CHAPTER 1. INTRODUCTION AND DEFINITION OF PROBLEM

Clinical laboratory testing has become an important element of modern health care. Its utilisation is regarded as essential in the screening, diagnosis and monitoring of most forms of disease.

However the utilisation of laboratory tests has increased markedly during the past 10 - 15 years, being accompanied by undesirable economic and associated clinical problems. A number of studies have shown that as much as 50% to 60% of laboratory test ordering may be inappropriate or unnecessary.4-5

Inappropriate test utilisation results from the overutilisation, underutilisation or general misuse of laboratory services. It provides major concern since it ultimately affects the quality and cost of health care provided to the patient.

Although the majority of data on the utilisation of laboratory tests originates from the USA, recent investigations undertaken in Australia confirm the problems reported elsewhere.6 Nevertheless, one needs to cautiously interpret such data from the USA since that nation’s health expenditure approximates 14% (as a proportion of gross domestic product) in comparison to Australia’s 8.5%, as well as there being substantial structural and administrative differences between the two systems.
The conventional approach to solving the problem of inappropriate clinical laboratory testing has largely been to target for improvement the practice and behaviour of the test requesting doctor.\textsuperscript{7-9} However, such strategies of implicating the doctor as the root cause of the problem have met with little success, and in fact have probably exacerbated the situation even further.

This investigation examined the impact that the alternative management strategy of Total Quality Management (TQM) has on improving the appropriateness of clinical laboratory test utilisation in the early management of patients with acute myocardial infarction\textsuperscript{10} (AMI). Several individual continuous quality improvement (CQI) exercises were undertaken in order to achieve the desired improvement to the total system of pathology services.

1.1 Preliminary definitions of terms
Although the background and nature of TQM is to be discussed in detail in Chapter 4, some basic definitions are provided here in order that this discussion of the problem is explicable.

Although the terms TQM and CQI are often used interchangeably, TQM essentially refers to the overall approach of managing the total aspects of an organisation’s quality, whereas CQI refers to one specific element of the total system concerned with
individual improvement of processes.\textsuperscript{11}

Individual CQI strategies were introduced to improve all pathology customer service areas in the early management of AMI. Improvement was directed at the total system, and not just test ordering, because appropriate test ordering was closely dependent upon all other aspects of the pathology-customer service cycle.

The pathology-customer service cycle is a concept that has been developed in this study to represent the complex sequence of tasks carried out each time a clinical laboratory test is ordered and performed in hospital.

The major processes and information flows of this cycle are shown in Figure 1.1. The cycle commences once a test is required and is completed with pathology reports being received in the ward for tests ordered. Each stage of the cycle is critical to the customers of the service and affects the quality of the tests ordered.

It was concluded from this investigation that test ordering cannot be improved significantly without consideration being given to all relevant aspects of this cycle.

1.2 Goals and hypotheses of the investigation

1.2.1 Goals of the investigation

The investigation had two main goals:

The first goal was to undertake a quasi-experimental
FIGURE 1.1 Pathology-customer service cycle for test ordering
investigation using a TQM approach. This involved the
development of a hypothesis and various sub-hypotheses,
presented in 1.2.2.

The second goal was to plan, implement, and monitor the
TQM program as the independent or experimental variable,
being the intervention strategy in this investigation.
This involved the development of five specific
objectives, listed in 1.2.3. It is emphasised that,
because of its integral importance, the stages and
experiences in this TQM intervention have been fully
described as a secondary but potentially replicable part
of the investigation.

1.2.2 Goal 1- The hypotheses of the quasi-experimental
investigation
The overall broad hypothesis of the investigation was
that the introduction of the alternative management
strategy of TQM would result in a significant improvement
in the appropriateness of clinical laboratory test
ordering in the early management of acute myocardial
infarction (AMI).

This hypothesis may be conveniently broken down to the
following sub-hypotheses:

1. There is a significant increase in the selection of
clinically recommended clinical laboratory tests for AMI
as a function of the introduction of TQM intervention.
2. There is a significant decrease in the selection of non-clinically indicated clinical laboratory tests for AMI as a function of the introduction of TQM intervention.

3. There is a significant improvement in the clinically recommended timing of cardiac enzyme testing for AMI as a function of TQM intervention.

4. There is a significant decrease in the total cost of clinical laboratory tests per AMI admission as a function of TQM intervention.

5. There is no significant change in the quality of patient care for AMI as a function of TQM intervention.

1.2.3 Goal 2- The objectives of the intervention
The second overall goal of the investigation was to plan, implement, and monitor the TQM program. This was achieved through the development of the following five objectives:

1. To develop a TQM environment for pathology services delivered in the first 90 hours of the management of patients with AMI.

2. To develop a CQI model using the principles of TQM for appropriate utilisation of laboratory tests in the first 90 hours of the management of patients with AMI.

3. To introduce CQI strategies for improving all customer pathology service areas involved in the first 90 hours of
the management of patients with AMI. These service areas primarily involve test ordering, turnaround time of test results, reporting procedures, and the delivery of specimens and request forms to the Pathology Department.

4. To assess the effect of the TQM approach on improving the appropriateness of laboratory test utilisation provided to the patient with AMI.

5. To assess the effect of the TQM approach on the overall quality of care provided to the patient with AMI.

1.3 Organisation of the thesis

1.3.1 Plan of the analysis

The study was conducted at two public hospitals in Sydney, Australia. One hospital group of patients was designated the ‘experimental group’, and the other the ‘control group’.

The study was undertaken over a 30 month period and in two stages; ‘pre’ and ‘post’ the TQM intervention. During the pre-test period, no CQI measures were introduced to either groups, and staff remained unaware of the major intervention that would follow. After the initial 15 month pre-test period, the CQI intervention strategies were introduced to the experimental group.

In the study, a multi-disciplinary CQI Project Team involved in the process of laboratory test ordering was empowered to improve the appropriateness of test
utilisation in AMI patients within the experimental group.

Using this approach, the CQI tools of ‘brainstorming’, cause-and-effect diagrams, and flow charts were used by the Project Team to identify, implement and evaluate pathology service system improvements.

1.4 The problem
Rapid advancements in medical science and technology have provided an expanded capacity to diagnose, monitor and treat illness. Such advancements have however been accompanied by a growing tendency to overuse costly hospital services.

There are currently a wide range of activities involving governments, the professions, health care institutions and other organisations, that relate directly to finding ways of improving the utilisation of health services.¹²⁻¹³

The widespread inappropriate use of diagnostic clinical laboratory services is increasingly becoming one such problem area that is being closely monitored by Government policy makers.¹⁴⁻¹⁷ This is because laboratory test usage and its resulting costs have markedly increased at a time when resources remain limited.

In addition, there is a growing realisation that the relationship between test utilisation and outcomes of
care are unknown for many health problems.\textsuperscript{18-19} A presumption tends to exist that more information must improve diagnostic accuracy and thus the quality of treatment.\textsuperscript{20-21} However, this linkage has yet to be proven in the usage of laboratory tests.\textsuperscript{22}

During the past twenty years there has been a significant increase in the number of pathology laboratory tests being ordered, with numerous studies indicating that many of the tests were inappropriately used, especially in the teaching hospital setting.\textsuperscript{23-27}

In Australia, the number of Pathology episodes increased markedly by 4.83 million (59.4\%) during the period 1984-1990. Amongst the various divisions of Pathology, Haematology (10.3 million services p.a.) and Clinical Chemistry (10.1 million services p.a.) accounted for 63.8\% of all pathology services in 1988-89. Clinical Chemistry showed the highest rate of growth, expanding by 78.3\%, while Haematology showed a 37.4\% growth in services.\textsuperscript{28} About 41\% of all patients in Australia now have pathology tests ordered for them at least once a year and for women the rate is over 60\%. There is no evidence that the increase is slowing down or vice versa.

This investigation specifically examined the inappropriate use of laboratory tests in the early management of hospitalised patients with AMI. Testing in the management of such patients largely involves the
utilisation of Clinical Chemistry and Haematology services.

AMI continues to be a common cause for hospital admission to acute geriatric units and a major cause of cardiovascular morbidity and death. In Australia, 18 668 deaths occurred as a result of AMI during 1993.29

The clinical suspicion of a myocardial infarction affects important short and long term management strategies, commencing with triage decisions.30 In addition, rapid exclusion of this diagnosis allows for better management of patients without myocardial infarction. It is therefore important that the diagnosis is made both accurately and as early as is possible.

Clinicians in fact tend to rely a great deal on diagnostic laboratory testing to either confirm cardiac necrosis in a person with a suspected AMI or to exclude it. In the past 10 years, serum proteins, specifically cardiac enzymes, have become the major determinant by which AMI and reperfusion are diagnosed or excluded.31-33

The ordering patterns for tests used in the diagnosis of AMI have indicated considerable misuse.34-39 Despite such waste of resources, strategies are not routinely introduced in hospitals to remedy the situation.

Cardiac enzyme tests are generally being used
inappropriately through the ordering of only single serum creatine kinase isoenzyme (CK-MB) tests, or by the ordering of repetitions of CK-MB tests at excessively short or long intervals. In addition, other Clinical Chemistry and Haematology based tests have also reportedly been inappropriately used in AMI.

1.5 Framework of the thesis

This investigation was developed around a framework that drew on several areas of study in order to establish its objectives. The thesis has been divided into ten chapters, each one focusing on a different phase of the research process.

Chapter 2, Inappropriate Test Utilisation, consists of a review of the literature of the process of clinical laboratory test utilisation, including the development of test ordering strategies in AMI. An account is provided of the problem areas resulting from inappropriate test utilisation, the major factors influencing such test ordering behaviour, and the overall implications of such actions. An assessment is provided of the extent that inappropriate test utilisation is evident.

In Chapter 3, A Traditional Improvement Approach, a review is provided of the current and traditional strategies that have been used in an endeavour to improve the appropriateness of test utilisation in the management
of AMI. Strategies aimed at targeting clinician behaviour, and their actual impact on test utilisation are discussed in detail.

Chapter 4, Total Quality Management Approach, presents a discussion on the proposed new TQM approach to the problem. The essential features of TQM, its introduction and application to health care, its potential for improving laboratory test utilisation, and some of the main difficulties faced in its proposed implementation are discussed.

Chapter 5, Method, outlines the research design and includes the justification of using a quasi-experimental design, a description of the study setting and the patient population groups, the objectives and hypotheses used, the quality control measures, and an assessment of the potential untoward effects of intervention. The timetable of the investigation is also presented.

In Chapter 6, TQM Intervention Procedure, detailed information is provided on the TQM process improvement procedures, including the design and implementation of the CQI strategies.

Chapter 7, Collection and Analytical Procedures, provides a comprehensive account of the procedures used for the collection and analysis of the data in the investigation. The data attained from the analysis is presented in the
two ‘Results’ chapters 8 and 9. Whilst Chapter 8, Results 1- Test Utilisation Analysis, provides all the data concerned with the utilisation of laboratory tests, Chapter 9 Results 2- Process Improvement Analysis, includes the results specifically concerned with process improvement.

The investigation concludes with Chapter 10, Conclusions and General Discussion, providing a discussion of the outcomes of the research. A final assessment of the impact that the TQM approach has had on improving the appropriateness of test utilisation is provided.

In order to avoid possible confusion between material referred to within the general body of the thesis and the detailed CQI procedures provided as appendices, a system of reference has been developed as follows. All references made to Tables, Figures and sections of text within the appendices are preceded by the word ‘Appendix’. In addition, within appendices only, any reference made to sections of chapters found within the general body of the thesis are preceded by the word ‘Chapter’.
REFERENCES AND NOTES


10. Acute myocardial infarction essentially refers to the death of cardiac muscle as a result of impaired blood supply to the muscle.


12. Deeble & Lewis-Hughes, op.cit; pp.53-76.


20. Connelly & Steele, op. cit; p.59.


23. S.A. Schroeder, I.H. Lamb & M. Hu, 1980. 'Do patients in whom myocardial infarction has been ruled out have a better prognosis after hospitalization than those surviving infarction?' *New England Journal of Medicine, 303*, pp.1-5.

24. Connelly & Steele, op. cit; p.59.


28. Deeble & Lewis-Hughes. op. cit; p.35.


32. Lee & Goldmann, op. cit; p.221.


41. Wong & Lincoln, op. cit. p.2511.

42. Gama, Nightingale & Ratcliffe. op. cit. p.224.

43. Ratnaike, Hunt, Eilermann, Hazen & Deam, op. cit; p.669.
CHAPTER 2. INAPPROPRIATE TEST UTILISATION

This chapter discusses the development of definitions for appropriate and inappropriate test utilisation. An analysis is undertaken of the processes that underlie the selection of diagnostic testing strategies and the problems associated with this task. A literature review of test ordering behaviour is included to establish the extent to which inappropriate test utilisation exists. Finally, an account of the problem areas resulting from inappropriate test utilisation, the major factors influencing such test ordering behaviour and the overall implications of such actions, is provided.

2.1 Definition of inappropriate utilisation

Developing a definition is the first step towards preparing strategies for improving the appropriateness of laboratory test utilisation in the management of AMI as the lack of a simple definition of an ‘appropriate’ test has made it difficult to objectively assess the scale of the problem.¹

In this investigation, appropriate utilisation was essentially regarded as the effective and efficient use of laboratory tests in attaining the best possible health outcome for the patient. It involved the clinical team maximising its use of the various decision making tools and integrating information derived from diagnostic
tests with clinical judgement.²

Inappropriate utilisation essentially results from the misuse of laboratory services. It occurs through the overutilisation, underutilisation or the poor selection of non-specific and non-sensitive tests. It is a major concern since it ultimately affects the quality and cost of health care provided to the patient with AMI.

Overutilisation of laboratory tests specifically results whenever superfluous or repetitious data are obtained at inappropriate times in random or illogical sequences. It includes the ordering of a series of tests at excessively short intervals.³

Far from assisting the clinical management of the AMI patient, overutilisation of tests in fact may delay treatment or cause unnecessary discomfort or danger. It certainly consumes resources that might otherwise have been used for other aspects of the patient's care.⁴

On the other hand, underutilisation of tests occurs when pertinent laboratory data is not sought or obtained. Such inappropriate testing includes the ordering of a series of tests at excessively long intervals. Underutilisation of necessary tests generally results in poor clinical outcomes for those patients being tested.⁵

Laboratory investigations are furthermore misused with the selection of tests with relatively low sensitivity⁶
and specificity' that could have been more efficiently and cost effectively managed by another means.

However as will be discussed further in 2.3, numerous studies have incorrectly assumed that overutilisation is equivalent by definition to inappropriate test utilisation. Therefore attempts at solving the problem have often been aimed at reducing the number of tests requested and not necessarily at achieving 'appropriate' testing levels as defined in the above discussion.

Although the overall number of tests may be reduced through the introduction of various strategies, it is essential that the tests that are subsequently ordered are in fact the 'appropriate' ones for good patient care. As recently reported by Burke*, decreased test utilisation is not synonymous with appropriate use. The real danger with test reduction measures is that necessary tests as well as unnecessary ones are often eliminated.

2.2 Diagnostic testing strategies

The process for the development and selection of appropriate laboratory testing strategies for patients with suspected AMI has proved over time to have been poorly undertaken by clinicians. In this section of the chapter, an outline is provided of the many issues faced in the decision making process of test ordering. According to some investigators, the problem appears to
stem back to the lack of training given to medical students on the principles that underlie clinical decision making.

2.2.1 Decision-making processes

Although the selection of diagnostic strategies for patients presenting with a suspected AMI may appear to be relatively straightforward, the processes that underlie this achievement are poorly understood.9-11

According to Kassirer the ability to make rational decisions that lead to optimum therapeutic outcomes is one of the chief characteristics of an outstanding clinician.12 The author argued that most of the energy expended in the education of medical students and house officers is directed into teaching a huge body of facts and methods for gathering and interpreting data, with little or no attention being given to the principles that underlie clinical decision making. In fact, the principles of decision making are regarded as being often obscured by the substitution of established protocols.

It has been argued that laboratory test ordering was often neither carefully planned nor thoughtfully studied.13 Tests were not always selected with care, and results were often not used to benefit the patient. Ideally, laboratory tests for the management of AMI should be ordered in accordance with a standard plan developed and monitored by all the key clinical and
laboratory staff involved in the process of test ordering.

Clinical laboratory tests should only be ordered when the information available from the history, physical examination, and previous test data is insufficient to handle the questions at hand. The ordering of a specific laboratory test should therefore be undertaken on the assumption that the resulting data would appreciably lower the clinical uncertainty and significantly change the pre-test probability that the disease is present.\(^*\)

The overall decision-making process involves information about the patient being accumulated in a stepwise fashion. One begins with a degree of uncertainty about an eventual diagnosis and work towards reducing the uncertainty to zero. Each step, each new piece of information, obliterates an amount of uncertainty until so little uncertainty remains that the clinical team is willing to accept the diagnosis as a premise for therapy and management.\(^*\)

Selecting which tests to order in the early management of AMI and with what frequency therefore should involve the clinical team weighing the potential benefits of accurate information against the cost of these assays and the implications of misleading results. However, such team developed strategies are rarely in use.
Knowledge of test characteristics is crucial for the clinical team in deciding which test is appropriate for a given purpose. As an example, insufficient knowledge of test sensitivity and specificity has been identified as a major reason for the poor use of laboratory services.\textsuperscript{16} If two or more tests are available for the diagnosis of AMI, the one with the highest sensitivity should generally be selected if it is most important to rule out disease, and the one with the highest specificity should be selected if it is most important to confirm the presence of disease.\textsuperscript{17}

The purpose of the test is affected by the clinician’s estimate of the pretest likelihood of disease based on an assessment of the available clinical information. The use of a test to exclude or to confirm a diagnosis should indicate that the best estimate after a careful evaluation of the patient’s problem is that the diagnosis in question is either relatively unlikely or probable, respectively. When these principles are followed, the conclusions reached from laboratory test results are likely to be correct and lead to appropriate action.\textsuperscript{18}

Very sensitive tests are most effective in reducing the probability of disease and in ruling out individual diagnoses, such as AMI.\textsuperscript{19-20} Such tests, when normal, usually permit the clinical team to confidently exclude the presence of disease.
2.2.2 Laboratory test practice guidelines

A practice guideline is essentially a specific, recommended course of action taken for typical patients under typical circumstances.\textsuperscript{21} Test practice guidelines have been advocated as an effective measure for assisting clinical decision making.\textsuperscript{22-23} Guidelines are developed to improve the process, outcome, or efficiency of care. Although guidelines have been used as a means of achieving appropriate test utilisation, very few studies have shown any degree of success in attaining compliance to the test ordering recommendations.

The American College of Physicians (ACP) in association with the Blue Cross and the Blue Shield Association have published guidelines for the appropriate utilisation of clinical laboratory tests in a wide range of clinical disorders.\textsuperscript{24} According to Alper\textsuperscript{25}, the ACP test guidelines when first published in 1987, were proposed to restrict the unnecessary use of many commonly used tests, including Clinical Chemistry panels and blood counts.

The early experience with practice guidelines is clearly that unless clinicians are involved in their development, the guidelines are doomed to failure.\textsuperscript{26-28} Although practice guidelines for test usage in the management of AMI have been available for many years,\textsuperscript{29-30} clinicians have generally failed to follow them and inappropriate testing has often resulted.\textsuperscript{31}
Some successes have however been reported with the use of laboratory testing guidelines. Travers\textsuperscript{32} recently reported a moderately successful introduction to a large pathology service of optimal diagnostic test guidelines that recommended testing strategies for 20 diseases. The use of these strategies resulted in improved diagnostic test utilisation.

In another study, testing guidelines were prepared by hospital based physicians and resident medical officers for 14 diagnoses.\textsuperscript{33} Clinicians were asked to imagine the typical patient and delineate for each day the necessary diagnostic tests. Strict guidelines were provided for testing patients with suspected AMI. On day 1, test orders could only include LD 1,2 (3X), CK-MB, glucose, electrolytes, urea, creatinine, full blood count, prothrombin activity, and urinalysis. On days 2 and 3, only CK-MB tests could be ordered. Overall, substantial reductions in test utilisation were achieved without any demonstrable adverse effect on quality of care as measured by deaths and readmissions. No clear indication was however provided as to whether the tests ordered were clinically appropriate to the condition of the patient.

Optimal testing guidelines for nine common medical emergencies were also used by Fowkes et al.\textsuperscript{34} The guidelines were prepared through consultation between clinical and laboratory staff. The introduction of the
guidelines resulted in overall reductions in test usage. No indications were provided as to whether the post-intervention tests were in fact appropriately utilised. The study group however warned that sustaining such reductions in test usage over an extended period of time involved firm commitment by the ward staff in ensuring that the guidelines were adhered to.

In practice, clinical guidelines for test usage are more likely to be complied with if the staff involved in test ordering had also been involved in the development, implementation and ongoing evaluation of such guidelines.

2.2.3 Cardiac enzyme test characteristics

Over the past 20 years medical laboratory science has witnessed the development of clinical laboratory tests of increasing complexity. The tests have in many areas provided greater opportunities to detect a wide range of disorders. In many cases such tests have emerged as the 'gold standard' by which such diseases are diagnosed and monitored. Serum cardiac enzyme tests have been used in such a capacity in the diagnosis of coronary artery disease. These laboratory tests have redefined the clinical entity that they are used to identify by revealing areas of cardiac necrosis that hitherto could not be detected. Enzyme levels are now recognised by health care workers as the major determinant by which AMI is diagnosed or excluded.35-37
Enzymes are released in large quantities into the blood from necrotic muscle following AMI, with various enzymes reaching peak serum levels at different times. This is accounted for by differences in enzyme leakage from damaged cells, transport through the lymphatic system, and clearance into the circulation.

The enzyme creatine kinase (CK) is found largely in myocardial and skeletal muscle. CK begins to rise within 4 to 8 hours after acute myocardial injury, reaching a peak in 12 to 24 hours, and returning to normal within 3 to 4 days.\(^3\)

CK has three isoenzymes, CK-MM, CK-BB, and CK-MB. Of these only CK-MB is found in significant amounts within the myocardium. According to Apple, CK-MB has become the most important serum enzyme test in the diagnosis of AMI.\(^3\) This is because most CK-MB laboratory assays generally meet the desired criteria of cardiac specificity, specificity of detection, sensitivity of detection, rapid availability, prolonged detection, and economy of detection. After myocardial infarction, the level of CK-MB begins to rise within 4 to 8 hours, reaching a peak in 12 to 20 hours. The level of CK-MB usually returns to normal within 2 to 3 days.\(^4\)

As a consequence of the many individual characteristics of the cardiac enzymes, laboratory tests therefore need to be ordered appropriately with respect to the type and
frequency of testing, and timing of blood collection. Total CK and CK-MB assays should be sampled serially during the first 20 to 24 hours in order to rule in or rule out myocardial infarction.⁴¹⁻⁴²

On some occasions, false-positive and false negative CK and CK-MB results occur. False-negative CK-MB results are invariably due to inappropriate sampling, such as once per 24 hours, or sampling well after the infarction when CK-MB levels have returned to normal.⁴³ Overall, false-positive CK results occur more commonly than do false-positive CK-MB results. False elevations of CK-MB arise from various sources including spillover of CK-MM, isoenzyme variants, skeletal muscle trauma, diabetes mellitus and pulmonary embolism.⁴⁴ False-negative CK results usually reflect failure to sample frequently enough or soon enough.⁴⁵

A number of other enzymes, including lactic dehydrogenase (LDH) and aspartate aminotransferase (AST), were for many years used widely in the diagnosis of AMI. However, these tests have somewhat fallen out of favour in more recent times.⁴⁶⁻⁴⁸ The use of LDH is no longer recommended.⁴⁹ It rises later (24 to 48 hours) and remains elevated for as long as 7 to 14 days.⁵⁰⁻⁵² However, the LDH test has been found useful if the patient presents in the Emergency Department more than 24 hours after chest pain and the total CK and CK-MB are normal.⁵³ Since the time course of
elevation of AST is intermediate between CK and LDH, it offers little advantage. In addition AST has been shown to lack tissue specificity.  

As can be noted from the varying characteristics of the cardiac enzyme tests, it is important that firm and planned testing strategies are in place so that only appropriate laboratory tests are ordered with respect to the type and frequency of testing.

2.2.4 Testing strategies

Several studies have shown that in patients who are evaluated within 24 hours of the onset of chest pain, serial CK-MB testing has a remarkable degree of diagnostic accuracy with almost 100% sensitivity and specificity. In most cases of myocardial infarction, estimation of total CK and CK-MB on samples taken serially at admission, and 6, 12 and 24 hours later provide adequate biochemical confirmation. Therefore the finding of normal levels of total CK and CK-MB throughout the first 24 hours virtually rules out myocardial infarction. After the peak activities of CK and CK-MB have passed, there is no real advantage in further testing, unless there is clinical evidence of reinfarction.

Those patients presenting with chest pain more than 24 hours after the onset of symptoms may just be too late for serial CK-MB testing to be diagnostic. They should
have a single determination of serum LD with isoenzymes. In most cases, such testing will be sufficient to make the diagnosis. The value of only single CK and CK-MB levels in decision making is however limited and therefore generally inappropriate. Among patients with acute chest pain, the sensitivity and specificity of a single CK estimation are only 38% and 80%, respectively. Similarly, the sensitivity and specificity of a single CK-MB estimation are 34% and 88%, respectively. Single CK and CK-MB values may be helpful if positive but are not sufficient to rule out infarction if negative.

Besides the regular cardiac enzyme test profiles, other clinical chemistry and haematology laboratory tests are required during the early management of AMI. Samples should be drawn on admission for baseline coagulation tests, blood count, electrolytes, creatinine and glucose estimation. A fasting sample should also be collected during the next morning for triglyceride and cholesterol determination. Patients on heparin or tissue plasminogen activator (TPA) therapy need to be monitored by measuring the activated partial thromboplastin time (APTT).

As cardiac arrhythmias are the most common complication of AMI affecting about 75%-95% of patients, it is important to eliminate electrolyte imbalance which would tend to increase the incidence of potentially fatal
arrhythmias. Daily electrolyte laboratory testing is therefore recommended. In addition, when arrhythmias are actually present the testing profile should also include magnesium, calcium and phosphate.

Other Clinical Chemistry and Haematology laboratory testing in the early management of uncomplicated AMI is not generally recommended and therefore regarded as inappropriate.

Overall, the appropriate selection of clinical laboratory tests in AMI is rather a complex exercise involving the development of diagnostic strategies for a number of tests that need to be drawn at pre-determined times and with varying frequencies.

2.3 Test ordering behaviour

An extensive review of the English language literature of the past 20 years on the utilisation of clinical laboratory tests has clearly shown that test ordering has been considerably misused. In relation specifically to AMI, laboratory testing has similarly been found to have been inappropriately used. This section of the chapter endeavours to establish the extent to which inappropriate test utilisation is found in the hospital setting.

A large body of literature has specifically focused on the overutilisation of tests\(^{69-71}\), rather than the total problem of inappropriate test utilisation, which by
definition (see 2.1) should also include the underutilisation and poor selection of tests.\textsuperscript{72-73} Some of the reported studies in fact assumed that the terms overutilisation and inappropriate utilisation were in fact of equivalent meaning.\textsuperscript{74-75} Based on such an assumption, and also on the widespread attention currently being given to cost containment, test ordering improvement strategies have generally aimed at reducing the overall number of tests and not necessarily at achieving ‘appropriate’ testing levels as defined in the current investigation.\textsuperscript{76-77}

There is generally a widespread tendency to overrely on diagnostic tests, often at the expense of the valuable information derived from the history and physical examination.\textsuperscript{78} It is commonly believed that results of diagnostic tests are the most valid and proper way to make diagnoses.\textsuperscript{79} The available evidence on the usefulness of laboratory investigations has shown that tests should generally be used sparingly.\textsuperscript{80-85} Wide variations in patient testing has been found to occur between clinicians, between hospitals, and between countries.\textsuperscript{86-88}

In some hospitals more than 90\% of investigations conducted on emergency medical admissions were found to be unimportant in the management of patients.\textsuperscript{89} Other findings indicate that in a teaching hospital setting as
much as 60% of laboratory service ordering may be unnecessary.\textsuperscript{90-93}

In a major two year study involving 1,663 patients of a Teaching hospital, Schroeder et al. found that up to 65% of the orders for selected individual laboratory tests were clinically unnecessary\textsuperscript{94}, and that 30% of the urgent laboratory requests were clinically inappropriate.

Dixon & Laszlo also analysed the utilisation of laboratory tests by hospital based clinicians.\textsuperscript{95} It was found that only 5% of the clinical chemistry laboratory data that is ordered is actually used in the diagnosis and treatment of patients. It was found that many unnecessary tests were being performed. In cases where test results of the admission profile were normal and non-indicated repeat tests performed, the study team found no useful data had been derived. Similarly, they reported that the additional electrolyte profiles that were being tested, had failed to alter patient care and were thus deemed to have been ordered unnecessarily.

The study by Ratnaike et al. reported an excessive use of clinical chemistry test profiles in patients admitted to hospital with chest pain.\textsuperscript{96} Test profiles were used excessively instead of targeted tests as recommended by clinical guidelines prepared by the hospital expert committee. Prior to the introduction of the clinical guidelines, the research group found that there were
three times as many clinical chemistry tests ordered as were appropriate. Overall, 13% of the tests ordered were actually not listed by the expert committee as appropriate in the management of chest pain. Requests were being made for test profiles such as ‘liver function tests’ and ‘urea, creatinine and electrolytes’, rather than the recommended targeted tests for potassium and creatinine. In addition, the study revealed that cholesterol tests were requested less often than suggested by the clinical guidelines, and were frequently requested for inappropriate samples.

Goldman found that although some tests may be totally superfluous, much of the current variability and presumed excess in the ordering of tests probably reflects the use of relatively low yield tests. He found that decisions about quality and appropriateness as well as the definition of overuse depend on agreement about the ideal trade-off between the cost of a test and the potential value of its result.

Grantham & Weinstein reported that up to 20% of all laboratory tests ordered at their hospital were unnecessary. Examples of such test ordering included the duplicate ordering of identical tests, too frequent repeat ordering of tests, and the selection of panels of tests when only single tests were needed. Daily liver function tests were perhaps the most obvious example of
too frequent test ordering, the results of which were unlikely to change during the time period between orders.

Sandler also showed that routine haematology and urine testing contributed to only 1% of the diagnoses. 99

Korvin et al. audited 1,000 patient records for benefits attributable to laboratory admission test profiles. 100 Although 83 new diagnoses on 77 patients had resulted, the research team concluded that none had been unequivocally beneficial to the patient.

In an outpatient setting, resident interns were found to differ by as much as 20 fold in mean annual charges per patient for laboratory and X-ray services on similar patients. 101-102

Myers and Schroeder also found that doctors order more services in highly ambiguous situations. 103 Certain situations of clinical diagnosis and treatment may be complex and thus entail greater areas of uncertainty. 104 Junior hospital medical staff are particularly vulnerable to the fear of missing information, in part because attending doctors and senior house staff are more likely to criticise them for ordering too few rather than too many tests and procedures. 105-106 Uncertainty about how to use hospital services, added to the ambiguity of clinical situations and the fear of missing vital clinical information, may account for much of the overuse observed
in hospitals.\textsuperscript{107}

Several reports have shown that laboratory test ordering is considerably misused in patients with suspected AMI.\textsuperscript{108-114} In fact, no published report has yet provided evidence of appropriate laboratory test utilisation during the management of AMI.

Despite findings of some limitations of clinical laboratory tests, doctors tend to rely almost exclusively on them to confirm their diagnosis of AMI.\textsuperscript{115} In the process of such decision making, numerous tests are ordered without any real clinical indication. It has been reported that the habitual ordering of many tests, as in the case of the cardiac enzyme tests in AMI, can become so ingrained amongst clinicians, that they can be easily ordered in inappropriate situations as a ‘rote’ reaction.\textsuperscript{116}

Henderson & Gardner found a significant international difference in test utilisation for clinical chemistry ordering in patients with suspected AMI.\textsuperscript{117} Canadian clinicians were found to have ordered up to eight times as many tests than their British counterparts. As an example, the average number of total CK requests per AMI patient was 2.17 in a British hospital, as compared to 10.17 in a Canadian hospital. An earlier report by Eisenberg et al. showed a 50% overutilisation rate for the cardiac enzyme LDH at the Hospital of the University
of Pennsylvania.\textsuperscript{118}

Clinical protocols outlining specific laboratory testing recommendations for patients with suspected AMI are documented as policy in many hospitals. Despite the existence of such protocols, numerous tests outside of these guidelines are still being requested.\textsuperscript{119}

Saxena et al. found that despite this availability of published guidelines for the use of laboratory tests for AMI, tests were ordered inappropriately at their large teaching hospital.\textsuperscript{120} In their study, only 38% of suspected AMI patients received the recommended series of three tests over the first 24 hours of presentation. When two or more CK-MB tests were ordered, the period between the first and second tests was inappropriately short in 70% and inappropriately long in 24% of cases. The recommended timing for the third CK-MB sample was appropriately followed in only 4% of cases.

Similarly, Wong & Lincoln had earlier reported that the sampling intervals for cardiac enzyme testing had been regularly ignored in the management of AMI.\textsuperscript{121} The tests were also found to have been ordered at much shorter intervals and over longer periods of time than was appropriate.

Harrison, Rapaport & Thibault also found that routine orders were frequently wasteful because unnecessary tests
were repeated over several days, often providing no new information concerning the AMI patient. Unnecessary testing was particularly evident for batteries of clinical chemistry tests, including serum enzymes. The use of routine standing orders within the coronary care unit (CCU) contributed significantly to unnecessary testing. Routine orders often included testing for total CK and CK-MB during the first 3 days, and testing for both total LDH and LDH isoenzyme on day 3.

Wong, McCarron & Shaw also found considerable unnecessary utilisation of laboratory tests in AMI. When a series of CK and LDH isoenzyme tests were ordered, the time intervals were often inappropriately short or long, ranging from every two hours to every 48 hours. Almost 75% of the LDH isoenzyme tests were regarded as unnecessary because of repetition at very short intervals, or evidence that the patient was discharged before the test results were reported.

Winkel and Statland also reported inappropriate laboratory test usage of the cardiac enzymes CK, AST, and LDH. CK was regarded as being inappropriately used when the patient tested was not suspected of having had an AMI. Similarly, AST was not required when there was no interest in assessing muscle damage or hepatocellular destruction. LDH was also unnecessarily tested when only muscle damage was to be monitored.
2.4 Implications of inappropriate testing

Inappropriate clinical laboratory testing has been shown to have several important economic, clinical, quality care and service delivery implications.\(^{125-127}\)

2.4.1 Economic implications

The use of services that are ineffective or only marginally effective contributes to the present high cost of medical care.\(^{128-129}\) Overutilisation of tests results in wasted resources, including an increased ‘length of stay’ (LOS) in hospital.\(^{130}\)

In a recent White Paper of the Clinical Laboratory Management Association (CLMA), it was argued that because clinical laboratory testing has become a central element of modern health care, it was essential that best value in test utilisation be pursued.\(^{131}\)

According to the White Paper,

CLMA holds that, in a truly reformed health-care delivery system, the incentives for laboratory test use should be determined exclusively by the pursuit of the best value.

We can define this as optimizing quality in terms of contribution to patient clinical management (i.e.; the dollar value of improvements in test accuracy, turnaround time, appropriateness, interpretation) for the cost
in terms of health-care dollars expended on screening, diagnosis, or monitoring.

Costs of laboratory testing have shown a disproportionate rate of growth in comparison with other hospital costs.\textsuperscript{132-133}

Deeble and Lewis-Hughes found that the overuse of pathology services contributed significantly to escalating health costs. They reported that pathology in Australia was a billion dollar per year industry that is growing annually by at least $60 million. The estimated annual 1988-89 cost for Pathology Services was $606.8 M (Medicare covered) and $ 331.8 M (outside Medicare). In the ten months to 30 April 1991, Medicare benefits for pathology rose by 13.6%, of which only 3.2% was due to fee increases and 1.5% to population growth. It is a rate to test the capacity of any financing system.\textsuperscript{134}

In many other nations, a similar explosion in the types and volume of clinical laboratory testing has resulted in major increases in health care expenditure.

In the USA, the problem is of far greater magnitude with clinical laboratory testing accounting for approximately 3.5% of total health care spending, or about $30 billion in 1992. The level of spending for clinical laboratory testing has nearly doubled since 1985.\textsuperscript{135} In Canada,
laboratory testing represents an estimated 8% of total health spending, while in the UK the volume of tests has been increasing by 10% each year over the 20 years to 1984.\textsuperscript{126}

Diagnostic tests required for AMI and other emergencies constitute almost half of the costs in the Emergency Department.\textsuperscript{137} In addition, the 16 most commonly used laboratory tests and radiographs contribute to 72% of the total expenditure for testing in Accident and Emergency Departments.

Since AMI constitutes a medical emergency, appropriate testing strategies require that an early and accurate diagnosis is made. The early use of thrombolytic agents significantly improves patient care. It has been associated with reduced infarction size, mortality and thus LOS in hospital.\textsuperscript{138-140} An early diagnosis can also result in substantial cost savings through the efficient allocation of coronary care unit resources.\textsuperscript{141-143} Triage of patients with chest pain to a coronary care unit, or to a less costly intermediate care ward, will be facilitated by an early and appropriately ordered laboratory test aided diagnosis.\textsuperscript{144-145}

\textbf{2.4.2 Clinical implications}

Increased costs are only part of the burden of the inappropriate utilisation of tests.\textsuperscript{146} Tests ordered
inappropriately have been found on some occasions to have led to undesirable clinical consequences.\textsuperscript{147-148} Extra testing also often contributes to delays in patient treatment as clinicians await the reporting of the test results.

Even relatively noninvasive procedures such as laboratory tests carry health risks for the patient. Schimmel\textsuperscript{149} found that almost 3% of the patients in a University medical service suffered ill effects in response to diagnostic tests. According to Benson, every unnecessary investigation puts the patient in jeopardy of incurring the ‘Ulysses Syndrome’\textsuperscript{150}

False-positive results from unnecessary tests may lead to costly and sometimes harmful interventions.\textsuperscript{151} They can misdirect doctors and patients into clinical ‘wild goose chases’ through more unnecessary tests and diagnostic procedures, and in some instances even surgery.\textsuperscript{152-154}

One serious clinical ramification of an overreliance and overutilisation by clinical staff of laboratory tests is that it can lead to a deterioration of skills in history taking and physical examination.\textsuperscript{155}

The inappropriate use of cardiac enzyme tests commonly occurs in AMI. Blood specimens are often drawn at inappropriate times and tests ordered too frequently.\textsuperscript{156} Such poor testing often fails to provide the clinical
staff with the most accurate information. Saxena et al. recently found that in a large teaching hospital, CK-MB testing was used inappropriately to exclude the diagnosis of AMI. In their study, 38% of the patients only received a single CK-MB test and not the series of tests as was recommended for quality patient care. When these tests were ordered serially, they were often ordered inappropriately at too short an interval. The third and final CK-MB sample was frequently ordered only 10–14 hours after the patient had presented. Such early sampling may not have allowed sufficient time to elapse for the level to become abnormal in actual AMI.

Gama et al. also found important benefits in reducing the number of inappropriate tests. In a study on the utilisation of cardiac enzyme tests in the diagnosis of AMI in the elderly, the authors argued that fewer false positive results would be expected to lead to a reduction in further unnecessary investigations and that one less venepuncture and a more rapid diagnosis for the AMI patient being subjected to unnecessary tests, represented an improvement in the quality of care.

Whilst the problem of overuse of tests is often studied, the equally important issue of underutilisation of services is rarely investigated. It was argued that test underutilisation often occurred as a result of poor training and knowledge in test usage. In an earlier
clinical study, Wheeler et al.\textsuperscript{160} found that a large proportion of anaemic patients had inadequate testing and poor clinical follow-up.

### 2.4.3 Quality care implications

Some clinicians may well argue that close, and thus increased laboratory monitoring, might decrease the overall cost of care by shortening the length of stay (LOS) or might improve clinical outcome by allowing early detection and treatment of complications. Similarly, critics of cost containment strategies may warn that quality of care will suffer under policies of constraint.\textsuperscript{161-162}

Such lines of argument however cannot be supported by clinical evidence. If as earlier defined in 2.1, appropriate utilisation is the effective and efficient use of laboratory tests in attaining the best possible health outcome for the patient, then no matter how many additional tests are ordered, quality of care would not necessarily be enhanced.

Studies have in fact shown that the quality of care provided by doctors is not significantly correlated with increased laboratory test use.\textsuperscript{163} Reports have suggested that much of the information generated by additional clinical tests is redundant and often has little effect on treatment.\textsuperscript{164-168}
According to Myers & Schroeder, the law of diminishing returns applied to the relation between intensity of service use and outcome of patient care, demonstrates the weakness of a 'more is better' approach. Every unit of care provided has a relative clinical value for that patient. Yet as increasing amounts of an input are used in a production process, all other things being held constant, each additional unit of input will generally yield a relatively smaller benefit. The 'improvement' of the product associated with the addition of one more unit of input may actually be reduced to nothing or even become detrimental.

Grantham & Weinstein found that strategies to reduce inappropriate test usage had no negative effect on the quality of patient care. In addition, complaints were not received from any clinicians that such measures hampered patient care.

Wachtel & O'Sullivan also found that patient care was not affected by the use of practice guidelines to reduce inappropriate laboratory testing. Patient care in the study was measured by deaths in the hospital, deaths within 90 days of discharge, and readmissions within 90 days of discharge.

Ratnaike et al. also reported that the reduction of unnecessary tests had no detrimental effect on patient outcome as measured by LOS, readmission rate and
mortality.\textsuperscript{172}

The outcome of care for many diseases has not improved despite increased testing.\textsuperscript{173}

Hubbell et al.\textsuperscript{174} also found that increased biochemical testing did not decrease LOS or improve clinical outcomes. Careful studies of patients with pulmonary oedema and acute myocardial infarction, also failed to show better outcomes when more diagnostic tests were used.\textsuperscript{175}

In one coronary care study, it was found that although the number of clinical chemistry tests had increased 20-fold, there had been no significant change in LOS or in hospital mortality.\textsuperscript{176} This was one of the few early studies to even actually use a rudimentary check on quality of care (by observing mortality rate).

Routine pre-operative investigations ordered without clinical indication were found to have little influence on patient management and care.\textsuperscript{177-180}

Kaplan et al. also found that the consequences of abandoning routine testing at their hospital would result in only one additional death in 100 years.\textsuperscript{181} The hospital performed about 8600 procedures annually.

Similarly, Blery et al.\textsuperscript{182} implemented a protocol for the selective ordering of preoperative tests and assessed its
implications on quality of care. The research team found that only 0.4% of non-ordered tests would have been potentially useful. The protocol therefore had little adverse effect on patient care and was found to be acceptable to the clinicians of the hospital.

Kroenke et al.\textsuperscript{183} argued that ideally, positive intervention to improve test utilisation should result in the continued ordering of clinically appropriate tests with a selective elimination of unnecessary tests. Unnecessary tests were defined as those tests which were not clinically indicated. The study group found that the resulting reduction of tests did not sacrifice the overall quality of patient care.

It is therefore quite clear from the numerous studies that have been undertaken, that quality of care is not significantly improved with increased test utilisation.

\subsection*{2.4.4 Laboratory service delivery implications}

Inefficiencies in laboratory service delivery in turn occur as a result of the inappropriate use of tests. Increased laboratory workloads contribute significantly to problems in workflow organisation, ‘turnaround time’ of reporting and therefore productivity of the laboratory service.\textsuperscript{184-185}

Achieving streamlined laboratory workflow through the elimination of unnecessary tests allows for the earliest
availability of test results and thus the potential for a rapid diagnosis of AMI and improved outcomes.\textsuperscript{186}

2.5 Factors influencing inappropriate utilisation

Numerous factors have been identified as contributing to the inappropriate use of laboratory tests in hospitalised patients, including those with AMI. These include the characteristics and training of clinicians, decisions made in isolation, organisational issues, lack of control, new developments, litigation and patient influence.\textsuperscript{187-188}

2.5.1 Characteristics and training of doctors

A number of studies have identified various characteristics of doctors as being associated with particular test ordering patterns. Such characteristics have included, age of the doctor, duration of practice, medical school attended, geographic location, and the influence of respected peers and leaders.\textsuperscript{189-191}

Freeborn et al. was able to correlate laboratory use among experienced clinicians to the place of their training, age and board certification.\textsuperscript{192} It was particularly noted that more junior members of the staff tended to follow the example set by the leaders of their service.

Pineault also examined the effect of medical training factors on test utilisation behaviour.\textsuperscript{193} Doctors trained
in medical schools and hospitals with a scientific medical orientation generally used fewer such resources than other doctors. However under conditions of uncertainty (when diagnosis is unknown) such doctors tended to use more services. Overall, such doctors were found to be conservative in their use of resources when ambiguity was low, but liberal when ambiguity increased.

Another commonly reported factor centres on the lack of proper education of medical students and residents concerning the proper use and costs of laboratory tests. Although medical students are taught to make most diagnoses with information obtained from a thorough history and physical examination, they are not provided with data to show how predictive such information can be. The authors report that the end result is often the unnecessary use of laboratory tests. Kassirer found that doctors often judge the likelihood of diseases and outcomes erroneously and also combine data on probabilities inaccurately. Young found that unnecessary investigations occurred largely because of ignorance, lack of thought, vagueness and duplication.

Other factors suggested stem from the doctor’s personal practices and whims, among them curiosity about test results, ignorance of test characteristics, financial motives, and irrational and ossified habits.

Although no consensus has been reached about which
elements contribute most, Kassirer argued that one neglected cause, attributable to the individual doctor, is the "inordinate zeal for certainty".

According to Geller, Faden & Levine, the practice of medicine has always been characterised by uncertainty, arising from limitations of professional knowledge, problems of diagnosis, ambiguities of treatment and outcome, and the unpredictability of patient response.

Kassirer also found that doctors test excessively to reduce their level of uncertainty. He argued that clinicians have woven the goal of reducing uncertainty into everyday clinical practice and teaching. Often the overriding reason is reassurance of the doctor while the perceived benefit to the patient becomes a secondary consideration. Kassirer also explored the reasons of why doctors would feel uneasy with uncertainty, arguing that they have been taught to think categorically and thus often falter when thinking in terms of probabilities. Although doctors tend to disregard uncertainty or behave as if it does not exist, they use inexact expressions such as ‘probable,’ and ‘likely’ to describe the chance nature of events and efficacies of treatment.

Despite evidence that uncertainty in medicine contributes to variation in medical practice patterns as well as the use and cost of care, the influence of tolerance for
ambiguity on doctors' practice is not well understood, and has been overlooked in the selection and training of medical students.\textsuperscript{206-208} Tolerance for uncertainty is becoming increasingly important as technological advances add to the ambiguities of medicine.

Furthermore, routinely performing low-yield tests raises the cost of health care without much benefit. Doctors with a low tolerance for uncertainty may seek relief in performing tests that have a low yield.

2.5.2 Decision making in isolation

Although many factors have been identified, a significant contribution to the problem arises from the lack of any real driving force to sustain ongoing improvement in the ordering of laboratory tests.\textsuperscript{209} This occurs as a result of the poor, or lack of, ongoing communication and teamwork between the requesting medical officers, the ward nursing staff and the laboratory scientists and pathologists who provide the service. No team plan generally exists towards improving the process of test selection and ordering. Test ordering is in most instances undertaken by individual clinicians working in isolation from the other customers and providers of the pathology testing service.

Doctors who make test ordering decisions in 'isolation' tend to utilise the laboratory services poorly. According to Travers\textsuperscript{310}, there is not enough interest or
participation of either senior clinicians or pathologists in informing resident medical staff about the nature of the tests. Travers found that doctors generally thought that they must order numerous tests because ordering small numbers was not complete care.

An example of such test ordering being undertaken in isolation was recently highlighted by Saxena et al.\textsuperscript{211} In a large teaching hospital, serial estimations of CK-MB to exclude the diagnosis of AMI were often ordered inappropriately at far too short time intervals between tests. On many occasions, the resident medical staff were found to have tested the third and final CK-MB sample only 10-14 hours after the patient was admitted, and not at 24 hours as recommended. This was found in many cases as an attempt on their part to make an early decision so as to reduce the overcrowding of the medical admitting area. However by collecting the sample too early, there may not have been sufficient time elapsed for the level to become abnormal in actual AMI. The result was that some patients with AMI were incorrectly excluded from having had it. This example illustrates how inappropriate test utilisation does occur when test ordering is undertaken without any close links between the user and the provider of the service.

\subsection*{2.5.3 Organisation of clinical practice}

A recent editorial in The Lancet explored the issue of
why inappropriate testing persisted despite conclusive findings that many tests were "a waste of time and money".\textsuperscript{212} The report largely attributed the problem to more fundamental reasons concerning the organisation of clinical practice and the attitudes of doctors, noting that in hospitals, a decision to order a routine test is usually taken by the most junior member of the medical staff, the intern or resident medical officer. Often the tests are ordered as a matter of habit\textsuperscript{213} and the medical officer is frequently ignorant about the value of the test requested.\textsuperscript{214} The tendency of these habits to be passed from one generation to another encourages 'occupational rituals' in patient management.\textsuperscript{215}

Hubbell et al. also found that test ordering depended more on habit than on the clinical status of the patients.\textsuperscript{216} Resident medical staff were shown to frequently pre-order liver function tests routinely every 2-3 days on their patients regardless of whether the tests were directly justified.

