

Evaluation of appropriateness methods to define and improve access across primary, secondary and tertiary care among people with angina

Revised report to the National Co-ordinating Centre for NHS Service Delivery and Organisation R&D (NCCSDO)

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Glossary of key terms and acronyms

Term or acronym	Definition
ACRE	Appropriateness of Coronary Revascularization
ACS	Acute coronary syndrome: encompasses both unstable angina and MI
Angina	Symptom of chest pain or discomfort, brought on by exercise (or stress) and relieved by exercise
ARIA	Appropriateness of Referral and Investigation of Angina
CABG	Coronary artery bypass graft: involves opening the patients chest under general anaesthetic and bypassing the narrowed arteries with vessels from elsewhere in the same patient (e.g. leg veins, internal mammary artery)
CAD	Coronary artery disease: the narrowing and irregularities of the blood supply to the heart, which are demonstrated by coronary angiography and underlie CHD
CHD	Coronary heart disease: a spectrum of clinical disorders including stable and unstable angina and acute MI
Coronary angiography	X-ray in which dye is injected into the coronary arteries in order to identify areas of narrowing of the arteries
Coronary revascularization	Invasive, physical means of overcoming the narrowings in coronary artery disease. There are two kinds: CABG and PTCA
ECG	Electrocardiography: non-invasive investigation to test heart function, either measuring electrical currents of the heart at rest or while exercising on a treadmill

LREC	Local research ethics committee
MI	Myocardial infarction: patient notices prolonged chest pain at rest; caused by a thrombosis (blood clot) causing a blockage in the coronary artery
Morbidity	Suffering from disease, short of death (mortality)
MREC	Multi-centre research ethics committee (now replaced by REC)
NICE	National Institute for Clinical Excellence
NSF	National Service Framework
PTCA	Percutaneous transluminal coronary angioplasty: a local anaesthetic procedure in which a balloon is inserted and inflated to dilate the narrowed coronary artery. Re-stenosis (re-narrowing) of this artery is a problem, hence stents are increasingly deployed. Percutaneous coronary intervention (PCI) is the generic term for PTCA with or without stent
RAND	("R and D") US research institute which developed method of measuring appropriateness with panels of experts
ROC	Receiver operating curve: measure of the sensitivity of a test (to identify true cases) and specificity (to exclude non-cases). A test with a ROC of 0.5 does not discriminate between cases and non-cases at all, whereas a ROC of 1 means perfect discrimination
Secondary prevention	Medication to prevent death or further heart disease events in patients with established CHD: aspirin, beta-blockers, ACE inhibitors and lipid lowering agents
Stent	A metal tube inserted across the narrowed coronary artery to hold it open, can be drug-eluting (coated with anti-coagulants)
Unstable angina	Pain at rest, usually resulting in hospitalisation. Intermediate in prognostic severity between angina and MI

LAY SUMMARY

We know that access to tests for patients with angina – a common form of heart disease – varies widely. Patients who do not receive these tests may be denied subsequent treatments, like heart surgery. We also know that some patients such as women or patients of South-Asian ethnicity tend to receive fewer tests than others.

In response to this problem, the National Institute for Clinical Excellence (NICE) and medical societies have published guidelines to help doctors make the right decisions, which incorporate the latest scientific knowledge on a subject. These guidelines are general in nature and are difficult to apply to an individual patient. Studies have shown that guidelines are not very effective at changing physician behaviour and have not substantially reduced the variations in clinical practice.

A promising new technology called appropriateness ratings may be better at changing doctor's decision making, as these ratings incorporate expert recommendations. These recommendations are for a combination of specific patient characteristics and can be applied to individual patients. However, appropriateness ratings have not been routinely used in clinical practice and we do not know whether they would be any better at changing doctors' behaviour than clinical guidelines. We also do not know whether doctors find such ratings from experts acceptable and whether other factors which are not incorporated into these ratings would mean that patients still do not get tested when they should (or get tested even though they do not need it), despite the ratings. Such factors include patient preference, non-attendance or other patient or clinician characteristics.

We therefore aimed to examine how effective and feasible the appropriateness ratings would be in helping doctors make better decisions in patients with angina and improve access for all patient groups. We addressed the following 4 questions with our project:

First, how effective are appropriateness ratings compared with conventional guidelines in improving appropriate and equitable decision making in primary and secondary care physicians?

To compare the effect of appropriateness ratings and conventional guidelines on doctors' recommendations for tests in patients with angina we carried out a randomised study with hypothetical patients (ARIA trial).

Second, we wanted to know how effective appropriateness ratings and guidelines would be in changing doctors' decision making in patient groups we know have less access to tests.

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Therefore we looked at the effect of appropriateness ratings and conventional guidelines on doctors' recommendations for tests in specific patients, i.e. in older patients, women and south Asians as part of the ARIA trial.

Third, how acceptable are appropriateness ratings to doctors and patients and what barriers to their use exist in day-to-day clinical practice?

We addressed this question using qualitative research methods (interviews with patients and doctors).

Fourth, what factors may prevent appropriate care once a patient has been tested?

We looked at possible doctor or patient factors (patient preference, co-morbidity, type of doctor, non-attendance rates) that may explain why some patients who should have received appropriate treatment did not receive it. (**Objective 4**) For this question we examined data from patients who had already undergone coronary angiography (a test to detect blocked vessels around the heart) and who took part in the ACRE study. We wanted to know why some patients who were thought to benefit from bypass surgery did not receive it.

Methods and Results

Appropriateness in Referral and Investigation in Angina (ARIA) randomised controlled trial (questions 1 and 2)

Interventions

Doctors were randomly allocated to receive either appropriateness ratings, which were individualised to specific patient characteristics and developed by two independent expert panels, or conventional guidelines from the American Heart Association, European Society of Cardiology and North of England evidence based guidelines development project.

Participants and patient vignettes

292 clinicians (189 general practitioners and 103 cardiologists) from 9 regions in the UK were recruited. 145 received appropriateness ratings and 147 guidelines. Each doctor was asked to make a decision on whether to test or not to test in 24 hypothetical patients: 12 without and then 12 with decision support (either ratings or guidelines). We looked at decisions for two tests: firstly the exercise treadmill test (exercise electrocardiogram or ECG) and secondly angiography (for an angiogram dye is injected into the heart to detect blocked vessels on x-ray). We analysed 5938 decisions for exercise ECG and 6291 decisions for angiography.

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We were interested in the proportion of appropriate recommendations made by doctors with either decision support. For the second objective we examined the number of appropriate recommendations made for specific patient groups (by age, gender and ethnicity) with appropriateness ratings and guidelines.

Findings of the trial

Our work confirmed that guidelines had little effect on changing doctors' decisions on testing, regardless of whether the doctor was a GP or a specialist. Before being given the decision support, doctors in both trial arms made similar decisions. Once doctors were given the ratings or guidelines, doctors who received the ratings made more appropriate decisions for exercise treadmill testing (819/1281 (63%) than doctors who received the guidelines (619/1281 (48%)). This was similar for angiography decisions (1274 /2292 (56%) vs 1018/2292 (44%)). When we looked at decisions made for specific patient groups such as elderly patients, women and South-Asian patients, we found that the improvement in appropriate decision making seen with the appropriateness ratings was consistent. We also showed that the use of appropriateness ratings in clinical practice would probably result in more exercise treadmill tests and angiograms being recommended by both GPs and cardiologists.

ARIA – QUAL (question 3)

We observed a total of 115 clinical consultations and conducted interviews with 14 patients who attended a rapid access chest pain clinic or a cardiology clinic using qualitative methods. This method goes into depth using patient interviews, observations and the like and analysing themes emerging from it, while quantitative methods use statistics to examine a research question. We tried to select a variety of different patients to represent a diversity of experience. We also interviewed 20 doctors, 10 technicians and 2 administrators based in the clinic. In these interviews and observations we wanted to establish how a diagnosis and decisions on tests and treatment are currently made without any available decision support. Later on we interviewed 8 doctors, 4 technicians and 1 research manager on their views regarding appropriateness ratings and guidelines. Finally six patients (5 men and 1 woman) recruited from the cardiac rehabilitation clinic participated in an extended (3 hours) focus group, as information given in a group context can sometimes provide additional information not obtained in 1 to 1 interviews. Based on transcripts of tape recorded interviews and detailed notes taken during and immediately following periods of observation we analysed the collected material and identified significant themes.

Findings from the qualitative study

Our qualitative work showed that there were potential barriers to the use of appropriateness ratings that would need to be addressed before they could be used in clinical practice. For example, inappropriate tests were sometimes carried out to reassure a patient or the doctor or information emerging in the

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consultation was not included in the appropriateness ratings, for example the patient's inability to perform an exercise test. Language barriers often made it more difficult for the doctor to understand the exact nature of the chest pain and lowered the threshold for ordering an exercise ECG. Reasons for not doing a test included patient's unfitness to have the test done due to obesity or co-morbidity for example. We found scepticism of junior and senior doctors working in the cardiac team regarding the appropriateness ratings, but there was high acceptance for the ratings amongst interviewed GPs. Conventional guidelines were generally thought not to be helpful. Focus group patients were overall enthusiastic about the idea of doctors using decision support technology to help them make the right decisions. In summary, the dialogue between patient and clinician leading up to a diagnosis and the decision to do a test were complex. Our work highlighted the fact that tests were often carried out for reasons independent of appropriateness. Interestingly, patients attending chest pain clinics were sometimes unaware of the nature of the clinic and ignorant of the fact that they were seeing a heart specialist.

ACRE study (question 4)

We collected information from hospital and GP case notes in 2593 participants from the original ACRE cohort who agreed to be followed up. We aimed to compare 927 patients thought to be appropriate for bypass surgery (CABG) by the ACRE expert panel in order to find out why some patients did not receive it. We used standard statistical techniques for analysis.

Findings from the analysis

Our analysis of ACRE study data showed that on a large scale, patient preference or non-attendance did not explain why patients did not receive a CABG. It was also not explained by individual doctors making consistently 'wrong' decisions. Patient preference or non-attendance was virtually unrecorded in a large sample of case notes. This raises important questions about the way patient involvement and decisions of the clinical team are documented. It also calls for further explorations of why treatment is not given when it should be, as often-cited reasons such as patient preference or clinician outliers do not seem to explain this phenomenon. Together with insights from the qualitative work our results suggest that ratings should be rolled out to all doctors rather than targeting some doctors who might make less appropriate decisions.

Overall conclusion

In the ARIA trial we have shown in hypothetical patients that appropriateness ratings could substantially change doctors' test ordering behaviour, but this needs to be tested in real practice. What doctors do in real life may differ from what they say that they would do.

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The implementation of appropriateness ratings needs to consider the clinical culture and the nature of clinical decision making. Therefore, a trial in real patients needs to be designed as a complex intervention and address shortcomings of the appropriateness method and reasons why clinicians do not follow the recommendations. Patient preferences, non-attendance rates and undue physician variation seem to play a minor role in influencing investigation in appropriate patients, although it is inconclusive whether this is due to lack of reporting on clinical notes or a true finding.

What next?

Randomised trials of appropriateness ratings in real patients should be carried out, which also look at clinical outcomes such as mortality in these patients.

Appropriateness ratings need to be further developed and improved, so that they are more reliable and are able to deal with a rapidly changing clinical environment and the challenges of clinical practice.

Appropriateness ratings should be given to all doctors rather than a selected few who make less appropriate decisions, as we found that the existing variation in testing is a result of all doctors contributing a little variation rather than a few doctors making consistently different decisions from the rest.

Patients need to be involved in decision making. A study in which consultations are observed might help understand the role of patient preference. Our findings show that despite efforts to increase patient involvement preferences may not materially influence clinical decisions. The other explanation could be that they are not routinely written down, hence the quality of reporting of clinical decisions should be reviewed.

Executive summary

This study was commissioned by the NHS Service and Delivery Organisation R&D programme. It examined the effectiveness and feasibility of appropriateness ratings devised by experts in improving appropriate and equitable access to investigations in patients with angina.

Access to investigation (i.e. tests) for angina remains highly variable; coronary mortality among patients who are not investigated is higher than in the general population. Conventional guideline recommendations such as those endorsed by NICE tend to relate to broad groups of patients rather than individual, specific patient characteristics, and such conventional guidance has had limited success in reducing practice variations or altering clinician behaviour.

Appropriateness ratings constitute a novel decision support technology, which incorporates expert panel recommendations for individualised, specific patient indications. The impact of such specific decision support on physician decision making has been unclear. Also unclear is the acceptability and feasibility of such ratings in clinical practice and whether factors which are not incorporated into such ratings, for example patient preference, non-attendance rates or other patient or clinician characteristics would influence investigation and treatment despite the use of appropriateness technology.

Given the complex nature of the enquiry we used several data sources and analysis techniques in an attempt to answer the following three questions and meet the four associated research objectives.

Question 1: How effective are appropriateness ratings compared with conventional guidelines in improving appropriate and equitable decision making in primary and secondary care physicians?

- **Objective 1** To compare the effect of specific vs. conventional guidelines on physician recommendations for investigation of angina as a means to improving appropriate access
- **Objective 2** To determine impact on access to investigation among older patients, women and south Asians. (*ARIA randomised controlled trial*)

Question 2: How acceptable are appropriateness ratings to clinicians and patients and what barriers to their use exist in day to day clinical practice?

- **Objective 3** To determine the acceptability of appropriateness ratings to clinicians and patients. (*ARIA-QUALitative research*)

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Question 3: What other barriers may exist further down the patient pathway that may prevent appropriate care despite the use of appropriateness ratings?

Objective 4: To determine the extent of physician and patient barriers in mediating underuse of revascularization. (*ACRE secondary data analysis*).

Methods and Results

ARIA randomised controlled trial (Objectives 1 and 2)

Interventions

One trial arm received decision support via appropriateness ratings individualised to specific patient characteristics, which were rated by two independent expert panels in agreement, the other trial arm received decision support via conventional guidelines from the American Heart Association, European Society of Cardiology and North of England.

Participants and patient vignettes

292 clinicians (189 general practitioners and 103 cardiologists) from 9 regions in the UK were recruited. 145 were randomised to patient-specific appropriateness ratings and 147 to conventional guidelines. Clinicians were unaware of the trial objective. Each clinician made recommendations on investigation of 24 patient vignettes (from a pool of 48 unique vignettes): 12 without and then 12 with decision support intervention. We analysed 5938 decisions for exercise ECG and 6291 decisions for angiography.

Outcomes

The primary outcome was the proportion of recommendations made by doctors that agreed with those made by two independent national expert panels as well as the proportion of recommendations made by clinicians in agreement with their own intervention. As a secondary outcome we examined the effect of appropriateness ratings and guidelines on appropriate decision making in pre-specified patient groups (by age, sex and ethnicity).

ARIA – QUAL design and participants (Objective 3)

Interviews with a purposeful sample of 14 patients attending a rapid access or a cardiology clinic. Interviews with doctors (20), ECG technicians (10) and administrators (2) based in the clinics. Observation of 115 clinical consultations and interviews with doctors (20), patients (14), ECG technicians (10) and administrative staff (2). Interviews on use of decision support tool with doctors (8), technicians (4) and a research manager (1). The everyday work of one clinical cardiology team (10 doctors and 8 ECG technicians over the fieldwork period) was observed over fourteen weeks. We observed 115

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individual consultations in the two clinics. Six patients (5 men and 1 woman) recruited from the cardiac rehabilitation clinic participated in an extended (3 hours) focus group.

Data sources

Interviews with six doctors who piloted the ARIA decision support tool using data from 15 consultations that they had just completed. Interviews with 10 doctors who participated in the ARIA trial. Focus group of six patients recruited from the cardiac rehabilitation clinic.

Analysis

Based on transcripts of audio-tape recorded interviews and transcripts of the detailed notes taken during and immediately following periods of observation. Thematic analysis using grounded theory significant themes underpinning the process of diagnosis and decision-making, from patient and clinician perspectives.

ACRE design and participants (Objective 4)

We abstracted case note data among participants from the original ACRE cohort who consented to 7 year follow-up (n=2593) in order to select and compare management after angiography in patients who were rated appropriate for CABG by the ACRE expert panel (n=927). We compared patients in whom CABG was rated appropriate who did (n= 530) and did not (n = 397) undergo CABG in terms of important patient, clinical and care characteristics. We used logistic regression for analysis.

Results

Our work confirmed that conventional guidelines had little effect on outcome within or between trial arms for either investigation, or in either speciality. After intervention, the proportion of recommendations made in agreement with the expert panel recommendations for exercise ECG increased (819/1281 (63%) vs. 619/1281 (48%), $P<0.0001$ and for coronary angiography 1274 /2292 (56%) vs. 1018/2292 (44%) $P<0.0001$ with the ratings arm. Within trial arm comparisons, using clinicians as their own controls, showed very similar effects. Pre-defined analyses of sub-groups for which inequitable access has been observed, showed that improvements in agreement with specific recommendations were robust at older ages, among women, and among south Asians. The change in decisions associated with specific decision support resulted in an increased use of exercise ECG and angiography for both GPs and cardiologists.

While the trial demonstrated a clear proof of concept and showed that appropriateness ratings have significant potential to improve clinical decision making, our findings from the qualitative work show that any implementation of appropriateness ratings needs to consider the clinical culture and the

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nature of clinical decision making. We identified a variety of criteria which were influential in unaided decision making in the diagnosis of angina, such as patient perspective (development of the angina/heart disease narrative, role of family or work stressors, ambiguity of family history, faith in cardiological interventions and notions of invincibility), clinical context and role of place, including the diversity of consultations, the effect of the physical clinic space and its impact on decision making and systemic factors.

In terms of acceptability and feasibility of appropriateness ratings in clinical practice we found that several reasons accounted for ordering an inappropriate investigation, for example patient or doctor reassurance and information emerging in the consultation that is not a variable used in the ARIA tool (e.g. inability to perform ETT or inconclusive result when deciding about an angiogram), language barrier making history less reliable and therefore lowering threshold for an ETT. Reasons for underuse of appropriate investigations included conviction of a diagnosis of non-cardiac chest pain or patient's unfitness for ETT or angiogram due to obesity or co-morbidity for example. We found scepticism of junior and senior doctors working in the cardiac team contrasted with relative acceptance by GP informants regarding the concept of an expert panel. The concept of expertise in relation to formal recommendations embedded in decision support tool was seen as problematic by many informants. But conventional guidelines were perceived as even less reliable. Focus group patients were generally enthusiastic about the notion of decision support technology to aid clinical decision making.

In summary, the dialogue between patient and clinician leading up to a working diagnosis and the decision to investigate further were highly complex with multiple influences. The use of the decision support tool raised issues about the face validity of experts and about the role of patient factors that were not included in the decision support variables. The work highlighted the fact that tests were often carried out for reasons independent of appropriateness, such as reassurance of patient and doctor, a means of communicating with other doctors or hesitance to disagree with senior doctors. Interestingly, patients attending chest pain clinics were sometimes unaware of the nature of the clinic and ignorant of the fact that they were seeing a heart specialist.

On a large scale, patient preference, non-attendance or clinician outliers were not found to explain the significant underuse of revascularization in appropriate patients. For CABG this underuse ranged between clinicians from 54-75%, for PCI it ranged from 36-78%. Patient preference or non-attendance was virtually unrecorded in a large sample of case notes. This raises important questions about the way patient involvement and decisions of the clinical team are documented. It also calls for further explorations of why this substantial underuse of revascularization occurs, as often cited reasons such as patient preference or clinician outliers do not seem to explain this phenomenon. Our findings from the ACRE analysis as well as ARIA-QUAL suggest that a whole system approach is needed as it is likely to be the small variation within all clinicians who make investigation decisions often for

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reasons other than clinical appropriateness, rather than a few doctors making consistently inappropriate decisions.

Overall conclusion

Specific decision support lead to changes in clinician recommendations for the investigation of angina, but widely advocated conventional guidelines had very little effect despite tipping the scales in their favour by providing easily accessible electronic presentation of the relevant guideline sections. This effect was robust among vignettes in older people, women and south Asians. Randomised trials in real patients should now be carried out to test whether specific decision support can improve access to care and, ultimately, patient prognosis. Based on the findings from ARIA-QUAL such a trial should be designed as a complex intervention and need to address shortcomings of the appropriateness method and reasons why clinicians do not follow the recommendations. Patient preferences, non-attendance rates and undue physician variation seem to play a minor role in influencing investigation in appropriate patients, although it is inconclusive whether this is due to lack of reporting on clinical notes or true absence of these factors.

Implications for clinical practice, policy and access and disparity research

Our findings support the consideration of:

- Randomised trials of appropriateness tools in decision support in real patients, with assessment of clinical outcomes, which should be conceived and developed as a complex intervention.
- Expert panel ratings need to be further developed and improved, so that they have higher reliability (less disagreement amongst experts) and deal with a rapidly changing clinical environment, lack of evidence and missing data in real patients.
- The need for a whole system approach to designing interventions to improve access to care, as highlighted by our finding that variation was not due to some clinicians being outliers but due to consistent underuse of revascularization by all clinicians.
- Patient involvement in decision making. A prospective study in which consultations are observed might elucidate the role of patient preference. Our findings show that despite increased patient involvement preferences rarely influence clinical decisions.
- Better primary studies on which to base investigation decisions (for example randomised trials of different investigation strategies) are needed. Appropriateness ratings may help identify focussed areas of uncertainty where evidence is needed.

Section 1 Background to the study

1.1 Introduction

This report addresses issues of access in services for patients with suspected or confirmed coronary artery disease. Improving the outcomes of coronary heart disease (CHD), the single largest cause of premature mortality in the UK, remains a high priority for the NHS. The 2004 Progress Report of the CHD National Service Framework (NSF, 2004) highlights a 23% reduction in CHD mortality from 1996/7. Considerable improvements have been documented, for example with the Myocardial Infarction National Audit Project (MINAP), in the quality of care of acute myocardial infarction (www.rcplondon.ac.uk/pubs/books/minap).

However it is less clear whether the NHS is “winning the war” (NSF, 2004) in the management of angina. The burden of coronary disease is changing, with the incidence of acute myocardial infarction declining, but hospital admissions for all coronary disease increasing (Murphy, 2004). The incidence of angina consultations in primary care increased between 1981 and 1991 according to the Royal College of General Practitioners Morbidity survey (McCormick, 1995). Currently there are no national data on the incidence of angina detected in primary care, but prescribing of anti-anginal medication in primary care did continue to increase during the 1990s (GPRD, 2000) The Department of Health’s *Strategic Review of Research and Development: CHD* highlighted angina as a condition with “relatively few” research projects (Department of Health, 2003 page 2). Based on best estimates from epidemiological studies cited in the British Heart Foundation Heart Statistics, the total number of new cases of angina per annum in England (338,000) exceeds that for acute MI and heart failure combined.

1.2 Prognosis of patients with angina

Does it matter that angina prevalence and potentially incidence are increasing? Our work has shown that undiagnosed angina (the submerged part of the clinical iceberg) is associated with adverse prognosis.⁶(Hemingway 2003) In addition, the prognosis of patients with angina is not as benign as once thought (Mozaffarian, 2003) and patients identified as having non-cardiac chest pain still have a greater hazard of developing a cardiac event compared with the general population (SDO/32/2002 *Timmis et al* <http://www.sdo.lshtm.ac.uk/access.htm#timmis>).

A fundamental challenge in improving the prognosis of people with angina lies in the consideration of the steps in referral and investigation, which must be negotiated after the patient first develops symptoms. Investigations with imaging techniques or laboratory tests are commonly a prerequisite to

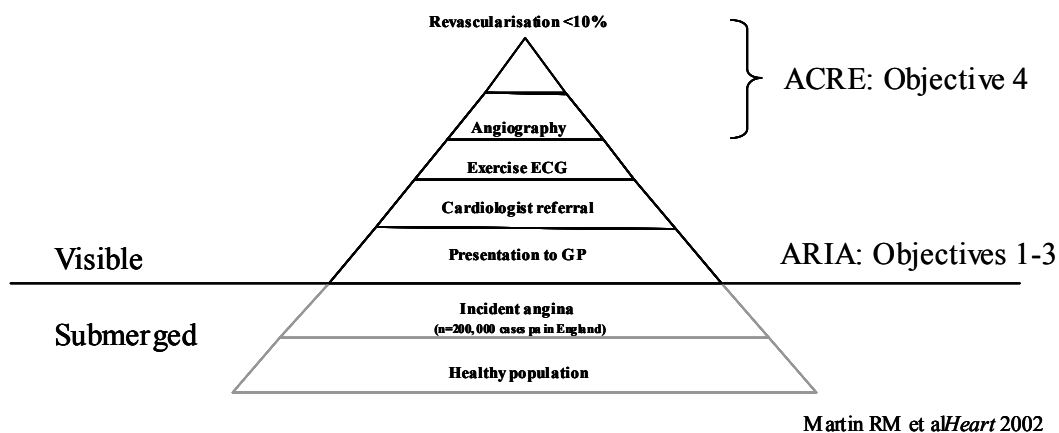
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confirming the right diagnosis and deciding on appropriate management, with varying consequences for patient prognosis. Getting investigated at the time of presentation is therefore crucial.

However, significant heterogeneity exists in the number of requested investigations (Verstappen, 2005). Such variation is not explained by clinical need or simple practice-related covariates (Verstappen, 2005; Scholer, 1996). In addition, heterogeneity may result in inequity between patient groups (Feder, 2002). Initial investigation of common symptoms is important as variations in care (cost and outcomes) may become amplified by later decisions in the management "cascade." Fewer patients are present at each step of the investigation and referral pathway, as illustrated in the pyramid in figure 1.

At the base of the pyramid, the person may not seek medical care and therefore has no formal diagnosis. During the 1990s a minority of patients with angina diagnosed in primary care were subsequently referred for specialist opinion and investigation (Clarke, 1994). There are wide national variations in coronary angiography rates; there are no national data on variations in exercise ECG. Angiography is currently the only widely used means to assess the presence and severity of coronary *artery* disease (CAD).

Figure 1: Pyramid of patient populations with angina



*estimates of numbers at each level are found in Martin et al 2002

1.3 Policy context

The National Service Framework (NSF, 2004) and the new GP contract mark a decisive initiative in the management of angina. Standard 8 of the National Service Framework states that "people with symptoms of angina or suspected angina should receive appropriate investigation and treatment to relieve their symptoms and decrease their risk of coronary events" (NSF, 2004). The new GP contract says that "all new cases of angina should be referred to a cardiologist or undergo investigation" (GMS, 2003). Early NSF implementation priorities have resulted in a marked increase in the capacity for coronary angiography, the provision of rapid access chest pain clinics and establishment of coronary heart disease registers in primary care.

A central question now is how to define appropriate management of angina at each step in the referral pathway. This is essential to monitor progress against National Service Framework (NSF) standards and to ensure that increased capacity is used to its maximal effect. Implementation of the NHS plan and Coronary Heart Disease National Service Framework (CHD-NSF) will increase access to diagnostic and therapeutic intervention in secondary care for patients with angina. This will be achieved by increasing the number of cardiologists, expanding cardiac surgery capacity, and implementation of rapid access chest pain clinics (DH, 2002). The CHD-NSF advocates the use of guidelines. However, this approach is known to have limited effect on clinical-decision making and may increase variation due to proliferation of local protocols. The central challenge is to identify a methodology or technology, which improves decision making at key points in the patient journey and thus ensures that additional and existing investment improves access. At the same time, there is a need to understand the organisational, professional and patient barriers, which may deny patients appropriate access through

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different steps of the patient pathway in order to implement whole system interventions.

1.4 Access and appropriateness

Facilitating access is defined by the SDO programme as helping people to command appropriate healthcare resources in order to preserve or improve health. The definition clarifies the symbiotic relationship between access and appropriateness. Appropriateness may be defined as the extent to which benefit exceeds harm for a specific aspect of medical care applied to a specific patient. In a situation where supply of services is increasing, it is essential to ensure the appropriateness of clinical decision making to prevent increases in the absolute level of inappropriate care (a rising tide lifts all boats). There is significant concern that certain groups may not receive specialist cardiac care despite their ability to benefit. In particular, the SDO programme has identified inequitable access by older people as a concern. We have evidence that these factors may unfairly affect certain groups. In the Appropriateness of Coronary Revascularization (ACRE) study, we found that patients of South Asian origin were less likely to receive surgery despite appropriate clinical decision making and referral (Feder, 2002). The extent to which this systematic access bias was due to organisational and administrative factors (age, gender, geographical variation, physician specialty, patient non-attendance or refusal etc.) is not known.

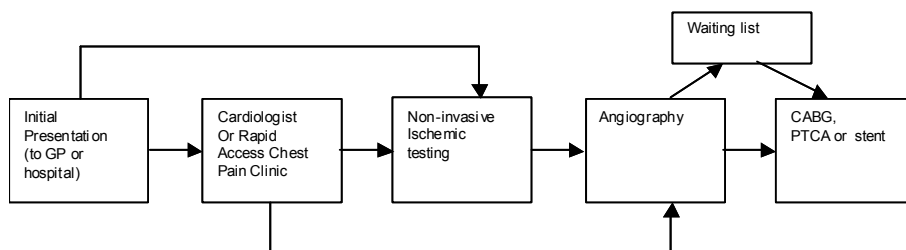
1.5 Barriers to accessing cardiac services across patient pathway

Variation in access and utilisation is greatest for investigations and treatments for which there is significant clinician discretion and limited evidence base to support decision-making (Rayner, 2002). The patient pathway from initial symptoms of angina to receiving appropriate revascularization is complex. Barriers to access arise at a number of points in the patient pathway from presentation in primary care to revascularization in a tertiary centre, including variation in decision making by clinicians due to the aforementioned lack of standard of care laid down by research evidence and guidelines or non-compliance of patients with recommended management strategies. Organisational barriers may limit access but the complexity arises from appropriate decisions that need to be made by patients and clinicians on a minimum of four occasions to allow access to the next stage of investigation or management (horizontal arrows in figure 2). For patients who may benefit from revascularization, if only ten percent of decisions are inappropriate at each stage, less than 66 out of 100 appropriate patients will receive an intervention, irrespective of service capacity or investment. Furthermore, the development and expansion of open-access exercise ECG services extends the requirement for appropriate decisions by generalists in primary care.

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For many conditions, including angina, patients are identified in primary care but investigation and intervention is only available through secondary care. A key barrier to access is decision making in primary care by generalists, acting as gate-keepers.

Figure 2 Access to care: the patient pathway in angina



Even if appropriate decisions are made, not all patients receive the appropriate investigation or treatment. The reasons for this are poorly understood and probably relate to patient and organisational factors. What is the reason for patients who have progressed through the system not to get revascularised despite being appropriate?

Age and sex influence access to investigation

With colleagues at Stakes, Helsinki we identified all new patients with angina using linked primary care registries in Finland between 1996-98 (unpublished data presented at ESC, Stockholm, 2005). We excluded patients with a prior history of myocardial infarction or revascularization. A unique feature of these data is that patients who have a diagnosis of angina without support from investigation abnormality ("nitrate cases") can be distinguished from cases with an abnormal electrocardiogram or coronary angiogram ("test angina"). Only the minority of all cases were investigated. This was particularly so for women in whom 17% (11,428 / 68,088) of the cases were investigated compared to men in whom 31% (15,839 / 50,922) were investigated. Figure 3 shows the influence of age and gender on all patients with angina (n=121,020) who are investigated and found to have a test abnormality. As the figure shows, lack of investigation became more marked at older ages.

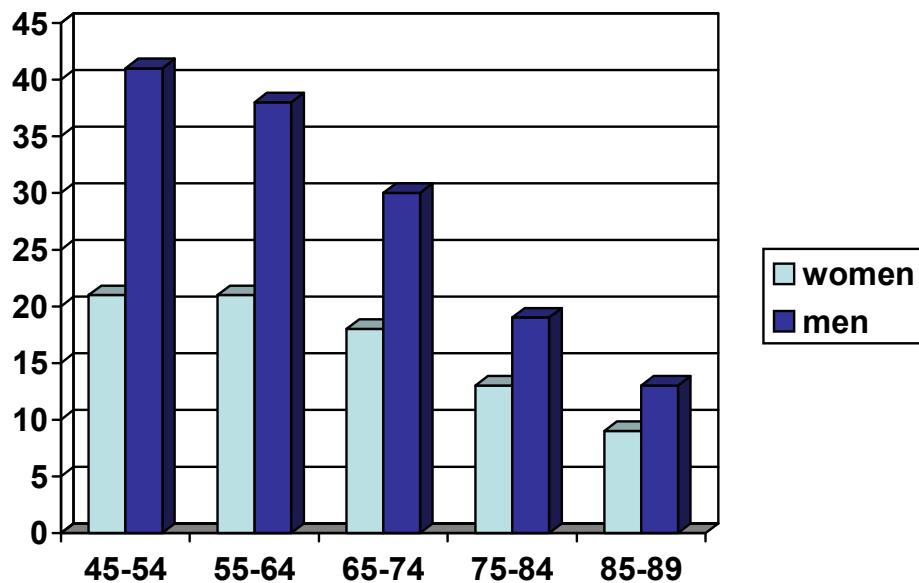
Access to investigation: association with coronary mortality

Patients with nitrate angina – those who have not been investigated – have a consistently higher coronary mortality than the general population. For example among patients aged 55-64 years, the standardised coronary mortality ratio of nitrate angina was 2.67 (95%CI 2.23-3.19) in women and 2.24 (2.02-2.49) in men. This effect is observed within each age and sex

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stratum. These data are the best prognostic evidence that investigation of angina is underused.

Figure 3 Age and gender influence on % of all patients with angina



1.6 Limitations of current technology

Significant efforts are directed at changing physician behaviour in order to improve health outcomes. Guidelines, and to a lesser extent educational programmes of varying formats and impact are the dominant medium for improving the quality of clinical practice in Northern America and Europe. Governments (NICE, 2001; Office of Quality and Performance, 2005) and medical societies (Gibbons, 2002) have made a large investment in the development and, to a lesser extent, the implementation of clinical guidelines in order to improve quality of care. Retrospective audit and individualised feedback were shown to reduce unnecessary investigations in the long term (Winkens, 1996), although a recent Cochrane systematic review found the effects to be generally small (Thomson O'Brien, 2000) and neither method is implemented into routine care. Audit and guidelines are not commonly cited as reason for changing practice patterns (Davis, 1995). Despite this, both professional bodies and government policy continue to advocate guidelines as the preferred approach for guiding decisions by patients and clinicians and reducing inequity.

Recent systematic reviews of guidelines have identified their limited effectiveness in modifying clinician behaviour, except in the context of intensive implementation programmes (NHS Centre for Reviews, 1999). Despite this investment, the impact of conventional guidelines on decision making by clinicians and outcomes for patients is modest (Grimshaw, 2004) when tested in controlled studies and no consistently successful implementation method could be identified (Eccles, 2002). In the context of routine practice in the UK, most National Institute of Clinical Excellence guidelines have not consistently and measurably influenced clinical decision making (Sheldon, 2004) and controlled studies find no, or modest, effectiveness of guidelines in changing physician behaviour (Grimshaw, 2004). There is no evidence that conventional guidelines reduce inequities in patient management. Trials of conventional guidelines in the investigation and management of coronary artery disease (Eccles, 2002; Feder, 1999; Verstappen, 2003) show no effect on physician behaviour. Underuse of appropriate investigation in primary and secondary care, both globally (Hemingway, 2003; Clarke, 1994; Carlisle, 1999) and among older patients, women, and ethnic minorities, (Feder, 2002) thus remains a public health concern.

In addition, guidelines are less effective in complex situations or where the evidence base is uncertain; however, evidence on patients with angina in particular is sparse. When deciding who should get access to treatment, evidence is needed to show who benefits and who doesn't. Ideally these questions would be answered by randomised trials. However, there are no randomised trials of different investigation strategies of angina in primary care – and thus this study design can offer no direct evidence for defining appropriate care near the base of the pyramid. The majority of trials are

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concerned with populations at the apex, in the minority of patients who undergo angiography and revascularization. One of the main concerns is the fact that measurable standards of appropriate care are often developed on the basis of these trials and these standards are then applied to all patients, despite the fact that trial populations are often selective and unrepresentative of the population of patients with CHD.

Existing guidelines in the field of angina may be a relatively blunt tool, requiring clinicians to translate generic statements to guide the care of individual patients. The degree of clarity and specificity of guideline recommendations may be an important factor in determining whether clinicians actually use guidelines (Grol, 1998). Guideline recommendations may be so general as to be "non-actionable" (McDonaldd, 1994). The North of England group have developed nationally recognised guidelines for use with angina patients in primary care (Ecccles, 1998; Freemantle, 1997). These guidelines recommend exercise electrocardiography for "all patients with clinically certain angina." Such guidance leaves many questions unanswered for an individual patient. The clinician has to determine whether the patient has clinically certain angina and whether an exercise ECG might be inappropriate or contra-indicated. Such guidance does not recognise limited service capacity, or support management of waiting lists, whereas appropriateness ratings do by giving explicit rankings. The American Heart Association guidelines (Gibbons, 1998; Chatterjee, 1990; Gibbons, 1999) do offer more specific recommendations but were not developed for use in primary care.

1.7 Appropriateness ratings as an alternative to guidelines

Decision support which provides clinicians with patient specific recommendations may be a more effective method for delivering guidance than conventional guidelines, particularly if provided automatically in a computerised format as part of the clinician workflow. (Kawamoto, 2005) Appropriateness ratings (Shekelle, 2004) are tailored to individual patient characteristics and offer unambiguous recommendations and more straightforward implementation in computerised decision support. Furthermore, appropriateness ratings can explicitly incorporate the expert judgements of both general practitioners and specialists. There have been no randomised trials of patient-specific decision support vs conventional guidelines in investigations decisions.

Guideline recommendations on investigation of chest pain made by cardiologists (Snow, 2004; Gibbons, 2002; Gibbons, 2003; Scanlon, 1999; Williams 2001) all adhere to a Bayesian principle: exercise ECG has the greatest diagnostic yield when the pre-test probability of disease based on only a few patient and clinical factors is intermediate; if it is too low a positive test is likely to be false and when too high a negative test is likely to be false. Appropriateness ratings developed using the RAND method on the other hand are tailored to specific patient characteristics and the ordinal appropriateness

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scale facilitates formal assessments of reliability (Shekelle, 1998; Raine, 2004) and utilisation in computerised decision support.

Appropriateness ratings are based on the views of an expert panel, which synthesises published evidence and clinical expertise to apply a rating for a specific intervention or procedure for a large number of potential combinations of relevant clinical factors, representing the diversity of real patients. As such they are derived similarly to guidelines in a consensus-based process. However, the difference lies in the fact that guideline development groups discuss available evidence to form general recommendations while expert panels for appropriateness ratings apply the available evidence to specific patient scenarios and use the consensus method to find agreement on recommendations for these specific scenarios.

This information is codified in a computer system that can be used in day to day clinical practice. It prompts the clinician to enter relevant clinical data (e.g. nature of symptoms, age, risk factors). The system then offers an appropriateness rating for that patient, based on the expert panel's consensus. The appropriateness rating is explicitly and specifically "actionable". The clinician and patient may then discuss this recommendation and decide on the next management step. This approach is analogous to the widely adopted use of computerised coronary risk calculators based on the Framingham equation to guide primary prevention of coronary heart disease (Robson, 2004). Hence appropriateness ratings may improve clinical decision making by firstly prompting a systematic collection of relevant clinical information and, more importantly, offering the clinician and patient a specific recommendation based on this information.

1.8 Appropriateness to measure uncertainty and standard of care

Studies using appropriateness methods have highlighted the issue of underuse (Carlisle, 1999; Kravitz, 1995; Laouri, 1997; Carlisle, 1995; Leape, 1990). Well designed expert panels can closely reflect the views of practicing hospital specialists (Ayanian, 1991) and the expert panel method of detecting underuse of revascularization is highly reproducible (Shekelle, 1998; Kahan, 1994). As far as the applicants are aware there has been only one randomised trial comparing appropriateness ratings with guideline recommendations (Shekelle, 2000). This trial found that clinicians receiving appropriateness ratings ordered more electrodiagnostic tests for back pain vignettes for appropriate indications and fewer for inappropriate indications than did the clinicians who received the guidelines. Patient vignettes have been shown to be a valid and comprehensive means of assessing quality of care (Peabody, 2000). To date however there have been no trials comparing appropriateness ratings vs guidelines in the management of coronary disease.

1.9 Appropriateness ratings and access to care

In the ACRE study, we have shown that management based on appropriateness ratings might improve clinical outcomes. A 9-member expert panel rated the appropriateness of coronary angiography, angioplasty and coronary artery bypass grafting (CABG) on a scale from one (highly inappropriate) to nine (highly appropriate), using the RAND method. We identified significant under use of revascularization. One third of patients deemed appropriate for revascularization by the expert panel were managed conservatively. Crucially, the group who did not undergo surgery, despite being appropriate, had worse survival at 2.5 years than patients who underwent CABG (79% vs 94%, $p < 0.0001$), independent of co-morbidity and other risk factors (Hemingway, 1995; Crook, 1997; Hemingway, 2001). This suggests that management based on appropriateness ratings may be superior to current clinical decision making.

A major access barrier to cardiac services is referral from primary care to secondary care for opinion and investigation. We have developed appropriateness ratings for the key clinical decisions of requesting a non-invasive cardiac stress test (exercise ECG) and angiography. Based on our experience in the ACRE study (Hemingway, 1995; Crook, 1997; Hemingway, 2001) and our RCT of back pain management (Shekelle 2000) we anticipate that clinical decisions based on these ratings would improve access and reduce variations in management compared to guidelines. In addition, appropriateness ratings offer an explicit tool for managing demand and waiting lists. Both locally and nationally, thresholds for interventions based on appropriateness ratings could be used to match demand with supply and also to assess need for expansion of services.

1.10 Framework for evaluation

Appropriateness ratings are a promising innovation in health care technology, which demands a multi-faceted evaluation to assess its effectiveness, impact on equity and acceptability to patients and clinicians. In addition, we need to understand the relative contribution of clinical decision making and organisational and patient barriers in determining access to appropriate care to allow development of whole system approaches for facilitating access to cardiac surgery.

1.11 Aims and objectives of this report

How effective are appropriateness ratings vs guidelines? (objective 1) While appropriateness ratings are a promising technology to improve access we do not know if they are any better than traditional guidelines. We have compared both methods in a trial where both generalists and specialists were either given appropriateness ratings or guidelines and made recommendations on 24 hypothetical patients with angina.

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Do appropriateness ratings reduce inequities? (objective 2) Since appropriateness ratings focus on the severity of the patient's condition, and give clear recommendations, unbiased by age and gender, we were able to test whether appropriateness ratings are better than guidelines in reducing inequalities with regard to clinician variability, geographical factors, age, sex and ethnicity.

Patient and physician usefulness (objective 3) Acceptability of these ratings tools in clinical practice is crucial in order for them to work in real life. We conducted interviews with clinicians and patients to find out how they feel about the ratings, whether they would adopt them and how they might be implemented. We also examined factors which determine outcome in the patient-doctor interaction and possible barriers to the diagnosis and referral of patients.

Barriers to accessing revascularization (objective 4) Finally we examined what difference appropriateness ratings make in reality once patients are "in the system". We made detailed comparisons between the patient records of patients who did not get treated with those who did and investigated the impact of clinician and patient related factors on the appropriate management of patients.

