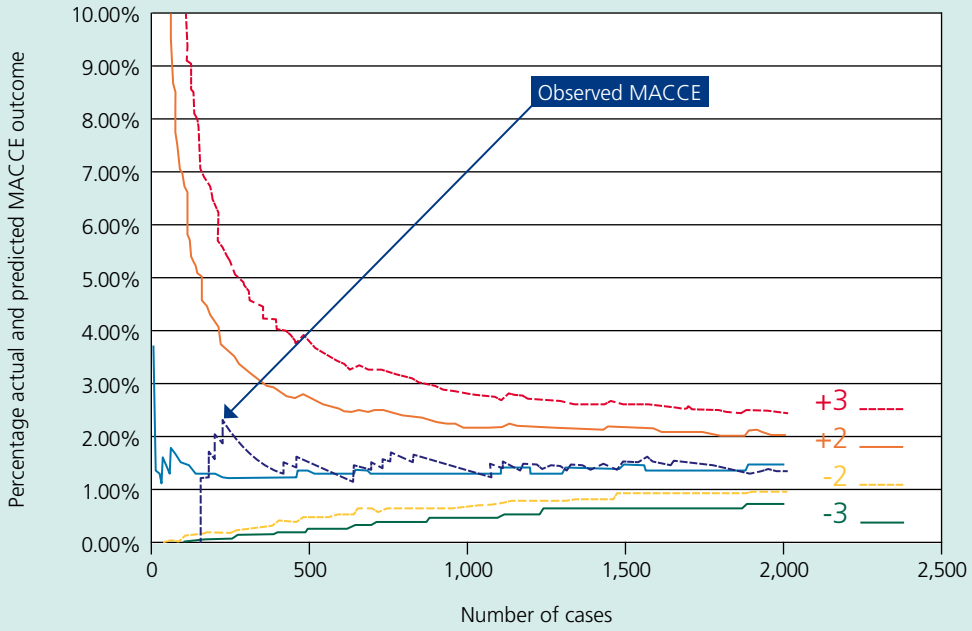


Figure 22: Observed MACCE (dark blue) for successive PCI procedures performed at one unit. Predicted MACCE is plotted in light blue, and the 2 and 3 sigma lines are labelled. It can be seen that this unit's performance is almost exactly as would be predicted from the risk model used, and that the overall risk of in hospital MACCE for that unit is just under 1.5%

4.0 The Future

Statistical process control charts will be used to provide units with feeback about their performance. In the first instance we plan to send the cummulative funnel plots of risk adjusted outcomes (as seen in figure 22), and also process control charts of 'door to balloon' times. The plan is to send these reports to all contributing units in a monthly basis.

Other plans include the development of a web browser based interface to integrate the input of data for the BCIS and MINAP datasets. This will help in the linking of these datasets and should reduce duplicate data entry. In addition it may allow data from an admitting hospital to be available to a PCI hospital where they are geographically separate.

5.0 Glossary

A number of terms are essentially synonymous and used to describe the same procedure: thus a coronary angioplasty is also called a percutaneous coronary intervention, abbreviated to PCI.

Coronary artery bypass surgery, sometimes abbreviated to bypass surgery or CABG

Other abbreviations in alphabetical order:

BCIS: British Cardiovascular Intervention Society
CCAD: Central Cardiac Audit Database
DES: Drug eluting stent
HSCIC: Health and Social Care Information Centre
MINAP: Myocardial Ischaemia National Audit Project
NCASP: National Clinical Audit Support Program
NSTEMI: Non ST elevation myocardial infarction
STEMI: ST elevation myocardial infarction

6.0 References

[1] Some patients are treated with a coronary artery bypass operation (CABG). Another audit describes outcomes for these patients, and a 'public portal' website allows patients to see the results for their local heart surgery centre [http://heartsurgery.healthcarecommission.org.uk]. The Healthcare Commission also funds audits of heart attacks, heart failure and other aspects of heart disease.

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