Excessive testing has also been implicated as a function of the forces imposed on the doctor by the system of patient care.\textsuperscript{217} Such factors include pressure from peers and supervisors, the convenience with which tests are ordered, the demands of the patient or family, and the desire to avoid malpractice claims.\textsuperscript{218-220}

The editorial reported that resident medical staff often
believe that consultants wish them to order certain tests, although the consultants’ wishes may never have been stated overtly.\textsuperscript{221} Resident medical staff have not only perceived pressure from consultants, but generally feel that they will get in trouble if they do not order certain tests.\textsuperscript{222} Certainly consultants do tend to criticise junior staff for failing to request particular tests\textsuperscript{223–225} and such censure may partly explain the greater use of diagnostic tests by younger doctors.

Harrison, Rapaport & Thibault explored what they described as the ‘fallacy’ of routine laboratory testing orders in the Coronary Care Unit.\textsuperscript{226} They found that the existence of routine test orders for AMI within the CCU contributed to test overutilisation because unnecessary tests were repeated over several days without adding any further useful information towards patient care. In the typical CCU standing order, overtesting of total CK and CK-MB to day 3, and then further LDH and LDH isoenzyme determinations well after the diagnosis has been accomplished was totally unnecessary.

Hardwick et al. found that resident medical staff tended to order more tests as a precaution.\textsuperscript{227} In the diagnosis of AMI, they found that the habitual ordering of numerous cardiac enzyme tests can become so ingrained that they can be easily ordered in nonrelevant situations as ‘a rote reaction’.
2.5.4 Lack of clinical control measures

Travers also attributed several other factors to the inappropriate use of tests. She found that doctors prefer to use the 'shotgun approach' and order larger test profile groups, instead of specific tests. This approach she claimed was a learned behaviour pattern which had been widely practiced since the advent of multiphasic automated testing in the late 1960s. It was relatively easy to order tests because hospitals generally failed to have any real clinical control measures over ordering practices. There was also no formal mechanism to encourage doctors to look at the outcome of the result of a series of tests. These were described as the "missing components" in medical diagnosis. However, Travers stressed that a major hurdle existed in that there was nothing substantial in the literature to provide outcome analysis for a group of tests and procedures.

Kassirer argued that the virtual freedom of doctors to use laboratory tests and procedures with very little control has accustomed us to levels of diagnostic certainty higher than was required for optimal decision making.

2.5.5 New developments in medicine and the laboratory

According to Deeble & Lewis-Hughes, increased accessibility to services has been a significant factor
in the increased volume of tests. 232

Historically, the introduction of new automated technology to the clinical laboratory resulted in many clinical chemistry and some haematology tests becoming relatively less expensive when performed in large volumes.233-235 Multichannel clinical chemistry analysers allowed certain tests to be profiled together and conveniently tested as a group on a single serum sample. This essentially encouraged clinicians to generously utilise the tests at all stages of care including the initial evaluation, the diagnosis and the disease management. Wong & Saxena argued that many of the tests that were subsequently ordered in such a fashion were inappropriate and thus could not be justified clinically.236

In a study on the ordering of cardiac isoenzyme tests for the diagnosis of AMI, Wong et al.237 also found that part of the increased use of tests is caused by new developments in medicine. Not only have new tests become available, but also new therapies have required intensive use of laboratory tests to monitor patients closely.238 Whereas in 1960 the average hospital laboratory only offered about 75 tests, today the range has expanded to at least twice that, and in most cases the interpretation of results is more complex.239
2.5.6 Organisational failures

Edwards & Lapsley\textsuperscript{240} argued that organisational failures within the hospital contributed significantly to the ordering of unnecessary tests. Such problem areas included the failure of systems to track patient movements within the hospital and laboratory information systems and report delivery systems not being integrated with patient tracking systems. These systems problems often resulted in tests that had already been ordered in the Emergency Department being repeated on admission before the first set of results had become available.

2.5.7 Medical litigation

The fear of medical litigation is also increasingly contributing to the unnecessary use of tests.\textsuperscript{241-244} According to Sox the doctor is concerned with avoiding mistakes that could cause harm to the patient, thereby leading to possible lawsuits.\textsuperscript{245} For many doctors, ordering a test is a good way to ensure against mistakes, even if there is little chance of a result that would change the management of the patient. Allison reported that obstetricians in one region were now found to be ordering more diagnostic tests than five years ago. The single most attributable factor to such inappropriate testing was identified as the fear of litigation.\textsuperscript{246} However such a belief may often be mistaken. Ordering a test with a highly false negative rate is no insurance against missing disease, and doing a test with a high
false positive rate may lead to the danger of wrongly attributing a positive test result.

2.5.8 Influence of the patient

Kreig, Gambino & Galen argued that in addition to seeking confirmation of a clinical impression, doctors often request laboratory services to show the patient that something is being done, even if an abnormal result will never lead to any change in diagnosis or therapy.\textsuperscript{247}

Myers & Schroeder found that patients significantly influenced doctors in the ordering of hospital services by requesting particular treatment or by reinforcing liberal ordering practices. Patients were found to associate advanced technological procedures and medications with good care.\textsuperscript{248}

Sox reported that patients were concerned with maximising their expected gains. He found that many believe that the way to accomplish such goals was to get as much health care as possible for as little out-of-pocket expenditure.\textsuperscript{249} Patients may thus pressure the doctor to order tests that are not indicated, because of their false impression that more tests result in better care.

2.6 Assumptions and limitations

The present review of the literature on laboratory test utilisation identified several limitations amongst the studies undertaken. The results and other findings of the
studies will therefore need to be interpreted cautiously, especially when attempting to extrapolate the data across the health system.

Schroeder reported that although most of the hospital based studies seemed impressive, they had four clear methodological limitations.  

Firstly, the majority of the studies have been undertaken at academic medical centres and largely from internal medicine services. Whether or not the findings also hold for other types of hospitals, and for non-internal medicine services is still unclear.

Secondly, although the reports are largely hospital based, many of the studies have extrapolated the findings to the wider health system which also includes outpatient and general practitioner test ordering.

Thirdly, the reports almost exclusively tend to concentrate on the more high throughput, high volume and low unit price laboratory services than on the more expensive ‘high ticket’ items. The implication is that the majority of studies may not be representative of the total system of test ordering, and that caution should thus be taken when interpreting the data.

Finally, Schroeder described the studies as ‘asymmetric’, in that they largely ignored test underutilisation. Most of the studies in fact investigated overutilisation and
not essentially inappropriate test utilisation as defined in 2.1.

As discussed in 2.3, the incorrect assumption in many reports\textsuperscript{251-253} was that overutilisation was a term that was interchangeable by definition with inappropriate test utilisation. Although overutilisation provides the major source of inappropriate testing, the definition also includes the underutilisation and poor selection of tests. Therefore based on this false assumption, the follow up improvement strategies in some reports have invariably been aimed at reducing the number of tests requested, and not necessarily to achieve ‘appropriate’ testing levels as defined in the current research project. The problem with studies that essentially target test reduction are that appropriateness of testing is rarely achieved since necessary tests as well as unnecessary ones are often eliminated.

Epstein, Begg & McNeil also found that many investigations have been based on poor methodology.\textsuperscript{254} In particular, they reported that most studies which have attempted to identify clinicians that they termed as ‘high testers’, have either not used a uniform case mix or have used atypical practice settings.\textsuperscript{255-257} The major weakness with such an approach is that in the grouping of a number of clinical disorders together it does not allow for any valid analysis of the appropriateness of testing
for any specific disorder.

2.7 Summary

Chapter 2 essentially examined a number of important issues that relate to the appropriateness of clinical laboratory test utilisation in the early management of AMI. Several areas were focused upon, including the development of testing strategies, the decision making process, test ordering behaviour, the implications of inappropriate testing, and the various factors that influence inappropriate utilisation.

The process for the development and selection of appropriate testing strategies for patients with suspected AMI has proved to have been poorly undertaken by clinicians. Research studies have shown that test ordering was often neither carefully planned nor thoughtfully studied.

An extensive review of the English language literature covering the past 20 years on the utilisation of clinical laboratory tests, has clearly shown that test ordering has universally been considerably misused. Specifically in relation to AMI, laboratory testing has similarly been found to have been inappropriately utilised. A number of studies have shown that in AMI, tests are often ordered too frequently and the blood samples collected at inappropriate times.
The review of the literature did however identify several factors of concern with the methodology used for some of the research undertaken. The majority of the studies were undertaken at academic medical centres and largely from internal medicine services. The reports also almost exclusively concentrated on the more high throughput, high volume and low unit price laboratory services than on the more expensive ‘high ticket’ items. Whether or not the findings also hold for other types and sizes of hospitals, for non-internal medicine services, and for outpatient and general practitioner services is still unclear.

The investigations also largely ignored test underutilisation. Most of the reports in fact investigated overutilisation and not inappropriate test utilisation as defined in 2.1.

Some of the reported studies in fact assumed that overutilisation was a term that was interchangeable by definition with inappropriate test utilisation. Based on such an assumption, and also on the widespread attention currently being given to cost containment, test ordering improvement strategies have generally aimed at reducing the overall number of tests and not necessarily at achieving ‘appropriate’ testing levels as defined in the current research project.
Numerous factors have been identified as contributing to the inappropriate use of laboratory tests in hospitalised patients, including those with AMI. These include the characteristics and training of clinicians, decisions made in isolation, organisational issues, lack of control, new developments, litigation and patient influence.

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7. Specificity measures the proportion of negative (normal) results in patients without disease.


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17. Black, Panzer, Mayewski & Griner, op. cit; p.4.

18. ibid; p.4.

19. Krieg, Gambino & Galen, op. cit; p.76.

20. Black, Panzer, Mayewski & Griner, op. cit; p.2.


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103. Myers & Schroeder, op. cit; p.481.


119. Eisenberg, Sankey, Garner, Viale & Smits, op. cit; p.918.


121. Wong & Lincoln, op. cit; p.2510.

123. Wong, McCarron & Shaw, op. cit; p.3076.

124. Winkel & Statland, op. cit; p.418.


126. Griner & Glaser, op.cit; p.1336.


132. Connelly & Steele, op. cit; p.59.

134. Deeble & Lewis-Hughes, op. cit; p.7


147. Connelly & Steele, op. cit; p.59.


The ‘Ulysses Syndrome’ refers to a situation where a healthy person has the misfortune of having a false positive result emerge from a battery of screening tests.
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CHAPTER 3. TRADITIONAL IMPROVEMENT APPROACH

Chapter 3 provides a detailed review of the various current and traditional strategies that have been used to improve the appropriateness of clinical laboratory test utilisation. However most, if not all, of the measures used have failed to improve the situation. As will be shown, most efforts have laid blame on test requesting doctors as the cause of the problem, and directed strategies at changing their test ordering behaviour.

In Australia, as well as in many other nations, a succession of regulatory and non-regulatory strategies have been used in an attempt to reduce the overutilisation of clinical laboratory testing. Such measures have been directed at both the demand\(^6\) and supply\(^2\) of pathology services.\(^3\)\(^-\)\(^5\)

Most efforts to reduce inappropriate laboratory testing in AMI and other clinical conditions, have involved hospital based, non-regulatory strategies directed at the demand for pathology.\(^6\) Such measures have attempted to influence the doctors' ordering patterns in hospitals through educational programs, feedback, administrative rules, financial incentives, and financial penalties.

Whereas a few studies have reported some reductions in inappropriate test ordering following strategies targeted directly at doctors\(^7\)\(^-\)\(^8\), the majority of research has shown
little or no sustained improvement from such measures.\textsuperscript{9-11} As an example, educational strategies require continuous reinforcement or else behaviour reverts to the previous state in a relatively short time.\textsuperscript{12}

Strategies have also been directed at the supply of pathology services in an attempt to control rising costs. In Australia, such cost containment measures have been driven by the Federal Government, and have included the restructuring of the Medicare Benefits Schedule of fees for pathology, including several progressive reductions of rebates for common tests.\textsuperscript{13-14}

In the United States, government and private third party payers of health care have also embarked on numerous strategies to contain the ever increasing costs attributable to pathology testing.\textsuperscript{15-17} Such regulatory strategies have largely been measures of cost containment directed at reducing overutilisation, and not necessarily aimed at improving the appropriateness of testing. However, despite the existence of such measures, laboratory utilisation has continued to grow.\textsuperscript{18}

3.1 The current management climate
The current approach to health services management is essentially one of traditional, hierarchical control of the management process.

According to Mayer\textsuperscript{19}, current management practice relies
considerably on both authority and inspection for its central motivation. He argued that such a philosophy invariably resulted in constant crisis management. Under such circumstances, the manager is predominantly dealing with deviations from the expected norm and not with the more productive areas of planning and designing for the products and processes at hand.

The current emphasis is rather more on improving individual performance than on improving organisational processes and systems. However, when the improvement of processes, such as the appropriateness of laboratory test utilisation is called for, the approach invariably adopted is that of ‘Whose fault is it?’.

Figure 3.1 illustrates the traditional hospital management approach taken when expenditure for clinical testing has exceeded the amount budgeted. In this organisational chart, communication is primarily up and down the chain of command. Clinical staff are often targeted in order to restrict test orders.

3.2 Targeting clinician behaviour

Overall, most strategies to improve the utilisation of tests have been directed at changing the behaviour of the requesting clinician. The rationale being used is that since doctors are legally and solely responsible for the ordering of laboratory tests, then influencing their behaviour is likely to reduce the problem of
inappropriate testing. Some doctors are therefore invariably regarded as 'bad apples' and the strategy essentially is to 'weed them out'.²¹-²²

Several measures to change clinician test ordering practices have been implemented in hospitals, generally across a wide range of clinical conditions. Only a few studies have in fact specifically targeted AMI or other specific disorders for test utilisation improvement.

As will be shown in this chapter, a number of studies
have been purely cost containment exercises largely designed to decrease test utilisation and not necessarily to improve or enhance the appropriate use of tests. In such studies, success was often measured by a decrease in test usage or as often termed an improvement in 'test ordering behaviour', regardless of whether the tests used provided appropriate and quality care as defined in 2.1.

The interventions used have primarily consisted of educational programs, feedback, administrative rules, financial incentives, and financial penalties.

3.2.1 Education

The most popular approach to changing the test ordering behaviour of clinicians has been to establish education programs. \(^{23}\) A variety of educational methods have been used, including group discussions, seminars, workshops, informative newsletters, and peer reviews of medical records.

However, a large number of studies have clearly shown that modifying the test ordering behaviour of clinicians cannot be accomplished simply by educational programs alone. \(^{24-26}\) Simply issuing junior doctors with handbooks and guidelines or providing feedback on the numbers and costs of tests requested seems to have had very little long-term impact. \(^{27-28}\) Nevertheless, education in the appropriate use of laboratory tests commencing with early medical training and continuing in their subsequent
career has been suggested as a worthy long term measure.\textsuperscript{20}

In their investigation into laboratory test ordering, Wong & Lincoln\textsuperscript{20} found that coronary care unit staff had used tests inappropriately during the diagnosis and management of patients with AMI. These investigators revealed that informal test ordering protocols, not following a physiological rationale, were common in teaching hospitals and represented part of the ‘folklore of resident practice’.

Wong, McCarron & Shaw\textsuperscript{21} further reported that such test ordering protocols for the diagnosis and management of AMI had been developed without any due consideration of the appropriate and efficient use of laboratory tests. Such protocols were said to have been passed on to successive groups, serving as a main area of ‘education’ for the resident medical staff in laboratory testing.

Initially, Wong and Lincoln\textsuperscript{22} had assumed that the problem required education of the staff on the appropriate use of tests. On closer examination they found that the formal protocol for the evaluation and care of suspected AMI was being ignored for test ordering. The medical staff had however sanctioned for general use an informal protocol that was a product of accumulated anecdotal experience.

Overall, the use of educational programs had failed to improve the ordering of laboratory tests because it had
been assumed wrongly that the cause was a defect in
cognitive knowledge. However, the test ordering behaviour
was not found to depend on cognition but on the firm
acceptance of an in-house informal protocol.

Saxena et al.\textsuperscript{33} also recently reported that they were not
aware of any previous studies where educational measures
had been successful in the long-term improvement of
laboratory test ordering by clinicians. They found that
despite the availability of published guidelines for the
use of laboratory tests for AMI, tests continued to be
ordered inappropriately at their large teaching hospital.

Schroeder et al.\textsuperscript{34} also found that in the absence of other
cost containing incentives, doctor education alone is not
an effective hospital cost containment strategy.

Eisenberg et al.\textsuperscript{35} targeted clinicians with an educational
program designed to reduce the overutilisation of LDH and
calcium. During the study period, 51\% of the audited
patient charts showed inappropriate use of the cardiac
enzyme LDH. However, the educational program was found to
be ineffective.

Several reports have argued that the ultimate success of
the programs depend largely on the leadership and
enthusiasm of the senior medical staff, and that any
improvements are difficult to maintain and sustain.\textsuperscript{36-38}

Many studies have shown that education needs continuous
reinforcement or else test ordering behaviour returns to the previous state in a relatively short period of time.\textsuperscript{39} Eisenberg found that an intensive educational program comprising posters, conferences, and mailings to the resident medical staff of a hospital resulted in a significant improvement to the problem of the overutilisation of prothrombin time tests.\textsuperscript{40} However, when the educational program had ceased, test use returned to its baseline level within a matter of only six months. Similarly, Rhyne & Gelbach succeeded only temporarily in improving the appropriateness of thyroid function testing.\textsuperscript{41} Once the educational program to clinicians had been withdrawn previous unacceptable test ordering returned.

Greco & Eisenberg found that most strategies were inherently ineffective, especially when used in isolation.\textsuperscript{42} They argued that success was largely dependent on the circumstances in which they were used. Combinations of methods were generally found to be far more superior than single forms of intervention. It was also found that strategies needed to be carefully planned prior to implementation.

3.2.2 Feedback

The provision of information feedback to clinicians has been another strategy that has been used in an attempt to improve the appropriateness of test ordering.\textsuperscript{43-45}
Feedback involves providing clinicians with some information about how their test ordering practices, costs and patient outcomes compare with those of other clinicians or with objective standards for appropriate test use.\textsuperscript{46-47} Although a few studies have reported some success of feedback in reducing test usage, no study has yet shown it to result in an overall improvement to the appropriateness of test utilisation as defined in section 2.1. Brodie argued that information about the prices of tests must be readily available to doctors if they are expected to practice cost-efficient medicine.\textsuperscript{48}

In a recent review of several research articles written on the effects of feedback of information on clinical practice, including 10 studies on laboratory test ordering, it was found that feedback was most likely to influence test ordering if it was part of a strategy to target decision makers who had already agreed to review their practice.\textsuperscript{49}

Feedback that provides clinicians with a greater awareness of laboratory costs is generally intended to provide a more discerning use of the laboratory by the requesting doctor. The rationale behind the strategy in place is that clinicians who are made cognisant of the costs of care will become more judicious in their test ordering behaviour.

Overall, the strategy of feedback has however only had
limited success in improving the appropriateness of test ordering.\textsuperscript{50-51} Although a few interventions resulted in reduced test ordering and therefore lowered costs, it was not necessarily accompanied by improved appropriateness of test usage. Such investigations were generally aiming at reducing test usage and not targeting improvements in the form of appropriate test type, frequency and time of collection. The incidence of underutilisation was also not considered.

A few studies have shown that if the information is timely and readily understandable, it provides some effectiveness,\textsuperscript{52-55} especially when used with educational programs.\textsuperscript{56-58} Gama, Nightingale & Ratcliffe reported some success through the introduction of educational feedback. Information was provided to clinicians on their requesting patterns for cardiac enzyme tests in the diagnosis of AMI.\textsuperscript{59} Although the strategy led to a significant decrease in the ordering of LDH, there were no significant changes in the number of CK tests ordered per AMI patient.

Other reports have also indicated that feedback did not contribute substantially to any improvements,\textsuperscript{60-63} or when achieved were difficult to sustain for any reasonable length of time.\textsuperscript{64}

According to an editorial in \textit{The Lancet},\textsuperscript{65} it has been suggested that strategies involving feedback and chart
review may well act by triggering clinicians to think more carefully when ordering tests, but they do not get to the root of the problem. The article strongly argues that such strategies will have no long term impact because of the deeply ingrained attitudes to testing. The author warns that these attitudes must be changed if long term rational use of laboratory tests is to be achieved.

Greco & Eisenberg reported that feedback had very little effect on clinicians' practices.66 The authors argued that such failures, although unfortunate, do provide useful information for the ultimate development of effective feedback strategies. For this to occur, clinicians should recognise that their practices needed improvement. The clinician receiving the feedback must then be in a position to act accordingly. They stressed that clinicians may not respond to feedback if unable to do so immediately.

Nevertheless Tierney et al. reported that the strategy of audit-feedback has provided the most consistently favourable results in reducing overusage of tests.67 However, such measures are labour intensive and have been found to have little carry-over effect once discontinued.68

Pugh et al. used a controlled intervention on two medical wards in a private tertiary care medical centre to examine the effect of daily charge feedback on inpatient
charges. The intervention comprised feedback being provided on the following information: the patient’s probable diagnosis related group (DRG) assignment, current diagnoses, procedures undertaken thus far, cumulative charges for room, laboratory tests and radiology, and length of stay (LOS) to date. For comparative use, data was also provided on average charges and average LOS for recent patients under the same DRG. The sheets bearing this information were placed within the patient’s medical chart each day on the feedback ward only. Overall, the investigating team found that charge feedback alone provided an effective measure for reducing charges. However, it was also noted that its effect would probably be enhanced if it was combined with other strategies such as teaching or financial incentives.

Wones also found that although computer generated audits with feedback were effective in improving the resident medical staff’s awareness of test utilisation, it had no effect in improving test ordering behaviour.

Similarly, Grivell et al. initiated a program whereby clinicians were provided with regular feedback on their clinical chemistry laboratory test ordering patterns. At monthly intervals doctors received data identifying the number and costs of tests ordered. The authors found that such a measure had no influence on reducing the
unnecessary tests being experienced at the hospital.

In a controlled trial of two strategies for improving test ordering, Everett compared the use of education with feedback about actual test utilisation.\textsuperscript{72} The study clearly showed that neither strategy, either singly or combined, had any effect on test ordering behaviour.

Mitchell & Fowkes also found that simply feeding back information to doctors on performance has almost no impact on changing clinical behaviour.\textsuperscript{73} However, feedback combined with other educational measures appeared to have some success in changing practice.

Tierney, Miller & McDonald also studied the effect of informing doctors of the costs for outpatient diagnostic services on their ordering of such tests in a teaching hospital.\textsuperscript{74} During the 6 month intervention period, the doctors in the study ordered 14\% less tests per patient than those in the control group. However, during the 19 week period that followed the 6 month intervention, the number of tests ordered was only 7.7\% lower than the control group. The effects of the feedback were therefore not completely sustained.

3.2.3 Administrative rules
According to Greco & Eisenberg, when all other strategies fail, changes in test ordering practices can be sought by way of administrative changes.\textsuperscript{75} Such strategies simply
make it more difficult for the clinician to order a laboratory test. They are not necessarily directed at improving the appropriateness of test usage. The strategy is usually achieved by imposing a direct burden on the requesting doctor. Examples of such measures include, changes to requesting procedures and in particular request forms, placing a requirement for approval from a higher authority before specialised laboratory tests can be utilised, and introducing a mechanism of rationing on test usage.

Changes in test request procedures have had moderate effects on reducing laboratory test utilisation. Peters & Broughton found that redesigning the request form, for example, by listing tests in alphabetical order, or by providing a blank form where the clinician must write the tests required, has resulted in a decrease in the number of tests ordered.

Zaat, Van Eijk & Bonte also achieved positive results by limiting the choice of specific tests listed on the laboratory request form. By not displaying an open choice of tests, this strategy resulted in clinicians being more careful in the ordering of tests. However, as with many other strategies, the investigators found that the effects were only temporarily sustained. Once the previous request form had been reissued, most clinicians returned to their earlier test ordering
behaviour.

In Australia, the problem of the request form listing pre-printed test names is no longer an issue. Since 1987, menu or 'tick a box' request forms which might influence excessive test ordering have been eliminated by legislation. Only blank form ordering is now permitted.

Griner also introduced several administrative changes in an attempt to change poor test ordering behaviour. Under this system, it was mandatory that resident medical staff order tests in the ward medical order book and not onto the highly structured request forms. In addition, resident medical staff were strategically rotated through various departments. As an example, third year residents with known performance in ordering tests appropriately were moved from elective rotations not requiring test ordering, to ward rotations involving direct patient care decisions. Also, less experienced residents were moved to the elective rotations. Griner combined these administrative changes with an educational program, achieving moderate success in decreasing test usage.

Access to certain tests can be readily limited by administrative decisions. As an example, Rutledge achieved a reduction in test usage through the requirement that a telephone confirmation by the requesting medical staff must be made for certain test procedures.
Eisenberg & Williams also reported that many hospital Pathology Departments require prior approval for certain tests before they are performed. However, the authors questioned whether such an administrative rule is cost effective since the cost of having senior medical staff evaluate each situation is a major expense in itself.

Similarly, Gray & Marion reported reduced anticoagulation testing by resident medical staff who were required to consult a laboratory Haematology resident prior to ordering the tests.

Kroenke et al. also achieved some success through an administrative rule requiring the intern to list on the request form the reason for ordering the test. This strategy resulted in improved test ordering.

Dixon & Laszlo achieved a 25% reduction in test utilisation by limiting resident medical staff to only eight tests per patient per day.

The strategy of rationing laboratory tests has however generally been regarded as impractical and limited. The measures have invariably been aimed at reducing test usage and not necessarily at improving the appropriateness and quality of test selection.

3.2.4 Financial incentives and penalties
A small number of studies have investigated efforts to
alter clinician test ordering behaviour through the offering of financial rewards when the desired appropriate behaviour is achieved.\textsuperscript{93-94}

However most of the studies have shown that such strategies have had no real effect on test ordering behaviour.\textsuperscript{95-96} As an example, Martin et al. investigated the effect of a small financial incentive, in the form of educational books, for reducing the usage of clinical laboratory tests.\textsuperscript{97} Resident medical staff were each placed into one of three groups. The first group received the financial incentive, the second group met weekly to undertake a detailed review of charts but were not paid, while the third acted as a control group. Once the trial had been completed, the financial incentive group had attained reductions in test ordering but this was however less than the second group that reviewed charts. It also performed the least well when compared to the other groups in all respects. Overall, the financial incentive scheme had generated very little enthusiasm. Some doctors in fact were found to have reacted negatively to the notion of altering their behaviour for monetary purposes.

Wickings on the other hand reported that some doctors in the United Kingdom reacted positively to measures that permitted them to redeploy any monies saved.\textsuperscript{98}

In addition, in most fee-for-service systems, test ordering patterns adjust quite readily to the addition or
withdrawal of a fee, so that indirect links between payment and performance are accepted. However, of importance is the finding that clinicians have displayed a strong resistance to incentives which link their behaviour with personal rewards."

Another measure, the use of financial penalties, has also been suggested in a few reports as an alternative risk sharing strategy. Under such a measure clinicians would become financially accountable for their practice behaviour.\textsuperscript{100–101}

Jackson & Peters proposed several potential measures for cost sharing by which clinicians who overutilised health services would suffer a financial penalty.\textsuperscript{102} Similarly, Eisenberg & Rosoff argued that until doctors were personally held liable for financial risks associated with the overutilisation of their services, health care expenditures would continue to rise.\textsuperscript{103}

On the other hand, Grossman argued strongly that the use of penalties were unrealistic and promised very little for long term success.\textsuperscript{104}

3.2.5 Efficacy of the strategies

As discussed, most of the strategies outlined above have essentially sought to reduce the number of tests being used and not necessarily to improve the appropriateness of test selection. Only a few studies in fact considered
underutilisation of tests as relevant in their improvement strategies.\textsuperscript{105}

It is therefore not surprising that none of the measures outlined above have been found to be effective in improving the appropriateness of test utilisation. In fact only a few have reported moderate success in decreasing test usage, but not necessarily over an extended period of time.

Combinations of methods were generally found to be far more superior than single forms of intervention in the overall attempt to decrease test utilisation. It was also found that strategies needed to be carefully planned prior to implementation.

Most of the traditional strategies directed at the clinician have been found to be difficult, labour-intensive and expensive to administer.\textsuperscript{106-108} Moreover, directives aimed broadly at reducing test usage and not improving test appropriateness. As discussed earlier, such measures can create additional problems by reducing both useful and useless testing.\textsuperscript{109-111}

3.3 Targeting the supply of services
Strategies have also been directed at the supply of pathology services. A succession of regulatory measures have been used in an attempt to reduce the growth and therefore costs of clinical laboratory testing.
In Australia, cost containment measures have been driven by the Federal Government, and have included the restructuring of the Medicare Benefits Schedule of fees for pathology including several progressive reductions of rebates for common tests.\textsuperscript{112-113} Numerous other measures, including the introduction of a licensing system to rationalise the number of pathology specimen collection systems, have also recently been used.

In the United States, government and private third-party payers of health care have embarked on numerous strategies to contain the ever increasing costs attributable to pathology testing.\textsuperscript{114-116} Diagnosis related groups (DRGs)\textsuperscript{117} and prospective payments\textsuperscript{118} were introduced as tools to improve the efficiency of clinicians and institutions.

However such measures are global and do not differentiate between necessary, appropriate care and that which is not.\textsuperscript{119} Essentially, such regulatory strategies have largely been measures of cost containment, not necessarily aimed at improving the appropriateness of laboratory testing. However, despite the existence of such measures, laboratory utilisation has continued to grow.\textsuperscript{120-121}

In Australia pathology services are almost entirely funded by the Federal Government. The third party funders, in particular the Health Insurance Commission\textsuperscript{122},
constantly monitor pathology utilisation and cost.

During the financial year 1991/1992, the Health Insurance Commission took positive action to reduce service utilisation within Australia. General practitioners were provided with personal data on their medical services rendered, the associated benefit costs, and the nature and cost of their pathology test ordering. Their personal data were compared with the modal ranges for the state that they practise in. Wilson described as 'dramatic', the effects that such a strategy had caused. The rate of referral was decreased, as was the number of tests requested per patient. The savings to Medicare were estimated to be over 86 million dollars.

However, the Australian Government's strategies have had very little impact on the growth and utilisation of pathology services within the public hospital system. This is largely because the schedule restructuring and the utilisation inhibition largely affects private practice incomes.

The health system in the United States has had a history of major cost containment strategies being implemented. Medicare's prospective payment system based on DRGs led the way, with health maintenance organisations, preferred provider organisations, state regulatory agencies, and deductibles and coinsurance just behind.
In the United States, the entire health care system is currently being restructured in accordance with the new Clinton plan, the Health Security Act.\textsuperscript{125-126} A new order of managed competition is planned, with almost all sections of the clinical laboratory system being greatly impacted.\textsuperscript{127} Under the current but fading fee-for-service payment system, the laboratory is a revenue and income generator. When managed care begins to take a leading role, more doctors and laboratory services will become ‘capitalised’.\textsuperscript{128} The resulting system will be structured with a reimbursement limit per individual despite the amount of tests ordered or services rendered.

As was the case with Australia, such strategies have been measures of cost containment aimed at reducing overutilisation, and not necessarily measures designed on improving the appropriateness of testing.

3.4 Effect on quality of care
Schroeder argued that whether strategies directed at changing a clinician’s behaviour will ultimately effect the quality of care depends upon the population affected and the services reduced.\textsuperscript{129} If the burden of the strategies effects patients who already have poor access to health care, then the quality of patient care will suffer.

The traditional strategies have generally aimed at reducing the overall number of tests and not necessarily
at achieving appropriate testing levels for good patient care. The real danger with such test reduction measures is that necessary tests as well as unnecessary ones are often eliminated.

The traditional strategies have rarely focused their attention on the underutilisation of important tests, preferring to concentrate on reducing overusage.\textsuperscript{130} Underutilisation of tests is just as undesirable as overutilisation since the real cost to the AMI patient of omitting a necessary test is as high as that for performing the unnecessary ones.\textsuperscript{131}

3.5 Summary

Chapter 3 examined the various strategies that have been used by hospitals and Governments alike to improve the appropriateness of clinical laboratory test utilisation.

The present approach to health services management does not appear to be conducive to the provision of continuous improvement of test utilisation. The traditional approach to quality in the provision of clinical laboratory testing services has been too narrow, focusing mainly on technical performance and not on the requirements of its customers.

The strategies used to improve test utilisation have essentially been directed at both the demand and supply of pathology services. In most cases, the strategies have
been ones of cost containment aimed at reducing the overall number of tests used, and not necessarily improving the appropriateness of test usage. Such measures not only fail to motivate the staff involved in the process of test ordering, but also can create additional problems through the potential reduction of useful tests for the patient.

Whereas a few studies have reported some reductions in inappropriate test ordering following strategies targeting doctors, the majority of research has shown little or no sustained improvement for such measures.

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118. In the USA, Medicare’s prospective payment system was based on DRGs.

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CHAPTER 4. TOTAL QUALITY MANAGEMENT APPROACH

As discussed in Chapter 3, the current strategies being used to improve the appropriateness of hospital based laboratory test utilisation appear to have failed because they have been largely directed at individual test requesting clinicians, targeting them as the root cause of the problem and not the total system that they are working within. In the light of this evidence, this investigation attempts to test the efficacy of a possible 'TQM' solution, taken originally from manufacturing industry and now being embraced by the health care system.

This chapter discusses the proposed TQM approach, its development and features, its introduction and application to the health care system, its potential for improving laboratory test utilisation, and some of the main difficulties and barriers faced in its proposed implementation.

4.1 Total quality management
Although the terms TQM and CQI are often used interchangeably, TQM essentially refers to the overall approach of managing the total aspects of an organisation's quality, whereas CQI refers to one specific element of the total system concerned with continuous improvement of processes.
TQM represents a solid management approach with a strong statistical background that stands in clear contrast to traditional management as found today.²

4.1.1 Development of TQM

W. Edwards Deming and Joseph Juran have essentially been the two major contributors to the understanding of the TQM movement. Their approaches have not been competitive but complementary.³ Deming⁴ and Juran's⁵ principles of quality management assisted the industrial complex of Japan to emerge out of the destruction of World War II to become a world force in manufacturing.

Deming contributed in a major way to the success of Japanese manufacturing by the 14 points of his Deming system.⁶ He understood the role of work processes and systems, and the effect of variation on them. In acknowledging that people play an important part in the search for quality, he stressed that quality was achieved through improving systems, not with blaming people.

According to Deming, TQM involves a modern method of leadership whereby workers are encouraged to take part in decision making processes and where departmental boundaries are abolished.

Juran was a contemporary of Deming, who like Deming stressed that there was a quality crisis in senior
management. Juran's approach focused on three processes, later termed the 'Juran Trilogy'—quality planning, quality control, and quality improvement.

Quality planning starts the overall quality management process and consists of developing the products and processes needed to meet customer needs. This stage involves a number of steps including identifying customers, determining needs, developing product features to meet such needs, developing appropriate processes, and transferring resulting plans to the operating forces.

Quality control is Juran's second element. This involves the assessment of actual performance, comparison of that performance with the goals determined earlier in the planning process, and the identification of any further action required.

Quality improvement is the final element of the Juran trilogy. This involves initially developing the necessary infrastructure for improvement. Specific needs for improvement are then clearly identified and a project team established. A planned process for improvement is undertaken.

According to Fox, the leading industrial companies have one real aspect in common. They have a relentless drive for excellence—a total commitment to quality. Quality commitment requires the development of a strategy for
quality improvement. This should have clearly defined leadership, and channels of communication and responsibility which necessitates the allocation of 'quality time' on the part of all managers.

Leadership commitment and strong employee motivation are essential driving forces for an effective TQM system. This can only be achieved if there is the total commitment of the organisation's senior executives in the transformation of the culture.

4.2 Application to the health care system

While there have been numerous successful applications of TQM in the manufacturing industries, it is only recently that the number of applications have grown in service industries, including the health care industry.\textsuperscript{11-12} Health care has been relatively slower than the general service industry to adopt the new TQM paradigm. Its move towards TQM coincides with the recent recognition that service delivery contained a strong customer satisfaction focus.\textsuperscript{13}

The TQM approach represents a total paradigm shift in health care management and thinking.\textsuperscript{14-15} It involves changing the way quality is viewed, thereby changing the culture of the health system. It provides a new way of thinking and a different way of managing services.\textsuperscript{16}

Many health care organisations in the USA have based
their TQM programs on the Deming method. Originally, the Hospital Corporation of America (HCA) experienced increased quality improvement through this method. Today, HCA TQM teams are at work on most administrative processes, including billing, bed management and clinical processes.

The introduction of such a major philosophical change to the culture of the health system requires that a range of significant issues in service delivery and management be addressed. Such issues include redefining the role of health care workers, redefining the corporate culture and attainment of the "new skills" of TQM and CQI.

4.2.1 Features of TQM in health care

The features of TQM in health care are similar to those found in manufacturing. Such features include executive level commitment, transformation of the organisational culture, participation of the staff, and the need for new skills.

4.2.1.1 Executive level commitment

Executive level commitment to TQM is crucial to its success. The quality management concept must be firmly accepted by senior management before any attempt is made to empower and educate other staff within the organisation.

O'Leary & O'Leary found that there must be a clear single
direction for the organisation and that this needed to be supported by all senior staff including clinicians.\textsuperscript{19} It was stressed that the senior executive must do more than just advocate the TQM philosophy. They argued that this commitment needs to be backed up with the necessary resources, and that the executive need to live the TQM philosophy by example each and every day.

Atchison also found that TQM will only succeed if it is accepted and driven by senior administration.\textsuperscript{20} Lack of support or weak support is regarded as a recipe for failure. It was found that assessing a hospital’s readiness for TQM, starts with an assessment of the Chief Executive Officer’s attitudes about the effort. It was argued that there was a need to ascertain whether the board of directors, doctors and senior managers also showed commitment to TQM.

Whetsell found that the logic behind TQM was intuitively simple.\textsuperscript{21} If the entire organisation was dedicated to meeting customer expectations and to delivering products and services at a competitive price, then success was virtually guaranteed.

Similarly, Westgard & Barry found that senior management must provide commitment to quality if it is to reap the benefits and meet customer expectations of the laboratory service.\textsuperscript{22}
4.1.3.2 Transformation of the culture

If the TQM approach is to succeed, then it must become part of the organisation's culture. In the long term this requires the transformation of beliefs and values about quality improvement and the adoption of a customer oriented approach. Key changes include those of trust building, clear communication, and increased staff participation. The cultural transformation is viewed as an ongoing organisational growth process, and not a one-time event.

According to Barros, a hierarchical and authoritarian style of management will not produce the desired quality clinical laboratory service. It was argued that managers who do not involve their laboratory and other staff in decision making will experience difficulties in attaining the desired improvement.

The TQM culture relies on changing the attitudes of management and employees to that of teamwork, participative management and customer focus. Management needs specifically to give up its short-term focus in exchange for the longer term view of the organisation, its problems and solutions.

4.2.1.3 Participation of staff

TQM provides participatory mechanisms whereby everyone involved in the process is encouraged to contribute to quality improvement. The communication barriers
between the various workers involved in a process needs to be cast aside if TQM is to make any firm inroads.\textsuperscript{29}

Research has shown that when problems do occur they are often at the boundaries or interfaces among functions.\textsuperscript{30} Within the current system of test ordering, staff and departments remain largely bound in well fenced functional subdivisions or compartments, making it easy for people to work in isolation, and blame the other for the problem. The experience of process failure in the ordering of inappropriate laboratory tests is frustrating and demoralising for the clinical and laboratory staff involved. When poor laboratory utilisation does occur, blame is often placed by one group of workers on the other. For example, doctors may blame nurses, nurses blame laboratory staff, laboratory staff blame doctors, and one department blames another. In the current system it is often difficult for any of these staff to see the processes of work as a whole in a way that other customers experience it.

Joiner & Nelson found that the involvement of doctors in the design of TQM programs and other administrative strategies offers an opportunity to develop a working formula for ongoing success.\textsuperscript{31}

Professional group participation involving all workers in the process of test ordering appears to be a more effective way of changing behaviour. Neither doctors nor
any other health care workers could be expected to respond favourably after being blamed for the problem and then forced to make changes."

In such teams hierarchy, education, and status count for little compared with knowledge of the processes and a willingness to contribute ideas.

Evidence shows that doctors in particular should be encouraged to participate in the TQM process. James stressed that several issues should be addressed when planning to involve doctors in TQM projects. Quality improvement theory should be presented as a direct extension of the principles that the medical profession has always espoused. The doctor's self-perceived role as a customer or provider also needs some consideration when the project is being planned. In addition James stressed that caution needs to be taken when examining the diagnostic and treatment processes, since doctors control the major steps.

Bluth et al. found that the traditional notion of the doctor and patient being the only customers needs to be changed. In their study to improve the laboratory turnaround time of reporting results, success was only achieved by the contribution of all staff involved in the process. A team of front desk personnel, medical technologists, pathologists, nurses, doctors and messengers all contributed to the understanding and
improvement of the complexity of processes involved. This multidisciplinary approach of Bluth et al. to improvement has also been adopted in the present research study.

According to Dorsey, the concern about inappropriate laboratory testing has led to a growing realisation that the pathologists should do more than control internal quality, and direct traffic through the laboratory.\textsuperscript{35} The author argued that the pathologist should come out of isolation and play an active role in helping to decide which tests will give value for money, as well as assist in the interpretation of test results and the application of laboratory data to the diagnosis of diseases.

Wong and Lincoln\textsuperscript{36} similarly argued that the laboratory and clinical pathologists can contribute to improved test ordering by working with clinicians to find answers to diagnostic questions. The authors expect that areas such as those in which multiple tests should be used in a logical sequence, are most likely to benefit from the participative team approach.

Murphy and Henry also emphasised the importance of pathologists participating on ward rounds and in clinical conferences.\textsuperscript{37} They argued that pathologists should see first-hand the logic of the requesting doctor’s demand for increasing, varied, or highly specialised laboratory services.
Once worker participation involving all relevant staff has been achieved, the challenge is then that of sustaining such involvement.

4.2.1.4 Need for new skills

The transformation to TQM requires that workers accept a body of new skills to learn and practise in an interdependent system of care. The required skills for staff include the ability to work in interdisciplinary teams, to understand health care as a continually changing and updated process, and to collect and interpret data on patient needs, satisfaction, and values, as well as outcome. The authors reported that staff also may be required to collect, aggregate, analyse and interpret data on the processes of care, and to facilitate the exchange of information with fellow staff.

4.2.2 Tools of TQM and CQI

TQM is invariably associated with a series of problem analysis tools and techniques related to statistical process control.

Generally, data alone does not provide sufficient information for decision making. Data are facts that need to be summarised and displayed in a meaningful way to make them interpretable by the CQI team.

The main tools and monitoring techniques that have been used for process improvement include, flow charts,
Pareto diagrams\textsuperscript{41}, control charts\textsuperscript{42}, cause-and-effect diagrams\textsuperscript{43}, nominal group techniques\textsuperscript{44}, surveys and brainstorming\textsuperscript{45}.

4.3 A quality system for clinical laboratory testing
Traditionally, the overall definition of quality in the provision of clinical laboratory testing has been too narrow. The goal has essentially been to achieve standards representing current laboratory technical performance, based on procedure oriented quality control rather than satisfying the requirements of all its customers— including doctors, nurses and the patient.\textsuperscript{46}

The pursuit for new approaches to improvement has led to the recognition that clinical laboratories can benefit from TQM programs that have taken place within manufacturing organisations.

4.3.1 The traditional quality system
The traditional focus to quality has invariably been one of searching for negative factors, such as mistakes, incompetence, or harmful outcomes and to introduce corrective action. The emphasis has been largely on inspection and fault finding.\textsuperscript{47}

The overall narrow focus on just the technical quality of the clinical laboratory service is now seen as a somewhat inadequate and poor strategy for market success and organisational survival today.\textsuperscript{48}
The history of quality control in the clinical laboratory dates at least to 1950. In 1950, Levey & Jennings described the application of basic statistical practices to chemical tests that had been originally proposed by Shewhart for monitoring the quality of industrial products. Quality control provided a statistical tool to monitor technical performance, identify problems, and correct errors before the final report was issued to the requesting clinician.

In the 1980s, quality assurance concepts were introduced to extend the monitoring to other quality characteristics, such as turnaround time, sample identification and labelling, and test utilisation. However, such quality assurance practices have tended to direct the blame for problems on the people who are doing the actual work. As an example, when inappropriate laboratory testing is identified, the doctor who orders the tests is likely to be implicated and no review generally undertaken of the processes and systems involved with poor test ordering.

Traditionally, quality assurance practices in the United States have tended to follow the standards and required characteristics of the Joint Commission for Accreditation of Healthcare Organisations (JCAHO). According to the authors, JCAHO’s objectives of the 1980’s essentially involved monitoring the quality and appropriateness of
services. This they argued only resulted in the pointless accumulation of volumes of data. Such information gathering was considered ineffective since it essentially only provided the formal documentation of quality assurance, regardless of whether or not the problems were in fact solved. In reality, many of the problems were inherently complex ones involving processes that crossed departmental lines within the organisation.

Using the TQM philosophy, major problems, such as the one being presently investigated, seemingly require a structured organisational wide commitment to quality improvement. No such mechanisms for the ordering of tests and the monitoring of test utilisation are in place within traditionally managed health care institutions.

As discussed in Chapter 2, decisions to select diagnostic laboratory testing strategies in the management of AMI and other disorders are often made without specific planning, and without consultation with other medical, nursing and laboratory colleagues. All too often patients receive inaccurate diagnoses and are subjected to tests that are unnecessary, expensive, or dangerous.55

A recent report argues that the clinical laboratory of today needed to redefine its mission so as to include concrete responsibility for monitoring and managing with its service partners the clinical appropriateness of test utilisation.56
Over the past four years, one promising development has been that the JCAHO has progressively changed its accreditation standards, calling for the implementation of a new approach to quality, that of CQI.\textsuperscript{57} This has offered some hope towards improvement of test utilisation in the United States.

According to Saxena and co-workers, JCAHO’s move towards CQI offers an opportunity to renew discussions with clinicians in order to rectify their problem of the inappropriate use of cardiac isoenzyme tests in AMI.\textsuperscript{56}

The more recent JCAHO standards of 1994 include further positive moves towards CQI. The word ‘quality’ is now being replaced by the term ‘dimensions of performance’. This term defines what is done and how well it was done.\textsuperscript{59}

4.3.2 Pursuit of total quality

The current evidence of the widespread inappropriate use of clinical laboratory tests has obviously cast doubts on the current management approach of the providers of health care. Health care workers have inherently lacked the incentive to integrate internal management processes within an organisation, depending largely on external quality assurance and standards set by accrediting bodies and professional organisations.\textsuperscript{60} Major changes in the definition and perceptions of quality are now required if processes, such as the appropriateness of test utilisation, are to improve.
Rakich, Darr & Longest recently argued that such changes to ‘total quality’ are required at two levels.\textsuperscript{61} Firstly, the definition of quality requires change. As discussed in 4.3.1, quality of care and service traditionally involved the meeting of specifications or standards. However, quality is now being seen as conforming to requirements and fitness for use. Such total quality includes customer satisfaction and meeting customer expectations and needs.\textsuperscript{62-63} Secondly, the emphasis is now on the improvement of inputs and processes that produce service outputs.

TQM clearly emphasises the importance of defining quality on the needs and expectations of customers. It challenges the status quo and insists that everything an enterprise does and how it does it, can be improved to the greater satisfaction of its customers.

Bartlett also defined ‘quality’ as meeting customer requirements.\textsuperscript{64} The definition of customers was broadened to include all immediate internal and external customers of the service. Thus a clinical laboratory’s immediate customers are doctors, nurses and other support and ancillary personnel, as well as the ultimate customer, the patient.\textsuperscript{65} The clinical laboratory service needs to closely communicate with its customers in order to determine whether their service needs are being met.
Figure 4.1 illustrates this new approach to total quality. As shown in Figure 4.1, a set of activities transforms inputs into outputs. For each specific process an analysis should be undertaken of its boundaries; and all suppliers, customers, inputs and outputs clearly defined.

In the utilisation of clinical laboratory testing services in AMI, suppliers and customers comprise a wide range of internal and external individuals and groups, and may even include real or inanimate objects. Inputs can include a number of items such as equipment, supplies, financial resources, staff and specimens. Similarly, outputs cover a wide range of areas including information, results, consultation and printed reports. As discussed earlier, such changes in pursuit of total quality have been supported by new quality initiatives in
the United States. JCAHO's recent 'Agenda for Change' has cleared the way for a framework of quality improvement in that nation. In Australia, the Australian Council of Healthcare Standards has undertaken similar initiatives through the 'Charter for Change'. New Accreditation directions towards improved quality of health care are currently being undertaken.