Section 2 Appropriateness vs. guidelines: the ARIA randomised controlled trial

2.1 Background

This chapter addresses objectives 1 and 2 of the study: are appropriateness ratings more effective than guidelines in increasing the proportion of appropriate investigations, and do appropriateness ratings reduce inequity in access? The contents are derived from the Appropriateness of Referral and Investigation of Angina (ARIA) randomised controlled trial.

2.1.1 Evidence on appropriateness of investigation in primary and secondary care

The ARIA trial was informed by a systematic literature review, which was carried out to inform panellists of the two expert panels and was not part of this project. The literature review and expert panel protocol can be viewed in full on www.ucl.ac.uk/peg/studies/. We searched MEDLINE and EMBASE as well as the Cochrane library, hand-searched key medical journals such as the NEJM, BMJ, Lancet and JAMA for example and used forward and backward citation to identify key papers. Findings of the literature review are briefly summarised in this section. Although the American Heart Association (Snow, 2004; Gibbons, 2003) and others have reviewed the literature on exercise ECG and angiography for their guidelines there are two important reasons why these reviews do not directly answer questions on appropriateness of referral in primary care. First, the AHA review is written from the perspective of a hospital physician or cardiologist. There is little explicit consideration for the situation in primary care, which in the UK is the clinical setting for initial referral decisions. This is important because decisions to investigate depend on the pre-test probability of coronary disease. The only widely used methods of predicting this probability – Diamond Forrester (Diamond, 1979) and Duke (Pryor, 1983; Pryor, 1991)– were derived from hospital populations and have been shown to overestimate markedly the pre-test probability of coronary disease in primary care (Sox, 1990).

The appropriateness of exercise ECG and angiography may be judged according to whether the test revises the pre-test estimate of the diagnosis (i.e. the probability of underlying angiographically demonstrated coronary artery disease (CAD)), or revises the pre-test estimate of prognosis (e.g. risk of death) by a sufficient margin to change subsequent decisions on treatment or investigation which are expected to confer more health benefit than an alternative. The incremental diagnostic or prognostic value of a test is the extent to which it adds information beyond that provided from basic clinical

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assessment; particularly where it moves a patient across a threshold for subsequent action.

There are no randomised controlled trials in patients in primary or secondary care on initial investigations and only one randomised trial was identified which directly tested the impact on clinical outcomes of different investigation strategies (the TIME trial), albeit in patients who already had confirmed coronary artery disease. (TIME 2001)⁶⁶ This problem extends to observational studies, which are also subject to referral or work up bias in which patients in the studies have already been selected based on previous test results. Few studies are without such bias. Even fewer studies report the *incremental* diagnostic or prognostic value of exercise ECG or angiography, over and above basic clinical information. Three highly influential studies – Diamond-Forrester, Coronary Artery Surgery Study and the Duke registry are difficult to apply to primary care for that same reason. For many patient indications – particularly among the elderly and among those with non-specific chest pain – there are no empirical estimates of the pre-test probabilities.

In hospital based studies age, sex and typicality of symptoms are strongly and consistently associated with differences in pre-test probability of CAD. These estimates range from 2% (woman aged 30-39 with non-specific chest pain) to 94% (man aged 60-69 with typical angina). In these studies, the additional information of risk factors and resting ECG abnormalities improved these predictions, but studies varied on which risk factors were important. However, using samples of patients who have all undergone angiography to develop prediction equations for the CAD overestimates the pre-test probability of CAD in primary care, where the prevalence of CHD is lower.

The addition of exercise ECG findings to a basic clinical assessment may make only a modest contribution to the pre-test probability of disease. One study found that the area under the ROC curve increased from 0.74 (basic clinical information alone) to 0.78 with the addition of exercise ECG findings (0.5=no discriminatory power between patients with and without coronary disease, 1=perfect discrimination). The incremental value of the exercise ECG is particularly low where pre-test probability is low or high, as willingness to refer someone with a low probability is low despite a possible positive exercise ECG result and high in patients with a high probability of CAD but a negative exercise ECG result. Similar findings to CAD presence were found when examining the incremental value for CAD severity published to date. In one study the area under the ROC curve increased from 0.66 (basic clinical information alone) to 0.72 with the addition of findings from the exercise ECG (Pryor, 1991).

Arbitrary thresholds of pre-test probability of 10-20% (low) and 80-90% (high) are used, but there has been little attempt in the literature to link test characteristics to treatment thresholds. The threshold of diagnostic certainty above which secondary prevention would be initiated and below which it would be stopped remains unclear from the randomised trial evidence. Trials of CABG suggest that the treatment threshold for which surgery offers

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prognostic benefit is three-vessel disease or left main stem disease. The TIME trial compared angiography with non-invasive management among patients aged over 75, and found that an initial invasive strategy was safe (TIME, 2001).

There are more than a hundred studies reporting diagnosis or prognosis in relation to exercise ECG and angiographic findings but few are directly useful for decision making in primary care, either because of a failure to report incremental value or because of referral bias. Few papers report the impact of test findings on crossing treatment thresholds. This lack of research evidence may contribute to wide variations in the management of angina by primary care physicians and specialists. In the absence of prognostic studies in primary care populations, clinicians may make subjective estimates based on the prevalence of coronary disease in their patient population. Our findings from the systematic review reveal the scarcity of evidence on which to base management decisions in angina and highlight the need for expert guidance, which combines best evidence with clinical experience across both primary and secondary care that is applicable to individual patients.

2.1.2 Appropriateness ratings for the appropriateness of investigation in angina

Despite the importance of management and referral decisions facing primary and secondary care the Appropriateness of Referral and Investigation in Angina (ARIA, 2003) appropriateness ratings are the first to have been developed internationally. Thirteen clinical descriptors (see Box 1) were identified which influence the decision to perform exercise ECG or angiography on people with suspected or confirmed angina, based on a literature review (ARIA 2003) and guidelines (Vader 2000; Eccles 2001). Clinically meaningful combinations of these factors were used to define specific clinical indications (hypothetical patients sharing the same clinically relevant characteristics) spanning the range of pre-test probability of coronary disease from very low (<5%) to very high (>95%). An example of such an indication would be a male patient aged 75-84, who had a normal angiogram in the last 12 months, but who now presented with atypical angina, with mild functional impairment and had two coronary risk factors. A total of 3072 indications were grouped in six broad clinical presentations: previous abnormal coronary angiogram, previous normal coronary angiogram, previous acute coronary syndrome, typical angina symptoms, atypical angina symptoms, non-specific chest pain, reflecting the range of clear cut and "grey" cases seen in primary and hospital care. Two independent expert panels comprising 11 family physicians and cardiologists each rated the appropriateness of coronary angiography in these 3072 patient scenarios according to the RAND Delphi method. Exercise ECG was rated among the subset of 1128 indications in which a previous exercise ECG had not been performed.

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Box 1 Illustration of the contrast between a broad guideline recommendation and specific judgements of appropriateness, tailored by clinical descriptors

<p>American Heart Association Class I* guideline recommendation</p>	<p>Specific appropriateness ratings in ARIA (n=1128 indications for exercise ECG)</p>		
<p>“Patients with intermediate pre-test probability of coronary artery disease” should undergo exercise ECG</p>	<p>13 clinical descriptors (maximum) cross classified to define a single indication</p>	<p>Examples of 3 specific indications which match general guideline recommendation for intermediate pre-test probability of CAD</p>	<p>Expert panel recommendation on exercise ECG for these indications (rating of Panel A, rating of Panel B)</p>
	<p>previous angiography result (abnormal, normal) previous revascularization (yes, no) timing of angiogram (<= last year, one year +) previous acute coronary syndrome (yes, no) timing of acute coronary syndrome (<=last year, one year +) age (<40, 40-49, 50-59, 60-74 and 75-84) sex (women, men) typicality of symptoms (typical, atypical, non-specific) severity of symptoms (Canadian Cardiovascular Society Class I/II (mild), III (moderate), IV (severe)) risk factors (low, medium, high) resting ECG (normal, abnormal)</p>	<p>Man or woman between 75 and 84 who had a normal angiogram in the last year, atypical symptoms, a medium risk factor profile and mild functional impairment (CCS I/II)</p>	<p>Exercise ECG inappropriate (ratings 2,3)</p>
	<p>exercise ECG findings (none, normal, abnormal, very abnormal) medication for symptoms (sub-maximal, maximal)</p>	<p>Man between 75 and 84 with non-specific chest pain, no previous exercise test result, moderate functional impairment, low risk factor profile, normal resting ECG result and maximal anti-anginal therapy</p>	<p>Exercise ECG uncertain (ratings 5,5)</p>
		<p>Man between 40 and 49 with typical angina symptoms, no previous exercise test result, severe functional impairment, CCS III, high risk factor profile, normal resting ECG result and submaximal anti-anginal therapy</p>	<p>Exercise ECG appropriate (ratings 9,7)</p>

- Conditions for which there is evidence and / or general agreement that a given procedure or treatment is useful and effective

2.1.3 Advantages and disadvantages of the appropriateness ratings

Appropriateness ratings are tailored to specific patient characteristics (unlike most guideline recommendations) and the ordinal appropriateness scale facilitates formal assessments of reliability. The Box gives an example of how three indications match to one guideline recommendation, but to three different appropriateness ratings. Their distinct advantage lies in the recommendation given for the combination of clinical and patient factors which are often compartmentalised into separate chapters in the guidelines (e.g. recommendations for elderly patients, recommendations for female patients etc.) and may sometimes be conflicting. Another advantage is their succinctness, which makes them eminently suitable for clinicians with time constraints, and their relevance for both primary and secondary care. We found that GPs were in general more conservative than cardiologists, reflecting the lower probability of CAD seen in primary care.

However, appropriateness ratings are a relatively new health technology and need further development. Our findings comparing results from the two independent expert panels show that consensus within panels ($\geq 9/11$ panellists rating within one point of the median) was reached only in 19% (panel A) and 10% (panel B) of indications for exercise electrocardiography and 37% and 51% for angiography. However, consensus was very high ($>89\%$) for appropriateness of general investigation (either test).

Table 1: Agreement within and between expert panels

	Consensus within panels*			Appropriateness categories: all indications (indications rated with strong consensus)			Agreement between panels	
	Strong: At least 9 panel members	Intermediate 6-8 panel members	Absent: Less than 6 panel members	Inappropriate	Uncertain	Appropriate	Close agreement between panels †	Weighted kappa
Exercise ECG n = 1128 indications								
Panel A	19	60	21	3 (4)	21 (11)	76 (85)	56	0.15
Panel B	10	52	38	7 (8)	63 (35)	30 (57)		
Coronary angiography n = 3072 indications								
Panel A	37	22	42	32 (36)	24 (3)	44 (61)	63	0.52
Panel B	51	43	6	12 (9)	32 (19)	56 (72)		

All values are row percentages of indications, except kappas.

* Number of panellists (maximum =11) rating within 1 point of the median of the whole panel

† Median of one panel within 1 point of the median of the other panel

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Table 1 shows the influence of the pre-test probability of underlying coronary artery disease on rating exercise ECG as appropriate. Panel A was strongly influenced by the pre-test probability of coronary disease. Thus panel A rated exercise ECG appropriate among fewer indications with very low, or very high pre-test probability of disease, compared to those with intermediate probability. The ratings of Panel B showed no relationship with Duke score. Panel B favoured angiography whenever the resting ECG was abnormal. For example, among typical chest pain indications in the setting of an abnormal resting ECG, panel A rated 89% of indications as appropriate for exercise ECG and 52% appropriate for angiography; the corresponding proportions for panel B were 0% and 90%. The presence and extent of exercise ECG abnormality was the strongest influence on rating angiography as appropriate and the degree of consensus. Disagreement was at its worst for angiography in the absence of an exercise ECG result, due to panel A's preference for exercise ECG.

Appropriateness methods for defining and improving access to angina care

Figure 3: Influence of pre-test probability of coronary artery disease on rating ETT appropriate

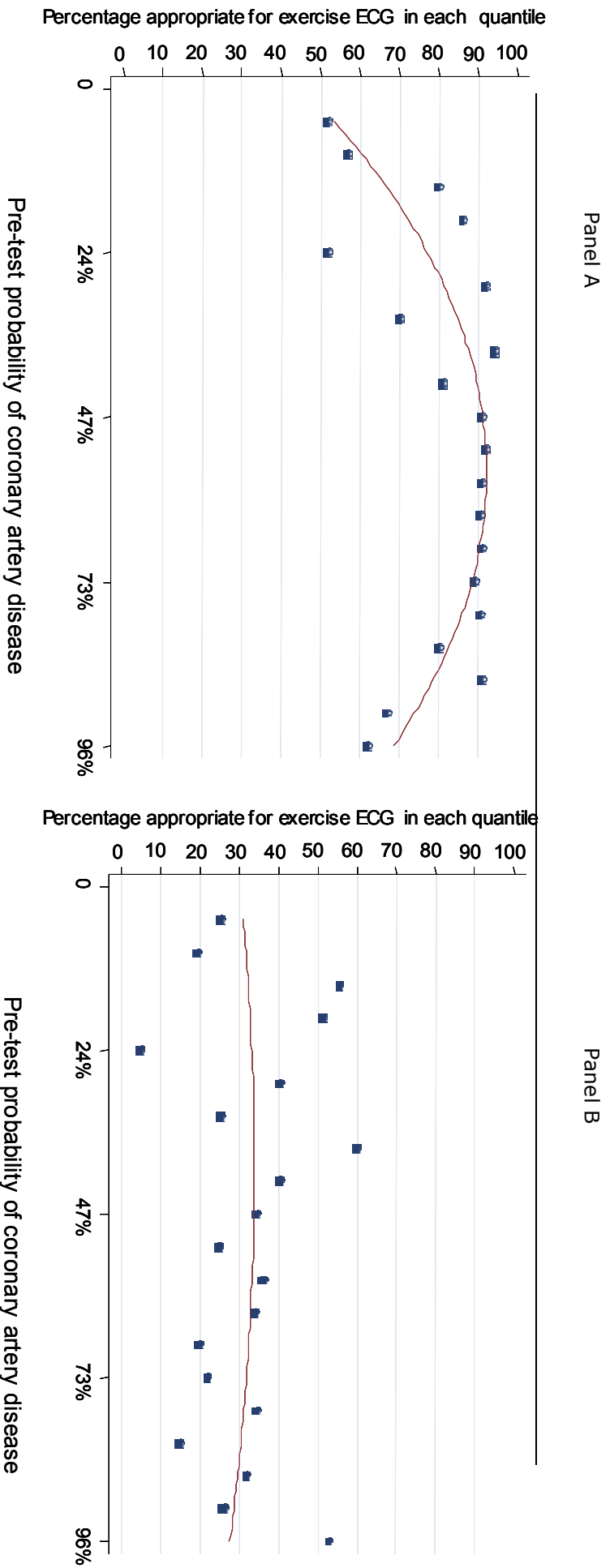
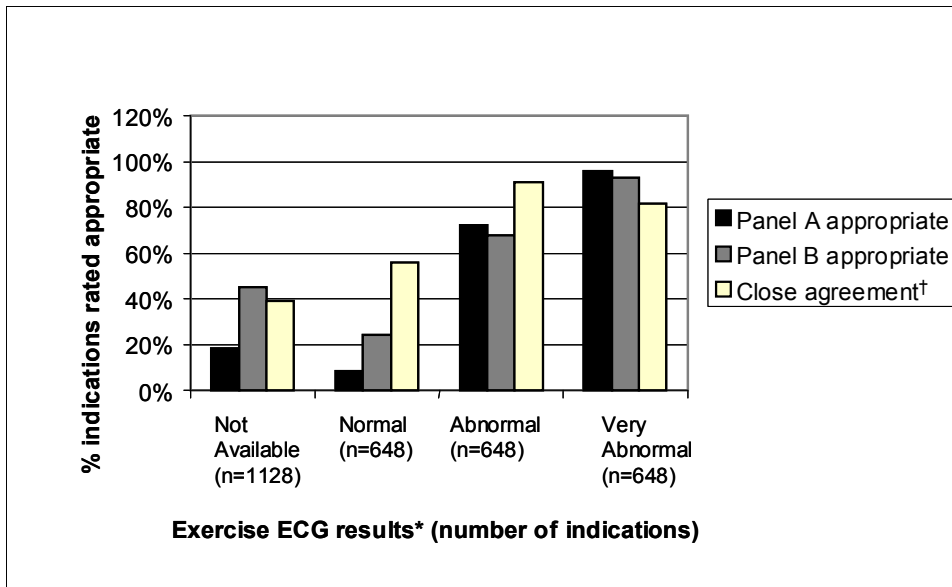


Figure 4: Influence of exercise ECG results on the appropriateness of angiography



Total number of indications = 3072 (1128 in patients without exercise ECG, 648 in each of the exercise ECG result categories)

*** Exercise ECG results:**

Normal = At least 85% of predicted maximum heart rate, or rate pressure product of at least 250, or 10 METS or completed stage IV

Abnormal = After the first three minutes of the test the patient develops typical angina or 1mm or more of horizontal or down sloping ST segment depression that is present 80ms after the J point.

Very abnormal = same changes as for an abnormal test occurring during the first three minutes; test is stopped due to a fall in blood pressure; two consecutive 10mmHg drops in systolic blood pressure from baseline or more than 2mm ST depression or persistence of ST depression for more than 6 minutes after the test.

† **Close agreement** between panels = Median of one panel within 1 point of the median of the other panel

2.1.4 Implications for the ARIA trial

Because of the disparity between the two panels we only chose to use indications that were rated in agreement by both panels, in order to ensure that the results were not sensitive to the type of panel chosen for the ratings. Agreement was calculated as the number of panellists rating within one point of the panel median with $\geq 9 / 11$ denoting strong consensus. *Between panel agreement* was examined using the weighted kappa statistic which assesses the agreement beyond chance for the appropriateness ratings, 1-9. Since ratings were commonly concentrated at one end of the scale, the weighted kappa will tend to underestimate agreement. Therefore we also defined between group "close" agreement as occurring when the median of one group was within a 1 point range of the median of the second group.

Despite the difference between the panels, both showed underuse of exercise ECG in the range of 13-25% and underuse of angiography in the range of 6-13%, when matched to real patients attending national Rapid Access Chest Pain Clinics (RACPCs) (table 2). Overuse of both procedures was negligible according to both panels (table 2). In addition, the ratings of both panels predicted all cause mortality in these patients, giving some reassurance to the validity of the appropriateness method as a whole (figure 6).

Appropriateness methods for defining and improving access to angina care

Table 2 Underuse and overuse of investigation in patients with angina

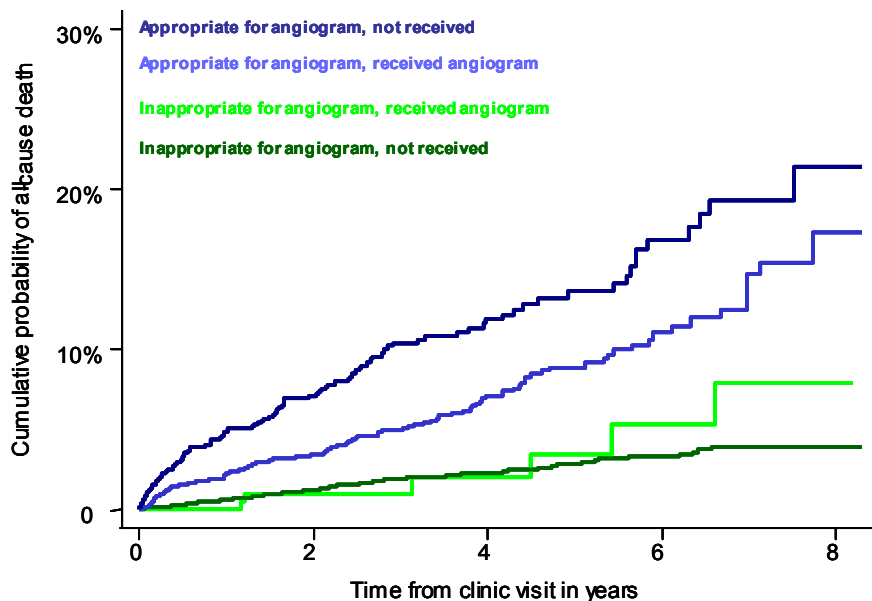
Investigation	N	Indications represented by patients	Investigation deemed appropriate according to expert panel		Underuse: Investigation not performed among patients deemed appropriate		Investigation deemed inappropriate according to expert panel		Overuse: Investigation performed among patients deemed inappropriate	
			N (%) [95% CI]		N (%) [95% CI]		N (%) [95% CI]		N (%) [95% CI]	
			Panel A	Panel B	Panel A	Panel B	Panel A	Panel B	Panel A	Panel B
Exercise ECG	264	10711	7736 (72%) [71-73%]	4820 (45%) [44-46%]	2669 (25%) [24-26%]	1440 (13%) [13-14%]	971 (9%) [9-10%]	1112 (10%) [10-11%]	291 (3%) [3-3%]	390 (4%) [3-4%]
Coronary angiography	476	10711	1092 (10%) [7-11%]	1943 (18%) [17-19%]	652 (6%) [6-7%]	1396 (13%) [12-14%]	8250 (77%) [76-78%]	5881 (55%) [54-56%]	88 (1%) [1-1%]	21 (0%) [0-0%]

* denominator for all percentages in the table

Prognostic validity of appropriateness ratings

An important test of the validity of expert panel ratings of appropriateness of investigation lies in their ability to lead to different causes of management, which improve patient outcomes. We tested the hypothesis that patients in whom angiography was deemed appropriate who received it, should have better outcomes than those appropriate for angiography, but who did not receive it. These better outcomes arise because the result of the angiogram leads to different treatments. Revascularisation with PCI or CABG can only occur once an angiogram has been performed. Furthermore, it is plausible that secondary prevention medication and lifestyle advice may be more intense when coronary disease has been visualised at angiography. Using the outcome of all cause mortality, Figure 6 shows evidence in support of this hypothesis. **Patients who were appropriate for angiography but did not receive it had a higher probability of death than patients who were appropriate and received angiography. Appropriateness ratings therefore have the potential to improve patient outcome if the panel recommendations are adhered to.** Similar findings were made using panel A or panel B ratings. Although these are observational data, and we cannot exclude the possibility that patients undergoing angiography were selected on fitness, these are the best data available to support the validity of guidance in consecutive, real world patients.

Figure 5: Prospective prognostic validity of the ARIA expert panel ratings



2.2 Rationale and objectives of the ARIA trial

Any decision support tool needs to reduce overall heterogeneity in access to investigations (objective 1) as well as systematic variations in access to care (objective 2). We therefore compared conventional guidelines with patient-specific appropriateness ratings in a randomised controlled trial of decision support using 24 patient vignettes. At this stage appropriateness ratings are a new technology not currently used in routine practice in the UK and it would be premature and unethical to conduct an RCT on their effectiveness with actual patients. Apart from this, vignettes had the advantage over real patients of reliably controlling for case-mix variation and ensuring that cases were identical in each arm. This would not have been feasible or even possible with real patients in such a large number of clinicians in a variety of settings. Therefore, we addressed the essential prior trial question: **Faced with identical patients vignettes are the decisions of generalists and specialists improved when supported by appropriateness ratings compared to guidelines or unsupported decision making?**

2.3 Methods

2.3.1 Summary of study design

We carried out an internet based trial in which doctors were randomised to patient-specific decision support or conventional guideline recommendations, with the outcome of appropriate exercise ECG and coronary angiography decisions. Both trial arms first assessed a number of vignettes without any support and thus acted as their own controls. In total 189 GPs and 103 cardiologists from 9 regions in the UK and Ireland were randomised to either guidelines or expert panel ratings balanced by specialty and centre using minimisation software (<http://www.sghms.ac.uk/depts/phs/guide/minim.htm>). Figure 7 shows the flow of clinicians through the trial. Clinicians were asked to complete the patient vignettes online (<http://www.ucl.ac.uk/aria>) within two weeks of starting to assess the vignettes.

2.3.2 Definitions

Appropriateness ratings: the RAND – Delphi method

Twenty two clinicians from 9 centres in England, Ireland and Scotland took part in two independent expert panels to rate the appropriateness of exercise ECG and angiography for each of the 3072 indications (combinations of pre-specified patient and clinical characteristics representing a unique patient group with the same characteristics). Clinicians were chosen to reflect a balance of age

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(years since qualification), sex, service and academic contracts and, among specialists, invasive and non-invasive practice. All generalists had a special interest in angina, clinically or academically. Each panel consisted of 5 family physicians, 5 cardiologists and 1 cardiothoracic surgeon.

The RAND Delphi method is a consensus-based method. The process consisted of two stages. Firstly, panellists made their recommendations independently (first round rating). Each panellist rated the 3072 indications on a scale from 1 to 9 (1-3 inappropriate, 4-6 uncertain, 7-9 appropriate). We developed software for the panellists to enter and review their own ratings and access definitions of terms (software available from the authors). Panellists were invited to base their ratings on peer reviewed research evidence where available and were provided with a literature review, carried out in 2003 (ARIA 2003).

After returning their individual recommendations we identified areas of disagreement between the panellists on each panel and invited the panellists for a meeting to discuss these areas of disagreement. Panels met over two days in July 2003 with an identical protocol. Each panel had a facilitator (Nick Black, Harry Hemingway) who was unaware of the ratings of the other panel. Members of each panel were also unaware of the ratings of the other panel. Facilitators did not partake in the discussion or influence the results but were responsible for focussing the discussions. Each panellist was provided with a personalised report containing their own first round ratings, the medians of their whole panel, with areas of disagreement highlighted. Panellists had the opportunity to change their ratings in the light of the panel discussion if they were persuaded by the evidence (second round ratings).

Appropriateness

The most appropriate management step (rated 9) was defined as one in which benefit so clearly outweighs harm that it would always be carried out or it would be wrong not to do it. For an investigation to yield benefit, it must change the pre-test probability of diagnosis or prognosis by a sufficient margin to change subsequent management. The most inappropriate management step (rated 1) was defined as one in which harm so clearly outweighs benefit that it would never be carried out or it would be wrong to do it.

Assumptions about health services and patients

Ratings were made in the context of a health service without waiting lists and in which exercise ECG and angiography can be ordered directly by generalists. The purpose of these assumptions was to ensure that ratings were developed according to clinical need, independent of the health care setting they were developed in. With regard to the patient it was assumed that all patients are treated with

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secondary prevention medication where indicated, have identified angina or chest pain as a significant symptom from which they are actively seeking relief and are without a strong preference for a particular investigation. These assumptions were made, as absolute indications or contra-indications, patient preference or significant co-morbidity will override any considerations of appropriateness. These assumptions were communicated to the trialists, i.e. they gave their recommendations with the assumption that they had no financial constraints and that there were no patient preferences or co-morbidities that they needed to take into consideration.

2.3 Trial participants

We tested the expert panel ratings against guidelines in general practitioners and cardiologists, as both specialties make decisions in the management of patients with angina. As initial denominator for the trial we chose all eligible general practices in 9 regions with wide geographical spread in the UK and Ireland, and all cardiologists registered with the British Cardiac Society as of March 2005 (n=1302). Initially, all general practices within the geographic boundaries of one major referral centre in each region were eligible to participate in the trial (n=744). To increase recruitment rates we then expanded the boundaries of each region outward, balanced by size in iterative steps, to achieve recruitment targets. The stopping rule for the trial was the completion of 24 vignettes each by 200 GPs and 100 cardiologists. We achieved the recruitment of 299 clinicians and a decision was made to terminate recruitment as of June 2005. We invited the senior partner or asked him or her to nominate another GP from the practice for the study, as only one doctor per practice was eligible to participate. Names for all practices were obtained from each Primary Care Trust or the NHS online practice directory. We sent invitations out by postal questionnaire and sent three follow-up invitations subsequently. The clinicians in the initial denominator were invited by mail in September 2004. The additional GPs in the expanded denominator were invited in January 2005. A second and final expansion mail-out was carried out in May 2005. Clinicians who had registered with the study on-line but had not completed their vignettes were emailed three reminders 4, 8 and 12 weeks after registration.

Clinicians were told that this was a study of their decision making practice and that they would be paid for completing the task. They were not told that this was a trial or that two types of decision support were being compared in order to minimise potential bias if clinicians had a strong preference for either intervention. Clinicians were asked to give details of their own practice. The trial design and examples can be viewed on www.ucl.ac.uk/aria.

2.3.4 Sample size calculation

The trial was designed to give >80% power to detect a difference of 10% (70% cf 60%) in the expert panel ratings group compared with the guidelines group, at a 5% significance level. We were interested in the odds of a correct recommendation, comparing at vignette level whether there was a 10% difference in the proportion of correct recommendations in each group. As the intervention was a group intervention at doctor level, the vignettes were clustered by clinician and we therefore assumed an intra-cluster correlation between clinicians of 0.06. The design further assumed an intra-cluster correlation between vignettes of 0.04. The sample size calculation estimated that we needed 200 GPs, 100 cardiologists and 48 unique vignettes to detect a minimum difference of 10% between the two arms. Each clinician would see 24 vignettes, 12 before and after the intervention.

2.3.5 Vignettes

Selection of indications

The patient narratives (vignettes) assessed by the clinicians represented 48 hypothetical patients with suspected or confirmed angina presenting in primary or secondary care. The vignettes were based on the indications, which had been rated for appropriateness of investigation (exercise ECG and angiography) by the two expert panels (see Interventions below). The indications for the trial were chosen out of a pool of 658 indications that were rated in agreement by both panels. Agreement was defined as the number of panellists rating within one point of the panel median. We then matched these ratings to 10,343 patients with recorded chest pain who were seen in five Rapid Access Chest pain clinics in the UK and 1234 patients from the Whittington hospital outpatients database in order to ensure that indications were clinically credible and occurred frequently in clinical practice.

To select the 48 final vignettes we then chose 4 times 12 indications (4 blocks of 12) to (i) represent a wide range of patient types seen routinely in primary care and (ii) to represent a cross section of the indications rated by the panels. The blocks were required to ensure an efficient trial design (see Interventions).

There were 12 indications with typical angina, 12 with atypical angina, 10 with non-specific chest pain, 14 with previous CHD history in the final 48 vignettes and 25 of those had an exercise ECG available. These factors were distributed more or less equally across each of the 4 blocks. In the indications with no previous CHD (n=34) a balance of indications were chosen with normal/abnormal resting ECG, and other characteristics (maximal therapy, functional impairment and risk profile) as far as possible. Finally, we tried to avoid repetitive indications and aimed to achieve an equal balance of age and sex in

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each block of vignettes. Eighty percent of the final 48 indications were rated either 2, 3 (inappropriate), 7 or 8 (appropriate) as we assumed that indications rated 1 (harmful) or 9 (necessary) were cases in which decision support is least likely to be of additional value in clinical practice. However, 10 indications with a rating of 1 for angiography were included as "anchors" to check the validity of the recommendations. I.e. vignettes with a rating of 1 in which a test was deemed necessary may indicate a validity problem. Eleven vignettes were rated uncertain for one decision, although every vignette had at least one definitely appropriate or inappropriate decision.

Development of vignettes

Patient narratives (vignettes) were written up by CJ, AT, GF and HH. Cues in the vignettes were based on factors in the indications: age, sex, previous angiographic disease or normal angiogram or revascularization or acute coronary disease, symptom typicality, functional impairment, level of anti-anginal therapy, results of exercise or resting ECG and risk profile for coronary artery disease (see box 2). In addition, "noise" variables not included in the rating exercise, such as patient occupation, were added to resemble real life patients. The vignettes were successfully back-translated into indications by a cardiologist (NS) and a GP (MJ) for validation. The study was powered on one decision (outcome) per vignette but 35 of the 48 unique indications were assessed for a decision on angiography and a decision on exercise ECG (those without any previous exercise ECG results).

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Box 2: Example of indication and corresponding vignette

Indication	Vignette
Male, aged 75-84	History
Typical angina symptoms (defined as pain or discomfort retrosternal or in arms or chest (location), precipitated by exercise, cold or emotion (precipitation) and relieved by rest or GTN (relief)	A 77 year old white retired car mechanic consulted his general practitioner complaining of chest pain. He had first noticed this a few months ago while pushing his car at which time he thought that he had pulled a muscle. Over the previous 4 weeks a similar pain had returned and become increasingly disabling. He was very active for his age but found that he could do little before getting this "bad ache" in his chest. At the time of the consultation he reported 3 episodes when the pain had come on when he was sitting reading his newspaper. His uncle, a heavy smoker, had died with a heart attack 2 years previously. The patient had stopped smoking two years ago, although his alcohol consumption was excessive (40 units per week).
No Exercise ECG done at the time	Examination
Mild functional impairment (CCS I/II)	On examination he had a regular pulse and his blood pressure was 132 / 78. He had a soft ejection murmur at the base of the heart but the carotid upstroke was normal and he was not in heart failure.
Low risk for Coronary Artery Disease (defined as low (0 factors), medium (1-2) or high (3+) based on smoking, hypertension, lipids, family history, obesity, south Asian ethnicity, diabetes and arterial disease in non-coronary circulations.)	Investigation
recent normal resting ECG result	The resting ECG was reported as normal.
Submaximal therapy (defined as one or two anti-anginal agents (nitrates, calcium channel blockers, beta blockers), leaving therapeutic options to control symptoms with drugs, compared with maximal therapy (3+ agents)	

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Recommendations for investigation:	Exercise ECG	Coronary Angiography
Expert panel rating	do (7 (appropriate))	do (7 (appropriate))
AHA guidelines	don't do (CAD prob>80%)	do (CAD prob >80%)
ESC guidelines indicated)	don't do (CAD prob>80%)	don't do (not
NE guidelines	do (certain angina)	N/A

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Allocation of vignettes

Each clinician was randomised to either conventional guidelines or appropriateness ratings, balanced by specialty and centre using minimisation software (www.sghms.ac.uk/depts/phs/guide/minim.htm). The web-based trial (<http://www.ucl.ac.uk/aria>) was designed to the effect that each clinician should see 24 unique vignettes: 12 without and 12 with decision support. Clinicians were unable to return to the first 12 vignettes once they had started assessing the 12 vignettes with decision support. To ensure an efficient design the vignettes were grouped into 4 blocks of 12 with randomly ordered vignettes in each. Clinicians were then randomly assigned to a block sequence (12 possible combinations: AB, AC, AD, BC, BD, CD, BA, CA, DA, CB, DB, DC) to ensure that each vignette was viewed approximately equal times.

2.3.6 Interventions

Pre-intervention

Both trial arms were asked to assess 12 patient vignettes without decision support. Thus we were able to test the assumption that both arms make similar decisions without decision support and each arm acted as their own control. Once the clinicians had given their recommendation on exercise ECG and angiography for the first 12 vignettes they moved on to the next 12 vignettes with decision support. Once they had started to give recommendations on the next 12 vignettes they were unable to change their decisions on the pre-intervention vignettes. Both arms were able to comment on the vignettes at any stage throughout the trial.

The trial design and all 24 vignettes can be viewed directly on www.ucl.ac.uk/aria.

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ARIA website homepage:



ARIA - home

Contact us

FAQ



The Appropriateness of Referral and Investigation in Angina (ARIA) study

This study aims to test the effectiveness and acceptability of decision support tools for referral and investigation in patients with suspected or confirmed angina in primary and secondary care. Thank you for your interest in this important study. To read more please click the informaton button above.

If you have a username and password please

LOG IN HERE




To obtain a username and password please


REGISTER HERE



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Pre-intervention vignette sample screen for both interventions for vignettes 1 to 12:

Address  http://www.ucl.ac.uk/aria/aria/vignette1.php  Go  Links >>

**ARIA - Patient vignettes**DefinitionsContact usFAQStudy guidehome page

Patient 2

History

A 39 year white unemployed IT consultant went to see his general practitioner following an episode of chest pain which had come on during a domestic argument. He was heavy smoker on treatment with amlodipine for hypertension. He admitted to previous episodes of chest pain, usually in relation to emotional stress, but there was no clear exertional component. The pains were described as an aching discomfort across the top of the chest lasting no longer than 15 minutes although residual 'heaviness' in the chest often persisted for several hours. Despite the symptoms being 'unpleasant' he could still do his occasional job as a bicycle courier to earn some money.

Examination

On examination he had a ragged scar in the left side of the chest where he had injured himself in a cycling accident only 3 years previously. He has a regular pulse with the blood pressure at 152/86.

Investigation

He had a total cholesterol of 5.8 mmol/l. An exercise ECG was organised and although this failed to provoke chest pain, it was reported as being abnormal with 1.5mm of ST depression in the inferior leads.

Resting ECG not available

Your recommendation:

Would you recommend an angiogram in this patient?

Definitely	Probably	Unsure	Probably not	Definitely not
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please add a comment if you wish:

Previous patient Next patient

Save and Exit

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Conventional guidelines

The guideline group received an ad verbatim summary of all paragraphs concerning the use of exercise ECG or angiography for each guideline (North of England stable angina guidelines (Eccles, 1998), American Heart Association stable angina guideline (Gibbons 1999; Snow 2004), European Society of Cardiology angina guidelines (European Society of Cardiology, 1997)) with links to the full text guidelines. This guideline support was the same for each vignette (see appendix for guideline summaries shown in trial). The clinicians were free to use any or all of the guidelines, as they would in clinical practice. The number and type of guidelines opened by each clinician was recorded on the database. Doctors were then asked to give their recommendation for each investigation on a 5 –point scale (definitely do, probably do, unsure, probably don't do, definitely don't do). The guideline summaries and full text guidelines can be accessed on www.ucl.ac.uk/aria.

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Sample screen for guidelines arm for vignettes 13 to 24:

History

This 56 year old white sculptor was seen in the outpatient department of her local hospital for review after acute myocardial infarction for which she had been admitted 14 months previously. The infarct was her first cardiac presentation. She had received thrombolytic therapy in the emergency department. Soon after discharge, she started experiencing occasional central chest pains similar to the 'indigestion' she had experienced before the infarct. These were usually provoked by exertion, with radiation into the jaw. The glyceryl trinitrate spray she had been given to take home produced prompt relief of her symptoms and they did not stop her from working on a large commission for a city bank. Her lower back pain did require her to take some time off work. Over the past 6 weeks her general practitioner had gradually increased her medication so in addition to her short acting nitrate she was given a high-dose beta blocker and a calcium channel blocker, but her symptoms continued to recur.

Examination

On examination she was overweight, had a regular pulse and a blood pressure of 125/84.

Investigation

None

Having 1400ms available

Below are sections from three guidelines on angina relevant to this patient. You may find these helpful.

[Click here to see recommendations from AHA guideline.](#)
[Click here to see recommendations from ESC guidelines.](#)
[Click here to see recommendations from North England guidelines.](#)

Would you recommend an exercise test in this patient?

Definitely	Probably	Unknown	Probably not	Definitely not
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Would you recommend an imaging test in this patient?

Definitely	Probably	Unknown	Probably not	Definitely not
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please add a comment if you wish.

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Specific decision support (appropriateness ratings)

The ratings group were given expert panel ratings from the two ARIA panels. Doctors were asked to classify the typicality, risk profile and functional status of the patient first. This was done to preserve the context of the intervention, as clinicians would have to give information on these factors in order to get a rating for a particular patient if the ratings tool was to be used in day to day clinical practice. They were then given the rating derived by the expert panel for each indication and asked to give their own recommendation for each investigation on a 5 -point scale (definitely do, probably do, unsure, probably don't do, definitely don't do).

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Sample screen for ratings arm for vignettes 13 to 24:

How would you classify the functional impairment caused by the symptoms?
[View definition of functional impairment](#)

Mild Moderate Severe

How would you classify the patient's risk for ischaemic heart disease?
[View definition of risk](#)

Low risk Medium risk High risk

[Find out more about the expert panel ratings](#)

The expert panel is uncertain about the appropriateness of this patient rating [Rating 0.0](#)

Would you recommend an exercise ECG in this patient?

Definitely Probably Unsure Probably not Definitely not

The expert panel recommends angiography in this patient [Rating 0.0](#)

Would you recommend an angiogram in this patient?

Definitely Probably Unsure Probably not Definitely not

[Find out more about the expert panel ratings](#)

Please add a comment if you wish:

[Back](#) [Next](#)

[Print](#)

2.3.7 Outcome

We analysed two outcomes. Firstly, we compared the proportion of recommendations in agreement with the appropriateness ratings. Secondly, we compared the proportion of recommendations in agreement with the Duke score in indications without exercise test result or prior confirmed coronary artery disease. The rationale for choosing these outcomes was the extent to which they related to the trial arms: if we showed that conventional guidelines were less effective than patient-specific appropriateness ratings in increasing the proportion of appropriate decisions it could be argued that this was because they were not measured by their own standard. When comparing both types of decision support against the Duke score one would however expect an increase in appropriate recommendations in the guidelines arm, given that the guidelines are largely based on the Duke score.

Outcome 1: Expert panel ratings

We compared the proportion of agreement with the expert panel ratings in each group prior to the intervention and afterwards. Agreement was defined as a recommendation of 'Definitely do' or 'Probably do' when the expert panel had rated the vignette as appropriate for investigation and a recommendation of 'Definitely don't do' and "Probably don't do" in vignettes rated inappropriate for investigation. A recommendation of "Don't know" was considered disagreement with the panel rating. Decisions for which the expert panel gave an uncertain rating were not included in the analysis.

Outcome 2: Duke score

In vignettes without prior exercise ECG result we also measured agreement with the Duke score (probability of Coronary Artery Disease). We assigned each indication (vignette) a pre-test probability of significant coronary artery disease according to the Duke score based on age, sex, smoking, cholesterol, diabetes, resting ECG abnormalities and history of myocardial infarction (Pryor, 1993). A score between 20% and 80% was deemed appropriate for exercise testing whereas percentages outside this range were deemed inappropriate. The Duke score is a validated assessment of the pre-test probability of disease based on age, sex, risk factors and previous history of myocardial infarction. Non-invasive investigation is most appropriate where the pre-test probability of coronary disease is intermediate and least appropriate when the pre-test probability of disease is very low.

2.3.8 Statistical analysis

Uncertain vignettes were excluded from the analysis. Clinicians who answered the first 12 vignettes but none of the second set of vignettes were excluded from the analysis, however missing vignettes in

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clinicians who completed all 24 vignettes were not answered were excluded. Although the website was designed to prevent doctors from completing the trial if they had missing recommendations, in a small minority of doctors without enabled java script this did not work. We therefore did comprehensive analyses on missing values to examine if our results could have been biased by these missing values. We analysed all data using random effects logistic regression, adjusted to allow for clustering by clinician and by vignette block. All analyses in this report were carried out using Stata 7.0 (Texas). Forrest plots were done in SPSS.

2.3.9 Development and piloting of the website

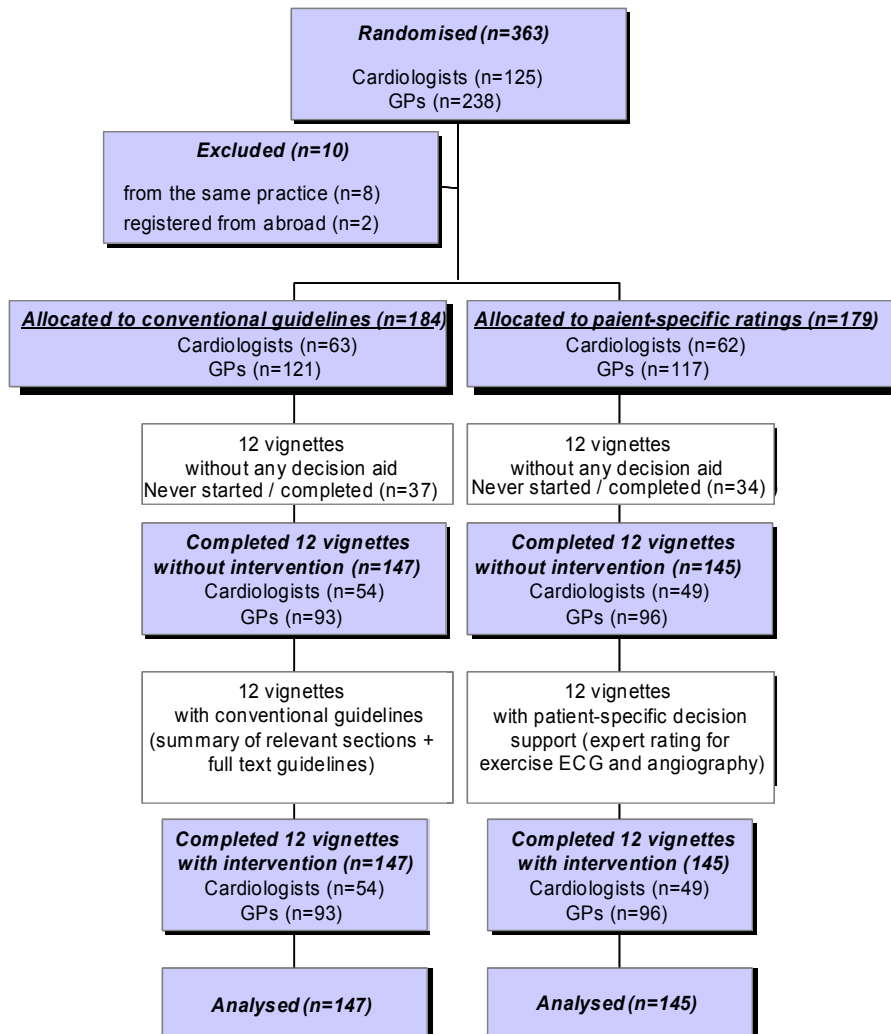
The website for the trial was developed over the space of 6 months and piloted by 3 general practitioners and 4 cardiologists, who were collaborators or colleagues of co-applicants. In addition, the website was made available for testing to the 22 GPs and cardiologists who participated in the ARIA expert panels. Significant changes were made to the website after piloting. For example our original design to ask for justification of each decision was viewed too labour-intensive and was changed into an optional comment facility. Other major changes to the website concerned increasing technical compatibility and ease of navigation (seamless transition from first 12 vignettes to last 12 to prevent drop-outs after the first 12).

2.4 Results

2.4.1 Participant and vignette characteristics

The flow chart in figure 7 shows that 363 doctors registered and 292 (78%) completed the trial. Doctors who did not give any recommendations with decision support were excluded from the analysis (n=37 in guidelines arm, n=34 in ratings arm). General practitioners and cardiologists did not differ between trial arms with respect to practice characteristics (table 3) or region (table 4). GPs did not differ between trial arms with respect to average number of partners, estimated number of cardiological referrals per month, proportion full time or senior partners, or years since qualification. Cardiologists did not differ between trial arms in the proportion that carried out angiography, consultant grade, or years since qualification.

Figure 6: Trial flow chart



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Table 3 Baseline characteristics of participants by intervention

Characteristics	Conventional guidelines	Patient-specific ratings
GPs who completed the trial (n=189)		
GP characteristics	(n=93 (100%))	(n=96 (100%))
Median yrs practice (IQR)	24 (16.5-28)	25 (18-31)
Average practice size	1838	1742
Average number of partners	4 (0-10)	4 (0-10)
N angina patients p month** (incident+prevalent)	18 (10-30)	15 (2-50)
N cardio refs / month	2 (1-10)	2 (0-12)
N full-time	67 (72%)	69 (72%)
N Senior partners	57 (61%)	61 (64%)
Cardiologists who completed the trial (n=103)		
Cardiologist characteristics	(n=54 (100%))	(n=49 (100%))
Median yrs practice (IQR)	15 (11-21)	14 (11- 22)
0 angiograms/ month	11 (20%)	5 (10%)
1-10 angiograms/ month	1 (2%)	6 (12%)
>10 angiograms/ month	42 (78%)	38 (78%)
Consultant grade	30 (56%)	27 (55%)
Registrar grade	22 (40%)	21 (43%)
Other grade	2 (4%)	1 (2%)

Table 4 Baseline characteristics of participants by intervention (region)

Characteristics	GPs (n=244)				Cardiologists (n=129)			
	Conventional guidelines		Patient-specific ratings		Conventional guidelines		Patient-specific ratings	
	Registered (n=122)100 %	Completed * (n=93)76 %	Registered (n=122)100 %	Completed * (n=98)80 %	Registered (n=66)100 %	Completed * (n=54)82 %	Registered (n=64)100 %	Completed * (n=49) 77%
Ireland	10 (8%)	7 (8%)	9 (7%)	7 (7%)	3 (5%)	3 (6%)	2 (3%)	2 (4%)
London	48 (39%)	33 (35%)	49 (40%)	35 (36%)	15 (23%)	12 (22%)	15 (23%)	11 (22%)
Mid-England	8 (7%)	8 (9%)	8 (7%)	8 (8%)	11 (17%)	9 (17%)	10 (16%)	8 (16%)
NE England	8 (7%)	8 (9%)	8 (7%)	7 (7%)	6 (9%)	5 (19%)	6 (9%)	5 (10%)
NW England	9 (6%)	5 (5%)	8 (7%)	6 (6%)	7 (11%)	5 (19%)	7 (11%)	4 (8%)
Oxfordshire	0 (0%)	0 (0%)	0 (0%)	0 (0%)	6 (9%)	5 (9%)	6 (9%)	4 (8%)
Scotland	13 (11%)	11 (12%)	11 (9%)	11 (11%)	4 (6%)	4 (7%)	4 (6%)	3 (6%)
SE England	2 (2%)	1 (1%)	2 (2%)	2 (2%)	7 (11%)	5 (9%)	6 (9%)	6 (12%)
SW England/ Wales	26 (21%)	20 (22%)	27 (22%)	22 (22%)	7 (11%)	6 (11%)	8 (13%)	6 (12%)

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Vignettes

Table 5 shows vignette characteristics previously described in .3.5.1. The 4 blocks of 12 vignettes were equally distributed by specialty and intervention (table 6). Overall, missing values represented 3% of all exercise ECG (134/5109) and angiography decisions (194/7008). No specialty or intervention was prone to more missing vignettes compared to the others (P for difference by intervention=0.35 for missing ECG values; P=0.34 for missing angiography values, corresponding values for difference in missing values by specialty: P=0.88; P=0.89).

Missing data in each vignette block was not expected to lead to any bias, as the combination of 12 blocks with random ordering of vignettes ensured that drop-outs or a 'learning effect' did not affect some vignettes more than others.

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Table 5: Characteristics of vignettes

Characteristics included in the indications	N =48 (100%)
Demographic factors	
Female	24 (50%)
Male	24 (50%)
<=75 years of age	40 (83%)
75+ years of age	8 (17%)
assigned ethnicity: Caucasian	41 (85%)
assigned ethnicity: South Asian	7 (15%)
Previous history of CAD	
Previously revascularised	4 (8%)
Previous angiographic disease	6 (13%)
Previous normal angiogram	1 (2%)
Previous acute coronary syndrome	7 (15%)
Typicality of symptoms	
Typical angina	12 (25%)
Atypical angina	12 (25%)
Non-specific chest pain	10 (21%)
Symptom severity	
CCS class I/II, mild/moderate impairment	34 (71%)
CCS class III/IV, severe impairment	14 (29%)
Previous investigations	
Normal previous exercise ECG	7 (15%)
Abnormal previous exercise ECG	6 (13%)
No previous exercise ECG	35 (73%)
Normal resting ECG	13 (27%)
Abnormal resting ECG	12 (25%)
Risk of developing CAD	
High risk profile	11 (23%)
Medium or low risk profile	23 (48%)
Intermediate probability of CAD (20-80%) acc to Duke	15 (31%)
Low probability of CAD (<20%) acc to Duke	8 (17%)
High probability of CAD (>80%) acc to Duke	2 (4%)
Medical therapy	
Submaximal therapy	32 (67%)
Maximal therapy	15 (31%)
Expert panel ratings	
Rated appropriate by the panel for exercise ECG/angiography	25 (52%) /25 (52%)
Rated inappropriate by the panel for exercise ECG/angiography	5 (10%) /17 (35%)
Rated uncertain by the panel for exercise ECG/angiography	5 (10%) /6 (13%)
Rated appropriate for angiography and exercise ECG/angio only	10 (21%) /15 (31%)

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Table 6: Distribution of vignettes by intervention group and specialty

Vignette Blocks (N vignettes (%))*	ARIA Ratings				Guidelines			
	C		GP		C		GP	
	N (%)	n*	N (%)	n*	N (%)	n*	N (%)	n*
A (1,735 (25))	312 (27)	6 (2)	587 (26)	14 (2)	301 (23)	6 (2)	535 (24)	10 (2)
B (1,834 (26))	286 (25)	8 (3)	564 (25)	20 (4)	348 (27)	8 (2)	636 (29)	18 (3)
C (1,751 (25))	265 (23)	4 (2)	593 (26)	18 (3)	336 (26)	0 (0)	557 (25)	26 (5)
D (1,624 (23))	300 (26)	8 (3)	552 (24)	14 (3)	300 (23)	6 (2)	472 (21)	12 (3)
6,944 (100)	1,163	26 (2)	2,296	66 (3)	1,285	20 (2)	2,200	66 (3)

*two blocks per clinician **n missing (% of N)

Table 7: Percentage agreement with panel ratings and missing decisions by vignette factors

decisions excluding uncertain decisions for ETT (5938) and angiography (6291)	% Agreement before		% Agreement after		N missing (218)	
	ETT	Angiogram	ETT	Angiogram	ETT (89)	Angio (130)
Blocks						
A (n=2750)	38%	68%	44%	78%	18	27
B (n=2910)	36%	58%	46%	66%	27	38
C (n=2634)	42%	56%	50%	66%	24	33
D (n=2172)	36%	50%	44%	60%	20	32
Inappropriate rating ETT (n=744)	42%	76%	54%	84%	11	11
Appropriate rating ETT (n=3406)	64%	50%	76%	56%	59	59
Inapprop rating angio (n=2579)	46%	62%	56%	70%	35	46
Appropriate rating angio (n=3737)	26%	66%	30%	76%	41	71
Male gender (n=4931)	34%	56%	42%	66%	41	65
Female gender (n=5535)	42%	62%	50%	70%	48	65
Typical chest pain (n=2155)	34%	70%	38%	78%	39	59
Atypical chest pain (n=2310)	38%	48%	50%	56%	29	46
Non-specific chest pain (n=1414)	46%	58%	54%	66%	21	25
Prior history of CHD < 1yr	-	56%	-	74%	-	3
Prior history of CHD >1yr	50%	46%	58%	54%	16	21
ETT result normal	-	62%	-	70%	-	30
ETT result abnormal	-	54%	-	58%	-	20
ETT not done	14%	70%	18%	80%	14	55

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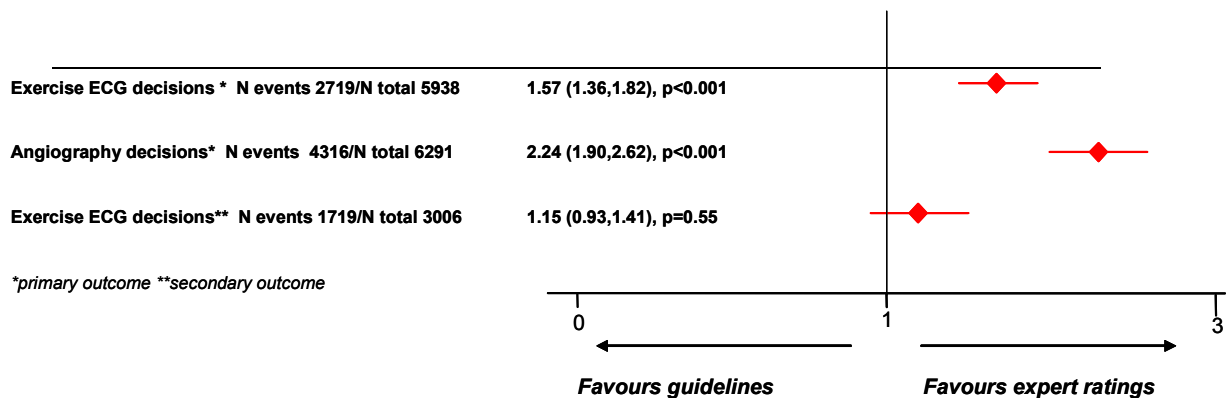
Table 7 shows that missing decisions did not vary by vignette characteristics or block and that it did not unduly influence agreement with the panel standard.

2.4.2 Effect of ratings versus guidelines on appropriate decision making

Prior to the intervention there was no difference between the trial arms in the proportion of appropriate recommendations made (primary outcome: OR 0.97 (95%CI 0.84-1.12 comparing ratings arm versus guidelines arm) for exercise ECG, 1.02 (95%CI 0.88-1.18) for angiography, secondary outcome (Duke score): OR 0.94 (95%CI 0.76-1.15) for exercise ECG (*data not shown*).

Figure 8 shows the odds of reaching better decisions following the intervention in the appropriateness ratings arm compared with the guidelines arm. Doctors with the patient-specific ratings were 50% more likely to make recommendations in line with best evidence (primary outcome) than doctors in the guidelines arm (OR 1.57 (95%CI 1.36-1.82) for exercise ECG, OR 2.24 (95%CI 1.90-2.62) for angiography). There was no effect of either guidance on the secondary outcome (agreement with guidelines based on Duke score), although there was some evidence of improvement in the ratings group (OR 1.15 (95%CI 0.93-1.41)).

Figure 8 Odds of rating in line with recommendations of expert panels and guidelines



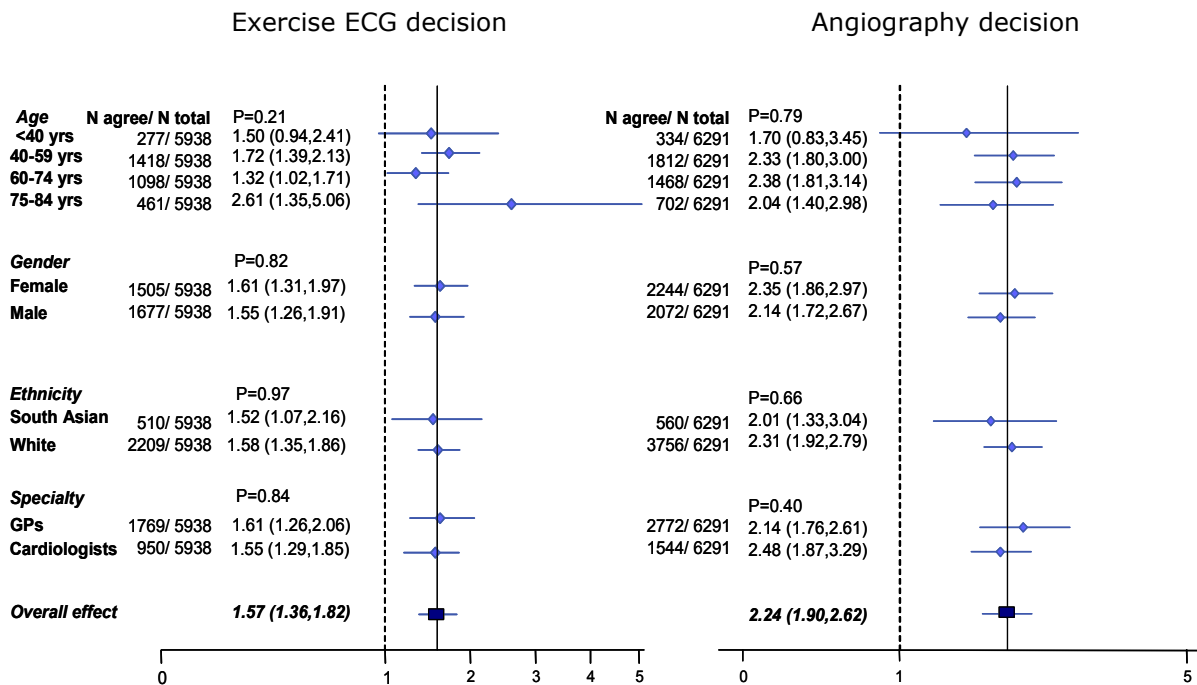
Odds ratios (95%CI), P for difference, comparing patient-specific expert ratings versus conventional guidelines (reference group)

The effect of the intervention was observed among general practitioners as well as cardiologists for both tests (Figure 9). The effect for an interaction of specialty with the intervention was non-significant for exercise ECG recommendations (OR 1.08 (95%CI 0.66-1.77), P=0.76) as well as angiography (OR 1.16 (95%CI 0.82-1.63), P=0.40) (*data not shown*). Figure 9 also shows effects by pre-specified patient groups with p-values from formal interaction terms. The

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superiority of patient-specific decision support was consistent across these patient groups and there was no significant interaction of these factors with the intervention, indicating that patient-specific ratings allowed doctors to make better decisions in all pre-specified patient groups.

Figure 9 Odds of agreement with expert panel recommendations by sub-groups



Odds ratios (95%CI), P for interaction with intervention, comparing patient-specific ratings with conventional guidelines (reference group) by clinician specialty and pre-specified patient characteristics

2.4.3 Effect of ratings and guidelines on physician behaviour

While figure 8 and 9 compared doctors in both arms following the intervention, to see whether one intervention was better than the other in guiding decisions consistent with best evidence, we were also interested in the magnitude of change in doctors after the intervention compared with before. We therefore assumed that each intervention was also its own gold standard. Hence, if guidelines were effective in changing physician behaviour towards recommendations promoted by the guidelines, there should be a greater number of recommendations in line with the guideline evidence (Duke score) after the intervention compared with before. Similarly, there should be more

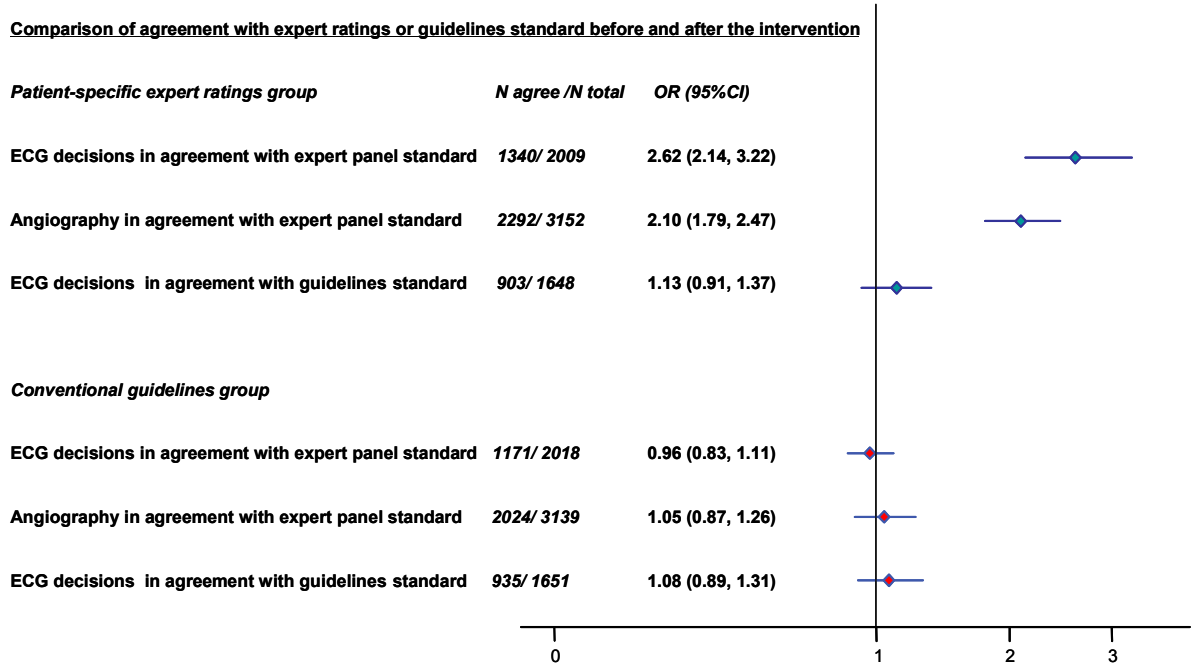
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recommendations in line with the expert panel recommendations in the appropriateness ratings arm.

We found that patient-specific expert panel ratings had a significant effect on agreement with expert panel standards on both exercise ECG (OR 2.62 (95%CI 2.62- 3.22)) and angiography recommendations (OR 2.10 (95%CI 1.79-2.47)). Conventional guidelines had no statistically significant effect on agreement with the guidelines after compared with before the (for exercise ECG: OR 1.08 (95%CI 0.89-1.31)) (figure 10).

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Figure 10 Odds of changing recommendations after the intervention in each arm



Odds of agreement with expert panel and guideline standards: Odds ratios (95%CI), after the intervention compared with before (reference group)

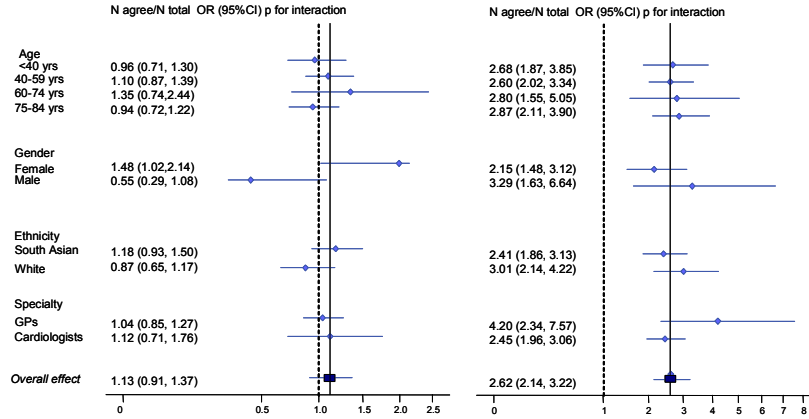
Figure 11 shows the effect of patient-specific decision support and conventional guidelines on pre-specified patient groups and physician specialties. The main effect of patient-specific ratings on changing test ordering behaviour was consistent across different ages, gender, ethnicity and by specialty, although it seemed to have a greater but statistically non-significant effect on GPs compared with cardiologists for exercise ECG (P for interaction=0.54). With regard to the guidelines standard the observed effect was modest and statistically non-significant in the ratings arm, this effect was however consistent across patient groups and specialty. The lack of a main effect in the guidelines arm was also observed across patient groups and specialties, although there was considerable heterogeneity across subgroups for exercise ECGs when compared to either standard.

Figure 7 Odds of changing recommendations after intervention by sub-groups

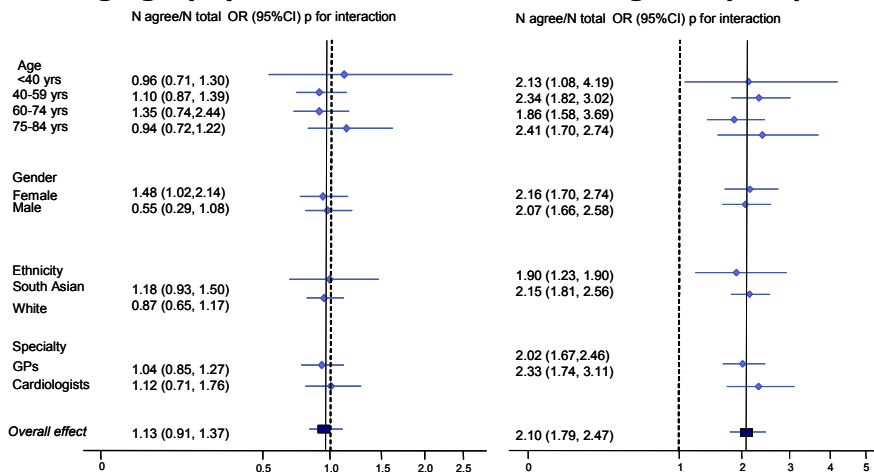
Conventional guidelines group

Patient-specific ratings group

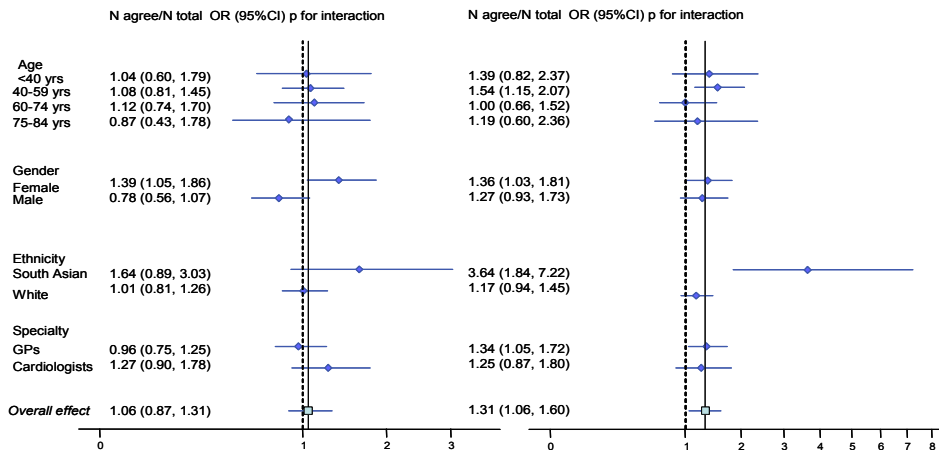
Exercise ECG recommendations according to expert panel standard



Angiography recommendations according to expert panel standard



Exercise ECG recommendations according to guideline standard (Duke)



2.4.4 Effect of guideline use (data not shown)

Eighty-six percent of participants in the guidelines arm (n=127) opened at least one guideline and 56% (n=103) participants looked at all guidelines at least once. Any guideline was opened on average 3 times (IQR 1-11). Use of guidelines had no effect on agreement with the panel ratings (OR 1.02; 95% CI 0.66-1.59) or Duke (OR 1.13; 95%CI 0.73-1.75) for exercise ECG decisions or angiography decisions (OR 1.63; 95%CI 1.20-2.20). There was some evidence of a dose response relationship for opening one guideline or two or more guidelines compared with none for exercise ECG (OR 1.08 (95%CI 0.65-1.79), OR 1.16 (95%CI 0.74-1.81), P for trend=0.69) and angiography (OR 1.53 (95%CI 1.08-2.18), OR 1.66 (95%CI 1.22-2.27) (P for trend=0.003)).

2.4.5 Effect of specific decision support on the volume of requested tests

Overall, there was an 11% increase (n=177) in the proportion of appropriately (according to panels) ordered exercise ECGs following interventions (158 in the arm with patient-specific expert ratings and 19 with conventional guidelines) and a 7% increase in requested angiograms (n=139; 128 in the ratings arm and 11 in the guidelines arm).

2.4.6 Uncertainty of appropriateness of investigation

There were 571 decisions for angiography and 1012 decisions for exercise ECG, where both panels judged the appropriateness of investigation uncertain. We conducted additional analyses in these decisions to examine whether this uncertainty was shared by the trial participants.

After being given the patient-specific expert ratings - where uncertainty was explicitly stated - the doctors in the ratings arm were three times more likely to state that they were themselves uncertain about the right course of action regarding exercise ECG than before the intervention (OR 3.04 (95%CI 1.58-5.83, P<0.001) but not with regard to angiography (OR 1.27 (95%CI 0.68-2.36)) (*data not shown*). In the guidelines arm this was not observed (exercise ECG: OR 1.68 (95%CI 0.75-3.77), angiography: OR 1.12 (95%CI 0.56-2.22)).

2.5 Discussion

2.5.1 Principle findings and research context

Effectiveness of appropriateness ratings

In this randomised controlled trial based on patient vignettes, specific expert ratings were associated with marked changes in test requesting behaviour compared with conventional guidelines. Based on over 10,000 investigation decisions in the management of suspected or confirmed angina in nearly 300 physicians, these findings suggest that specific decision support tools might be superior to conventional guidelines in improving appropriate investigation among people with angina in primary and secondary care. As far as the authors are aware this is the first trial comparing specific versus conventional computerised decision in any aspect of cardiovascular disease or investigations or in a computerised format.

Lack of effect of conventional guidelines

Since the guidelines are largely based on the Duke score, it would be reasonable to expect increased agreement with it in the guidelines arm but not in the ratings arm. However, we found no association of conventional guideline use with increased agreement with the guideline standard. This is unsurprising, given that computerised guidelines were shown not to improve management of patients with asthma or angina in a randomised comparison of electronic guidelines versus no decision support (Eccles, 2002). The authors concluded that this was likely due to the poor uptake of the guidelines in their trial. Our findings do not support this. Providing relevant sections and readily accessible full-text guidelines, as we have done, is likely to facilitate their use and the vast majority of the participants in the guidelines arm accessed them.

We propose that the nature of the guidelines may be responsible for the effect observed in our study, making them difficult to apply to individual patients with complex histories and presentations. In addition to the necessity to read through a large amount of text, guidelines often present compartmentalised evidence on particular patient groups, but clinicians are left to their own devices when facing potentially conflicting characteristics in the same patient. A lack of simplicity and inability to apply to individual patients was identified as barrier to effectiveness of guidelines in qualitative research previously (Rousseau, 2003). A recent review on clinical guidance stated that computerised provision of recommendations at the time and location of the decision was associated with improved decision making (Kawamoto, 2005). Appropriateness ratings but not guidelines satisfy all of these criteria. Indeed, when appropriateness ratings and guidelines on back pain were developed by the same experts based on the same evidence, appropriateness ratings but not guidelines were

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shown to improve decision making in hypothetical patients in the US (Shekelle, 2000).

Lets take the example vignette given in box 2. The expert panel recommended both an exercise ECG (rating 7) and angiography in this patient. The Duke score does not include patients over 65 but for someone aged 65 (and presumably older) with typical symptoms it would be 86% and hence falls into the category of high risk of CAD, depending on whether the 80% or 90% cut-off is used. In these patients the AHA does not advise an exercise ECG (Gibbons, 1993). It does however recommend angiography in patients with a high pretest probability of left main or three-vessel CAD (Level of Evidence: C). The ESC similarly does not recommend exercise ECG in patients with a high probability of CAD (>80%) and recommends that elderly patients with anginal symptoms should be evaluated in general and managed in the same way as younger ones, but emphasise that with increasing age, a less well proven diagnosis of chronic stable angina pectoris is acceptable and treatment for evaluation of its efficacy can be commenced. The ESC does not recommend angiography, as only patients with severe stable angina, those with chronic stable angina in case of a history of MI, evidence of myocardial ischemia at a low work load, previous revascularization or with bundle branch block, serious ventricular arrhythmias or patients with stable angina who are considered for major vascular surgery are explicitly recommended for angiography. None of these criteria apply to the example patient. The New England stable angina guidelines give no recommendations on angiography apart from recommending referral in patients on uncontrolled maximal medical therapy (Eccles, 1998). They recommend an exercise ECG in all patients with clinically certain angina, which presumably applies to the example patient given the high probability of CAD. Hence, this patient would have been appropriate for angiography according to the AHA, inappropriate for angiography according to the ESC, appropriate for exercise ECG according to the North England stable angina guidelines but inappropriate according to the AHA and ESC.

Potential reduction of inequity in investigation

Apart from increasing appropriate test requesting behaviour and reducing inappropriate tests, further value of the ratings lies in their potential to reduce inequities in access to investigation and addressing uncertainty in clinical practice in a specific and useful way. We have shown that ratings remained superior to guidelines across all patient groups and specialties and test ordering behaviour improved consistently for all groups in the ratings arm. This is important in improving patient outcomes across the patient pathway and suggests that appropriateness ratings have the potential to homogenise decision making and reduce potential inequities in investigations by age, gender or ethnic origin of the patient. We also demonstrated that doctors in the ratings arm shared the uncertainty of the panel, thus

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helping to identify areas in which further research is needed to address this uncertainty.

Judging each standard by their own merit

To examine the magnitude of change in test ordering behaviour amongst physicians we assumed in addition that each intervention was also its own gold standard. Assuming that expert panel ratings and evidence-based guidelines are always correct, we would hope to see ideally maximum 'compliance' with the ratings or guidelines after they had been given to the doctors. We know that this assumption is fallacious, as there are no randomised controlled trials of different investigation strategies among patients with chest pain in the community, and a true gold standard does not exist. Some degree of disagreement with both guidelines and ratings is therefore inevitable.

Furthermore, the lack of effect may have been attributable to the smaller number of decisions analysed for the Duke score, as it only applies to patients without a history of coronary artery disease and those who have not had a previous exercise test result. Given that the information on which the ratings are based is contained within the guidelines though, one would expect there to be at least some effect of guidelines on agreement with the ratings, where all decisions were analysed.

Increase of appropriate procedures

The increase in appropriate recommendations lead to an increase in the volume of referrals in the ratings arm. This is consistent with our findings of underuse of testing within RACPCs (see Background .1.3). Estimates of underuse in chest pain clinics – with dedicated testing facilities – may even underestimate the true population incidence of underuse in primary care. Patients with acute myocardial infarction admitted to a hospital with on-site angiography are more likely to undergo the procedure than those who are admitted to hospitals without onsite facilities (Every, 1993). There are no previous studies of underuse of angiography for angina. A US study rating the appropriateness of either diagnostic test among patients presenting to the emergency department found 22% underuse. (Carlisle, 1999).

2.5.2 Strengths and weaknesses

Lack of gold standard

There are no randomised controlled trials of different investigation strategies among patients with chest pain in the community. In the light of this lack of a gold standard we chose as our standard the recommendation made by two recent independent national expert panels. The prospective prognostic clinical validity of the ARIA expert panel ratings of appropriateness is supported by the findings in Figure 6. We purposely excluded indications in which investigation decisions

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were obvious or panels rated in disagreement, given the disparity of the panel ratings. We acknowledge that there is circularity in the argument - clinicians who are given the ratings are more likely to agree with the ratings. However, the consensus of the expert panel is an evidence-based view of best clinical practice and as such serves as a "best practice" standard. In addition, clinicians did not have to agree with the ratings and were invited to base their recommendations on their own judgement and experience.

One could argue that the presence of an effect of patient-specific ratings may have been due to GPs injudiciously agreeing with the panel, as few make decisions on exercise ECGs and none of them make decisions on angiography. However, the effect of the ratings was also seen in cardiologists, the majority of whom were consultants. It is therefore more plausible to assume that the ratings were both clinically credible and unambiguous. Our finding, that the effect of patient-specific ratings was consistent across patient groups and physician specialties when compared to any standard lends further support to the superiority of patient-specific ratings over conventional guidelines in changing physician behaviour.

The Duke score, our secondary outcome, may be considered a more objective and tested gold standard. However, the Duke score is limited as it applies only to patients without a history of coronary artery disease and those who have not had a previous exercise test result. Furthermore it is of uncertain applicability in primary care where the probability of coronary artery disease is much lower than in the angiographic cohort on which the Duke score is based. Hence GPs may have disagreed with our gold standard more than cardiologists, although we found no evidence for this. It could be argued that the Duke score alone cannot be equated to the guidelines, as they are only a quantitative part. At the same time, the majority of recommendations in the guidelines are based on the Duke score and this was the only objective way to apply 'guidelines' to the vignettes without clouding it with subjective judgement by the person interpreting the guidelines.

Lack of real patients

The most important limitation of our study is that the decisions were not reached in real patients. On the other hand, vignettes have an important advantage to real patients in a study such as ours, as we were able to control the case mix as well as any confounding factors in our study and were therefore able to examine the effect of patient-specific ratings and conventional guidelines on particular patient groups. One could argue however that vignettes merely reflect clinical competence rather than real clinical practice. Vignettes performed less well than standardised patients for history and treatment, particularly in coronary artery disease, but were equivocal to standardised patients in the evaluation of diagnostic accuracy and superior for physical examination (Peabody, 2000). They were shown to be a close

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approximation to clinical practice in an outpatient setting and in primary care, similar to our settings (Peabody, 2000). Hence it is likely that the same decisions would have been observed in real patients in the absence of any extrinsic factors. With regard to reducing inequities in access for specific patient groups however, this is likely to be more complex in real practice. Inequities in ethnic groups or by age and gender are often due to cultural barriers or other factors such as patient preference or co-morbidity, which vignettes are not able to capture adequately. In addition, cost constraints, patient preferences, co-morbidities and hospital or practice culture are likely to introduce heterogeneity.

Disagreement among experts

This trial demonstrated the effectiveness of ratings as 'proof of concept' using ratings which were rated in agreement by the two independent expert panels. However, to apply the ratings to clinical practice the further refinement of specific guidance for investigation is needed. Although 658 indications were rated in agreement between the two panels, many were not. The disparity between the panels mainly arose due to the distinction between angiography and exercise ECG investigations and the difference each panel attached to the importance of an abnormal previous test result. When examining both investigations together panel 1 and panel 2 have high concordance on the appropriateness of further investigation (see Background). Improving the reliability of specific guidance involves both better primary evidence and focused, trained panels.

Generalisability and applicability to primary and secondary care

Despite reimbursement and numerous reminders we recruited a low proportion of eligible doctors (7% overall). While many randomised trials do not report recruitment rates among all those eligible, nor against the target population, those that do, commonly report such low rates and amongst physicians who are asked to do such a task in their spare time it is entirely expected. Does this low overall recruitment rate matter for the validity and generalisability of our findings? We feel that our findings are generalisable and valid for the reasons outlined below.

We sought to minimise potential bias by recruiting doctors from 9 geographical centres with nationwide coverage and by stratifying randomisation by specialty and region. We also collected data to compare characteristics of recruited doctors. The measured characteristics of GPs and cardiologists who did participate suggest that these doctors may be reasonably representative of the target population of doctors who make decisions in patients with angina, but we cannot fully exclude the possibility of sample bias. Access to a computer was mandatory in order to complete this study, which may have biased towards younger, less clinically experienced clinicians. The large proportion of senior partners and consultants however

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argues against this. It is also likely that the majority of doctors is computer-literate or does have access to the internet, given their relatively high socio-economic status. In any case, physician characteristics did not vary by trial arm, hence it would not have contributed bias towards a particular intervention. Findings were similar regardless of speciality, which would suggest that ratings could be a valuable tool for improving decision making in primary as well as secondary care.

The strength of our study lies in the relatively large number of doctors in various geographical settings with different practice populations that we DID recruit to the trial. We were adequately powered to show a significant difference between the trial arms as we achieved our set out recruitment target, irrespective of the large number of eligible doctors in the denominator.

2.5.3 Clinical, scientific and policy implications

Our finding that specific guidance leads to better outcomes should now be tested among real patients. Firstly, specific guidance for investigation needs to be further refined and expanded to other imaging modalities used in patients with angina, such as echocardiography or CT scans. Secondly, any ratings implemented in clinical practice would need to deal with missing data, assume a format suited to the doctors working with the decision support tool (Tierney, 2005) and the context in which they are used needs to be addressed (Grol, 1998). Investigations may be used for reasons other than clinical appropriateness, e.g. for reassurance of both patient and doctor, or as a way to negotiate between doctors (see Objective 3). Thirdly, ratings would need regular updating to keep abreast of the evidence base.

If expert ratings prove to be useful in clinical practice they could potentially be embedded in electronic health records already widely promoted in clinical practice. Expert ratings could provide a benchmark against which to measure health inequalities and under and overuse of investigations and treatment and may be applicable to other conditions besides angina. In addition, appropriateness ratings have the potential to pinpoint specific areas of uncertainty and guide future research.

Finally, our study calls into question the way in which guideline implementation is currently pursued. Guidelines are meant to be unrestrictive and allow clinicians to apply their clinical judgement in specific cases while at the same time being used (inappropriately) as a quality benchmark. The Office of Quality and Performance in the US states on its website that "the guidelines may be viewed as an educational tool analogous to textbooks and journals, but in a more user-friendly format." While guidelines have an important place in clinician education and to underpin evidence-based medicine, they are

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not designed to be used within the consultation. Our findings support the contention that it is not the lack of effective implementation of interventions or improved access to guidelines, which are responsible for the lack of a clear effect of guidelines on clinical practice, but their inherent inability to support decision making in the individual patient. Ratings may assume this role, as they are based on evidence underpinning the guidelines but are applied to specific patients. The need for decision support tailored to the patient is likely to gain importance in the future, when increasingly older patients are likely to present with more complex clinical pictures and patient-specific therapies emerge (Garfield, 2000).

Our findings revealed an increase in the number of tests ordered with patient-specific appropriateness ratings, which could address the well - documented underuse of investigations in patients with angina and improve patient prognosis if we assume appropriateness ratings to be a true gold standard.

2.5.4 Conclusion

Patient specific decision support influences testing behaviour among general practitioners and cardiologists, but conventional guidelines did not. They address underuse and potential inequity of investigations and specific areas of uncertainty in which focussed evidence is needed. Efforts should be made to develop expert panel ratings further and test their effectiveness in clinical practice.

Section 3: Are appropriateness ratings acceptable to patients and clinicians? : A parallel qualitative study

In the ARIA trial we compared the effect of appropriateness ratings compared to conventional guidelines on decision making by clinicians with regards to referral for exercise ECG and coronary angiography. The trial, based around patient vignettes, showed “proof of concept” for the potential of appropriateness ratings to improve referral decisions. This is only a first step to demonstrating that decision support incorporating appropriateness ratings for cardiological investigations is actually effective in real patient care. Another step is understanding the contexts within which this decision support would be used and the potential obstacles to implementation. In this chapter we report the qualitative study carried out in parallel to the trial to explore current decision making about referral in these contexts and the acceptability of the appropriateness rating decision support software used in the trial to clinicians.

3.1 Background

Qualitative research can lead to a better understanding of the results of randomized controlled trials, particularly for health service interventions, (Bradley, 1999; Featherstone, 1998) by examining the process and context of the interventions, through observation and interviews with patients and health service providers. Although the web-based ARIA trial with virtual patients did not have a context as such, we were able to study current decision making in cardiological settings and test the acceptability of the decision support tool used in the trial to clinicians and to their patients. We carried out an ethnographic study focusing on consultations between clinicians and patients presenting with new onset chest pain.