In their recent position statement on United States health care reform and the clinical laboratory, the Clinical Laboratory Management Association (CLMA) announced that the incentives for test utilisation should be determined exclusively by the pursuit of the best value.6" This was defined as optimising quality in terms of the contribution to patient care. This included improvements in the appropriateness of test ordering, accuracy, and turnaround time.

The use of clinical practice test guidelines has been proposed as one means of introducing appropriate practice.68-70 It has been suggested that widespread use of these guidelines will improve the quality of care by assisting providers in making more informed decisions.71

As discussed in Chapter 2, the early experience with guidelines is clearly that unless clinicians are involved in their development and implementation, they are doomed to failure.72 A TQM approach will therefore need to be considered as essential in any planned introduction of
clinical guidelines.

4.4 Applications of COI to clinical laboratory testing
As mentioned earlier, an extensive review of the relevant internationally based English language literature has shown that until now, no report has yet been published that has used a TQM or CQI approach to specifically improve the appropriateness of diagnostic laboratory test usage in AMI.

Very recently however, Nardella et al.\textsuperscript{73} reported some success with a CQI approach designed to improve the appropriateness of test ordering for bleeding times using a seven-step CQI process involving an advisory structure, focused feedback sessions and test ordering guidelines. The study was however not controlled for the influences of extraneous variables, such as for example, attendance of clinical staff at continuing education programmes on test utilisation. Nevertheless, the study provided positive signs that the CQI approach can improve the appropriateness of testing and thereby significantly reduce costs of the service.

According to Westgard and Barry, solving difficult problems such as the appropriate use of clinical laboratory services, is the domain of TQM.\textsuperscript{74} The authors argued that quality assurance efforts alone are inadequate because they are basically detection mechanisms. The need to attain improved performance
requires that the process be changed and improved.

One recent study did in fact examine standing test orders for open heart surgery as an area of opportunity for continued improvement.\textsuperscript{75} A multidisciplinary team developed a unified set of testing orders with resulting reductions in blood group and crossmatch requests and the number of chest radiographs needed. Overall, there was a decrease in total tests ordered per case by 11\% and total charges by 9.3\%. It however remained unclear as to whether in fact TQM initiatives had been used or whether strict rules for test ordering had been enforced. In addition, no assessment was provided of the overall effect of the reduced testing on the quality of patient care.

The majority, if not all, of the reported CQI studies dealing with pathology services have however focused on issues affecting such parameters as turnaround time of reporting, specimen delivery time, workflow of urgent tests, blood collection procedures, correct completion of request forms, and reduction of errors in laboratory reports.\textsuperscript{76–79}

4.4.1 The FOCUS-PDCA model
Numerous process improvement models have been used to introduce CQI into the workplace. Some of the common elements of the models include the identification of a process or problem, the identification of customer needs
and concerns, the development of an Improvement Plan, and the collection of data.

The FOCUS-PDCA quality improvement model that was chosen for the present investigation, has been widely accepted and used as standard process improvement methodology.\textsuperscript{80-81} The model used was adapted from the model developed by the Hospital Corporation of America.\textsuperscript{82}

The FOCUS-PDCA model uses the following standardised format:

1. Find a process to improve
2. Organise a team that knows the process
3. Clarify current knowledge of the process
4. Understand causes of process variation
5. Select the process improvement
6. Plan the process improvement.
7. Do the improvement, data collection, and analysis.
8. Check the results and lessons learned.
9. Act by adopting, adjusting, or abandoning the change.

The model includes many key elements. Quality is defined in terms of customer needs. Senior management drives the change process which involves major staff input. The systems are analysed for errors and variations.

The FOCUS-PDCA model provides the structured mechanism to improve various processes that extends across different hospital departments and professional groups. The quality
team approach is focused upon because no one person, profession, section or department at the hospital has the knowledge and skills to identify the cause or to develop and implement the solution.

4.5 Barriers to implementation
Since TQM involves a complex paradigm shift in institutional culture, a number of important barriers will need to be overcome if it is to be introduced and accepted in the process of laboratory test utilisation.

In the present study and other studies involving TQM interventions, there is no doubt that acceptance of TQM will require extraordinary leadership, with clear vision, a depth of understanding, careful planning, and patience.83

There are at least four important barriers to overcome. These barriers are time, territory, tradition and trust.84

Introducing TQM strategies to improve the appropriateness of laboratory test utilisation will involve a great deal of time. The time to meet with others, learn methods, collect data on processes and results, discuss progress and suggestions for improvement, and teach. Doctors and other health care staff used to being very busy may find making time to participate in such activities difficult. According to Berwick, Enthoven and Bunker85, this barrier
must be overcome so as to allow staff to become involved within the constraints of their already busy lives.

The second important barrier is that of territory. Once implemented TQM establishes control over work processes, thus enabling those doing the work to carry on with a reduced sense of frustration, waste and helplessness. Paradoxically, such control by people over their own work is attained only when the individuals are willing to see themselves as bound in unavoidable interdependency with others.

Historically, doctors have come to expect autonomy and accountability only to themselves as the norm. With TQM, both the process and the implicit higher level of institutional accountability provides a true culture shock to them."

Traditionally, the complexity of medical care and practice of focusing on individual cases to identify quality kept doctors essentially immune from outside challenge. Further, the concept of "professionalism" as a special status granted by society, earned through years of dedicated study and service, has guaranteed relative autonomy to those who have been able to attain professional status.

Thus for staff used to some clarity about whose working area is whose, TQM would most likely create an atmosphere
of discomfort and loss. Clearly TQM requires that such barriers between functional areas be eliminated so that cross functional processes can become streamlined and improved.

Bluth et al. found that once TQM was introduced to a laboratory service for urgent testing, traditional barriers between services diminished considerably. Different specialists working in the team became more aware and sympathetic of the problems of others. Communication and process problems were found to have become immediately obvious. As an example, a nurse and a clinician from the same ward realised that when describing the same ordering process, the nurse had mistakenly thought that the doctor had required that all the requested tests be ordered urgently.

Historically, there has been a reluctance for clinical laboratory staff and other health care workers to move outside of their secure departmental boundaries. This made it easier for laboratory staff to blame other staff, say doctors or nurses, for problems that occurred.

An example of this is illustrated by Bartlett who argued that at no point in time have pathologists and laboratory managers had the authority to completely control quality in testing services within the entire organisation.

According to Merry, the "TQM generation" of doctors is
however, the first to be exposed to the modern quality process tools and techniques. It should thus be not surprising that their initial reaction to such perceived intrusion is less than enthusiastic.

The third barrier of tradition, ingrained habits and rituals, also needs to be broken if quality improvement is to be achieved. However this may prove difficult since many habits are subtle unspoken rules, such as who may speak when and to whom.

The final important barrier is the one of trust. Working effectively in teams, sharing responsibilities and relinquishing absolute professional autonomy to others, involves having a great deal of trust in others. Trust, like other aspects of human relationships and communication, is likely to build up over time as other barriers dissipate.

As will be shown in 6.2, trust building is one of the key elements of creating a TQM environment for the present project. Gates reported that cooperation and trust follows commitment. However he warns that fear prevents cooperation and that it was important to ensure that any guidelines developed were not used to regulate clinician practice.

According to Walker et al. there are however many considerations to take into account before implementing a
TQM program. The organisation needs to focus on the barriers to successful implementation and assess closely their readiness for TQM in the light of such obstacles.

4.6 Difficulties in implementation

The introduction of a TQM and CQI system is not always successful. In many instances TQM projects have been poorly planned and many potential pitfalls and barriers not appropriately addressed.

From the outset it needs to be emphasised that not all hospitals are ready for TQM. As discussed in 4.5, the barriers to a successful implementation need to be carefully examined before a firm commitment is given to introduce TQM.

If TQM is to succeed in improving the appropriateness of test utilisation, then it must become part of the organisation's culture. In the long term this requires major changes to the beliefs and values held by individuals about quality improvement.

Badrick emphasised the importance of leadership in the implementation of TQM. He stressed that lack of leadership was a common cause of failure of the implementation process.

According to Beesley et al., the traditional top-down management organisation is difficult to change because its managers and supervisors have been trained and have
worked in the traditional system.

Bartlett\textsuperscript{104} found a variety of reactions from managers when they are initially confronted with CQI. The reactions ranged from being quite comfortable to that of doubting that there would be sufficient time for team activities.

One important element in the entire process is that of building and attaining trust. Fear is driven out of the organisation by assuring all staff that the system of clinical laboratory test utilisation is the problem and not the clinicians ordering the tests.

Another pitfall to avoid is that of underestimating the time and commitment that is required to change processes through TQM and CQI.\textsuperscript{105} The fundamental concept of TQM and CQI is that success is achieved only through step-by-step processes that evolve over time.\textsuperscript{106} Even after a five year period of CQI achievements, laboratory staff may still show some frustration over the length of time it may have taken to accomplish their goals.\textsuperscript{107}

Bluth et al.\textsuperscript{108} also reported that the greatest difficulty encountered by their CQI team was that the process was somewhat cumbersome and lengthy. They found that teams could not simply meet, plan and achieve instantaneous results. This was because the process was essentially a lengthy one in which data is collected and analysed on an
ongoing basis over a period of time. The research group stressed that even after intervening and improving the process, there is always potential for additional improvement and therefore the improvement cycle continues.

4.7 Summary

Chapter 4 provided details on the central theme of the research, the TQM solution to improving the appropriateness of test utilisation in AMI. Traditionally, the overall definition of quality in the provision of clinical laboratory testing services has been too narrow.

The pursuit for new approaches to improvement has led to the recognition that clinical laboratories, and indeed health service organisations as a whole, can benefit from TQM programs that have taken place within manufacturing organisations.

Thus far, the TQM projects involving clinical laboratory services that have been reported in the literature have involved a variety of improvements of such areas as, for example, turnaround time of laboratory reports, workflow of urgent tests, blood collection procedures, correct completion of request forms and reduction of errors in laboratory reports.
An extensive search of the relevant English language literature has shown that until now, no report has yet been published that has used TQM to specifically improve the appropriateness of diagnostic laboratory test usage in AMI. However, a recent study showing cost savings and improvements in the appropriateness of bleeding time testing using a CQI approach offers similar hope for laboratory test improvement in the early management of AMI.

A number of features of TQM were identified as essential in the test ordering improvement process. Such features included executive level commitment, transformation of the organisational culture, participation of the staff, and the need for new skills.

The introduction of a TQM and CQI system is not always successful. In many instances projects have been poorly planned and many potential pitfalls and barriers not appropriately addressed.

REFERENCES AND NOTES


7. Deming, op. cit.


24. Baird, Cadenhead & Schmele, op. cit; p.94.


32. Berwick, op. cit; p.53.


40. Flowcharts are tools which provide a graphic representation of a step-by-step sequence of processes and subprocesses, including events, reactions, and decisions.

41. A Pareto diagram is used to display the causes of a quality problem in descending order of importance.

42. Control charts are tools designed to monitor a process over time and to study its trend and variation.

43. Cause-and-Effect diagrams are useful tools in the identification of the causes and subcauses of a problem.

44. The nominal group technique is a continuation of brainstorming. Once a list of ideas is generated, then the process of prioritising or ranking of ideas begins.

45. Brainstorming is a group oriented technique whereby a group of individuals meet to generate an exhaustive list of ideas regarding a topic at hand.

47. R.C. Bartlett, 1990. 'Trends in quality management', Archives of Pathology and Laboratory Medicine, 114, pp.1126-1130.


49. Bartlett, op. cit; p.1126.


53. Westgard, Burnett & Bowers, op. cit; p.1713.

54. Westgard, Burnett & Bowers, op. cit; p.1716.


60. Milakovic, op. cit; p.9.

61. Rakich, Darr & Longest, op. cit; p.292.


64. Bartlett, op. cit; p.1129.

65. Westgard, Burnett & Bowers, op. cit; p.1712.

66. Burnett, Mackay, Costaganna & Shaw, op. cit; p.48.


74. Westgard & Barry, op. cit; p.241.


78. Burnett, op. cit; pp.3-10.


85. ibid; p.307.

86. Merry, op. cit; p.102.


89. Bartlett, op. cit; pp.1126-1127.

90. Merry, op. cit; p.102.


93. Walker, Crossett, Smith-Blair & Cordell, op. cit; p.164.

94. Gershon, op. cit; p.49.


98. Gershon, op. cit; p.49.


100. Walker, Crosset, Smith-Blair & Cordell, op. cit; p.165.

101. Rakich, Darr & Longest, op. cit; p.299.


104. Bartlett, op. cit; p.1129.


CHAPTER 5. METHOD

Chapter 5 provides in detail the research methodology. It includes a procedural overview, the research design, a description of the study setting, the patient populations used, the justification of using a quasi-experimental design, the hypotheses, the quality control measures and an assessment of the study's possible contamination effects. The timetable of the investigation is also presented. It is noted that Chapters 6 and 7 also deal with methodological issues and that Chapter 7, Collection and Analytical Procedures, which could also logically be placed within this Chapter 5, has in fact been placed after the discussion of the complex intervention strategy in Chapter 6, for clarity.

5.1 Procedural overview

Using the principles of TQM, a CQI approach was used in an attempt to improve the appropriateness of clinical laboratory test utilisation in the management of early AMI. A series of process improvement intervention strategies were introduced at a 454 bed Teaching Hospital while another Teaching Hospital of similar size (415 beds) acted as the control group for the investigation.

The period of investigation was 30 months and comprised two distinct stages, 'pre' and 'post' the TQM intervention. Two broad areas of data were collected.
Firstly, test utilisation data were collected throughout the investigation on all patients with confirmed uncomplicated AMI. Appropriate comparisons based on measurements taken before and after the intervention were used to test the various hypotheses. Secondly, process improvement data from suspected AMI patients were obtained from the experimental group throughout the post-TQM period. This data provided the CQI Project Team with the necessary information for the ongoing development, implementation and monitoring of the process improvement strategies.

5.2 Research design

This study is best conceptualised as a non-equivalent pretest-posttest control group quasi-experimental design. It departs from classical experimental models by the introduction of sequential measurements before and after treatment intervention by the investigator and his team, and an obligatory use of different but demonstrated equivalent pre and post test populations in both the naturally assembled non-equivalent experimental and control groups. However in all other regards it conforms to fundamental experimental principles allowing adequate control over major threats to internal and because of its field setting, external validity.

The research design is outlined schematically in Figures 5.1 and 5.2. This period of investigation comprised two
FIGURE 5.1 Schematic representation of the non-equivalent quasi-experimental research design

\[ m_1 \rightarrow X \rightarrow m_3 \]

\[ m_2 \rightarrow m_4 \]

- measurement(s) of test utilisation in the experimental group, pre-CQI;
- measurement(s) of test utilisation in the control group, pre-CQI;
- measurement(s) of test utilisation in the experimental group, post-CQI;
- measurement(s) of test utilisation in the control group, post-CQI;

\[ X = \text{intervention} \]

FIGURE 5.2 Applied quasi-experimental design

Time

0

experimental group 1

measurement

- \( m_1 \)
- \( \cdots \)
- \( m_n \)

15months

comparisons

TQM intervention

comparisons

measurement

- \( m_3 \)
- \( \cdots \)
- \( m_n \)

30months

comparisons

control group 2

measurement

- \( m_2 \)
- \( \cdots \)
- \( m_n \)
15 month stages, 'pre' and 'post' the TQM intervention. One group of hospital patients was designated the 'experimental' group, and the other the 'control' group. In the study the independent variable was the use of TQM strategies. The dependent variable, appropriate test utilisation, was evaluated for each population group by comparing the change from pre-test to post-test over the period of the investigation. Comparisons were also made of test utilisation between the two population groups.

Figure 5.3 provides a summary of the schedule that was undertaken for the research study. A more detailed timetable is provided as Appendix 1. The pre-test phase was used as a baseline and preparation period for the study. During this period the research protocol was finalised, preliminary discussions held with key staff, ethics committee approval attained to undertake the research, and patterns of laboratory test resource utilisation were prospectively identified and analysed for the 15 month pre-test period.

At the commencement of the sixteenth month, a multidisciplinary Project Team was established at the Bankstown-Lidcombe Hospital (the experimental institution) to review the baseline data, specify opportunities for improving efficiency, and to develop and implement appropriate TQM interventions. The effects of the interventions were monitored for a period of 15
FIGURE 5.3 Schedule of the research study

<table>
<thead>
<tr>
<th></th>
<th>Pre-test</th>
<th></th>
<th>Post-test</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Opportunity for</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>improvement defined</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2. Preliminary</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>discussions with</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>key staff</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3. Ethics committee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>approval</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Pre-test data</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>collected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Management</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>commitment</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>6. Project team</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>established</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. TQM intervention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Data collected</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Data analysed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Changes introduced</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>to hold the gain</td>
<td></td>
<td></td>
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</tbody>
</table>
months.

The feasibility of the project was discussed with senior staff of the Bankstown-Lidcombe Hospital Emergency Department (ED), CCU, Cardiology, Pathology and Medical Records Departments. Besides attaining background information relating to the processes involved in test ordering, cooperation and commitment was sought and obtained from the Heads of these Departments. Similar discussions were also held at Nepean Hospital (the control institution) with the Heads of the ED, Cardiology, CCU and the Medical Records Department.

Using specifically a CQI FOCUS-PDCA model, a multidisciplinary team at Bankstown Hospital was empowered to make appropriate changes in order to improve various problem areas that affected the total pathology service and therefore ultimately test utilisation. The TQM strategies were directed at specific aspects of the Pathology-customer service cycle which were identified by the study’s CQI Project Team as critical to the customers of the pathology testing service in the early management of AMI.

5.3 Justification of the quasi-experimental method used
Classical experimental designs enable investigators to establish cause and effect relationships: to predict and explain. In these studies a 'cause' must precede an effect in time, the independent (treatment or
intervention) variable must be associated with the dependent (outcome) variable and evidence must rule out other factors as influencing or determining the dependent variable. The Nonequivalent Pretest-Posttest Control Group Design as used here maintains many of the strengths of pure experimental approaches. This is arguably the strongest design available when random assignment into a control and treatment or different treatment groups is not possible.

5.3.1 External validity and sample

The chosen design and the manner of its implementation attempted to ensure that the results can be generalised within limits to different subjects, populations and settings. Indeed, Portney & Watkins found that quasi-experimental designs may accommodate for the limitations of natural settings, where scheduling treatment conditions and random assignment cannot always be controlled.²

This study took place in a field setting under conditions alien to the often artificial laboratory or de facto laboratory setting. It is obviously incumbent upon the investigator to produce sufficient evidence that this noisy and contaminated real world environment does not impinge upon the validity of results.

In the study, the experimental and control groups each comprised the total populations of naturally assembled
cases of suspected uncomplicated AMI patients that were admitted at each hospital over the 30 month duration of the investigation. Therefore the methodological problems often encountered with sample size and selection were not an issue.

5.3.2 Internal validity – major threats
The threat to internal validity of Selection refers to a tendency in non-random experimental and control allocation for groups not to be alike. As an example, if those subjects in the experimental group were younger or stronger AMI patients than those in the control group, changes in the appropriateness of test utilisation may have been related to clinicians ordering greater or fewer tests because of the general physical state of the patients. Such improved test utilisation could have been mistaken for the effect of the TQM strategies. This was controlled by equivalence of the groups being based on pre-defined demographic and clinical characteristics including age and sex, and the use of strict inclusion and exclusion criteria for the pre and post test groups of both the experimental and control arms of the study.

The threat of History refers to any event other than the independent or treatment variable occurring between the pre and post measurement that might affect the dependent variable, in this instance any influences on the outcome of test utilisation. Examples include events such as
clinicians receiving influential publications strongly advocating or guiding particular test usage, or attendance at continuing education seminars on test utilisation. This was controlled by the presence of a demonstrably equivalent control group which was presumed to be as equally susceptible as the experimental group to these possible influences.

The threat of Maturation refers to processes within the respondents that change as a function of time. Examples include the aging process and naturally increasing morbidity. This is normally controlled in the same way as for History by the inclusion of a control group, within which respondents are assumed to change at the same rate and in the same way as the experimental subjects. In this instance there are different subjects at pre and post test and therefore Maturation is not an issue.

The threat of Testing refers to the effect of being tested, measured or evaluated on retest results. This, again, is not an issue in this instance as it is controlled by the use of different subjects at pre and post test.

5.4 Study setting
The study was conducted between 2.3.92 and 26.8.94 at The Bankstown-Lidcombe Hospital and Nepean Hospital in Sydney, N.S.W. As shown in Table 5.1, both hospitals were of similar size and cared for a similar number of
TABLE 5.1 Selected comparative hospital data for the 30 month period of the study

<table>
<thead>
<tr>
<th></th>
<th>Bankstown-Lidcombe Hospital (Experimental)</th>
<th>Nepean Hospital (Control)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. hospital admissions from the Emergency Department</td>
<td>21,724</td>
<td>20,485</td>
</tr>
<tr>
<td>Total no. Emergency Department attendances</td>
<td>72,240</td>
<td>70,125</td>
</tr>
<tr>
<td>Total no. hospital admissions to CCU.</td>
<td>2,355</td>
<td>1,891</td>
</tr>
<tr>
<td>Total no. confirmed (uncomplicated) AMI patients</td>
<td>493</td>
<td>434</td>
</tr>
</tbody>
</table>

patients throughout the study period.

The Bankstown-Lidcombe Hospital is a 454 bed Teaching Hospital of the University of Sydney located in the inner west of the Sydney Metropolitan area. The CCU has 6 beds. The Hospital is part of the South Western Sydney Area Health Service (SWSAHS) and serves the local government area of Bankstown comprising a population of 162,300 persons.

On the other hand, The Nepean Hospital is a 415 bed Teaching Hospital of the University of Sydney, located on
the western periphery of the Sydney Metropolitan area. The CCU has 4 beds. The Hospital is part of the Wentworth Area Health Service and serves the local government areas of Penrith, Hawkesbury and the Blue Mountains comprising a population of 290 000 persons.

Both hospitals offer similar services to the patients of their health service. Such services include Emergency, Obstetrics, Paediatrics, General and Specialist Surgery, General and Specialist Medicine, Renal Dialysis, Neurology, Intensive and Coronary Care, Psychiatry, Cardiology, Day Surgery, Outpatients, Neonatology and Allied Health.

The South Western Sydney Area Pathology Service (SWAPS) provides the Pathology Service to the South Western Sydney Area Health Service (SWSAHS), including the Bankstown-Lidcombe Hospital. The central laboratory is located in the nearby suburb of Liverpool. The Nepean Hospital Pathology Department provides the Pathology Service to the Wentworth Area Health Service.

At each hospital, the majority of the clinical laboratory test ordering for the management of patients with AMI in the E.D. and CCU is undertaken by hospital employed Resident Medical Officers. Tests usually required 'stat' within 20-60 minutes of the blood specimen being collected are performed at the on site laboratories. An onsite Pathology Service is provided daily by SWAPS at
the Bankstown-Lidcombe Hospital, between 0730 and 2400 hours. A rapid courier and back up taxi cab service is provided to transport other urgent and routine tests to the central SWAPS laboratory at Liverpool. Appendix 2 lists the SWAPS schedule of stat and urgent tests for the Bankstown-Lidcombe Hospital.

5.4.1 Patient population
The definitions and criteria for AMI outlined in this section were developed in close liaison with the Director of Cardiology of the Bankstown-Lidcombe Hospital.

AMI was classified according to predefined diagnostic criteria established by the World Health Organisation, WHO (1981). The diagnosis of AMI was confirmed if a patient had at least two of the three classic findings. These were the presence of a typical history of characteristic chest pain, new electrocardiogram (ECG) changes of pathological Q waves, and serum enzyme elevations.

Specifically, the study only included those patients that presented less than 24 hours after the onset of symptoms, and whose chest pain was at least of 20 minutes duration. In addition, the following ECG changes needed to be present in AMI. Electrocardiographic signs of $\geq 0.1$ mV of ST-segment elevation in two or more limb leads or $\geq 0.2$ mV in two or more contiguous precordial leads. The Minnesota code was used to classify Q wave changes in
AMJ.\(^3\)

Serum enzyme elevations were confirmed with the demonstrated presence of a rise of total serum creatine kinase (CK) to twice the upper limit of the reference range values from blood samples drawn during the first 90 hours following admission. The upper limit of the total CK reference range at each of the two hospitals in the study was 195 U/L. Enzyme elevations were therefore confirmed when the total CK rose to 390 U/L and above during the first 90 hours of admission.

In the study, the experimental and control groups each essentially comprised the total populations of naturally assembled cases of uncomplicated AMI patients that were admitted to the Coronary Care Unit (CCU) of each Hospital over the 30 month duration of the investigation. Inclusion and exclusion of such patients however was dependent upon the criteria defined in this section of the Chapter.

Within the study populations, two distinct groups of AMI patients were identified—‘suspected AMI’ and ‘confirmed AMI’. The ‘suspected AMI’ group included all patients that were admitted to the CCU via the Emergency Department with chest pain and electrocardiographic signs suggesting AMI. These patients were registered in the study as ‘suspected AMI’.
Not all of these cases of ‘suspected AMI’ did in fact progress to AMI. Therefore, eligibility for inclusion in the second group, the ‘confirmed AMI’, was dependent on the patient having had a primary discharge diagnosis of AMI in accordance with the WHO criteria (1959) described above.

Also, since the study was investigating the early management of the disorder, ‘confirmed AMI’ patients needed to have been hospitalised with AMI for at least 90 hours, and have spent a minimum of 48 hours in the CCU.

In the ‘confirmed AMI’ group, only those patients relatively free of any associated clinical complications were included. The criteria for exclusion were: an age of 75 years or over; the presence of ventricular tachycardia or fibrillation; persistent sinus bradycardia of <40 beats/min; second or third-degree atrioventricular block; atrial fibrillation or flutter; persistent sinus tachycardia; pulmonary oedema or persistent S3 gallop; shock or hypotension; postinfarction angina; or re-infarction.

Data on the duration of chest pain, electrocardiographic and enzyme changes were used to include or exclude patients from the study.

In addition, the experimental and control group populations were analysed for equivalence on a number of
key patient characteristics. The two groups were compared for sex, age, length of stay (LOS), discharge status and readmission status, before and after the TQM intervention. The data analysis technique that was used is described in 7.7.1.

5.5 Goals and hypotheses of the investigation

5.5.1 Goals of the investigation

The investigation had two main goals:

The first goal was to undertake a quasi-experimental investigation using a TQM approach. This involved the development of a hypothesis and various sub-hypotheses, presented in 5.5.2.

The second goal was to plan, implement, and monitor the TQM program as the independent or experimental variable, being the intervention strategy, in this investigation. This involved the development of five specific objectives listed in 5.5.3. It is emphasised that, because of its integral importance, the stages and experiences in this TQM intervention have been fully described as a secondary but potentially replicable part of the investigation.

5.5.2 Goal 1- the hypotheses of the quasi-experimental investigation

The overall broad hypothesis of the investigation is that the introduction of the alternative management strategy
of TQM would result in a significant improvement in the appropriateness of laboratory test ordering in the early management of acute myocardial infarction (AMI).

This hypothesis may be conveniently broken down to the following sub-hypotheses:

1. There is a significant increase in the selection of clinically recommended clinical laboratory tests for AMI as a function of the introduction of TQM intervention.

The variable is examined according to test type and group during the 90 hour period following the AMI patient’s admission into hospital. This is measured in terms of the total number of clinically recommended tests.

2. There is a significant decrease in the selection of non-clinically indicated clinical laboratory tests for AMI as a function of the introduction of TQM intervention.

The variable is examined according to test type and group during the 90 hour period following the AMI patient’s admission into hospital. This is measured in terms of the total number of non-clinically indicated tests.

3. There is a significant improvement in the clinically recommended timing of cardiac enzyme testing for AMI as a function of TQM intervention.

This is examined in terms of time of blood collection.
The variable is measured by determining the median time intervals between the blood collections of the first four total CK tests ordered on patients with confirmed AMI.

4. There is a significant decrease in the total cost of clinical laboratory tests per AMI admission as a function of TQM intervention.

This is examined in terms of the total costs of tests. This variable is measured in terms of total costs per AMI admission during the 90 hour period following the AMI patient’s admission into hospital.

5. There is no significant change in the quality of patient care for AMI as a function of TQM intervention.

This is examined in terms of discharge status, readmission to hospital and length of stay.

Data for each variable were collected from the medical records of AMI patients. Data for the variable discharge status were classified for each admission as discharged home, transferred to another health care institution, or died. Data for the variable readmission to hospital was measured in terms of any readmission within 30 days of discharge. Data for the variable length of stay was measured as the period of time between admission and discharge from hospital.
5.5.3 Goal 2- the objectives of the intervention

The second overall goal of the investigation was to plan, implement, and monitor the TQM program. This was achieved through the development of the following five objectives:

1. To develop a TQM environment for pathology services delivered in the first 90 hours of the management of patients with AMI.

The accomplishment of this objective was assessed using criteria developed by the investigator to determine whether elements of a TQM environment had emerged for pathology services. The criteria used are shown in Table 5.2. They were adapted to the pathology services environment from earlier investigations.5-6

The investigator assessed whether each of the 10 elements in Table 5.2 were evident for pathology services at the experimental group hospital at the end of the investigation.

2. To develop a CQI model using the principles of TQM for the appropriate utilisation of laboratory tests in the first 90 hours of the management of patients with AMI.

The accomplishment of this objective was confirmed through the development of a CQI model based on improving organisational systems and processes. Such models utilise
TABLE 5.2 Criteria used to determine whether a TQM environment had been developed for pathology services.

1. CQI training in quality principles and process improvement provided to all key personnel.

2. Staff empowered to make decisions individually and as part of work teams.

3. Each staff member's role in the improvement process is effectively communicated.

4. Customers are identified and their needs defined.

5. Measurement criteria for customer satisfaction are developed and used.


7. Positive trends are present in all customer satisfaction indicators.

8. The organisation responds quickly to changing customer needs.

9. Strong emphasis is placed on prevention of problems rather than inspection.

10. Quantitative measures of process performance and quality extend into all areas of laboratory test ordering.

A scientific approach to problem solving that necessitates returning to various steps in the model in order to reevaluate the work that was done at that time and may require new strategies then being formulated.

3. To introduce CQI strategies for improving all customer
pathology service areas involved in the first 90 hours of the management of patients with AMI. The accomplishment of this objective was confirmed on examination of the systems improvement strategies that were introduced. Table 5.3 lists the elements that were required to be present.

The investigator assessed whether each of the 10 elements in Table 5.3 were evident at the end of the investigation

<table>
<thead>
<tr>
<th>TABLE 5.3</th>
<th>Criteria used to determine whether CQI strategies had been developed for improving all customer pathology service areas.</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Customers are identified and their needs and requirements defined.</td>
</tr>
<tr>
<td>2.</td>
<td>Use of cross functional teams that include customers to review and improve customer pathology service areas.</td>
</tr>
<tr>
<td>3.</td>
<td>Encourage widespread participation in quality meetings.</td>
</tr>
<tr>
<td>4.</td>
<td>Improve customer and provider relationships through the encouragement of closer communication and joint-problem solving.</td>
</tr>
<tr>
<td>5.</td>
<td>Measurement criteria for customer satisfaction are developed and used.</td>
</tr>
<tr>
<td>6.</td>
<td>Identify root causes of problems in the delivery of pathology services.</td>
</tr>
<tr>
<td>7.</td>
<td>Process improvement strategies developed to meet customer needs and requirements.</td>
</tr>
<tr>
<td>8.</td>
<td>Communicate improvement strategies to all customers.</td>
</tr>
<tr>
<td>9.</td>
<td>Positive trends are present in all customer satisfaction indicators.</td>
</tr>
<tr>
<td>10.</td>
<td>The organisation responds quickly to changing customer needs and requirements.</td>
</tr>
</tbody>
</table>
period for the improvement of customer pathology service areas at the experimental group hospital.

4. To assess the effect of the TQM approach on improving the appropriateness of laboratory test utilisation provided to the patient with AMI.

The accomplishment of this objective was assessed by examining the type of data and other information that was collected throughout the period of investigation. The required information included the total number of clinically recommended tests, the total number of non-clinically indicated tests, the appropriateness of the time of cardiac enzyme blood collections, and the total costs of tests.

5. To assess the effect of the TQM approach on the overall quality of care provided to the patient with AMI.

This objective is similar to that of sub-hypotheses 5 outlined in 5.5.2. It was examined in terms of discharge status, readmission to hospital and length of stay.

5.6 Experimental and quality control
The high level of control engendered by the use of the quasi-experimental design has been highlighted under the previous discussion on internal and external validity in 5.3. This in general resulted in substantial control over other potential influences.
As the Chief Hospital Laboratory Scientist, the investigator made every effort possible throughout the period of investigation to maintain the highest level of scientific and procedural rigour. This included the introduction of several quality control measures directed largely at minimising the error of measurements involving clinical data from both the medical records of patients and from a variety of CQI exercises.

As the investigator was the sole rater of the data from the medical records examined in both the experimental and control groups, this ensured consistency within the investigation. It was therefore not necessary to establish interrater reliability.

The patient’s medical record provided the primary source of data for the measurement of test utilisation during the investigation. As the accuracy of the information recorded in it was critical to that patient’s ongoing care, its contents were therefore maintained at high levels of accuracy. The provision of timely and accurate clinical information was supported by rigorous medico-legal standards imposed by State Government legislation and monitored on an ongoing basis by Hospital Medical Records Committees and Patient Care Review Committees.

Although the process improvement data were included as a secondary part of the study, several quality control measures were undertaken throughout the period of
investigation to ensure the integrity of the data collected. Although data derived from pathology request forms, and specially designed 'turnaround time' registers were collected by a variety of clerical, nursing and laboratory personnel, supervision of the collection process was maintained throughout the period of investigation. Supervision was provided by the Senior Technologist for the Pathology data collection process and by the investigator for the other data collected. Random audits and re-checks were also undertaken for the data collected in accordance with the detailed procedures described in Chapter 6.

5.7 Potential untoward effects of intervention
In order to assess whether or not there were any untoward outcomes from the intervention, two areas of potential concern were investigated.

Firstly, an assessment was made of whether any major disruptions in the workplace had in fact occurred as a result of the introduction of the CQI strategies. To this end, close lines of communication were kept with each participating department. Progress reports were received at CQI Project Team meetings from the Department representatives. Problem areas, particularly those arising from the implementation of change were able to be voiced at each meeting. In addition, the Team Leader and Quality Advisor kept in close contact with all
departments throughout the entire Project. This allowed these two officers to directly attend to problems and to also assist in preventing any potentially disruptive situations.

Throughout the 15 month intervention period there were no reports or incidences of significant disruptions in departmental activities as a result of the TQM initiatives. Careful observation showed that most staff involved with the Project found the entire exercise rewarding.

Secondly, as discussed in 5.5.2, it was critical to determine what effect the intervention had on the overall quality of care provided to the AMI patient and to exclude any untoward effects resulting from the intervention.

5.8 Summary
This chapter described the research design of the investigation. This entailed the justification of using a quasi-experimental design, a description of the study setting and the patient population groups, the objectives and hypotheses, the quality control measures and an assessment of the potential untoward effects of intervention. The timetable of the investigation was also presented.
REFERENCES AND NOTES

1. The Pathology-customer service cycle is a concept developed in this study that represents the complex sequence of tasks carried out each time a clinical laboratory test is ordered and performed. The concept was discussed earlier in Chapter 1.


4. A Coronary Care Unit is a designated ward or area of a hospital which cares for adult patients with coronary vascular or cardiac rhythm disorders and provides continuous ECG monitoring and its own emergency cardioversion service.


CHAPTER 6. TOM INTERVENTION PROCEDURE

Chapter 6 provides in detail the procedures used for the development and implementation of the CQI model that was used in the investigation.

6.1 Development of CQI model

In accordance with Objective 2 of the intervention, a CQI model was developed by the Project Team in an attempt to improve the appropriateness of test utilisation in the early management of AMI.

The Hospital Corporation of America’s (HCA) FOCUS-PDCA quality improvement model\(^1\) was adapted and modified for use in the present study. The HCA model has been widely accepted and used as a standard process improvement methodology.

The general principles of the FOCUS-PDCA model were described earlier in 4.4.1.

Figure 6.1 illustrates the FOCUS-PDCA model that was developed for use in the present study.

6.2 Developing a TQM environment

In accordance with Objective 1 of the intervention objectives, a TQM environment was developed for pathology services in the early management of AMI.

Preparations for the development of a TQM environment for pathology services were helped along by the decision of
FIGURE 6.1 The FOCUS-PDCA COI Model used in the study

1. **Find a process to improve**
   - Formation of team
   - COI education
   - Team ground rules
   - Team building

2. **Organisation of Project Team**
   - Boundaries of processes
   - Flow charts of processes
   - Identify problems
   - Customer requirements

3. **Clarification of process knowledge**
   - Causes of variation
   - Collect data
   - Determine key aspects that are measurable

4. **Uncover causes of poor quality**
   - Determine proposed improvements
   - Prioritise

5. **Select process improvement**

6. **Act to hold the gain**
   - Determine effectiveness of actions
   - Determine whether policies need revision
   - Standardise procedures
   - Establish monitoring process
   - Plan continuous improvement

7. **Check results**
   - Check lessons learnt
   - Assess whether process improved as expected
   - Determine how team effort could be improved

8. **Do the improvement**
   - Pilot test
   - Implement Plan
   - Collect and analyse data

9. **Plan process improvement**
   - Improvement Plan
   - Who, what, when, where, why and how
   - Plan the pilot study

10. **Start Plan-Do-Check-Act Cycle**
senior management of the hospital to introduce a 'Quality Management Plan' for the organisation. An extract from the Bankstown-Lidcombe Health Service’s 'Quality Management Plan', showing the mission and vision statements is provided as Appendix 3. The Hospital’s intentions towards the TQM path is clearly indicated in their Plan.

Figure 6.2 illustrates the four key elements that were important to the creation of the TQM environment at the Bankstown-Lidcombe Hospital. These were changes to the management culture, fostering an attitude that customers come first, team work and continuous feedback to staff. These four initiatives also assisted in overcoming a number of the barriers to TQM implementation, that were outlined earlier in 4.5.

From the outset it was realised by the CQI Project Team that the cultural transformation would be an ongoing organisational growth process, and not a one-time event. The objective was the development of a TQM environment to assist the improvement of the overall process of test ordering. It was well appreciated that a complete conversion of the culture would take several years to accomplish.

Firstly, establishing and maintaining the cultural change required total commitment to TQM from senior management. Senior management’s intentions towards TQM was
FIGURE 6.2 The key elements in the development of a TQM environment

Management
   cultural
   change

* Leadership
* Commitment
* Personal involvement
* Communication

Customers
   come
   first

* Identify suppliers
  and customers
* Customer focus
* Meeting key customers
* Representation of customers
* Determine needs and requirements

Team work

* Staff involved in
  process change
* Team building
* Trust building
* Empowerment
* Pride in performance
* CQI training

Continuous
feedback to
staff

* Department meetings
* Participation
* Performance measured
* Communication of successes
demonstrated as follows. There was personal involvement of some senior executives in promoting quality through such activities as promoting innovation, encouraging CQI Project Team activities, participation in education and training, and meeting with suppliers and customers. There was also the promotion of close working relationships and trust building between a number of departments. Quality was integrated into day-to-day management, including such activities as meetings, decision making, redevelopment planning, and the preparation of the Hospital's Corporate Plan.

Secondly, another factor critical to the development of a TQM environment was that of fostering an attitude that customers come first. In the present investigation, this was demonstrated from the following actions. Customers and providers were identified and had representation on the CQI Project Team. The relationships between customers and providers were improved through the encouragement of closer communication and joint problem solving. From the outset, customer needs and requirements were determined and plans developed to meet them.

Thirdly, another factor critical to the development of a TQM environment, was the encouragement of effective team work. All staff involved in the process of test ordering were encouraged by the Project Team to contribute to the improvement process. Employees were empowered to identify
problems and become involved in process change. During the first few months, the CQI Project Team leader and the Quality Advisor focused particularly upon team building and trust building amongst the various service partners on the CQI Project Team. Such strategies attempted to break down long standing departmental barriers, thereby requiring staff to work as a team. A detailed account of the way this was undertaken is provided in 6.3.3. As discussed previously in 4.3.2, doctors in particular were targeted for encouragement to participate in the study. As will be shown in 6.3.3, several medical staff participated actively in the Project. Their enthusiasm and responsiveness grew as the Project progressed with success.

The final critical factor was the emphasis placed by the Project Team on continuous feedback to staff. Feedback in the form of progress reports and minutes from meetings were regarded as important measures in ensuring cooperation and continued participation in the change process. Keeping staff informed of the quality improvement efforts also greatly minimised resistance to the proposed changes. Overall, these strategies played a major role in the development of a TQM environment that was so necessary for the overall plan of improving the appropriateness of test ordering.
6.3 CQI implementation process- FOCUS steps

The FOCUS-PDCA CQI model described earlier in 6.1 was introduced by the CQI Project Team at the Bankstown-Lidcombe Hospital over a 15 month period commencing as at 7.6.93. This section provides a detailed description of the procedures used to implement the FOCUS steps of the CQI model. The PDCA steps will follow in section 6.4.

Many of the team meeting arrangements and team problem solving techniques that were used throughout the implementation process were adapted by the CQI Project Team from the widely used text, 'The Team Handbook' by Peter Scholtes.²

6.3.1 Timetable of the Project

The FOCUS-PDCA CQI Model for quality improvement was developed and introduced at the Bankstown/Lidcombe Hospital in accordance with the Research Study Implementation Plan provided earlier as Appendix 1. The Project was undertaken in the following stages:

6.3.2 Find a process

6.3.2.1 Opportunity statement

The first stage of the Quality Improvement Process involved the preparation of a clearly written opportunity statement for improvement (Table 6.1). This was undertaken by senior management of the Hospital and was based on documented quality problems and brainstormed opportunities for improvement of the pathology service.
TABLE 6.1 Opportunity statement for the project

**OPPORTUNITY STATEMENT**

An improvement opportunity exists within

The Bankstown/Lidcombe Health Service to improve the appropriateness of Pathology Laboratory testing services in the early management of acute myocardial infarction (AMI).

beginning with

the laboratory test ordering on patients presenting to the Emergency Department with a suspected AMI

and ending with

test ordering 90 hours following admission into hospital.

The current process causes:

* Some user dissatisfaction;
* Inadequate customer/provider relationships and communication in the provision and development of pathology services in the early management of AMI;
* Variation in laboratory test usage because of an absence of test ordering guidelines for test requesting clinicians.

An improvement should result in

The development of systems to facilitate effective, efficient and appropriate use of laboratory testing, focusing on customer needs

for the

patients admitted with AMI.

The process is important to work on now because an improvement exercise would provide for

* Appropriate management of patients with AMI;
* An organised and cohesive team approach to the use of laboratory services in the care of patients with AMI;
* The appropriate utilisation of resources;
* A reduced variation in test ordering practice;
* Improved communication between the laboratory service providers and users.
6.3.2.2 Ethics committee approval

Preliminary discussions were held with key medical, nursing and laboratory staff from both hospitals in order to receive advice, information and cooperation for the Project ahead. Once a positive response was received from both hospitals, applications were lodged with the Ethics Committees for approval to undertake the research project.

6.3.2.3 Pre-test data collected

Once Ethics Committee approval had been attained, an assortment of data were collected for the 15 month pre-test period. The data were collected in accordance with the protocol described in Chapter 7.

6.3.2.4 Commitment of management

Once Ethics Committee approval had been received, The General Manager of the Bankstown-Lidcombe Hospital authorised the undertaking of the study. From the outset, the Hospital’s senior management showed positive involvement and commitment to the Project. A representative of the Hospital management, the Deputy Medical Superintendent, was appointed to the project team.

Under the direction of the CQI Project Team, the staff involved in the process of test ordering in AMI were empowered by senior management to make the necessary decisions and improvements to the delivery of pathology
services.

6.3.3 Organisation of project team

From the outset it was deemed essential to set the proper foundations for a successful Project by clarifying the roles of team members, establishing the structure and framework for meetings, and implementing CQI education programs for staff.

6.3.3.1 CQI education plan

The Quality Advisor was given the task of providing CQI education to the Project Team and the staff members of the Departments involved in the Project.

An educational package was developed and forwarded to all members of the CQI Project Team prior to the first meeting. The package included information on TQM, the essentials of the CQI FOCUS-PDCA Plan, the CQI meeting process, the roles of Project Team members, the quality improvement tools and copies of recent articles focusing on TQM projects in health care. The education plan was designed essentially to train all Project Team members in team-building activities and the skills of CQI. Team members were encouraged to pass on such newly acquired information and skills to staff within their departments.

6.3.3.2 Formation of project team

The Quality Team comprised two main groups, the CQI
Project Team and the Guidance Team.

The CQI Project Team was functionally based and comprised staff involved in the process of test ordering in the early management of suspected AMI. The staff that comprised this team carried out project assignments and instigated improvements. The team had the following members:

1. Chief Hospital Scientist (Team Leader and Investigator).
2. Director of Emergency Department.
3. Senior Medical Officer, Emergency Department.
4. Asst Director of Nursing (ADON), Emergency Department.
5. Clinical Nurse Specialist (CNS), Emergency Department.
6. Nurse Unit Manager (NUM), Coronary Care Unit.
7. Clinical Nurse Specialist (CNS), Coronary Care Unit.
8. Senior Technologist, Pathology Department.
9. Project Team Quality Advisor.

The Guidance Team supported the Project Team's activities, secured resources, and removed potential organisational barriers as they arose. Guidance Team members were invited to attend project team meetings. The team had the following members:

1. Director of Cardiology.
2. Director of Pathology.
3. Deputy Medical Superintendent.
Figure 6.3 illustrates the CQI Project Team and its membership.

As the Chief Hospital Scientist, I was appointed the Project's Team Leader with the task of running the team, arranging logistical details, keeping in very close contact with the affected departments, communicating with senior management and facilitating meetings.
The Hospital's Quality Assurance Officer was appointed as the Quality Advisor for the Project. The Quality Advisor was trained and experienced in Total Quality Management, the scientific approach and in the implementation of the FOCUS-PDCA model. This officer assisted in keeping the team on track and provided the CQI training as required.

6.3.3.3 Team boundaries and support
Senior management determined the boundaries and support that the CQI Project Team would receive. It was decided that the Project would run for a minimum of 15 months, with regular progress reports being provided to senior management. Requests by the CQI Project Team for financial resources would be assessed by the Guidance Team and where necessary, funded by the Division of Medical Services. The CQI Project Team were also given the authority to make changes as necessary to improve the work processes under review.

6.3.3.4 Framework for meetings
Effective meetings were vital to ensure steady progress and productivity of the team. Each meeting was structured, and utilised agendas, warm-ups, team-building exercises, feedback sessions, and the maintenance of records including minutes of proceedings. Agendas were drafted at the previous meeting and developed in detail by the Team Leader and the Quality Advisor. The agendas included the topics for discussion, the presenters,
the allocated time per item, a quick review of the agenda, and meeting evaluation. On the day of the meeting, the agenda would also be clearly displayed on a whiteboard.

The Team Leader was assigned the task of being the facilitator of the meeting. During the first two meetings, TQM/CQI training was provided to members by the quality advisor. The educational component focused on providing information on TQM, the FOCUS-PDCA process of CQI, customers and suppliers, the seven quality improvement tools, team building, empowerment and self-directed work groups.

One of the main goals for the first few meetings was for team members to understand the project and the expectations of senior management. In addition they were required to understand the process, how it functioned, who its customers were, what quality issues were involved, and what problems were occurring. There was a need to also identify resources that would be required to undertake the project.

At the completion of each meeting, an evaluation of the proceedings was undertaken by the quality advisor. The method of the meeting evaluation was adapted from the technique used by Scholtes.³ Table 6.2 shows the evaluation survey used at the end of each meeting. A rating scale 1-6 was used.
TABLE 6.2 Project Team meeting evaluation format

Our meeting today was:

<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wonderful</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lousy</td>
</tr>
<tr>
<td>Very focused</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Rambling</td>
</tr>
<tr>
<td>Energetic</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>Lethargic</td>
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<tr>
<td>Interesting</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Boring</td>
</tr>
<tr>
<td>Productive</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Waste of time</td>
</tr>
<tr>
<td>Cooperative</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Divisive</td>
</tr>
<tr>
<td>Used scientific approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Shooting from the hip</td>
</tr>
</tbody>
</table>

6.3.3.5 The mission statement

The mission statement for the overall project was developed at the first project team meeting. It was based on the previously prepared opportunity statement for improvement developed by senior management of the hospital.

The overall mission statement determined by the project team was:

To ensure the pathology services that are utilised in the first 90 hours of the management of patients with suspected acute myocardial infarction are
appropriate, effective, and efficient for supporting clinical care.

At subsequent meetings, mission statements or standards were also prepared for each specific process or problem under investigation.

6.3.3.6 Baseline data
In the early stages of the project, relevant baseline data on test utilisation were provided to team members by the Team leader in accordance with the protocol described in 7.3.1.