There are a number of studies examining the patient perspective of chest Pain (Hilden, 1987; Gardner, 1999; Richards, 2002) and heart disease (Hunt, 2001). Such studies have explored how family histories of heart disease are constructed (Hunt, 2001) and the socioeconomic variations in response to chest pain (Richards, 2002). Richards and colleagues (Richards, 2002) found that respondents from deprived areas perceived a greater vulnerability to heart disease, but were less likely to seek medical attention because they feared disapproval of their risk behaviours and often blamed themselves for their heart disease. A number of studies have focused on gender differences in understanding heart disease and chest pain. White and Johnson (White, 2000) found that men who had been admitted to hospital with a myocardial infarction often perceived themselves as healthy and

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tended to rationalize and deny early warning signs before seeking medical attention. Different reasons for delay in seeking medical advice have been identified in women. Schoenberg and colleagues (Schoenberg, 2003) suggest that women have negative encounters with healthcare providers and find that their symptoms, which do not always fit the male norm, are disregarded.

A small number of studies have explored ethnicity and chest pain (Krause, 1989; Ismail, 2004). The focus of these studies has been the identification of factors that have led to an increased prevalence of heart disease in people of south Asian descent. They have explored lay beliefs, healthcare seeking behaviours, health care access and socio-economic contributory risk factors. These themes are all relevant to our study as 46% of patients attending the clinics in which the study was based belonged to a south Asian community.

Studies examining heart disease from the patient perspective have found that patients develop complex lay understandings. "Lay epidemiologies" of heart disease were first articulated by Davison and colleagues in the late 1980s (Davison, 1989) and is still the subject of recent publications. In addition, they suggest that patient perceptions are influenced by gender, socio-economic status, and environment (Richards, 2002) and socio-economic factors have long been recognized as contributing to the incidence of heart disease (Stern, 1951; Syme, 1963). In addition, different social, cultural, ethnic and religious groups perceive heart disease in different ways (Fischbacher, 2001) and there is evidence that patients commonly invoke notions of fate, faith and chance to make sense of their condition (Davison, 1991; Tod, 2001).

These themes form an important body of work within which this study is situated. However, few studies have examined heart disease or chest pain beyond the patient perspective. The difficulty in classifying angina and distinguishing it from non-cardiac chest pain has been identified (Gardner, 1999) but qualitative researchers have not hitherto studied clinical decision making in the diagnosis and management of angina. In our study, we have examined these themes within the context of clinical settings, situating the patient within the context of their interaction with the clinical team. We have examined the ways in which patients and practitioners make sense of, classify and interpret symptoms in the field of cardiology and specifically in the diagnosis and management of angina. This approach has allowed us to shed light on the ways in which diagnosis and decision making takes place in everyday practice. The process of unaided decision making must be understood, prior to the introduction of decision support tools.

There have been a small number of studies using qualitative methods to examine the adoption of computerized decision support by practitioners (see for example Rousseau, 2003), however, none have examined decision making and decision support. Two recent studies examining guidelines do, however, provide valuable insights into the

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social and cultural processes that underpin the transfer of clinical guidance into clinical practice (Gabbay, 2004) and the social construction of guidelines (Moreira, 2005). Gabbay and colleague's work develops a concept of 'mindlines' to describe the informal networks that transfer 'evidence' from various sources including guidelines into clinical practice and suggest that these networks are the key to conveying evidence to clinicians. They suggest that practitioners do not read guidelines, but work with 'knowledge in practice' rather than codified knowledge. Moreira suggests that clinical guidance comes into existence through 'repertoires of evaluation' that are centred upon four epistemic criteria (robustness, usability, acceptability and adequacy). In studies of guideline development groups he shows that discourses of 'science', 'practice', 'politics' and 'process' interact to generate guideline content and structure. Moreira argues that an understanding of what types of knowledge are incorporated or synthesised in guidelines should inform how such guidance is implemented and used in practice – something that we have addressed in this study. Ferlie and colleagues, using a case study method, showed only a weak relationship between the strength of research evidence and its diffusion in clinical settings and argue that the implementation of evidence-based medicine is a complex and contested process (Ferlie, 2000).

Our study contributes to existing anthropological studies on the social and cultural factors that frame the social organisation and implementation of medical knowledge.

3.2 Aims and objectives

Exploration of the process of clinical decision making and the presentation and diagnosis of angina in order to provide a wider context for understanding the potential role of an electronic decision support tool

1. Examination of patient perspectives of the diagnosis and management of angina
2. Examination of the acceptability of an electronic decision support tool based on appropriateness ratings to clinicians and patients

Objectives

- Observation of patients attending the clinic at different stages of the disease pathway, and thus gain insights into the ways in which clinicians and patients construct a diagnosis
- Observation of two different types of clinics, to identify different forms of clinical decision making *in practice*.

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- Understanding the structural and organizational factors that may affect health care delivery within the clinic.
- Examination of the use of technologies and the role of technicians in decision-making, classification, and the adjudication of cases.
- Examination of the transmission of knowledge, the training of junior clinicians, and the ways in which they learn to make a diagnosis of angina.
- Observation of the wider processes involved in the assessment and adjudication of different types and sources of knowledge in the formation of a diagnosis.
- Modification of the study design from the original proposal has enabled us to develop and extend our approach to investigate the ways in which decision making occurs *in practice* through the addition of an extensive period of in-depth ethnographic data collection. This allowed us to contextualize the ways in which appropriateness ratings (the ARIA study decision making tool) and other decision support tools are understood and utilised within the context of every-day clinical practice.

3.3 Methods

The methodological approach of this qualitative study was ethnographic. Ethnography is part of an anthropological tradition and refers to the qualitative description of human social phenomena, based on fieldwork. Typically, ethnography involves the detailed study of a small group of subjects within their own environment (in this case a clinical team and their patient population) and this process provides a detailed cultural understanding of the phenomena under study (Hammersley, 1995) The fieldwork within this study includes: observation of clinical consultations; interviews with patients, clinicians and technicians; a patient focus group; and a database audit.

3.3.1 Data sources for aims 1&2

Interviews with patients

Interviews were carried out with patients (n=40) recruited in general practice for a pilot cohort study (Junghans, 2005) to examine their experiences of angina and these data have been drawn upon in the course of the study. An in-depth recorded interview with doctor or nurse was carried out in a sub sample of consecutive patients who were seen in the clinic. No patient declined to be interviewed. Due to time restraints we conducted these interviews only in the first 40

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patients seen. They lasted on average an hour and focussed mainly around the history of experience of chest pain. In addition, interviews were also carried out with patients (14) attending rapid access and cardiology clinics to examine their experiences of angina. The initial pilot sample was selected purposefully, to represent a range of referrals attending the clinic and the demographic characteristics (ethnicity, gender and age) of the patient population. The later interviews were carried out with patients who were attending the clinics and they were asked to participate once their clinical consultation had been observed. This process allowed initial analytic themes to be tested and refined within later interviews.

Interviews with clinicians

Interviews have been carried out with clinicians (20), technicians (10) and administrators (2) within the clinical setting to explore how they arrived at their diagnosis and decision through discussion with the researcher.

Observation of clinical consultations

The everyday work of one clinical cardiology team (10 clinicians and 8 technicians over the fieldwork period) has been observed over fourteen weeks. More specifically, we have observed consultations within two clinics with different patient populations: a rapid access chest pain clinic (n=70) and a cardiology outpatient clinic (10). In total, 115 individual consultations were observed (35 patients were observed over two consultations), with the length of time allocated to each consultation varying from 20 minutes to one hour. The researcher noted the content of the consultations: 80,000 words of near verbatim text were generated in field notes, observation of patient-clinician dialogue and formal and informal interviews. We also observed the clinical team in meetings and in less formal settings, such as over lunch, coffee, between consultations and quiet times during the clinics, and this provided insights into the everyday transmission and adjudication of knowledge and their practical decision making processes. In addition, we were able to follow and observe Senior House Officers (n = 4) throughout their 6 week rotation within the cardiology clinic.

GP referral forms

GP referral forms and other routinely collected data generated by an audit of the RACPC database (January 2000-December 2003) were examined to provide background patient information, diagnostic data and the clinical investigations carried out by the team.

Focus Group

Six patients (5 men and 1 woman) recruited from the cardiac rehabilitation clinic participated in an extended (3 hours) focus group.

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Eight patients were contacted by telephone; 7 agreed to participate and 1 cancelled on the day due to ill-health. Seven of the participants were white British and one was Asian. Information about ages was not collected. All had been diagnosed with angina and had undergone angiography and insertion of coronary stents. This focus group was audio-taped and transcribed verbatim. Discussion focussed on 3 themes: patient experiences, decision making, and beliefs about the future. Supplementary questions were posed by the researcher when unusual or unanticipated discussion and opinions arose. The purpose of this was to test emergent themes in the analysis based on the other data sources and to examine whether there was a consensus of opinion among participants.

3.3.2 Data sources for aim 3

Use of the tool within the RACPC

The tool was tested within the clinic using a laptop computer. The tool offered a rating of 1-9 on the appropriateness of angiography and/or exercise ECG for each patient. The researcher observed the initial consultation with 16 patients and following each consultation, the clinician entered the patient data into the programme which then provided a rating score for the appropriateness of angiography and/or exercise ECG for each patient. The researcher discussed use of the tool with the clinicians throughout this process, asking them to "think out loud" and explain their decisions and response to the program while they were using it and eliciting their opinions about the appropriateness ratings it provided. When the clinicians disagreed with the ratings they were asked to provide their reasons and the researcher then discussed this in relation to their actual decision for each patient to explore in-depth their reasons for each decision. Clinicians were asked to record their reasons for disagreement in their own words on the laptop and additional verbal comments were recorded as hand-written notes at the time and later transcribed and analysed to identify core themes and these themes were discussed with the participating clinicians in a process of verification. Verbatim quotes from clinicians are used to illustrate and support their perspectives.

Interviews with clinicians within the RACPC

Informal interviews were conducted with all clinicians practicing at the RACPC (n= 6), a clinical research manager (n=1) and technicians conducting resting and exercise ECGs (n= 4).

Use of tool with trial participants

The ARIA decision making tool was developed by RS and was tested with a sub-sample of the clinicians participating in the ARIA trial (n = 10) to assess and evaluate the potential impact of the tool on their

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decision making and everyday practice. Of note, the decision making tool was not previously piloted and was not designed to deal with missing values. Hence, some shortcomings of the tool itself rather than the ratings may be reflected in the reaction of patients and physicians.

Patient focus group

We demonstrated the decision making tool during the focus group to explore how patients viewed such technologies and the decision making processes of diagnosis, classification, and treatment.

Using decision support in actual consultations

We had planned to interview patients about the use of the decision support tool during their consultation. However, in practice, we were faced with an ethically difficult situation: the appropriateness ratings on which the tool was based were not validated at the time of this study. It was not necessarily the case that management in line with the ratings would improve patient outcomes, although this has now been confirmed. Therefore it would not have been ethical to involve patients in the use of the tool during their consultation. Patients often attend an RACPC only a few hours after experiencing new chest pain and are generally anxious about their referral, investigation and potential diagnosis. We felt that to interview these patients about the process of decision making would unnecessarily increase their anxiety at a time when they are seeking reassurance and clear information regarding the cause of their chest pain from their clinician. Thus, we adapted our method accordingly. The researcher still observed all of the consultations where the tool was tested and followed the clinician from patient, to tool, and back to patient, discussing the decision as it was assembled and how they responded to the recommendations generated by the decision support tool.

Patient characteristics

A total of 3555 patients had been entered onto the RAPC database audit from January 2000 to February 2004. 52% were men, 48% women. Ethnicity was only recorded in large categories: 46% (south) Asian, 40% white, 16% black. One quarter of patients were given the diagnosis of angina and three quarters were deemed to have non-cardiac chest pain. 81% had a normal resting ECG. Nearly half of the south Asian patients observed during the ethnographic fieldwork did not speak English and communicated to their clinician via a translator, usually a son or daughter.

3.3 Analysis across all data sources

We identified a number of significant themes underpinning the process of diagnosis and decision-making, from patient and clinician

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perspectives. The analysis is based on transcripts of audio-tape recorded interviews and transcripts of the detailed notes taken during and immediately following periods of observation. Where possible biographical and clinical data were taken from GP referral forms and collected at the time of observation. The interviews and observational field notes were transcribed and stored as text-files and we used a Microsoft Access database to manage patient biographical and medical data, along with the core analytic themes.

The interpretive strategy used in the collection and analysis of the data was grounded theory, an approach widely used by social scientists and this provided us with "a way of thinking about and conceptualising data" (p.275) and provides a specific method for theory development and verification (Glaser, 1967). This approach involves the interpretation and understanding of the actions of those being studied from the perspectives of the participants themselves and provides a systematic set of procedures in order to develop inductively derived theory about phenomena. This approach is often called the 'constant comparative' method, with verification of the main themes emerging from the research carried out through the close connection of data collection and analysis throughout the research process.

As Hammersley and Atkinson note, analysis is not a discrete phase within the research process; rather it begins prior to fieldwork in the formulation and clarification of the research questions and continues through the process of publication.

Within this study, data collection (observation, semi-structured interviews, and focus group) and data analysis continued concurrently, in line with constant comparison methods. Qualitative data were collected and at the same time concepts and hypotheses were developed in relation to that data. Further qualitative data were then collected in relation to these emerging concepts. Claire Somerville carried out the main thematic analysis. The first stage involved a detailed scrutiny of the transcripts to familiarise herself with the data, in this case the observation and interview transcripts. This 'raw' data (in this case text) was then broken down and each idea or event given a conceptual label to represent that phenomenon. The second stage was to identify common themes that she coded. Coding is the initial process of data analysis and "represents the operations by which data are broken down, conceptualized, and put back together in new ways. It is the central process by which theories are built from data" (Strauss, 1990 p.57). These initial conceptual names were written directly onto the transcripts and these coded segments of text were grouped, given conceptual labels and included in separate word processing files. These files were expanded as new transcripts were completed and were refined, focused or altered as new themes emerged. Each observation transcript and individual's narrative was also examined independently to establish the context and to verify the emerging themes.

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Thus the initial process of coding the transcripts ensured that all the relevant data were brought together in relation to a particular category/theme. This is a form of sign posting, with data stored together under general codes with identifiers for each segment of text so that the original and subsequent locations can be traced. The coding of the transcripts was a recurrent process. As new transcripts were coded, new categories emerged and previous transcripts were then re-examined in light of these new categories. The data were interrogated until there was an established framework of categories with which to code all the transcripts. As these categories were developed and refined, so the themes become more defined (Hammersley 1995). The next stage was 'axial coding' (p.96), the process of developing connections and giving statements of relationships between categories and sub-categories (Strauss and Corbin, 1990). However, this process of both open and axial coding was an interchangeable and ongoing process (Strauss and Corbin, 1990).

The development of categories also facilitated the next step within the analysis, which was to examine the relationships between themes and categories (Strauss and Corbin, 1990). Data were examined for similarities and differences within themes, retaining the context of the discussion and characteristics of the individuals to aid understanding and to allow the interpretation and development of explanations (Glaser and Strauss, 1967). At this stage the data were also interrogated to check for patterns between the themes, initially by contrasting and comparison, noting where there is anything surprising or puzzling. The process of questioning such as who, what, where, how, why, was central to the development and refinement of these categories (Strauss and Corbin, 1990) and is part of the 'constant comparative method of analysis' (pp. 101-106) (Glaser and Strauss, 1967).

Throughout the process of data analysis, a number of transcripts were also coded by Katie Featherstone, Gene Feder and Shelia Hillier and emergent themes cross-checked. These emergent themes were presented to the wider ARIA research team to see whether the findings resonated with the experience of clinical colleagues. We have also fed back findings to participants in the research (patients and clinicians) and engaged in an ongoing process of discussion that has shaped and verified our findings. Verification of the findings using secondary informants is a technique used to test the accuracy and validity of the research findings. This approach must take into account the fact that groups may hold a range of different perspectives (Bloor, 1997).

The audit trail is an important procedure for ensuring the validity of qualitative research, and each stage of data collection and analysis must be explicit so that it can be tested (Hammersley, 1995). All extracts have been anonymised and tidied for public consumption, by removing anything that does not add to the meaning of a quote, such

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as 'um', 'er' and 'yknow'. In this report we have used direct quotes from informants to illustrate the meaning of concepts and themes. In the following section, we present the main themes that have emerged from the analysis.

3.4 Results

3.4.1 The context of the angina diagnosis: everyday decision making in the clinic

This qualitative ethnographic study provides a detailed analysis of decision making in clinical practice prior to the introduction and piloting of the ARIA decision support tool. We have integrated the results from observation, interviews and the focus group in this section. In relation to the ARIA trial, it thus provides a context in which the trial results can be further understood. We have revealed and described the multiple components that influence clinical decision making in practice. The main themes are:

- *patient perspectives*, including development of the angina/heart disease narrative, role of family or work stressors, ambiguity of family history, faith in cardiological interventions and notions of invincibility
- *clinical context and role of place*, including the diversity of consultations, the effect of the physical clinic space and its impact on decision making and systemic factors
- *transfer of medical knowledge*, including how to see, hear and touch and schooling in the language of the clinic
- *display of expertise*, including confirmation and refutation of diagnoses, ambiguity and complexity of diagnoses, the meaning of diagnoses in different contexts
- *decision making and classification*, including joint decision making, hierarchies of decision making and the role of authority. This section includes the use of diagnostic technologies.

This report represents an initial, first order analysis of these themes. More detailed second order analyses will be disseminated via peer-reviewed publications.

3.4.2 Patient Perspectives

Development of the angina narrative

We observed different patients at two contrasting stages of the disease trajectory in different clinical settings giving us a strong sense of the way patient understandings of angina change, or sometimes not, over time. Patients attending the rapid access chest pain clinics were undiagnosed 'virgin' patients and had not, to our knowledge,

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been exposed to processes of cardiac 'medicalization' (Conrad, 1992) or schooling. Their narratives were relatively unrehearsed and uninformed by medical acculturation.

By way of contrast, patients attending cardiology outpatient clinics presented with a diagnosis (although we observed that patients were not always aware of their disease /diagnostic status); they were usually taking cardiac medication and frequently had undergone invasive diagnostic intervention or treatment such as angiography and revascularization. By observing patients at different stages of the disease pathway we were able to gain insights into how patients develop or change their understanding of their disease and symptoms.

The ways that patients present their illness within the clinic appears to evolve during the consultation with the clinician who helps to construct their story. Over time patients develop narrative accounts that reflect their illness experiences as they pass through various treatments and interventions. Some events become memorable while others are forgotten. These narratives tended to be more firmly situated in everyday life and indicated how patients come to terms with and made sense of their condition.

Each patient offered accounts of their illness trajectory. The beginning of the problem was always elaborated in great detail. Each individual story was indexed by external social factors that mark out each narrative as uniquely individual: '*My daughter had just got engaged*', '*it was St Patrick's Day*', and '*I was at the gym*'. All of the patients described how they had tried to identify the cause of their pain before seeking medical help. They contrasted their pain to previous similar types of pain, most commonly indigestion and, for one woman, her previous hernia. Patients reported that it was only once they had evaluated their symptoms and considered that this was different or more severe that they sought medical advice. Several patients had tried to alleviate their symptoms at home using common remedies; most frequently indigestion tablets, milk, or pain killers. Once in hospital all of the patients expressed surprise at the severity of their diagnosis (either angina or heart attacks) because they did not feel particularly 'ill'. Common responses to an angina diagnosis included an assumption that the cause of pain was indigestion, muscular pain, stress or general fatigue or over exertion: "*I thought it was just the big night out I had on holiday; I drank too much*" (RA41).

An inability to describe pain characteristics was a feature of the majority of new patients observed in all the clinics. In the majority of clinical encounters observed in the RACPC the patients appeared to have difficulties describing where the pain was located or the type of pain they were experiencing. Only those patients who had previously been diagnosed with angina were able to quickly and immediately classify their pain and did so only in reference to the pain they had experienced before. Additionally, within the consultations, patients often agreed with the suggested descriptions presented to them by

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their clinician and would offer positive responses even if, from a clinical perspective, the pain responses appeared somewhat contradictory. The difficulties that patients have in describing their pain makes problematic the initial classification of chest pain into cardiac and non-cardiac which is based on the characteristics of the pain. Construction of an angina diagnosis relies on a standardisation of pain descriptors. This issue is explored in more detail in the decision making and classification section.

Beliefs about causes of heart disease and treatment

Reference to family stresses, especially distance from loved ones in India, Pakistan and Bangladesh, and marriage concerns were cited as the 'cause' of heart trouble by a number of south Asian patients. Many patients perceived 'stress' as a casual factor in heart-related illness although it is notable that white patients frequently cited work, while south Asians more frequently cited family as the main cause of stress. As we see in the following example:

As the clinician writes up the patient's notes in front of the two women, the friend (unprompted) begins to talk freely to the clinician. She explains that the patient's husband died a year after they came to England and that she only has one of her children in the UK. The other child is "*forbidden*" to come and "*no one knows why*". As the friend narrates the problems and pressures under which the patient is suffering, the patient begins to cry. The friend explains that X worries so much, "*she worries all the time because the children are not married and what can she do?*"RA24.

All of the patients participating in the focus group demonstrated a reasonably detailed knowledge of the procedures that they had undergone in hospital:

They said I had 3 arteries that were blocked, but at the time they only cleared one of them – and they did a stent because of my other conditions. Then in August last year I came in again for an angiogram. [Focus group participant: Pat]

Patients in the focus group discussed with one another the number of stents they had in place and the percentage blockage of their arteries. There appeared to be an element of competitiveness in their discussions as this extract from the focus group illustrates:

Pat: I had a 90%, an 80% and a 60%

Andrew: Yeah, I had a 90% one and then the others were 60%. They say you can get by with one that is below 90% blocked- they can leave them for a while.

Brian: Well when I was last in there was a bloke in the next bed – he'd had 3 open surgeries – I mean over the last 20 years and 4 stents put in – and he was in there again for more work!

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Several patients were able to recount in detail their history of cardiological problems and the treatments/interventions they had received over a number of years. For example, Andrew described his experiences over the previous 10-15 years from the time he was first admitted during the early 1990s:

I stayed in for a fortnight- they don't do that now, but then they didn't have all this angio stuff back then – everything was controlled by tablets. It just didn't exist...Anyway, they gave me these tablets which I took under my tongue when I got the pain...It was first thing in the morning, when I start to walk, I got the chest pain. Especially on the cold mornings. He asked me what do I do, and I said, I slow right down, sometimes stop, and then it goes. So he said I think I'll put you in for another look at the hospital... So they put me on the exercise machine and he said he wanted me to go as hard as you can. And after he said you have got a problem, you have got 2 more arteries that are blocked. He said that it was the aorta- that's the one giving you the problem. He said they wanted me in to operate but he said that he didn't think I'd go straight away – so I spent 5 weeks in here waiting for the operation...They really involved me in everything. I was well pleased. And it had all changed so much since I was last there. All these new things they could do- before it were just tablets.

All of the patients participating in the focus group felt that they had received good treatment and were unmoved by experiences that other patients might have become irritated by, for example, lost notes, delays, contradictory advice. Their positive illness experiences outweighed chaotic administrative processes and prolonged waiting times and occasional mistakes in blood testing and missing results. These findings are of course filtered through memory and are recreated as narratives to be told and re-told when required. Interactions that take place within the clinic take on a quite different momentum. However, there is likely to be a strong bias towards positive experiences in this motivated sample. All participants were recruited from a patient support group and there was additional self-selection to participate in the focus group.

Family history

Risk of coronary artery disease has a genetic dimension. When asked about family history of heart disease in the consultation, patients often produced a range of responses. It was not uncommon for patients to respond to a family history question by citing non-blood relations as their own kin and therefore vectors for the transferral of risk. Husbands, wives, in-laws were occasionally cited as members of family whose risk they believed to be connected to their own. The significance of general cultural beliefs about inheritance, relationships, health and illness are increasingly being recognised (Featherstone et al, 2006). On a number of occasions, patients interpreted their family history in relation to increased environmental risk factors caused by other members of their family. For example, one Cypriot woman said

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that, although she had never smoked, she lived with her husband who had smoked 40 a-day for over 30 years (RA92). More commonly, patients did not know their family history of disease. This was often recorded by the clinicians in the medical record as "no family history".

The fact that many patients did not know whether they had a family history of heart disease is not surprising, particularly for the high proportion of patients from migrant communities whose contact with parents and extended families in countries of origin may not have extended to sharing intimate health information. Within the clinic patients often stated that they had irregular contact with siblings and that they did not know the cause of their parents' deaths. Others invoked lay beliefs such as '*they say he had a bad heart*' or '*he had stress so I think his heart suffered.*' Families transfer interpretations of family disease history (Davison, 1991) and these come to form an explanatory narrative that is passed on across generations.

In contrast, some patients described an extensive family history of heart disease and seemed to use this information to try to persuade the clinicians to take them seriously. An example was a 50-year old Frenchman who when asked '*Any family history of heart disease?*' responded emphatically and at length:

Oh yes, all of them! Really, all of them. (he said with an excited laugh) My brother died four years ago, so did my mother and my sister. And my two remaining brothers have heart problems.(RA31)

Aware that a positive family history was relevant to their health risk, some patients described their extensive family history with enthusiasm and seemed to actively engage in the diagnostic process.

All of the participants within the focus group described a family history of heart disease. This familiarity and personal experience of heart disease among close relatives gave patients an expectation that they too were likely to experience the same fate. It did not come as an overwhelming shock that they had developed heart problems; at some level they expected this to happen. An extract of the focus group discussion illustrates this:

I think it must run in families, because my father he was only 59 when he had his – not angina but heart attack. He was going to be discharged the next day but then middle of the night he got up to go to the toilet and sat down like, and he went out like that – that's it! But all the family with our name have all got it. I started to do a bit of family history and I came across one woman and she said she wasn't actually a x (name) but she said 'I married one and we've all got it'. And she said to me, 'I'll tell you one thing – we don't make old bones'
focus group participant: Andrew

Yeah, my father had it too. He died at 52. But they didn't have all this back then. And I don't remember him getting angina – just heart attack and gone. focus group participant: Colin

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Yeah, same here – my father had 2 heart attacks in just a few days – survived the first but died from the second. focus group participant:
Brian

All three of these men had outlived other family members with similar heart conditions. In this sense, they were survivors in two senses, and were all positive about their futures.

Faith in technology and notions of invincibility

We found that patient beliefs about their future were rarely if ever discussed during clinical consultations. Neither patients nor practitioners raised the issue of prognosis. We explored this in more detail through the focus group where all the participants expressed extremely positive views of their future: they did not feel that their lives had been unduly affected by heart disease and all expected to continue living long and healthy lives. There was total consensus among all participants on this point.

Participants' beliefs about their future were shaped in part by their view of surgical advances and their remarkable confidence in the development of relatively non-invasive and innovative procedures. All the participants of the focus group marvelled at the speed and direction of new technologies and the capacity of their physicians to undertake what once involved complex surgery but now meant scar-less, pain-less and speedy '*little operations*', as one participant who had recently undergone two stenting procedures put in. Being awake and talking to their physician during a surgical procedure seemed to diminish the seriousness of their hospitalisation and even their heart conditions.

Well, it's the stenting isn't it? Last time I was up on the ward, the nurse came along to take my pulse and she said if I'd been there 2

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year ago they wouldn't be doing more than 2 stents a time – they just couldn't do it. Now, they do as many as they like. They've just progressed so much. It's amazing. And the thing is, the nurse, she was so delighted too. You could tell she was excited about it, almost as much as me! I mean when I first had mine they'd only do 1. And the first time afterwards you had to lie there really still like a board – you weren't allowed to move for 6 hours – Now, they take it out (the angiography catheters) – all casual like and say 'up you get, here's a cup of tea'! What I find just amazing is that you have this happen inside you – and there's no scar! Can't see nothing! focus group participant: Andrew

That's right – after I asked where the scar was and the nurse pointed to this tiddly widdly little mark! focus group participant: Colin

All of these participants were fascinated by and seemed familiar with such procedures from television dramas and documentaries. All demonstrated delight at being able to watch what was happening on screen – *I even took the CD home*¹ said a female patient.

This group of patients viewed surgery, in particular stenting, as something that was easily repeatable. Indeed several had been admitted and had stents inserted on repeated occasions. Members of the focus group even joked about 'who had the most' – the winner proudly declaring he had 22! This buoyant optimism about the efficacy of interventions influenced their beliefs about the future. When asked specifically whether they thought about what would happen to them in the future and whether this had changed since their illness, their general response was that it had not at all. One woman said it was

¹ This patient had been referred by the NHS to a private hospital. She was given a copy of the procedure to keep.

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like childbirth – you soon forget the pain and “*you’re happy to do it all again.*”

All agreed that they had soon forgotten what they have been through and just got on with life. One man said he saw it as “*a second chance*”, another said he went out and brought a new car straight away and another joked he had just bought his road tax for another year. One man related the story of his neighbour who had heart surgery at the age of 70 and was told they’d given him another 10 years. He was 80 this last year and went back in to hospital to ask for another 10 years; was operated on and doing well.

These participants described that they soon forgot about their surgery and, with a little time, their heart condition, because of the ease and simplicity of interventions and because they felt so much better afterwards.

In summary, we can identify a number of reasons why patients in the focus group viewed their futures in such a positive light:

- surgery was experienced and viewed as simple, effective and repeatable.
- patients felt they have been given a second chance – in effect they had years added to their lives
- patients quickly forget what they have been through in hospital and forget they have had /have a heart condition during everyday life
- they had generally positive illness experiences: speedy ambulances, good clinicians; two in the focus group has been referred to private hospitals for quicker treatment, good follow up care (all patients were at home in the cardiac rehab unit, making tea and joking with staff) and all felt involved in their treatment and care.
- all had a family history which seems to have prepared them for what they have experienced and gave them a sense of being ‘a survivor’.

However, these findings must be interpreted with caution, as there was likely to have been a strong bias towards positive experiences within this group. All participants were recruited from a patient support group and there was additional self-selection to participate in the focus group. In addition to the implications of self-selection, these findings are based on one group and would need to be tested with other focus groups and individual informants. Overall, there was substantial variation in how patients with recent onset angina described their symptoms with more convergence once they had more contact with cardiac services. In the following section we explore how patient perspectives interact with that of clinicians they encounter within cardiac services and show how the diagnosis of angina is constructed.

3.4.3 Clinical context and the role of place

The clinics within which we conducted our study operated differently: patients in cardiology outpatient clinics had usually waited several months for their appointments and often received the results of diagnostic tests and recent interventions during the consultations. They commonly attended with relatives who participated or took an interest in the consultation. Patients in these clinics realized they were in a cardiology clinic. In contrast, patients in the RACPC were referred directly from their GP, usually within hours and never more than a few days of their initial consultation in primary care. They were not prepared for a hospital appointment, were frequently anxious or shocked at having been sent directly to hospital and often did not realise that cardiology specialists were assessing them.²

In the curtained cubicles of the RACPC, decision making was almost never made in isolation; clinicians referred to each other and arrived at joint decisions³ sometimes also consulting with experienced technicians who conducted exercise ECGs and echocardiograms in nearby curtained cubicles. The physical layout of the RACPC facilitated, even enforced, joint decision-making. Curtained cubicles facilitated ease of movement, because clinicians could easily step out of the consultation to write up notes away from their patient and seek second opinions. Furthermore, because consultations could be overheard between curtained cubicles, clinicians were able to listen to other clinicians and their patients and, if they felt they could assist,

² This is reinforced by the title of the clinic (chest pain) which, patients associate with an array of potential medical specialties. A number of patients observed expressed surprise at being seen by 'heart clinicians'.

³ Even the most senior clinician I observed rarely took decisions in isolation, even if his consultation with others was a mechanism for teaching his juniors.

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could easily step in and offer guidance. If the consultant or another senior clinician were in attendance, they might step in to discuss a complex case. The tendency towards joint-decision making also appeared to reflect the complexity of making an initial diagnosis of cardiac chest pain.

In contrast, the outpatient cardiology clinics were conducted in a series of individual rooms stretched out over a large ground floor area in the hospital. Patients and clinicians sat together at a table (rather than the patient lying on a bed and clinician standing) and engaged in a lengthy discussion as the clinician searched the patient notes and attempted to piece together the clinical picture. The physical layout of this clinic with individual rooms, fixed doors and desks did not facilitate joint decision making between clinicians. Furthermore, the decisions to be made are often clearer than those within the RACPC. They are often based upon test results and expert opinion (from other specialists) rather than patient narratives. Although patient descriptions of their symptoms and medical history still played a role, within this clinic the clinicians had other data to guide their decisions: such as echocardiograms, coronary angiograms and recent blood results.

By observing these two clinics we were able to compare appointment and non-appointment (rapid access) clinics from the perspective of patients, administrators and clinicians. Patients attending non-appointment RACPCs expressed appreciation and surprise at their speedy referral, which was often on the same day. A couple in their early 70s who were offered a cup of tea while they waited to be seen by a doctor (the husband was the patient, accompanied by his wife) expressed a renewed confidence in the NHS, discussing with one another whether they should cancel their private health insurance as the NHS *'...seems to have improved. I even wonder if it's better than the private?'* (RA71). Like others who attended the clinic they were impressed with the overall service and attention they received. This man was especially pleased when he was told that he had most probably pulled a muscle and should simply take pain killers for a few days until the pain had subsided. Although others were anxious about attending a hospital clinic, they were routinely reassured by the doctors using comforting phrases such as: *'it is better to be on the safe side'* (RA111) while patients occasionally referred to their impromptu visit to a heart specialist as an 'MOT'.

Those that were not reassured by their referral to the RACPCs were those who were not fluent in English. A Sinhalese speaker accompanied by a friend who tried with great difficulty to translate, became physically distressed by the experience and shed tears as she tried to understand and respond to the questions posed by the cardiologist. On many occasions there were hospital workers and also doctors who spoke a wide variety of languages and could offer an impromptu translation service, but on this and a few other occasions

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(other examples were Farsi speakers from Afghanistan and Polish and Russian speakers) this was not possible.

In observing two types of clinics we were able to explore how clinical decision making differs in different clinical contexts (i.e. the same doctors operate differently according to clinics). The physical structure of the clinic, and the systemic factors that determine how the clinic works (for example, availability of translation services, the referral system), had an impact upon the ways in which decisions were made. In addition, the physical set up of a clinic can either facilitate or inhibit joint decision making between clinicians and learning. We now move to discussion of a key process in the clinic: transfer of medical knowledge about making the diagnosis of angina.

3.4.4 The transfer of medical knowledge

The clinic is not only a place where diagnosis, investigation, and treatment take place, but is also an important site of the transfer of medical knowledge. Within these clinics, there are weekly formal undergraduate teaching sessions. Less explicit, more tacit processes of learning occurred in the everyday mundane work of the clinic and these encapsulated the tacit, embodied, or experiential nature of cardiological expertise.

As part of the formal process of teaching, cases were presented for the purposes of teaching juniors in two ways: the consultants presented the history of one of their patients and juniors were asked to construct the diagnosis and management plan or juniors presented "worked up" cases and the consultants adjudicated. Juniors typically saw patients attending the RACPC, took a medical history, and reported their findings to a senior colleague.

We were able to follow and observe four relatively newly qualified senior house officers throughout their 6-week rotation within the cardiology clinic. During the first week they saw on average 7-8 patients, and at this stage they all appeared hesitant in seeing patients alone and tried to see their caseload with a senior clinician present. During this first week they appeared to have little knowledge of the aims of the cardiac consultation and none took the classic form visible in a cardiology clinic. At this stage they all took generalised medical histories, did not ask patients to describe their pain in any detail (if at all) and focused the consultations on identifying cardiac risk factors. Thus, when these juniors first entered the clinic, typically the first question they asked was *'can you tell me what's wrong?'* or use the GP referral form as their prompt: *'so your GP says you've not been well'* or *'what did you see your GP about?'*

They had yet to understand the centrality of the patient's pain narrative to the diagnostic process or pick up the short cuts and prompts that the cardiologists use to facilitate an efficient and accurate cardiac diagnosis. However, after the first week, their technique of history taking mirrored word-for-word the phrases used

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by the senior registrars and the consultant within their team. The first question they then asked was: *'can you tell me about your pain'* or *'can you describe your pain to me'*. Those who were coming to the end of their rotation also explained to patients the importance of their pain narrative in making an accurate diagnosis *'its really important that you tell me about your pain, it really helps me to know how it feels'*. At the end of the consultation, they also began to ask the patient to explain and clarify their pain once more *'can you tell me again about your pain'*. For example:

A junior half way through his first week takes a clinical history from a 44 year old white British man referred to the clinic by his GP after complaining of left sided chest pain. During the consultation, it emerges that he has a family history of heart disease and diabetes and is being treated for high blood pressure by his GP. The junior asks him briefly to describe his symptoms, examines the patient, takes his BP (140/80), listens to his chest and heart and feels his pulse, asks his occupation, his medical history and risk factors. The patient looks anxious and seems keen to expose his various risky behaviours (alcohol intake, a smoker and stressful office based job) to the young clinician who confirms to the patient that he has quite a few of the risk factors associated with heart problems. The junior leaves the cubicle, closes the curtain, and rewrites his notes on a new medical history sheet in a different order before seeking a senior to consult. An SHO hovers and asks if he has finished with the patient and the junior shows his rewritten notes and runs through the history, emphasising the risk factors and clinical measurements. The SHO asks what sort of pain the patient was experiencing. This had not been explored during the consultation, but the junior reads from the GP referral letter that he had left sided pain in his chest area and the senior suggests they see the patient together. The senior clinician asks much more about the pain, the patient tells him he played squash at the weekend and the SHO decides it is musculoskeletal pain, he tells the junior to record this as *'non cardiac'* chest pain. (RA49)

Juniors are coached by the seniors in a form of history-taking that will enable them to classify the patient as cardiac or non-cardiac. Specifically, they learn the stock phrases by watching the seniors that elicit key diagnostic information and understand the centrality of the pain narrative. For example, when senior clinicians are called in to see a patient after a junior has taken the history the more senior clinician often begins once again by asking the patient to *'tell me about your pain'* – the most frequently used phrase to begin a consultation. Senior clinicians often return to this question towards the end of a consultation, seeking clarity from the patient and giving the patient a chance to describe their pain once again. As junior clinicians become more experienced, they also begin to follow the same pattern and come to rely more on the patient pain narrative rather than other technologies such as a resting or exercise ECG result.

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In addition, they are instructed in the skills of how to see, hear, and touch the body; to read the signs and signifiers that determine whether a symptom is cardiac or non-cardiac. Like patients, juniors do not have the shared vocabulary with which to describe what they see and hear. Thus, not only are they taught how to see, hear, and touch, but are instructed in how to describe and classify this within the language of the clinical speciality. Some of these skills are taught in an explicit way such as tutoring a junior clinician on reading an ECG or through explanation. For example:

A new clinician considered exercising a woman of 42 who had presented with exertional chest that was not relieved by aspirin. The young clinician had filled out the appropriate form and handed it to the technician who was to conduct the exercise ECG. The technician questioned the decision and sought confirmation from the consultant, who then explained to the junior that an exercise ECG in such a young woman with so few risk factors was likely to produce a false positive result. The consultant used this as an opportunity to explain the sensitivity and specificity of an exercise ECG. (RA104)

However, other diagnostic skills, such as touch are not taught so explicitly but picked up by an implicit process of watching the seniors perform. The following extract demonstrates an opportunity for juniors to engage in active embodied learning that could not have been acquired in a classroom or through verbal explanation. For example:

A middle aged white British man [RA51] presents in clinic and is examined by a senior registrar. After taking a history, the registrar listens to his heart for some time and declares with great certainty, "yes, *I think this pain is connected to the heart*" and explains that he would like to seek the opinion of his consultant, that he had an interesting heart beat and would like some of his colleagues to listen. He reassures the man this was not serious, but because it is unusual to "*get such a clear sound like you have*". The registrar asks the juniors what they can hear: the first exclaims '*I can hear something, but I don't know what it is*' and fails to offer a diagnosis. The second junior hesitates and mimics the sound, blowing breath through his pursed lips to make a sound of air passing through a small hole. The registrar asks what this sound might be, the first suggests it is '*wave-like, 'gushing*' and related to a valve. The registrar nods and explains that this is a fantastic example of a '*leaky*' valve and prompts them that they would have read about the '*whooshing*' sound present when there is a regurgitation as the blood flows back through the valve. The registrar finds the consultant with some excitement, '*come and listen to this*' and the consultant listens and turns to the registrar and a few student clinicians in ear-shot and declares this was one of the best examples of '*regurgitation*' he had heard. He beckons to the 8 or 9 students nearby to come over and they stand in line to listen to the man's heart through their stethoscopes. The consultant asked the group what they thought they could hear. They wait for the consultant to prompt '*whooshing*' and agree that this is what they can hear

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through the stethoscope and emulate the sound by blowing air through their tightened lips as if to make a silent whistle. Each offered a slightly different answer, some described the sound while others tried to work out the cause, as they get closer to the answer the consultant interrupts *'Yes, you heard that whooshing sound. It is very distinctive and this is a very clear example it would not usually be quite so clear'*. The prompt of *'whooshing sound'* triggered a textbook memory for one of the students who went on to give a definition of the problem. Some of the students listen again to the patient's heart as the consultant explains that they should try to remember about the sound for future cases and matches the sound-effect of *'whooshing'* to the work of the valve.

In the extract above, when the juniors attempt to describe what they 'hear', both the registrar and the consultant re-word their comment so that it fits within the language of the clinic. The seniors ask them to describe the significant features and then modify their statements within the language of the clinical speciality. They describe the sound as *'whooshing'* and its classification, in this case, an example of *'regurgitation'* and the juniors are coached to observe, to know what to look for and how to 'hear' cardiac conditions. They must remember that sound and use it as a diagnostic sound in future cases; a form of tacit, embodied knowledge that cannot be learnt from a textbook or in the classroom, it has to be experienced. The seniors, on using this 'classic' case focus a great deal of attention on helping juniors to fix this sound to memory; this is an important skill and they must recall it in the future. An important part of the process of developing expertise is the collection of types and cases, diagnostic experiences that become career-long points of reference. This highlights the value of case-by-case experience as a core form of knowledge and such case knowledge, gained from ones own experience, forms the primary source of skill acquisition and ability.

One senior clinician emphasized that decision making depends on complexity or simplicity of cases and grade and seniority of the person who assess the patients and suggested that decisions about patients in 'the middle' (i.e. neither clearly non-cardiac not clearly cardiac) were more likely to be taken together rather than alone.

"Speaking for myself, looking at interventional cases I occasionally speak to colleagues at other locations" (Consultant Interview 01)

Thus, we can see both horizontal and vertical joint decision making in the clinician hierarchy. Below consultant level, hospital clinicians refer upwards if a joint decision is necessary and then across to other consultants if further opinion is required. However, GPs may consult with their GP colleagues (horizontally) first and then refer into the hospital hierarchy – not knowing whether their patient will see a junior clinician or a consultant once they attend clinic.

3.4.5 The display of expertise

Clinical expertise is performed through the pronouncements of senior clinicians. Within the cardiology clinic this is commonly displayed by doubt being cast on any prior diagnosis a patient arrives with. In addition, the authority a diagnosis has may change as it travels out to different arenas, the complexity of a diagnosis becomes effaced and a clear diagnostic category is maintained.

Casting doubt on prior diagnoses

Once the patient enters the clinic, previous diagnoses are disregarded and the assembly of the diagnosis starts again or, at least, that is how the diagnostic process in the RACPC was represented by clinicians. At the start of the consultation a patient will commonly offer up explanations or diagnoses they have acquired previously from other clinicians or come with notes or medical records that indicate a cardiac diagnosis. On such occasions, the doctors in the clinic always attempt to establish who has made this prior diagnosis. Once they established the pedigree of the prior clinical classification, they routinely cast doubt on any prior diagnosis, particularly if it was made in another centre in the UK or, even worse, abroad. There is a hierarchy within the cardiology team of who can do this and although dismissing a diagnosis appeared to be harder to do if it came from within the team, this also occurred. For example:

Man aged 49, from Pakistan. (RA18)

The GP referral form states that he had been suffering from palpitations, chest tightness and raised BP. He was seen by a senior doctor who begins, as he always does, by asking:

D: Tell me about this chest pain you have been having...

P: I am having it since yesterday morning. I have pain in every muscle. It feels like a needle in my heart and then it went to my neck.

D: What time did it start yesterday?

P: As soon as I woke up.

D: And the pain was there all the time?

P: No, no. That pain went after 5 or 10 minutes. I took some Nurofen and since then my arm has been aching and I've had pain here (points to central chest area)

D: And is it continuous?

P: No, it comes and goes.

D: What makes it worse?

P: Well, I get short of breath. It presses when I take a deep breath.

D: Does eating make it worse?

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P: No, when I eat I vomit. Yesterday I vomited.

D: Ok, so have you had this before?

P: Yes, I have a history of left ventricular blockage. I was in the Cromwell in 1996. They put me on medications.

D: I see. But you have no palpitations?

P: Well I have them but they don't last very long. A few days ago I got them for about 10 minutes. Since 1996 I've been on medications. I used to work in the Pakistani high commission and they paid for everything. The Cromwell people said it wasn't dangerous, but yesterday I just felt like there was a knot in here (points to left side of chest) and it lasted about 10 or 20 minutes.

D: Do you have your notes from the Cromwell?

P: Yes, but not here.

D: And do you get pain when you breathe?

P: Yes.

At this point, the doctor turned to the researcher and stated: "he is clearly non-cardiac" although he then continued to ask questions and recap on the patient's description of pain symptoms. The patient explained that in 1986, when he was in Pakistan, he was told that he had premature heart beats. He says that he was fainting and collapsing and was taken to the intensive care unit in Pakistan. The clinician interrupted at this point as the information did not seem relevant to the diagnosis that he was trying to make in this clinic: that is, was the pain the man had at present cardiac or non cardiac.

The clinician explained that this man's chest pain was clearly non-cardiac, but he needed a 24-hour tape to investigate his claims of premature heart beats diagnosed in Pakistan. He explained to the patient that he would like to see him in his cardiology clinic to review his notes from the private hospital and assess his medications. The patient said that he was put on atenolol in Pakistan but that it '*never satisfied me*'. After listening to his heart, the clinician confirms that he can detect ventricle ectopics (extra beats), adding that he wanted the patient to have an exercise ECG to see what happens to the heart rate when he exerted himself. The exercise ECG came back normal and the patient was referred for a 24 hr tape.

The clinicians were often cautious about refuting another's diagnosis without first knowing who the clinician was and their level of seniority. When overturning a previous diagnosis, clinicians liked to have acquired some test-based evidence to support their opinion, something we describe in part 2 of our results as '*professional etiquette*'.

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Removal of ambiguity and complexity from the diagnosis

Another way in which authority is displayed is the way in which a clinical classification becomes fixed as it travels outside the cardiology clinic to other specialities, to general practice and to the patient themselves. All diagnoses travel between medical worlds, some expert, and some general and the authority of a diagnosis changes as it travels to different arenas.

We observed that as a diagnosis moves from the clinic to other external clinical settings, the ambiguity and complexity of a diagnosis that exists within the clinic is removed and the classification becomes reduced and fixed within a small number of broad, simplistic categories i.e. 'typical cardiac', 'atypical cardiac' and 'non-cardiac'. As the diagnosis travels from the clinic, all complexity is eradicated and it is transformed into a 'fact' within the public world. For example, there are a number of key words or phrases that can change the direction of the consultation and such key descriptors in patient pain narratives can confirm or refute an angina diagnosis; however, this was simplified and transformed when it travelled outside of the clinic.

Patients may arrive at a key descriptor spontaneously, however, most commonly; they are produced after prompts from the doctor during the taking of a history and, in some cases, only after consultations with several clinicians and/or other family members. Patients expressed such key descriptors in a variety of ways, but from the clinical perspective, they are trying to confirm certain statements through their discussion with the patient.

Within the clinical setting, we observed that patients were interrogated about key descriptors: precipitation of chest pain by exertion, relieved by rest, lasting for 10 to 15 minutes, and described as pressing, tightness, or squeezing. If they said yes to three of these descriptors, their pain was classified as cardiac in origin. In addition, if they also described associated symptoms such as shortness of breath on exertion or had significant risk factor such as smoking, diabetes, family history, high cholesterol, or hypertension, then the classification was further confirmed. Conversely, non-cardiac chest pain was identified by a different set of descriptors. If the pain occurred at rest, was relieved by painkillers, lasted for long period of time and was described as an ache or sharp pain or worse with movement, then a non-cardiac origin was suggested. In addition, if there were no cardiac risk factors or associated symptoms, as described above, then the classification was definitely non-cardiac chest pain. Thus, the diagnosis of angina ultimately appeared to be straightforward and uncomplicated; however, patients rarely if ever recalled and narrated their experiences of bodily pain in a form that provided or could be read as a clear and unambiguous diagnosis.

The cardiac team entered the details of each consultation (based on the case notes and memory) onto a database. These data were acquired by the team during the course of the consultation and

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reflected their diagnostic interpretation of patient descriptions of their symptoms and pain. Only one descriptor of pain can be recorded on the database per patient, however, patients commonly used more than one to refer to their pain over the course of the consultation. In addition, there were only four categories in which to classify pain within the database, 'constricting', 'stabbing', 'aching' and 'non-descript' and none of these matched clearly the categories either provided by patients or used by the team in the everyday work of making a cardiac diagnosis.

Thus, what was recorded onto the database was a pain descriptor identified and classified by a member of the clinical team (usually a junior) post-diagnosis. The reality was somewhat more complicated as patients moved between descriptors in response to prompts, memory recall and processes of articulation. Diagnosis and classification of patients was often not fixed and was often partial in nature, for example, as patients descriptions of their pain change or become clearer. However, the database fixed the classification of the patient and this information was printed onto the letters to GP's and referral letters to other specialities. The following example was one of several where clinicians were placed in compromising circumstances where a previous diagnosis had been made (often by another member of their own team) which appeared to contradict their own opinion. A woman in her early 70s arrived in clinic and responded to the doctor's initial question with a question of her own:

Clinician: Can you tell me about your pain?

Patient: Well, I want to know if there is anything wrong with me, They put me on these heart pills and then my GP took me off.

Clinician: Ok, lets start from the beginning

Patient: Well, I came here. They put me on the treadmill and gave me these pills (she holds out a half empty packet of atenolol). And then a few weeks later my GP got a letter saying I was all clear. So he took me off them. And then another clinician, a new one this morning, she sent me here again and she mentioned something about seeing a heart clinician?' (CO12)

The patient was quite confused, understandably, and was seeking clarification and, more importantly, wanted an authoritative opinion on whether she should be taking the pills. Such confusions were not unusual and were most probably the result of both patient recall –and indeed patient desperation to be given a firm diagnosis- and a consequence of the difficulty in definitively diagnosing the presence of angina. Invariably the seniority of the diagnostician became the deciding factor. Diagnoses by more junior doctors were more easily overturned than those of senior practitioners. This may well have contributed to patients' confusion and was one of the reasons why so few patients observed were able to clearly assert of what was wrong with them. The display of expertise and the role of the experts are

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discussed in greater detail and in relation to the ARIA decision making tool in the following section. (p. 33)

3.4.6 Decision making and classification

As discussed above, a key function of the RACPC and, to a lesser extent, the cardiology outpatient clinic was the classification of patients into cardiac and non-cardiac and that was the central decision with regards to initial diagnosis. In order to reach this decision, a range of techniques, including eliciting the patient narrative, were brought to bear in the consultation and through investigations.

Joint decision making with colleagues

It was common practice for clinicians within the team to seek the views of colleagues in the RACPC, with few decisions being made by a clinician alone. Nearly all diagnostic decisions were made jointly, either by discussing an interpretation of an ECG result, inviting a second clinician to speak to a patient or by running through the patient history with colleagues within the clinic. A following extract is a typical example of this:

The clinician leaves to discuss the patient with a colleague. They agree that an exercise ECG would be appropriate. The technician is informed of the decision and visits the patient to explain what is about to happen. The problem, of course, is that the technician does not speak Sinhalese. In such cases (an exercise ECG can not be taken unless a translator / advocate who speaks the same language as the patient is present) the hospital translation service is contacted. On this day no Sinhalese-speaking staff were available and so the patient is sent home and told that she will be sent an appointment to return for the test when a translator is available. The third clinician becomes involved. The three clinicians reassess the evidence again, together. They study the ECG at length and decide that, on more careful examination that the patient has tachycardia. In response to the examining clinicians retelling of the patient history, which is now condensed to its shortened version of: *'chest pain lasting a few minutes, sometimes on exertion, diabetic, south Asian, raised BP'* one clinician suggests that the pain may in fact be cardiac. This discussion goes on in front of the patient and her friend, and the friend, eager to provide additional information interrupts the clinicians and says *'She never sleep you know. It is all the worry. She needs something to help her sleep'*. The examining clinician explains who the friend is and that the patient was under great family stress (in fact, as he say this he also glances at the GP referral form which mentions family problems and anxiety). The patient continues to sit in tears as her friend comforts her. The three clinicians review the case once again and decide *'to medicate'*. They prescribe beta-blockers and a very small dose of temazepam to be reviewed by the GP. The patient and her friend (with palpable relief in their faces) are discharged with a

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prescription and told that they will hear from the clinic soon about a 'treadmill test' and that she needs to visit her GP for further supplies of medications and for BP monitoring.

Particularly in cases such as these, where there are additional complexities in using the patient narrative and eliciting diagnostic information from the patient, adjudication of diagnosis is made in collaboration. In such cases, the clinical team usually use further technologies such as the exercise ECG. There are a number of diagnostic technologies the clinical team use in the process of diagnosis and classification.

Patient narratives

Patient narratives are essential to achieving a diagnosis and although other technologies may be used, they do not enable a classification to be fixed. The clinicians begin all consultations by inviting their patient to describe their pain, and this, as we have shown, can elicit a variety of response some of which immediately guide a diagnosis (where the diagnosis is distinguishing cardiac from non cardiac chest pain) whereas others lead the dialogue into circles of repetition, contradiction and confusion. During this process, the clinical team appear to be waiting for a moment of clarity; however, the diagnosis rarely becomes apparent in this way. To illustrate this we provide an extract from a consultation from a RACPC:

A female Sri Lankan patient and her friend sat side by side in the cubicle occasionally sharing physical gestures of comfort through touch as the clinician stood leaning against the bed. The patient is asked to describe her pain and responded by turning to her friend who then points to the patient's body to show the clinician where the pain was located. *'It's here'*, she says as she spread her hand across the left side of her friend's chest. Unprompted by the clinician the friend continued *'She thought it was heartburn. It comes and goes and she feels her heart beating as well and then she doesn't feel like eating anymore'*.

For the clinician this statement poses two contradictory indicators. First the association with food might suggest that the pain in indigestion, however, the presence of a sensation where the patient feels her heart beating might suggest palpitations. This was something that occurred regularly and required disentanglement. In pursuing this puzzle the clinician asks a question that might help differentiate cardiac pain from digestive pain:

Does the pain go anywhere or stay in the same place? He asks, directing the question to the patient who looks blankly back at the clinician. The friend, once again, responds on behalf of the patient, without even glancing at the patient.

Friend: It stays in the same place and then comes again after a while and goes again.

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Doctor: *How long does it last for?* this time addressing both of the women.

This time the friend asks the patient and then after a conversation in Sinhalese responds: May be 5 minutes. Or may be half an hour. She doesn't know. When she takes spices she feels it more.

For the doctor, this response offers little diagnostic information, as he explained to the researcher that if the pain really did last just 5 minutes then the possibility that the cause might be angina might be pursued further, however if it lasted for half an hour or so and was associated with food than one might pursue a non-cardiac diagnosis. In this case, the clinician chose to first exclude the possibility of a muscular cause as he moved between 3 possible causes of chest pain: digestive, muscular and cardiac.

Doctor: Does the pain change when she takes a deep breath

The friend translates and speaks to the patients and then responds: *Yes she feels pain.*

Once again, the clinician is not receiving information that really helps him differentiate the possible causes of the pain and goes on to pursue the muscular diagnosis:

Doctor: And when she moves back and forth?

This time the friend doesn't ask the patient but responds directly to the clinician's questions with a similar response as before: *Yes, she gets the pain. She feels her heart beating.*

In this consultation, as in many others observed, the circularity of responses to reasonably abstract pain questions leads to more concrete 'stock' medical questions that give patients' an object with which to recall and convey their pain. The following, used in this consultation is common.

Doctor: Does she get the pain when she's climbing stairs?

This question usually elicits a diagnostically useful response, unless (and this was not unusual) a patient responds by saying they do not have stairs at home, or they always take the lift.

In the consultation under discussion, the friend turns to ask the patient and then responds: Yes, she gets the pain.

The women then talk to one another for some time while the clinician looks on and the friend eventually says: *Walking? She doesn't know what to say but she has difficulty with stairs.*

Doctor: Does she get giddiness or fainting when she gets the pain?

Friend: No, well, she feels sick when the pain comes. And then over the past 2 weeks, no more, one year or 6 months she's getting this pain.

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Still trying to establish if the pain might be musculo-skeletal, and using one of the core stock deciding questions commonly used by cardiologists, the clinician asks:

Doctor: Has she taken painkillers?

Friend: Yes, the doctor gave her something for her stomach and that helped, I remember.

The patient remains silent through this and does not appear to be following the questioning and dialogue that ensues between the clinician and her friend. Eventually, moving away from questions that try to elicit the type, duration, precipitator and location of pain, the clinician decides to switch tack and enquires about common risk factors that are associated with cardiological problems.

This pattern of consultation (i.e. questions relating to pain, then risk factors) was used in every RACP clinic consultation observed. In this case, like so many others observed by Somerville, it was extremely hard for the clinician to determine where the pain was located or what type of pain the woman was suffering from. The clinician explained to Somerville that when she (the patient) pointed to the site of the pain it seemed localised, but because the woman wasn't able to describe the pain it was very hard to determine. This was exacerbated by the language difficulty and need for translation but was by no means caused entirely by this. Struggling to describe the pain in a way that the clinician found acceptable was a feature of the majority of consultations by patients with relatively recent onset of chest pain. Only those patients who had previously been diagnosed with angina were able to quickly and immediately classify their pain and did so only by comparison to the pain they had experienced before. Additionally, in the consultation described above, like many other patients, the woman tended to agree with everything the clinician said. The clinician would ask if 'this' or 'that' were painful and the patient (or her friend) would offer positive responses even if, from a clinical perspective, the pain responses were somewhat contradictory.

The skills of listening and hearing

In addition to cardiac history taking, juniors are instructed in the skills of how to see, hear, and touch the body; to read the signs and signifiers that determine whether a symptom is cardiac or non-cardiac. Like patients, juniors do not have the shared vocabulary with which to describe what they see and hear. Thus, not only are they taught how to see, hear, and touch, but are instructed in how to describe and classify this within the language of the clinical specialism. Some of these skills are taught in an explicit way such as tutoring a junior doctor on reading an ECG or through explanation. For example:

On one occasion a new clinician considered exercising a woman of 42 who had presented with exertional chest pain. The young doctor had filled out the appropriate form and handed it to the technician who

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was to conduct the exercise ECG. The technician questioned the decision and sought confirmation from the consultant, who then explained to the junior that an exercise ECG in such a young woman with so few risk factors was likely to produce a false positive result. The consultant used this as an opportunity to explain the sensitivity and specificity of an exercise ECG.

However, other diagnostic skills such as touch are not taught so explicitly but picked up by an implicit process of watching seniors perform. The following extract demonstrates an opportunity for juniors to engage in active embodied learning that could not have been acquired in a classroom or through verbal explanation.

A middle aged white British man [RA51] presents in clinic and is examined by a senior registrar. After taking a history, the registrar listens to his heart for some time and declares with great certainty, *'yes, I think this pain is connected to the heart'* and explains that he would like to seek the opinion of his consultant, that he had an interesting heart beat and would like some of his colleagues to listen. He reassures the man this was not serious, but because it is unusual to *'get such a clear sound like you have'*. The registrar asks the juniors what they can hear: the first exclaims *'I can hear something, but I don't know what it is'* and fails to offer a diagnosis. The second junior hesitates and mimics the sound, blowing breath through his pursed lips to make a sound of air passing through a small hole. The registrar asks what this sound might be, the first suggests it is *'wave-like, 'gushing'* and related to a valve. The registrar nods and explains that this is a fantastic example of a *'leaky'* valve and prompts them that they would have read about the *'whooshing'* sound present when there is a regurgitation as the blood flows back through the valve. The registrar finds the consultant with some excitement, *'come and listen to this'* and the consultant listens and turns to the registrar and a few student clinicians in ear-shot and declares this was one of the best examples of *'regurgitation'* I have heard. He beckons to the 8 or 9 students nearby to come over and they stand in line to listen to the man's heart through their stethoscopes. The consultant asked the group what they thought they could hear. They wait for the consultant to prompt *'whooshing'* and agree that this is what they can hear through the stethoscope and emulate the sound by blowing air through their tightened lips as if to make a silent whistle. Each offered a slightly different answer, some described the sound while others tried to work out the cause, as they get closer to the answer the consultant interrupts *'Yes, you heard that whooshing sound. It is very distinctive and this is a very clear example it would not usually be quite so clear'*. The prompt of *'whooshing sound'* triggered a textbook memory for one of the students who went on to give a definition of the problem. Some of the students listen again to the patient's heart as the consultant explains that they should try to remember about the sound for future cases and matches the sound-effect of *'whooshing'* to the work of the valve.

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In this extract above, when the juniors attempt to describe what they 'hear', both the registrar and the consultant re-word their comment so that it fits within the language of the clinic. The seniors ask them to describe the significant features and then modify their statements within the language of the clinical specialism. They describe the sound as '*whooshing*' and its classification, in this case, an example of '*regurgitation*' and the juniors are coached to observe, to know what to look for and how to 'hear' cardiac conditions. They must remember that sound and use it as a diagnostic sound in future cases; a form of tacit, embodied knowledge that cannot be learnt from a textbook or in the classroom, it has to be experienced. The seniors, on using this 'classic' case focus a great deal of attention on helping juniors to fix this sound to memory; this is an important skill and they must recall it in the future. An important part of the process of developing expertise is the collection of types and cases, diagnostic experiences that become career-long points of reference. This highlights the value of case-by-case experience as a core form of knowledge and such case knowledge, gained from ones own experience, forms the primary source of skill acquisition and ability.

3.5.7 Using decision support for the diagnosis and management of angina

We tested the ARIA decision making tool in two setting: RACP clinics where we elicited the views of practitioners; and a focus group where we explored how acceptable decision making tools were to patients.

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Figure 8: the ARIA expert ratings tool



The screenshot shows the "PREVIOUS ABNORMAL ANGIOGRAM" screen of the ARIA expert ratings tool. The screen contains several questions with dropdown menus for answers:

- Has the patient been revascularized? (no, yes) - "yes" is selected.
- Has the patient had an exercise ECG? (No Ex ECG, Ex ECG normal, Ex ECG abnormal, Ex ECG very abnormal) - "Ex ECG abnormal" is selected.
- How old is the patient? (age <60, age 60-74, age 75-84) - "age 75-84" is selected.
- Does the patient show typical angina symptoms? (typical, atypical) - "atypical" is selected.
- What is the patient's CCS score? (CCS II, CCS III/IV) - "CCS III/IV" is selected.
- What level of therapy has the patient received? (maximal therapy, submaximal therapy) - "submaximal therapy" is selected.

A back arrow button is located at the bottom left of the form.

Sixteen patient case studies were tested using the wizard. The clinicians agreed (6) and disagreed (9) with the panel recommendations. In one case the clinician disagreed with the panel recommendation the first time round and in response, changed the variables entered into the wizard and then agreed with the recommendation. However, in no case did the panel recommendations appear to influence or change a clinician's decision. Figure x shows key pages from the "front end" of the tool used with clinicians.

Reasons for ordering an inappropriate test

There were two primary reasons for disagreeing with panel recommendations not to order an ETT:

patient / clinician reassurance

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information emerging in the consultation that are not variables on which the recommendation in the ARIA tool are based (e.g. different diagnosis, results of other tests)

On many occasions during the initial ethnographic fieldwork, patients who presented with chest pain that was classified as atypical or non-specific were nevertheless asked to undertake a treadmill test. The reason for this was reassurance, primarily for the patient, but also for the clinician who could then discharge the patient with a non-cardiac diagnosis. Anxious patients who may have already begun to limit their daily activities, taken time off work or simply felt anxious about the cause of their chest pain were offered tests so that they could leave the clinic and resume normal life. This reason for exercise testing was articulated during the testing of the ARIA tool. For example:

A 43 year old female patient presented in the RACP clinic with non-specific chest pain. She was a heavy smoker but had no other known risk factors. She described the pain as 'intrusive' and said that it stopped her from doing things. Despite the fact the panel recommendation that an ETT was inappropriate, the clinician felt that this woman needed an ETT for reassurance and to reduce her anxiety over the cause of her pain. When asked to explain this reasoning in more depth the clinician explained that if faced with the same patient, the experts on the ARIA panel would probably do the same. The patient described her pain as '*sharp at first and then dull after a few minutes.*' She repeated the same description to two clinicians and the ETT technician. The result was expected to be negative and this would allow the clinicians to tell both the patient and her GP that the pain she was experiencing was not coming from the heart. The test was negative and the patient was discharged with a label of non-cardiac chest pain and advised to stop smoking.

In a similar second case, where the ARIA panel rating indicated that it was inappropriate to do an ETT, the clinician offered an explanation more specific to the structure of the ARIA tool. He pointed out that the classification that the tool employed differed from that used in clinic. The tool offered 3 options for classifying pain: typical angina, atypical angina and non-specific chest pain. The clinician pointed out that in clinic they used typical and atypical *chest* pain that may or may not be cardiac and therefore may or may not be angina. In the case of this woman patient, the clinician felt he could only enter non-specific chest pain as a suitable classification of his patient's pain which radiated to her arm. He wished to perform an ETT because of this radiation (and this he had explained on many occasions previously as common in women suffering from angina) and because she had two risk factors: high cholesterol and hypertension. The test is negative and the patient discharged.

In both of these cases, an ETT was conducted to reassure patients and their GPs that the pain was non-cardiac on origin. This response to the recommendations in the ARIA tool confirms the evidence collected

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during the earlier observational fieldwork conducted in clinic which found that reassurance was a valid and appropriate reason to perform an ETT. To some extent there was an expectation that most patients would have an ETT even if the result is expected to be negative and even in cases where the ARIA panel would rate an ETT as inappropriate. As a consultant cardiologist pointed out, in other chest pain clinics, especially nurse-led clinics,

“which are protocol driven they practically always put patients on the treadmill and then the vast majority of treadmill positive patients will get an angiogram. That will be the proforma. The vast majority of negatives will get a diagnosis of non-cardiac chest pain or angina with good prognosis, no invasive test.” Consultant Interview 01

Although stress testing was not part of the protocol in the clinic studied above, an ETT was easily available in an adjoining room and the technicians who conducted the ETT were part of the cardiology team and therefore there was easy access to the test. The ETT technicians and machine was exclusively available to the cardiologists during the 2-hour RACP clinic. Therefore conducting an ETT was simple, available and offered immediate results. As a consultant in the clinic pointed out:

“staff grade or SHOs etc might assess the patient and out them on the treadmill themselves because that is essentially expected, you know, it’s chest pain, there’s a treadmill there, do it”. Consultant Interview 01

This confirms that availability is a factor that encourages clinicians to stress test patients for reassurance. The facility is there and offers a quick result that can send a worried patient home reassured with a non-cardiac diagnosis after just 20 minutes.

However, it is not only ETTs that are conducted for reassurance purposes. A consultant cardiologist explained that it was possible to go as far as angiogram for the same reason in persistent clinic patients whose chest pain continues:

“The problem in practice [is] you often get to the end of you tether or the patient does because they have got symptoms which quite honestly you don’t really think are cardiac, and they’ve had perhaps one test perhaps an exercise ECG or a thallium, but the problem is that just because you say ‘this pain isn’t coming from the heart and I am really not worried about it’, they often still have their symptoms and they come back to clinic enough that whatever this appropriateness rating for an angiogram might be, quite often they will end up having one, rightly or wrongly, to reassure them that having seen their coronary anatomy that you know for certain ‘I told you all along it was not coming from the heart’ or ‘well yes, you have got coronary disease’ which may be responsible for those symptoms.” Consultant interview 03

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The technologies are not conclusive/definitive

A further reason for going ahead with an angiogram against the panel recommendation is when an ETT result is inadequate or inconclusive. Occasionally patients tire, develop breathing difficulties, knee problems or even chest pain during an exercise test and do not reach the target heart rate necessary to interpret the result. When problems occur the tests are stopped immediately and recorded as inadequate or equivocal. Between January 2000 and December 2003 this occurred in 10% of cases seen in this RACP clinic (RACPC Database Audit conducted as part of this qualitative study). When this occurs, and the clinician still suspects from the patient's chest pain description, that there is a strong possibility that the pain is cardiac, the patient may be referred directly for an angiogram. Patients are screened by the ETT technicians before undergoing the test and most patients unlikely to complete the test are excluded at this point. These patients, following further consultation, may be referred directly for angiogram.

Reassurance was the most common, but not the only reason for conducting an ETT against the recommendation of the ARIA panel. GPs occasionally prescribed nitrates for their patients in cases where cardiologists think it is unnecessary, since in their opinion the patient's pain is not cardiac. A GP described these 'grey area cases':

Sometimes I just give them a trial of GTN and see if it relieves their symptoms. They might come back and say it gave them a splitting headache and made no difference. It's not diagnostic but it's another thing that helps you in whether or not angina is likely. If they come back and say 'doctor can I have some more' then you say 'oh right, lets do some more tests'. GP Interview 01

A case like this, referred from a different GP, occurred during the testing of the ARIA tool in the RACP clinic. A 48 year old white man presented in clinic with non-exertional left-sided chest pain that occurred 'at rest'. He had a normal resting ECG and a cholesterol of 5.9. The GP had been concerned about the man's family history (his mother had a myocardial infarct aged 60) and prescribed the patient a GTN spray. The appropriateness rating for an ETT was 1 (i.e. highly inappropriate). The consultant did not believe that the patient was suffering from cardiac chest pain and considered that an MI aged 60 did not constitute a positive family history. The man had no other risk factors, but the consultant decided to order an ETT to justify taking the man off the nitrate spray. This decision not only provided empirical evidence on which to remove the medication but might also be a matter of professional etiquette. The consultant wished to overturn the GPs prescription and, thus, refute the diagnosis. A negative ETT result would reinforce this decision without risking offending the GP. In this case the test was, as predicted, negative and the man was discharged with non-cardiac chest pain and told to stop using the GTN spray.

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Language

Lastly, the clinic where the ARIA tool was tested has a large south Asian population; 46% of patients seen in RACPC between January 2000 and December 2003 were south Asia (RACPC Database audit conducted for this qualitative study). Nearly half of the south Asian patients observed during the ethnographic fieldwork did not speak English and communicated to their clinician via a translator, usually a son or daughter. A qualitative observation by the researcher that these patients were more likely to be given an ETT was also observed by a white consultant cardiologist who saw this in his own practice. When asked whether his practice and decision making differed in the different clinics in which he worked in London he explained:

"hmm, well the language is a problem; there is no doubt about it because when you have a translator it's different. The way that Bengali people express pain I am sure is different to the way we do so even if you have a translator and you are sure they say 'arhh, yes, the chest pain is sharp' I am not sure what they mean by sharp is the same as we mean by sharp – and so I think you are much more test-based. Well certainly my decisions are. The history I think has to become less important and they may still give you a classical history of angina when it is valid, but they may also give you an atypical history for angina and you have got to question whether it is because we are not linking up on a language angle, or whether their pain is not cardiac and in that situation I think tests, which are objective hard facts, whether they are right or wrong, they are hard facts, become more important – an exercise test, thallium scan or whatever – echo or perhaps even an angiogram" Consultant Interview 01

Communication, as is shown in the ethnographic data in this study, is significant in the process of determining the cause of chest pain and identifying angina. Therefore it is not surprising that there would be a tendency to be more test-based when there are communication difficulties.

Reasons for not ordering an appropriate test

There were fewer reasons on fewer occasions not to conduct an ETT in clinic than there were to go ahead with a test. The two reasons that did emerge for not undertaking an ETT or angiogram, despite the recommendations of the panel were:

a certain diagnosis of non-cardiac chest pain, usually because another cause of the pain is identified during the consultation

a patient is simply unfit for ETT or angiogram.

It should be noted that the ARIA panel (and thus the decision support tool) did not include the outcomes of other diagnostic tools that are used in clinical practice. For example, echocardiograms and thallium tests are used as additional or alternatives to ETT and /or angiograms. In cases where the clinician had thought that these were more

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appropriate tests the ARIA decision making tool was irrelevant. This occurred in one of the sixteen cases that were tested in clinic where the panel recommendation was 7 for an ETT and 3 for an angiogram. The consultant who had seen the patient disagreed with the panel recommendation and was referring his patient directly for an angiogram. The man had a previous inadequate ETT (here, the clinician was forced to enter 'no ETT' onto the screen of the tool as there is no "inadequate" option, hence the high rating for an ETT) and a positive thallium test (reversible anterolateral ischemia). In another case, a 48 year old woman who was unable to complete the ETT (where panel recommendation for ETT was 7 and angiogram 3) and thus the result was described as 'borderline' was referred for an echocardiogram and depending on the result of this would be referred for an angiogram.

Patient's ability to undertake tests

Physical capacity to undertake an ETT was the primary reason for not conducting the test on patients who were considered appropriate for ETT by both the panel, as reflected by the ARIA tool, and the clinicians. This occurred twice during the piloting of the tool on 16 patients, but was observed to occur on a regular basis during the ethnographic fieldwork part of the study: in over a third of cases where clinicians would like to have done an ETT the patient was deemed unfit. This was most commonly caused by musculo-skeletal problems, asthma or obesity or general old age. In the cases tested on the ARIA tool, the reasons were dizziness in a patient who also had high blood pressure on the day of attending clinic. His pain was atypical, but lasted 5 to 10 minutes. He had a history of MI and an inconclusive resting ECG. The decision was to refer direct for an angiogram despite the panel recommendation that this was inappropriate. A similar case was a man who was hypertensive with an abnormal resting ECG. The panel ratings were 7 for ETT and 5 for angiogram. The man was simply unfit for an ETT and referred directly for angiogram.

The same reason would be applicable to not conducting an angiogram despite panel recommendations. Although this did not occur during the testing of the tool it was observed to occur quite often during earlier fieldwork where patients were considered to be at too higher risk to undergo angiography. This was confirmed by a consultant cardiologist who also pointed out that the tool did not take account other problems that a patient may have:

"you might strongly suspect that a patient has coronary disease but for whatever reason you might think an angiogram is right – or your program says it is appropriate, your patient might have had two recent strokes or be wheelchair bound and you wouldn't do it.

"Consultant Interview 01

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Non-cardiac diagnosis

The other main reason for not following a panel recommendation for an ETT was an alternative non-cardiac diagnosis that was obvious during the consultation. This occurred in 2 of the 16 cases tested with the ARIA tool. The first was the case of a 55 year old south Asian man who presented with chest pain in the RACP clinic. He was seen initially by a clinician new to the team, reviewed by a junior doctor and then by a consultant. The man coughed heavily throughout the consultation. He had been diabetic for 12 years and had recently been prescribed insulin. He also took a statin for his raised cholesterol that he thought he had been on for 2 years and was also asthmatic. The consultation was difficult since the man found it difficult to place time frames on his recent symptoms and medical history. He was asked about his risk factors: he was an ex-smoker, drank 3 units of alcohol per day and took pan (chewing tobacco). He had no history of heart disease. The initial clinician who saw him did not feel that the pain was coming from the heart since the pain only occurred while coughing but sought to verify this opinion with the junior doctor who spoke to the patient himself:

So you never get chest pain when you walk?

No

When you climb stairs?

Well, may be after I had flu.

Do you only get the pain when you cough?

Yes (he coughs to illustrate this and says he has pain)

Is it dull or sharp?

No, it's just when I cough.

The two clinicians leave the consultation area and enter the data on the ARIA tool which recommends an ETT. At the same time a consultant interjects and also sees the patient, repeating the questions above. They decide together that this is not cardiac pain and related to the man's cough. He is discharged with non-cardiac chest pain and not asked to undertake an ETT.

In the second case of a 60 year old man presenting with chest pain the clinicians again disagree with the panel recommendation to perform an ETT. The clinician explains:

"This man has dyspepsia. It is clear from what he is saying. The programme is wrong! You can't tell unless you see the patient"

This clinician continued to explain his problem with the programme asking him to classify angina pain as typical or atypical – something that had frustrated him since first viewing the programme. He said:

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"I have known a patient with pain behind his ear and no other chest pain but turned out to have a triple ventricular block"

Thus, there were a number of reasons for disagreement with the panel recommendation. Clinicians who tested the tool decided not to order an ETT or angiogram, even though the panel recommended a test for a number of reasons: the case was clearly non-cardiac from the patient narrative; the patient was unfit for an ETT, or there was a positive thallium test. By way of contrast, the clinicians decided to order an ETT or angiogram against panel recommendation for a number of reasons: the patient description of radiating pain suggesting possible cardiac pain; to provide patients (and also clinicians) with reassurance; the patient's GP prescription of nitrates which the clinician believed to be unnecessary but required a greater weight of evidence to overturn.

Response to concept of expert panel

Our analysis shows that there were two opposing views of the expert panel that generated the recommendations in the decision support tool. A GP interviewed felt that he could trust such a panel:

"Well yes, I think so. If they were experts, why not? They are the ones I assume that are out there doing this stuff".

However, this view was not shared by a consultant cardiologist or even more junior hospital doctors working in RACP clinics. Although none of the non-consultant clinicians inquired about whom the expert panel was, they were sceptical that a computer programme that offered expert panel recommendations could reach a better decision than they could, when faced with a real patient. An experienced junior doctor on seeing a 54 year old woman whom he referred for an ETT tried out the ARIA tool which gave him an appropriateness rating of 2 (inappropriate) for ETT and exclaimed:

'They are wrong!' If the ETT is positive I'll tell these people!'

His reason for ordering an ETT was that the woman's pain radiated to her arm and she had 2 coronary risk factors (hypertensive and high cholesterol). He said her pain was 'non-descript'. He explained that the panel could not assess such a patient unless she was in front of them and describing her radiating pain, which he said was not uncommon in women whose non-specific chest pain turned out to be cardiac.

A second example from the same clinician was the case of a 44 year old south Asian man presenting with non-specific chest pain. The panel recommendations were 6 for an ETT – an indication that the panel were uncertain, and 2 for angiogram. The clinician had decided to order ETT. During the test the patient experienced chest pain and the test was classified as positive. The clinician expressed his response:

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'Look, I am right, your system is wrong – they didn't know if it was necessary and they said he didn't need an angio!'

In these instances, the clinician derived some amusement from 'beating' the system and demonstrated that his own clinical judgment, *in situ*, was more correct than an expert panel.

A consultant cardiologist was sceptical about the authority of an expert panel for different reasons. When asked what he thought about an expert panel he said:

'Well I sometimes think it is a flawed concept because of course it depends how expert this panel is. I can sit down with my three colleagues for example, x, xx and xxx and we could be seen as an expert panel, but our decision making process might be different from another expert panel, in quotes, from down the road at St Mary's or Bart's lets say.'

The interview continued:

Do you think you could be convinced of the authority of the expert panel?

I could be convinced that they were expert certainly, but that is rather different. Experts can disagree.

So could you be convinced enough to allow them to influence your decision?

I think in difficult cases expert panels would hold more value and might influence my decision making but in straight forward or perhaps even moderate or slightly difficult cases you would probably go with your own decision what ever the expert panel say but you would hope that they agreed with you in the easier cases. Consultant Interview 01

The notion that the panel should agree with the clinicians' in practice (rather than they agree with the panel) was also shared by all of the clinicians who tested the tool in RACP clinics.

The consultant also expressed a second interesting view: he felt that the use of an expert panel might disrupt the established hierarchy of learning in medicine. He added '*you've got to have some pride in you ability,*' suggesting that deferring to an expert panel would in some way undermine the decision making ability of a clinician and perhaps even cause of loss in pride.

Response to Guidelines

The ARIA trial showed a significant difference between the guidelines and appropriateness rating arms of the trial in favour of the latter (the decision support tool). Our qualitative data helps to explain why this is the case. A GP who participated in the guidelines arms of the trial knew very little about the guidelines for referral and when he used them in the trial he said:

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"The guidelines actually confused me more than help me I think." GP Interview 01

In response to more general guidelines the same clinician said:

"I will follow some. I mean, NICE guidance, when that comes out I suppose I read it and I don't necessarily follow it. Hypertension is a problem because you have got different people telling you different things".

The multiple sources of guidance that may at times appear contradictory was also a concern raised by other clinicians observed in RACP clinics. While most clinicians were aware of the existence of guidelines, none were able to recall the details or followed specific guidelines in their daily practice. A consultant cardiologist who participated in the appropriateness ratings arm of the trial said that:

"The problem is if you actually look these up they are 40 or 50 pages in length. And actually, probably the only time I do look them up is if I am giving a talk – it's good to say 'and the AHA says...' or whatever, which I am sure isn't how they are suppose to be used." Consultant Interview 01

Other guidelines, he felt, were more about cost constraint than evidence and he was concerned about the motivation behind such guidelines. Both of these clinicians expressed doubts about the value of guidelines and had just a general idea of what they said. They also believed that this was not uncommon:

"I think people [clinicians] would be broadly aware that the guidelines were there and how to access them, but I would be surprised if people knew them better than that." Consultant Interview 01

Thus, due to both practical constraints, evidence from the ARIA trial demonstrating superiority of the decision support arm, we have concentrated our qualitative work on the testing of the tool and on consultations without use of either guidelines or the tool.

Decision Making and use of Decision Making Tool: patient perspective

We explored the acceptability of decision support tools with patients in a focus group. Patients felt involved in the treatment and management of their conditions and were generally comfortable with the idea of their physicians using computer aided decision making tools. Their primary concern was that their own clinicians should not be forced to abide by computerised recommendation but could still rely on their own judgement. All of the patients in the focus group felt that they had been involved in the decisions about their care and all felt confident in being guided by their physicians:

You're in their hands aren't you? They know what they are doing and you rely on what they're saying. If they say have a cup of tea, you have a cup of tea! They give you a choice, but at the end of the day,

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you have no choice – they know what they are doing. I mean, you've seen that many on television that you just accept it! focus group participant: Pat

Beliefs that they were well informed and part of the decision making process gave patients additional confidence in their clinicians and their own future as heart patients.

All of the patients in the focus group expressed general support and confidence in the potential use of decision support tools, such as the ARIA computerised tool, in the treatment and management of their condition. However, they voiced major concerns: that their own clinician who knew them and their case best, should be able to override any recommendation that decision support might suggest. All had formed long term and close relationships with their cardiologists and did not want that relationship disrupted by a computerised decision. As Irene noted, *'no one knows you like your own clinician'*. Although George pointed out:

If it gets you a quicker diagnosis, then surely that is a good thing. That is of some benefit isn't it? But with angina and the pains, there is such a variation, like back ache or other stuff – I always thought mine was indigestion – it can be hard to tell. And the clinician has to ask you all these questions – and if the computer helps him cut those down, well that's well and good.

All agreed with Brian's concern when he raised the issue of disagreement between the clinician's opinion and the computer generated decision:

Can they depart from what the computer tells them to do? Will they be admonished if they do?

Colin, along with the others agreed with the concern and proclaimed:

Well, a computer can't beat what the clinician knows.

All of the participants of the focus group felt that if there was disagreement between the computer recommendation and their own clinician's opinion, their clinicians should use their own judgement and experience and follow their own decisions.

They (clinicians) wouldn't just do something on the say so of a computer. Andrew

Despite the fact that the computerised decision making tool was based upon 'expert' panel ratings developed in the ARIA study, the focus group participants believed that it was the computer making the decision. Their distrust was centred upon the fact that the recommendation came from the computer rather than human beings or 'real doctors'.

Another concern was that use of the decision support tool would affect relationships with their physicians. They valued these relationships and were discouraged by the use of computers by their GPs, who they

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felt always looked at their computer screens rather than talking to them. In addition, they were concerned that medical information kept on computers could be accessed by insurance companies, as John explained:

Thing is, if the insurance people get hold of it, it effects everything. And if the computer tells the clinician to do one thing but the clinician decides to do something different – and it's all there on computer, than what a mess you might end up in with the insurance!

3.5 Discussion

Through this qualitative, ethnographic study we have identified and described some of the factors that influence clinical decision making in the chest pain consultation.

In short, we have described the culture of the clinic in which decision making takes place and we then evaluated, in practice, the acceptability of a decision making tool. Our fieldwork, both with and without the ARIA decision making tool, has demonstrated the power of the clinic in shaping how and why decisions are made in everyday clinical practice. We have mapped how the use of technologies – in which we include verbal and non-verbal diagnostic dialogues – is determined by clinical and most importantly non-clinical factors.

Clinic layout and space

We have shown how the physical layout of the clinic determines the extent to which decisions are made in collaboration with other clinicians in a process of joint decision making and learning that reflects the social and systemic hierarchy of medical practice.

Clinic as site of learning

The hierarchical system of decision making and referral supports the clinic as a site of learning where the experience and expertise of senior clinicians is transferred to junior practitioners.

Embodied and peer-based knowledge

We have suggested that knowledge from case by case experience and evidence filtered through by respected peers is the primary method by which change in practice and new evidence and technologies become implemented and accepted into everyday practice.

Non verbal communication

Our work has shown the power of non-verbal communication in guiding the diagnosis of cardiac and non-cardiac chest pain and in particular we found that the use of physical touch was especially important in aiding communication between clinicians and their patients. Other non-verbal communications that guided decision

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making and diagnosis included the use of hands to express or illustrate pain, and body language to demonstrate the intensity of pain.

Established cultures of decision making and rituals of hierarchy

Our work has shown that there are established rituals of decision making that form the basis of the culture of the clinic and everyday practice. This culture does not easily adopt change and new technologies unless approved by the hierarchy.

Non-clinical reasons for investigations

The clinic is not just a place of diagnosis and intervention but also a place of reassurance. Discharging patients with a non-cardiac label, even in the absence of any other confirmed diagnosis, is a core role of the clinic.