6.3.3.7 CQI education for staff
CQI training sessions were arranged by the Quality Advisor for staff members working within departments affected by this Project. These sessions consisted mainly of providing basic information on TQM, team-building activities, empowerment and self-directed work groups.

6.3.4 Clarify current knowledge of the process

6.3.4.1 Boundaries of the processes
At the first meeting it was confirmed that the project would run for approximately 15 months, with progress reports being provided to senior management by the Team Leader. It was decided that project meetings would be run weekly (for months 1-2), fortnightly (for months 3-4), and monthly (for months 5-15).
As had been determined from the outset by senior management, requests by the Project Team for financial resources would be assessed and where necessary, funded by the Division of Medical Services.

For each specific process, boundaries were to be set to clearly define the key areas under investigation. This involved the CQI Project Team defining where each process under review commenced and finished; what inputs and suppliers were part of each process; what the outputs of each process were; who the internal customers of the output were; who will use the service being provided by each process.

6.3.4.2 Flowcharts of current processes

As previously outlined in Section 4.2.2, one of the major tools used in this project was the flowchart. It was used to investigate and describe the various processes under review. During the course of the investigation the team studied issues, brainstormed process mechanisms and drew flowcharts for each of the identified processes.

Flowcharts were developed to display every detail and step of the process.

The first step in this exercise was that of team members understanding the process under review. The process was described in terms of how it currently operated, and what it was supposed to achieve. For each process the team examined who did what, when, where, why and how.
In line with the mission statement of the study, the Project Team identified four interrelated sub-processes that were ultimately critical to the central process of appropriate test utilisation. These were the request of a test or group of tests; specimen and request form delivery; accessing computer terminal results; and receiving printed laboratory reports. The workflows for the total process were developed and are provided as Appendix 4. Each process step is numbered to provide easy reference to the text.

6.3.4.3 Identifying the process problems

Once the workflows had been developed, each sub-process was studied in depth to identify key problem areas that required improvement. Brainstorming sessions at project team, Emergency Department, Coronary Care Unit and Pathology Department meetings were used extensively to identify the various problems.

Each process under investigation was analysed through brainstorming and general discussion in terms of when and where it did occur. This was achieved by clearly defining recurring problems and localising each major problem in terms of when and where it normally occurs, which work areas tend to have the problem most often, and what other problems often occur with these major problems.

Table 6.3 lists the five major process problems that were identified by the CQI Project Team.
<table>
<thead>
<tr>
<th>1. Test requesting</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Poor test ordering practices.</td>
</tr>
<tr>
<td>* Overutilisation of some tests observed.</td>
</tr>
<tr>
<td>* Blood samples for cardiac enzyme testing drawn at incorrect intervals.</td>
</tr>
<tr>
<td>2. Delivery of specimens and requests from the E.D.</td>
</tr>
<tr>
<td>* Delays in specimen transport.</td>
</tr>
<tr>
<td>* Slow response time from wardspersons.</td>
</tr>
<tr>
<td>* 'Batching' of specimens before transport to Pathology.</td>
</tr>
<tr>
<td>* Specimens left unattended by wardspersons in Pathology.</td>
</tr>
<tr>
<td>* Delays in Emergency Department staff receiving patient labels for specimens.</td>
</tr>
<tr>
<td>* Delays caused by specimen rejection by Pathology.</td>
</tr>
<tr>
<td>* Delays caused by request form rejection by Pathology.</td>
</tr>
<tr>
<td>* Delays caused by a 'lost' specimen.</td>
</tr>
<tr>
<td>* Delays caused by only single blood tube being collected for tests requiring both</td>
</tr>
<tr>
<td>on-site and off-site testing.</td>
</tr>
<tr>
<td>* Delays caused by failure to indicate 'stat' status on request form.</td>
</tr>
<tr>
<td>* No available medical staff to sign request forms in CCU.</td>
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<tr>
<td>* Specimens stored overnight in Emergency Department refrigerator resulting in</td>
</tr>
<tr>
<td>delays and deterioration of specimen.</td>
</tr>
<tr>
<td>3. Turnaround time for test results</td>
</tr>
<tr>
<td>* Turnaround time from some tests unacceptable.</td>
</tr>
<tr>
<td>e.g: APTT results, although required rapidly for patient management, are not</td>
</tr>
<tr>
<td>received early enough (performed off-site).</td>
</tr>
<tr>
<td>4. Reporting procedures: Computer terminal results</td>
</tr>
<tr>
<td>* Failure to access results on computer terminal after expected turnaround time.</td>
</tr>
<tr>
<td>* Current process is cumbersome and time consuming. No alert provided that results</td>
</tr>
<tr>
<td>* Unnecessary telephone enquiries are made when results are not available on computer.</td>
</tr>
<tr>
<td>5. Reporting procedures: Printed reports</td>
</tr>
<tr>
<td>* The dispatch to the Emergency Department of numerous duplicated interim reports.</td>
</tr>
<tr>
<td>* Wasted resources from handling the unnecessary duplicated printed reports. This</td>
</tr>
<tr>
<td>results in medical staff having to continuously review newly arrived, but</td>
</tr>
<tr>
<td>irrelevant, reports. For many of the interim reports received, the Medical</td>
</tr>
<tr>
<td>Records Department is requested to retrieve records, file the records on</td>
</tr>
<tr>
<td>completion, and then possibly retrieve the records once again when a further set</td>
</tr>
<tr>
<td>of reports arrive.</td>
</tr>
</tbody>
</table>
The first major process problem was that of poor test ordering. The Project Team found that many tests were inappropriately requested. In addition blood samples were often drawn at incorrect times.

The second major process problem was that of the delivery of specimens and requests from the Emergency Department. Numerous problems were identified and included the slow response time from wardspersons, the batching of specimens prior to delivery, specimen rejection, delays in the printing of specimen patient labels, lost specimens, and the unavailability of medical staff to sign the request forms.

The third major problem was the unacceptable turnaround time for some test results, especially those requiring transport to the central laboratory at Liverpool.

The fourth major problem was the somewhat cumbersome, time consuming and non-user friendly process of accessing computer terminal results. Often staff had to check intermittently during their busy work shift for urgently requested results, only to find that the results were unavailable. Unnecessary telephone enquiries for results often then followed.

The final major problem was the poor system used for the provision of printed reports to the Emergency Department. The process involved the dispatch from the Pathology
Department of all interim reports as soon as they became available. This resulted in the Emergency Department receiving numerous unnecessary reports that required medical staff follow-up and the retrieval of patient records.

6.3.4.4 Identifying customer requirements

One of the key aspects of the study was the necessity to meet customer needs and expectations. At various sessions involving brainstorming and general discussion, the Emergency Department and CCU medical and nursing staff together with their laboratory service partners, were given the opportunity to talk about their specific needs and expectations.

As discussed, five specific areas were identified as being critical to the customers of the service. These areas were test requesting, delivery of specimens and requests from the Emergency Department, turnaround time for test results, accessing computer terminal results and receiving printed reports.

For each specific area of concern, the CQI Project Team in consultation with the staff of the Emergency Department and the CCU, defined the customer service requirements as follows:

1. Test requesting: A standard set of test ordering guidelines was to be established, outlining specific
appropriate tests, test frequency and blood collection
times.

2. Delivery of specimens and requests from the Emergency
Department. The CQI Project Team specifically required
that 95% of Emergency Department specimens reach the
Pathology Department within 30 minutes of blood
collection.

3. Turnaround Time: The specific turnaround time for
tests usually requested in the first 90 hours of the
management of patients with suspected AMI, were to be
determined. The determined list of required times is
provided in 6.7.

4. Reporting Procedures- Computer terminal results for
the Emergency Department. The specific needs of customers
were to be established in relation to accessing computer
terminal results. The needs were to be defined in terms
of ease of accessibility to results, time of availability
of results, and ease of contact in making test result
enquiries. The requirements will be specifically defined
during the discussion on the development of the
Improvement Plan in 6.8.

5. Reporting Procedures- Printed reports for the
Emergency Department. The specific needs of customers
were to be established in relation to the provision of
printed reports. The needs were to be defined in terms of
time of availability, frequency of printouts, and mode of
provision. The requirements will be specifically defined
during the discussion on the development of the
Improvement Plan in 6.9.

6.3.5 Uncover the causes of poor quality

6.3.5.1 Potential causes of poor quality
The root causes of each of the five major process
problems were investigated and identified in a systematic
manner. This was attained through the use of
brainstorming techniques at CQI Project Team meetings to
develop cause-and-effect diagrams. All potential causes
were documented.

The cause-and-effect diagrams are illustrated in
Appendix 5. Since the problems associated with computer
terminal results and printed reports were of a similar
nature, it was decided to draw a combined cause-and-
effect diagram for such reporting procedures.

6.3.5.2 Data collection plan
Once an extensive list of potential causes had been
developed, individual causes were checked with existing
information that was provided by the CQI Project Team to
confirm or reject them. Data were also collected to
further substantiate that they were in fact the root
causes of the problems.

Table 6.4 summarises the data collection plan that was
<table>
<thead>
<tr>
<th>CAUSES OF POOR QUALITY</th>
<th>DATA COLLECTION PLAN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Urgency of test incorrectly specified.</td>
<td>All request forms from the E.D. for tests on suspected AMI patients were examined and the urgency of the tests noted.  i.e; routine, urgent or stat. (14 day period).</td>
</tr>
<tr>
<td>2. Delays in receiving printed reports</td>
<td>A register was set up in Pathology to determine the TAT for printed reports.  i.e; time taken from when the specimen was collected to the time the first interim and final printed report were delivered. (14 days).</td>
</tr>
<tr>
<td>3. Delays in E.D. staff receiving patient labels for use on specimen tubes.</td>
<td>A register was used to determine the time it took the clerical office of the E.D. to print labels on patients with suspected AMI. The register was maintained by the clerical staff of the E.D. (28 day period).</td>
</tr>
<tr>
<td>4. Delays in E.D. specimen pickup.</td>
<td>A register was set up to determine the time it took for a wardperson to arrive to the E.D. after being called to deliver a patient specimen to Pathology. The register was maintained by E.D. clinical staff. The time E.D. placed the specimen in the E.D. specimen pickup box was also recorded on the Pathology request form. (14 days).</td>
</tr>
<tr>
<td>5. Specimens 'lost' in transit.</td>
<td>A record was kept by the Pathology staff of all 'lost' specimens from the E.D. A specimen was defined as lost if for whatever reason it failed to reach the Pathology Department within a 2 hour period. (14 days).</td>
</tr>
<tr>
<td>6. Specimens left unattended in Pathology Department.</td>
<td>Pathology staff kept records of all E.D. specimens not handed to a staff member on delivery. (14 day period).</td>
</tr>
<tr>
<td>7. Turnaround times for some test results inappropriate.</td>
<td>A register was set up in the Pathology Department to determine the TAT for all tests ordered in the first 90 hours of the management of patients with suspected AMI.  i.e; time from when specimen was received in Pathology to the time all results were available on the computer. The clerk was to search each set of results at 30 min intervals on the computer. (28 day period).</td>
</tr>
<tr>
<td>8. Computer terminal downtime.</td>
<td>A register was set up in the E.D. to record the frequency of occasions that the HOSLAB computerised laboratory information system was down when a result enquiry was attempted on the computer. (14 day period).</td>
</tr>
<tr>
<td>9. Laboratory analyser breakdown.</td>
<td>A record was kept by the Pathology Department of the number of occasions on which breakdowns occurred to the main analysers of the Clinical Chemistry and Haematology Departments. (14 day period).</td>
</tr>
</tbody>
</table>
used to substantiate the causes of poor quality.

As will be shown in 9.1, only five of the nine causes listed in Table 6.4 (i.e; Cause Numbers 2, 3, 4, 6 & 7) were in fact substantiated by the data collected over the period of investigation. All data were summarised and then discussed at Project Team meetings.

The Project Team information and the data subsequently collected, confirmed that many of the suspected causes of problems related to the central process of appropriate test utilisation. Table 6.5 lists the root causes that were able to be substantiated from process information and the data collected.

6.3.5.3 Improving sources of variation

Once the flow charts, cause-and-effect diagrams, process problems list, root causes list, and data had been reviewed at Project Team meetings, it was determined which causes of variation could be changed to improve the process. It was decided that all the causes of variation that were listed in Table 6.5 would be targeted for change. Therefore appropriate strategies covering these were to be incorporated into the Improvement Plans for the project.

6.3.6 Selecting the process improvement

6.3.6.1 Determine proposed improvements

The Project Team determined that five Process Improvement
<table>
<thead>
<tr>
<th></th>
<th>Root causes of problems in the process of appropriate test utilisation</th>
</tr>
</thead>
</table>
| 1. Test requesting | * No guidelines or standardisation exists  
* Inability or failure to obtain previous results  
* Delays in receiving printed reports  
* Lack of a clinical team effort in test requesting  
* No feedback to clinicians of test requesting practice  
* No monitoring of appropriateness of test utilisation |
| 2. Delays in specimen and request form delivery from the Emergency Department to Pathology | * Slow response time from wardspersons  
* Delays in receiving patient labels for use on specimen tubes  
* Specimens left unattended in Pathology Department  
* Staff unfamiliar with request form requirements  
* Staff unfamiliar with specimen requirements  
* Poor handling of after-hours non-urgent blood collections  
* No policies exist for the delivery of specimens  
* Specimens sometimes batched before delivery |
| 3. Turnaround time for test results | * Off-site testing often results in delays  
* Poor communication between service providers and customers |
| 4. Reporting procedures: Computer terminal results | * Current process is cumbersome and time consuming  
* No alert provided to advise that results are available on the computer  
* Lack of customer focus |
| 5. Reporting procedures: Printed reports | * Disjointed dispatch of numerous, often duplicated, interim printed reports  
* Lack of customer focus |
Plans would be developed. These were:

1. Plan 1: Improving the appropriateness of test ordering in the early management of AMI.

2. Plan 2: Improving the delivery of specimens and request forms from the Emergency Department to Pathology.

3. Plan 3: Improving the turnaround time of test results in the early management of AMI.

4. Plan 4: Improving the clinician’s ease of accessibility to computer terminal laboratory results in the early management of AMI.

5. Plan 5: Improving the system for the distribution of printed laboratory reports to the Emergency Department on patients with suspected AMI.

6.3.6.2 Prioritise process improvements

The following priorities were set by the CQI Project Team for the introduction of the Improvement Plans. It was decided to initially implement Plans 1 and 2. After a further 10 weeks, Plan 3 was introduced. Finally after a further 8 weeks, it was decided that Plans 4 and 5 would be simultaneously implemented.

The priorities were largely based on two factors—the Project Team’s immediate needs for laboratory service improvement and their personal availability to implement the necessary aspects of the process Improvement Plans.
6.4 CQI implementation process- Improvement Plans

The process Improvement Plans were developed, implemented and maintained in accordance with the PDCA cycle portion of the FOCUS-PDCA model outlined in 6.1.

The PDCA cycle commenced with an Improvement Plan being developed. The second stage involved its implementation, with collection and analysis of data about the impacts of the changes. The third stage involved a check of whether the changes had resulted in any improvements as expected. An assessment was then made of how the team effort could have been further improved.

The next stage involved taking appropriate action to hold the gain in improvement. This involved an assessment of whether further changes were needed, the standardisation of procedures, the establishment of a measurement and monitoring process, and the training of people.

Once these measures had been undertaken to hold the gain, a plan was prepared for the next steps of continuous improvement. As shown in Figure 6.1, the PDCA cycle then continued. As discussed in 6.3.5.3 it was decided that the Improvement Plans would target for change all the causes of variation that were listed in Table 6.5.

The five Plans listed in 6.3.6.1 are briefly described below. Complete details of the Plans and their implementation are provided as Appendix 6.
6.5 PLAN 1: Appropriateness of test requesting

PLAN 1: Improving the appropriateness of test requesting in the early management of AMI.

The CQI Project Team determined that guidelines would be introduced for laboratory testing in the early management of AMI.

In brief, Plan 1 was introduced as follows:
1. The mission statement was defined.

2. The process improvement strategies were developed and focused on the development of the guidelines for test requesting; strategies for implementation of the guidelines; data collection plan; and pilot testing the Plan. Figure 6.4 illustrates the flow chart that was used to depict the laboratory test guidelines.

3. The implementation of the Plan was then undertaken.

4. A check was then made of the lessons learnt.

5. The final strategy was to implement measures to hold the gain.

Complete details of Plan 1, including flow charts, is provided as Appendix 6.1.

6.6 PLAN 2: Delivery of specimens and request forms

PLAN 2: Improving the delivery of specimens and request
FIGURE 6.4 LABORATORY TESTING GUIDELINES IN SUSPECTED A.M.I.

1. **Patient arrives with chest pain. Suspected of having A.M.I.**

2. **Tests ordered:** FBC, Na/K/Cl, creat, glucose, APTT/FI, Total CK CK-MB.

3. **Is it <24 hrs after onset of symptoms?**
   - NO → **LDH test also ordered.**
   - YES → **Request forms prepared for Total CK/CK-MB, for 6, 12 hours.**

4. **Is there arrhythmia?**
   - NO → **Also ordered:** magnesium, calcium, phosphate.
   - YES → **Also ordered:** blood gases.

5. **Is patient starting on TPA and/or Heparin?**
   - NO → **Is there dyspnoea, left vent failure, or cardiogenic shock?**
     - NO → **Patient transferred to CCU.**
     - YES → **Request forms prepared for 'stat' APTT 6, 12 hours after starting TPA/Hep.**
CORONARY CARE UNIT

1

Tests ordered at 24hrs: CK/CK-MB; Na/K/Cl; fast AM glucose, chol/triglyceride.

Also ordered at 48 and 72 hrs: Na/K/Cl.

Is patient on TPA and/or heparin?

YES

APTT test ordered 24 hrs after starting therapy.

NO

APTT tests ordered daily to guide infusion rate.

Is APTT <60 secs or >100 secs

NO

'Stat' APTT test ordered in 6 hours.

YES

Laboratory testing completed.
form from the Emergency Department to Pathology.

The CQI Project Team developed a set of strategies to improve the process of specimen and request form delivery from the Emergency Department to the Pathology Department.

In brief, Plan 2 was introduced as follows:

1. The mission statement was defined.

2. The process improvement strategies were developed and focused on re-examining the processes and the roles of individuals involved in the handling and transportation of blood specimens and test request forms the Emergency Department to Pathology. Through the CQI process, policies, procedures and education programmes were established for key process areas.

3. The implementation of the Plan was then undertaken.

4. A check was then made of the lessons learnt.

5. The final strategy was to implement measures to hold the gain.

Complete details of Plan 2 are provided as Appendix 6.2.

6.7 PLAN 3: Turnaround time of test results

PLAN 3: Improving the turnaround time of test results in the early management of AMI.
The CQI Project Team developed a Plan whereby the customer required turnaround times for test results were determined, and then strategies developed to meet these requirements.

In brief, Plan 3 was introduced as follows:

1. The mission statement was defined.

2. The process improvement strategies were developed and focused on determining the customer requirements for turnaround time of test results; developing the process of data collection in order to establish current turnaround times for test results; assessing the improvement potential of tests with poor turnaround times; the provision of education programmes for clinicians; and pilot testing the plan.

3. The implementation of the Plan was then undertaken.

4. A check was then made of the lessons learnt.

5. The final strategy was to implement measures to hold the gain.

The customer requirements for turnaround time of results are shown in Table 6.6. Complete details of Plan 3 are provided as Appendix 6.3.
### TABLE 6.6 Customer requirements for turnaround time of test results

<table>
<thead>
<tr>
<th>Tests</th>
<th>Required Turnaround Time (hours)*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>baseline</strong></td>
<td></td>
</tr>
<tr>
<td>Full blood count</td>
<td>2.0</td>
</tr>
<tr>
<td>Na K Cl</td>
<td>1.0</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1.0</td>
</tr>
<tr>
<td>APTT</td>
<td>4.0</td>
</tr>
<tr>
<td>PT</td>
<td>4.0</td>
</tr>
<tr>
<td>CK</td>
<td>2.0</td>
</tr>
<tr>
<td>CK-MB</td>
<td>4.0</td>
</tr>
<tr>
<td><strong>6 hours</strong></td>
<td></td>
</tr>
<tr>
<td>APTT</td>
<td>1.5</td>
</tr>
<tr>
<td>CK</td>
<td>2.0</td>
</tr>
<tr>
<td>CK-MB</td>
<td>4.0</td>
</tr>
<tr>
<td><strong>12 hours</strong></td>
<td></td>
</tr>
<tr>
<td>APTT</td>
<td>1.5</td>
</tr>
<tr>
<td>CK</td>
<td>2.0</td>
</tr>
<tr>
<td>CK-MB</td>
<td>4.0</td>
</tr>
<tr>
<td><strong>24 hours</strong></td>
<td></td>
</tr>
<tr>
<td>CK</td>
<td>2.0</td>
</tr>
<tr>
<td>CK-MB</td>
<td>4.0</td>
</tr>
<tr>
<td>Na K Cl</td>
<td>4.0</td>
</tr>
<tr>
<td>Fasting glucose</td>
<td>4.0</td>
</tr>
<tr>
<td>Cholesterol</td>
<td>8.0</td>
</tr>
<tr>
<td>Triglyceride</td>
<td>8.0</td>
</tr>
<tr>
<td>APTT</td>
<td>1.5</td>
</tr>
<tr>
<td><strong>48 hours</strong></td>
<td></td>
</tr>
<tr>
<td>Na K Cl</td>
<td>4.0</td>
</tr>
<tr>
<td><strong>72 hours</strong></td>
<td></td>
</tr>
<tr>
<td>Na K Cl</td>
<td>4.0</td>
</tr>
</tbody>
</table>

* Required turnaround times for 95% of all requests after arrival at the Pathology Department of the Bankstown-Lidcombe Hospital.
6.8 PLAN 4: Accessibility to computer results

PLAN 4: Improving the clinician's ease of accessibility to computer terminal laboratory results in the early management of AMI.

In brief, Plan 4 was introduced as follows:

1. The CQI Project Team investigated the various options that could be used to improve the current poor process of accessing urgently required clinical laboratory test results from the computer terminal. The CQI Project Team, in consultation with the customers of the clinical laboratory service, considered four main options as potential solutions to the problem.

2. The mission statement was defined.

3. The four options were given due consideration by the CQI Project Team and the preferred option chosen for implementation.

Complete details of Plan 4 are provided as Appendix 6.4.

6.9 PLAN 5: Distribution of laboratory reports

PLAN 5: Improving the system for the distribution of printed laboratory reports for patients with suspected AMI.

The CQI Project Team developed a Plan to improve the
system for the distribution of printed laboratory test reports to the Emergency Department, on patients with suspected AMI.

In brief, Plan 5 was introduced as follows:

1. The mission statement was defined.

2. The process improvement strategies were developed and focused on determining the customer requirements; developing and introducing the data collection process; providing education programmes; and pilot testing the plan.

3. The implementation of the Plan was then undertaken.

4. A check was then made of the lessons learnt.

5. The final strategy was to implement measures to hold the gain.

Complete details of Plan 5 are provided as Appendix 6.5.

6.10 Post CQI process

Once the process improvement Plans 1-5 had been implemented a new series of flowcharts were developed to indicate the new processes. The post CQI process of pathology test utilisation in early AMI is provided as APPENDIX 7. The main process improvements were those of test ordering, specimen and request form handling and distribution of printed reports.
6.11 Summary

This chapter essentially described in detail the development and implementation of the procedures for the TQM intervention of this investigation.

Using the principles of TQM, a CQI approach was used to improve the appropriateness of clinical laboratory test utilisation in the management of early AMI. The Hospital Corporation of America's (HCA) FOCUS-PDCA quality improvement model was adapted and modified for use in the present study. The HCA model has been widely accepted and used as standard process improvement methodology.

A regime of the development and implementation of the five CQI Improvement Plans used in the study were outlined, more detail being provided in Appendix 6.

REFERENCES AND NOTES


3. Scholtes, op. cit; p.4-34.
CHAPTER 7. COLLECTION AND ANALYTICAL PROCEDURES

Chapter 7 provides specifically a comprehensive account of the procedure used in the study for the collection and analysis of the data.

7.1 Data collection

Essentially, two broad areas of data were collected throughout the period of investigation.

Firstly, CQI process improvement data were obtained prospectively from the experimental group following intervention. The data were derived through the use of a population of patients suspected of having had an AMI. As such data became available throughout the course of the study, it provided a major focus of attention for the CQI Project Team. The data in essence contributed the necessary information for the Project Team to proceed and develop further continuous improvement initiatives. Such data were constantly sought and fed back to the staff of the various departments. It acted as a driving force for further quality improvement.

Secondly, test utilisation data were also collected. This was largely undertaken, pre and post CQI intervention for both the experimental and control group populations. Such data were essentially derived to test the hypotheses of study.
7.1.1 Data collection overview

The process improvement data collection systems that were used involved the initial collection of baseline data during suspected AMI, and the follow up ongoing collection of data following the introduction of the various CQI strategies. An assessment was also undertaken to determine whether the five objectives of the intervention had been accomplished.

In addition, pre and post CQI data providing information on test utilisation and test appropriateness were measured for both the experimental and the control groups. Such data were necessary not only for measuring the effect of the TQM strategies on test usage, but also to initially include or exclude patients for the study.

7.2 Process improvement data collection

7.2.1 Substantiating causes of poor quality

As outlined in 6.3.5.2; a data collection plan was designed to determine whether the CQI Project Team’s suspected causes of inappropriate test utilisation were in fact responsible for the problems at hand. The information also provided valuable baseline data for future comparisons. The data were collected at the Bankstown-Lidcombe Hospital in July 1993.

7.2.2 Data collection techniques for Plan 1

An audit to assess the level of compliance to the AMI
laboratory testing guidelines was undertaken prospectively during the Plan 1 post-test implementation period, which also included the 7 day pilot test.

Once the ‘suspected AMI’ patients were transferred to the CCU, the following information was obtained by designated members of the CQI Project Team. This was obtained for each suspected AMI patient during the first 90 hours of their hospitalisation:

1. Whether the special AMI pre-stamped pathology request forms were being used in accordance with the AMI laboratory testing guidelines. A ‘yes’ or ‘no’ record was made on a specially designed worksheet at 0, 6, 12, 24, 48 and 72 hours.

2. Whether blood tests were being collected at appropriate times and dates, in accordance with the AMI laboratory testing guidelines.

The worksheet that was used to collect the data for the audit is provided as Appendix 8.

The data on test compliance were collected daily for 28 days during every alternate month. Once the intervention had occurred, the first month’s audit was established and undertaken by the CCU Working Team. Subsequent audits were performed by the CQI Project Team Leader in collaboration with another Team member, the Senior Technologist of the Pathology Department. The findings
were reported to the Emergency Department and CCU staff, and at the regular CQI Project Team meetings.

7.2.3 Data collection techniques for Plan 2

In order to determine the time taken for Emergency Department specimens to reach the Pathology Department, the following data were recorded:

1. blood collection time was recorded on the request form by the Emergency Department staff member collecting the patient’s blood specimen.

2. time specimen bag placed in Emergency Department ‘specimen pick-up box’ (ED box) was recorded on the request form by the person placing the specimen bag in the ED box.

3. time specimen bag was delivered to the Pathology Department was recorded by the wardsperson delivering the specimen. This was achieved by the wardsperson clocking in the time on the request form by using the stamping device found at the Pathology Reception desk.

Under the supervision of the Senior Technologist of the Pathology Department, a data worksheet was maintained. The worksheet that was used to collect the data for the audit is provided as Appendix 9.

Data were collected for 28 day periods on alternate months over the post-CQI period, commencing from
October 1993. However, after 4 weeks from the commencement of the collection of data, the practice of recording the time the specimen was placed in the ED box was discontinued.

As discussed earlier in Appendix 6.2, a review was also undertaken of specimen delivery times just prior to the staff being formally asked to record data of the times of collection and delivery. This was achieved by reviewing all request forms from the Emergency Department that were from the 28 day period just prior to the introduction of the formal data collection process described above. The time of blood collection and the time of arrival at the Pathology Department were noted from these forms.

The register that was established in 6.3.5.2 section 3 to determine the length of time that it took the clerical office staff of the Emergency Department to print labels on patients with suspected AMI was introduced and maintained for a period of 4 weeks during October 1993. The register was maintained by the nursing staff of the Emergency Department.

7.2.4 Data collection techniques for Plan 3
The special Pathology Department TAT register that was established in 6.3.5.2 (Table 6.4) to determine the turnaround time of each test result was reintroduced. Commencing from October 1993, data were collected for 28 day periods on each alternate month throughout the
remainder of the post CQI intervention period.

7.2.5 Data collection techniques for Plan 4

Data derived from the special Pathology Department TAT register established in 7.2.4 were used to estimate the degree of accessibility to computer terminal results. The degree of accessibility to computer terminal results on patients with suspected AMI was determined over a four week period in December 1993. This was achieved by recording the number of attempts that were required in order to obtain the complete set of baseline test results from the computer terminal.

7.2.6 Data collection techniques for Plan 5

The special Pathology Department TAT register established in 6.3.5.2 was adapted for use in this exercise. The register was previously established to record the necessary information that was required to calculate the turnaround time of all printed reports. The register was maintained by the clerical staff of the Pathology Department. Supervision of the register was undertaken by the Senior Technologist. The register was modified to also include information on the number of interim reports dispatched, the number of final reports dispatched, and the number of reports still awaiting results.

The CQI data comprised the number of interim printed reports dispatched to the wards, and the number of final printed reports dispatched to the wards. Overall, data
were collected for 14 day periods on alternate months throughout the duration of the post CQI intervention period, commencing from December 1993. The worksheet that was used to collect the data is provided as Appendix 10.

Data were also collected on the number of medical records that were requested by the clinical staff of the Emergency Department. The records were used by the clinical staff to follow up the laboratory results received from the printed reports. A record was maintained by the clerical staff of the Emergency Department of all patient records that were requested for the Emergency Department. This list was then matched with the list of names found in the Special Pathology Department TAT register discussed above. The number of requested medical records was then counted for all patients that had printed reports dispatched to the Emergency Department. The data on the number of medical records requested were only compiled over a 6 week period, which included a 14 day pretest period just prior to the pilot study commencing.

7.2.7 The objectives of the intervention

An assessment was undertaken to determine whether the five objectives of the TQM intervention had been accomplished. The criteria that was used to assess this was outlined earlier in 5.5.3.
7.2.7.1 Objectives 1 and 3

A three point scale of scoring was used to assess whether objectives 1 and 3 had been accomplished. For each criterion statement listed in Table 5.2 (Objective 1) and Table 5.3 (Objective 3), the investigator determined to what degree each had been introduced for the pathology services of the experimental group hospital.

Each criterion statement was scored in accordance with the following three point scale:

‘Introduced’ (I): the organisation has fully introduced the characteristic described to all relevant areas.

‘Partially Introduced’ (PI): the characteristic has been introduced within major parts of the organisation.

‘Not Introduced’ (NI): the introduction of the characteristic has been minimal or non-existent.

Scoring for each statement was as follows:
I = 3, PI = 2, NI = 1.

The total score for the ten criterion statements of each Objective was then calculated and broadly interpreted in accordance with Table 7.1.

7.2.7.2 Objective 2

The accomplishment of this objective was confirmed by determining whether the developed model for process improvement had the key characteristics of the CQI
TABLE 7.1 Broad interpretation of the scores for Objectives 1 and 3

<table>
<thead>
<tr>
<th>Score*</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 - 30</td>
<td>Very High- fully effective integration of TQM principles</td>
</tr>
<tr>
<td>21 - 25</td>
<td>High- good integration of TQM principles</td>
</tr>
<tr>
<td>16 - 20</td>
<td>Average- moderate to good integration of TQM principles</td>
</tr>
<tr>
<td>11 - 15</td>
<td>Low- only some evidence of attention to TQM principles</td>
</tr>
<tr>
<td>5 - 10</td>
<td>Very Low- little or no evidence of attention to TQM principles</td>
</tr>
</tbody>
</table>

*Combined score obtained for the ten statements of each Objective.

approach as listed in Table 7.2.

For each criterion listed in Table 7.2, the investigator determined at the completion of the investigation to what degree each had been introduced for improving pathology services within the experimental group hospital.

TABLE 7.2 Key characteristics of the COI model approach

1. Model based on improving organisational systems and processes.
2. Scientific approach to problem solving.
3. Formation of a team comprising members who represent all key areas of the process being targeted for improvement.
4. Various team based techniques used to uncover causes of poor quality.
5. Identification of customer needs and concerns.
6. Improvement process often necessitates returning to various steps in the model to reevaluate the work that was done at that time and may require new strategies to be developed.
7. Improvement processes are planned on the basis of the data analysis and the findings from the use of other COI tools (e.g; flow charts and cause-and-effect diagrams).
Using the three point scale of 7.2.7.1, each criterion statement was scored. The total score for the seven criterion statements was then calculated and broadly interpreted in accordance with Table 7.3.

**TABLE 7.3 Broad interpretation of the total scores for Objective 2**

<table>
<thead>
<tr>
<th>Score*</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>19 - 21</td>
<td>Very High- fully effective integration of TQM principles</td>
</tr>
<tr>
<td>16 - 18</td>
<td>High- good integration of TQM principles</td>
</tr>
<tr>
<td>13 - 15</td>
<td>Average- moderate to good integration of TQM principles</td>
</tr>
<tr>
<td>10 - 12</td>
<td>Low- only some evidence of attention to TQM principles</td>
</tr>
<tr>
<td>7 - 9</td>
<td>Very Low- little or no evidence of attention to TQM principles</td>
</tr>
</tbody>
</table>

*Combined score obtained for the ten statements of each Objective.

### 7.2.7.3 Objective 4

As discussed in 5.5.3 the accomplishment of this objective was confirmed by determining whether the type of data collected throughout the investigation complied with all the requirements listed in Table 7.4.

**TABLE 7.4 Specific data requirements for the accomplishment of Objective 4 of the intervention.**

1. The total number of clinically recommended tests throughout the pre and post test period.

2. The total number of non-clinically recommended tests throughout the pre and post test period.

3. The median time intervals between blood collections of the first four total CK tests ordered on patients with confirmed AMI throughout the pre and post test period.

4. The total costs of tests per AMI admission throughout the pre and post test period.
7.2.7.4 Objective 5

As outlined earlier in 5.5.2, this objective was examined in terms of discharge status, readmissions to hospital within 30 days of discharge, and length of stay.

7.3 Test utilisation data collection

7.3.1 'Pre-test' utilisation

'Pre-test' data providing baseline test utilisation and test appropriateness were measured for both the experimental and the control groups. This provided valuable information to the CQI Project Team on the extent of the presenting problem, and was necessary for the overall measurement of improvement.

The CCU Patient Registers at each hospital were used to identify all patients that had been admitted to the CCU with chest pain and electrocardiographic signs suggestive of AMI during the 'pre-test' period March 2nd 1992 and June 6th 1993.

The CCU Registers provided detailed information on each patient admitted to the CCU. The information contained in the CCU Register included:

1. Patient details- Name, date of birth, sex, address, Medical Record Number, Medical Officer;

2. Admission- time and date admitted to CCU; admission diagnosis; discharge- time and date discharged; location
discharged to; and, discharge diagnosis.

The medical records for these 'suspected AMI' patients were then examined to confirm the diagnosis of AMI and to collect key demographic and clinical data on these 'confirmed AMI' patients. The patients were registered as 'confirmed AMI' if they met the strict criteria defined in 5.4.1. The information that was abstracted from each medical record is provided in 7.4.

7.3.2 'Post-test' utilisation

Once the baseline pre-test data had been derived, TQM strategies were developed and introduced only at the Bankstown-Lidcombe Hospital. As the control group for the study, no intervention occurred at Nepean Hospital.

At the Bankstown-Lidcombe Hospital and the Nepean Hospital, all patients that presented to the Emergency Department with 'suspected AMI' during the 'post-test' period June 7th 1993 and August 26th 1994, inclusive, were prospectively registered as 'suspected AMI' for the study. Patients were registered as 'suspected AMI' in accordance with the criteria defined in 5.4.1.

The CCU Patient Registers of each hospital were used to ensure that all 'suspected AMI' patients eligible for inclusion were in fact included in the study.

The medical records for these 'suspected AMI' patients of both hospitals were then examined to confirm the
diagnosis of AMI and to collect key demographic and clinical data on these 'confirmed AMI' patients. The patients were registered as 'confirmed AMI' if they met the strict criteria defined in 5.4.1. The information that was abstracted from the medical records of 'confirmed AMI' patients is provided in 7.4.

For the purposes of additionally comparing the two population groups in the post test period, the age and sex were also collected from the medical records of patients earlier identified to be in the 'suspected AMI' group.

7.4 Data collected from the medical records

Table 7.5 outlines the data that were obtained from the medical records of patients in both the pre-test and post-test populations of the experimental and control groups. The entire process of collecting data from the medical records of both study populations was undertaken by the investigator, the Chief Hospital Laboratory Scientist of the Bankstown-Lidcombe Hospital.

The worksheet that was used to collect the laboratory test data is provided as Appendix 11.

7.5 Plan for data analysis

Once data were abstracted from the patient's records or other sources as described, they were coded and statistical analysis performed using the software package
<table>
<thead>
<tr>
<th>TABLE 7.5  Data collected from the medical records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient details</td>
</tr>
<tr>
<td>1. Age</td>
</tr>
<tr>
<td>2. Sex</td>
</tr>
<tr>
<td>Admission details</td>
</tr>
<tr>
<td>3. Length of stay</td>
</tr>
<tr>
<td>4. Ward names</td>
</tr>
<tr>
<td>5. Duration in CCU</td>
</tr>
<tr>
<td>6. Discharge status</td>
</tr>
<tr>
<td>7. Readmission to hospital</td>
</tr>
<tr>
<td>Clinical details</td>
</tr>
<tr>
<td>8. E.D. presentation</td>
</tr>
<tr>
<td>9. Duration of chest pain</td>
</tr>
<tr>
<td>10. Principal diagnosis</td>
</tr>
<tr>
<td>11. Secondary diagnoses/complications</td>
</tr>
<tr>
<td>12. ECG changes</td>
</tr>
<tr>
<td>13. Time and date of blood collections</td>
</tr>
<tr>
<td>14. Additional tests</td>
</tr>
<tr>
<td>15. Peak total CK value</td>
</tr>
</tbody>
</table>

SWSAHS- South Western Sydney Area Health Service; WAHS- Wentworth Area Health Service; E.D.- Emergency Department; CCU- Coronary Care Unit.
SPSS/PC+ 4.0. All data coding, data entry and statistical analysis was undertaken by the writer.

7.5.1 Data analysis overview

A two stage process was used to analyse the data generated from the study—first descriptive and then analytic.

Initially there was an examination of the frequency distribution of values for each variable collected. Using SPSS/PC+ 4.0, the Lilliefors statistical test was used to test for the presence of a normal distribution. From the observed significance level of the Lilliefors test and the magnitude of the departure from normality, a statistic was determined where necessary to estimate the central tendency and spread of the data. The mean was used when the data were approximately normally distributed (p>0.05, Lilliefors test). With skewed distributions, the median was used.

The next stage involved the analysis of associations among predictor and outcome variables. The statistical significance of associations among variables was determined through the use of a number of statistics including the $t$-test and chi-square, $\chi^2$. SPSS/PC+ 4.0 was used to perform the statistical analysis.
7.6 Process improvement data analysis

7.6.1 Substantiating causes of poor quality

The following analysis was performed on data that were collected to substantiate certain suspected causes of inappropriate test utilisation. The method of data collection was earlier outlined in 7.2.1.

The following analytical procedure was performed in July 1993:

1. Urgency of test incorrectly specified.
   The frequency and relative frequency of the various categories of test request urgency was determined over a 14 day period for all cases of suspected AMI.

2. Delays in receiving printed reports.
   The turnaround time for each interim printed report (Clinical Chemistry and Haematology) and each final printed report (Clinical Chemistry and Haematology) was determined over a 14 day period. The overall median turnaround time for receiving interim and final printed reports was determined for the period of investigation.

3. Delays in receiving patient labels for specimen tubes.
   The turnaround time for the printing of patient labels in the Emergency Department was determined for all cases of suspected AMI. The median time for receiving patient labels was determined.
The length of time it took for a wardsperson to arrive at the Emergency Department after being called was determined over a 14 day period. The median response time was determined. In addition, for a 14 day period, the following turnaround times were determined: interval between time blood collected in the E.D. and the time specimen bag was placed in the E.D. specimen pickup box; and, interval between time specimen bag placed in E.D. specimen pickup box and the time delivered to the Pathology department.

5. Specimens ‘lost’ in transit.
The frequency of ‘lost’ specimens was determined over a 14 day period from all Emergency Department specimens received in the Pathology Department.

6. Specimens left unattended in Pathology Department.
The frequency of Emergency Department specimens that were left unattended in the Pathology Department by wardspersons was determined over a 14 day period.

7. Turnaround time for tests.
The turnaround time for test results on suspected AMI patients was determined over a period of 28 days. The median time was determined for each test and test groups ordered per request form.

In addition, using the data derived in the
abovementioned sections 4 and 7, a sub-process breakdown of turnaround times was provided for the major process of reporting test results. This major process commenced at the point of blood collection and concluded with the availability of the results on the ward computer terminal. Using Pareto diagrams, the various sub-processes were quantified for this major process of test reporting.

The frequency of computer terminal breakdowns in the Emergency Department was determined.

9. Laboratory analyser breakdown.
The frequency with which breakdowns occurred to the main analysers of the Clinical Chemistry and Haematology Departments was determined.

7.6.2 Data analysis for Plan 1
At each recommended time of blood collection (i.e; 0, 6, 12, 24, 48 and 72 hours), a record was made of the clinical staff’s compliance to using the special AMI pre-stamped pathology request forms for patients with suspected AMI.

Using the data for each four week data collection period, the degree of compliance was calculated as a percentage of the total number of patients with suspected AMI. The significance of any difference in four weekly
compliance rates was tested at each recommended blood collection time using the $\chi^2$ statistic (6 x 2 table).

In addition, at each recommended time of blood collection (i.e.; 0, 6, 12, 24, 48 and 72 hours), a check was made of whether the specimen was collected at the appropriate time. This was undertaken in accordance with the previously defined requirements of 6.5 (Table 6.6). The rate at which blood for each group of tests ordered was collected at appropriate times was calculated for each four week period. This was expressed as a percentage of the total number of pathology requests made. The significance of any difference in the rate of appropriate timing of blood collections was tested at each four week period over the duration of the post-CQI period, using the $\chi^2$ statistic (6 x 2 table).

7.6.3 Data analysis for Plan 2
For the period of the first four weeks, the following turnaround times were recorded:

1. time blood collected in the Emergency Department to the time specimen bag was placed in the ED specimen pickup box.

2. time placed in ED specimen pickup box to the time delivered to the Pathology Department.

The median for each of these two time intervals was determined for the four week period of data collection.
The median time taken for Emergency Department specimens to reach the Pathology department was determined on alternate four week periods throughout the post CQI period, commencing from October 1993.

The Mann-Whitney U test was used to test individually the difference between the delivery times for each post-CQI four week period against the pre-CQI group of September 1993.

The next stage was to determine whether specimen delivery delays occurred more frequently at certain times throughout the normal operating hours of the Pathology Department, 0800- 2300 hours. Median delivery times at each of the predefined 3 hour time periods were determined for each post-CQI four week period.

A record was also made of the number of times that the blood collection time was recorded on the pathology request forms of patients with suspected AMI. The compliance rate was calculated as a percentage of the total number of request forms used.

In addition, during the first four week post-CQI period, the median time taken to receive printed patient labels in the Emergency Department was determined. This turnaround time was then compared to the corresponding pre-CQI median time (determined in 7.2.1) by using the Mann-Whitney U test.
7.6.4 Data analysis for Plan 3

Turnaround times were recorded for each recommended test and test group during the 90 hours following the admission of the patient with suspected AMI. The median turnaround times for each group of laboratory test results were then determined for each four week period of data collection.

Commencing from October 1993, and on each alternate month, each four weekly median test turnaround time was compared with the corresponding pre-CQI data (from 7.2.1) using the Mann-Whitney U test.

7.6.5 Data analysis for Plan 4

The degree of accessibility to computer terminal ED baseline test results was determined by recording the number of attempts that were required in order to obtain the desired test results from the computer terminal.

7.6.6 Data analysis for Plan 5

The following data were derived: the number of interim reports dispatched by Pathology specialty and the number of final printed reports dispatched by Pathology specialty.

Following the introduction of the Improvement Plan, the overall change in the actual number of dispatched printed interim reports was determined. The mean number of interim reports per total episodes of testing was then
calculated for each 14 day period of data collection. Each set of post-CQI data was then individually compared with the 14 day pre-CQI data using the t-test.

In addition, the total number of medical records requested by the Emergency Department on patients undergoing Pathology testing was determined over a period of 6 weeks, which included a 14 day pre-CQI period. The 6 week period of data collection was divided into three 14 day periods for the purposes of statistical comparison. The mean rate that medical records were being requested by the E.D. on patients that had undergone Pathology testing was calculated for each of the 14 day periods. The data from each period was then compared with the pre-CQI data using the t-test.

7.6.7 The objectives of the intervention
The analytical procedure used was outlined earlier in 7.2.7.

7.7 Test utilisation data analysis

7.7.1 Population characteristics

7.7.1.1 Age
The mean and standard deviation was calculated for the age of the following population groups:
1. confirmed AMI, pre-test experimental
2. confirmed AMI, pre-test control
3. confirmed AMI, post-test experimental.
4. confirmed AMI, post-test control.
5. suspected AMI, post-test experimental.
6. suspected AMI, post-test control

Group equivalency for age between the various experimental and control groups was tested using the $t$-test. A $p$ value of 0.05 or less was considered statistically significant.

7.7.1.2 Gender

The proportion of males (%) and females (%) were calculated for the experimental and control confirmed AMI groups, and the post-test suspected AMI groups. Group equivalency was tested for gender using the $\chi^2$-test (2 x 2 table) in the confirmed AMI groups, and then in the suspected post-test AMI groups.

7.7.1.3 Length of stay

The median length of stay was calculated for the experimental and control confirmed AMI populations. Group equivalency between the various population groups was tested using the Mann-Whitney U Test.

7.7.1.4 Discharge status

The number of patients in each of the three discharge categories was calculated for the experimental and control confirmed AMI groups. Group equivalency between the various population groups was tested using the $\chi^2$-test (3 x 2 table).
7.7.1.5 Readmission status

The number of patients that required readmission to a SWSAHS or WAHS hospital within 30 days of discharge was determined for the experimental and control groups. Group equivalency between the various population groups was tested using the $\chi^2$-test (2 x 2 table).

7.7.2 Test utilisation

From the laboratory records of the ‘confirmed AMI’ groups, the volume of clinical laboratory tests ordered during the 90 hours following admission were determined as follows:

1. total number of tests by test type and test group during the pre-test and post-test periods.

2. mean number of tests per admission by test type and test group during the pre-test and post-test periods.

Group equivalency between the pre-test and post-test groups was tested using the t-test for each set of data for the mean number of tests per admission by test type and test group.

3. total number of Clinical Chemistry, Haematology and Microbiology tests during the pre-test and post-test periods.

4. mean number of Clinical Chemistry, Haematology and Microbiology tests per admission during the pre-test and
post-test periods. Group equivalency between the pre-test and post-test groups was tested using the $t$-test for each set of data for the mean number of tests per admission by Pathology discipline group.

7.7.3 The sub-hypotheses of the investigation

7.7.3.1 Sub-hypothesis 1- Selection of clinically recommended tests

For each of the experimental and control confirmed AMI groups, the following were determined by the investigator:

1. the number of clinically indicated tests that were requested by the clinicians, by test type or test group. Clinically indicated tests comprised all tests as recommended by the AMI test guidelines and 'additional tests' as previously defined in Table 7.5.

2. total number of tests that were clinically indicated for each AMI patient, but not necessarily requested by the clinicians, by test type or test group. Clinically indicated tests comprised all tests as recommended by the AMI test guidelines and 'additional tests' as previously defined in Table 7.5.

3. the overall percentage change in the number of clinically recommended tests requested by the clinicians as a function of the introduction of the TQM
intervention.

7.7.3.2 Sub-hypothesis 2- Non-clinically indicated test utilisation

For each of the confirmed AMI groups, the following were determined:
1. total number of non-clinically indicated tests ordered by test type or test group.
2. mean number of non-clinically indicated inappropriate tests per admission by test type or test group.

Non-clinically indicated tests were defined as tests ordered that were not indicated by the AMI test guidelines. The clinically indicated additional tests previously identified in 7.4 were not included as non-clinically indicated tests. The overall change in the use of non-clinically indicated tests was determined for the pre-test and post-test periods of both the experimental and control groups. Group equivalency between the pre-test and post-test groups was determined using the t-test for each set of data for the mean number of non-clinically indicated tests per admission by test type and test group.