3.6 Limitations of the ARIA QUAL study method

The findings reported here were based on the ethnographic study of one cardiology team in one hospital in east London. A drawback of all intensive ethnographic fieldwork is that it is localised and specific. Therefore we cannot claim that these findings are generalisable to other teams elsewhere in the UK. However, we did feedback our findings to the clinical and research team many of whom have experience in other settings and locations.

Our use of non-participant observation in the clinic allowed us to observe the clinical team and their patients at work in their natural environment and therefore we recorded what was happening rather than influencing events. However, in seeking not to guide or influence their work during consultations we sacrificed some consistency in the collection of patient biographical and clinical/medical data collection. We collected this type of data as it became apparent in each consultation, but in keeping with observing rather than participating we did not actively seek to request missing data during consultations.

The participants in the focus group were recruited from a cardiac patient advisory group. Their membership of this group and willingness to participate in the research suggests that they were 'active' and even 'expert' patients. We can not assume that they were typical of the majority of cardiac patients, but were a sample of the advisory group.

Our use of an interpretive analysis, as in all qualitative research, is subject to researcher interpretive bias. The direction of observation and interpretation of data are subjective although we sought to reduce such bias by ensuring data and analysis were viewed and discussed by 3 different researchers.

3.7 Implications

3.7.1 Improving access with clinical decision support

The results of ARIA-QUAL have important implications for our understanding of the ARIA trial result. In the trial we found a large difference in favour of specific decision support using expert panel ratings over broad conventional guidelines. ARIA-QUAL demonstrates the challenge of design and implementation of decision support intervention within real clinical settings. The trial was intentionally de-contextualised, in order to address proof of concept.

Interventions to improve access to health services require an understanding of social and clinical context. Complementing the trial, ARIA-QUAL investigates a number of contexts with an in-depth ethnographic method. The focus was on clinical settings in which the decision support tool tested in the trial could be implemented.

We do not know of any decision support system that has focused on a condition where the symptoms are so central to diagnosis. A global finding is the multiple influences on the initial diagnostic decisions by specialists when consulted by patients with new onset chest pain. It was particularly striking that the dialogue leading up to diagnosis was highly complex and variable, quite different from the measurement of, say, blood pressure or cholesterol which can easily be codified in a decision support system.

3.7.2 Implications for current practice

While the definition and measurement of many aspects of healthcare are becoming increasingly standardised, the symptom history that the patient gives is seldom obtained in a structured fashion. Consideration should be given to standardised methods of taking a history among patients with suspected angina. This in itself might have the function of reducing practice variations and would facilitate the introduction of decision support.

We found that patients attending the RACP clinic were unaware of the nature of the clinic, not always aware that they were seeing a heart specialist. Patient information needs to be prioritised as much at the beginning of the patient journey as later on, even though this requires the sharing of uncertainty, which doctors, particularly specialists, find difficult.

3.7.3 Implications for design of patient decision support trials

From the ARIA trial with virtual patients and the findings of this qualitative study, the next step is to carry out a randomised trial of decision support within an actual patient population. In this 'real

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world' trial, we will take account of the clinical context in design, conduct, analysis and interpretation. A major finding of ARIA-QUAL is the realisation of just how important that context is likely to be in the effectiveness of any decision support system. In other words, decision support systems may appear as if they are simple interventions, but, given the complex nature of the decision making process, it may be more helpful to consider the design of the trial as a complex intervention from the start.

From ARIA-QUAL, we can say that the following contextual features appear to be important: The culture of decision making within the clinic. The power of consultants within the clinic setting will have a major influence on the acceptability of decision support systems. Consistent with the opinion leader model of clinician behaviour change, any implementation of such systems requires their commitment.

The physical space of the clinic.

The effect of curtained cubicles in contrast to rooms on peer involvement in clinical decision was one of the surprising findings of this study. Implementation of decision support may be a greater challenge in an open (i.e. curtained) setting where the decision making is less individual.

Views about epistemological status of the ratings expressed as scepticism about the expertise of the panel and doubt in the face of panel ratings that are discordant with their own views. This suggests the importance of, for example, selecting the 'right' experts on appropriateness panels so that their judgements are likely to find currency among a wide constituency of clinicians. If expert panels are seen as an extra (or higher) tier in the decision making process, then system-wide aspects of the intervention, involving training workshops may be required. Since an individual clinician may lose confidence in the tool if it appears unhelpful in even a small number of consecutive patients, feedback of results of decision making at both a centre and clinician level may also be required to maintain confidence in the tool across larger numbers of patients.

Older people, women and ethnic minorities may use verbal and non-verbal communication, and negotiate the physician consultation, in ways which differ from younger people, men, and a white English population. Improving access to investigations that are equitable across age, sex, and ethnicity, needs to pay attention to these differences.

3.8 Dissemination to date

These findings were presented at the European Association of Social Anthropology Biennial Conference, Vienna 8th-12th September 2004. *Non-verbal communication in a Chest Pain Clinic: Tactile Cardiologists*

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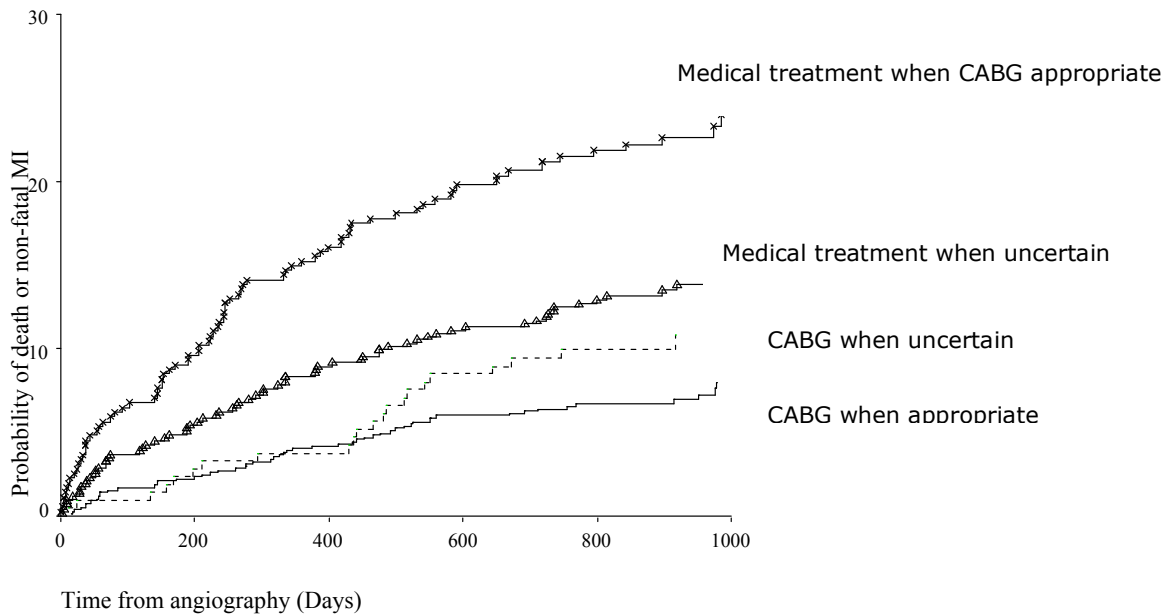
and Patient Body Language and at the British Sociological Association, 36th Annual MedSoc Conference, York 16th-18th September 2004.
Pathways to Diagnosis: Making Sense of Patients' Descriptions of Chest Pain.

Section 4: Understanding barriers to access

The overarching goal of this SDO proposal was to understand methods of improving access to investigation among patients with angina. In Section 2, which discusses the ARIA randomised controlled trial, we demonstrate “proof of concept” that specific guidance, using expert panel derived ratings of appropriateness, can improve access to investigation, whereas broad conventional guidance does not. In Section 3, which reports parallel ARIA-QUAL study, we identified key themes in the production of a history, prior to formulation of a diagnosis or testing decision, which need to be considered in future designs of complex interventions of decision support.

Here, in seeking to meet objective 4 for the study (see section 1.11 Aims and objectives, page yy) we sought further insights crucial to the understanding of interventions to improve access. Findings from the ACRE study revealed significant underuse of coronary revascularization (Hemingway, 1995; Crook, 1997; Hemingway, 2001). Here we have previously compared clinical outcomes between patients managed medically after angiography and patients who underwent revascularization, within groups defined by ratings of revascularization appropriateness. Of patients rated appropriate for CABG, those who received medical management had worse primary outcome of death or non-fatal myocardial infarction (Figure 13).

Figure 13: All cause mortality and non-fatal myocardial infarction after angiography



Cumulative probability of mortality and non-fatal myocardial infarction by appropriateness of CABG and actual management

4.1 Aims and objectives

Given the ACRE findings of the prognostic importance of underuse, we set out to investigate factors that may act as barriers to accessing appropriate revascularization. What if patient preference were a common reason for not undergoing a procedure even when deemed appropriate? With SDO support we collected new data in the Appropriateness of Coronary Revascularization (ACRE) study to determine the frequency of patient preference. We specifically focused on a case (appropriate for CABG but did not undergo it) control (appropriate for CABG and did get it) design.

Organisational and administrative factors might offer barriers to access. For example, were patients "DNA" (did not attend) for the appointment at which revascularization was to be discussed? How often were translation or advocacy services available and used? Were patients put on the waiting list and then taken off? If so why? We sought answers to such questions in the case control study.

What if physician variability was largely accounted for by one or two outliers? In other words, underuse of revascularization in a population might be explained if a small number of cardiologists exhibited extreme differences compared to the expert panel and seldom revascularized their patients. If this were the case then this has major implications for policy, suggesting that such clinicians should be

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identified and reasons for their decisions clarified. With SDO support we carried out new analyses in the ACRE dataset to test this hypothesis.

4.2 Methods

4.2.1 The ACRE study cohort

Full details on the ACRE study have been published elsewhere (Martin, 2002; Feder 1999; Hemingway, 1995; Crook, 1997; Hemingway, 2001; Hemingway, 2000a; Banerjee, 2001; Hemingway, 2000b; Hemingway 2001; Philpott, 2001; Hemingway 2002a; Hemingway 2002b Hemingway 2004). In brief, 4021 consecutive patients undergoing coronary angiography at Barts and the London Chest hospitals were assigned an appropriateness rating, but managed independent of these ratings. Detailed baseline clinical and demographic information was collected and patients were followed up for 2.5 years for subsequent receipt of revascularizations, hospital admissions with myocardial infarction, mortality and angina status. Seven-year follow-up for the cohort had been accomplished in 2004/5.

4.2.2 Appropriateness ratings

The ACRE appropriateness ratings for coronary angiography were determined in 1995 prior to recruitment of the cohort and their validity and reliability have been reported.(Hemingway1999b) Using the RAND - Delphi technique (Pill 1971), a nine member expert panel (four cardiologists, three cardiothoracic surgeons, a general physician and a general practitioner) rated 2178 mutually exclusive indications for coronary angiography. A specific indication is defined by logical combinations of clinical presentation, test results and current treatment. Gender was not used to define patient indications for revascularization. Median scores ranged from 1-9, with 1-3 being inappropriate, 4-6 uncertain, and 7-9 appropriate. Angiography was "inappropriate" when risks exceeded benefits and "uncertain" when benefits and risks were nearly equal or when the expert panel was divided in its judgement. Patients with a particular indication should be homogeneous in the sense that performing the procedure would be equally appropriate (or inappropriate) for all of them. The panel's rating of appropriateness was assigned to each patient in the cohort.

4.2.3 Patients

Patients were eligible for inclusion in the ACRE study if they underwent emergency or elective coronary angiography at the hospitals comprising Barts and the London NHS Trust between April 15 1996 and April 14 1997 and they lived within an area defined by the five contiguous (former) health authorities of the City, east London and Essex. These boundaries correspond, since 2002, to two strategic

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health authorities (SHA): North East London SHA and Essex SHA. There were no exclusion criteria and 4121 patients were identified. The resident population of the health authorities was 2.833 million (procedure rate 1700 per million) and 89% of the angiographies performed on their residents were done at this centre. Ethical approval for the study from the five Local Research Ethics Committees and written informed patient consent were obtained.

4.2.4 Clinical record data

On the day of their index coronary angiography, eligible patients were identified by examination of ward admission and catheter laboratory log books. Data were extracted from case notes by trained nurses using standardised recording forms. Details were obtained on: clinical presentation (RAND definitions – see Bernstein, 1992), functional severity of angina (Canadian Cardiovascular Society (CCS) classification (Campeau, 1976), present medications, smoking status, history of hypertension, plasma cholesterol, diabetes, weight, height, exercise electrocardiogram (ECG) results, time spent on the waiting list and the cardiologist's intended management after angiography (medical, coronary angioplasty, or coronary artery bypass grafting). These data items were then used to allocate each individual patient to a specific, pre-defined clinical indication for angiography based on RAND.

4.2.5 Angiographic data

Angiographic findings were obtained from the free text angiogram report held in the case notes and coded blind to the clinical details by a trained coder. The severity of disease in each of 27 coronary artery segments (as defined by the Coronary Artery Surgery Study) was coded from 1 (none) to 6 (occluded) and the number of diseased vessels calculated (Ringqvist, 1983; Freisinger, 1970). In order to assess the reliability of this approach, two cardiologists over-read a random sub-sample of 209 angiograms, blind to clinical details. The cardiologists showed agreement beyond chance with the trained coder, with weighted kappas of 0.64 and 0.63 (0=no agreement beyond chance, 1=perfect agreement) (Banerjee, 2000).

4.2.6 Data completeness

Data were available from 4021 (98%) case notes and 4076 (99%) angiogram reports. In 226 (6%) patients the indication for angiography was not found in the pre-defined indication lists (in the majority of cases this involved angiography as part of a clinical trial or as pre - CABG assessment after a prolonged wait). 3631 (88%) patients satisfied a pre-defined indication, had complete data and were assigned an appropriateness rating.

4.2.7 Follow up and outcomes

First revascularization procedures performed after index coronary angiography were identified by cross checking electronic information systems nationally (the National Health Service Wide Clearing System) and at the Barts and the London Trust against catheter laboratory and theatre log books. All patients were followed up for death or non-fatal myocardial infarction until 14 April 1999 giving a median (range) follow up of 30 (0-36) months. Over 99% of patients were flagged for mortality at the Office for National Statistics central registry and the date of death notified. Potential cases of non-fatal myocardial infarction were ascertained by flagging patients at the national health service-wide clearing system for coronary artery disease coded discharges, using the unique identifier of their new NHS number. The completeness of these data was further checked by manually searching admission records in the 13 referring hospitals. Twelve months after revascularization or after angiography in the absence of revascularization participants were sent a questionnaire including the Canadian Cardiovascular Classification scale for the presence and severity of angina.

4.2.8 Individual clinicians

At the time of angiography, patients were under the care of one consultant cardiologist who performed the angiography procedure and made the initial decision on whether to refer the patient for CABG or not. Of the 2552 patients with an appropriateness rating, 15 individual cardiologists were responsible for the majority (>90%) of these patients.

4.2.9 New data collection

With written informed patient consent, and approval from MREC we examined patient case notes among 397 patients in whom CABG was appropriate but the procedure was not performed (cases) and 530 patients in whom it was appropriate and it was performed (controls). This exceeded the 222 cases and 444 controls as originally stated in the grant. Trained nurses abstracted onto standardised forms details from case notes, discharge summaries, clinic letters and reports. In many situations this involved scrutinizing more than one set of case notes from different hospitals. Details were sought on written record of patient preference expressed at different stages in the decision making process: consideration for revascularization, being put on the waiting list for revascularization, attendance for revascularization procedure. We sought details of waiting lists (date put on, date taken off with reasons), outpatient attendances and non attendance (DNA) occurrences, invitations to come in for a procedure, use of advocacy or translation services.

4.2.10 Statistical analysis

(i) Patient preference and predictors of undergoing CABG among patients rated appropriate

Logistic regression was used to investigate predictors of undergoing CABG. Potential predictors were taken from the components of the appropriateness ratings: number of diseased vessels, angina severity, medication, left ventricular impairment, history of previous MI, previous revascularization, exercise ECG and operative risk.

In addition to these the following variables were also considered: age, sex, ethnicity and cardiologist. Each variable was considered separately, with the most important factors then incorporated into a multivariable model to identify independent predictors of undergoing CABG. Analyses were performed in STATA 7.0.

(ii) Measuring variation across cardiologists in the proportion of revascularization procedures performed among appropriate patients

Funnel plots were used to measure the variation in the proportion of CABG performed among appropriate patients across cardiologists. This method was chosen instead of our initial proposal to measure clinician variation using kappas, as each clinician was responsible for an independent group of patients. Using kappa statistics are appropriate when independent raters (in this case cardiologists) review the same subjects (patients). The method we used is well known for assessing publication bias in systematic reviews and used more recently for presenting hospital performance indicator results (Spiegelhalter, 2003).

For patients rated appropriate for CABG, the number of patients under consideration by each cardiologist was plotted against the proportion of CABG performed. 95% control lines were calculated using twice the standard deviation of the overall proportion. These control lines indicate the range of values expected for 95% of samples drawn from the given sample size, that is the number of patients under each cardiologist. We would expect 5% of data points to lie outside the control lines therefore with 15 cardiologists, 1 data point outside but near to the control lines cannot be considered a true outlier.

4.3 Results

4.3.1 Characteristics of appropriate patients by management

Baseline demographic and clinical data comparing patients who underwent CABG with those that did not are presented in Table 8. Patients who underwent CABG had more severe disease (higher number of diseased vessels) and were more likely to have undergone previous CABG compared with patients who did not.

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Table 8 Baseline characteristics of patients with or without CABG

Case notes seen	All patients (n=2593)		Patients appropriate for CABG (n=927)	
	CABG performed (n=742)	CABG not performed (n=1851)	CABG performed (n=530)	CABG not performed (n=397)*
	n (%)	n (%)	n (%)	n (%)
Demographic				
Median age (year)	63	60	63	62
Female	142 (19)	588 (32)	92 (17)	83 (21)
South Asian	69 (9)	186 (10)	50 (9)	47 (12)
Clinical				
<i>Medication</i>				
Aspirin	587 (79)	1379 (75)	422 (80)	329 (83)
Beta-blocker	366 (49)	777 (42)	280 (53)	199 (50)
Calcium antagonist	428 (58)	817 (44)	316 (60)	229 (58)
ACE inhibitor	167 (23)	390 (21)	109 (21)	94 (24)
Nitrate	527 (71)	1026 (55)	386 (73)	273 (69)
Statin	189 (26)	361 (20)	142 (27)	108 (27)
Diabetes	104 (14)	216 (12)	70 (13)	57 (14)
<i>Severity of angina</i>				
CCS class I or II	258 (44)	621 (51)	185 (41)	125 (39)
CCS class III or IV	332 (56)	597 (49)	264 (59)	194 (61)
Previous myocardial infarction	350 (47)	765 (41)	243 (46)	208 (52)
<i>Angiographic findings</i>				
1 Diseased vessel	107 (14)	607 (33)	51 (10)	118 (30)
2 Diseased vessels	229 (31)	286 (16)	144 (27)	122 (30)
3 Diseased vessels/LMS	388 (52)	269 (15)	335 (63)	157 (40)
Impaired LV function	173 (29)	310 (20)	116 (27)	79 (25)
Previous PTCA/stent	51 (7)	185 (10)	27 (5)	41 (10)
Previous CABG	50 (7)	208 (11)	27 (5)	61 (15)

*176 patients underwent PTCA

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Table 9 shows the results from the logistic regression analysis.

Table 9 Determinants of CABG among appropriate patients

	n CABG/ n total	Univariable results* OR (95% CI)	Multivariable results OR (95% CI)
<i>Patients rated appropriate for CABG</i>	765/1119		
<i>Demographic</i>			
Age (Per year increase)	765/1119	1.01 (0.99,1.02)	0.99 (0.98,1.01)
Female	144/207	1.05 (0.75,1.45)	-
South Asian	89/156	0.58 (0.41,0.82)	0.49 (0.34,0.71)
<i>Medication</i>			
Aspirin	613/898	0.99 (0.72,1.36)	-
Beta-blocker	408/558	1.57 (1.22,2.02)	1.62 (1.23,2.14)
Calcium antagonist	446/651	1.00 (0.77,1.29)	-
ACE inhibitor	158/244	0.81 (0.60,1.10)	-
Nitrate	539/790	0.96 (0.73,1.27)	-
Statin	192/270	1.22 (0.90,1.65)	-
<i>Angina (Vs No Angina)</i>			
CCS class I or II	275/405	1.32 (0.91,1.94)	1.22 (0.82,1.82)
CCS class III or IV	391/551	1.53 (1.07,2.23)	2.03 (1.37,3.02)
Previous myocardial infarction	335/518	0.73 (0.57,0.95)	0.75 (0.57,0.99)
<i>Angiographic findings (Vs Single vessel disease)</i>			
2 Diseased vessels	197/315	1.78 (1.20,2.64)	1.70 (1.12,2.57)
3 Diseased vessels/left main stem	494/651	3.36 (2.32,4.86)	3.24 (2.18,4.82)
Impaired left ventricular function	175/259	0.96 (0.71,1.28)	-
Previous PTCA/stent	37/60	0.75 (0.44,1.30)	-
Previous CABG	35/104	0.20 (0.13,0.30)	0.21 (0.13,0.34)
High Operative Risk (Parsonnet score >8)	228/346	0.74 (0.55,1.00)	0.83 (0.60,1.17)

OR=Odds Ratio, CI=Confidence Interval, all variables yes versus no unless stated

*All adjusted for age

Among those that were appropriate for CABG, patients were more likely to undergo the procedure if they had higher number of diseased

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vessels, had no history of previous CABG or myocardial infarction, severe angina, or were on a beta-blocker. Further, South Asian patients were less likely to undergo CABG. While high operative risk patients were less likely to undergo CABG in the univariable analysis, in the multivariable model this was no longer a significant factor.

Case note data were abstracted for 2593 patients. Among these patients, 927 were appropriate for CABG, of whom 530 (57%) underwent CABG and 397 (43%) did not (patients underwent PTCA (n=176) or were managed medically).

Table 10 shows that patient preference was recorded as a reason for not undergoing CABG, but that this was rare. When it was recorded there was little additional information. Data on "did not attend", reasons for coming off the waiting list, use of translation and advocacy services and other "administrative" factors was missing and hence was not included in the table.

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Table 10 Procedure preference comparing patients

	All patients (n=2593)			Patients appropriate for CABG (n=927)		
	CABG performed (n=742)	CABG not performed (n=1851)	Data missing	CABG performed (n=530)	CABG not performed (n=397)	Data missing
	n (%)	n (%)	%	n (%)	n (%)	%
Reason patient not considered for PCI			86.3			82.8
Patient preference	0	5 (2)		0	2 (4)	
Reason patient not put on waiting list for PCI			99.9			99.8
Patient preference	0	1 (100)		0	1 (100)	
Reason patient did not receive PCI			99.5			99.7
Patient preference	0	1 (10)		0	0	
Reason patient not considered for CABG			97.1			98.0
Patient preference	1 (20)	3 (4)		1 (20)	1 (7)	
Reason patient not put on waiting list for CABG			99.8			99.7
Patient preference	0	2 (50)		0	2 (67)	
Reason patient did not receive CABG			99.7			99.2
Patient preference	0	3 (33)		0	1 (14)	

4.3.2 Variation in revascularisation of appropriate patients across cardiologists

In the ACRE cohort, 1353 patients were rated appropriate for CABG, of whom 234 patients underwent PTCA. Of the remaining 1119 patients, 765 (68%) underwent CABG and the remainder were managed medically (32%). 908 patients were rated appropriate for PTCA, of whom 273 patients underwent CABG. Of the remaining 635 patients 327 (52%) underwent PTCA and the remainder (48%) were managed medically.

Table 11 shows the breakdown of procedures performed for each cardiologist among patient rated appropriate for specific revascularization procedure. Across individual cardiologists the proportion undergoing CABG ranged from 54% (cardiologist I) to 75% (cardiologist C). Patients under 'Other' cardiologist include a combination of cardiologists performing a small number of angiography procedures as well as patients already being considered for CABG by a surgeon. Therefore, not surprisingly a higher proportion of these patients underwent CABG (84%). For patients rated appropriate for PTCA, the proportion undergoing PTCA ranges (across individual cardiologists) from 36% (cardiologist I) and 78% (cardiologist O).

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Table 11 N CABG and PTCA procedures performed

Cardiologist	Appropriate for CABG	CABG n (%)	Appropriate for PTCA	PTCA n (%)
A	116	74(64)	83	46(55)
B	8	6(74)	6	3(50)
C	132	99(75)	41	15(37)
D	38	28(74)	32	23(72)
E	115	84(74)	58	34(59)
F	112	77(69)	75	41(55)
G	65	42(65)	31	10(32)
H	116	69(60)	61	29(48)
I	24	13(54)	11	4(36)
J	32	23(72)	21	10(48)
K	24	14(58)	38	26(68)
L	14	8(57)	8	4(50)
M	89	61(69)	54	23(43)
N	103	60(58)	74	40(54)
O	20	14(70)	9	7(78)
Other [†]	111	93 (84)	32	13 (40)
Total n (%)	1119*	765(68)	635**	327(51)

[†]Includes patients under consideration by a surgeon

*A further 234 patients were rated appropriate for CABG and underwent PTCA

**A further 273 patients were rated appropriate for PTCA and underwent CABG

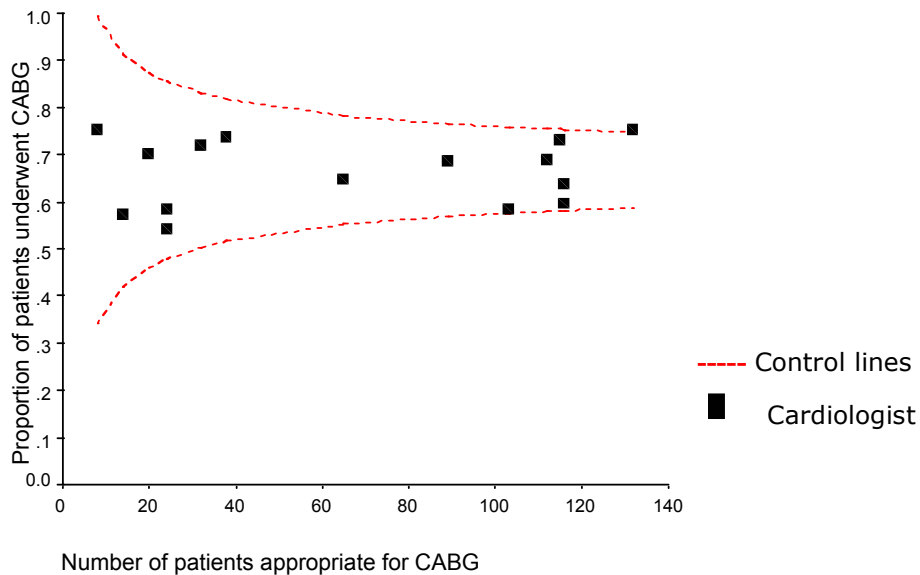
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Figures 14 and 15 are funnel plots, which show for each individual cardiologist the number of their patients rated appropriate for a specific procedure plotted against the proportion of patients undergoing that procedure. Cardiologists (black squares) falling outside the control lines (dashed lines) are considered outliers.

For patients rated appropriate for CABG, no individual cardiologist varies systematically from another, as all data points lie within the control lines (figure 14).

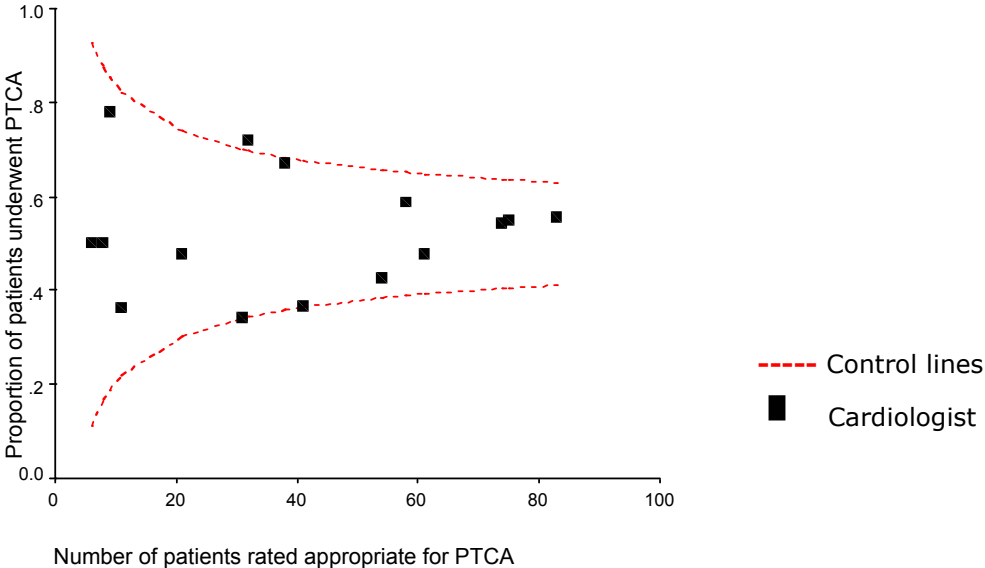
For PTCA, although one cardiologist lies just outside the control lines we would expect to see this by chance (figure 15). Therefore as for CABG, no cardiologist varies systematically in terms of the proportion of patients undergoing PTCA.

Figure 14 Variation in CABG in patients rated appropriate across cardiologists



*rated appropriate for CABG

Figure 15 Variation in PTCA in patients rated appropriate across cardiologists



**rated appropriate for PTCA*

4.4 Discussion

4.4.1 Patient preference as a factor in access

We found that patient preference is a rarely recorded reason for not undergoing coronary revascularization. This is consistent with studies among insured populations in the US. However, there is an important limitation in the study: the data were obtained by retrospectively reviewing case records, and cannot reflect the process by which a patient has, or expresses, a preference. A prospective study in which consultations are observed might elucidate the role of patient preference. Further, it is likely that patient preference may increase in importance over time. Patient involvement in clinical decision making is increasingly advocated and it is increasingly recognised that the utilities of angina determined by patients differ materially from those assigned by their doctors (Nease, 1995).

4.4.2 Organisational and administrative barriers to access

We found that south Asians were less likely to undergo CABG among patients for whom the procedure was deemed appropriate. Importantly there was no difference among ethnic groups in the physician recommendation for revascularization. One possible explanation is that consultations took place without translation or advocacy services. We found no record of such services, nor other aspects of the organisation or administration of care which might allow better understanding of the reasons for this poor access. A whole system approach to improving access to care, should consider how it implements and monitors the communications of decisions once reached. A limitation of our study is that we examined organisational barriers downstream from primary care and are unable to elucidate the contribution of general practitioners as gate keepers to barriers of access. Implementing the appropriateness ratings in primary care (where our qualitative work has shown general acceptance of the expert panel ratings) is likely to improve underuse of investigations, but a trial involving real patients is needed to determine this.

4.4.3 Outlier physicians as barriers to access

We found no evidence for the hypothesis that individual physicians systematically differed with the expert panel and contributed unduly to practice variations. Instead we found evidence that each physician underused revascularization within statistical limits. This observation underscores the importance of interventions to improve access which are system wide and involve all decision makers.

4.4.4 Conclusions

This study was unable to demonstrate the relative importance of patient preference in underuse of revascularization although the qualitative study suggests that on a smaller scale patient preference does matter, at least earlier on in the patient pathway. Whether patient involvement differs by procedure is unknown but it is possible that patients may not wish to be or feel less able to be involved were clinical decisions are perceived as complex and far reaching as with surgery for example. Our research highlights the lack of documentation of patient preference or decisions of the clinical team and further research needs to elucidate whether this is due to a genuine lack of patient involvement or simply not recorded. However, from a medicolegal point of view it seems unlikely that a patient's refusal of surgery would go unrecorded.

We found no evidence for the hypothesis that individual physicians systematically differed with the expert panel and contributed unduly to practice variations. Instead we found evidence that each physician underused revascularization within statistical limits. This observation underscores the importance of interventions to improve access, which are system wide and involve all decision makers. Some possible reasons for this individual variation within all clinicians were highlighted by our qualitative research. A system-wide use of appropriateness ratings, once they are sufficiently developed to be used in clinical practice, may help reduce this overall small variation in decision making which seems to account for the observed underuse of procedures.

Section 5 Summary of findings, conclusions and implications

This project aimed to evaluate appropriateness ratings as an innovative healthcare technology to improve access to effective care for patients with angina by:

- Evaluating the effectiveness of appropriateness ratings compared to guidelines in a randomised trial of intended access to hospital management.
- Evaluating, as part of the randomised trial, the appropriateness ratings against criteria of equity.
- Evaluating the acceptability of appropriateness ratings to patients and clinicians in a qualitative study.
- Evaluating organisational, professional and patient barriers to access to revascularization using appropriateness methodology.

5.1 Summary of findings

This section summarises the findings, based on results from all four research objectives.

We found that conventional guidelines had little effect on outcome within or between trial arms for either investigation, or in either speciality. However, the ratings intervention resulted in twice as many recommendations, which were in concordance with best practice. We have shown that, measured against best practice standards used in the guidelines, providing clinicians with facilitated access to relevant guideline extracts (optimum conditions) had no effect on testing behaviour. Older, female and south Asian patient vignettes demonstrated the same degree of increased agreement among specific decision support, highlighting the potential capacity of ratings to reduce inequities in access.

Despite these positive findings, insights from the qualitative component of our study and findings from the comparison of two independent expert panels revealed that the ratings tool itself needs to be developed further and it is not known whether ratings have the capacity to change decision making in real life. In addition, resistance to change and scepticism need to be overcome in any implementation strategy for it to be successful. ARIA –QUAL demonstrated the challenge of design and implementation of decision support intervention within real clinical settings.

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Our analysis of existing data in the ACRE study showed that deviation from best practice was not due to clinician outliers and that there was little evidence that patient preference or non-attendance played a major role in explaining heterogeneity. We found that patient preference is a rarely recorded reason for not undergoing coronary revascularization.

We found no evidence for the hypothesis that individual physicians systematically differed with the expert panel and contributed unduly to practice variations. Instead we found evidence that each physician underused revascularization within statistical limits. This observation underscores the importance of interventions to improve access which are system wide and involve all decision makers.

5.2 Generalisability of results

Our findings, both quantitative and qualitative, may, with caution, be generalised to other conditions. For example, the fact that patients felt comfortable with clinicians using computer aided decision making tools, the physical space of the clinic, the joint nature of decision-making, the importance of the culture of decision-making, or the context of decision making in relation to complex/simple cases, may all be relevant in other chronic conditions. Another crucial issue applicable to health care per se is that improved access requires an understanding of social and clinical contexts. This is not unique to heart disease. Nor is the importance of verbal and non-verbal communication.

5.3 Implications

5.3.1 Implications for clinical practice

The findings from the ARIA trial will be of interest to GPs in terms of referral and communicating referral to patients (many patients attending the chest pain clinics were unaware that they were seeing a 'heart doctor'). It will also be of interest to secondary/tertiary care doctors both in terms of medical curricula (the importance of the ARIA-QUAL findings on context, collegiate versus single decision-making, non-verbal communication, non-clinical holistic criteria such as reassurance etc) and more senior doctors (in terms of recognising the role of context in decision-making). Older people, women and ethnic minorities may use verbal and non-verbal communication, and negotiate the physician consultation in ways which differ from younger people, men, and whites. Improving access to investigation which is equitable across age, sex and ethnicity needs to pay attention to these differences.

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Implementation of appropriateness ratings may need to differ in primary and secondary care, as in the latter decisions in outpatient departments or chest pain clinics are often made within the team. In primary care, appropriateness ratings may make a significant difference, as this is where most of the decisions not to refer are likely to occur. We have shown that appropriateness ratings are acceptable to GPs and to a lesser extent to specialists.

Consideration should be given to standardised methods of taking a history among patients with suspected angina in primary and secondary care. This in itself might have the function of reducing practice variations and would facilitate the introduction of decision support with appropriateness ratings which by their nature, require history to be classified (as typical, atypical or non-specific).

We found that clinicians used ETTs inappropriately where it was a convenient way to reassure patients or overturn the diagnosis of a colleague. Evaluating and dealing with these issues is paramount to prevent inappropriate decisions being made despite the ratings. However, if the culture in the clinic can be changed appropriateness ratings have the potential to improve decision making in cardiologists as well as general practitioners as we have demonstrated in the ARIA trial.

5.3.2 Implications for patients

A prospective study in which consultations are observed might elucidate the role of patient preference, which we have found not to play a major role, consistent with literature from the UK and the US. However, it is likely that patient preference may increase in importance over time. Patient involvement in clinical decision making is increasingly advocated and it is increasingly recognised that the utilities of angina determined by patients differ materially from those assigned by their doctors. In addition, meeting patient information is important from the initial consultation, and requires revision as new information comes to light. However this involves clinicians sharing uncertainty, which is a challenge. We found that patients attending RACPCs were unaware of the nature of the clinic, not always aware that they were seeing a heart specialist. Informing patients and improving communication and shared decision making represents a major challenge to making the appropriateness ratings work in clinical practice.

5.3.3 Implications for policy makers

The role of guidelines

Our results from the ARIA trial as well as the qualitative work have demonstrated little impact of conventional guidelines amongst physicians. This calls into question the way guidelines are currently

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promoted as a quality of care benchmark and a means of improving clinical decision-making.

Ratings as quality benchmark and measure of need

Our qualitative and quantitative findings support the future use of appropriateness ratings in clinical practice. Government is an audience in terms of improving appropriateness ratings (see 5.3.5 on implications for research). If the distinction between exercise ECG and angiography is critical, then the two fold differences in underuse defined by the ARIA panels suggests that the criteria are not yet sufficiently reliable for policy use. However if the policy question is broader – which patients should receive either exercise ECG or angiography? – the criteria showed close agreement between two panels of experts in 89% of all indications.

In addition, appropriateness ratings offer an explicit tool for managing demand and waiting lists. Both locally and nationally, thresholds for interventions based on appropriateness ratings could be used to match demand with supply and also to assess need for expansion of services.

Insights from ARIA-QUAL suggest the importance of selecting the right experts on appropriateness panels so that their judgements are likely to find currency among a wide constituency of clinicians. If expert panels are seen as an extra tier in the decision making process then system-wide aspects of the intervention, involving training workshops may be required. Since an individual clinician may lose confidence in the tool if it appears unhelpful in even a small number of consecutive patients, feedback of results of decision making at a centre and clinician level may also be required to maintain confidence.

Implementation of appropriateness ratings in clinical practice

Institutional barriers such as the culture of the clinic need to be overcome for the ratings to work. Improving the ratings tool and testing the ratings in real patients will go some way in improving the acceptability of the ratings tool to clinicians.

The implementation of appropriateness ratings calls for a system-wide approach to improve decision making, based on our findings in objective 4. ARIA-QUAL provided an insight into the culture of decision making within the clinic: The power of consultants within the clinic setting will have a major influence on the acceptability of decision support systems. Consistent with the opinion leader model of clinician behaviour change, any implementation of such systems requires their commitment. The effect of curtained cubicles in contrast to rooms on peer involvement in clinical decision was one of the surprising findings of this study. Implementation of decision support may be a greater challenge in an open (i.e. curtained) setting where the decision making is less individual.

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Documentation in clinical practice

Much has been done already to improve documentation and continuity by introducing and improving comprehensive databases in primary and secondary care. However, improving the documentation of decision processes including patient preferences and decisions of the clinical team along the patient pathway present a further challenge highlighted by our findings in objective 4.

5.3.4 Implications for Research

Improving the appropriateness ratings

Improving the reproducibility of guidance for investigation requires a combination of better trial and observational evidence and refinements in methods for producing guidance. Our previous findings on the disparity of the two expert panels highlight three areas, which future panels might address. First, each panel appeared to develop its own culture of judgement, with agreement more likely between generalists and specialists on one panel than with their professional counterparts on the other panel. Panel A rated exercise ECG in accordance with the Bayesian testing principle adopted by all existing guidelines. Panel B did not rate according to this principle, and adopted a simpler heuristic based on the resting ECG. Social interactions within groups are recognised to influence the formulation of guidance (Pagliari, 2002) but research is required to elucidate its impact on between group differences.

Second, both panels were reluctant to rate exercise ECG as inappropriate, even in the large number of indications where the pre-test probability of disease was very low. This may reflect the difficulty clinicians have in actively deciding to "do nothing" particularly when the harm of doing an investigation like exercise ECG is perceived as low. The low rates of overuse for angiography are consistent with previous studies (Bernstein, 1993; McGlynn, 1994; Bengtson, 1994; Topol 1995). Third, the strongest determinant of an appropriate angiography was the presence or extent of exercise ECG abnormality, consistent with doctors being more influenced by a test result, than the whole patient (Topol, 1995). Since symptom relief is a major goal of revascularization, the comparative lack of influence of symptom severity was somewhat surprising. More research into developing the appropriateness method needs to start with research into the panel process and improving its reliability and reproducibility.

Randomised controlled trials involving real patients

The most important limitation of the ARIA trial is the lack of real patients. The positive trial supports the argument for further, albeit more costly, randomised trials to test whether among real patients specific guidance leads to better decisions and better outcomes (coronary death, non-fatal heart attack, angina symptoms). What

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clinicians say they will do on the web, and what they actually do in practice may not be the same thing. In addition, reducing inequity in patients of different age, sex and ethnicity needs to take account of different causal factors. Active discrimination on the part of clinicians seems rare, while different methods of communication between physician and patient (e.g. different description of symptoms, cultural differences, language barriers) may be important. The next step is to carry out a randomised trial of decision support in real patients. In the real world trial we will take account of the clinical context (i.e. culture) in design, conduct, analysis and interpretation. A major finding of ARIA-QUAL is the realisation of just how important that context is likely to be in the effectiveness of any decision support system. Thus, decision support systems may appear as if they are simple interventions, but, given the complex nature of the decision making process, it may be more helpful to consider the design of the trial as a complex intervention.

5.4 Conclusion

In summary, given the large heterogeneity of access to investigation and the comparatively poor prognosis of patients who are not investigated on the one hand, and the potential for implementation of appropriateness ratings into computerised clinician records on the other, the appropriateness method is a promising new technology.

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Appendix I Annotated bibliography of previous ACRE findings

1. Rating the appropriateness of coronary angiography, coronary angioplasty and coronary artery bypass grafting: the ACRE study. *J Public Health Med* 1999 Details the methods validity (internal consistency) and reliability of the ACRE expert panel ratings of appropriateness.

2. The magnitude and consequences of error in coronary angiography interpretation *Am J Cardiol* 2000 The agreement beyond chance between (1) the number of narrowed arteries on an angiographic report extracted from case notes and independent assessments by 2 cardiologists, and (2) actual patient management over an 18-month follow-up period and each cardiologist's hypothetical management proposal based on abstracted clinical details. In routine clinical practice, the agreement beyond chance in interpretation of the number of narrowed arteries was good. Disagreements on subsequent patient management arose as a result of, and independent of, errors in angiographic interpretation.

3. Waiting for coronary angiography: is there a clinically ordered queue? *Lancet* 2000 Among over 3000 patients undergoing coronary angiography in the absence of a formal queue-management system, we found that a-priori urgency scores were strongly associated with waiting times, prevalence of coronary-artery disease, rate of revascularization, and mortality. These data challenge the widely held assumption that such waiting lists are not clinically ordered; however, the wide variation in waiting times within urgency categories suggests the need for further improvements in clinical queuing.