7.7.3.3 Sub-hypothesis 3- Blood collection timing

In accordance with the AMI test ordering guidelines, it was decided to determine whether the total CK cardiac enzyme test was being collected at the clinically recommended times of 0, 6, 12 and 24 hours after
admission.

The median time intervals between the blood collections of the first four total CK tests ordered, were determined for each of the confirmed AMI groups as follows:

1. First CK and second CK ordered.
2. First CK and third CK ordered.
3. First CK and fourth CK ordered.

For each experimental and control group population, the pre-test and post-test median times for each of the three designated intervals were compared using the Mann-Whitney U Test.

7.7.3.4 Sub-hypothesis 4- Cost analysis and projections

The costs of all tests ordered during the first 90 hours of admission were calculated for each patient of the confirmed AMI population groups (pre-test and post-test). Test costs were based on the Pathology Services Schedule of the Australian Commonwealth Medical Benefits fee schedule. Therefore the costing process involved classifying all tests and groups of tests in confirmed AMI according to the published item numbers found in this Schedule.

Within each confirmed AMI group, the following costs were determined:

1. total cost of tests ordered;
2. mean cost per patient admission;
3. total cost of tests ordered by Pathology specialty;

The following projections were undertaken:

**Projection 1:** annual cost savings for all pathology test usage on suspected AMI patients at the Bankstown-Lidcombe Hospital.

**Projection 2:** annual cost savings for all pathology testing at the Bankstown-Lidcombe Hospital as a result of extending the CQI strategies to include all pathology testing.

**Projection 3:** annual cost savings for pathology nationwide if such CQI strategies were to be introduced throughout all hospitals within the Australian Health Care System.

The calculated projected annual savings from pathology test usage in suspected AMI (Projection 1) was checked for accuracy by determining the actual costs and savings involved during 3 months of testing (pre and post-CQI) patients with suspected AMI at the Bankstown-Lidcombe Hospital. All costs and tangible benefits that could be valued in dollar terms were included in the cost analysis undertaken for the suspected AMI group.

In preparing Projections 2 and 3, it was assumed that the improvements in test utilisation attained in AMI would be achieved for all testing within hospitals, both locally and at a national level.
As reported by Edwards and Lapsley, data on the use and therefore cost of pathology testing in Australian public hospitals are extremely limited.

For patients in public hospitals, Medicare data are essentially limited to pathology services utilised by private inpatients. Based on the available Health Insurance Commission data, an estimate was undertaken of the cost of services for non-private inpatients, including those of veterans affairs. This estimate was undertaken in consultation with Mr. Ed Wilson and provided an estimate of the national cost for hospital pathology services.

Results of this estimation are provided in detail in Appendix 12.

7.7.3.5 Sub-hypothesis 5- Indicators of quality of care
As discussed in 5.5.2, three indicators were used to measure any changes in quality of care for the confirmed AMI population groups. These were discharge status, readmissions to hospital within 30 days of discharge, and length of stay. The data for these indicators had earlier been analysed in accordance with the protocol provided in 7.7.1.

7.8 Summary
This chapter essentially provided the specific plans and procedures used in the study for the collection and
analysis of the data. In line with the research design outlined in the previous chapter, two broad areas of data were collected throughout the period of investigation.

Firstly, CQI process improvement data were obtained from the experimental group following intervention. The data were derived through the use of a population of patients suspected of having had an AMI.

As such data became available throughout the course of the study, they provided a major focus of attention for the CQI Project Team. The data in essence contributed the necessary information for the Project Team to proceed and develop further continuous improvement initiatives.

Such data were constantly sought and fed back to the staff of the various departments. They acted as a driving force for further quality improvement.

Secondly, test utilisation data were also collected pre and post CQI intervention, for both the experimental and control group populations. Such data were essentially derived to test the hypothesis of the study.

REFERENCES AND NOTES


3. Mr. Ed Wilson is a leading Australian Pathology Services Consultant. He was formerly the general manager of Dorevitch Pathology, a private Pathology company.
CHAPTER 8. RESULTS 1- TEST UTILISATION ANALYSIS

Chapter 8 provides the first 'Results' chapter. These results are primarily concerned with the measurement of the appropriateness of laboratory test utilisation, before and after the CQI intervention. The data was derived to test the hypothesis and five sub-hypotheses of the investigation.

The chapter also includes information on the demographic characteristics of the study groups, the costs of laboratory services, the projected savings if the strategies were introduced across the Australian health care system, and the effects of the intervention on the quality of patient care.

8.1 Population characteristics

Tables 8.1 - 8.5 provide comparisons of the various

| TABLE 8.1 Age, gender and LOS characteristics of the post CQI suspected AMI group populations |
|-----------------------------------------------|----------------|----------------|
| Characteristics                               | Experimental   | Control        | p value  |
|                                               | (n=896)         | (n=748)        |          |
| Age, mean (SD) years                          | 62.8 (13.6)     | 61.2 (12.1)    | p = 0.3280 |
| Male, %                                       | 69.1            | 64.0           | p = 0.3814 |
| Female, %                                     | 30.9            | 36.0           | X²=0.7662, d.f.1 |
| Median LOS, days                              | 7.90            | 7.20           | p=0.2455 |

Comparison tests- Age: t-test; Gender: X² test; Length of stay (LOS): Mann-Whitney U test
demographic characteristics of the study group populations. The experimental and control study group populations were not significantly different on a range of demographic characteristics, including age, gender, length of stay, discharge status and readmission status.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Experimental (n=252)</th>
<th>Control (n=203)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) years</td>
<td>60.3 (9.9)</td>
<td>59.2 (9.7)</td>
<td>p=0.1520</td>
</tr>
<tr>
<td>Male, %</td>
<td>71.8</td>
<td>77.1</td>
<td>p=0.2395</td>
</tr>
<tr>
<td>Female, %</td>
<td>28.2</td>
<td>22.9</td>
<td>$X^2=1.3833$, d.f.1</td>
</tr>
<tr>
<td>Median LOS, days</td>
<td>8.80</td>
<td>8.00</td>
<td>p=0.3110</td>
</tr>
</tbody>
</table>

Discharge status

<table>
<thead>
<tr>
<th></th>
<th>Experimental</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharged home</td>
<td>231</td>
<td>182</td>
<td>p=0.2410</td>
</tr>
<tr>
<td>Transferred to another health care institution</td>
<td>20</td>
<td>16</td>
<td>$X^2=1.2115$, d.f.2</td>
</tr>
<tr>
<td>Died</td>
<td>6</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Readmission status

<table>
<thead>
<tr>
<th></th>
<th>Experimental</th>
<th>Control</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Readmitted (within 30 days of discharge)</td>
<td>7</td>
<td>4</td>
<td>p=0.3860</td>
</tr>
<tr>
<td>Not readmitted</td>
<td>245</td>
<td>199</td>
<td>$X^2=0.8513$, d.f.1</td>
</tr>
</tbody>
</table>

Comparison tests- Age: t-test; Gender: $X^2$ test; Length of stay (LOS): Mann-Whitney U test; Discharge status: $X^2$ test; Readmission status: $X^2$ test.
TABLE 8.3 Comparison of post-CQI characteristics of the experimental and control confirmed AMI group populations.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Experimental (n=253)</th>
<th>Control (n=211)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) years</td>
<td>61.0 (10.0)</td>
<td>59.6 (10.7)</td>
<td>0.0710</td>
</tr>
<tr>
<td>Male, %</td>
<td>74.7</td>
<td>70.8</td>
<td>0.3829</td>
</tr>
<tr>
<td>Female, %</td>
<td>25.3</td>
<td>29.2</td>
<td>(X^2=0.7611,\ d.f.1)</td>
</tr>
<tr>
<td>Median LOS, days</td>
<td>8.05</td>
<td>7.30</td>
<td>0.2805</td>
</tr>
<tr>
<td>Discharge status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharged home</td>
<td>223</td>
<td>192</td>
<td></td>
</tr>
<tr>
<td>Transferred to another</td>
<td></td>
<td></td>
<td>0.3142</td>
</tr>
<tr>
<td>health care institution</td>
<td>16</td>
<td>12</td>
<td>(X^2=1.0463,\ d.f.2)</td>
</tr>
<tr>
<td>Died</td>
<td>8</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Readmission status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Readmitted (within 30</td>
<td>7</td>
<td>6</td>
<td>0.4112</td>
</tr>
<tr>
<td>days of discharge</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not readmitted</td>
<td>246</td>
<td>205</td>
<td>(X^2=0.7914,\ d.f.1)</td>
</tr>
</tbody>
</table>

Comparison tests—Age: t-test; Gender: \(X^2\) test; Length of stay (LOS): Mann-Whitney U test; Discharge status: \(X^2\) test; Readmission status: \(X^2\) test.
As shown in Tables 8.4 and 8.5, equivalence was also confirmed when the study groups were compared at the pre-CQI and post-CQI stages of the investigation.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pre-CQI (n=252)</th>
<th>Post-CQI (n=253)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) years</td>
<td>60.3 (9.9)</td>
<td>61.0 (10.0)</td>
<td>0.1480</td>
</tr>
<tr>
<td>Male, %</td>
<td>71.8</td>
<td>74.7</td>
<td>0.2610</td>
</tr>
<tr>
<td>Female, %</td>
<td>28.2</td>
<td>25.3</td>
<td>(X^2=0.8514, \text{d.f.1})</td>
</tr>
<tr>
<td>Median LOS, days</td>
<td>8.80</td>
<td>8.05</td>
<td>0.2910</td>
</tr>
<tr>
<td>Discharge status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharged home</td>
<td>231</td>
<td>223</td>
<td></td>
</tr>
<tr>
<td>Transferred to another health care institution</td>
<td>20</td>
<td>16</td>
<td>(X^2=0.6730, \text{d.f.2})</td>
</tr>
<tr>
<td>Died</td>
<td>6</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Readmission status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Readmitted (within 30 days of discharge)</td>
<td>7</td>
<td>7</td>
<td>(p=0.9940)</td>
</tr>
<tr>
<td>Not readmitted</td>
<td>245</td>
<td>246</td>
<td>(X^2=0.0001, \text{d.f.1})</td>
</tr>
</tbody>
</table>

Comparison tests: Age: t-test; Gender: \(X^2\) test; Length of stay (LOS): Mann-Whitney U test; Discharge status: \(X^2\) test; Readmission status: \(X^2\) test.
TABLE 8.5 Comparison of characteristics of the pre-CQI and post-CQI confirmed AMI group populations.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Pre-CQI (n=203)</th>
<th>Post-CQI (n=211)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD) years</td>
<td>59.2 (9.7)</td>
<td>59.6 (10.7)</td>
<td>0.1340</td>
</tr>
<tr>
<td>Male, %</td>
<td>77.1</td>
<td>70.8</td>
<td>0.3310</td>
</tr>
<tr>
<td>Female, %</td>
<td>22.9</td>
<td>29.2</td>
<td></td>
</tr>
<tr>
<td>Median LOS, days</td>
<td>8.00</td>
<td>7.30</td>
<td>0.2610</td>
</tr>
<tr>
<td>Discharge status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discharged home</td>
<td>182</td>
<td>192</td>
<td></td>
</tr>
<tr>
<td>Transferred to another health care institution</td>
<td>16</td>
<td>12</td>
<td>0.6011</td>
</tr>
<tr>
<td>Died</td>
<td>5</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>Readmission status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Readmitted (within 30 days of discharge)</td>
<td>4</td>
<td>6</td>
<td>0.5629</td>
</tr>
<tr>
<td>Not readmitted</td>
<td>199</td>
<td>205</td>
<td></td>
</tr>
</tbody>
</table>

Comparison tests: Age: t-test; Gender: $X^2$ test; Length of stay (LOS): Mann-Whitney U test; Discharge status: $X^2$ test; Readmission status: $X^2$ test.
8.2 Clinical laboratory test utilisation

Figures 8.1 - 8.4 and Tables 8.6 and 8.7 show the changes that have occurred in the laboratory utilisation of individual tests over the period of investigation.

**FIGURE 8.1** Changes in the number of Clinical Chemistry tests used per admission for the experimental confirmed AMI group.

No. tests/admission

Tests utilised

Na,K,Cl Urea Cr Glu C,Mg,P CE LFT C/Trig TFT Misc

Pre-CQI Post-CQI

Na,K,Cl electrolytes; Cr creatinine; Glu glucose; C,Mg,P calcium, magnesium & phosphate; CE cardiac enzymes; LFT liver function tests; C/Trig cholesterol & triglyceride; TFT thyroid function tests.

**FIGURE 8.2** Changes in the number of Haematology tests used per admission for the experimental confirmed AMI group.

No. tests/admission

Tests utilised

ABC Blood film PI APTT Misc

Pre-CQI Post-CQI

ABC automated blood count- Hb,WCC,RCC & platelets; PI prothrombin index; APTT activated partial thromboplastin time.
FIGURE 8.3 Changes in the number of Clinical Chemistry tests used per admission for the control confirmed AMI group.

No. tests/admission

Tests utilised

<table>
<thead>
<tr>
<th>Test</th>
<th>Pre-CQI</th>
<th>Post-CQI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na, K, Cl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glu</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C, Mg, P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C/Trig</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TFT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Na, K, Cl electrolytes; Cr creatinine; Glu glucose; C, Mg, P calcium, magnesium & phosphate; CE cardiac enzymes; LFT liver function tests; C/Trig cholesterol & triglyceride; TFT thyroid function tests.

FIGURE 8.4 Changes in the number of Haematology tests used per admission for the control confirmed AMI group.

No. tests/admission

Tests utilised

<table>
<thead>
<tr>
<th>Test</th>
<th>Pre-CQI</th>
<th>Post-CQI</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Blood film</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>APTT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ABC automated blood count; Hb, WCC, RCC & platelets; P1 prothrombin index; APTT activated partial thromboplastin time.
<table>
<thead>
<tr>
<th>Test/Test Group</th>
<th>Pre-CQI (n=252)</th>
<th>Post-CQI (n=253)</th>
<th>% Reduction</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tests/</td>
<td>Tests/</td>
<td>Tests/</td>
<td>(Increase)</td>
</tr>
<tr>
<td></td>
<td>admission</td>
<td>admission</td>
<td>admission</td>
<td></td>
</tr>
<tr>
<td>Na, K, Cl</td>
<td>3805</td>
<td>2715</td>
<td>10.73</td>
<td>28.9</td>
</tr>
<tr>
<td>Urea</td>
<td>1268</td>
<td>355</td>
<td>1.40</td>
<td>72.1</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1274</td>
<td>526</td>
<td>2.08</td>
<td>58.9</td>
</tr>
<tr>
<td>Glucose</td>
<td>318</td>
<td>396</td>
<td>1.57</td>
<td>(24.0)</td>
</tr>
<tr>
<td>Ca, Mg, PO4</td>
<td>1361</td>
<td>367</td>
<td>1.45</td>
<td>73.1</td>
</tr>
<tr>
<td>Cardiac enzymes*</td>
<td>1882</td>
<td>2098</td>
<td>8.29</td>
<td>(11.0)</td>
</tr>
<tr>
<td>Liver function tests**</td>
<td>2261</td>
<td>546</td>
<td>2.16</td>
<td>75.9</td>
</tr>
<tr>
<td>Cholesterol/triglyceride</td>
<td>557</td>
<td>448</td>
<td>1.77</td>
<td>19.9</td>
</tr>
<tr>
<td>FT4, TSH</td>
<td>52</td>
<td>26</td>
<td>0.10</td>
<td>50.2</td>
</tr>
<tr>
<td>Misc Clinical Chemistry tests</td>
<td>324</td>
<td>127</td>
<td>0.50</td>
<td>61.0</td>
</tr>
<tr>
<td>Total</td>
<td>13102</td>
<td>7604</td>
<td>30.06</td>
<td>42.2</td>
</tr>
<tr>
<td>ABC***</td>
<td>3056</td>
<td>1076</td>
<td>4.25</td>
<td>64.9</td>
</tr>
<tr>
<td>Blood film</td>
<td>110</td>
<td>59</td>
<td>0.23</td>
<td>46.6</td>
</tr>
<tr>
<td>Prothrombin index</td>
<td>279</td>
<td>266</td>
<td>1.05</td>
<td>5.0</td>
</tr>
<tr>
<td>APTT</td>
<td>962</td>
<td>874</td>
<td>3.45</td>
<td>9.5</td>
</tr>
<tr>
<td>Misc Haematology tests</td>
<td>24</td>
<td>45</td>
<td>0.18</td>
<td>(86.8)</td>
</tr>
<tr>
<td>Total</td>
<td>4431</td>
<td>2320</td>
<td>9.17</td>
<td>47.8</td>
</tr>
<tr>
<td>Urine micro examination</td>
<td>14</td>
<td>19</td>
<td>0.08</td>
<td>(35.2)</td>
</tr>
<tr>
<td>Misc Microbiology</td>
<td>16</td>
<td>28</td>
<td>0.11</td>
<td>(74.3)</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>47</td>
<td>0.19</td>
<td>(56.0)</td>
</tr>
<tr>
<td>TOTAL</td>
<td>17563</td>
<td>9971</td>
<td>39.41</td>
<td>43.5</td>
</tr>
</tbody>
</table>

*Cardiac enzyme profile- CK and CK-MB; **Liver function tests- Total bilirubin, AST, ALT, GGT, ALP, Protein, Albumin. ***ABC, automated blood count- Hb, WCC, RCC and platelets.
<table>
<thead>
<tr>
<th>Test/Test Group</th>
<th>Pre-COI (n=203)</th>
<th>Post-COI (n=211)</th>
<th>% Reduction</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total tests</td>
<td>Tests/ admission</td>
<td>Total tests</td>
<td>Tests/ admission</td>
</tr>
<tr>
<td>Na, K, Cl</td>
<td>2 568</td>
<td>12.65</td>
<td>2 516</td>
<td>11.92</td>
</tr>
<tr>
<td>Urea</td>
<td>857</td>
<td>4.22</td>
<td>853</td>
<td>4.04</td>
</tr>
<tr>
<td>Creatinine</td>
<td>879</td>
<td>4.33</td>
<td>871</td>
<td>4.13</td>
</tr>
<tr>
<td>Glucose</td>
<td>261</td>
<td>1.28</td>
<td>277</td>
<td>1.31</td>
</tr>
<tr>
<td>Ca, Mg, PO4</td>
<td>286</td>
<td>1.40</td>
<td>193</td>
<td>0.91</td>
</tr>
<tr>
<td>Cardiac enzymes*</td>
<td>2 706</td>
<td>13.33</td>
<td>2 766</td>
<td>13.11</td>
</tr>
<tr>
<td>Liver function tests**</td>
<td>1 666</td>
<td>8.21</td>
<td>1 477</td>
<td>7.00</td>
</tr>
<tr>
<td>Cholesterol/triglyceride</td>
<td>493</td>
<td>2.43</td>
<td>643</td>
<td>3.05</td>
</tr>
<tr>
<td>FT4, TSH</td>
<td>32</td>
<td>0.16</td>
<td>34</td>
<td>0.16</td>
</tr>
<tr>
<td>Misc Clinical Chemistry tests</td>
<td>184</td>
<td>0.91</td>
<td>140</td>
<td>0.66</td>
</tr>
<tr>
<td>Total</td>
<td>9 932</td>
<td>48.93</td>
<td>9 770</td>
<td>46.30</td>
</tr>
<tr>
<td>ABC***</td>
<td>1 948</td>
<td>9.60</td>
<td>2 160</td>
<td>10.24</td>
</tr>
<tr>
<td>Blood film</td>
<td>87</td>
<td>0.43</td>
<td>94</td>
<td>0.45</td>
</tr>
<tr>
<td>Prothrombin index</td>
<td>296</td>
<td>1.46</td>
<td>261</td>
<td>1.24</td>
</tr>
<tr>
<td>APTT</td>
<td>567</td>
<td>2.79</td>
<td>536</td>
<td>2.54</td>
</tr>
<tr>
<td>Misc Haematology tests</td>
<td>21</td>
<td>0.10</td>
<td>14</td>
<td>0.07</td>
</tr>
<tr>
<td>Total</td>
<td>2 319</td>
<td>11.42</td>
<td>2 389</td>
<td>11.32</td>
</tr>
<tr>
<td>Urine micro examination</td>
<td>18</td>
<td>0.09</td>
<td>27</td>
<td>0.13</td>
</tr>
<tr>
<td>Misc Microbiology</td>
<td>15</td>
<td>0.07</td>
<td>12</td>
<td>0.05</td>
</tr>
<tr>
<td>Total</td>
<td>33</td>
<td>0.16</td>
<td>39</td>
<td>0.18</td>
</tr>
<tr>
<td>TOTAL</td>
<td>12 284</td>
<td>60.51</td>
<td>12 198</td>
<td>57.81</td>
</tr>
</tbody>
</table>

*Cardiac enzyme profile- CK, CK-MB, AST, LD; **Liver function tests- Total bilirubin, AST, ALT, GGT, ALP, Protein, Albumin. ***ABC, automated blood count- Hb, WCC, RCC and platelets.
Highly significant reductions were found in clinical laboratory test utilisation as a result of the CQI intervention for the experimental confirmed AMI group. As shown in Table 8.6, Clinical Chemistry tests were reduced by 42.2% (p<0.0001), and Haematology tests by 47.8% (p<0.0001).

In the experimental group, most clinical laboratory tests recommended in the early management of AMI were significantly reduced as a result of the intervention (p<0.0001). As examples, creatinine testing was reduced by 58.9%, liver function testing by 75.9%, and automated blood counts by 64.9%.

However, in the control group, no significant difference in test utilisation was found over the period of investigation. As shown in Table 8.7, Clinical Chemistry test usage remained relatively constant over the period of investigation (p=0.3810). Similarly, Haematology tests showed no significant differences in the post-CQI period (p=0.4110).

As shown in Table 8.8, the greatest reduction in tests was attained in the latter stage of the post-CQI period. Over the 15 month post-CQI period, 41.7% tests/admission were requested during months 1-5, 39.7% tests/admission during months 6-10, and 36.5 tests/admission during months 11-15.
TABLE 8.8 Changes in the total clinical laboratory test utilisation for the experimental confirmed AMI group.

<table>
<thead>
<tr>
<th>Period</th>
<th>No. of admissions</th>
<th>Total tests</th>
<th>Tests/admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar 1992 - Jul 1992</td>
<td>76</td>
<td>4938</td>
<td>65.0</td>
</tr>
<tr>
<td>Aug 1992 - Dec 1992</td>
<td>85</td>
<td>6013</td>
<td>70.7</td>
</tr>
<tr>
<td>Jan 1993 - May 1993</td>
<td>91</td>
<td>6612</td>
<td>72.7</td>
</tr>
<tr>
<td>Jun 1993 - Oct 1993</td>
<td>83</td>
<td>3459</td>
<td>41.7</td>
</tr>
<tr>
<td>Nov 1993 - Mar 1994</td>
<td>95</td>
<td>3774</td>
<td>39.7</td>
</tr>
<tr>
<td>Apr 1994 - Aug 1994</td>
<td>75</td>
<td>2738</td>
<td>36.5</td>
</tr>
</tbody>
</table>

Similarly, Table 8.9 shows the changes in total laboratory test utilisation for the control group.

Figures 8.5 and 8.6 illustrate the changes in total

TABLE 8.9 Changes in the total clinical laboratory test utilisation for the control confirmed AMI group.

<table>
<thead>
<tr>
<th>Period</th>
<th>No. of admissions</th>
<th>Total tests</th>
<th>Tests/admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mar 1992 - Jul 1992</td>
<td>69</td>
<td>4176</td>
<td>60.5</td>
</tr>
<tr>
<td>Aug 1992 - Dec 1992</td>
<td>58</td>
<td>3410</td>
<td>58.8</td>
</tr>
<tr>
<td>Jan 1993 - May 1993</td>
<td>76</td>
<td>4698</td>
<td>61.8</td>
</tr>
<tr>
<td>Jun 1993 - Oct 1993</td>
<td>59</td>
<td>3547</td>
<td>60.1</td>
</tr>
<tr>
<td>Nov 1993 - Mar 1994</td>
<td>80</td>
<td>4590</td>
<td>57.4</td>
</tr>
<tr>
<td>Apr 1994 - Aug 1994</td>
<td>72</td>
<td>4061</td>
<td>56.4</td>
</tr>
</tbody>
</table>
laboratory test utilisation for the experimental group and control groups respectively.

FIGURE 8.5 Changes in total clinical laboratory test utilisation for the experimental confirmed AMI group. No. tests (Thousands)

FIGURE 8.6 Changes in the total clinical laboratory test utilisation for the control confirmed AMI group.
Table 8.10 provides a summary of the overall changes.

<p>| TABLE 8.10 Summary of the overall changes in clinical laboratory test usage for the confirmed AMI groups. |
|--------------------------------------------------|---------------|--------------|-------------|---------------|</p>
<table>
<thead>
<tr>
<th></th>
<th>Pre-CQI</th>
<th>Post-CQI</th>
<th>% Reduction</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experimental Group</td>
<td>n=252</td>
<td>n=253</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total tests ordered</td>
<td>17,563</td>
<td>9,971</td>
<td>43.2</td>
<td>-</td>
</tr>
<tr>
<td>Tests/admission</td>
<td>69.69</td>
<td>39.41</td>
<td>43.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Control Group</td>
<td>n=203</td>
<td>n=211</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total tests ordered</td>
<td>12,284</td>
<td>12,198</td>
<td>0.7</td>
<td>-</td>
</tr>
<tr>
<td>Tests/admission</td>
<td>60.51</td>
<td>57.81</td>
<td>4.5</td>
<td>0.1830</td>
</tr>
</tbody>
</table>

*p significance level from the comparison of individual pre-CQI and post-CQI data by use of the t-test.

8.3 The sub-hypotheses of the investigation

8.3.1 Sub-hypothesis-1 Selection of clinically recommended tests

Table 8.11 shows the percentage changes in the selection of clinically recommended tests for the experimental confirmed AMI group over the period of the investigation. Overall, there was a significant increase of 10.63% in the request of clinically recommended tests as a result of the TQM intervention.

As shown in Table 8.12, no such corresponding change towards more clinically recommended tests was found for the control group over the same period of time.
TABLE 8.11 Changes in the selection of clinically recommended tests for the experimental confirmed AMI group.

<table>
<thead>
<tr>
<th>Test/Test Group</th>
<th>Pre-CQI (n=252)</th>
<th>Post-CQI (n=253)</th>
<th>% Increase requested clinically indicated tests (decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinically indicated tests</td>
<td></td>
<td>Clinically indicated tests</td>
</tr>
<tr>
<td></td>
<td>No. requested</td>
<td>No. indicated</td>
<td></td>
</tr>
<tr>
<td>Na, K, Cl</td>
<td>2 193</td>
<td>3 394</td>
<td>64.61</td>
</tr>
<tr>
<td>Urea</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td>175</td>
<td>329</td>
<td>53.19</td>
</tr>
<tr>
<td>Glucose</td>
<td>310</td>
<td>529</td>
<td>58.60</td>
</tr>
<tr>
<td>Ca, Mg, PO4</td>
<td>75</td>
<td>81</td>
<td>92.59</td>
</tr>
<tr>
<td>Cardiac enzymes*</td>
<td>1 860</td>
<td>2 016</td>
<td>92.26</td>
</tr>
<tr>
<td>Liver function tests**</td>
<td>147</td>
<td>154</td>
<td>95.45</td>
</tr>
<tr>
<td>Cholesterol/triglyceride</td>
<td>479</td>
<td>584</td>
<td>95.04</td>
</tr>
<tr>
<td>FT4, TSH</td>
<td>30</td>
<td>42</td>
<td>71.43</td>
</tr>
<tr>
<td>Misc Clinical Chem tests</td>
<td>116</td>
<td>116</td>
<td>100.00</td>
</tr>
<tr>
<td>**Total</td>
<td>5 385</td>
<td>7 165</td>
<td>75.16</td>
</tr>
<tr>
<td>ABC***</td>
<td>1 136</td>
<td>1 304</td>
<td>87.12</td>
</tr>
<tr>
<td>Prothrombin index</td>
<td>252</td>
<td>252</td>
<td>100.00</td>
</tr>
<tr>
<td>Misc Haematology tests</td>
<td>24</td>
<td>24</td>
<td>100.00</td>
</tr>
<tr>
<td>**Total</td>
<td>1 412</td>
<td>1 580</td>
<td>89.37</td>
</tr>
<tr>
<td>Urine micro examination</td>
<td>11</td>
<td>11</td>
<td>100.00</td>
</tr>
<tr>
<td>Misc Microbiology</td>
<td>16</td>
<td>16</td>
<td>100.00</td>
</tr>
<tr>
<td>**Total</td>
<td>27</td>
<td>27</td>
<td>100.00</td>
</tr>
<tr>
<td>TOTAL</td>
<td>6 800</td>
<td>8 772</td>
<td>77.52</td>
</tr>
</tbody>
</table>

*Cardiac enzyme profile- CK and CK-MB; **Liver function tests- Total bilirubin, AST, ALT, GGT, ALP, Protein, Albumin.
***ABC, automated blood count- Hb, WCC, RCC and platelets; # No. requested- total number of clinically indicated tests that were requested; ## No. indicated- total number of tests that were clinically indicated but not necessarily requested.
<table>
<thead>
<tr>
<th>Test/Test Group</th>
<th>Pre-CQI (n=203)</th>
<th>Post-CQI (n=211)</th>
<th>% increase requested clinically indicated tests (decrease)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Clinically indicated tests</td>
<td>Clinically indicated tests</td>
<td></td>
</tr>
<tr>
<td></td>
<td>No. requested</td>
<td>No. indicated</td>
<td>% requested</td>
</tr>
<tr>
<td>Na, K, Cl</td>
<td>2475</td>
<td>2936</td>
<td>84.30</td>
</tr>
<tr>
<td>Urea</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Creatinine</td>
<td>216</td>
<td>235</td>
<td>91.69</td>
</tr>
<tr>
<td>Glucose</td>
<td>244</td>
<td>446</td>
<td>54.71</td>
</tr>
<tr>
<td>Ca, Mg, PO4</td>
<td>33</td>
<td>45</td>
<td>73.33</td>
</tr>
<tr>
<td>Cardiac enzymes*</td>
<td>2526</td>
<td>248</td>
<td>77.77</td>
</tr>
<tr>
<td>Liver function tests**</td>
<td>105</td>
<td>126</td>
<td>83.33</td>
</tr>
<tr>
<td>Cholesterol/triglyceride</td>
<td>406</td>
<td>426</td>
<td>95.31</td>
</tr>
<tr>
<td>FT4, TSH</td>
<td>20</td>
<td>52</td>
<td>38.46</td>
</tr>
<tr>
<td>Misc Clinical Chem tests</td>
<td>132</td>
<td>132</td>
<td>100.00</td>
</tr>
<tr>
<td>Total</td>
<td>6157</td>
<td>7646</td>
<td>80.53</td>
</tr>
<tr>
<td>ABC***</td>
<td>928</td>
<td>1032</td>
<td>89.92</td>
</tr>
<tr>
<td>Prothrombin index</td>
<td>203</td>
<td>203</td>
<td>100.00</td>
</tr>
<tr>
<td>Misc Haematology tests</td>
<td>21</td>
<td>21</td>
<td>100.00</td>
</tr>
<tr>
<td>Total</td>
<td>1152</td>
<td>1256</td>
<td>91.72</td>
</tr>
<tr>
<td>Urine micro examination</td>
<td>16</td>
<td>16</td>
<td>100.00</td>
</tr>
<tr>
<td>Misc Microbiology</td>
<td>15</td>
<td>15</td>
<td>100.00</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
<td>31</td>
<td>100.00</td>
</tr>
<tr>
<td>TOTAL</td>
<td>7340</td>
<td>8933</td>
<td>82.17</td>
</tr>
</tbody>
</table>

*Cardiac enzyme profile - CK and CK-MB; **Liver function tests - Total bilirubin, AST, ALT, GGT, ALP, Protein, Albumin.

***ABC, automated blood count - Hb, WCC, RCC and platelets; # No. requested - total number of clinically indicated tests that were requested;

## No. indicated - total number of tests that were clinically indicated but not necessarily requested.
8.3.2 Sub-hypothesis 2- Non-clinically indicated test utilisation

The CQI intervention not only led to a highly significant decrease in test utilisation, but also to a highly significant decrease in the number of non-clinically indicated tests utilised.

As shown in Table 8.13, non-clinically indicated Clinical Chemistry tests were reduced by 77.9% (p<0.0001), and Haematology tests by 96.9% (p<0.0001).

For the experimental group, Figures 8.7 and 8.8 illustrate the individual non-clinically indicated Clinical Chemistry and Haematology tests respectively.

**FIGURE 8.7 Utilisation of non-clinically indicated Clinical Chemistry tests for the experimental confirmed AMI group.**

<table>
<thead>
<tr>
<th>Non-clinically indicated tests</th>
<th>Pre-CQI</th>
<th>Post-CQI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Na, K, Cl</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urea</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glu</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C, Mg, P</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LFT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>C/Trig</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TFT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Misc</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Na, K, Cl electrolytes; Cr creatinine; Glu glucose; C, Mg, P calcium, magnesium & phosphate; CE cardiac enzymes; LFT liver function tests; C/Trig cholesterol & triglyceride; TFT thyroid function tests.
<table>
<thead>
<tr>
<th>Test/Test Group</th>
<th>Pre-CQI (n=252)</th>
<th>Post-CQI (n=253)</th>
<th>% Reduction Tests/admission</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-clinically indicated No. tests</td>
<td>Tests/admission</td>
<td>Non-clinically indicated No. tests</td>
<td>Tests/admission</td>
</tr>
<tr>
<td>Na, K, Cl</td>
<td>1 612</td>
<td>6.40</td>
<td>84</td>
<td>0.33</td>
</tr>
<tr>
<td>Urea</td>
<td>1 268</td>
<td>5.03</td>
<td>355</td>
<td>1.40</td>
</tr>
<tr>
<td>Creatinine</td>
<td>1 099</td>
<td>4.36</td>
<td>245</td>
<td>2.08</td>
</tr>
<tr>
<td>Glucose</td>
<td>8</td>
<td>0.03</td>
<td>21</td>
<td>0.08</td>
</tr>
<tr>
<td>Ca, Mg, PO4</td>
<td>1 286</td>
<td>5.10</td>
<td>343</td>
<td>1.45</td>
</tr>
<tr>
<td>Cardiac enzymes*</td>
<td>22</td>
<td>0.09</td>
<td>136</td>
<td>0.54</td>
</tr>
<tr>
<td>Liver function tests**</td>
<td>2 114</td>
<td>8.39</td>
<td>469</td>
<td>1.85</td>
</tr>
<tr>
<td>Cholesterol/triglyceride</td>
<td>78</td>
<td>0.31</td>
<td>10</td>
<td>0.04</td>
</tr>
<tr>
<td>FT4, TSH</td>
<td>22</td>
<td>0.09</td>
<td>6</td>
<td>0.02</td>
</tr>
<tr>
<td>Misc Clinical Chemistry tests</td>
<td>208</td>
<td>0.83</td>
<td>41</td>
<td>0.16</td>
</tr>
<tr>
<td>Total</td>
<td>7 717</td>
<td>30.62</td>
<td>1 710</td>
<td>6.76</td>
</tr>
<tr>
<td>ABC***</td>
<td>1 920</td>
<td>7.62</td>
<td>48</td>
<td>0.19</td>
</tr>
<tr>
<td>Prothrombin index</td>
<td>27</td>
<td>0.11</td>
<td>13</td>
<td>0.05</td>
</tr>
<tr>
<td>Misc Haematology tests</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>1 947</td>
<td>7.73</td>
<td>61</td>
<td>0.24</td>
</tr>
<tr>
<td>Urine micro examination</td>
<td>3</td>
<td>0.01</td>
<td>5</td>
<td>0.02</td>
</tr>
<tr>
<td>Misc Microbiology</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>3</td>
<td>0.12</td>
<td>5</td>
<td>0.02</td>
</tr>
<tr>
<td>TOTAL</td>
<td>9 667</td>
<td>38.36</td>
<td>1 776</td>
<td>7.02</td>
</tr>
</tbody>
</table>

*Cardiac enzyme profile- CK and CK-MB; **Liver function tests- Total bilirubin, AST, ALT, GGT, ALP, Protein, Albumin.
***ABC, automated blood count- Hb, WCC, RCC and platelets.
There was an 81.7% reduction in the number of non-clinically indicated tests per admission. The number of inappropriate tests per admission decreased from 38.4 in the pre-CQI period to 7.0 in the post-CQI period (p<0.0001).

On the other hand, as shown in Table 8.14, there was no significant reduction in the total number of non-clinically indicated tests per control group admission (p=0.4840). Figures 8.9 and 8.10 illustrate the non-clinically indicated individual Clinical Chemistry and Haematology tests respectively.
<table>
<thead>
<tr>
<th>Test/Test Group</th>
<th>Pre-CQI (n=203)</th>
<th>Post-CQI (n=211)</th>
<th>% Reduction Tests/admission (Increase)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-clinically Indicated No. tests</td>
<td>Tests/admission</td>
<td>Non-clinically Indicated No. tests</td>
<td>Tests/admission</td>
</tr>
<tr>
<td>Na, K, Cl</td>
<td>93</td>
<td>0.46</td>
<td>12</td>
<td>0.06</td>
</tr>
<tr>
<td>Urea</td>
<td>857</td>
<td>4.22</td>
<td>853</td>
<td>4.04</td>
</tr>
<tr>
<td>Creatinine</td>
<td>663</td>
<td>3.27</td>
<td>642</td>
<td>3.04</td>
</tr>
<tr>
<td>Glucose</td>
<td>17</td>
<td>0.08</td>
<td>24</td>
<td>0.11</td>
</tr>
<tr>
<td>Ca, Mg, PO4</td>
<td>253</td>
<td>1.25</td>
<td>166</td>
<td>0.79</td>
</tr>
<tr>
<td>Cardiac enzymes*</td>
<td>180</td>
<td>0.89</td>
<td>150</td>
<td>0.71</td>
</tr>
<tr>
<td>Liver function tests**</td>
<td>1 561</td>
<td>7.69</td>
<td>1 407</td>
<td>6.67</td>
</tr>
<tr>
<td>Cholesterol/triglyceride</td>
<td>87</td>
<td>0.43</td>
<td>221</td>
<td>1.05</td>
</tr>
<tr>
<td>FT4, TSH</td>
<td>12</td>
<td>0.06</td>
<td>6</td>
<td>0.03</td>
</tr>
<tr>
<td>Misc Clinical Chemistry tests</td>
<td>52</td>
<td>0.26</td>
<td>38</td>
<td>0.18</td>
</tr>
<tr>
<td>Total</td>
<td>3 775</td>
<td>18.60</td>
<td>3 519</td>
<td>16.68</td>
</tr>
<tr>
<td>ABC***</td>
<td>1 020</td>
<td>5.02</td>
<td>1 272</td>
<td>6.03</td>
</tr>
<tr>
<td>Prothrombin index</td>
<td>93</td>
<td>0.46</td>
<td>50</td>
<td>0.24</td>
</tr>
<tr>
<td>Misc Haematology tests</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>1 113</td>
<td>5.48</td>
<td>1 322</td>
<td>6.27</td>
</tr>
<tr>
<td>Urine micro examination</td>
<td>2</td>
<td>0.01</td>
<td>7</td>
<td>0.03</td>
</tr>
<tr>
<td>Misc Microbiology</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>0.01</td>
<td>7</td>
<td>0.03</td>
</tr>
<tr>
<td>TOTAL</td>
<td>4 890</td>
<td>24.09</td>
<td>4 848</td>
<td>22.98</td>
</tr>
</tbody>
</table>

*Cardiac enzyme profile- CK, CK-MB; **Liver function tests- Total bilirubin, AST, ALT, GGT, ALP, Protein, Albumin.
***ABC, automated blood count- Hb, WCC, RCC and platelets.
FIGURE 8.9 Utilisation of non-clinically indicated Clinical Chemistry tests for the control confirmed AMI group.

No. tests

Non-clinically indicated tests

Na,K,CI | Urea | Cr | Glu | C,Mg,P | CE | LFT | C/Trig | TFT | Misc

Pre-CQI | Post-CQI

Na,K,CI electrolytes; Cr creatinine; Glu glucose; C,Mg,P calcium, magnesium & phosphate; CE cardiac enzymes; LFT liver function tests; C/Trig cholesterol & triglyceride; TFT thyroid function tests.

FIGURE 8.10 Utilisation of non-clinically indicated Haematology tests for the control confirmed AMI group.

No. tests

Non-clinically indicated tests

ABC | PI

Pre-CQI | Post-CQI

ABC automated blood count- Hb,WCC,RCC & platelets; PI prothrombin index;
### 8.3.3 Sub-hypothesis 3- Blood collection timing

As indicated in Table 8.15 and Figure 8.11, highly significant changes were achieved, resulting in improvements in the clinically recommended timing of

| Table 8.15 Changes to the timing of blood collections for total CK in the experimental confirmed AMI group. |
|---|---|---|---|
| Interval | Pre-CQI | Post-CQI | p value* |
| | No. | Median time, hours. | No. | Median time, hours. |  |
| First to second blood collection | 186 | 24.0 | 195 | 7.9 | <0.0001 |
| First to third blood collection | 193 | 36.1 | 191 | 16.2 | <0.0001 |
| First to fourth blood collection | 190 | 40.3 | 188 | 27.3 | <0.0001 |

*Significance level obtained from the comparison of pre-CQI and post-CQI data by use of the Mann-Whitney U test.

### FIGURE 8.11 Changes to the timing of blood collections for total CK in the experimental confirmed AMI group.

Median time (hrs)
total CK testing. On the other hand, as shown in Table 8.16 and Figure 8.12, the blood collection timing for total CK in the control group remained virtually unchanged throughout the study, differing significantly to that outlined in the AMI test ordering guidelines.

Table 8.16 Changes to the timing of blood collections for total CK in the control confirmed AMI group.

<table>
<thead>
<tr>
<th>Interval</th>
<th>No.</th>
<th>Pre-CQI Median time, hours.</th>
<th>Post-CQI Median time, hours.</th>
<th>p value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>First to second blood collection</td>
<td>154</td>
<td>27.3</td>
<td>159</td>
<td>25.9</td>
</tr>
<tr>
<td>First to third blood collection</td>
<td>158</td>
<td>39.6</td>
<td>163</td>
<td>41.2</td>
</tr>
<tr>
<td>First to fourth blood collection</td>
<td>162</td>
<td>63.2</td>
<td>164</td>
<td>65.4</td>
</tr>
</tbody>
</table>

*p value obtained from the comparison of pre-CQI and post-CQI data by use of the Mann-Whitney U test.

**FIGURE 8.12 Changes to the timing of blood collections for total CK in the control confirmed AMI group.**

Median time (hrs)

<table>
<thead>
<tr>
<th>Time interval between blood collections</th>
<th>pre-CQI</th>
<th>post-CQI</th>
<th>recommended</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st to 2nd</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st to 3rd</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1st to 4th</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
8.3.4 Sub-hypothesis 4- Cost analysis and projections

As indicated in Tables 8.17 and 8.18, and Figure 8.13, there were substantial reductions in the cost of pathology services as a result of the CQI intervention on the experimental confirmed AMI group.

8.3.4.1 Cost analysis

![Figure 8.13 Changes in the cost of pathology services for the experimental confirmed AMI group.](image)

Such data only provides preliminary information on savings from reduced test ordering. It does not include other costs and benefits associated with the introduction of TQM. Such data has however been included into the cost analysis for the projected savings provided in 8.3.4.2.

Also, as expected from the available test utilisation data, no significant savings were achieved for the
<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit Cost*, (A$)</th>
<th>No. ordered</th>
<th>Cost, (A$)</th>
<th>Cost (A$)/ admission</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Clinical Chemistry</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66211</td>
<td>6 or more routine chemistry tests</td>
<td>19.55</td>
<td>1 097</td>
<td>21 446</td>
<td>85.10</td>
</tr>
<tr>
<td>66209</td>
<td>5 routine chemistry tests</td>
<td>18.00</td>
<td>43</td>
<td>774</td>
<td>3.07</td>
</tr>
<tr>
<td>66207</td>
<td>4 routine chemistry tests</td>
<td>15.95</td>
<td>8</td>
<td>128</td>
<td>0.51</td>
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<tr>
<td>66205</td>
<td>3 routine chemistry tests</td>
<td>13.90</td>
<td>2</td>
<td>28</td>
<td>0.11</td>
</tr>
<tr>
<td>66203</td>
<td>2 routine chemistry tests</td>
<td>11.85</td>
<td>94</td>
<td>1 114</td>
<td>4.42</td>
</tr>
<tr>
<td>66201</td>
<td>1 routine chemistry test</td>
<td>9.00</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>66291</td>
<td>Thyroid function tests</td>
<td>40.00</td>
<td>26</td>
<td>1 040</td>
<td>4.13</td>
</tr>
<tr>
<td>-</td>
<td>Other tests</td>
<td>-</td>
<td>49</td>
<td>848</td>
<td>3.37</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>1 319</strong></td>
<td><strong>24 530</strong></td>
<td><strong>97.33</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Haematology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65003</td>
<td>Automated blood count</td>
<td>7.60</td>
<td>764</td>
<td>5 806</td>
<td>23.04</td>
</tr>
<tr>
<td>65005</td>
<td>Examination of blood film</td>
<td>10.00</td>
<td>110</td>
<td>1 100</td>
<td>4.37</td>
</tr>
<tr>
<td>65029</td>
<td>Coagulation test, 1 estimation</td>
<td>12.10</td>
<td>704</td>
<td>8 518</td>
<td>33.80</td>
</tr>
<tr>
<td>65031</td>
<td>Coagulation test, 2 estimations</td>
<td>16.00</td>
<td>239</td>
<td>3 824</td>
<td>15.17</td>
</tr>
<tr>
<td>65033</td>
<td>Coagulation test, 3 estimations</td>
<td>19.90</td>
<td>14</td>
<td>279</td>
<td>1.11</td>
</tr>
<tr>
<td>-</td>
<td>Other tests</td>
<td>-</td>
<td>11</td>
<td>174</td>
<td>0.69</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>1 842</strong></td>
<td><strong>19 701</strong></td>
<td><strong>78.18</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Microbiology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>69217</td>
<td>Urine examination</td>
<td>19.60</td>
<td>14</td>
<td>274</td>
<td>1.09</td>
</tr>
<tr>
<td>-</td>
<td>Other tests</td>
<td>-</td>
<td>16</td>
<td>339</td>
<td>1.35</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>613</strong></td>
<td><strong>2.44</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td><strong>3 191</strong></td>
<td><strong>44 844</strong></td>
<td><strong>177.95</strong></td>
<td></td>
</tr>
</tbody>
</table>

*Test costs were based on the Commonwealth Medical Benefits fee schedule effective from 1 November 1992.
TABLE 8.18 Post-CQI cost of pathology services for the experimental confirmed AMI group.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit Cost* (A$)</th>
<th>No. ordered</th>
<th>Cost (A$)</th>
<th>Cost (A$)/ admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>66211</td>
<td>6 or more routine chemistry tests</td>
<td>19.55</td>
<td>843</td>
<td>16 481</td>
<td>65.14</td>
</tr>
<tr>
<td>66209</td>
<td>5 routine chemistry tests</td>
<td>18.00</td>
<td>38</td>
<td>684</td>
<td>2.70</td>
</tr>
<tr>
<td>66207</td>
<td>4 routine chemistry tests</td>
<td>15.95</td>
<td>11</td>
<td>175</td>
<td>0.69</td>
</tr>
<tr>
<td>66205</td>
<td>3 routine chemistry tests</td>
<td>13.90</td>
<td>3</td>
<td>42</td>
<td>0.17</td>
</tr>
<tr>
<td>66203</td>
<td>2 routine chemistry tests</td>
<td>11.85</td>
<td>112</td>
<td>1 327</td>
<td>5.25</td>
</tr>
<tr>
<td>66201</td>
<td>1 routine chemistry test</td>
<td>9.80</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>66291</td>
<td>Thyroid function tests</td>
<td>40.00</td>
<td>14</td>
<td>560</td>
<td>2.21</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td>-</td>
<td>20</td>
<td>338</td>
<td>1.34</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
<td></td>
<td>841</td>
<td>19 607</td>
<td>77.50</td>
</tr>
<tr>
<td></td>
<td><strong>Haematology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65003</td>
<td>Automated blood count</td>
<td>7.60</td>
<td>269</td>
<td>2 044</td>
<td>8.08</td>
</tr>
<tr>
<td>65005</td>
<td>Examination of blood film</td>
<td>10.00</td>
<td>59</td>
<td>590</td>
<td>2.33</td>
</tr>
<tr>
<td>65029</td>
<td>Coagulation test, 1 estimation</td>
<td>12.10</td>
<td>661</td>
<td>7 998</td>
<td>31.61</td>
</tr>
<tr>
<td>65031</td>
<td>Coagulation test, 2 estimations</td>
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<td>173</td>
<td>2 768</td>
<td>10.94</td>
</tr>
<tr>
<td>65033</td>
<td>Coagulation test, 3 estimations</td>
<td>19.90</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td>-</td>
<td>31</td>
<td>543</td>
<td>2.15</td>
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<td></td>
<td><strong>Total</strong></td>
<td></td>
<td>1 193</td>
<td>13 943</td>
<td>55.11</td>
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<tr>
<td></td>
<td><strong>Microbiology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>69217</td>
<td>Urine examination</td>
<td>19.60</td>
<td>19</td>
<td>372</td>
<td>1.47</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td>-</td>
<td>28</td>
<td>630</td>
<td>2.49</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>47</td>
<td>1 002</td>
<td>3.96</td>
</tr>
<tr>
<td></td>
<td><strong>TOTAL</strong></td>
<td></td>
<td>2 081</td>
<td>34 552</td>
<td>136.57</td>
</tr>
</tbody>
</table>

*Test costs were based on the Commonwealth Medical Benefits Fee schedule effective from 1 November 1992.
control group over the duration of the investigation (Tables 8.19 and 8.20, and Figure 8.14).

**FIGURE 8.14  Changes in the cost of pathology services for the control confirmed AMI group.**

Cost (A$) per admission

<table>
<thead>
<tr>
<th>Pathology services</th>
<th>Pre-CQI</th>
<th>Post-CQI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Chemistry</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Haematology</td>
<td>80</td>
<td></td>
</tr>
<tr>
<td>Microbiology</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Table 8.21 provides a summary of the cost of pathology services for the confirmed AMI groups. The CQI intervention resulted in a 23.0% savings in the cost of pathology usage. Only 0.8% savings were attained for the control group.

As shown in Table 8.21, a savings of 23.0% was achieved on the cost of pathology usage for confirmed AMI during the post-CQI period. The costs for pathology usage were reduced from $177.95 per admission (pre-CQI) to $136.57 per admission (post-CQI).
TABLE B.19 Pre-CQI cost of pathology services for the control confirmed AMI group.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit Cost*, (A$)</th>
<th>No. ordered</th>
<th>Cost, (A$)</th>
<th>Cost (A$)/ admission</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Chemistry</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66211</td>
<td>6 or more routine chemistry tests</td>
<td>19.55</td>
<td>784</td>
<td>15 327</td>
<td>75.50</td>
</tr>
<tr>
<td>66209</td>
<td>5 routine chemistry tests</td>
<td>18.00</td>
<td>19</td>
<td>342</td>
<td>1.68</td>
</tr>
<tr>
<td>66207</td>
<td>4 routine chemistry tests</td>
<td>15.95</td>
<td>18</td>
<td>287</td>
<td>1.42</td>
</tr>
<tr>
<td>66205</td>
<td>3 routine chemistry tests</td>
<td>13.90</td>
<td>93</td>
<td>1 293</td>
<td>6.37</td>
</tr>
<tr>
<td>66203</td>
<td>2 routine chemistry tests</td>
<td>11.85</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>66201</td>
<td>1 routine chemistry test</td>
<td>9.80</td>
<td>12</td>
<td>118</td>
<td>0.58</td>
</tr>
<tr>
<td>66291</td>
<td>Thyroid function tests</td>
<td>40.00</td>
<td>16</td>
<td>640</td>
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</tr>
<tr>
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<td>Other tests</td>
<td>-</td>
<td>36</td>
<td>653</td>
<td>3.22</td>
</tr>
<tr>
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<td><strong>Total</strong></td>
<td><strong>978</strong></td>
<td><strong>18 660</strong></td>
<td><strong>91.92</strong></td>
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</tr>
<tr>
<td></td>
<td>Haematology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65003</td>
<td>Automated blood count</td>
<td>7.60</td>
<td>487</td>
<td>3 701</td>
<td>18.23</td>
</tr>
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<td>Examination of blood film</td>
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<td>870</td>
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</tr>
<tr>
<td>65029</td>
<td>Coagulation test, 1 estimation</td>
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<td>571</td>
<td>6 909</td>
<td>34.03</td>
</tr>
<tr>
<td>65031</td>
<td>Coagulation test, 2 estimations</td>
<td>16.00</td>
<td>143</td>
<td>2 288</td>
<td>11.27</td>
</tr>
<tr>
<td>65033</td>
<td>Coagulation test, 3 estimations</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td>-</td>
<td>8</td>
<td>125</td>
<td>0.62</td>
</tr>
<tr>
<td></td>
<td><strong>Total</strong></td>
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<td><strong>13 893</strong></td>
<td><strong>68.44</strong></td>
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</tr>
<tr>
<td></td>
<td>Microbiology</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>69217</td>
<td>Urine examination</td>
<td>19.60</td>
<td>18</td>
<td>353</td>
<td>1.74</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td>-</td>
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<td></td>
<td><strong>TOTAL</strong></td>
<td><strong>2 307</strong></td>
<td><strong>33 217</strong></td>
<td><strong>163.63</strong></td>
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</tr>
</tbody>
</table>

*Test costs were based on the Commonwealth Medical Benefits fee schedule effective from 1 November 1992.
<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit Cost(^*), (A$)</th>
<th>No. ordered</th>
<th>Cost, (A$)</th>
<th>Cost (A$)/ admission</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Clinical Chemistry</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66211</td>
<td>6 or more routine chemistry tests</td>
<td>19.55</td>
<td>796</td>
<td>15 561</td>
<td>73.75</td>
</tr>
<tr>
<td>66209</td>
<td>5 routine chemistry tests</td>
<td>18.00</td>
<td>28</td>
<td>504</td>
<td>2.39</td>
</tr>
<tr>
<td>66207</td>
<td>4 routine chemistry tests</td>
<td>15.95</td>
<td>31</td>
<td>494</td>
<td>2.34</td>
</tr>
<tr>
<td>66205</td>
<td>3 routine chemistry tests</td>
<td>13.90</td>
<td>64</td>
<td>890</td>
<td>4.22</td>
</tr>
<tr>
<td>66203</td>
<td>2 routine chemistry tests</td>
<td>11.85</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>66201</td>
<td>1 routine chemistry test</td>
<td>9.80</td>
<td>8</td>
<td>78</td>
<td>0.37</td>
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<tr>
<td>66291</td>
<td>Thyroid function tests</td>
<td>40.00</td>
<td>17</td>
<td>680</td>
<td>3.23</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
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<td>28</td>
<td>507</td>
<td>2.41</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>972</td>
<td>18 714</td>
<td>88.70</td>
</tr>
<tr>
<td></td>
<td><strong>Haematology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65003</td>
<td>Automated blood count</td>
<td>7.60</td>
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<td>3 534</td>
<td>16.75</td>
</tr>
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<td>Examination of blood film</td>
<td>10.00</td>
<td>94</td>
<td>940</td>
<td>4.45</td>
</tr>
<tr>
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<td>Coagulation test, 1 estimation</td>
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<td>523</td>
<td>6 328</td>
<td>29.99</td>
</tr>
<tr>
<td>65031</td>
<td>Coagulation test, 2 estimations</td>
<td>16.00</td>
<td>161</td>
<td>2 576</td>
<td>12.21</td>
</tr>
<tr>
<td>65033</td>
<td>Coagulation test, 3 estimations</td>
<td>19.90</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td></td>
<td>6</td>
<td>92</td>
<td>0.44</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>1 249</td>
<td>13 470</td>
<td>63.84</td>
</tr>
<tr>
<td></td>
<td><strong>Microbiology</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>69217</td>
<td>Urine examination</td>
<td>19.60</td>
<td>27</td>
<td>529</td>
<td>2.51</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td></td>
<td>12</td>
<td>246</td>
<td>1.17</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>39</td>
<td>775</td>
<td>3.66</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td>2 260</td>
<td>32 959</td>
<td>156.20</td>
</tr>
</tbody>
</table>

\(^*\) Test costs were based on the Commonwealth Medical Benefits fee schedule effective from 1 November 1992.
### TABLE 8.21 Summary of the cost of pathology test usage for the confirmed AMI group.

<table>
<thead>
<tr>
<th>Group</th>
<th>No. admissions</th>
<th>Cost A$ / admission</th>
<th>Total costs, A$</th>
<th>Savings A$, (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-CQI, experimental</td>
<td>252</td>
<td>177.95</td>
<td>44 844</td>
<td>10 292 (23.0%)</td>
</tr>
<tr>
<td>Post-CQI, experimental</td>
<td>253</td>
<td>136.57</td>
<td>34 552</td>
<td></td>
</tr>
<tr>
<td>Pre-CQI, control</td>
<td>203</td>
<td>163.63</td>
<td>33 217</td>
<td>258 (0.8%)</td>
</tr>
<tr>
<td>Post-CQI, control</td>
<td>211</td>
<td>156.20</td>
<td>32 959</td>
<td></td>
</tr>
</tbody>
</table>

### 8.3.4.2 Projected savings in suspected AMI

As the AMI test ordering guidelines were in fact specifically designed for suspected AMI, an estimate was made of the annual savings in pathology services on patients with suspected AMI. The estimate was checked for accuracy using actual cost data for suspected AMI.

As shown in Table 8.22, the annual savings for pathology test usage in suspected AMI as a result of the CQI interventions were estimated to be $29,354. This estimate was derived using the assumption that the CQI strategies affected the utilisation of pathology services similarly for both suspected and confirmed AMI cases.

The accuracy of this estimate was checked using actual
TABLE 8.22 Estimate of annual cost savings from test usage for the experimental suspected AMI group.

<table>
<thead>
<tr>
<th>Annual cost</th>
<th>A$</th>
</tr>
</thead>
<tbody>
<tr>
<td>717 suspected AMI admissions per year</td>
<td></td>
</tr>
<tr>
<td>Cost of pathology usage/admission</td>
<td>178</td>
</tr>
<tr>
<td>Annual cost of pathology test usage</td>
<td>127,626</td>
</tr>
<tr>
<td>Savings</td>
<td></td>
</tr>
<tr>
<td>23.0% post-CQI savings for confirmed AMI</td>
<td></td>
</tr>
<tr>
<td>Estimated annual savings for suspected AMI</td>
<td>29,354</td>
</tr>
</tbody>
</table>

cost data derived from pathology service testing for suspected AMI over three month periods, before and after the CQI interventions.

As shown in Tables 8.23 - 8.25, an annual savings of $31,132 was projected from the data. This represented a 22.8% savings in pathology test usage and therefore very closely matched the 23.0% savings obtained from the confirmed AMI data.

Table 8.26 provides details of the data used to determine the total benefits of the TQM intervention. Overall, the $29,853 saved from the introduction of the strategies is similar in value to the amount previously estimated to be
<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit Cost*, (A$)</th>
<th>No. ordered</th>
<th>Cost, (A$)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Clinical Chemistry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66211</td>
<td>6 or more routine chemistry tests</td>
<td>19.55</td>
<td>892</td>
<td>17 439</td>
</tr>
<tr>
<td>66209</td>
<td>5 routine chemistry tests</td>
<td>18.00</td>
<td>30</td>
<td>540</td>
</tr>
<tr>
<td>66207</td>
<td>4 routine chemistry tests</td>
<td>15.95</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>66205</td>
<td>3 routine chemistry tests</td>
<td>13.90</td>
<td>12</td>
<td>167</td>
</tr>
<tr>
<td>66203</td>
<td>2 routine chemistry tests</td>
<td>11.85</td>
<td>59</td>
<td>699</td>
</tr>
<tr>
<td>66201</td>
<td>1 routine chemistry test</td>
<td>9.80</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>66291</td>
<td>Thyroid function tests</td>
<td>40.00</td>
<td>15</td>
<td>600</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td></td>
<td>31</td>
<td>511</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
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<td></td>
<td>19 956</td>
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<tr>
<td></td>
<td><strong>Haematology</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>65003</td>
<td>Automated blood count</td>
<td>7.60</td>
<td>608</td>
<td>4 620</td>
</tr>
<tr>
<td>65005</td>
<td>Examination of blood film</td>
<td>10.00</td>
<td>76</td>
<td>760</td>
</tr>
<tr>
<td>65029</td>
<td>Coagulation test, 1 estimation</td>
<td>12.10</td>
<td>571</td>
<td>6 909</td>
</tr>
<tr>
<td>65031</td>
<td>Coagulation test, 2 estimations</td>
<td>16.00</td>
<td>163</td>
<td>2 608</td>
</tr>
<tr>
<td>65033</td>
<td>Coagulation test, 3 estimations</td>
<td>19.90</td>
<td>6</td>
<td>1 194</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td></td>
<td>14</td>
<td>233</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>1 438</td>
<td></td>
<td>16 324</td>
</tr>
<tr>
<td></td>
<td><strong>Microbiology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>69217</td>
<td>Urine examination</td>
<td>19.60</td>
<td>11</td>
<td>216</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
<td></td>
<td>12</td>
<td>249</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>23</td>
<td></td>
<td>465</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td>2 500</td>
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<td>36 745</td>
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</table>

*Test costs were based on the Commonwealth Medical Benefits fee schedule effective from 1 November
TABLE 8.24 Three monthly data on the post-COI cost of pathology usage for the experimental suspected AMI group.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Unit Cost*, (A$)</th>
<th>No. ordered</th>
<th>Cost, (A$)</th>
</tr>
</thead>
<tbody>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Clinical Chemistry</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>66211</td>
<td>6 or more routine chemistry tests</td>
<td>19.55</td>
<td>697</td>
<td>13 626</td>
</tr>
<tr>
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<td>5 routine chemistry tests</td>
<td>18.00</td>
<td>91</td>
<td>1 638</td>
</tr>
<tr>
<td>66207</td>
<td>4 routine chemistry tests</td>
<td>15.95</td>
<td>13</td>
<td>207</td>
</tr>
<tr>
<td>66205</td>
<td>3 routine chemistry tests</td>
<td>13.90</td>
<td>16</td>
<td>222</td>
</tr>
<tr>
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<td>41</td>
<td>486</td>
</tr>
<tr>
<td>66201</td>
<td>1 routine chemistry test</td>
<td>9.80</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>66291</td>
<td>Thyroid function tests</td>
<td>40.00</td>
<td>3</td>
<td>120</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
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<td>473</td>
</tr>
<tr>
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<td>Total</td>
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</tr>
<tr>
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<td>Haematology</td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>Automated blood count</td>
<td>7.60</td>
<td>193</td>
<td>1 467</td>
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<td>10.00</td>
<td>38</td>
<td>380</td>
</tr>
<tr>
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<td>12.10</td>
<td>511</td>
<td>6 183</td>
</tr>
<tr>
<td>65031</td>
<td>Coagulation test, 2 estimations</td>
<td>16.00</td>
<td>176</td>
<td>2 816</td>
</tr>
<tr>
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<td>Coagulation test, 3 estimations</td>
<td>19.90</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Other tests</td>
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<td>Total</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Microbiology</td>
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</tr>
<tr>
<td>69217</td>
<td>Urine examination</td>
<td>19.60</td>
<td>6</td>
<td>118</td>
</tr>
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<td>Other tests</td>
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</tr>
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<td></td>
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<td>586</td>
</tr>
<tr>
<td></td>
<td>TOTAL</td>
<td></td>
<td>1 880</td>
<td>28 962</td>
</tr>
</tbody>
</table>

*Test costs were based on the Commonwealth Medical Benefits fee schedule effective from 1 November 1992.
TABLE 8.25 Summary of the cost of pathology test usage for the experimental suspected AMI group.

<table>
<thead>
<tr>
<th>Group</th>
<th>No. admissions</th>
<th>Cost A$ / admission</th>
<th>3 month costs, A$</th>
<th>est. 12 month costs, A$</th>
<th>Savings A$, (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-CQI</td>
<td>195</td>
<td>188.43</td>
<td>36 745</td>
<td>146 980</td>
<td>31 132 (22.8%)</td>
</tr>
<tr>
<td>Post-CQI</td>
<td>199</td>
<td>145.54</td>
<td>28 962</td>
<td>115 848</td>
<td></td>
</tr>
</tbody>
</table>

due to the reduction in test usage (i.e. $29 354).
Therefore the staffing and other costs associated with the introduction of TQM were offset by similar savings acquired through tangible benefits.

8.3.4.3 Projected savings in total pathology services
An estimate was also undertaken of the savings that would be achieved if the CQI strategies were to be directed at the entire pathology service of the experimental group, and not just suspected AMI.

Table 8.27 indicates that a savings of $371 073 would have been achieved from such strategies being introduced across the entire pathology service.

8.3.4.4 Projected national savings in pathology services
Each year approximately 41% of all Australian pathology services are provided on patients in hospitals.
<table>
<thead>
<tr>
<th>Items analysed</th>
<th>Time hrs/wk</th>
<th>Staff</th>
<th>Salary/hr</th>
<th>Annual</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BENEFITS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduction in test usage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduced laboratory clerical time**</td>
<td>4.0</td>
<td>Clerk</td>
<td>$12.00</td>
<td>$29 354</td>
</tr>
<tr>
<td>Reduced no. of specimen collections</td>
<td>3.5</td>
<td>TA</td>
<td>$12.50</td>
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</tr>
<tr>
<td>Reduced specimen transport</td>
<td>3.5</td>
<td>Wardsperson</td>
<td>$10.50</td>
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</tr>
<tr>
<td>Reduced MRO clerical time**</td>
<td>2.0</td>
<td>Clerk</td>
<td>$12.00</td>
<td>$1 248</td>
</tr>
<tr>
<td>Reduced medical officer workload in reviewing</td>
<td>3.0</td>
<td>RMO</td>
<td>$25.50</td>
<td>$3 978</td>
</tr>
<tr>
<td>patients' records</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduced staff time spent chasing up computer</td>
<td>2.0</td>
<td>RMO</td>
<td>$25.50</td>
<td>$2 652</td>
</tr>
<tr>
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<td>RN</td>
<td>$20.50</td>
<td>$3 731</td>
</tr>
<tr>
<td><strong>Total Benefits</strong></td>
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<td></td>
<td></td>
<td>$47 645</td>
</tr>
<tr>
<td><strong>COSTS</strong></td>
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<td></td>
</tr>
<tr>
<td><strong>Staffing</strong>*</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical</td>
<td>1.0</td>
<td>RMO</td>
<td>$25.50</td>
<td>$1 326</td>
</tr>
<tr>
<td>Nursing</td>
<td>2.5</td>
<td>RN</td>
<td>$20.50</td>
<td>$2 665</td>
</tr>
<tr>
<td>Clerical (E.D)</td>
<td>2.5</td>
<td>Clerk</td>
<td>$12.00</td>
<td>$1 560</td>
</tr>
<tr>
<td>Laboratory (Technical)</td>
<td>0.5</td>
<td>STO</td>
<td>$21.20</td>
<td>$551</td>
</tr>
<tr>
<td>Laboratory (Clerical)</td>
<td>2.0</td>
<td>Clerk</td>
<td>$12.00</td>
<td>$1 248</td>
</tr>
<tr>
<td>Wardsperson</td>
<td>0.5</td>
<td>Wardsperson</td>
<td>$10.50</td>
<td>$273</td>
</tr>
<tr>
<td>Quality Advisor</td>
<td>3.0</td>
<td>QA</td>
<td>$22.80</td>
<td>$3 557</td>
</tr>
<tr>
<td><strong>Other Costs</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catering (meetings)</td>
<td></td>
<td></td>
<td></td>
<td>$710</td>
</tr>
<tr>
<td>Secretarial</td>
<td></td>
<td></td>
<td></td>
<td>$1 092</td>
</tr>
<tr>
<td>Additional specimen transport****</td>
<td></td>
<td></td>
<td></td>
<td>$4 160</td>
</tr>
<tr>
<td>Stationery</td>
<td></td>
<td></td>
<td></td>
<td>$650</td>
</tr>
<tr>
<td><strong>Total Costs</strong></td>
<td></td>
<td></td>
<td></td>
<td>$17 792</td>
</tr>
<tr>
<td><strong>COST SAVING</strong></td>
<td></td>
<td></td>
<td></td>
<td>$29 853</td>
</tr>
</tbody>
</table>

MRO—Medical Record Department; TA—Technical Aide; RMO—Resident Medical Officer; RN—Registered Nurse; STO—Senior Technical Officer; QA—Quality Advisor; E.D.—Emergency Department.

*preparation, distribution and filing of reports; **retrieving patients' records; ***time spent undertaking TQM related activities including training, meetings and data collection. ****costs involved using taxi-cabs.
TABLE 8.27 Estimate of annual cost savings for total pathology services in the experimental group.

<table>
<thead>
<tr>
<th>Annual cost</th>
<th>AS$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-CQI pathology services*</td>
<td>1 613 359</td>
</tr>
</tbody>
</table>

Savings

| 23.0%   | 371 073 |

*SWAPS charge to the experimental group hospital for the provision of pathology services. Data derived for the 12 month period prior to the introduction of the CQI intervention.

Table 8.28 provides an estimate of the annual national savings in pathology services if the CQI strategies were to be introduced throughout all hospital across Australia. An annual savings of $107.4M would have been achieved from such strategies being introduced.

TABLE 8.28 Estimate of annual national savings for pathology services.

<table>
<thead>
<tr>
<th>Annual cost</th>
<th>AS$M</th>
</tr>
</thead>
<tbody>
<tr>
<td>National hospital pathology services (1994)*</td>
<td>467.0</td>
</tr>
</tbody>
</table>

Savings

| 23.0%   | 107.4 |

*National annual cost of pathology services on patients in hospitals, 1994. Data provided (personal communication) by Mr Ed Wilson, a leading Australian Pathology Services Management Consultant. Further details are provided in Appendix 12.
8.3.5 Indicators of quality of care (Sub-hypothesis 5)

As shown earlier in Tables 8.4 and 8.5, the intervention had no significant effect on the quality of patient care. For the experimental group, no significant differences were found between the pre-CQI and post-CQI period for all the investigation's quality of care indicators: discharge status (including death rate), readmission to hospital, and length of stay.

Similarly for the control group, no significant differences were found for all three quality of care indicators measured.

REFERENCES AND NOTES

CHAPTER 9. RESULTS 2- PROCESS IMPROVEMENT ANALYSIS

Chapter 9 provides the second ‘Results’ chapter. The data was obtained from the process improvement analysis that was undertaken only at the experimental group hospital. It includes baseline data which was collected to substantiate the causes of poor test utilisation, data obtained from the introduction of the five process improvement plans and data collected to establish the accomplishment of the objectives of the intervention.

9.1 Substantiating the causes of poor quality

9.1.1 Urgency of tests incorrectly specified

The data derived in Table 9.1 clearly confirmed the early suspicions that an excessive number of tests for suspected AMI were being requested as either urgent or stat. Overall, 69.8% of all requests that had indicated on the form the degree of urgency were in fact ordered for urgent or stat results.

<table>
<thead>
<tr>
<th>Degree of urgency</th>
<th>Frequency of requests</th>
<th>Relative Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine</td>
<td>39</td>
<td>19.7</td>
</tr>
<tr>
<td>Urgent*</td>
<td>28</td>
<td>14.1</td>
</tr>
<tr>
<td>Stat**</td>
<td>62</td>
<td>31.3</td>
</tr>
<tr>
<td>Not indicated on form</td>
<td>69</td>
<td>34.9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>198</td>
<td>100.0</td>
</tr>
</tbody>
</table>

* results of tests are usually required 20-60 minutes after blood specimen collected.
**results of tests are usually required 1-2 hours after blood specimen collected.
9.1.2 Delays in receiving printed reports

The pre-CQI data for the turnaround time in receiving printed interim and final reports is provided in Tables 9.2 and 9.3.

For the pre-CQI period, the baseline median turnaround time for printed interim reports was 10.0 hours (Clinical Chemistry and Haematology). The median turnaround time for final reports was 27.0 hours (Clinical Chemistry) and 28.0 hours (Haematology).

9.1.3 Delays in receiving specimen tube labels

The data confirmed that major delays were being experienced by E.D. staff in receiving patient labels from their clerical office for use on specimen tubes.

As shown in Table 9.4, the median time for receiving labels was 28.0 minutes, and ranged from 2.0 to 54.0 minutes over the period of data collection.

9.1.4 Delays in E.D. specimen pickup

An analysis of the response time of wardspersons to the E.D. for specimen pickup also revealed some major delays.

As shown in Table 9.5, the median response time was 22.0 minutes, and ranged from 2.0 to 43.0 minutes over the period of data collection.

Delays such as those experienced with the printing of
TABLE 9.2 Turnaround time for dispatched printed interim reports (Pre-CQI)

<table>
<thead>
<tr>
<th>Turnaround time, hours</th>
<th>No. of Clinical Chemistry Reports</th>
<th>No. of Haematology Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-3</td>
<td>-</td>
<td>10</td>
</tr>
<tr>
<td>4-6</td>
<td>30</td>
<td>26</td>
</tr>
<tr>
<td>7-9</td>
<td>30</td>
<td>33</td>
</tr>
<tr>
<td>10-12</td>
<td>22</td>
<td>23</td>
</tr>
<tr>
<td>13-15</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>16-18</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>19-21</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>22-24</td>
<td>13</td>
<td>13</td>
</tr>
<tr>
<td>25-27</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>28-30</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>151</td>
<td>147</td>
</tr>
</tbody>
</table>

Clinical Chemistry- Median time 10.0 hours (Range 2.0 - 30.0).
Haematology- Median time 10.0 hours (Range 2.0 - 29.0).

TABLE 9.3 Turnaround time for dispatched printed final reports (Pre-CQI)

<table>
<thead>
<tr>
<th>Turnaround time, hours</th>
<th>No. of Clinical Chemistry Reports</th>
<th>No. of Haematology Reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>11-20</td>
<td>35</td>
<td>34</td>
</tr>
<tr>
<td>21-30</td>
<td>66</td>
<td>58</td>
</tr>
<tr>
<td>31-40</td>
<td>24</td>
<td>25</td>
</tr>
<tr>
<td>41-50</td>
<td>22</td>
<td>25</td>
</tr>
<tr>
<td>51-60</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>61-70</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>71-80</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>81-90</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>91-100</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>167</strong></td>
<td><strong>163</strong></td>
</tr>
</tbody>
</table>

Clinical Chemistry- Median time 27.0 hours (Range 4.0 - 98.0).
Haematology- Median time 28.0 hours (Range 4.0 - 99.0).
<table>
<thead>
<tr>
<th>Turnaround time, minutes</th>
<th>No. of requests for labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–5</td>
<td>1</td>
</tr>
<tr>
<td>6–10</td>
<td>2</td>
</tr>
<tr>
<td>11–15</td>
<td>2</td>
</tr>
<tr>
<td>16–20</td>
<td>5</td>
</tr>
<tr>
<td>21–25</td>
<td>9</td>
</tr>
<tr>
<td>26–30</td>
<td>13</td>
</tr>
<tr>
<td>31–35</td>
<td>6</td>
</tr>
<tr>
<td>36–40</td>
<td>8</td>
</tr>
<tr>
<td>41–45</td>
<td>2</td>
</tr>
<tr>
<td>46–50</td>
<td>0</td>
</tr>
<tr>
<td>51–55</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>49</strong></td>
</tr>
</tbody>
</table>

Median time 28.0 mins (Range 2.0 – 54.0).

<table>
<thead>
<tr>
<th>Turnaround time, minutes</th>
<th>No. of pickup requests</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–5</td>
<td>8</td>
</tr>
<tr>
<td>6–10</td>
<td>12</td>
</tr>
<tr>
<td>11–15</td>
<td>16</td>
</tr>
<tr>
<td>16–20</td>
<td>26</td>
</tr>
<tr>
<td>21–25</td>
<td>22</td>
</tr>
<tr>
<td>26–30</td>
<td>33</td>
</tr>
<tr>
<td>31–35</td>
<td>10</td>
</tr>
<tr>
<td>36–40</td>
<td>2</td>
</tr>
<tr>
<td>41–45</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>130</strong></td>
</tr>
</tbody>
</table>

Median time 22.0 mins (Range 2.0 – 43.0).
labels, and the poor response time of wardspersons, contributed to the overall poor delivery times shown in Table 9.6.

TABLE 9.6 Specimen delivery delays from E.D. to Pathology (Pre-CQI).

<table>
<thead>
<tr>
<th>Delivery time, minutes</th>
<th>Number of specimen deliveries</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood collection to E.D. box</td>
<td>E.D. box to Pathology</td>
</tr>
<tr>
<td>0 - 10</td>
<td>16</td>
<td>19</td>
</tr>
<tr>
<td>11 - 20</td>
<td>13</td>
<td>14</td>
</tr>
<tr>
<td>21 - 30</td>
<td>23</td>
<td>25</td>
</tr>
<tr>
<td>31 - 40</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>41 - 50</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>51 - 60</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>61 - 70</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>71 - 80</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>TOTAL</td>
<td>79</td>
<td>79</td>
</tr>
</tbody>
</table>

Blood collection to E.D. box- Median time 25.0 mins (Range 3.0 - 77.0).
E.D. box to Pathology Dept- Median time 23.0 mins (Range 2.0 - 68.0).

Overall, the median time from blood collection in the E.D. to placement in the specimen pickup box was 25.0 minutes. Similar delays were found with the delivery of the specimens from the pickup box to the Pathology Department (median time of 23.0 minutes).

Such baseline delivery times compared poorly with the customer requirements for the service as outlined previously in 6.6.
Response time for specimen pickup of 'stat' tests was required by customers within 15 minutes of the call being received by the wardsperson. Overall, the customers required the entire process from blood collection to delivery to be completed within 30 minutes.

9.1.5 Specimens 'lost' in transit
No E.D. specimens were found to have been 'lost' during the period of data collection.

9.1.6 Specimens left unattended in Pathology Department
As illustrated in Figure 9.1, a large number of specimens were left unattended by wardspersons and other staff when delivered to the Pathology Department. Although the problem was observed at most times throughout the normal

---

**FIGURE 9.1 Specimens left unattended in Pathology Department.**

<table>
<thead>
<tr>
<th>Pathology Department Operating Hours</th>
<th>No. of Specimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>0800-1059</td>
<td>70</td>
</tr>
<tr>
<td>1100-1359</td>
<td>50</td>
</tr>
<tr>
<td>1400-1659</td>
<td>60</td>
</tr>
<tr>
<td>1700-1959</td>
<td>40</td>
</tr>
<tr>
<td>2000-2330</td>
<td>70</td>
</tr>
</tbody>
</table>

- **Attended Specimens**
- **Unattended Specimens**
working day, it was particularly evident during the 1700-1959 hour period.

9.1.7 Turnaround time for tests

Table 9.7 shows the pre-CQI turnaround times obtained for the various tests used in the early management of AMI.

<table>
<thead>
<tr>
<th>Test/test group</th>
<th>Median time, hours</th>
<th>Range, hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full blood count (baseline)</td>
<td>2.5</td>
<td>1.0 - 6.0</td>
</tr>
<tr>
<td>Electrolytes and creatinine (baseline)</td>
<td>1.5</td>
<td>0.5 - 7.0</td>
</tr>
<tr>
<td>Electrolytes and creatinine (24hr-72hr)</td>
<td>3.5</td>
<td>0.5 - 11.0</td>
</tr>
<tr>
<td>PT and APTT (baseline)</td>
<td>3.0</td>
<td>2.5 - 6.0</td>
</tr>
<tr>
<td>APTT (6hr-72hr)</td>
<td>1.5</td>
<td>0.5 - 5.5</td>
</tr>
<tr>
<td>Total CK</td>
<td>2.5</td>
<td>1.5 - 5.5</td>
</tr>
<tr>
<td>CK-MB</td>
<td>3.5</td>
<td>3.0 - 6.0</td>
</tr>
<tr>
<td>Cholesterol and triglyceride</td>
<td>3.5</td>
<td>2.0 - 7.5</td>
</tr>
</tbody>
</table>

PI prothrombin index; APTT activated partial thromboplastin time; Total CK and CK-MB cardiac enzyme tests.

A Pareto diagram is also provided to illustrate the delays associated with the process of reporting FBC test results (Figure 9.2; Table 9.8).

Overall, laboratory processing occupied 75.8% of the total process time involved in reporting FBC test results, while specimen pickup and delivery; and blood
FIGURE 9.2 Pareto diagram of the delays in the reporting of an E.D. FBC test result (Pre-CQI).

![Pareto diagram showing delays in FBC result reporting]

<table>
<thead>
<tr>
<th>Delays in FBC result reporting</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>laboratory processing</td>
<td>75.8%</td>
</tr>
<tr>
<td>blood collection and specimen preparation</td>
<td>12.0%</td>
</tr>
<tr>
<td>specimen pickup and delivery</td>
<td>11.8%</td>
</tr>
</tbody>
</table>

TABLE 9.8 Turnaround times of the various sub-processes in the reporting of an E.D. FBC test result (Pre-CQI).

<table>
<thead>
<tr>
<th>Sub-process</th>
<th>Median time, minutes</th>
<th>Range, minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood collection and specimen preparation</td>
<td>25.0</td>
<td>3.0 - 77.0</td>
</tr>
<tr>
<td>Specimen pickup and delivery</td>
<td>23.0</td>
<td>2.0 - 68.0</td>
</tr>
<tr>
<td>Laboratory processing</td>
<td>150.0</td>
<td>60.0 - 360.0</td>
</tr>
</tbody>
</table>

collection and specimen preparation occupied 11.6% and 12.6% of the time respectively.
9.1.8 Computer terminal breakdowns
Over a 14 day period there was only one incident recorded of computer terminal downtime in the E.D. This was not regarded as significant by the CQI Project Team of the investigation.

9.1.9 Laboratory analyser breakdown
Over a 14 day period there were no incidents recorded of major breakdowns to the main analysers of the Clinical Chemistry and Haematology Departments.

9.2 Process improvement Plan 1
As shown in Table 9.9, a high compliance rate was achieved following the introduction of the strategies of Plan 1.

The compliance rate however decreased markedly at about 5 months after the Plan had been originally introduced. However, the use of further staff education resulted in significant improvements throughout the duration of the investigation.

As shown in Table 9.10, a high rate of appropriate timing for specimens was attained following the introduction of the strategies of Plan 1. No statistically significant difference in the rate of appropriate timing was found throughout the post-CQI period.

9.3 Process improvement Plan 2
The data on E.D. specimen delivery delays that were
TABLE 9.9 Compliance rate of the usage of pre-stamped pathology forms in suspected AMI.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes  No  %</td>
<td>Yes  No  %</td>
<td>Yes  No  %</td>
<td>Yes  No  %</td>
<td>Yes  No  %</td>
<td>Yes  No  %</td>
<td></td>
</tr>
<tr>
<td>0 hours</td>
<td>39  12  76</td>
<td>57  16  78</td>
<td>43  25  63</td>
<td>49  11  82</td>
<td>47  15  76</td>
<td>51  11  82</td>
<td>8.66, p=0.1235</td>
</tr>
<tr>
<td>6 hours</td>
<td>40  11  78</td>
<td>57  16  78</td>
<td>43  25  63</td>
<td>49  11  82</td>
<td>47  15  76</td>
<td>51  11  82</td>
<td>8.86, p=0.1146</td>
</tr>
<tr>
<td>12 hours</td>
<td>37  14  73</td>
<td>54  19  74</td>
<td>45  23  66</td>
<td>47  13  78</td>
<td>47  15  76</td>
<td>50  12  81</td>
<td>4.34, p=0.5014</td>
</tr>
<tr>
<td>24 hours</td>
<td>35  16  69</td>
<td>54  19  74</td>
<td>48  20  71</td>
<td>50  10  83</td>
<td>51  11  82</td>
<td>47  15  76</td>
<td>5.84, p=0.3225</td>
</tr>
<tr>
<td>48 hours</td>
<td>35  16  69</td>
<td>55  18  75</td>
<td>51  17  75</td>
<td>49  11  82</td>
<td>50  12  81</td>
<td>47  15  76</td>
<td>3.37, p=0.6424</td>
</tr>
<tr>
<td>72 hours</td>
<td>36  15  71</td>
<td>51  22  70</td>
<td>39  29  57</td>
<td>49  11  82</td>
<td>47  15  76</td>
<td>50  12  81</td>
<td>13.05, p=0.0229</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>-------------------</td>
</tr>
<tr>
<td>0 hours</td>
<td>Yes 39</td>
<td>Yes 57</td>
<td>Yes 43</td>
<td>Yes 49</td>
<td>Yes 47</td>
<td>Yes 51</td>
<td>5.13, p=0.3998</td>
</tr>
<tr>
<td>6 hours</td>
<td>No 0</td>
<td>No 0</td>
<td>No 0</td>
<td>No 0</td>
<td>No 0</td>
<td>No 0</td>
<td></td>
</tr>
<tr>
<td>12 hours</td>
<td>Yes 22</td>
<td>Yes 34</td>
<td>Yes 23</td>
<td>Yes 36</td>
<td>Yes 30</td>
<td>Yes 31</td>
<td>10.12, p=0.0719</td>
</tr>
<tr>
<td>24 hours</td>
<td>No 8</td>
<td>No 10</td>
<td>No 10</td>
<td>No 4</td>
<td>No 8</td>
<td>No 9</td>
<td></td>
</tr>
<tr>
<td>48 hours</td>
<td>Yes 19</td>
<td>Yes 40</td>
<td>Yes 39</td>
<td>Yes 39</td>
<td>Yes 24</td>
<td>Yes 36</td>
<td></td>
</tr>
<tr>
<td>72 hours</td>
<td>No 5</td>
<td>No 4</td>
<td>No 4</td>
<td>No 4</td>
<td>No 24</td>
<td>No 36</td>
<td></td>
</tr>
<tr>
<td>48 hours</td>
<td>Yes 16</td>
<td>Yes 36</td>
<td>Yes 32</td>
<td>Yes 38</td>
<td>Yes 32</td>
<td>Yes 36</td>
<td></td>
</tr>
<tr>
<td>72 hours</td>
<td>No 5</td>
<td>No 11</td>
<td>No 8</td>
<td>No 5</td>
<td>No 9</td>
<td>No 3</td>
<td></td>
</tr>
<tr>
<td>48 hours</td>
<td>Yes 20</td>
<td>Yes 32</td>
<td>Yes 25</td>
<td>Yes 28</td>
<td>Yes 26</td>
<td>Yes 31</td>
<td></td>
</tr>
<tr>
<td>72 hours</td>
<td>No 6</td>
<td>No 7</td>
<td>No 7</td>
<td>No 8</td>
<td>No 9</td>
<td>No 8</td>
<td></td>
</tr>
</tbody>
</table>

TABLE 9.10 Appropriateness of the timing of blood collection in suspected AMI.
obtained during the pilot testing of Plan 2 are shown in Table 9.11.

<table>
<thead>
<tr>
<th>Delivery time, minutes</th>
<th>Number of specimen deliveries</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Blood collection to E.D. box</td>
</tr>
<tr>
<td>0 - 10</td>
<td>109</td>
</tr>
<tr>
<td>11 - 20</td>
<td>38</td>
</tr>
<tr>
<td>21 - 30</td>
<td>36</td>
</tr>
<tr>
<td>31 - 40</td>
<td>18</td>
</tr>
<tr>
<td>41 - 50</td>
<td>11</td>
</tr>
<tr>
<td>51 - 60</td>
<td>12</td>
</tr>
<tr>
<td>61 - 70</td>
<td>9</td>
</tr>
<tr>
<td>71 - 80</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>235</td>
</tr>
</tbody>
</table>

Blood collection to E.D. box—Median time 11.0 mins (Range 1.0 - 73.0).
E.D. box to Pathology Dept—Median time 14.0 mins (Range 1.0 - 72.0).

As mentioned previously in Appendix 6.2, the initial request for wardspersons to commence recording the time of specimen delivery resulted in an immediate significant improvement in the delivery time. This was confirmed when the data was compared with the pre-CQI data provided earlier in Table 9.6.

Table 9.12 illustrates the significant improvement in E.D. specimen delivery time over the period of the investigation. There was a highly significant difference
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 14</td>
<td>17</td>
<td>82</td>
<td>103</td>
<td>79</td>
<td>82</td>
<td>105</td>
<td>99</td>
</tr>
<tr>
<td>15 - 29</td>
<td>25</td>
<td>58</td>
<td>53</td>
<td>67</td>
<td>93</td>
<td>86</td>
<td>102</td>
</tr>
<tr>
<td>30 - 44</td>
<td>31</td>
<td>16</td>
<td>18</td>
<td>29</td>
<td>17</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>45 - 59</td>
<td>25</td>
<td>38</td>
<td>21</td>
<td>6</td>
<td>8</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>60 - 74</td>
<td>10</td>
<td>6</td>
<td>12</td>
<td>3</td>
<td>4</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>75 - 89</td>
<td>9</td>
<td>10</td>
<td>16</td>
<td>5</td>
<td>2</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>90 - 104</td>
<td>12</td>
<td>4</td>
<td>7</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>105 - 119</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>0</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>120 - 134</td>
<td>10</td>
<td>1</td>
<td>0</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>135 - 149</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>150 - 164</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>165 - 179</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>145</td>
<td>220</td>
<td>235</td>
<td>196</td>
<td>209</td>
<td>207</td>
<td>216</td>
</tr>
<tr>
<td>Median time (mins)</td>
<td>44.0</td>
<td>21.0</td>
<td>18.0</td>
<td>19.0</td>
<td>17.0</td>
<td>14.0</td>
<td>15.0</td>
</tr>
<tr>
<td><strong>p value</strong></td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* pre-CQI test data
** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test.
in the individual pre-CQI and post-CQI delivery times (p<0.0001). Also, the median delivery time for each post-CQI data collection period was well within the customer requirements of 30.0 minutes.

Similarly, Figure 9.3 shows that delivery times in the post-CQI period met customer requirements throughout all of the various time periods of the normal Pathology operating hours. Also, as shown in Table 9.13, there was a highly significant difference in the individual pre-CQI and post-CQI delivery times at the various corresponding periods of the day (p<0.0001).

Table 9.14 shows that over the post-CQI period, the compliance rate for the recording of the blood collection time on the Pathology request form ranged from 79.1% to
TABLE 9.13 E.D. specimen delivery times at various periods of the day.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>p**</td>
<td></td>
<td>p**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0800 - 1059</td>
<td>45.0</td>
<td>23.0</td>
<td>&lt;0.0001</td>
<td>15.0</td>
<td>&lt;0.0001</td>
<td>18.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1100 - 1359</td>
<td>38.0</td>
<td>22.5</td>
<td>&lt;0.0001</td>
<td>16.0</td>
<td>&lt;0.0001</td>
<td>24.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1400 - 1659</td>
<td>48.0</td>
<td>26.0</td>
<td>&lt;0.0001</td>
<td>20.0</td>
<td>&lt;0.0001</td>
<td>18.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>1700 - 1959</td>
<td>42.0</td>
<td>21.0</td>
<td>&lt;0.0001</td>
<td>21.5</td>
<td>&lt;0.0001</td>
<td>17.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>2000 - 2330</td>
<td>46.0</td>
<td>20.0</td>
<td>&lt;0.0001</td>
<td>21.0</td>
<td>&lt;0.0001</td>
<td>18.5</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

* pre-CQI test data

** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test.
TABLE 9.14 Recording of blood collection time on the pre-stamped Pathology request forms in suspected AMI.

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of pre-stamped forms used</th>
<th>Number of occasions collection time was recorded</th>
<th>Rate recorded (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oct 1993</td>
<td>222</td>
<td>174</td>
<td>79.1</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>324</td>
<td>273</td>
<td>84.3</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>269</td>
<td>221</td>
<td>82.2</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>293</td>
<td>246</td>
<td>84.0</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>288</td>
<td>238</td>
<td>82.6</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>296</td>
<td>246</td>
<td>83.1</td>
</tr>
</tbody>
</table>

84.3%. This was a marked improvement from the pre-CQI compliance rate which approximated only 50%.

As shown in Table 9.15, a highly significant improvement in the turnaround time of receiving patient labels was obtained in the post-CQI period. The median time was reduced from 28.0 minutes to 8.0 minutes (p<0.0001).

9.4 Process improvement Plan 3
Appendix 13 illustrates the post-CQI turnaround times for each test and test group. Comparisons are also provided with the corresponding pre-CQI data.
TABLE 9.15 Turnaround time for receiving patient labels for specimen tubes (Post-CQI)

<table>
<thead>
<tr>
<th>Turnaround time, minutes</th>
<th>No. of requests for labels</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-5</td>
<td>8</td>
</tr>
<tr>
<td>6-10</td>
<td>23</td>
</tr>
<tr>
<td>11-15</td>
<td>10</td>
</tr>
<tr>
<td>16-20</td>
<td>2</td>
</tr>
<tr>
<td>21-25</td>
<td>6</td>
</tr>
<tr>
<td>26-30</td>
<td>1</td>
</tr>
<tr>
<td>31-35</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>51</strong></td>
</tr>
</tbody>
</table>

Pre-CQI: Median time 28.0 mins (Range 2.0 - 54.0) (Table 7.4)
Post-CQI: Median time 8.0 mins (Range 3.0 - 33.0) (Table 7.14)
p<0.0001 (Mann-Whitney U test).

During the pre-CQI period, full blood count (FBC), activated partial thromboplastin time (APTT) and creatine kinase (CK) tests were specifically found to have turnaround times outside of the acceptable customer required times.

Only one test, APTT (6 - 90 hour samples), failed to meet customer requirements throughout the post-CQI period.

9.5 Process improvement Plan 4
Table 9.16 shows that on 42.3% of occasions, three to four attempts were required by E.D. staff to computer
TABLE 9.16  Number of attempts required to computer access the complete set of baseline test results in suspected AMI.

<table>
<thead>
<tr>
<th>Required number of attempts</th>
<th>Frequency</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>30.8</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>26.9</td>
</tr>
<tr>
<td>3</td>
<td>17</td>
<td>32.7</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
<td>9.6</td>
</tr>
<tr>
<td>5</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>52</td>
<td></td>
</tr>
</tbody>
</table>

access baseline clinical laboratory test results for patients with suspected AMI.

9.6 Process improvement Plan 5

A streamlined distribution of printed reports was found to have occurred in the post-CQI period.

As shown in Tables 9.17 and 9.18, a significant decrease occurred in the number of printed interim clinical laboratory test reports being dispatched to the E.D. (p<0.0001).

As shown in Table 9.19, the strategies resulted in decreased numbers of interim reports and therefore fewer medical records being requested by E.D. staff (p<0.0001).
### TABLE 9.7 Changes to the number of interim Clinical Chemistry printed reports being dispatched to the E.D.

<table>
<thead>
<tr>
<th>Month</th>
<th>No. interim reports</th>
<th>No. interim reports/total episodes of testing</th>
<th>p value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>151</td>
<td>0.90</td>
<td>-</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>49</td>
<td>0.28</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>38</td>
<td>0.25</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>41</td>
<td>0.25</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>38</td>
<td>0.24</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>43</td>
<td>0.26</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

* pre-CQI test data  
** significance level obtained from the comparison of the pre-CQI and individual post-CQI data by use of the t-test.

### TABLE 9.18 Changes to the number of interim Haematology printed reports being dispatched to the E.D.

<table>
<thead>
<tr>
<th>Month</th>
<th>No. interim reports</th>
<th>No. interim reports/total episodes of testing</th>
<th>p value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>147</td>
<td>0.90</td>
<td>-</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>42</td>
<td>0.25</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>35</td>
<td>0.23</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>39</td>
<td>0.25</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>37</td>
<td>0.24</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>36</td>
<td>0.23</td>
<td>&lt; 0.0001</td>
</tr>
</tbody>
</table>

* pre-CQI test data  
** significance level obtained from the comparison of the pre-CQI and individual post-CQI data by use of the t-test.
TABLE 9.19 Number of medical records requested by the E.D. on patients undergoing clinical laboratory testing.

<table>
<thead>
<tr>
<th>Period</th>
<th>No. of records requested</th>
<th>No. of records requested/total episodes of testing</th>
<th>p value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov 1993*</td>
<td>43</td>
<td>0.54</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>(wks 3-4)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dec 1993</td>
<td>15</td>
<td>0.18</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>(wks 1-2)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dec 1993</td>
<td>23</td>
<td>0.25</td>
<td>&lt; 0.0001</td>
</tr>
<tr>
<td>(wks 3-4)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* pre-CQI test data
** significance level obtained from the comparison of the pre-CQI and individual post-CQI data by use of the t-test.

9.7 The objectives of the intervention

As shown in Table 9.20 most of the elements assessed scored maximum points. Overall, this indicated that in accordance with Objective 1 of the intervention, the organisation had fully introduced the strategies that led to the establishment of a TQM environment for pathology services.

Also, as shown in Table 9.21 and in accordance with Objective 2 of the intervention, all of the elements considered to be necessary for the attainment of a CQI model for pathology services, were found to be present.
<table>
<thead>
<tr>
<th>Element</th>
<th>Score attained**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CQI training</td>
<td>2</td>
</tr>
<tr>
<td>2. Staff empowerment</td>
<td>2</td>
</tr>
<tr>
<td>3. Effective communication of staff's role in improvement</td>
<td>3</td>
</tr>
<tr>
<td>4. Customers and their needs defined</td>
<td>3</td>
</tr>
<tr>
<td>5. Measurement criteria for customer satisfaction</td>
<td>3</td>
</tr>
<tr>
<td>6. Processes for improving customer satisfaction exist</td>
<td>3</td>
</tr>
<tr>
<td>7. Positive trends in customer satisfaction</td>
<td>3</td>
</tr>
<tr>
<td>8. Quick response to changing customer needs</td>
<td>3</td>
</tr>
<tr>
<td>9. Strong emphasis on problem prevention</td>
<td>2</td>
</tr>
<tr>
<td>10. Quantitative measures of process performance and quality widespread</td>
<td>3</td>
</tr>
<tr>
<td>TOTAL</td>
<td>27</td>
</tr>
</tbody>
</table>

* previously defined in detail in 5.5.3.
** assessed by investigator at the completion of the investigation.