4. Underuse of coronary revascularization procedures in patients considered appropriate candidates for revascularization. *N Engl J Med* 2001 BACKGROUND: Ratings by an expert panel of the appropriateness of treatments may offer better guidance for clinical practice than the variable decisions of individual clinicians, yet there have been no prospective studies of clinical outcomes. We compared the clinical outcomes of patients treated medically after angiography with those of patients who underwent revascularization, within groups defined by ratings of the degree of appropriateness of revascularization in varying clinical circumstances. A total of 2552 patients were followed for a median of 30 months after angiography. RESULTS: Of 908 patients with indications for which PTCA was rated appropriate (score, 7 to 9), 34 percent were treated medically; these patients were more likely to have angina at follow-up than those who underwent PTCA (odds ratio, 1.97; 95 percent confidence interval, 1.29 to 3.00). Of 1353 patients with indications

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for which CABG was considered appropriate, 26 percent were treated medically; they were more likely than those who underwent CABG to die or have a nonfatal myocardial infarction--the composite primary outcome (hazard ratio, 4.08; 95 percent confidence interval, 2.82 to 5.93)--and to have angina (odds ratio, 3.03; 95 percent confidence interval, 2.08 to 4.42). Furthermore, there was a graded relation between rating and outcome over the entire scale of appropriateness (P for linear trend=0.002). CONCLUSIONS: On the basis of the ratings of the expert panel, we identified substantial underuse of coronary revascularization among patients who were considered appropriate candidates for these procedures. Underuse was associated with adverse clinical outcomes.

5. Hypothetical ratings of coronary angiography appropriateness: are they associated with actual angiographic findings, mortality, and revascularization rate? *Heart* 2001 The indications for coronary angiography were rated appropriate in 2253 (62%) patients. 166 (5%) coronary angiograms were performed for indications rated inappropriate, largely for asymptomatic or atypical chest pain presentations. The remaining 1212 (33%) angiograms were rated uncertain, of which 47% were in patients with mild angina and no exercise ECG or in patients with unstable angina controlled by inpatient management. Three vessel disease was more likely among appropriate cases and normal coronaries were more likely among inappropriate cases ($p < 0.001$). Mortality and revascularization rates were highest among patients with an appropriate indication, intermediate in those with an uncertain indication, and lowest in the inappropriate group (log rank $p = 0.018$ and $p < 0.0001$, respectively). We concluded that the ACRE ratings of appropriateness for angiography predicted angiographic findings, mortality, and revascularization rates. These findings support the clinical usefulness of expert panel methods in defining criteria for performing coronary angiography

6. Gender differences in descriptions of angina symptoms and health problems immediately prior to angiography: *Soc.Sci Med* 2001. Content analysis was used to analyse written accounts of 'symptoms and health problems' in 200 (96 female) patients randomly selected within age strata who were undergoing coronary angiography for chronic stable angina. We conclude that from the time of angiography, gender differences in language use do exist and description of angina pain may influence subsequent revascularization. Further research is necessary to investigate the nature and consequences of gender differences in language use at this and earlier stages in the referral process

7. Ethnic differences in invasive management of coronary disease: prospective cohort study of patients undergoing angiography. *BMJ* 2002 Among 502 south Asian patients undergoing coronary angiography in the ACRE study there was no difference between south Asian and white patients in the proportions

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deemed appropriate for revascularization (72% (361) v 68% (2022)) or in the proportions for whom the physician's intended management was revascularization (39% (196) v 41% (1218)). Among patients appropriate for revascularization, age adjusted rates of coronary angioplasty (hazard ratio 0.69, 95% confidence interval 0.47 to 1.00, P=0.058) and coronary artery bypass grafting (0.74, 0.58 to 0.91, P=0.007) were lower in south Asian than in white patients. There were no differences in mortality and non-fatal myocardial infarction between south Asian and white patients (1.07, 0.78 to 1.47).

8. Population need for coronary revascularization: are national targets for England credible? *Heart* 2002 Using ACRE data and population based estimates of need, this study found that the national target of 1500 revascularization procedures per million population is credibly related to population need, although upper estimates of need are considerably higher. Better understanding is required of the benefits of referring patients with specific indications from primary care. The greatest relative increase in provision is required for those aged 75 and older, among whom trial evidence of benefit is scant.

9. Measuring spatial effects in time to event data: a case study using months from angiography to coronary artery bypass graft (CABG). *Stat.Med.* 2003 While the "postcode lottery" has been widely described in large areas, there has been little previous work investigating the size of spatial differences in small areas (here 488 electoral wards), when adjustment is made for individual level patient characteristics which have a major influence on need for surgery. Using Bayesian hierarchical models to measure spatial effects in time to event data, receipt of CABG was found to vary two fold after adjustment for age and number of diseased vessels.

10. Prospective validity of measuring angina severity with Canadian Cardiovascular Society class: The ACRE study. *Can.J.Cardiol.* 2004 The severity of angina symptoms, as measured using the CCS class, was linearly associated with angiographic findings, revascularization rates, mortality and nonfatal myocardial infarction. These findings support the importance of a four-level grading of symptom severity among angina patients, a key measurement in decisions on investigation and referral.

British Sociological Association Annual MedSoc Conference, York 2004

Abstract for lay / professional interface

Title: Pathways to Diagnosis: Making Sense of Patients' Descriptions of Chest Pain. The specialism of cardiology within biomedicine is dominated by technological advances in surgical techniques, therapeutics and diagnostics. Despite these technological advances the patient pain narratives remain one of the oldest and most effective, non-invasive diagnostic tests.

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This paper highlights the highly narrative based diagnostic process in heart-related chest pain classifications. Drawing on pain narratives collected at a Rapid Access Chest Pain Clinic in East London, the paper demonstrates the processes of preliminary diagnosis and subsequent decision making for further investigation and treatment of cardiac chest pain. The paper further argues how in clinical practice, the ways in which a patient describes their pain is often considered the most sensitive test to distinguish between cardiac and non-cardiac chest pain. In so doing, the paper considers how such narratives produce a well established diagnostic tool.

European Association of Social Anthropology Biennial Conference, Vienna 2004.

Abstract for workshop: Patient embodiment: Cold Distance and Emotional Proximity in Medical Practice.

Non-verbal communication in a chest pain clinic: The Tactile Cardiologists.

The initial diagnosis of cardiac chest pain is almost exclusively judged upon patients' descriptions of pain. The location, duration, radiation, precipitators (i.e. exertion) and 'type' (i.e. heavy, pressured, stabbing, aching, constricting) of pain are the key indicators used to identify chest pain of cardiac origin. Thus the verbalizations of pain in patient narratives form an integral component of diagnosis. However, recalling and then describing bodily pain is a notoriously difficult exercise (Scarry, 1985).

In the absence of language both patients and doctors engage in elaborate non-verbal bodily forms of communication during clinic consultations. This paper, based upon observations of over 100 consultations in a Rapid Access Chest Pain Clinic in a hospital in East London, describes some of these forms of communication. The paper considers how touching bodies (feeling the heart, chest, pointing to sites of pain) and the performance of pain by the doctor (using their own bodies to demonstrate pain - for example, a clenched fist) creates a particular intimacy between the patient and doctor. The bodies of both the patients and doctors engage in a non-verbal dialogue that elucidates narratives of pain where the spoken word is inadequate.

It is argued that the limitations of language, together with the insensitivity of non-invasive diagnostic technologies in the diagnosis of cardiac chest pain, have lead to unusually tactile clinical consultations where the body has become the core means of communication.

Appendix II ARIA vignettes

Vignette A1

Typical angina symptoms - No ExECG - age <40 - Men - CCS I/II - high risk - abnormal resting ECG - submaximal therapy

A 39 year old white Scottish publican had recently been diagnosed with type 2 diabetes and was trying to stop smoking tobacco but without success. He consulted his general practitioner concerned about sexual dysfunction. It was a long drawn-out consultation during which he commented on the occasional chest discomfort he experienced while shifting crates in the cellar of his pub. He first put this down to a muscular strain but the symptom persisted and while on holiday in Menorca he saw the hotel doctor who described his ECG as abnormal and prescribed amlodipine which had "helped a little". "On examination, he was thin and had winging of both scapulae. He was in regular rhythm with a blood pressure of 125/70 and the rest of the cardiovascular examination was normal." The resting ECG was abnormal.

Vignette A2

Typical angina symptoms - No ExECG - age 60-74 - Women - CCS I/II - low risk - abnormal resting ECG - submaximal therapy

"This 62 year old white woman presented to her general practitioner with a history of recent chest pain. Last month while at work she had been mopping floors with her colleague when she experienced pains in the left side of the chest. She was a non-smoker and had no family history of premature heart disease. The pains were described as a heaviness and were quite unlike anything she had experienced before. They were typically provoked by walking up hills while carrying her shopping and were associated with troublesome shortness of breath. On the flat, however, her exercise tolerance was unrestricted and she had only sought medical attention on the advice of a friend. She had never experienced rest pain. " On examination she looked well. The pulse was regular and the blood pressure 136 / 74. The heart sounds were normal and the jugular venous pressure was not elevated. The resting ECG was abnormal.

Vignette A3

Typical angina symptoms - ExECG normal - Age 50-59 - men - CCS III - low risk - maximal therapy

"A 59 year old white electronics factory worker consulted his general practitioner because of worsening chest pain. He had presented with chest pain three months previously and received glyceryl trinitrate for symptom relief and was referred for an exercise ECG. He experienced continuing symptoms, despite using long acting nitrates, beta-blockers and a calcium channel blocker. His other medication included an SSRI after the recent divorce from his wife plunged him into a persistently low mood. He had never smoked but drank 45 units of alcohol per week, mostly at weekends. Exacerbations occurred in response to exertion, such that he could not walk more than 100 yards on the flat without stopping. He was anxious about the symptoms as he could not afford to give up his job, even though working in the factory was not particularly physically demanding. His medical history was uneventful apart from a carpal tunnel syndrome which was successfully treated with a decompression procedure." The cardiovascular examination was normal with a blood pressure of 130/72. Previous normal exercise ECG.

Vignette A4

Atypical angina symptoms - No ExECG - age <40 - Women - mild functional impairment - low risk - normal resting ECG - submaximal therapy

"This 38 year old white bakery assistant was seen at the cardiology outpatient clinic after attending the emergency room with chest pain two months ago. She had been watching television with her partner when an argument developed. She became extremely distressed and felt that she was being "gripped" by a pain in her central chest so that she could scarcely breathe. This was associated with pins and needles in her left arm. She went to the emergency room, but was allowed home after a negative troponin assay. Since then she had had further episodes of chest pain which tended to go away when she rested and did not interfere with daily activities, but did distress her. She didn't smoke but volunteered the information that her older cousin had angina." "She had a blood pressure of 136/76 with a regular pulse. Auscultation revealed a soft late systolic murmur at the cardiac apex, suggestive of mild mitral valve prolapse but there was no evidence of heart failure. " Her resting ECG was reported as normal.

Vignette A5

Atypical angina symptoms - No ExECG - age 40-49 - Women - mild functional impairment - high risk - normal resting ECG - submaximal therapy

"A 46 year old white nurse who had diabetes and smoked, consulted her general practitioner because of chest pain that had been occurring intermittently over the previous 12 months. The pain was central with an aching quality, lasting about 10 minutes at a time. It was usually associated with transient fluttering sensations in the chest and tended to occur when she was in a hurry, less often when she was watching television or lying in bed. Nevertheless, she had lost no time off work for these symptoms and remained an active member of the ballroom dancing club. On two recent occasions she had experienced stabbing pains in the right side of the chest that were more severe and on the advice of her ward sister had made an appointment to see her general practitioner. At the time of the consultation she was already on treatment with aspirin and nicorandil prescribed by the occupational doctor at her hospital. "The examination revealed a cholecystectomy scar and evidence of xanthelasmata, although there were no abnormal cardiovascular findings." The resting ECG was normal.

Vignette A6

Atypical angina symptoms - ExECG abnormal - Age <40 - men - mild functional impairment - high risk - submaximal therapy

"A 39 year white unemployed IT consultant went to see his general practitioner following an episode of chest pain which had come on during a domestic argument. He was heavy smoker on treatment with amlodipine for hypertension. He admitted to previous episodes of chest pain, usually in relation to emotional stress, but there was no clear exertional component. The pains were described as an aching discomfort across the top of the chest lasting no longer than 15 minutes although residual "heaviness" in the chest often persisted for several hours. Despite the symptoms being "unpleasant" he could still do his occasional job as a bicycle courier to earn some money." On examination he had a ragged scar in the left side of the chest where he had injured himself in a cycling accident only 3 years previously. He has a regular pulse with the blood pressure at 152/86. "He had a total cholesterol of 5.8 mmol/l. An exercise ECG was organised and although this failed to provoke chest pain, it was reported as being abnormal with 1.5mm of ST depression in the inferior leads."

Vignette A7

Non-specific chest pain - ExECG abnormal - Age 50-59 - men - mild to moderate functional impairment - medium risk - submaximal therapy

"A 52 year old white man with a long history of depression was seen in the rapid access chest pain clinic complaining of shooting pains in the chest and left arm, often associated with intermittent palpitations. The pains were transient and not consistently related to exertion so that he could still carry out any physical activity without restrictions. However the symptoms caused him considerable anxiety such that he now preferred to stay at home in the evenings rather than meet his friends in the local pub. He ran a failing mail order business and had long been under financial stress, possibly contributing towards his labile blood pressure, now controlled with atenolol and amlodipine. His only other medical treatment was sildenafil which he took very occasionally at weekends. " "On examination he had a deeply pigmented birth-mark on his right shoulder. The pulse was regular, the blood pressure 140/84, and the heart sounds were normal. " "A routine exercise ECG, performed as part of the chest pain clinic's protocol, failed to provoke symptoms but was associated with 1.5 mm of anteroseptal ST segment depression at peak exercise."

Vignette A8

Non-specific chest pain - No ExECG - Age 60-74 - women - mild to moderate functional impairment - low risk - normal resting ECG - maximal therapy "

A 72 year old white widow informed her general practitioner of intermittent chest pains occurring about once every 10 days. She had lived in Spain but returned to the UK recently after the death of her husband. She found the chest pain symptoms hard to differentiate from the indigestion that had been diagnosed a few years ago. The pains were central in the lower chest and epigastrium and had a burning character, usually occurring at night, rarely in relation to exertion. Indeed her ability to do housework and shopping was diminished more by loss of confidence than by the chest pain. However, the antacids were no longer effective and the introduction of nitrates, beta-blockers and finally calcium channel blockers had not relieved the symptoms. She had never smoked." "On examination her cardiovascular system was normal, although her epigastrium was tender on palpitation." The resting ECG was normal.

Vignette A9

Non-specific chest pain - No ExECG - Age 60-74 - men - mild to moderate functional impairment - medium risk - normal resting ECG - submaximal therapy"

A 67 year old Punjabi shop keeper requested an appointment with his general practitioner because of discomfort in the chest. These had been occurring about once a week for a year or more, and were described as a numbness in the left precordial region, often lasting several hours at a time. The numbness was not made worse by physical activity but the symptoms occurred more frequently when under stress such that he felt less able to run his business with the efficiency he was used to. He was a non-smoker, having stopped 9 years previously. When seen again 4 weeks later he reported only minor improvement in his symptoms which remained troublesome when under stress. He was treated with simvastatin, and a beta-blocker. "

His total cholesterol was 7.2 mmol/l. The resting ECG was normal.

Vignette A10

Previous abnormal angiogram - revasc - with ExECG - ExECG normal - age 60-74 - typical angina symptoms - CCS III/IV - submaximal therapy

"A 66 year old Bangladeshi retired child minder presented in cardiology outpatients for review. Nine months previously she had undergone coronary stenting for circumflex disease. Over the last 6 weeks she began to develop new symptoms. Whereas before she could walk to the mosque, now she had to have a lift from her son. On some days she got constricting pain in the middle of her chest when she was sitting reading. She was on aspirin, a statin and a long acting nitrate." "On examination she had a regular pulse, her blood pressure was 118/76 and she had a soft ejection murmur at the base of the heart, which had been previously noted. Otherwise her cardiovascular examination was normal." "The exercise ECG carried out at her outpatient visit was normal at peak exercise, when the patient achieved 80% of her predicted heart rate."

Vignette A11

Previous abnormal angiogram - no revasc - angio > 1 yr ago - without ExECG - age <60 - typical symptoms - CCS III/IV - maximal therapy

"A 59 year old white head mistress was seen as an outpatient for evaluation of chest pains. She was well known at the hospital and had a long history of irritable bowel symptoms which had been fully

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investigated by a gastroenterologist. After a sigmoidoscopy she developed pains in the chest resulting eventually in cardiac catheterisation two years ago. The angiogram showed significant circumflex disease. Aspirin, short acting nitrates and a beta-blocker were added to her treatment regime at that time and also a calcium channel blocker to manage her hypertension. However, epigastric and chest pains persisted, aggravated by eating and also on occasions by exertion, with some relief from both antacids and nitrates. Recently she had been woken from sleep on a number of occasions by pains in the lower part of the chest and she was finding it difficult to work." "On examination she was tender in the abdomen but there were no abnormal cardiovascular findings, with a well controlled blood pressure at 138/79."

Vignette A12

Previous acute coronary syndrome - ACS > 1 yr ago - without ExECG - age <60 - typical symptoms - CCS I/II - maximal therapy

"This 56 year old white sculptor was seen in the outpatient department of her local hospital for review after acute myocardial infarction for which she had been admitted 14 months previously. The infarct was her first cardiac presentation. She had received thrombolytic therapy in the emergency department. Soon after discharge, she started experiencing occasional central chest pains similar to the "indigestion" she had experienced before the infarct. These were usually provoked by exertion, with radiation into the jaw. The glyceryl trinitrate spray she had been given to take home produced prompt relief of her symptoms and they did not stop her from working on a large commission for a city bank. Her lower back pain did require her to take some time off work. Over the past 6 weeks her general practitioner had gradually increased her medication so in addition to her short acting nitrate she was given a high-dose beta blocker and a calcium channel blocker, but her symptoms continued to recur." "On examination she was overweight, had a regular pulse and a blood pressure of 126/84."

Vignette B1

Typical angina symptoms - No ExECG - age 40-49 - Women - CCS I/II low risk - normal resting ECG - submaximal therapy

"A 48 year old white IT manager consulted her general practitioner after her husband had had a heart attack. Since her husband's hospitalisation with myocardial infarction 6 weeks ago she had started to develop pain in her chest, which she described as "tight." This had started during a step class at her gym, and went away when she sat down in the changing rooms. She had continued to attend the gym, but was "taking it easy". She had never smoked." On examination she

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had a pulse rate of 65 and a blood pressure of 126/72. Her fasting venous plasma glucose was 5.9mmol/l and her total cholesterol was 4.2mmol/l. Her resting ECG was normal.

Vignette B2

Typical angina symptoms - No ExECG - age 50-59 - Women - CCS I/II - high risk - abnormal resting ECG - submaximal therapy

"A 59 year old white retired hairdresser consulted her general practitioner for a further opinion about troublesome chest pains. These had started 10 years previously at which time she had stopped smoking and started on treatment for hypertension and dyslipidaemia. Her medical history included a hysterectomy for fibroids and low back pain. On direct questioning, she described the chest pain as a mildly constricting discomfort that was retrosternal with radiation to the left arm. The symptoms were provoked usually by exercise although they rarely stopped her walking. She was taking a beta-blocker, aspirin, intermittent glyceryl trinitrate and a statin." On examination she had a regular pulse with a blood pressure of 154 / 92 and a body mass index of 34. Otherwise the cardiovascular examination was normal. Her total cholesterol was 6.7 mmol/l. The resting ECG was abnormal.

Vignette B3

Typical angina symptoms - No ExECG - age 75-84 - Men - CCS III - low risk - abnormal resting ECG - maximal therapy

"A 77 year old white retired car mechanic consulted his general practitioner complaining of chest pain. He had first noticed this a few months ago while pushing his car at which time he thought that he had pulled a muscle. Over the previous 4 weeks a similar pain had returned and become increasingly disabling. He was very active for his age but found that he could do little before getting this "bad ache" in his chest. At the time of the consultation he reported 3 episodes when the pain had come on when he was sitting reading his newspaper. His uncle, a heavy smoker, had died suddenly with a heart attack 3 months previously. The patient had stopped smoking two years ago, although his alcohol consumption was excessive (40 units per week). " On examination he had a regular pulse and his blood pressure was 132 / 78. He had a soft ejection murmur at the base of the heart but the carotid upstroke was normal and he was not in heart failure. The resting ECG was normal.

Vignette B4

Atypical angina symptoms - No ExECG - age 50-59 - Women - mild functional impairment - high risk - normal resting ECG - submaximal therapy

"This 59 year old Bengali grandmother spoke no English and the history was obtained from her 22 year old daughter who acted as interpreter. The patient had a long history of diabetes and raised blood pressure and had been chewing tobacco paan for most of her adult life. The woman was complaining of exertional shortness of breath over the previous 9 months but still went shopping to the local market, which was half a mile away, and cooked regular meals for her large extended family. The shortness of breath was inconsistently associated with right-sided chest pain which was localised with a stabbing quality. She denied orthopnoea and had occasional ankle swelling towards the end of the day. Treatment included metformin, a low dose thiazide, a calcium channel blocker and a statin." "On examination she was obese, but the blood pressure was well controlled at 134/76 and the cardiovascular examination was normal." The resting ECG was normal.

Vignette B5

Atypical angina symptoms - ExECG normal - Age 50-59 - men - mild functional impairment - low risk - maximal therapy

"A 58 year old white man consulted his general practitioner complaining of occasional aching pains sometimes in the left side of the chest sometimes in the right, often with radiation to the left arm. He had been given nitrates, a beta-blocker and aspirin by his GP but reported no improvement in his symptoms which were occurring 2 or 3 times a week sometimes (not always) in relation to exertion. He worked as a ticket inspector on the Eurostar train and found that very occasionally he had to sit down and rest although most of the time he could walk the length of the train without difficulty. He described them as an aching sensation lasting up to 20 minutes at a time and occurring 2 or 3 times a week, often (but not always) related to exertion. He had never smoked and there was no family history of premature heart disease." The cardiovascular examination was normal. He was referred for an exercise ECG recently which was normal.

Vignette B6

Atypical angina symptoms - ExECG abnormal - Age 60-74 - men - mild functional impairment - high risk - submaximal therapy

"A 66 year old white retired anthropologist, previously a university lecturer, consulted his general practitioner complaining of central chest pain over the previous 9 months. As a result of his fieldwork he contracted malaria several times, which had been effectively treated. The chest pain he complained of was intermittent, rarely lasting longer than 5 or 10 minutes and occurred without provocation and often at rest. There was no clear exertional component and he was able to lead a normal life, which included regular visits to his local gym. He was a cigarette smoker on treatment for hypertension with a strong family history of premature coronary artery disease, his brother having recently undergone coronary stenting. His general practitioner had prescribed aspirin, glyceryl trinitrate and a betablocker. " Auscultation revealed a late systolic murmur at the cardiac apex but there were no other abnormalities in his cardiovascular examination. An exercise ECG was carried out which showed abnormal results.

Vignette B7

Non-specific chest pain - No ExECG - Age 40-49 - women - mild to moderate functional impairment - medium risk - normal resting ECG - submaximal therapy

"A 43 year old white manager of a betting shop consulted her general practitioner because of pain in the jaw and neck. It had been coming and going over a period of 2 months with no clear provocative factors. She described it as a localised pain sometimes reaching the upper chest and usually lasting no longer than a minute or two at a time. She was puzzled by the fact that she "couldn't work out why it comes and goes". Although she was still able to work, some of the heavier housework had become more difficult because of the pain. She was a regular smoker but had no other risk factors for coronary artery disease." On examination she had a regular pulse with a blood pressure 146 / 90. The heart sounds were normal apart from a few crackles over the lung bases. There was no evidence of heart failure. The resting ECG was interpreted as normal.

Vignette B8

Non-specific chest pain - No ExECG - Age 60-74 - men - mild to moderate functional impairment - low risk - abnormal resting ECG - submaximal therapy

"A 72 year old white retired civil servant with no known cardiovascular risk factors had consulted a herbalist on a number of occasions,

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concerned about a sharp pain he had been experiencing in the lower part of the chest over the previous 6 years. This had worried him and he had cut back on some of his activities, resigning from the golf club even though the pains were not particularly associated with walking. Sometimes the pains would last a few seconds and sometimes they would last for a few hours. Indeed, the chest pains were usually unprovoked, but sometimes occurred while driving and on one occasion while arguing with his brother in law. He had been given various herbal remedies, which did nothing to improve his symptoms. He therefore turned to his general practitioner who recommended treatment with nitrates and a low dose of amlodopine. The symptoms became somewhat less troublesome on this regime but he remained unable to go to golf, which had been the mainstay of his social life since the death of his wife." His cardiovascular examination was normal. Previous abnormal resting ECG.

Vignette B9

Previous acute coronary syndrome - ACS in last year - with ExECG - ExECG normal - age <60 - typical angina symptoms - CCS I/II - submaximal therapy

"A 57 year old white night security officer was referred to a general medical outpatient clinic complaining of exertional shortness of breath. He was an overweight smoker who had had chronic constipation over many years. Six months previously he had been seen at his local emergency department with severe dyspepsia but after 3 days in hospital had been diagnosed with unstable angina and sent home on aspirin, and nitrates. His shortness of breath had started at about that time but only slowed him down on steep hills when it was associated on occasions with central chest discomfort. These symptoms resolved rapidly when he rested and had not caused him to adjust his life-style or take time off work. " On examination he had an irregular pulse caused by ectopic beats and auscultation of the chest revealed a bilateral expiratory wheeze and a reduced peak flow of 480 l/min. But the rest of his cardiovascular system was normal. The exercise ECG carried out in the outpatient clinic was normal.

Vignette B10

Previous abnormal angiogram - revasc - without ExECG - age <60 - typical symptoms - CCS I/II - maximal therapy

"This 59 year old white MP was seen by her general practitioner for an opinion about central chest pain over a period of 6 weeks. The pains had a constricting character and radiated to the left shoulder. They were particularly troublesome when walking after a heavy meal but otherwise they did not interfere unduly with her busy constituency and Westminster business. 18 months previously she had undergone angioplasty and stenting to her right coronary artery, which had

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abolished her angina. Her recurrent symptoms were similar to those she had experienced before the stent had been inserted. She had quit smoking at the time of the angioplasty. She was on treatment for hypertension with an ACE inhibitor. She was also on a statin and aspirin and her general practitioner had re-started amlodopine, atenolol and isosorbide mononitrate and a beta-blocker." "On examination she had pectus cavus, a regular pulse and signs of mild aortic regurgitation but no signs of heart failure."

Vignette B11

Previous acute coronary syndrome - ACS > 1 yr ago - without ExECG - age <60 - atypical symptoms - CCS I/II - submaximal therapy

"This 59 year old white carpet layer consulted his general practitioner complaining of neck and arm pains. There was a longstanding history of frozen left shoulder, which had been treated with injections. 6 months ago he had complained of neck pain radiating to the left arm. A recent neck X-ray had found signs of cervical spondylosis. In the last 2 months he said that these pains had got worse: "the stabbing has spread into my chest" and although he was still able to work he now found that he needed help carrying the carpets. He had had a single hospital admission 7 years previously for treatment of unstable angina. His current medication was daily low dose aspirin and ibuprofen." "On examination he was a thin man with a restricted range of movements in his neck, but no neurological signs. Cardiovascular examination was normal."

Vignette B12

Previous acute coronary syndrome - ACS > 1 yr ago - without ExECG - age 75-84 - atypical symptoms - CCS III/IV - maximal therapy

"A 75 year old Afro-Caribbean volunteer in an age concern shop on the high street presented to the emergency department with chest pain. She had been admitted with unstable angina 6 years previously. Thereafter she had remained well with complete resolution of her symptoms on a beta-blocker, nitrates, calcium antagonist, aspirin and statin. Over the past 4 months she experienced intermittent epigastric pain, sometimes radiating into the chest and associated with exertion. Sometimes it responded to peppermint capsules and she assumed it was part of her Irritable Bowel Syndrome she had been diagnosed with previously. However, a more severe episode took her to the emergency department. At that time she felt she could hardly walk and the pain was all-consuming. " On examination she had epigastric tenderness but the cardiovascular examination was normal.

Vignette C1

Typical angina symptoms - No ExECG - age 40-49 - Men - CCS III - low risk - abnormal resting ECG - submaximal therapy

"This 45 year old white welder sought advice from his general practitioner for chest pains that had become increasingly severe over the previous 9 months. The first episodes occurred when he was working on an oil rig in the North sea and he ascribed them to the cold working conditions, but they persisted on his return to London. He described a left sided aching discomfort. On occasions the pain would radiate into the throat. His symptoms were now quite limiting and he could only manage to walk just round the block on the flat before having to stop for a rest. He was a non-smoker, non-diabetic, without a family history of CVD. " The cardiovascular examination was normal. The resting ECG was abnormal.

Vignette C2

Typical angina symptoms - No ExECG - age 75-84 - Women - CCS I/II - medium risk - normal resting ECG - submaximal therapy

"A 78 year old white retired dinner lady consulted her general practitioner. She had a long history of low back pain thought to be due to osteoporosis of the lumbar spine. On direct questioning she complained of intermittent chest pain radiating into the back over the previous 3 months. The symptoms had recently become more troublesome, although they did not restrict her unduly in her daily activities. The pains were central and described as tight and lasting up to 10 minutes at a time, sometimes associated with shortness of breath. She was unsure of any specific provocative factors but on direct questioning acknowledged that walking up stairs was associated with the symptoms, although she was more disturbed by the light-headed feeling she got on exertion. She had been prescribed a long acting nitrate and aspirin, a statin and a beta-blocker. " On examination she had psoriatic plaques on the elbows and knees and a kyphotic thoracic spine. The pulse was regular and the blood pressure 165 / 104. She had mild ankle odema but otherwise the cardiovascular examination was normal. The resting ECG was normal.

Vignette C3

Typical angina symptoms - ExECG abnormal - Age 50-59 - women - CCS I/II - low risk - submaximal therapy

"A 53 year old white stockbroker was seen by her general practitioner complaining of an ""annoying discomfort"" in her chest. She had first noticed this when playing golf with some clients and was most troubled by her embarrassment at not being able to continue beyond

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the 13th hole. She said that her chest felt constricted, and that taking a deep breath was difficult. On this and subsequent occasions her symptoms would resolve within minutes of stopping exercise and had never occurred at rest. She had a past medical history of cholecystitis treated with laparoscopic cholecystectomy and treatment for anxiety. Her general practitioner had also started her on aspirin and a beta-blocker, in addition to her hormone replacement therapy." Her cardiovascular system was normal on examination. The general practitioner organised an exercise ECG which was reported as abnormal.

Vignette C4

Atypical angina symptoms - No ExECG - age 60-74 - Men - severe functional impairment - medium risk - abnormal resting ECG - submaximal therapy

"A 61 year old white schoolteacher with a long history of hypertension saw his general practitioner for a check up on his blood pressure control. While his blood pressure was being taken, he mentioned that he had been experiencing difficulties at work, with the impending visit of the national school inspectorate. This would cause him to lie awake at night worrying about the possible outcome and recently he had found that his chest was "tight", although he found it difficult to say whether this was a pain or a difficulty in breathing. He had noticed that his left arm did feel heavy at the same time and a hot drink relieved the whole episode in about 5 minutes. Over the last week this tightness was present most of the time, and was confining him to his house." His blood pressure was 146 / 82 and the rest of his cardiovascular system was normal. The resting ECG was abnormal.

Vignette C5

Atypical angina symptoms - ExECG normal - Age 60-74 - women - mild functional impairment - medium risk - maximal therapy

"A 62 year old white house-wife who was a heavy smoker, had repeatedly consulted her general practitioner over a number of years because of low back pain and multiple other minor symptoms. Apart from the smoking she had no other cardiac risk factors. On a recent consultation, she mentioned pains in the left side of the chest which had been intermittently troublesome the last 4 months, occurring infrequently - sometimes while hurrying for the bus but equally often with no obvious provocation. These new symptoms had not affected her day to day activities significantly and back pain remained her major preoccupation. She had been treated first with an increased dose of simple analgesics but when these failed to influence the chest pains she was prescribed nitrates with the later addition of beta-

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blockers and a calcium channel blocker, all to little avail. " Her cardiovascular examination was normal. An exercise ECG was organised which was reported normal.

Vignette C6

Atypical angina symptoms - No ExECG - age 40-49 - Men - mild functional impairment - high risk - normal resting ECG - submaximal therapy

"This 40 year old white man presented to the general practitioner out of hours service on a Saturday evening with central chest pain which had come on 8 hours previously while shifting some furniture in his basement. He had several similar episodes in the previous year, not always related to specific activities, but had not sought medical advice. The pain was initially sharp and localised but became more aching in quality as it spread across the chest and radiated into the left shoulder. It was associated with shortness of breath, which caused him to pause. Thereafter the pain eased off but never completely disappeared and while out shopping that same afternoon he had recurrent symptoms, although they remained mild. He was a cigarette smoker and currently taking oral hypoglycemics. He had a family history of premature myocardial infarction." Cardiovascular examination was normal. The resting ECG was normal.

Vignette C7

Non-specific chest pain - No ExECG - Age 40-49 - men - mild to moderate functional impairment - low risk - normal resting ECG - submaximal therapy

"A 49 year old white librarian was seen in the rapid access chest pain clinic complaining of pains in the left arm and intermittent palpitations. The pains were somewhat troublesome at night while lying in bed as were the palpitations which were described as fluttering sensations lasting no more than a second or two at a time, often associated with skipped beats. He was not troubled by pains on climbing the four flights of stairs to his flat. He had recently been prescribed a tricyclic antidepressant to help him sleep. He had never smoked and there was no family history of heart disease." On examination he was thin and had an irregular pulse. The blood pressure was 138 / 72. The resting ECG was normal.

Vignette C8

Non-specific chest pain - No ExECG - Age 60-74 - women - mild to moderate functional impairment - high risk - abnormal resting ECG - submaximal therapy

"A 72 year old white retired fashion buyer consulted her general practitioner complaining of intermittent pains localised to the lower part of the chest on the left hand side. The pains were sharp and lasted one or two minutes. There were occurring daily. Although she put them down to the strain of having to look after 3 young grandchildren, they did not seem to be related to physical activity as such. In any event she had indicated that she needed to give up some of her childcare responsibilities because of the pains. She was a lifelong smoker of 10 cigarettes a day." "On examination she was obese but normotensive (114 / 70 mmHg) with a regular pulse, normal heart sounds and no evidence of heart failure." She had a total cholesterol of 6.3 mmol/l and her fasting glucose was in the impaired tolerance range. The resting ECG was abnormal.

Vignette C9

Previous abnormal angiogram - revasc - with ExECG - ExECG abnormal - age 60-74 - atypical angina symptoms - CCS I/II - maximal therapy

"A 67 year retired white dermatologist consulted his general practitioner complaining of intermittent chest pains. He had been a frequent attender ever since a coronary artery bypass operation 18 months ago. Prior to surgery he has had troublesome exertional angina but had continued to experience chest pains ever since the operation, despite treatment with nitrates, beta-blockers, and a calcium-channel blocker. Overall the character of the pain was similar to his pre-operative pain but now bore no direct relation to exertion. He was a keen rambler but although he still went out walking every weekend with his Collie dog he found he was covering less ground than in previous years. His past medical history was uneventful except for a damaged knee meniscus from his rugby playing days." His cardiovascular system was normal on examination. An exercise ECG carried out at one of his recent visits was reported as abnormal.

Vignette C10

Previous abnormal angiogram - no revasc - angio > 1 yr ago - without ExECG - age 60-74 - typical symptoms - CCS III/IV - maximal therapy

"A 72 year old white retired post man presented to his general practitioner for review. He had undergone cardiac catheterisation 18

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months ago, which showed single vessel coronary artery disease which was managed medically with a beta blocker, calcium channel antagonist, aspirin and a long acting nitrate. His symptoms never really went away and about a month ago they became more frequent, occurring almost daily. He described a central chest pain that was crushing in nature. Sometimes it came on with exertion but recently he had had an episode while sitting in his armchair, watching television. " "On examination he had a chest wall deformity and tender to pressure over the left sternal edge. His blood pressure was 150/84, the heart sounds were barely audible and he had a normal pulse. His jugular venous pressure was raised 3 cms and he had mild peripheral oedema but clear lung fields."

Vignette C11

Previous acute coronary syndrome - ACS > 1 yr ago - without ExECG - age 60-74 - atypical symptoms - CCS III/IV - maximal therapy

"A 73 year old Indian retired Hoffmann presser in a clothes factory saw his general practitioner because of intermittent pains in the back, between the scapulae, often radiating through to the front of the chest. These had been troublesome over the previous 4 weeks, occurring without provocation and recently waking him at night. The pain had no clear relation to exertion but he was finding it increasingly difficult to manage the level walk to the nearby corner shop. Nine years previously he had spent 4 weeks in hospital in Delhi for treatment of a heart attack and had been taking aspirin, beta-blockers, and isosorbide dinitrate tablets since that time." On examination he had slightly swollen ankles but in other respects the cardiovascular findings were normal.

Vignette C12

Previous acute coronary syndrome - ACS > 1 yr ago - without ExECG - age 60-74 - atypical symptoms - CCS I/II - maximal therapy

"A 74 year old white retired bank manager presented to his general practitioner for review. He had been admitted with an acute myocardial infarction 2 years previously. The infarct was his first cardiac presentation and had been the culmination of 3 weeks of chest pains for which he had self-medicated with antacids. He had received thrombolytic therapy in the emergency department and apart from an episode of ventricular fibrillation the infarct had been uncomplicated. He developed no Q waves. Just recently he started to have recurrent discomfort in the central chest and upper abdomen, which prompted him to see his general practitioner. He could not discern a particular pattern to the pains: on a couple of occasions he found that hurrying to get the bus had brought the pains on, but resting did not reliably

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improve matters. Although he had cut down his activities a little he was still able to dig his garden. His general practitioner had added a nitrate and a calcium channel blocker to his medications. He was already on a statin, aspirin and a beta-blocker." "On examination he was overweight, with some tenderness in the epigastrium. The cardiovascular examination was normal, apart from a soft ejection murmur over the left sternal edge."

Vignette D1

Typical angina symptoms - No ExECG - age 50-59 - Women - CCS I/II - low risk - normal resting ECG - submaximal therapy

"A 55 year old white woman who was a fund-raiser for a national charity experienced an aching discomfort in her chest and left arm while carrying shopping into her house one morning. Her general practitioner treated her with a long-acting nitrate but she had another episode under similar circumstances 6 weeks later and then a third episode while organising a fun-run, which caused her to stop for a rest. She was a non-smoker, with no family history of premature heart disease." On examination her cardiovascular system was normal. A private medical check-up 5 years ago revealed a total cholesterol of 4.7 mmol/l. Her resting ECG was also normal.

Vignette D2

Typical angina symptoms - No ExECG - age 75-84 - Women - CCS III - low risk - abnormal resting ECG - submaximal therapy

A 78 year old white woman had been working as a street trader until a month before her consultation with her general practitioner when exertional central chest pains had become so troublesome that she had had to stay at home. Finally after a prolonged episode of rest pain she took herself to her doctor who noted that he had seen her only once before for treatment of a herpes zoster rash. She had never smoked and had 2 siblings older than her who were still alive.

"The cardiovascular examination was normal, the only notable finding was a rodent ulcer on her back." The resting ECG was abnormal.

Vignette D3

Typical angina symptoms - ExECG normal - Age 75-84 - men - CCS III - medium risk - maximal therapy

"This 78 year old white retired docker was diagnosed with angina 5 years previously when he received nitrates for his symptoms and treatment for hypertension, initially with a good symptomatic result.

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However 3 years later his symptoms returned although they remained very mild over the years and well controlled on treatment with a beta-blocker and aspirin in addition to his nitrates. His general practitioner had referred him for an exercise ECG at the time. In recent months the symptoms had got a lot more severe and at the time of his visit he was unable to walk more than 100 yards down the street without stopping. He rolled his own cigarettes and smoked about an ounce of tobacco a week." "On examination he was heavily tattooed, looked older than his years and had a rather ruddy complexion with a fine tremor. He was in sinus rhythm, the blood pressure 156/ 100. Auscultation revealed a late systolic murmur at the cardiac apex but there was no evidence of heart failure. He had a full set of pulses." The previous exercise ECG was normal.

Vignette D4

Atypical angina symptoms - No ExECG - age <40 - Men - mild functional impairment - high risk - abnormal resting ECG - submaximal therapy

"A 38 year old white advertising executive went on a team-building activity weekend which included paint balling, karaoke and raft construction. He had consulted a cardiologist four years previously during a visit to the United States following acute chest pain and shortness of breath associated with palpitations. This was attributed to a panic attack for which he was treated with a beta-blocker. Thereafter he had remained well until the activity weekend when he suddenly experienced intermittent stabbing pains in the middle side of the chest while retrieving material for the raft from the woods. He was worried enough to get his colleagues to take him to the local general practitioner. He smoked and had a strong family history of premature coronary artery disease." On examination there was no tenderness over the chest wall. He had a regular pulse with a blood pressure of 166 / 98 but the rest of the cardiovascular examination was normal. The resting ECG results were abnormal.

Vignette D5

Atypical angina symptoms - No ExECG - age 40-49 - Women - mild functional impairment - high risk - abnormal resting ECG - submaximal therapy

"A 45 year old Indian engineer consulted her general practitioner complaining of pains. She had noticed that when on site at work she was "seized" by a pain in the middle of the chest. Her colleagues had told her to sit down but this didn't seem to help. At other times the pain was described as sharp. Although the pain did not stop her from going about her daily business it started to worry her as she had a family history of premature coronary disease, her older brother (also a

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non-smoker) having recently had coronary angioplasty and stenting. She had a past medical history of diabetes and endometriosis. The only medication she was taking was an oral hypoglycaemic." On examination she had a normal pulse and a blood pressure of 168/ 95. She had normal heart sounds. Her pulses could not be felt in either foot but both appeared well perfused. The resting ECG was abnormal.

Vignette D6

Atypical angina symptoms - No ExECG - age 75-84 - Men - severe functional impairment - medium risk - abnormal resting ECG - submaximal therapy

"A 79 year white retired railway worker was being treated by his doctor for pains in the left shoulder which extended down the arm and also into the chest. These symptoms were often aggravated by movement of the neck, but also by simple physical activity although the relationship was not consistent. Nevertheless they were now causing him severe anxiety and had reached the point that he was largely confined to the house, lacking the confidence to go out to his evergreen club where he had been a stalwart for many years. He had quit smoking shortly after the war, and apart from hypertension treated with a low dose of diuretic he had an uneventful medical history. His general practitioner treated him with simple analgesics, a SSRI, and also a low dose of beta-blocker plus short acting nitrates." "On examination, he was in regular rhythm with occasional ectopic beats. The blood pressure was a little high at 178/95 and he had an ejection murmur at the base of the heart although the carotid upstroke was normal and there was nothing to suggest heart failure. " The resting ECG was abnormal.