<table>
<thead>
<tr>
<th>Element</th>
<th>Score attained**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Improvement of systems and processes</td>
<td>3</td>
</tr>
<tr>
<td>2. Scientific approach to problem solving</td>
<td>3</td>
</tr>
<tr>
<td>3. Wide representation on team</td>
<td>3</td>
</tr>
<tr>
<td>4. Team based techniques to uncover causes of poor quality</td>
<td>3</td>
</tr>
<tr>
<td>5. Customer needs and concerns identified</td>
<td>3</td>
</tr>
<tr>
<td>6. Improvement processes require reevaluation of work done and new strategies introduced as needed</td>
<td>3</td>
</tr>
<tr>
<td>7. Improvement processes are data driven</td>
<td>3</td>
</tr>
<tr>
<td>TOTAL</td>
<td>21</td>
</tr>
</tbody>
</table>

* previously defined in detail in 7.2.7.
** assessed by investigator at the completion of the investigation.
As illustrated in Table 9.22 and in accordance with Objective 3 of the intervention, most of the elements assessed had indicated that CQI strategies had been developed for improving customer pathology service areas.

<table>
<thead>
<tr>
<th>Element*</th>
<th>Score attained**</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Customers and their needs defined</td>
<td>3</td>
</tr>
<tr>
<td>2. Use of cross functional teams</td>
<td>3</td>
</tr>
<tr>
<td>3. Widespread participation in quality meetings</td>
<td>3</td>
</tr>
<tr>
<td>4. Customer and provider relationships encouraged</td>
<td>2</td>
</tr>
<tr>
<td>5. Measurement criteria for customer satisfaction</td>
<td>3</td>
</tr>
<tr>
<td>6. Identify root causes of problems</td>
<td>3</td>
</tr>
<tr>
<td>7. Customer focused process improvement strategies</td>
<td>3</td>
</tr>
<tr>
<td>8. Quick response to changing customer needs</td>
<td>3</td>
</tr>
<tr>
<td>9. Strong emphasis on problem prevention</td>
<td>3</td>
</tr>
<tr>
<td>10. Communicate improvement strategies to customers</td>
<td>3</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>29</strong></td>
</tr>
</tbody>
</table>

* previously defined in detail in 5.5.3.
** assessed by investigator at the completion of the investigation.

All four of the specific data requirements that were outlined earlier in 7.2.7.3, were found to have been included in the present investigation. Such findings were in accordance with the requirements for the accomplishment of Objective 4.
Also, in accordance with 7.2.7.4, Objective 5 was accomplished through an assessment being undertaken of the effect of the TQM approach on the overall quality of care in this investigation.
CHAPTER 10. CONCLUSIONS AND GENERAL DISCUSSION

This chapter provides the conclusions and general discussion of the research that has taken place. Although Goal 2, the development of the TQM intervention with its five objectives, is secondary to the undertaking of the quasi-experimental investigation, it is here discussed first as it provides the setting and background for the investigation. The accomplishment of the sub-hypotheses of Goal 1 are then discussed as well as the various economic, patient care and organisational wide implications of the findings. The discussion concludes with a brief review of some potential avenues for further research.

10.1 Discussion of the results of the study

10.1.1 Degree of accomplishment of the intervention objectives

10.1.1.1 Objective 1

As discussed in 6.2, the first objective of the intervention, the development of a TQM environment for pathology services, was accomplished through its introduction in the early stages of the post-CQI period.

As previously shown in Table 9.20 of the Results 2 Chapter, most of the required predefined elements of a TQM environment for pathology services had been
established. In accordance with Table 7.1, the attained score of 27 (out of a maximum of 30) indicated that the TQM principles had been fully introduced.

As a direct result of the intervention process, pathology services were provided in an environment characterised by many of the classic features of TQM.

Customer and staff involvement, leadership, teamwork, clarity of purpose, and empowerment were just some of the new environmental elements that developed within the overall process of laboratory test ordering in AMI. These important developments will now be discussed.

Prior to the introduction of the CQI approach, customer involvement was particularly poor and rarely encouraged. The introduction of CQI quickly transformed the service to one that was customer driven. Customers became actively involved in the assessment, delivery and monitoring processes for continuous improvement.

Similarly, the pre-TQM culture had generally not encouraged staff involvement in the process of improving test ordering. When it had previously occurred, involvement was usually only at the senior staff level and generally in the form of handling service complaints or enquiries.

The introduction of CQI created a leadership environment. Throughout the post-TQM period, a number of senior
managers led their staff from the front, inspiring their involvement in the overall mission of improving the quality of services. Others however were found to have maintained the status quo. The new approach to management has generally been one of 'guiding through' or 'showing the way', rather than 'directing' or 'controlling' the staff.

The teamwork approach to improving the test ordering process was clearly valued in the post-TQM period. It generally developed interdependence through improved communications, and the free exchange of ideas, knowledge, data and information. The new clarity of purpose for staff enabled them to see the direction that they were heading towards and also encourage them openly to contribute to service improvement. The empowerment of staff to feel, accept and discharge responsibility was a major contributor to the overall success of improving the process of test ordering. This in turn reflected the real effort and commitment of the majority of the senior staff in the overall shift towards a TQM environment.

The introduction of the CQI initiatives provided a sound basis for the ultimate pursuit of total quality in laboratory test ordering. As for other quality management endeavours, the development of the TQM environment is by no means complete. The effort in test ordering is seen as having a beginning but no end as the quality process
continues within the organisation.

10.1.1.2 Objective 2
As discussed in 6.1, the second objective of the intervention was successfully accomplished through the development of a CQI model for the Project. The established and widely used Hospital Corporation of America’s FOCUS-PDCA quality improvement model was adapted and slightly modified for use in the present study.

As shown in Table 9.21 of the Results 2 Chapter, all of the elements considered to be necessary for the attainment of a CQI model for pathology services were found to be present. In accordance with Table 7.3, the attained maximum score confirmed the accomplishment of Objective 2 of the intervention.

10.1.1.3 Objective 3
The third objective of introducing CQI strategies for improving customer pathology service areas was accomplished soon after the FOCUS-PDCA model had been established. As shown in Table 9.22 of the Results 2 Chapter, most of the elements assessed had indicated that CQI strategies had been introduced as required. In accordance with Table 7.1, the attained score of 29 (out of a maximum of 30) confirmed the accomplishment of Objective 3 of the intervention.
A well structured and sound methodologically based implementation programme had been developed and driven by the study's CQI Project Team. The programme essentially consisted of team building, strategic planning, education and training development, problem solving, and ongoing monitoring of performance through data collection and analysis.

Five major process improvement plans were introduced as CQI strategies for improving all customer pathology service areas. As was shown in Chapters 8 and 9, several statistically significant service benefits had resulted from the introduction of the strategic improvement plans.

**PLAN 1**

Process improvement Plan 1 resulted in statistically significant improvements in the overall appropriateness of clinical laboratory test ordering in AMI. A high level of compliance with the use of the appropriate tests recommended in the AMI laboratory testing guidelines was achieved following the introduction of the pre-stamped pathology request forms. For example, the compliance rate with the use of the recommended forms at the E.D. admission stage ranged from 63% to 82% throughout the duration of the study.

The intervention not only led to a highly significant decrease in test utilisation, but also to a highly significant decrease in the utilisation of non-clinically
indicated tests as will be discussed under Goal 1 Sub-
hypothesis 2.

PLAN 2
Process improvement Plan 2 resulted in a statistically
significant improvement in the delivery time of specimens
from the Emergency Department to Pathology. Over the
period of the investigation the median delivery time had
decreased from 44.0 minutes (pre-CQI) to 15.0 minutes
(final month of data collection in the post-CQI period).

PLAN 3
Process improvement Plan 3 resulted in a statistically
significant improvement in the turnaround time of most
clinical laboratory tests. In the study, turnaround time
was defined as the time taken from when the specimen was
received in the Pathology Department to the time all
results were available on the computer.

In accordance with the mission statement of Plan 3, the
majority of tests eventually complied with the customer
requirements for turnaround time. Only one test, APTT
(6-90 hour samples), failed to meet the requirements of
the customers throughout the post-CQI period.

The method for measuring the time that the laboratory
test results became available on the computer was however
limited by the poor system in operation for accessing
computer terminal results. The time of result
availability was achieved by the Pathology Department clerk searching on the computer for each set of results at 30 minute intervals. The turnaround time was therefore subject to data that was only available to the nearest 30 minutes. However, this degree of accuracy was quite acceptable to the clinician members of the CQI Project Team. The poor system of accessing results, necessitated the implementation of a separate plan (Plan 4) to improve the situation.

PLAN 4
The mission statement of Plan 4, improving the clinician’s ease of accessibility to computer terminal results, was not accomplished during the period of investigation.

As discussed in 6.8, the CQI Project Team determined that the clinician’s ease of accessibility to laboratory results would be improved through the introduction of automatic report printing in the E.D. Such an urgent software upgrade was requested by the Project Team from the Area Health Services Information Services Department. However due to other commitments and priorities, the required upgrade to the E.D.’s system was unable to be provided.

PLAN 5
Process Improvement Plan 5 resulted in the CQI Project Team’s mission statement being accomplished. Effective
systems were developed for the streamlined distribution to the Emergency Department of printed laboratory reports on patients with suspected AMI.

A significant decrease occurred in the number of printed interim clinical laboratory test reports being dispatched to the E.D. (p<0.0001). As a result, fewer medical records were requested by E.D. staff (p<0.0001). Although the finding of a reduced number of interim reports did in itself not indicate that a streamlined distribution of printed reports had been achieved, it did satisfy fully the requirements of all the E.D. staff on the Project Team.

The set of results indicating a highly significant reduction in the number of medical records requested by E.D. staff, do need, however, to be interpreted cautiously since the data was collected only over a 42 day period.

10.1.1.4 Objective 4

The fourth objective of assessing the effect of the TQM approach on improving the appropriateness of test utilisation was accomplished. As discussed in 9.7, all four of the specific data requirements that were defined in 7.2.7.3 were found to have been measured in the present investigation. Such findings confirmed the accomplishment of Objective 4 of the intervention.
10.1.1.5 Objective 5

As shown in 9.7, the fifth objective of assessing the effect of the TQM approach on the overall quality of patient care was also accomplished. This was essentially undertaken to determine what effect the intervention had on the overall quality of care provided to the patient and to exclude any untoward effects resulting from the intervention.

Overall, the TQM intervention was found to have had no statistically significant effect, detrimental or otherwise, on the quality of patient care as measured by a number of pre-defined indicators: discharge status (including death rate), readmission to hospital (within 30 days of discharge), and length of stay. Such information was derived over the 30 month period of the investigation, and involved comparisons of pre-CQI and post-CQI data. Comparisons were undertaken with the use of a concurrent control group population.

Although the major indicators of quality were not significantly affected as a result of the TQM intervention, other areas of patient care showed statistically significant improvement. These included overall improvements in the selection of clinically recommended laboratory tests, more clinically appropriate timing of blood collections for cardiac enzyme testing, and improved turnaround time of patient test results.
10.1.2 Goal 1- the quasi-experimental investigation: validation of the hypothesis and sub-hypotheses

The results of the investigation have clearly validated the hypothesis that the introduction of TQM would result in a statistically significant improvement in the appropriateness of clinical laboratory test ordering in the early management of AMI. This supports the recent findings of Nardella et al. of significant reductions in the cost of laboratory tests and increased appropriateness of testing through the use of a CQI approach using CQI strategies similar to those adopted in the present investigation for AMI testing.

As discussed in Chapter 5, the use of a non-equivalent pre-test post-test quasi-experimental design that incorporated a control group provided the necessary framework against alternative explanations for the highly significant improvements achieved to the appropriateness of test ordering. This was because the influences of extraneous variables that could have served as rival hypotheses to that of the effect of TQM were controlled.

The use of strict clinical inclusion and exclusion criteria for AMI and the demonstrated equivalence of the two populations based on several demographic characteristics also provided reasonable control over the effects of testing and instrumentation throughout the period of investigation.
Overall, the results of the investigation validated each of the five sub-hypotheses that were proposed and outlined previously in 5.5.2.

10.1.2.1 Sub-hypothesis 1

The results of the investigation showed that there was an increase in the selection of clinically recommended clinical laboratory tests for AMI as a function of the introduction of the TQM intervention.

As shown previously in Tables 8.11 and 8.12, there was an overall 10.6% increase in the number of clinically recommended tests requested by clinicians as a function of the CQI strategies. On the basis of these results the hypothesis was validated.

One potential problem area was ensuring the correct identification of ‘additional tests’. As discussed in 7.4 and Table 7.5, ‘additional tests’ were defined as tests outside the recommendations of the AMI test guidelines but which were clinically necessary because of a number of factors including the patient’s history, present condition, presence of accompanying disorders or complications, and the results of other diagnostic tests. All tests identified by the investigator as ‘additional tests’ were checked by a hospital medical officer and/or specialist Pathologist. A final decision to include the tests into the ‘clinically indicated’ category was based on the advice provided by the medical officer and/or specialist
Pathologist.

10.1.2.2 Sub-hypothesis 2
The results of the investigation showed that there was an
decrease in the selection of non-clinically indicated
clinical laboratory tests for AMI as a function of the
introduction of the TQM intervention.

As shown previously in Tables 8.13 and 8.14, there was an
overall 81.7% decrease in the number of non-clinically
indicated tests requested by clinicians. On the basis of
these results the hypothesis is validated.

10.1.2.3 Sub-hypothesis 3
The results of the investigation showed that there was an
improvement in the timing of cardiac enzyme testing for
AMI as a function of the introduction of the TQM
intervention.

As shown previously in Tables 8.15 and 8.16, there were
highly significant improvements as a function of the CQI
strategies (p<0.0001). On the basis of these results the
hypothesis is validated.

10.1.2.4 Sub-hypothesis 4
The results of the investigation showed that there was a
highly significant decrease in the total cost of
laboratory tests for AMI as a function of the
introduction of the TQM intervention.
A cost analysis has shown that almost $30,000 (23.0%) in savings were attained annually for the experimental group on pathology services in suspected AMI. All costs and tangible benefits that could be readily valued in dollar terms were included in the determination of the savings.

The major benefit, reduction in test usage, was determined through the measurement of changes in test utilisation. The other benefits were quantified in terms of the amount of staff time saved as a result of the improvements to the service. Such savings in the efforts of clerks, technical aides, wardspersons, medical officers and registered nurses were determined after post-CQI group appraisals of the improvements.

Similarly, the introduction of the TQM intervention, accompanied by various additional staffing and support service costs, was also taken into consideration. Such staffing costs included the time spent undertaking CQI related activities—training, meetings, data collection and analysis. Information on the staffing time involved was obtained from the records of meetings and training programmes, and from interviews with participating staff. Other associated costs were also considered. These included secretarial support, catering for meetings, stationery, and additional specimen transport (taxi-cab costs as a result of new after-hours policy). However, over time the additional costs may decrease when the CQI
strategies are the norm within the organisation.

As shown previously in Table 8.27, it was estimated that savings of $371,073 would have been achieved in the initial year from reduced costs for pathology services if the TQM strategies had been introduced across the entire pathology service. This projection represented 23.0% savings on the $1,613,359 annual expenditure for inpatient pathology services in the experimental group hospital. This estimate was based on the assumption that a similar success rate could be achieved for all inpatient pathology services as was attained for suspected AMI.

Theoretically, this assumption presented very few problems. The FOCUS PDCA model used in this study was quite flexible and adaptable to other clinical situations that involve the utilisation of pathology services. Essentially, the wider use of CQI would involve the formation of several Project Teams each empowered with missions to improve the appropriateness of test utilisation in a specific area of clinical practice. Process improvement plans for these would then be directed at test ordering in a similar manner to that undertaken for AMI. As was found with AMI, improvements in efficiency and reduced costs are realised with well designed structures, policies and guidelines developed from the CQI processes. Although an overall 23% savings
is expected, this projection still needs to be considered cautiously. The widespread introduction of CQI could conceivably result in some strategies providing very few benefits, while others may exceed expectations. The various barriers to change would operate with different effects throughout the many clinical areas where new test ordering strategies were being introduced.

It was projected that major savings of $107.4M could potentially be realised if the TQM strategies were introduced nationwide. Such a complete transformation, of course, is highly unlikely to occur because no nation in the Western world has ever adopted such a radical change in management philosophy across its entire health system. From an implementation perspective, such a widespread paradigm shift in hospital pathology service management could not be directed by the broad policy making of Government. The introduction of the TQM philosophy would therefore rest on each local hospital and health service. As such it is unrealistic to assume the TQM approach would receive instantaneous widespread acceptance.

In addition, as the strategies rely to a great extent on senior executive support and commitment, major changes would need to be undertaken at the most senior level of each hospital organisation, and not just the pathology service, for the test ordering process to achieve its desired goals. One might therefore expect that the TQM
approach will most likely be introduced gradually within the health system. It will essentially be driven in accordance with each particular organisation’s desire to ensure complete customer satisfaction in a context of optimum efficiency.

10.1.2.5 Sub-hypothesis 5
The results of the investigation showed that there was no significant change in the quality of patient care for AMI as a function of the introduction of the TQM measures.

As shown previously in 8.3.5, there were no significant differences between the pre-CQI and post-CQI period for all the investigation’s quality of care indicators: discharge status (including death rate), readmission to hospital, and length of stay. Such data were however limited by the fact that it was extremely difficult to compare morbidity states of the population groups over the period of the investigation. Nevertheless, the results indicated that the hypothesis was validated.

10.2 General discussion

10.2.1 Flexibility of the CQI model
The FOCUS-PDCA model that was adapted for use in this study has had widespread application within the health care system to effect systems improvement. The recent health care literature is abundant with the many applications of the model in various settings. These were
discussed extensively in Chapter 4.

Through the standard step-by-step systematic approach, the flexibility of the FOCUS-PDCA model is such that any organisation, regardless of its size or structure, can accomplish improvement. According to Westgard, Burnett & Bowers\textsuperscript{2}, such a quality management approach, as was used with the model, can be readily adapted to clinical pathology services to provide a logical framework for managing the quality of most areas of work.

Although theoretically adaptable to any health care organisation, the successful introduction or sustained success of the model will generally depend on whether that organisation was ready for a cultural change built around cooperative efforts, delegation, teamwork, systems thinking and risk taking.

As the difficulties in successfully introducing the study's CQI methodology have been previously comprehensively discussed in Chapter 6, these will not be restated in this section. Nevertheless, it is important to stress that health care organisations have traditionally had a strong foundation for seeking to improve the quality of care. It is largely for this reason that the TQM approach has thus far made significant inroads within the health care system.

Pathology laboratories in particular have shown
a favourable response to TQM. This is because they have traditionally placed the utmost importance on quality testing. In addition, the scientific and technical staff have had prior training in some key areas of the TQM philosophy. These include the concepts of the scientific method and the techniques of data analysis.

10.2.2 Generalisability to other clinical situations
As the TQM approach is process driven, the methodology is adaptable to all test ordering processes, regardless of their clinical nature.

In accordance with the TQM approach, each test ordering process in each clinical department or area can be analysed by an examination of the inputs and outputs. The TQM philosophy is clearly concerned with producing an output that meets the requirements of its customers.

Although theoretically there appear to be no major problems in being able to replicate the study to other clinical test ordering situations, a number of implementation issues are worthy of consideration.

Firstly, the introduction of the strategies across all major test ordering situations will result in the formation of numerous project teams. This potentially brings with it the problems normally encountered with the management of multiple teams and the need for some additional staff time to allow for the required
participation. Such issues will obviously need to be addressed. As with the majority of TQM studies, TQM itself provides major benefits through its improved efficiencies, including those of cost saving through reduced staff workloads. Any additional staffing time is invariably provided from within the department’s current resource structure as a result of efficiency gains in staffing time from other areas of the process.

Secondly, another practical issue may arise from the probable use of excessive pre-stamped forms or test ordering guidelines. These could potentially lead to confusion and other associated problems. However, if the Project teams progress as planned, such potential problems and others will be addressed and handled as the issues arise and appropriate strategies are developed. Thirdly, problems could occur with attempts to improve the appropriateness of test ordering of less well defined clinical situations. Again, this may not turn out to be a significant issue. If the entire pathology test ordering culture is transformed to that of TQM, then improvements for less well defined disorders will be catered for in a similar manner to that provided for the other test ordering processes. The new culture of TQM should by its very nature be able to handle test ordering situations as they arise.
10.2.3 Generalisability to other types of organisations

As the research was undertaken in a medium sized Teaching Hospital, it is important to determine whether or not the findings could be generalised to other hospitals of differing size, organisational structure, casemix and range of services being offered.

All types of hospitals have room for improvement in the process of test ordering. This is primarily as a result of the traditional narrow focus on quality. As discussed in Chapter 4, quality needs to be defined in terms of the needs and expectations of customers. The TQM approach therefore challenges the status quo and insists that everything an organisation (large or small) does and how it does it, can be improved to the greater satisfaction of its customers.

The experimental group hospital in the present study was a 454 bed medium size teaching hospital that provided a range of medical and surgical specialty and subspecialty services with a special emphasis on aged care, psychogeriatrics and inpatient rehabilitation. It provided an on-site stat and off-site routine pathology service.

At the hospital, junior medical staff were on rotating rosters, spending 10 weeks within clinical departments and wards. Nursing staff were permanently located, being headed in the E.D. by an Assistant Director of Nursing,
and in the CCU by a Nurse Unit Manager. The wardspersons who were responsible for the portering of laboratory specimens were under the supervision of the hospital's Director of Nursing, while the E.D. clerks were under the direction of the Medical Superintendent.

The CQI model developed in the present study does not depend on the size or any other special feature of the organisation for CQI strategy development and therefore ultimate process improvement. The methodology used in the present study should therefore be able to be replicated in any other hospital setting. The special features of the organisation will however affect the way the strategies are developed, but the model itself would essentially remain unchanged. Thus, for example, in a large teaching hospital pathology laboratory that services numerous customers in various clinical wards and departments, a more complex infrastructure and therefore communication link between service partners and providers exists for the process of test ordering. Although the process of test ordering would differ in such an organisation to that which was used in the present study, the model for change would remain essentially the same. The only change would be the implementation path, as this would reflect the individual processes of test ordering found at the local level.

Using the CQI model, this large pathology service would
in a similar manner to the present study, follow each stage of the plan. Initially, an opportunity statement for improvement would be prepared that reflected its own situation. Management commitment would then be sought. However, in such a large organisation this would most likely be a more involved process, with a number of key managers at different levels of the organisational structure being approached. The selection of members of the Project Team would again reflect a representation of the customers and providers involved in the specific process of test ordering being targeted. Once it was determined which processes were to be investigated, the Project Team would then need to clarify the current knowledge of them. Using similar techniques to those used in the present study, this would largely be achieved through the development of actual flows of the processes, specifically identifying process relationships and problem areas.

Although the process of test ordering would differ in such an organisation as a result of, for example, a totally on-site pathology service in operation or the existence of 12 week junior medical officer term rosters, the model for change would, again, essentially remain the same. In a similar manner, customer needs and requirements would then in turn be identified as the clarification process made advancements. The causes of process variation and poor quality would then be
investigated. Once the desired processes had been selected by the Project Team for improvement, the model’s PDCA cycle would be implemented in a similar manner to that used in this study. Improvement Plans would then be introduced as required.

Therefore the findings of the study could be replicated in other types of organisations, regardless of their size, structure, casemix, range of services and other features. The new TQM approach to quality and the methodology used to achieve it targets everything an organisation does and how it does it, and seeks improvement to the greater satisfaction of its customers.

10.3 Implications of the findings

The finding that a TQM approach has highly significant effects on improving the appropriateness of clinical laboratory test utilisation in AMI has a number of important economic, patient care and health service major implications.

10.3.1 Economic implications

In the present climate, health care services including pathology services, are facing extreme pressures to reduce costs in order to survive.

Most public hospital pathology departments are operating with reduced budgets, yet demand for their services are growing in volume by approximately 15% each year.
Although major restructuring has taken place in an attempt to achieve savings, expenditure is nevertheless on the rise.

On a national basis, costs arising from pathology testing have shown a disproportionate rate of growth in comparison to other clinical services in recent years. The number of pathology tests has been increasing at twice the rate of other medical services in Australia. Current growth rates of pathology test utilisation are adding over $60 million each year to Medicare costs alone.

Therefore the finding of a potential 23.0% saving to the overall cost of hospital inpatient pathology services has major implications for many laboratories, the health services they operate within, and of course the national economy. The projected national savings of $113 M would provide enormous economic benefits to the community. The reduction in expenditure through the elimination of inappropriate tests not only provides laboratory directors with some relief from the escalating costs, but also helps free resources for developing newer tests and quality testing strategies at best price for the future. Similarly, health administrators are provided with cost effective quality pathology services.
10.3.2 Patient care benefits

The TQM approach to quality in test ordering also provided major implications for patient care.

The overall benefits included an increase in the number of clinically recommended laboratory tests selected, an improvement in the clinically recommended timing of cardiac enzyme testing, an improvement in the turnaround time of results, an improved compliance by clinicians to the recommended AMI test ordering guidelines, an improvement in the delivery time for specimens, and the improved distribution of printed pathology reports.

More appropriate test ordering and blood specimen collection provides patients with improved health care. Although not found in the present investigation, reduced turnaround times in some cases allows patient treatment to be finished much earlier, thus reducing length of stay in hospital. Possible reductions in length of stay may eventuate when the TQM approach is extended across the entire pathology service and not just suspected AMI.

10.3.3 Organisation wide implications

The study has major implications for the way health service organisations are managed. In order to obtain the benefits of the TQM approach, a paradigm shift in health care management is required.

As the process of quality pathology test utilisation
involves numerous customers including resident medical officers, staff specialists, visiting medical staff, nurses, clerks, wardspersons, courier drivers, and blood collection staff, quality needs to become the culture of the entire organisation and be reflected by all of its people, and not just those of the pathology service.

To achieve similar benefits and rewards as found in the present study and to successfully expand the intervention strategies to include all pathology test ordering, the hospital’s systems and organisation that comprises its infrastructure must be changed to support a united total quality drive. A shared understanding of what the organisation is trying to achieve with respect to quality must therefore prevail at all levels. This is accomplished by ensuring that the implementation of TQM is integrated with the organisation’s overall planning and goals. These then must be driven through to all wards and departments, and on down to each staff member.

Several investigators have recently discussed some of the implications of the TQM approach on the current management of our health care organisations.6 7 8

Whereas the current approach examines the clinicians and others who provide care, TQM studies the processes of production. A systems oriented approach is therefore required. The worker must be able to see the whole picture, understand relationships and patterns,
and identify and collect data at various stages to achieve the desired customer requirements. Similar

ly, the traditional approach seeks to find out ‘Who does what here?’, while TQM asks ‘How is the work achieved?’ The traditional approach looks for deviations from the norm to correct poor quality. Although TQM also looks at deviations, it strives at improving processes. Whereas the traditional approach generally seeks to find out why there is a difference, TQM searches to make the system continuously better.

Whereas the current approach to quality uses performance standards and action plans when performance is poor, TQM endeavours to continuously improve the capability of the system to better meet the needs of its customers.

Another difference between the two approaches may even be seen in the presentation of the annual report. The traditional organisation might, for example, note that the hospital’s patient mortality is 4.5% below the national rate and that no significant problems were detected. However the TQM report would set a clear objective for the next year to reduce the rate, for example, to less than 3%.

The organisational wide policy on quality must be developed by the senior executives. It needs to provide a clear direction towards attaining customer satisfaction. This then sets the stage for the
development of departmental specific quality strategies. The planned quality change process aims at reaching all staff and involving them in the improvement process. Initially, this involves providing staff with an understanding of the mission of the hospital. Quality leadership must guide and drive them towards quality improvement behaviour.\textsuperscript{14}

After roles and responsibilities are defined, staff must receive training in the skills of CQI.\textsuperscript{15} Knowledge of quality concepts is essential to the success of the change effort. Everyone in the organisation must have a knowledge of who the customers are and what their needs may be. Training programmes are directed at such aspects as, identifying customers and suppliers, ascertaining their true needs, and monitoring changes in the requirements. The education programme also needs to focus on an understanding of inputs and processes and the monitoring of change through CQI strategies. The hospital must institute a process to define quality related education requirements and then make available the resources and systems to meet them.

10.3.4 Departmental implications

The organisation wide implications discussed in 10.3.3 result in major changes to the way hospital departments function and are managed.

The TQM approach results in many changes including
teamwork and employee empowerment, the recognition that all work takes place in systems, the reduction of traditional barriers between staff groups, the use of statistical tools to define and evaluate systems performance, an increased emphasis in education and training, and open dialogue maintained between the customers and suppliers. As the process of pathology test ordering involves customers and suppliers from numerous departments, the TQM approach to improvement requires major changes to the way health care workers go about their work. The barriers between functional areas must be broken down so that the cross functional processes of test ordering can be made more appropriate.

The TQM process essentially results in a complete reorganisation of the way departments operate. The search for quality needs to be managed in a systematic manner across all administrative and clinical areas, processes, and activities. The manager will need to strive for strategies that will allow quality to happen.

TQM requires that the manager exhibits leadership responsibility by facilitating change that will lead to improvement, train all staff in quality improvement skills, and encourage staff to be innovative and participative in CQI problem solving.

Whereas several levels of management currently exist
within organisations, the TQM structure is flattened wherever possible. In accordance with this, the department will require clarity of purpose as to where it is heading. This would allow staff to see the direction that they were going and also provide the necessary drive to be participative.  

For the process of test ordering to improve, departmental managers will need to implement the teamwork approach to problem solving. Team building strategies need to be introduced so that there is a willingness to work effectively in teams and to share the associated responsibilities. An essential aspect of the TQM approach is that departmental managers need to raise staff awareness on quality improvement. Staff views need to be clarified on TQM in order to provide commitment and positive attitude formation. In a TQM department hierarchy and status of position are not relatively important when process improvement strategies are being prepared. 

Staff should be encouraged to recognise that all work takes place in systems. Work needs to be regarded as a process that is contingent to ongoing improvement as new information becomes available. Each department must actively manage such processes in order to achieve the required mission.  

Departmental managers also need to base their decision
making on reliable data and information, rather than on opinions or speculation. With the TQM approach, quality tools and techniques, such as statistical methods and flow charts, are essential requirements for departments to continuously monitor performance.\textsuperscript{22}

The change process for departments should be supported by an increased emphasis on staff education and training. All staff require training in attaining the skills of achieving improvement.

Departments will focus their attention, time and effort to meeting their internal and external customer expectations. This may be a major change for many departmental staff who have been used to regarding patients as their only customers. The department should therefore maintain open dialogue with its customers and suppliers. This entails establishing ways to tune into their needs and expectations, developing processes for attaining feedback, establishing indicators, monitoring performance and then developing appropriate strategies for improvement.

10.3.5 Future control of pathology service growth
The study has obvious major implications for the measures currently being used to control the utilisation and therefore growth of hospital pathology services.

As discussed in Chapter 4, doctors have traditionally
been singled out as responsible for poor test ordering and the strategy has been to change such behaviour. Current strategies that have failed to improve the appropriateness of test utilisation have included educational programmes, feedback, administrative rules, financial incentives and financial penalties.

In accordance with the findings of the present study, clinicians are more likely to respond to improving the appropriateness of test ordering if they were encouraged to actively participate in the quality improvement process. Such strategies should therefore replace the failed current control measures.

10.4 Further implications
Although the TQM approach realised a range of major benefits, it would certainly have achieved a far greater impact had it not been for the presence of a number of barriers and constraints that were evident within the hospital and the area health service.

Major impediments to a smoother implementation process included the hospital’s divisional structure, a centrally managed pathology service, the visiting medical officers, a centrally managed information services department, and some less flexible hospital departments.

Whereas the hospital had undertaken preliminary steps towards its TQM goals, the divisional structure
essentially maintained its traditional hierarchical nature. Although divisional heads generally supported the CQI Project Team's initiatives, the structure within each division remained essentially the same for day-to-day management related activities. Consequently in the process of test ordering, a number of improvement strategies were not fully realised as planned primarily because traditional divisional structures had essentially hindered the communication flow from the Project Team to some of the staff involved in the process of test ordering. As an example, in the Division of Nursing all wardspersons involved in the transportation of pathology specimens may not have been contacted by divisional staff to be updated on the ongoing changes that arose from the Project.

Another significant impediment was that the pathology service was managed from outside of the experimental group hospital. Although the pathology service representatives on the Project Team were totally supportive and a major driving force for the improvements achieved, the traditionally managed and centrally controlled service was, however, not receptive to all requests for change.

As an example, poor turnaround times for APTT results identified the urgent need to have an onsite service for such tests at the experimental group hospital. The
purchase of a coagulation test analyser was therefore recommended by the Project Team. However, several months of inaction occurred, and it was presumed that the centrally controlled service had preferred such testing to be performed offsite and in accordance with its area wide policy for testing. Only after a considerable period of negotiation and the presentation of further convincing data by the Project Team, was the analyser was purchased and urgent APTT assays performed onsite. A locally managed pathology service under the direction of the hospital executive or a more customer focused area service may have been more receptive and understanding to the needs of the local clinicians.

Another example of a constraint was the pathology service courier timetable arrangements for taking specimens to the central laboratory for processing. As such arrangements were similarly controlled by the central laboratory service, only some flexibility for change was available to, for example, match courier pickups with the completion of ward blood collection rounds. As the central laboratory had to ensure that all seven of its hospital based pathology services were provided with appropriate courier services, the degree of flexibility to change remained minimal.

Another significant obstacle to the smooth introduction of the TQM strategies was the influence of the visiting
medical consultants, the VMOs. Although the majority of VMOs supported and complied with, for example, the laboratory test guidelines for AMI, a few pressured their junior medical staff to order some selected additional tests. Such an influence was probably one of the main reasons that contributed to a lower than 100% compliance rate being achieved.

Another significant hindrance was that a number of important hospital services were centrally managed by the area health service and not by the local hospital executive. Such services were generally being operated under more traditional structures and hierarchies. As an example, the Information Services Department, like the pathology service, was operated by the area health service. In the present study, the decision was made by the Project Team to urgently request the software upgrade of the pathology reporting system to the Emergency Department. The proposed system would have allowed new laboratory data to be instantly available in printed form to the Emergency Department staff. However, even after a considerable period of time and discussion between the parties concerned, the proposed system was not able to be developed apparently because of the other numerous high priority work requests of the Information Services Department.

Another potential barrier to the widespread introduction
of TQM across all pathology test ordering was that some local hospital departments also still operated under more traditional management structures and hierarchies. A cultural change would therefore be necessary if TQM was to be introduced to test ordering processes in such environments.

10.5 Areas for further research
The present study has opened the doors for more research on the further potential of TQM in the process of test utilisation.

It is important that more investigations be undertaken on the effects of TQM on a variety of other clinical disorders and situations, especially those that are less well defined clinically.

Research also needs to be carried out on the effects of the various aspects of organisational behaviour that influence TQM strategies for improving test ordering. It is important to determine what effect the influence of, for example, poor leadership, ineffective communication amongst staff, lack of commitment from senior management, shared responsibility, shared values, and trust and belonging, have on the success of the improvement strategies being implemented. Once such information has been evaluated, fewer problems should eventuate during the TQM implementation stage.
10.6 Concluding comments

In conclusion, the results of the study have clearly confirmed the hypothesis that the Total Quality Management approach to the delivery of pathology services significantly contributes to an improvement in the appropriateness of clinical laboratory test ordering in the early management of AMI.

Considerable success has been achieved in reducing non-clinically indicated test utilisation through the development of a CQI model that allows a group of workers to more easily examine and improve the various processes associated with the pathology service.

The TQM approach has resulted in a number of important economic and patient care benefits. It accomplished this by providing the necessary driving force for a committed, integrated and motivated clinical care effort empowered to achieve such improvements to patient care.

The thrust towards CQI was the belief that an organisation must move away from the current approach of targeting and blaming any individual or groups of doctors when inappropriate testing occurs. It is suggested that what is required is an overall review and improvement of the total systems and processes involved in test ordering.

The TQM approach clearly focused its attention on
cooperation between customer and supplier to meet the customer's requirements. The approach allowed the various staff members to become more aware and understanding of each other's problems and needs in the process of test ordering.

The research design used to test the effect of the TQM approach had major strengths. The inclusion of a pre-test and a concurrent control group resulted in substantial control over potential rival hypotheses.

Wide adoption of the successful new TQM approach would undoubtedly be a desirable strategy that should be explored by laboratory directors and health administrators interested in improving patient care while at the same time reducing expenditure.

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2. Organisation of Project Team

2.1 CQI plan for staff training
2.2 Formation of Project Team
2.3 Team boundaries determined
2.4 Framework for meetings
2.5 Mission statement
2.6 Baseline data
2.7 CQI training
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<td><strong>3. Clarification of current knowledge of the process</strong></td>
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<td>3.2 Prepare flow charts of processes</td>
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<td><strong>4. Uncover the causes of poor quality</strong></td>
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<td>6.1 Develop the process improvement plan- defining who, what, when, where and how the improvement will be achieved</td>
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<td>6.2 Determine plan for pilot testing the improvement and the collection of data</td>
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<td>6.3 Determine plan for implementing and measuring results</td>
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7. Do the improvement, data collection and analysis
   7.1 Pilot test the proposed changes
   7.2 Implement the improvement, collect and analyse data about the impact of the changes
   7.3 Determine whether there are significant difficulties in the change or data collection efforts

8. Check the results and lessons learnt
   8.1 Assess whether the process improved as expected
   8.2 Determine how the team effort could be improved
   8.3 Prepare post-test flow charts of the processes
   8.3 Analyse what was learnt from the effort
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<td>9. Act to hold the gain</td>
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<td>9.1 Determine what changes to procedures are necessary</td>
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<td>9.2 Determine what procedures need to be standardised</td>
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<td>9.3 Determine who needs to be made aware of the change</td>
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<td>9.4 Determine what education and training needs to be undertaken as a result of the changes</td>
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<td>9.5 Establish a measurement and monitoring process to hold the gain</td>
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<td>9.6 Implement the necessary steps of continuous improvement of this process</td>
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Clinical Chemistry: Blood (can be done on either serum or plasma unless stated otherwise):
amylase, blood gases (including $pO_2$, $pCO_2$, pH with calculation of base excess and bicarbonate)(whole blood),
calcium, creatinine kinase (total)*, carboxyhemoglobin*,
creatinine, glucose, magnesium, (serum only)*, osmolality*,
paracetamol (quantitative)*, phosphate*, potassium,
pregnancy test (qualitative detection beta subunit of human chorionic gonadotrophin)(serum only), salicylate (quantitative)*, sodium.

Cerebrospinal fluid: glucose, protein.

Urine: osmolality*, paracetamol screen, potassium, salicylate screen, sodium.

Haematology: activated partial thromboplastin time (APTT), erythrocyte count (with calculated indices), haematocrit, haemoglobin,
leucocyte count (total), differential leucocyte count*, platelet count, prothrombin time (PT)(including calculation of international normalised ratio - INR), malaria parasite detection (thick film)*, snake venom detection.

Microbiology: CSF - Cell count*, culture and gram stain*,
Urine obtained by bladder needle aspiration or catheter - cell count*, culture* and, if specifically requested, gram stain* (also see Note 2)
Operative specimens of tissue or body fluid - culture, microscopy and gram stain*.

Blood Bank: Cross-match and group and hold

PTO FOR NOTES
NOTE 1:
All tests in this schedule are available 24hrs a day 7 days a week and are done at the on-site satellite laboratory unless marked *** when the specimen must be sent to SWAPS Area Laboratories at Liverpool. If any test not on this schedule is required out-of-hours authorisation must be obtained from a staff specialist of the relevant department of SWAPS or from the Director. They can be contacted through Liverpool Hospital Switchboard (828 3000).

NOTE 2:
Microbiological examination of a mid-stream urine is not offered as a standard "stat" test - if this is required approval must be obtained from a staff specialist in microbiology, the Head of the Department of Microbiology or the Director of SWAPS unless it is a paediatric patient when the request can be approved by a VMO or hospital staff specialist.

(23/5/93)
APPENDIX 3  EXTRACT FROM THE BANKSTOWN-LIDCOMBE HEALTH SERVICE QUALITY MANAGEMENT PLAN (1993)

VISION STATEMENT

The Bankstown-Lidcombe Sector Health Service will deliver the highest possible standard of health services thereby satisfying customer expectations, both clients and staff, in a planned period of change and finite resources.

MISSION STATEMENT

We, the management of the Bankstown-Lidcombe Health Service are committed to providing the community with comprehensive health services which are efficient, of high quality, are effective and readily accessible.

Guiding Principles

We will accomplish this commitment by involving staff in decision making processes associated with determining the type, extent and location of each clinical and support service.

We will strive to provide a level of health care capable of delivering the required services within the community by

* facilitating continuity of care for patients/clients of the service;

* keeping a flat management structure with minimum administrative costs;

* ensuring strong lines of accountability where maximum delegation to managers exists;

* ensuring the management structure provides adequate control over the allocation of human and financial resources;

* establishing clear lines of communication both internally and externally to the organisation.
APPENDIX 4 OVERALL PRE-TEST PROCESS OF PATHOLOGY TEST UTILISATION IN EARLY A.M.I.

EMERGENCY DEPARTMENT (E.D.)

TEST REQUEST

1. Patient presents to E.D. with chest pain
2. Triage Nurse assigns priority of treatment
3. Observations, ECG taken
4. M.O. evaluation; history and physical exam.

5. Suspicion of AMI formed
6. Baseline blood tests ordered by Medical Officer

SPECIMEN/REQUEST FORM DELIVERY

7. M.O. Nurse collect blood sample
8. Are labels printed? NO clerical delays
9. Are delays to be lengthy? NO E.D. clerks advised labels needed ASAP
9(A). E.D. clerks advised labels needed ASAP
9(B). Labels acquired
9(C). Labels acquired

10. Specimen bag placed in E.D. 'pick-up' box
11. Wardsperson called to transport specimens

8(A). Are clerical delays? NO

12. Has wardsperson arrived? YES
12(A). Contact wardsperson again
13. Has wardsperson arrived? NO
13(A). Alternative transport arranged

YES
CORONARY CARE UNIT

37
Are tests required stat?

37(A)
Stat analysis undertaken in laboratory

38
Test results progressively validated in lab

39
All ED/CCU test reports printed & sorted in lab

40
Was patient admitted to ICU?

40(A)
All other interim and final printed reports to E.D.

41
Medical Officer obtains test result report

CCU DAY 2

42

CCU DAY 3

43
Patient assessed with view to transfer to ward

END

DISTRIBUTION OF PRINTED REPORTS FOR EMERGENCY DEPARTMENT

PAGE 5 OF 6
(APPENDIX 4)
DISTRIBUTION OF PRINTED REPORTS FOR EMERGENCY DEPARTMENT

45

Results checked by Emergency Department staff

46

Are results abnormal? NO

Sent to Medical Record Department for filing

46(A)

Medical Record Dept. requested to pull notes

YES

47

E.D Medical Staff check results against records

48

Was appropriate action taken at the time? NO

48(1)

Results noted

48(A)

Appropriate action is now taken

49

Have further reports been received? YES

NO

No further action

48(1)

Results noted

48(A)

Appropriate action is now taken

49

Have further reports been received? YES

NO

No further action

(APPENDIX 4)
APPENDIX 5 FIGURE 2 Cause-and-effect diagram for the delays in specimen and request form delivery

CUSTOMERS

- Lack of understanding by wardspersons of urgency of specimen delivery
- Priority setting for specimen tube label printing poorly defined
- Unfamiliar with specimen requirements
- Unfamiliar with request form requirements

POLICIES

- Urgency of test often incorrectly specified
- No policy exists for the delivery of specimens
- No mechanism for measuring performance of specimen delivery system

SERVICE PROVIDERS

- Laboratory requirements not well communicated
- Delays in E.D. staff receiving specimen tube labels
- No available CCU medical staff to sign request forms

PROCEDURES

- Wardsperson delays
- Specimens 'batched' before delivery
- Specimens 'lost' in transit
- Specimens left unattended in Path.
- Specimens 'miss' courier run

Delays in specimen and request form delivery
APPENDIX 5 FIGURE 3 Cause-and-effect diagram for unacceptable turnaround times for test results

CUSTOMERS
- poor communication between service provider and customers
- urgency of test often incorrectly specified

POLICIES
- customer needs not being sought in policy development
- TAT for tests during thrombolytic therapy inappropriate for A.M.I.
- TAT's for test results inappropriate for clinical management
- service provided on- and off-site
- limited range of on-site testing
- off-site testing causing delays

SERVICE PROVIDER
- service not directed towards patient care in A.M.I.
- lack of customer focus

PROCEDURES
- single specimen blood tube contains both on- and off-site testing
- computer terminal downtime
- transport system
  - wardsperson delays
  - urgent tests on routine courier
  - specimens 'miss' courier run
  - schedule of blood collection time does not complement lab testing starting times
- analyser breakdown causes delays

Unacceptable turnaround times for test results
APPENDIX 5 FIGURE 4 Cause-and-effect diagram for problems in reporting procedures: computer terminal and printed reports

CUSTOMERS

no easy access to urgently required results

if results not on computer terminal, need to make telephone enquiries

printed reports forwarded to wrong ward location

POLICIES

report dispatched to E.D. several days after patient initially presented

M.O. to re-access medical record and reassess patient in light of results

report printing not available in the E.D.

SERVICE PROVIDERS

lack of customer focus, results in database but not readily accessible

receive increased number of telephone enquiries for laboratory results

PROCEDURES

computer terminal downtime

terminal access for results non-user friendly non-integrated system unaware when results available mistake old results for current time consuming looking for data

Problems in reporting procedures: computer terminal and printed reports
APPENDIX 6: THE FIVE PROCESS IMPROVEMENT PLANS

Appendix 6.1 PLAN 1: Appropriateness of test requesting

PLAN 1: Improving the appropriateness of test requesting in the early management of AMI.

The CQI Project Team determined that guidelines would be introduced for laboratory testing in the early management of AMI. The Plan was introduced as follows:

1  The mission statement
The mission statement was defined:

To ensure that the Pathology services used are appropriate, effective and efficient for supporting clinical care in suspected AMI.

2  The process improvement strategies
The process improvement strategies focused upon:

2.1 Development of the guidelines
The clinical laboratory testing guidelines for AMI were developed through a participative multidisciplinary approach. All those involved in the process of test ordering were encouraged to contribute to the protocol.

At the request of the CQI Project Team, the Department of Cardiology prepared a draft protocol for laboratory test guidelines in the early management of AMI.

Once prepared, the draft guidelines were then circulated
to other clinical staff for comment. Input was sought from other Visiting Medical Officer (VMO) Cardiologists, Staff Specialists, CCU Medical and Nursing Staff, and Senior Pathology Laboratory staff, including the Specialist Haematologists. The draft guidelines were also discussed at CCU and ED staff meetings.

Suggestions for changes to the guidelines were invited, and fed back to the CQI Project Team for discussion and consideration.

After due consideration was given to the recommendations, some changes were incorporated into the guidelines by the Project Team. Figure 6.4 illustrated the flow chart on the laboratory testing guidelines that was produced by the Project Team.

2.2 Education

Once the guidelines had been finalised, education strategies were required to ensure their successful introduction.

Copies of the approved testing guidelines were distributed back to all VMO Cardiologists, Staff Specialists, Senior Medical and Nursing Staff of the Emergency Department and CCU, Senior Pathology Staff, and members of the CQI Project Team.

Flow charts of the approved test guidelines (as illustrated in Figure 6.2) were displayed in the
Emergency Department and CCU.

Staff meetings were held in both the Emergency Department and CCU to discuss the application of the testing guidelines, the possible use of pre-stamped pathology request forms, and the laboratory requirements for specimen collection. Feedback from the CQI Project Team meetings was also provided to staff.

It was also decided that information on the testing guidelines would be provided to all new staff at future orientation programmes in these departments.

In addition, information notices outlining the test guidelines were placed on noticeboards in the Emergency Department and CCU.

2.3 Request forms

In order to provide for a simplified and ‘user friendly’ system of test ordering, it was decided to utilise pre-stamped test request forms.

Through the CQI process, a series of six rubber stamps were designed. The stamps were to be used on pathology request forms to indicate the laboratory tests being ordered at 0, 6, 12 and 24 hours after admission of the patient. The six request forms used have been included as Appendix 6 Figure 1.