Vignette D7

Non-specific chest pain - ExECG normal - Age 60-74 - women - severe functional impairment - low risk - maximal therapy

"This 64 year old Gujarati woman consulted her general practitioner because she had ongoing chest pains and said she felt unable to "do anything". Her symptoms had been troublesome over the previous 2 years, so much so that she gave up her job at the local department store which she loved, and had brought her to medical attention several times. She described a feeling of ""pins and needles"" across the anterior chest wall interspersed with stabbing discomfort in the left axilla. The symptoms were now almost continuous and caused her increasing distress such that she no longer offered to look after her grandchildren a couple of days a week after school. Her general practitioner had tried every combination of anti-anginal drugs with minimal effect on her symptoms." On examination she had a normal rate irregular pulse with ectopic beats and normal blood pressure. She

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had evidence of mitral valve prolapse but there was no other abnormality detected on examination. Her exercise ECG was normal.

Vignette D8

Non-specific chest pain - No ExECG - Age 40-49 - men - mild to moderate functional impairment - high risk - abnormal resting ECG - submaximal therapy

"A 47year old white local authority manager was referred for cardiological assessment at his local hospital because of episodes of chest pain. The first episode had occurred when he had been watching his favourite football team play in the cup final – and after extra time there was no winner. His team eventually won on the penalty shoot out. Within minutes of the final whistle, the patient developed a pain in his chest, head and abdomen which he said: "was so bad I thought I was going to die". However because it resolved within 1 or 2 minutes and because he was drunk, he did not seek medical care. He had several further episodes of pain, with no clear provocative factors. He described a localised aching discomfort sometimes in the left submammary region and at other times in the right usually lasting no longer than a minute or two at a time. Although there was no clear exertional component he found his symptoms at least moderately disabling and had not gone to work for 2 weeks. He was a heavy smoker with type II diabetes which was controlled on diet." On examination he was anxious with regular heart rhythm and a blood pressure of 163 / 95. The rest of the cardiovascular examination was normal. The resting ECG was abnormal.

Vignette D9

Non-specific chest pain - No ExECG - Age 75-84 - men - mild to moderate functional impairment - medium risk - normal resting ECG - submaximal therapy

"An 80 year old white ex Royal Air Force wing commander was referred for cardiological assessment at his local hospital complaining of stabbing chest pains, often radiating into the head and the shoulders. His medical history included cataracts for which he had had successful surgery 6 years previously. He had also had a hip arthroplasty, which restored his mobility. The chest pain had been occurring intermittently over a period of 3 months with no clear exacerbating factors. His exercise tolerance was restricted by shortness of breath attributed to asthma for which he used a beta agonist inhaler. Despite the asthma he continued to smoke pipe." On examination he had a regular pulse with a blood pressure of 156 / 88. There was a soft ejection murmur but the rest of the cardiovascular examination was normal. The resting ECG showed no abnormalities.

Vignette D10

Previous acute coronary syndrome - ACS > 1 yr ago - with ExECG - ExECG abnormal - age 75-84 - typical angina symptoms - CCS I/II - submaximal therapy

"A 79 year old white man was seen at his local outpatients 15 months after an admission to hospital with chest pain that was diagnosed as an acute coronary syndrome. He was discharged on a statin, a beta-blocker and aspirin and his general practitioner had added sublingual glyceryl trinitrate by the time of the outpatient visit. Soon after discharge he had started experiencing occasional central chest pains which came on within a few minutes of eating a large meal or when he took his dog for a walk. His wife had volunteered the information, that despite these pains, his life had not been all that much affected." His cardiovascular system was normal on examination. An exercise ECG did not reproduce the symptoms but did show 1mm ST depression inferiorly at peak exercise and was reported as abnormal.

Vignette D11

Previous abnormal angiogram - revasc - without ExECG - age 60-74 - typical symptoms - CCS III/IV - submaximal therapy

"A 64 year old white retired police woman was seen at the chest pain clinic of her local hospital. 5 years previously she had been involved in a road traffic accident sustaining a severe whiplash injury to the neck. Only a week later she had developed chest pains, leading to an angiogram and going on to angioplasty and stenting after the angiographic findings showed significant narrowing of the right coronary artery. Thereafter she was prescribed aspirin, statins and a beta-blocker, but the neck injury remained troublesome with chronic headache and pains in both arms. On occasions she also experienced pains in the left part of the chest and shoulder, which were often worse while walking her dog. On the evening before the consultation the chest pain had occurred while watching television, persisting on and off for 45 minutes. This time it was much worse and she felt that the pain was "like a band tightening around her chest" and she had trouble breathing properly." On examination she was tender over the shoulder area and movements of the neck provoked pain down the left arm. The cardiovascular examination was normal.

Vignette D12

Previous normal angiogram - angio in last year - without ExECG - age 60-74 - atypical symptoms - CCS I/II - high risk

"A 63 year old partly retired general practice receptionist who originated from Greece was referred back to the cardiology clinic of her local hospital for further assessment of chest pain. She had

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presented 8 months previously with chest pains and a cardiac catheterisation was carried out which showed minor irregularities with no significant stenoses. She had been reassured and thereafter had remained well with complete resolution of her symptoms. She was currently treated for hypothyroidism. In recent months however there had been some recurrence of the chest pain and she described it as a left sided aching discomfort, which was almost continuous with some exacerbation while walking. She was reluctant to take time off work because she enjoyed the social stimulation and she had experienced no significant difficulty carrying out her work even at times when the practice was very busy. She was a cigarette smoker on treatment for hypertension with a strong family history of premature coronary artery disease, her father having died of a heart attack at the age of 56."Her cardiovascular system was normal on examination.

Appendix III: Case note data collection form for objective 4

REFERRAL FOR PCI AND CABG

1. Does the angiography report indicate narrowing of the coronary arteries?

No ¹ Form completed.

Yes ² date of angiography ___/___/____
dd mm yyyy

2. Record any comments the cardiologist has made about the appropriate treatment for this patient, with dates.

3. Was this patient considered for PCI?

Write details

No ¹ a) Referred for CABG ¹ (go to question 8)

b) Coronary artery anatomy ² _____

c) Patients' preference ³ _____

d) High PCI risk ⁴ _____

e) Patient died ⁵ _____

f) Other ⁶ _____

Yes ² Give date dd mm ___/___/____
yyyy

4 Was this patient referred for PCI?

No ¹ a) Patient moved away/could ¹ _____
not be contacted

b) Coronary artery anatomy ² _____

c) Patients' preference ³ _____

d) High operative risk ⁴ _____

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e) Patient died ⁵ _____
f) Other ⁶ _____
Yes ² give date dd mm ____/____/____
yyyy

5. Was this patient seen?

No ¹ a) Patient moved away/could ¹ _____
not be contacted
b) Patient DNA ² _____
c) Patients' preference ³ _____
d) High operative risk ⁴ _____

—
e) Patient died ⁵ _____
f) other ⁶ _____
Yes ² give date dd mm ____/____/____
yyyy

6. Was this patient put on the list for PCI?

No ¹ a) Patient moved away/could ¹ _____
not be contacted
b) Coronary artery anatomy ² _____
c) Patients' preference ³ _____
d) High operative risk ⁴ _____

—
e) Patient died ⁵ _____
f) other ⁶ _____
Yes ² give date dd mm ____/____/____
yyyy

7. Did the patient have PCI?

No ¹ a) Patient moved away/could ¹ _____
not be contacted

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- b) Coronary artery anatomy ² _____
- c) Patients' preference ³ _____
- d) High operative risk ⁴ _____

- e) Patient died ⁵ _____
- f) other ⁶ _____

Yes ² give date dd ____ / ____ / ____
mm yyyy

8. Was this patient considered for CABG?

- No ¹ a) Coronary artery anatomy ¹ _____
- b) Patients' preference ² _____
- c) High operative risk ³ _____
- d) Patient died ⁴ _____

- e) Other ⁵ _____

Yes ² give date ____ / ____ / ____
dd mm yyyy

9. Was this patient referred for CABG?

- No ¹ a) Patient moved away/could ¹ _____
not be contacted
- b) Coronary artery anatomy ² _____
- c) Patients' preference ³ _____
- d) High operative risk ⁴ _____
- e) Patient died ⁵ _____

- f) Other ⁶ _____

Yes ² give date ____ / ____ / ____
dd mm yyyy

10. Was this patient seen?

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No ¹ a) Patient moved away/could ¹ _____
not be contacted

b) Patient DNA ² _____

c) Patients' preference ³ _____

d) High operative risk ⁴ _____

e) Patient died ⁵ _____

f) Other ⁶ _____

Yes ² give date dd ____ / ____ / ____
mm yyyy

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11. Was this patient put on the list for CABG?

No ¹ a) Patient moved away/could ¹ _____

not be contacted

b) Coronary artery anatomy ² _____

c) Patient DNA ³ _____

d) Patients' preference ⁴ _____

e) High operative risk ⁵ _____

f) Other ⁶ _____

Yes ² give date
dd mm / / yyyy

12. Did the patient have CABG?

No ¹ a) Patient moved away/could ¹ _____

not be contacted

b) Coronary artery anatomy ² _____

c) Patient DNA ³ _____

d) Patients' preference ⁴ _____

e) High operative risk ⁵ _____

f) Patient taken of w/l ⁶ _____

Give date
dd mm yyyy

g) Other ⁷ _____

Yes ² give date
dd mm / / yyyy

Appendix IV Guidelines support ARIA trial

The guidelines and other aspects of the trial can be viewed under

www.ucl.ac.uk/aria

Guidelines of the American Heart Association

Recommendations for Exercise ECG

[<Click here to access full text guidelines>](#) [<back to vignette>](#)

[<Click here to access update>](#)

Recommendations on investigation in patients with stable angina from the AHA guidelines are listed below. For ease of reading references have been omitted, but links to the full text guidelines are provided.

(the headings below link to corresponding sections in the text beneath)

EXERCISE ECG

Exercise ECG for diagnosis

Exercise ECG for risk stratification and prognosis

 Risk Stratification with the exercise test

 Risk assessment and prognosis in patients with intermediate/high probability of CAD

 Risk stratification for Death or MI: general considerations

Use of exercise ECG in patient management

Exercise testing in patients with chest pain >6 months after revascularization

Exercise testing after CABG

Exercise testing after PTCA

Exercise testing in special groups

 The Elderly

 Women

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CORONARY ANGIOGRAPHY

Use of Angiography for diagnosis

Angiography after CABG

Angiography in special groups

The Elderly

Women

Exercise ECG for diagnosis

Resting ECG should be performed in all patients with symptoms that suggest angina. However, more than 50% of patients with chronic stable angina have normal results on resting ECG. Findings on resting ECG that favor the diagnosis of CAD are evidence of left ventricular hypertrophy or ST-T wave changes consistent with ischemia and evidence of previous Q-wave MI. Abnormalities such as atrial fibrillation, ventricular tachyarrhythmias, left bundle-branch block, bifascicular block (often left anterior fascicular block plus right bundle-branch block), or second or third-degree atrioventricular block are suggestive but nonspecific indicators of CAD.

Estimating the probability of significant CAD

Recommendation 1: In patients presenting with chest pain, the probability of CAD should be estimated on the basis of patient age, sex, cardiovascular risk factors, and pain characteristics (level of evidence: B). Patients with intermediate or high probability should undergo risk stratification through further testing. For patients with a low probability of CAD, the decision to pursue further testing should be based on a shared discussion between the patient and clinician.

Estimating the probability of significant CAD in patients with stable angina is essential because this information guides all further decisions about additional testing and management. However, there is no commonly accepted range for high and low risk. On the basis of expert opinion, cutoff points of less than 10% to 20% and more than 80% to 90% have been recommended for low and high probability, respectively (2). All patients in between these cutoff points can be characterized as having intermediate probability of CAD. Since these cutoff points are not absolute, there is no definite threshold of risk below which no further work-up is warranted. Therefore, the decision to pursue further testing must often incorporate other issues, such as patients' understanding of risk estimates, patients' cultural and personal values, local system-of-care issues, presence of coexisting conditions, and patients' willingness to undergo further diagnostic and treatment strategies. The probability of CAD can be readily estimated on the basis of the characteristics of the pain and the patients' age and sex (**Table 2**). The presence of risk factors, especially diabetes but also hyperlipidemia and smoking, increases the probability of CAD

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(**Table 3**). The probabilities for non-anginal chest pain and atypical angina are larger in primary care practice.

Table 2. Pretest Likelihood of Coronary Artery Disease in Symptomatic Patients, according to Age and Sex*

Age	Nonanginal Chest Pain		Atypical Angina		Typical Angina	
	Men	Women	Men	Women	Men	Women
y	← % →					
30-39	4	2	34	12	76	26
40-49	13	3	51	22	87	55
50-59	20	7	65	31	93	73
60-69	27	14	72	51	94	86

* Each value represents the percentage of patients with significant coronary artery disease on catheterization. Modified with permission from reference 2.

Table 3. Patients with Coronary Artery Disease in University Centers*

Age	Nonanginal Chest Pain				Atypical Angina			
	Men with CAD, without Diabetes, Smoking, or Hyperlipidemia	Men with CAD, with Diabetes, Smoking, or Hyperlipidemia	Women with CAD, without Diabetes, Smoking, or Hyperlipidemia	Women with CAD, with Diabetes, Smoking, or Hyperlipidemia	Men with CAD, without Diabetes, Smoking, or Hyperlipidemia	Men with CAD, with Diabetes, Smoking, or Hyperlipidemia	Women with CAD, without Diabetes, Smoking, or Hyperlipidemia	Women with CAD, with Diabetes, Smoking, or Hyperlipidemia
y	← % →							
35	3	35	1	19	8	59	2	39
45	9	47	2	22	21	70	5	43
55	23	59	4	25	45	79	10	47
65	49	69	9	29	71	86	20	51

* All values refer to patients with normal resting electrocardiogram. Data in table are the percentage of patients presenting to university centers with various types of chest pain syndromes who are found on testing to have coronary artery disease. CAD = coronary artery disease. Modified with permission from reference 4.

Recommendations for Diagnosis of Obstructive CAD With Exercise ECG Testing Without an Imaging Modality

Class I <[Click here to look up what Classes I, II a, b and III mean](#)>

Patients with an intermediate pretest probability of CAD based on age, gender and symptoms, including those with complete right bundle-branch block or <1 mm of ST depression at rest (exceptions are listed below in classes II and III). (Level of Evidence: B)

Class IIa

Patients with suspected vasospastic angina. (Level of Evidence: C)

<[Look up the definition of strength of evidence](#)>

Class IIb

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1. Patients with a high pretest probability of CAD by age, gender and symptoms. (*Level of Evidence: B*)
2. Patients with a low pretest probability of CAD by age, gender and symptoms. (*Level of Evidence: B*)
3. Patients taking digoxin whose ECG has <1 mm of baseline ST-segment depression. (*Level of Evidence: B*)
4. Patients with ECG criteria for LV hypertrophy and <1 mm of baseline ST-segment depression. (*Level of Evidence: B*)

Class III

1. Patients with the following baseline ECG abnormalities.
 - a. Pre-excitation (Wolff-Parkinson-White) syndrome. (*Level of Evidence: B*)
 - b. Electronically paced ventricular rhythm. (*Level of Evidence: B*)
 - c. More than 1 mm of ST depression at rest. (*Level of Evidence: B*)
 - d. Complete left bundle-branch block. (*Level of Evidence: B*)
2. Patients with an established diagnosis of CAD due to prior MI or coronary angiography; however, testing can assess functional capacity and prognosis, as discussed in section III. (*Level of Evidence: B*)

Exercise ECG for Risk Stratification and Prognosis

Risk Stratification With the Exercise Test

The risk of exercise testing in appropriately selected candidates is extremely low, and thus the main argument for not performing an exercise test is that the extra information provided would not be worth the extra cost of obtaining that information or the test might provide misinformation that could lead to inappropriate testing or therapy. Unless cardiac catheterization is indicated, symptomatic patients with suspected or known CAD should usually undergo exercise testing to assess the risk of future cardiac events unless they have confounding features on the rest ECG. Furthermore, documentation of exercise-induced ischemia is desirable for most patients who are being evaluated for revascularization. The choice of initial stress test should be based on the patient's rest ECG, physical ability to perform exercise, local expertise and available technologies. Patients with a normal rest ECG constitute a large and important subgroup. Most patients who present with angina for the first time have a normal rest ECG. Such patients are very likely (92% to 96%) to have normal LV function and therefore an excellent prognosis. The exercise ECG has a

Appropriateness methods for defining and improving access to angina care

higher specificity in the absence of rest ST-T changes, LV hypertrophy and digoxin. [<back to menu>](#)

Risk Assessment and Prognosis in Patients With an Intermediate or High Probability of CAD

Class I [<Click here to look up what Classes I, II a, b and III mean>](#)

1. Patients undergoing initial evaluation. (Exceptions are listed below in classes IIb and III.) *(Level of Evidence: B)* [<Look up the definition of strength of evidence>](#)
2. Patients after a significant change in cardiac symptoms. *(Level of Evidence: C)*

Class IIb

Patients with the following ECG abnormalities:

- a. Preexcitation (Wolff-Parkinson-White) syndrome. *(Level of Evidence: B)*
 - b. Electronically paced ventricular rhythm. *(Level of Evidence: B)*
 - c. More than 1 mm of ST depression at rest. *(Level of Evidence: B)*
 - d. Complete left bundle-branch block. *(Level of Evidence: B)*
2. Patients who have undergone cardiac catheterization to identify ischemia in the distribution of a coronary lesion of borderline severity. *(Level of Evidence: C)*
 3. Postrevascularization patients who have a significant change in anginal pattern suggestive of ischemia. *(Level of Evidence: C)*

Class III

Patients with severe comorbidity likely to limit life expectancy or prevent revascularization. *(Level of Evidence: C)*

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Risk Stratification for Death or MI: General Considerations

Risk stratification with the exercise test does not take place in isolation but as part of a process that includes other data from the clinical examination and other laboratory tests. Thus, the value of exercise testing for risk stratification must be considered in light of what is added to what is already known about the patient's risk status. Most research on exercise testing has concentrated on its relationship with

Appropriateness methods for defining and improving access to angina care

future survival and, to a lesser extent, freedom from MI. The summary presented here is based on the "ACC/AHA Guidelines for Exercise Testing". [<back to menu>](#)

Use of Exercise ECG Results in Patient Management

The results of exercise testing may be used to titrate medical therapy to the desired level of effectiveness. For example, a normal heart rate response to exercise suggests that the dose of beta-blocker should be increased. Testing for this purpose should generally be performed with the patient on medication. The other major management step addressed by the exercise test is whether to proceed with additional testing, which might lead to revascularization. Proceeding with additional testing usually involves imaging. Although both stress echocardiography and stress SPECT perfusion imaging have been used after exercise testing, only SPECT perfusion imaging has been studied in patients divided into risk groups based on the **Duke treadmill score**. In patients with an intermediate-risk treadmill score, imaging appears to be useful for further risk stratification. In patients with a high-risk treadmill score, imaging may identify enough low-risk patients who can avoid cardiac catheterization to justify the cost of routine imaging, but further study is required. Few patients (<5%) who have a low-risk treadmill score will be identified as high risk after imaging, and thus the cost of identifying these patients argues against routine imaging. Patients with a predicted average annual cardiac mortality rate of <1% per year (low-risk score) can be managed medically without the need for cardiac catheterization. Patients with a predicted average annual cardiac mortality rate >3% per year (high-risk score) should be referred for cardiac catheterization. Patients with a predicted average annual cardiac mortality rate of 1% to 3% per year (intermediate-risk score) should have either cardiac catheterization or an exercise imaging study. Those with known LV dysfunction should have cardiac catheterization [<back to menu>](#)

Exercise Testing in Patients With Chest Pain >6 Months After Revascularization

Class Iib [<Click here to look up what Classes I, II a, b and III mean>](#)

Patients with a significant change in anginal pattern suggestive of ischemia. (*Level of Evidence: B*) [<Look up the definition of strength of evidence>](#)

Rationale

There are two postrevascularization phases. In the early phase, the goal of exercise testing is to determine the immediate result of revascularization. In the late phase, which begins six months after revascularization and is the focus of this discussion, the goal is to assist in the evaluation and management of patients with chronic

Appropriateness methods for defining and improving access to angina care

established CAD. Exercise testing also may be helpful in guiding a cardiac rehabilitation program and return-to-work decisions. [<back to menu>](#)

Exercise Testing After CABG

Exercise testing distinguishes cardiac from noncardiac causes of chest pain, which is often atypical after surgery. After CABG, the exercise ECG has a number of limitations. Rest ECG abnormalities are frequent, and if an imaging test is not incorporated into the study, more attention must be paid to symptom status, hemodynamic response, and exercise capacity. Because of these considerations and the need to document the site of ischemia, stress evaluating patients in this group. [<back to menu>](#)

Exercise Testing After PTCA

Similar considerations apply to angioplasty patients. Restenosis is more frequent, however. Although most restenosis occurs 6 months after angioplasty, when these recommendations do not apply, restenosis does occur later. The exercise ECG is an insensitive predictor of restenosis, with sensitivities ranging from 40% to 55%, which are significantly less than those with SPECT or exercise echocardiography. Because of these considerations and the need to document the site of ischemia, stress imaging tests are preferred for evaluating symptomatic patients in this group. Some authorities advocate routine testing for all patients in the late phase after PTCA with either exercise ECGs or stress imaging, as restenosis commonly induces silent ischemia [<back to menu>](#)

The rationale for this approach is that ischemia, whether painful or silent, worsens prognosis. This approach seems particularly attractive for high-risk patients, for example, those with decreased LV function, multivessel CAD, proximal left anterior descending artery disease, previous sudden death, diabetes mellitus, hazardous occupations and suboptimal PTCA results. If routine testing is done, there are insufficient data to justify a particular frequency of testing after angioplasty. The alternative approach, which the committee labeled class IIb because the prognostic benefit of controlling silent ischemia needs to be proved, is to selectively evaluate only patients with a significant change in anginal pattern. [<back to menu>](#)

Exercise testing in special groups

The elderly

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Few data have been published about the use of exercise testing in people >70 years old. The 1989 National Health Interview Survey found that the diagnosis of CAD was reported by 1.8% in men and 1.5% in women >75 years old. Silent ischemia is estimated to be present in 15% of 80-year-olds. The performance of exercise testing poses additional problems in the elderly. Functional capacity often is compromised from muscle weakness and deconditioning, making the decision about an exercise test versus a pharmacologic stress test more important. More attention must be given to the mechanical hazards of exercise, and less challenging protocols should be used. Elderly patients are more likely to hold the hand rails tightly, thus reducing the validity of treadmill time for estimating METs. Arrhythmias occur more frequently with increasing age, especially at higher workloads. In some patients with problems of gait and coordination, a bicycle exercise test may be more attractive, but bicycle exercise is unfamiliar to most elderly patients. The interpretation of exercise test results in the elderly differs from that in the young. The greater severity of coronary disease in this group increases the sensitivity of exercise testing (84%), but it also decreases the specificity (70%). The high prevalence of disease means that more test results are false-negative. False-positive test results may reflect the coexistence of LV hypertrophy from valvular disease and hypertension, as well as conduction disturbances. Other rest ECG abnormalities that complicate interpretation, including prior MI, also are more frequent. Exercise testing in the elderly is more difficult both to do and to interpret, and the follow-up risks of coronary angiography and revascularization are greater. Despite these differences, exercise testing remains important in the elderly because the alternative to revascularization is medical therapy, which also has greater risks in this group. [<back to menu>](#)

Women

The use of exercise testing in women presents difficulties that are not experienced in men. These difficulties reflect the differences between men and women regarding the prevalence of CAD and the sensitivity and specificity of exercise testing. Although obstructive CAD is one of the principal causes of death in women, the prevalence (and thus the pretest probability) of this disease is lower in women than it is in men of comparable age, especially in premenopausal women. When compared with men, the lower pretest probability of disease in women means that more test results are false-positive. For example, almost half the women with anginal symptoms in the CASS study, many of whom had positive exercise test results, had normal coronary arteriograms. Exercise testing is less sensitive in women than it is in men, and some studies have found it also to be less specific. Among the proposed reasons for these differences are the use of different criteria for defining coronary disease, differences in the prevalence of multivessel disease and prior MI, differences in the criteria for St-

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segment positivity, differences in type of exercise, the inability of many women to exercise to maximum aerobic capacity, the greater prevalence of mitral valve prolapse and syndrome X in women, differences in microvascular function (leading perhaps to coronary spasm) and possibly, hormonal differences. To compensate for the limitations of the test in women, some investigators have developed predictive models that incorporate more information from the test than simply the amount and type of ST-segment change. Although this approach is attractive, its clinical application remains limited. The difficulties of using exercise testing for diagnosing obstructive CAD in women have led to speculation that stress imaging may be preferred over standard stress testing. Although the optimal strategy for diagnosing obstructive CAD in women remains to be defined, the ACC/AHA/ACP-ASIM Committee to Develop Guidelines for the Management of Chronic Stable Angina believes there are currently insufficient data to justify replacing standard exercise testing with stress imaging when evaluating women for CAD. In many women with a low pretest likelihood of disease, a negative exercise test result will be sufficient, and imaging procedures will not be required.

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Coronary angiography

Recommendations on investigation in patients with stable angina from the AHA guidelines are listed below. For ease of reading references have been omitted, but links to the full text guidelines are provided.

(the headings below link to corresponding sections in the text beneath)

Use of coronary angiography for diagnosis

Recommendations for Coronary Angiography to Establish a Diagnosis in Patients With Suspected Angina, Including Those With Known CAD Who Have a Significant Change in Anginal Symptoms [<back to menu>](#)

Class I [<Click here to look up what Classes I, II a, b and III mean>](#)

Patients with known or possible angina pectoris who have survived sudden cardiac death. (*Level of Evidence: B*) [<Look up the definition of strength of evidence>](#)

Class IIa

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1. Patients with an uncertain diagnosis after noninvasive testing in whom the benefit of a more certain diagnosis outweighs the risk and cost of coronary angiography. *(Level of Evidence: C)*
2. Patients who cannot undergo noninvasive testing due to disability, illness or morbid obesity. *(Level of Evidence: C)*
3. Patients with an occupational requirement for a definitive diagnosis. *(Level of Evidence: C)*
4. Patients who by virtue of young age at onset of symptoms, noninvasive imaging, or other clinical parameters are suspected of having a nonatherosclerotic cause for myocardial ischemia (coronary artery anomaly, Kawasaki disease, primary coronary artery dissection, radiation-induced vasculopathy). *(Level of Evidence: C)*
5. Patients in whom coronary artery spasm is suspected and provocative testing may be necessary. *(Level of Evidence: C)*
6. Patients with a high pretest probability of left main or three-vessel CAD. *(Level of Evidence: C)*

Class IIb

1. Patients with recurrent hospitalization for chest pain in whom a definite diagnosis is judged necessary. *(Level of Evidence: C)*
2. Patients with an overriding desire for a definitive diagnosis and a greater-than-low probability of CAD. *(Level of Evidence: C)*

Class III

1. Patients with significant comorbidity in whom the risk of coronary arteriography outweighs the benefit of the procedure. *(Level of Evidence: C)*
2. Patients with an overriding personal desire for a definitive diagnosis and a low probability of CAD. *(Level of Evidence: C)* [<back to menu>](#)

Angiography in patients with previous CABG

Patients who have previously undergone CABG are a particularly heterogeneous group with respect to the anatomic basis of ischemia and its implications for subsequent morbidity and mortality. Progression of native CAD is not uncommon, but more frequently saphenous vein graft attrition or the development of obstructive atherosclerotic vein graft lesions account for late recurrence of chronic stable angina. Saphenous vein graft lesions represent a particularly unstable form of atherosclerosis, which is prone to rapid progression and thrombotic occlusion. Consequently, a low threshold for

Appropriateness methods for defining and improving access to angina care

angiographic evaluation is recommended for patients who develop chronic stable angina 0.5 years after surgery, especially when ischemia is noninvasively documented in the distribution of a vein graft, the LAD is supplied by a vein graft, or multiple vein grafts are present. The outcome of patients with vein graft disease can be improved by reoperation, and in some patients, symptoms can be relieved by percutaneous catheter-based strategies [<back to menu>](#)

Special groups

The Elderly.

The evaluation of chest pain syndromes in the elderly can be difficult because complaints of chest discomfort, weakness and dyspnea are common, and comorbid conditions that mimic angina pectoris are frequently present. Reduced activity levels and blunted appreciation of ischemic symptoms become the norm with advancing age. In large community studies of men and women >65 years old, those with atypical symptoms and typical angina were shown to have similar three-year cardiac mortality rates. An increased frequency of abnormal ECGs at rest and inability to exercise complicate noninvasive diagnostic testing, as does the increased prevalence of disease, which reduces the value of a negative noninvasive test. Diagnostic coronary angiography has very little increased risk (compared with younger patients) in older patients undergoing elective evaluation and is commonly used; in many centers, most patients who undergo this study are .65-years-old. [<back to menu>](#)

Women

Direct referral for diagnostic coronary angiography may be indicated in patients with chest pain possibly attributable to myocardial ischemia when noninvasive testing is contraindicated or unlikely to be adequate due to illness, disability or physical characteristics. For example, a patient with chest pain suggestive of chronic stable angina and coexisting chronic obstructive pulmonary disease who is not a candidate for exercise testing because of dyspnea, perfusion imaging with dipyridamole or adenosine because of bronchospasm and theophylline therapy or stress-echocardiography because of poor images may undergo coronary angiography with minimal risk. Patients in whom noninvasive testing is abnormal but not clearly diagnostic may warrant clarification of an uncertain diagnosis by coronary angiography or in some cases by a second noninvasive test (imaging modality), which may be recommended for a low-likelihood patient with an intermediate-risk treadmill result. Coronary angiography may be most appropriate for a patient with a high-risk treadmill outcome. In patients with symptoms suggestive but not characteristic of stable angina, direct referral to coronary angiography may be indicated when the patient's occupation or activity could constitute a risk to

Appropriateness methods for defining and improving access to angina care

themselves or others (pilots, firefighters, police, professional athletes or serious runners). In certain patients with typical or atypical symptoms suggestive of stable angina and a high clinical probability of severe CAD, direct referral to coronary angiography may be indicated and prove cost-effective. The diagnosis of chronic stable angina in diabetic persons can be particularly difficult because of the paucity of symptomatic expressions of myocardial ischemia due to autonomic and sensory neuropathy, and a lowered threshold for coronary angiography is appropriate. The use of coronary angiography in patients with a high pretest probability of disease is in some patients as important in risk assessment (see Section III.A) as in diagnosis.

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Appropriateness methods for defining and improving access to angina care

Guidelines of the European Society of Cardiology

Exercise ECG

<Click here to access full text guidelines> <back to vignette>

Recommendations on investigation in patients with stable angina from the ESC guidelines are listed below. For ease of reading references have been omitted, but links to the full text guidelines are provided.

EXERCISE ECG

General recommendations

Use of exercise ECG to estimate the probability of CAD

Exercise testing in the Elderly

Conclusions and recommendations

CORONARY ANGIOGRAPHY

General recommendations

Indications for Coronary Angiography

Conclusions and recommendations

General recommendations

While history often suffices to establish the diagnosis of angina pectoris, additional investigations are usually needed to confirm the diagnosis, to assess prognosis and to select the most appropriate therapy. Different strategies may be followed depending on the patient's previous history and the severity (frequency and intensity) of their symptoms. In patients with new symptoms, in whom the diagnosis of coronary artery disease has not yet been established, the approach will differ in comparison with patients with known coronary artery disease, after previous coronary angiography or coronary intervention or after previous myocardial infarction. [<back to menu>](#)

Three diagnostic strategies can be distinguished:

It may be adequate to rely solely on the patient's history, supplemented by physical examination and a resting electrocardiogram. This approach shows often success in elderly

Appropriateness methods for defining and improving access to angina care

patients with mild symptoms responding promptly to medical therapy and in patients in whom coronary interventions are not considered a therapeutic option. [<back to menu>](#)

Another approach is based on a functional assessment of the presence or absence and extent of myocardial ischaemia, which may include exercise testing with electrocardiography, exercise (or other stress) myocardial perfusion imaging (thallium or one of the technetium-99 m labelled perfusion tracers), stress-echocardiography and, possibly, exercise radionuclide angiography. In patients with significant functional abnormalities, this may be followed by coronary angiography to assess whether coronary intervention is indicated and which intervention would be most appropriate. [<back to menu>](#)

A further option is to proceed immediately from history, physical examination and ECG to coronary angiography. This approach may be indicated particularly in patients with typical and severe symptoms, including unstable angina, patients with early post infarction angina, and in patients with early recurrence of symptoms after previous coronary intervention. In clinical practice, the second approach is followed most frequently. In patients with frequent or severe stable angina, functional assessment is often useful prior to or in addition to angiography. It should be appreciated that symptoms resembling angina do not necessarily have a causal relation to any coronary artery narrowings present. Thus, additional functional assessment may be needed in patients with less typical symptoms and moderately severe coronary artery narrowings. Furthermore, such an assessment may help to establish the functional significance of abnormalities observed in the coronary angiogram. For example, in a patient with both complete obstruction of one coronary vessel (and possibly previous myocardial infarction) and a moderately severe stenosis in another vessel, perfusion scintigraphy may help to decide whether symptoms are likely to be alleviated by percutaneous intervention (PTCA) of the moderately severe lesion only, or by surgical intervention of both vessels. [<back to menu>](#)

Use of exercise ECG to estimate the probability of coronary artery disease

In patients without previous diagnosis of coronary artery disease, a stepwise approach can be followed to assess the probability of significant coronary artery disease based on a combined analysis of factors such as age, gender and the type of chest pain, as well as presence and degree of ST segment changes during exercise. The probability of the presence of significant coronary artery disease can be refined by analysis of the presence and degree of ST segment changes during exercise. An exercise test will not be very useful to verify the diagnosis of coronary artery disease in a 64-year-old man with typical angina for example. Even in the absence of ECG changes during the test, the likelihood of coronary artery disease will still be 79%, while it would rise to 99% if 0.2 mV ST segment depression

Appropriateness methods for defining and improving access to angina care

were to occur. Yet the test may help to determine the functional impairment of that patient (exercise tolerance), to measure the blood pressure response (as an indicator of left ventricular function) and to estimate prognosis. [<back to menu>](#)

Similarly, the diagnostic value of exercise electrocardiography is low in asymptomatic men and women. The greatest diagnostic value is obtained in patients with an intermediate pre-test likelihood, for example between 20% and 80%. A further refinement is a multivariate analysis of stress test results, in which the probability is estimated based on a combination of heart rate at peak exercise, ST segment depression, the presence or absence of angina during the test, workload achieved and ST segment slope. Such estimation of the likelihood of coronary artery disease provides more insight into the actual situation of a patient than an arbitrary classification of normal or abnormal. In patients with a low probability of coronary artery disease (for example, <20%) and an adequate exercise tolerance, usually no further investigations will be necessary, even though the presence of coronary artery disease cannot be excluded. In patients with a high post test likelihood (for example >80%) the diagnosis of coronary artery disease has been established. If the symptomatology is moderately severe or severe, and not adequately controlled by medical therapy, coronary angiography is indicated to determine whether coronary intervention is warranted. In patients with an intermediate post test likelihood (between 20 and 80%) after a stress test, a second non invasive test will be helpful to distinguish between subgroups of patients with a higher or lower post test probability. Depending on facilities and experience in a given environment, either myocardial perfusion scintigraphy or stress echocardiography may be chosen as a second test.

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Exercise testing in the elderly

After the age of 75 years there is an equal prevalence of coronary artery disease in men and women. The disease is more likely to be diffuse and severe; left main coronary artery stenosis and triple vessel disease are more prevalent in older patients, as is depressed left ventricular function. Coexistent illness or a sedentary lifestyle may limit the usefulness of exertional chest pain as a diagnostic finding and exercise testing is less often of diagnostic value for technical reasons. Due to the diffuse distribution of coronary artery disease, there is a higher likelihood of non-specific ECG changes during the stress test. In general, elderly patients with anginal symptoms should be evaluated and managed in the same way as younger ones. With increasing age, however, many patients are willing to accept a less well proven diagnosis of chronic stable angina pectoris and to start treatment for evaluation of its efficacy. This means that not all elderly patients need be referred for exercise stress testing, especially when noncardiac factors might limit the test. [<back to menu>](#)

Conclusions and recommendations

(Source: [Click here to access full text guidelines](#))

(1) Stable angina pectoris due to coronary atherosclerosis is a common and disabling disorder. While compatible with longevity, there is a substantial risk of progression to myocardial infarction, and/or death. With proper management, the symptoms can usually be controlled and the prognosis substantially improved. In practice, it seems probable that there is both widespread underdiagnosis and overdiagnosis, and that optimal management strategies are often not implemented.

(2) Every patient with suspected stable angina requires prompt and appropriate cardiological investigation to ensure that the diagnosis is correct and that the prognosis is evaluated. As a minimum, each patient should have a carefully taken history and physical examination, an assessment of risk factors and a resting electrocardiogram. Ready access to diagnostic facilities should be available to general practitioners. Cardiology Departments should ensure that such patients are attended to without delay; some hospitals now provide a special Chest Pain clinic for this purpose. Three diagnostic strategies may be followed depending upon patient characteristics and the severity of symptoms:

- The minimal assessment, as described above, without additional investigations. This may suffice, particularly in elderly patients with readily controlled symptoms, or in those disabled or seriously ill for other reasons.
- An initial non-invasive strategy which is appropriate for most patients. This allows an assessment of the likelihood of and the severity of coronary heart disease in patients with mild to moderate symptoms e.g. exercise testing with or without perfusion scintigraphy or stress echocardiography. In many patients, this may lead to coronary angiography.
- Coronary angiography without prior functional testing. This may be an option for patients with uncontrolled severe symptoms in whom revascularization seems indicated urgently.

(3) It is essential in interpreting the findings of the exercise test, that the demographic and clinical features of the individual are taken into account, as well as the workload achieved and the blood pressure and heart rate responses. While of great value in many cases, however, this test may provide equivocal or misleading information in some. Alternative investigations are needed when the diagnosis remains uncertain or functional assessment is inadequate, especially when there are electrocardiographic features which are difficult or impossible to interpret. Myocardial perfusion imaging and stress echocardiography are of particular value in demonstrating the extent and localisation of myocardial ischaemia. Echocardiography and radionuclide angiography are helpful in evaluating ventricular function.

Appropriateness methods for defining and improving access to angina care

(4) The interpretation of chest pain is particularly difficult in young and middle-aged women. The classical symptom complex of chronic stable angina, which is a reliable indicator of myocardial ischaemia in men is not so in younger women. This problem is compounded by the relatively high prevalence of 'syndrome X' in women, and by the frequency of 'false positive' exercise tests. <[back to menu](#)>

Coronary angiography

<Click here to access full text guidelines> <back to vignette>

Recommendations on investigation in patients with stable angina from the ESC guidelines are listed below. For ease of reading references have been omitted, but links to the full text guidelines are provided.

(the headings below link to corresponding sections in the text beneath)

General recommendations

Coronary angiography has a pivotal position in the management of patients with chronic stable angina pectoris. It is currently the most reliable tool to ascertain the anatomical severity of coronary artery disease. However, necropsy and ultrasound studies have clearly demonstrated that the extent of plaque mass is grossly underestimated by this technique. It carries a small risk of mortality (<0.1%) and often needs to be supplemented by functional tests.

Indications for Coronary Angiography

Taking into account the development of new techniques of myocardial revascularization and the low risk of complications of coronary angiography, it should be considered in the following conditions:

- (1) Severe stable angina (Class 3 of the Canadian Cardiovascular Society Classification (CCS)), particularly if the symptoms are inadequately responding to medical treatment;
- (2) Chronic stable angina (Class 1 to 2) if there is a history of myocardial infarction or evidence of myocardial ischaemia at a low work load;
- (3) Chronic stable angina in patients with bundle branch block if readily-induced ischaemia is demonstrated by myocardial perfusion scintigraphy;
- (4) Patients with stable angina who are being considered for major vascular surgery (repair of aortic aneurysm, femoral bypass, or carotid artery surgery);
- (5) Patients with serious ventricular arrhythmias;
- (6) Patients previously treated by myocardial revascularization (PTCA or CABG) who develop recurrence of moderate or severe angina pectoris;

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(7) When it is essential to establish the diagnosis for clinical or occupational reasons.

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Conclusions and recommendations

(Source Click here to access full text guidelines)

(1) Stable angina pectoris due to coronary atherosclerosis is a common and disabling disorder. While compatible with longevity, there is a substantial risk of progression to myocardial infarction, and/or death. With proper management, the symptoms can usually be controlled and the prognosis substantially improved. In practice, it seems probable that there is both widespread underdiagnosis and overdiagnosis, and that optimal management strategies are often not implemented.

(2) Every patient with suspected stable angina requires prompt and appropriate cardiological investigation to ensure that the diagnosis is correct and that the prognosis is evaluated. As a minimum, each patient should have a carefully taken history and physical examination, an assessment of risk factors and a resting electrocardiogram. Ready access to diagnostic facilities should be available to general practitioners. Cardiology Departments should ensure that such patients are attended to without delay; some hospitals now provide a special Chest Pain clinic for this purpose. Three diagnostic strategies may be followed depending upon patient characteristics and the severity of symptoms:

(a) The minimal assessment, as described above, without additional investigations. This may suffice, particularly in elderly patients with readily controlled symptoms, or in those disabled or seriously ill for other reasons. [<back to menu>](#)

(b) An initial non-invasive strategy which is appropriate for most patients. This allows an assessment of the likelihood of and the severity of coronary heart disease in patients with mild to moderate symptoms e.g. exercise testing with or without perfusion scintigraphy or stress echocardiography. In many patients, this may lead to coronary angiography. [<back to menu>](#)

(c) Coronary angiography without prior functional testing. This may be an option for patients with uncontrolled severe symptoms in whom revascularization seems indicated urgently. [<back to menu>](#)

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North of England Guidelines

Recommendations for Exercise ECG

<Click here to access full text guidelines

Recommendations on investigation in patients with stable angina from the North England stable angina guidelines are listed below. These guidelines do only consider exercise ECG, not angiography.

General recommendation

All patients with clinically certain angina should have an exercise test, this will mean referral to an open access service where this is available and referral to a cardiologist where it is not. If a patient who requires an exercise test cannot fully perform the test they should be referred to a cardiologist for other forms of investigation.

Patients having an exercise test for prognostic investigation and treatment should have the test performed while taking their normal medication.

Whether or not a patient has diabetes and the oestrogen status of women should be recorded on a request form as it will influence the performance and interpretation of the test (B). [**<Look up the definition of strength of evidence A- D>**](#)

Patients who should not have an exercise test are:

Those whose symptoms are uncontrolled on maximal medical therapy (they should be referred to a cardiologist for consideration of angiography, not exercise testing) (D). [**<Look up the definition of strength of evidence A- D>**](#)

Those who are physically incapable of performing the test for reasons other than their angina (see above) (D).

Those with co-morbid illness that is currently more important (D).

Those who decline to have the test (D).

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Addendum

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