It was further decided by the CQI Project Team that a
### APPENDIX 6  FIGURE 1 Original pre-stamped suspected AMI test request forms

#### SOUTH WESTERN SYDNEY AREA HEALTH SERVICE APA
Private Mail Bag 17, Liverpool NSW 2170

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**COLLECTION DATE**

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**TESTS REQUESTED:**

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<td>FBC</td>
<td>Na</td>
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Private Mail Bag 17, Liverpool NSW 2170

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Page 1 of 3 (Appendix 6  Figure 1)
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Private Mail Bag 17, Liverpool NSW 2170

Please tick Anatomical Pathology Cytology Clinical Chemistry * Haematology Microbiology Serology

SOUTH WESTERN AREA PATHOLOGY SERVICE TEL 02-600-0555 SURNAME MRN
FAX. 02-601-8094 GIVEN NAME VAD

Director Associate Professor D. J. Davies

REQUESTED BY: [OR STAMP]

DOCTORS NAME

ADDRESS

PROVIDER NO.

SIGNATURE

DATE OF REQUEST / / 19

COLLECTION TIME DATE / / 19

Tests requested (In doctor's own handwriting)

SUSPECTED AMI 6 HRS AFTER ADMISSION

APTT

To be collected at approx

Specimen type if not listed

JUNE 90

SOUTH WESTERN SYDNEY AREA HEALTH SERVICE APA
Private Mail Bag 17, Liverpool NSW 2170

Please tick Anatomical Pathology Cytology Clinical Chemistry * Haematology Microbiology Serology

SOUTH WESTERN AREA PATHOLOGY SERVICE TEL 02-600-0555 SURNAME MRN
FAX. 02-601-8094 GIVEN NAME VAD

Director Associate Professor D. J. Davies

REQUESTED BY: [OR STAMP]

DOCTORS NAME

ADDRESS

PROVIDER NO.

SIGNATURE

DATE OF REQUEST / / 19

COLLECTION TIME DATE / / 19

Tests requested (In doctor's own handwriting)

SUSPECTED AMI 12 HRS AFTER ADMISSION

CK CK-MB

To be collected at approx

Specimen type if not listed

JUNE 90
### SOUTH WESTERN SYDNEY AREA HEALTH SERVICE APA

**HOSPITAL**

**Please tick**

**Anatomical Pathology**

**Cytology**

**Clinical Chemistry**

**Haematology**

**Microbiology**

**Serology**

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**Tests Requested (In Doctor's own Hand-writing)**

**SUSPECTED AMI**

**12 HRS AFTER ADMISSION**

**APTT**

To be collected at approx

-----------------

**SUSPECTED AMI**

**24 HRS AFTER ADMISSION**

Na K Cl

Fasting AM Glucose

Total CK CK-MB

Cholesterol Triglyceride

Specimen type if not listed

---

**JUNE 90**

**Page 3 of 3 (Appendix 6 Figure 1)**
working stock of the pre-stamped forms would be kept in a prime location, the ‘Receiving Desk’ in the Emergency Department. The six individual forms were stapled together for easy handling.

The ward assistant of the Emergency Department was given the responsibility of stamping the forms and keeping the stocks of the forms at appropriate levels.

In accordance with the CQI Project Team determination, Emergency Department medical staff treating the patient were required to pre-sign the 6-12 hour forms, forwarding them to the CCU when the patient was transferred.

It was also determined that if the pre-stamped forms were not received by CCU staff, an immediate telephone call would be made to the Emergency Department.

2.4 Blood collection
As the new test ordering guidelines required blood samples to be drawn at specific times, the entire blood collection service to the CCU was reviewed. It was decided that the CCU night staff would collect the early morning blood collections between 6.00 - 7.00 am.

In order to avoid disturbance of the patient during normal sleeping hours, and to maintain reasonably accurate intervals between blood collections, a blood collection protocol was established and provided as Appendix 6 Table 1.
# APPENDIX 6 TABLE 1  Routine blood specimen collection times for suspected AMI

If baseline blood was collected 0000-0559 hours

<table>
<thead>
<tr>
<th>sample</th>
<th>time/day to be collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>6hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>12hr</td>
<td>1200-1759 hours</td>
</tr>
<tr>
<td>24hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>48hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>72hr</td>
<td>0600-1159 hours</td>
</tr>
</tbody>
</table>

If baseline blood was collected 0600-1159 hours

<table>
<thead>
<tr>
<th>sample</th>
<th>time/day to be collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>6hr</td>
<td>1200-1759 hours</td>
</tr>
<tr>
<td>12hr</td>
<td>1800-2359 hours</td>
</tr>
<tr>
<td>24hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>48hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>72hr</td>
<td>0600-1159 hours</td>
</tr>
</tbody>
</table>

If baseline blood was collected 1200-1759 hours

<table>
<thead>
<tr>
<th>sample</th>
<th>time/day to be collected</th>
</tr>
</thead>
<tbody>
<tr>
<td>6hr</td>
<td>1800-2359 hours</td>
</tr>
<tr>
<td>12hr</td>
<td>0000-0559 hours</td>
</tr>
<tr>
<td>24hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>48hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>72hr</td>
<td>0600-1159 hours</td>
</tr>
</tbody>
</table>

If baseline blood was collected 1800-2359 hours

<table>
<thead>
<tr>
<th>sample</th>
<th>time/day to be collected</th>
</tr>
</thead>
<tbody>
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<tr>
<td>12hr</td>
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<td>48hr</td>
<td>0600-1159 hours</td>
</tr>
<tr>
<td>72hr</td>
<td>0600-1159 hours</td>
</tr>
</tbody>
</table>
2.5 The data collection plan

The data collection plan that was used is provided in Chapter 7.2.2. In brief, an audit was undertaken to assess the level of compliance to the laboratory testing guidelines, and to provide feedback to staff.

2.6 Pilot testing Plan 1

The proposed Plan was pilot tested over a seven day period. Staff meetings were held in the Emergency Department and CCU in preparation for the trial. All aspects of the Plan were discussed in detail with the relevant staff concerned.

The Pilot Study was designed primarily to determine whether the proposed strategies would function smoothly in the workplace. It was also implemented to ascertain whether all staff were aware of the improvement strategies and their specific roles in the proposed process. It also determined compliance to the proposed procedures. Data was collected by the CCU senior staff.

During the trial period, an evaluation was undertaken of the lessons learnt. The CQI Project Team investigated whether the process had improved as was expected, and whether the team effort could be further improved.

Feedback from the staff involved in the process and an examination of the data derived resulted in the CQI Project Team introducing the following five measures:
Firstly, further education of the staff on the use of the laboratory testing guidelines. It was found that although some doctors had used the pre-stamped forms, they had handwritten additional tests. A follow up investigation by CCU staff found that these additional tests could not have been clinically justified.

Secondly, further education of the staff on the need to comply with the timing requirements of the tests being requested. As an example, cholesterol testing was being requested (in handwriting) too early following admission.

Thirdly, the Pathology Department was asked to perform only those tests that had been requested on the form. The pilot study had shown that some additional tests (e.g. urea when only a creatinine was ordered) were being performed by the laboratory.

Fourthly, a distinctive red spot label was placed on the top form of the stapled bundle of pre-stamped request forms. This measure was designed to provide the forms with a distinctive, easy recognisable appearance.

Finally, at the request of the Pathology Department, the stamping of the request forms was now undertaken using black ink and not blue. This provided for clearer photostatted copies when distributed to the various laboratory departments within the Pathology service.
3 Implementation of the Plan

Once the pilot study had been completed and the procedural changes determined, the Improvement Plan was implemented. Data was collected and analysed in accordance with the methodology outlined earlier in this section of the chapter.

4 Check of the lessons learnt

Once the Plan had been implemented, the next stage was to check whether the changes had resulted in any improvements as had been expected. An assessment was made of how the team effort could be further improved. No further immediate changes were required to the Plan. However, over subsequent months the following process changes were introduced:

Firstly, as a result of the difficulties experienced by CCU staff in having the 24 hour request form signed, it was decided by the CQI Project Team that this form would also be signed by the Emergency Department medical staff.

Secondly, the wording of the test request form stamps was revised after 3 months of use. However no changes were made to the test types on the forms. The new forms have been included as Appendix 6 Figure 2.

Thirdly, after approximately 8 months it was decided that the Pathology Department’s blood collecting staff would once again be responsible for the early morning blood
### APPENDIX 6 FIGURE 2 Revised pre-stamped suspected AMI test request forms

#### SOUTH WESTERN SYDNEY AREA HEALTH SERVICE APA

**Private Mail Bag 17, Liverpool NSW 2170**

<table>
<thead>
<tr>
<th>Please pick</th>
<th>Anatomical Pathology</th>
<th>Cytology</th>
<th>Clinical Chemistry</th>
<th>Haematology</th>
<th>Microbiology</th>
<th>Serology</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOUTH WESTERN AREA PATHOLOGY SERVICE</td>
<td>TEL: 02-600-0555</td>
<td>FAX: 02-601-8074</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Director</td>
<td>Associate Professor D. J. Davies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**REQUESTED BY**

<table>
<thead>
<tr>
<th>(OR STAMP)</th>
<th>DOCTORS NAME</th>
<th>ADDRESS</th>
<th>PROVIDER NO</th>
<th>SIGNATURE</th>
<th>DATE OF REQUEST</th>
<th>COLLECTION TIME</th>
<th>CLINICAL DETAILS</th>
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</thead>
<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td>1/19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TESTS REQUESTED (In Doctor's own Handwriting)**

#### SUSPECTED AMI INITIAL ASSESSMENT

**FBC**
**APTT**
**P1**
**Na**
**K**
**Cl**
**Creatinine**
**Glucose**

**Total CK**

**CK-MB**

---

### SOUTH WESTERN SYDNEY AREA HEALTH SERVICE APA

**Private Mail Bag 17, Liverpool NSW 2170**

<table>
<thead>
<tr>
<th>Please pick</th>
<th>Anatomical Pathology</th>
<th>Cytology</th>
<th>Clinical Chemistry</th>
<th>Haematology</th>
<th>Microbiology</th>
<th>Serology</th>
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</thead>
</table>

- **SOUTH WESTERN AREA PATHOLOGY SERVICE**
- TEL: 02-600-0555
- FAX: 02-601-8074

**Director**

- Associate Professor D. J. Davies

**REQUESTED BY**

<table>
<thead>
<tr>
<th>(OR STAMP)</th>
<th>DOCTORS NAME</th>
<th>ADDRESS</th>
<th>PROVIDER NO</th>
<th>SIGNATURE</th>
<th>DATE OF REQUEST</th>
<th>COLLECTION TIME</th>
<th>CLINICAL DETAILS</th>
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<tbody>
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<td></td>
<td></td>
<td></td>
<td>1/19</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**TESTS REQUESTED (In Doctor's own Handwriting)**

#### SUSPECTED AMI 6 HRS AFTER ADMISSION

**Total CK**

**CK-MB**

To be collected at approx

**.................................**

- **Specimen type if not listed**

Page 1 of 3 (Appendix 6 Figure 2)
### SOUTH WESTERN SYDNEY AREA HEALTH SERVICE APA

**Private Mail Bag 17, Liverpool NSW 2170**

<table>
<thead>
<tr>
<th>Please Code</th>
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<th>Cytology</th>
<th>Clinical Chemistry</th>
<th>Haematology</th>
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<tr>
<td>Director Associate Professor D. J. Davies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**REQUESTED BY:** [OR STAMP]  
**DOCTORS NAME**  
**ADDRESS**  
**PROVIDER NO.**  
**SIGNATURE**  
**DATE OF REQUEST:** / / 19

**COLLECTION TIME**  
**DATE** / / 19

**CLINICAL DETAILS:**

Where relevant indicate:

Drug  
Last Dose = Date  
Time

**APTX**

**SUSPECTED AMI**  
6 HRS AFTER ADMISSION

**To be collected at approx**

**SPECIMEN:**

**HOSPITAL**

**SPECIMEN TYPE:**

**SPECIMEN TYPE:**

**APTX**

**SUSPECTED AMI**  
12 HRS AFTER ADMISSION

**Total CK**  
**CK-MB**

**To be collected at approx**

**SPECIMEN:**

**HOSPITAL**

**SPECIMEN TYPE:**

**SPECIMEN TYPE:**

Page 2 of 3 (Appendix 6 Figure 2)
collections in the CCU.

5 Act to hold the gain

The next stage involved taking appropriate action to hold the gain in improvement. This involved determining whether further changes were required, standardising the procedures for the laboratory testing guidelines, establishing a measurement and monitoring process, and training the appropriate staff of the Emergency Department, CCU and Pathology.

Once these measures had been carried out to hold the gain, the Project Team continued to meet over the 15 month period to monitor and plan for the next steps of continuous improvement of the process.
APPENDIX 6.2 PLAN 2: Delivery of specimens and request forms

PLAN 2: Improving the delivery of specimens and request form from the Emergency Department to Pathology.

The CQI Project Team developed a set of strategies to improve the process of specimen and request form delivery from the Emergency Department to the Pathology Department. The Plan was introduced as follows:

1. The mission statement

The mission statement was defined:

To ensure that 95% of Emergency Department specimens reach the Pathology Department within 30 minutes of blood collection.

This mission statement was agreed upon at the first CQI Project Team meeting that discussed customer requirements.

2. The process improvement strategies

As discussed earlier, the process improvement strategies targeted for change all the causes of variation that had been determined and subsequently listed in Table 6.5. Overall, the strategies focused upon:

2.1 Re-examining the processes of specimen delivery

A flow chart of the process of specimen and request form delivery from the Emergency Department to Pathology had
been developed at earlier meetings. This had been discussed previously in 6.3.4.2 and illustrated in the flowcharts included as Appendix 4.

In order for the process to be re-examined, the Team Leader met with the Deputy Director of Nursing, the Assistant Director of Nursing in-charge of the Emergency Department (ADON-ED), the Clinical Nurse Specialist of the Emergency Department (CNS-ED) and the Senior Wardsperson on a number of occasions.

At the Bankstown-Lidcombe Hospital all wardspersons are under the supervision of the Division of Nursing.

The role of each individual involved in the process of specimen delivery was clarified. The process under review commenced from the time at which the blood had been collected to its arrival in the Pathology Department.

It was decided that all staff involved in the process would be provided with the necessary information to clarify the steps involved in the appropriate delivery of specimens. Such education would be provided to nursing staff (by ADON-ED and CNS-ED), medical staff (by the Director of the Emergency Department), Pathology staff (by Senior Technologist) and wardspersons (by ADON-ED, CNS-ED and Team Leader).

2.1.1 Priority setting by wardsperson

In consultation with the Senior Wardsperson and the
Deputy Director of Nursing, a review was undertaken of the wardsperson’s setting of priorities in the transport of specimens.

This was undertaken with the prime objective of decreasing the response time for ‘stat’ deliveries to the Pathology Department.

It was decided at a CQI Project Team meeting that patient specimens for ‘stat’ testing would be picked up and delivered within 15 minutes of the call being received by the wardsperson.

All wardspersons, medical, nursing and Pathology staff were advised of the decisions made in this regard.

2.1.2 Acceptance and rejection of blood specimens

It was decided that the previously established policies for the requirements of specimen sample collection, labelling and storage would be made known to all staff involved in the collection, delivery and receipt of Pathology specimens.

It was also decided by the CQI Project Team that the minimum requirements for handwritten specimen labels would be: full name, medical record number, ward, and time and date of collection.

The policies were discussed at Emergency Department, CCU and Pathology Department staff meetings. Copies of the
policy were displayed in prominent positions in blood collection areas within each unit.

2.1.3 Acceptance and rejection of request forms
It was similarly decided that the previously established policies for the requirements of request form completion would be communicated to all staff involved in the collection, delivery and receipt of Pathology specimens.

The introduction of the pre-stamped forms however probably contributed to a decrease in some of the potential problems.

The policies were similarly discussed at Emergency Department, CCU and Pathology Department staff meetings. Copies of the policy were displayed in prominent positions in blood collection areas within each unit.

2.1.4 Specimen tube patient label printing
As there was no formal priority setting for label printing within the clerical services area of the Emergency Department, labels were generally printed in order of the patient’s arrival. Such a process invariably resulted in long delays for urgent cases awaiting patient specimen labels.

It was decided that it was paramount that communication between the Emergency Department clerical and clinical staff needed improvement. A meeting between representatives of both groups in fact decided that an
intercom should be installed in each area. Requests for the rapid printing of specifically named patient labels could then be undertaken over the intercom. It was also made policy that priority for label printing would be given to all patients in the observation ward of the Emergency Department.

All decisions in relation to label printing were formalised as departmental policy and the information brought to the attention of staff at meetings.

2.1.5 Specimen handover in the Pathology Department

The issue of the delivery and handover of patient specimens to Pathology staff was also discussed at the CQI Project Team meetings. Problems were in particular occurring during the ‘after hours’ when wardspersons would deliver specimens to the unattended Pathology Department office. During such occasions, the sole technologist on duty would often not find the specimen until a considerable time later.

It was decided that all specimens would be hand delivered to a member of the Pathology staff. If the office was unattended, wardspersons were now required to locate the Pathology Staff member within the laboratory working area.

All decisions in relation to specimen handover were formalised as departmental policy and the information
brought to the attention of the staff concerned through the various staff meetings.

2.1.6 After-hours 'non-urgent' specimens

Several problems associated with the non-urgent after-hours specimens were raised for discussion. These specimens were currently being left in the Emergency Department until the next morning when the Pathology Department was due to re-open. The issues of specimen deterioration and turnaround time of test results were particularly focused upon.

It was decided that only urgently required laboratory tests could be ordered during the period when the on-site Pathology service was not available at the Bankstown-Lidcombe Hospital. When patient specimens were collected during this period, arrangements were to be made to transport them across to the central laboratory at Liverpool.

All decisions in relation to the after-hours blood collections, especially non-urgent specimens and their handling, were formalised as policy and the information brought to the attention of the staff concerned through the relevant local staff meetings.

2.1.7 The data collection plan

The data collection plan that was used is provided in detail in Chapter 7.2.3. In brief, the following data was
recorded on the Pathology request form:

1. blood collection time- to be recorded by the person collecting the patient's blood specimen.

2. time specimen bag placed in Emergency Department 'box' (ED box)- to be recorded by the person placing the specimen bag in the ED box.

3. time specimen bag is delivered to the Pathology Department- to be recorded by the wardsperson delivering the specimen. The wardsperson is to clock in the time using the device found at the Pathology Reception desk.

2.1.8 Pilot testing Plan 2

The proposed Plan was pilot tested over a fourteen day period. Staff meetings were held in the Emergency Department and Pathology Department in preparation for the trial. All aspects of the Plan were discussed in detail with the relevant staff concerned.

One interesting finding was the fact that even prior to the pilot test being initiated, the single request for wardspersons to commence recording the time of specimen delivery to Pathology, resulted in a significant improvement in the overall specimen delivery time. This was confirmed when the data was collected, analysed and compared with the baseline data that had been derived two months earlier (as described in 6.3.5.2). The results are provided in Chapter 9.3. The CQI Project Team deduced
from this that such dramatic improvements resulted from
the perceived notion amongst the wardspersons and other
staff that an investigation was seemingly underway on
specimen transport delays. In order to obtain more recent
baseline data that was relatively contamination-free it
was decided to review recent request forms.

An audit was therefore undertaken by the Project Team
Leader of request forms during the 28 day period just
prior to the staff being formally asked to record the
various times of collection and delivery. Although only
about 48% of the 'pre-CQI' forms had blood collection
times recorded, the initial expectations of lengthy
delivery delays were confirmed when the new data was
collected and analysed. The results are provided in
Chapter 9.3.

During the trial period, an evaluation was undertaken of
the lessons learnt. The CQI Project Team investigated
whether the process had improved as was expected, and
whether the team effort could be further improved.

Feedback from the staff involved in the process and an
examination of the data derived, resulted in the CQI
Project Team identifying the following two issues that
require immediate attention:

1. Delays in the printing of labels. It was found that
the new intercom was not always being used to communicate
the priority of label printing. This invariably resulted in delays awaiting the printing of urgently required specimen labels. Discussions were held with the clerical and clinical staff of the Emergency Department. Emphasis was placed on the need to further improve the communication between the two areas. In addition, the clinical staff were also encouraged to handwrite patient details on specimen labels when it was obvious that there were delays in the printing of labels.

2. Blood collection times not being recorded. Initially only approximately 50% of request forms had blood collection times recorded. An education programme was devised whereby this aspect was stressed and encouraged at Emergency Department staff meetings.

2.2 Implementation of the Plan
Once the pilot study had been completed and the procedural changes determined, the Improvement Plan was implemented.

Data was collected in accordance with the methodology outlined earlier in this section of the chapter. However, after 4 weeks from the commencement of the collection of data, the practice of recording the time the specimen was placed in the ED box was discontinued.

2.3 Check of the lessons learnt
Once the Plan had been implemented, the next stage was to
check whether the changes had resulted in any improvements as had been expected. An assessment was made of how the team effort could be further improved.

No further immediate changes were required to the Plan.

2.4 Act to hold the gain

The next stage involved taking appropriate action to hold the gain in improvement. This involved determining whether further changes were required, standardising the procedures for the delivery of specimens and request forms, establishing a measurement and monitoring process, and training the appropriate staff of the Emergency and Pathology Departments.

Once these measures had been carried out to hold the gain, the Project Team continued to meet over the 15 month period to monitor and plan for the next steps of continuous improvement of the process.
APPENDIX 6.3  PLAN 3: Turnaround time of test results

PLAN 3: Improving the turnaround time of test results in the early management of AMI.

The CQI Project Team developed a Plan whereby the customer required turnaround times for test results were determined, and then strategies developed to meet these requirements. The Plan was introduced as follows:

1. The mission statement
The mission statement was defined:

   To ensure that Pathology test results are available within a clinically acceptable time frame for the appropriate, effective and sufficient support of clinical care in suspected AMI.

2. The process improvement strategies
The process improvement strategies were developed and focused on:

   2.1 Customer requirements
In liaison with the clinical staff of the Emergency Department and CCU, the CQI Project Team established what each individual test turnaround time (TAT) requirement was for all tests recommended in the guidelines for the first 90 hours of the management of AMI patients.

   The CCU clinical customers of the laboratory service had
voiced total dissatisfaction with the current arrangements that were in place for coagulation studies. The clinical staff had argued strongly that patients on antithrombolytic therapy required a responsive testing service that provided for rapid results of Activated Partial Thromboplastin Time (APTT), especially in the first 24 hours of therapy in AMI. Although a turnaround time of 1.5 hours was sought for APTT assay results, CCU staff stressed that it often took 3-5 hours to obtain results. The pathology service providers however disputed this, claiming APTT results would normally be available 1-1.5 hours after the specimens were received at the Liverpool central laboratory.

Table 6.6 listed the customer requirements for TAT of each test. The CQI Project Team determined that the quoted times were required for 95% of all requests. In this instance, the TAT was defined as the period of time from the specimen arrival at the Pathology Department of the Bankstown-Lidcombe Hospital to the time the results are made available on the ward computer terminal.

A special register was established in the Pathology Department of the Bankstown-Lidcombe Hospital for recording data on turnaround times for test results from patients with suspected AMI. For each specimen received, the following information was recorded in the register each day for a two month period by the clerical staff:
1. blood collection time
2. time specimen received in the Pathology Department.
3. time all results on each patient specimen became available on the computer. This aspect was achieved by the clerk searching for each set of results at 30 minute intervals, commencing from 1 hour after the specimen was received in the Pathology Department.

Further information on the data collection plan is provided in Chapter 7.2.4.

2.2 Improvement potential assessed
The current data on TAT for tests was reviewed and compared with the customer requirements that were listed earlier in Table 6.6. The complete set of results are provided in Appendix 13. Full blood count (FBC); baseline electrolytes and creatinine; APTT (6, 12 and 24 hour samples); and CK (6, 12 and 24 hour samples) were specifically found to have TAT's outside of the acceptable customer required times.

After careful consideration, it was firstly determined that the present off-site APTT testing arrangements could not provide test results consistently within the desired TAT. It was therefore decided that APTT testing would be provided on site at the Bankstown-Lidcombe Hospital. An analyser would be purchased for this purpose and appropriate training provided for the laboratory staff.
Secondly, it was further decided that an improvement exercise would be undertaken to ensure that CK, FBC, electrolyte and creatinine tests would meet customer requirements for TAT.

2.3 Improvement strategies

Several strategies were used to ensure that test results would meet acceptable TAT’s. The measures focused upon current CQI initiatives as well as the introduction of appropriate new ones.

The current strategies that were outlined in Plan 2 for the delivery of specimens and request forms were expanded to also include specimens from the CCU. Education strategies were developed and implemented in line with those previously described in Plan 2. The educational programmes were targeted at the medical and nursing staff of the CCU, and the wardspersons. In addition, it was also expected that the new arrangements for the CCU blood collections would have a positive impact on reducing the overall TAT of obtaining early morning CCU test results. These arrangements allow the CCU Night Staff to collect the early morning (0600-0700 hours) blood specimens and then arrange for their prompt transport to the Pathology Department. This would then allow the courier to transport these early morning specimens to the central laboratory at Liverpool.

One new strategy was the requirement that two blood
specimen tubes be provided when the tests requested included services to be provided both on-site and off-site. The requirement of the second specimen tube was introduced to eliminate the possibility of the specimen missing the courier run to Liverpool. This would occur because the single tube would require centrifugation to separate the serum required for the on-site testing before it was dispatched by courier. Education strategies were developed and implemented for the medical, nursing and laboratory staff.

Another strategy adopted by the CQI Project Team was the need to have specimen testing priority accurately reflected on laboratory test request forms. This was necessary so as to ensure a streamlined and efficient testing service. The rationale behind this move was to ease the bottleneck often created in the laboratory by routine tests being marked as 'stat'. Education programmes for the medical, nursing and laboratory staff were developed and implemented.

2.4 Pilot testing Plan 3
The improvement exercise component of the proposed Plan was pilot tested over a fourteen day period. Staff meetings were held in the Emergency Department, CCU and Pathology Department in preparation for the trial. All aspects of the Plan were discussed in detail with the relevant staff concerned. The CQI Project Team assessed
whether the process had improved as was expected and also
determined whether the overall team effort could be
improved. The data on TAT’s during the trial was
promising, with no further immediate changes required to
the Plan. The results are provided in Chapter 9.

3 Implementation of the Plan
Once the pilot study had been completed, the Improvement
Plan was implemented. Data was collected and analysed for
28 day periods on alternate months throughout the
duration of the CQI intervention. Data collection
commenced in October 1993.

4 Check of the lessons learnt
Once the Plan had been implemented, the next stage was to
check whether the changes had resulted in any
improvements as had been expected. An assessment was made
of how the team effort could be further improved. No
further immediate changes were required to the Plan.

After several months however, the CQI Project Team
decided to revert back to Pathology Department staff
collecting the early morning CCU specimens. An efficient
system accompanied this change with blood collecting
staff ensuring that patient specimens were forwarded to
the Pathology Department in adequate time for their pick-
up by the external courier to Liverpool.
5 Act to hold the gain

The next stage involved taking appropriate action to hold the gain in improvement in TAT. This involved determining whether further changes were required, and training the appropriate staff of the Emergency and Pathology Departments. Once these measures had been carried out to hold the gain, the Project Team continued to meet over the 15 month period to monitor and plan for the next steps of continuous improvement of the process.
APPENDIX 6.4  PLAN 4: Accessibility to computer results

PLAN 4: Improving the clinician's ease of accessibility to computer terminal laboratory results in the early management of AMI.

Data derived from the special Pathology Department TAT register established earlier was used to estimate the degree of accessibility to computer terminal results. The data clearly showed that the system was inefficient, with several attempts being necessary over a period of time to access most patient test results from the computer terminals. The results for the 4 week collection period are provided in Chapter 9.5.

The next stage involved the CQI Project Team investigating the various options that could be used to improve the current poor process of accessing urgently required clinical laboratory test results from the computer terminal. The CQI Project Team, in consultation with the customers of the clinical laboratory service, considered four main options as potential solutions to the problem. These options were:

1. Option 1: The current system is maintained but with CQI strategies introduced to provide improvements.

2. Option 2: The local Pathology Department is to monitor closely the availability of test results for the Emergency Department. Once available, the Pathology
Department would be responsible for providing the Emergency Department with regular updates.

Option 3: The central Pathology Department is to provide the Emergency Department with regular facsimile and/or telephone notification of urgent and abnormal test results.

Option 4: Automatic report printing provided to the Emergency Department. This would allow new laboratory data to be instantly available to the Emergency Department staff.

1. The mission statement
The mission statement was defined:

   To ensure that appropriate systems are in place for the easy access to timely pathology results for the management of patients with suspected AMI.

2. Options consideration
The four options were given due consideration by the CQI Project Team.

Option 1 was regarded as inappropriate by the CQI Project Team. Even when one considered the potential improvements, the current system was cumbersome and non-user friendly.

Option 2 was also regarded as an inappropriate option.
Although this option was regarded as having some merit, it was determined that it would create an added burden to an already very busy Pathology Department.

Option 3 was also regarded as an inappropriate option. There was some concern that this option may not always be possible or practicable for the central laboratory on a 24 hour basis, 7 days per week.

Option 4 was by far the preferred option of all the members of the CQI Project Team. A work order was subsequently submitted to the Area Health Service’s Information Services Department (Computer division), requesting an urgent software upgrade of the Pathology laboratory reporting system to the Emergency Department. To this end, automatic report printing would be provided to the Emergency Department. Such a system would allow new laboratory data to be instantly available to the Emergency Department staff.
APPENDIX 6.5  PLAN 5: Distribution of laboratory reports

PLAN 5: Improving the system for the distribution of printed laboratory reports for patients with suspected AMI.

The CQI Project Team developed a Plan to improve the system for the distribution of printed laboratory test reports to the Emergency Department, on patients with suspected AMI. The Plan was introduced as follows:

1. The mission statement
1. The mission statement was defined:

   To ensure that effective systems are in place for the streamlined distribution to the Emergency Department of printed laboratory reports on patients with suspected AMI.

2. The process improvement strategies

The process improvement strategies were developed and focused on:

2.1 Customer requirements

The CQI Project Team, in consultation with senior Emergency Department staff, determined the requirements for the provision and distribution of printed reports for the Emergency Department. The customers of the service stressed their desire to have a streamlined and efficient
system of receiving printed reports. There was an overwhelming desire to reduce the large volume of often duplicated interim laboratory reports that are received several times daily by the Emergency Department.

At present the disjointed dispatch of interim reports results in medical staff having to continuously review newly arrived reports. It was decided that interim printed laboratory reports would not be issued during the first 24 hours following admission. Interim results would however continue to be accessible from the computer terminals. It was further agreed that the final printed reports, and the interim reports still to be finalised at 24 hours following admission, would be dispatched to the ward as soon as possible.

2.2 The data collection plan

The data collection plan that was used is provided in detail in Chapter 7.2.6. Data was collected for frequency of interim and final printed reports, and the number of medical records requested by Emergency Department clinicians.

In brief, a data collection protocol was developed in order to establish post CQI intervention data. The baseline data had been previously collected over a 14 day period. The special Pathology Department TAT register established earlier was adapted for use in this exercise. The register maintained provisions for the recording of
details of the interim and final printed reports.

Data was also collected on the number of medical records that were requested by the clinical staff of the Emergency Department. The records were used by the clinical staff to follow up the laboratory results received from the printed reports. A record was maintained by the clerical staff of the Emergency Department of all patient records that were requested for the Emergency Department. This list was then matched with the list of names found in the Special Pathology Department TAT register discussed above. The number of requested medical records as then counted for all patients that had printed reports dispatched to the Emergency Department. The data was only compiled over a 6 week period, which included a 14 day pre-test period just prior to the pilot study commencing.

2.3 Education programmes

An educational programme was planned for the Pathology Department to involve all clerical staff in the development and implementation of the system to distribute printed reports to the Emergency Department. In liaison with the Emergency Department clinical staff, interim printed reports for the Emergency Department were to be held back, and only the final printed report forwarded to the Emergency Department. It was however stipulated that interim reports still awaiting results
after 24 hours of the blood being collected, are to be distributed as '24 hour interim reports' to the Emergency Department. An internal system was then developed by the Pathology Department clerks to record, collate and distribute the printed reports.

2.4 Pilot testing Plan 5
The proposed Plan was pilot tested over a fourteen day period. All aspects of the plan were discussed in detail with the relevant staff concerned. The Senior Technologist of the Pathology Department was assigned responsibility for the supervision of the system for the handling, collation and distribution of the printed reports to the Emergency Department. The data confirmed that the new strategies resulted in a significantly reduced number of requests for patient records when compared to the pre CQI period. The full set of results are provided in Chapter 9.

During the trial period, an evaluation was undertaken of the Plan. The CQI Project Team investigated whether the process had improved as was expected, and whether the team effort could be further improved. No significant problems were uncovered during the trial period.

3. Implementation of the Plan
Once the pilot study had been completed and it was decided that no changes were necessary, the Improvement Plan was implemented.
4. Check of the lessons learnt
Once the Plan had been implemented, the next stage was to check whether the changes had resulted in any improvements as had been expected. An assessment was made of how the team effort could be further improved. The full set of results are provided in Chapter 9. No further immediate changes were required to the Plan.

5. Act to hold the gain
The next stage involved taking appropriate action to hold the gain in improvement. This involved determining whether further changes were required, standardising the procedures for the handling, collation and distribution of printed reports, establishing a measurement and monitoring process, and training the appropriate staff of the Pathology Department. Once these measures had been carried out to hold the gain, the Project Team continued to meet over the 15 month period to monitor and plan for the next steps of continuous improvement of the process.

REFERENCES AND NOTES

1. An interim printed report lists results of available tests on a patient. When all results become available the interim report is replaced by a 'final' report.
APPENDIX 7 OVERALL POST-TEST PROCESS OF PATHOLOGY TEST UTILISATION IN EARLY A.M.I.

EMERGENCY DEPARTMENT (E.D.)

TEST REQUEST

1. Patient presents to E.D. with chest pain
2. Triage Nurse assigns priority of treatment
3. Observations, ECG taken
4. M.O. evaluation; history and physical exam.

5. Suspicion of AMI formed
6. CQI test guidelines followed

7. Pre-signed forms signed and used

8. Some tests to Liverpool?
   YES: Additional specimen tube to be collected
   NO: SPECIMEN/REQUEST FORM DELIVERY

8(A). M.O./Nurse collect blood sample
9. E.D. clerks advised labels needed ASAP
10. Tubes labelled; Request form completed
11. Specimen bag placed in E.D. 'pick-up' box
12. Wardsperson called to transport specimens

(NEW PAGE)
CORONARY CARE UNIT

5

34

Are tests required stat?

NO

34(1)

Routine analysis undertaken in laboratory

YES

34(A)

Stat analysis undertaken in laboratory

35

Test results progressively validated in lab

36

All ED/CCU test reports printed & sorted in lab

37

Was patient admitted to ICU?

NO

37(1)

Medical Officer obtains test result report

YES

7

Only final printed report or 24hr interim printed report to E.D.

CCU DAY 2

38 C

CCU DAY 3

39 C

40

Patient assessed with view to transfer to ward

41

END

DISTRIBUTION OF PRINTED REPORTS FOR EMERGENCY DEPARTMENT
DISTRIBUTION OF PRINTED REPORTS FOR EMERGENCY DEPARTMENT

471

42

Results checked by Emergency Department staff

43

Are results abnormal?

43A)

Sent to Medical Record Department for filing

43A)

Medical Record Dept. requested to pull notes

44

E.D Medical Staff check results against records

45

Was appropriate action taken at the time?

45A)

Results noted

45A)

Appropriate action is now taken

46

Have further reports been received?

No further action

PAGE 6 OF 6
(APPENDIX 7)
APPENDIX 8  Worksheet used to audit use of pre-stamped forms and check appropriateness of time of blood collections

<table>
<thead>
<tr>
<th>Admitted Time Date</th>
<th>Name</th>
<th>MRN</th>
<th>Use of pre-stamped forms (Yes/No)</th>
<th>Actual tests ordered collectn time date tests</th>
<th>Additional tests/Justification</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>0hr 6/6hr 12/12hr 24hr 48hr 72hr</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
APPENDIX 9  Worksheet used to record the delivery time of patient specimens from the Emergency Department

<table>
<thead>
<tr>
<th>Patient Name</th>
<th>MRN</th>
<th>Blood collection time</th>
<th>Time placed in 'ED' box</th>
<th>Time delivered to Pathology</th>
<th>TAT</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>MNH</td>
<td>Blood</td>
<td>Collected Time/Date</td>
<td>NO. of interim reports dispatched</td>
<td>Time/Date</td>
<td>Final report dispatched</td>
</tr>
<tr>
<td>------</td>
<td>-----</td>
<td>-------</td>
<td>---------------------</td>
<td>----------------------------------</td>
<td>-----------</td>
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<td></td>
</tr>
</tbody>
</table>
### APPENDIX 11 Worksheet used to collect laboratory test data from the patient medical records

| ID No. / MRN | time | Na | K | Cl | Ur | Cr | Gluc | CK | CK-MB | LD | AST | ALP | GGT | BilT | Prot | Alb | Ca | Mg | PO4 | SUA | Chol | Trig | FT4 | TSH | PI | APTT | WCC | RCC | Hb | Plat | Other tests |
|--------------|------|----|---|----|----|----|------|----|-------|----|-----|-----|-----|------|------|-----|----|----|-----|-----|------|------|-----|----|-----|-----|-----|----|-----|------------------|
|              |      |    |   |    |    |    |      |    |       |    |     |     |     |      |      |     |    |    |     |     |     |     |     |    |     |     |     |     |     |                 |
|              |      |    |   |    |    |    |      |    |       |    |     |     |     |      |      |     |    |    |     |     |     |     |     |    |     |     |     |     |     |                 |
|              |      |    |   |    |    |    |      |    |       |    |     |     |     |      |      |     |    |    |     |     |     |     |     |    |     |     |     |     |     |                 |

475
# APPENDIX 12  Estimated National Pathology Service Costs, Australia 1994

<table>
<thead>
<tr>
<th>Patient Category</th>
<th>Cost of Pathology Services (ASM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total services covered by Medicare*</td>
<td>778.0</td>
</tr>
<tr>
<td>Hospital private inpatients**</td>
<td>93.4</td>
</tr>
<tr>
<td>Other hospital inpatients***</td>
<td>373.6</td>
</tr>
<tr>
<td>Total hospital inpatients</td>
<td>467.0</td>
</tr>
</tbody>
</table>

* 1994 Health Insurance Commission data; includes out of hospital patients and private inpatients.

** 12% of total services covered by Medicare; and as private inpatients represent 20% of the total number of hospital inpatients utilising pathology services.

*** Includes non-private inpatients and veterans affairs inpatients; and represents 80% of total number of hospital inpatients utilising pathology services.
### APPENDIX 13 TURNAROUND TIMES FOR CLINICAL LABORATORY TESTS

#### Appendix 13 Table 1  Comparison of pre-CQI and post-CQI turnaround times for FBC test results

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of tests</th>
<th>Median TAT, hours</th>
<th>Range, hours</th>
<th>p**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>52</td>
<td>2.5</td>
<td>1.0 - 6.0</td>
<td>0.1451***</td>
</tr>
<tr>
<td>Oct 1993</td>
<td>46</td>
<td>2.0</td>
<td>1.0 - 4.0</td>
<td>0.1198***</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>63</td>
<td>2.0</td>
<td>1.0 - 4.0</td>
<td>0.0289</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>54</td>
<td>2.0</td>
<td>1.0 - 4.5</td>
<td>0.0313</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>56</td>
<td>2.0</td>
<td>1.0 - 4.0</td>
<td>0.0384</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>55</td>
<td>2.0</td>
<td>1.0 - 4.0</td>
<td>0.0093</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>55</td>
<td>2.0</td>
<td>1.0 - 4.5</td>
<td></td>
</tr>
</tbody>
</table>

* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.

#### Appendix 13 Table 2  Comparison of pre-CQI and post-CQI turnaround times for baseline electrolyte and creatinine test results

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of tests</th>
<th>Median TAT, hours</th>
<th>Range, hours</th>
<th>p**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>52</td>
<td>1.5</td>
<td>0.5 - 7.0</td>
<td>0.0246</td>
</tr>
<tr>
<td>Oct 1993</td>
<td>47</td>
<td>1.0</td>
<td>0.5 - 6.0</td>
<td>0.1127***</td>
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<tr>
<td>Dec 1993</td>
<td>63</td>
<td>1.5</td>
<td>0.5 - 6.0</td>
<td>0.8323***</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>55</td>
<td>1.5</td>
<td>0.5 - 7.5</td>
<td>0.0181</td>
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<tr>
<td>Apr 1994</td>
<td>56</td>
<td>1.0</td>
<td>0.5 - 5.5</td>
<td>0.0209</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>55</td>
<td>1.0</td>
<td>0.5 - 5.5</td>
<td>0.0190</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>55</td>
<td>1.0</td>
<td>0.5 - 5.5</td>
<td></td>
</tr>
</tbody>
</table>

* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.
Appendix 13 Table 3  Comparison of pre-CQI and post-CQI turnaround times for baseline coagulation studies test results

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of tests</th>
<th>Median TAT, hours</th>
<th>Range, hours</th>
<th>p**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>52</td>
<td>3.0</td>
<td>2.5 - 6.0</td>
<td>-</td>
</tr>
<tr>
<td>Oct 1993</td>
<td>46</td>
<td>2.5</td>
<td>2.5 - 4.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>62</td>
<td>3.0</td>
<td>2.5 - 7.0</td>
<td>0.4131**</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>55</td>
<td>3.0</td>
<td>2.5 - 6.0</td>
<td>0.2632**</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>56</td>
<td>2.5</td>
<td>2.0 - 5.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>56</td>
<td>2.5</td>
<td>2.5 - 6.5</td>
<td>0.0157</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>55</td>
<td>2.5</td>
<td>2.5 - 6.0</td>
<td>0.0275</td>
</tr>
</tbody>
</table>

* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.

Appendix 13 Table 4  Comparison of pre-CQI and post-CQI turnaround times for APTT test results

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of tests</th>
<th>Median TAT, hours</th>
<th>Range, hours</th>
<th>p**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>65</td>
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<td>2.5 - 6.0</td>
<td>-</td>
</tr>
<tr>
<td>Oct 1993</td>
<td>61</td>
<td>2.5</td>
<td>2.5 - 5.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>71</td>
<td>3.0</td>
<td>2.5 - 5.5</td>
<td>0.0802***</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>54</td>
<td>3.0</td>
<td>2.5 - 6.0</td>
<td>0.2314***</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>62</td>
<td>2.5</td>
<td>2.0 - 5.0</td>
<td>0.0013</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>58</td>
<td>2.5</td>
<td>2.5 - 6.0</td>
<td>0.0001</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>63</td>
<td>2.5</td>
<td>2.5 - 5.5</td>
<td>0.0183</td>
</tr>
</tbody>
</table>

* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.
Appendix 13 Table 5  Comparison of pre-CQI and post-CQI turnaround times for 24-72 hr electrolyte test results

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of tests</th>
<th>Median TAT, hours</th>
<th>Range, hours</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>136</td>
<td>3.5</td>
<td>0.5 - 11.0</td>
<td>-</td>
</tr>
<tr>
<td>Oct 1993</td>
<td>129</td>
<td>3.0</td>
<td>0.5 - 7.5</td>
<td>0.0027</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>152</td>
<td>3.0</td>
<td>0.5 - 7.0</td>
<td>0.0740***</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>144</td>
<td>3.5</td>
<td>1.0 - 8.5</td>
<td>0.0560***</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>146</td>
<td>3.0</td>
<td>0.5 - 10.0</td>
<td>0.0062</td>
</tr>
<tr>
<td>Jun 1994</td>
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<td>0.5 - 9.5</td>
<td>0.0001</td>
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<tr>
<td>Aug 1994</td>
<td>141</td>
<td>3.0</td>
<td>0.5 - 8.0</td>
<td>0.0017</td>
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</tbody>
</table>

* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.

Appendix 13 Table 6  Comparison of pre-CQI and post-CQI turnaround times for CK test results

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of tests</th>
<th>Median TAT, hours</th>
<th>Range, hours</th>
<th>p**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>199</td>
<td>2.5</td>
<td>1.5 - 5.5</td>
<td>-</td>
</tr>
<tr>
<td>Oct 1993</td>
<td>185</td>
<td>2.0</td>
<td>1.5 - 5.0</td>
<td>0.0015</td>
</tr>
<tr>
<td>Dec 1993</td>
<td>219</td>
<td>2.0</td>
<td>1.5 - 5.0</td>
<td>0.0001</td>
</tr>
<tr>
<td>Feb 1994</td>
<td>202</td>
<td>2.5</td>
<td>1.5 - 5.5</td>
<td>0.1603***</td>
</tr>
<tr>
<td>Apr 1994</td>
<td>195</td>
<td>2.0</td>
<td>1.5 - 6.0</td>
<td>0.0001</td>
</tr>
<tr>
<td>Jun 1994</td>
<td>207</td>
<td>2.0</td>
<td>1.5 - 5.5</td>
<td>0.0056</td>
</tr>
<tr>
<td>Aug 1994</td>
<td>192</td>
<td>2.0</td>
<td>1.5 - 5.5</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.
APPENDIX 13 TABLE 7  Comparison of pre-CQI and post-CQI turnaround times for CK-MB test results

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of tests</th>
<th>Median TAT, hours</th>
<th>Range, hours</th>
<th>p**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul 1993*</td>
<td>195</td>
<td>3.5</td>
<td>3.0 - 6.5</td>
<td>-</td>
</tr>
<tr>
<td>Oct 1993</td>
<td>182</td>
<td>3.0</td>
<td>2.5 - 5.0</td>
<td>0.0012</td>
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* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.

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* pre-CQI test data; ** significance level obtained from the comparison of individual pre-CQI and post-CQI data by use of the Mann-Whitney U test; *** not significant.
A TOTAL QUALITY MANAGEMENT APPROACH
TO APPROPRIATE CLINICAL LABORATORY TEST UTILISATION
IN ACUTE MYOCARDIAL INFARCTION

G. Isouard, B.Sc.(UNSW) M.H.A.(UNSW)

Doctor of Philosophy,
Faculty of Health,
The University
of Western Sydney Macarthur.

April, 1996
PLEASE NOTE

The greatest amount of care has been taken while scanning this thesis,

and the best possible result has been obtained.
I certify that this thesis has not been submitted for a higher degree to any other university or institution.

I also certify that this thesis is an original contribution. All sources of information (references) have been acknowledged.

........................
Godfrey Isouard
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I am enormously indebted to my supervisor, Professor Graeme Rawson, former Dean of the Faculty of Health, for his invaluable input to the study. Professor Rawson made valuable suggestions to the many drafts of this manuscript. I appreciate sincerely his guidance, encouragement, patience and personal support.

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This study is dedicated to my family. My loving wife Linda has been a tower of strength to me, providing love, support and encouragement when I needed it most. My children Amanda and Christopher have also been very understanding and I valued highly their love, patience, support and tolerance throughout this demanding period.
ABSTRACT

The first goal of this investigation was to undertake a non-equivalent quasi-experimental design to test the effect of a Total Quality Management (TQM) approach to improve the appropriateness of clinical laboratory test utilisation in the management of early acute myocardial infarction (AMI). As it is rare that any form of experimental design is used in such instances, the study is therefore characterised by demonstrably high levels of internal and external validity.

The study was conducted at two public hospitals in Sydney, Australia over a 30 month period, and in two stages—pre and post TQM intervention. One group of hospital patients was designated the ‘experimental’ group, and the other the ‘control’ group. Only the experimental group received the TQM intervention. Laboratory test ordering was predominantly undertaken by the Resident Medical Officers of each hospital.

It was hypothesised that a TQM approach to the delivery of pathology services would significantly contribute to an improvement in the appropriateness of clinical laboratory test ordering.

The second integral goal was to develop a TQM program as the intervention strategy. In order to test the hypothesis, the investigation sought to achieve several objectives. These included the development of a TQM environment for pathology services, the development of a TQM model for the appropriate
utilisation of laboratory tests in the early management of AMI, the introduction and evaluation of the TQM strategies, and an assessment of the TQM approach on the overall quality of care provided to the patient with AMI. These aspects, although integral to intervention in the study, also provide a valuable component in their own right and are therefore examined in detail to make the intervention process explicable and to aid subsequent replication.

Using specifically a Continuous Quality Improvement (CQI) FOCUS-PDCA model, a multidisciplinary team was empowered to make appropriate changes in order to improve a variety of problem areas that affected the total pathology service. The Project Team was functionally based and included representatives from the Emergency Department, Coronary Care Unit, Pathology Department, Cardiology Division and Medical Administration.

Improvement was directed at the total system of pathology testing and not just test ordering, because appropriate test ordering was considered to be dependent upon all aspects of the pathology service-customer relationship.

The existing system of testing at the experimental group hospital had the presenting problems typical of most hospital pathology services in Australia. There were significant delays in the pick-up and delivery of specimens, no standardised test ordering guidelines were available, blood specimens for critical tests were being drawn at
inappropriate times, a slow turnaround time for some test results existed, a non-user friendly reporting mechanism was in operation and there was poor communication between the laboratory service providers and its customers.

The introduction of the CQI strategies resulted in a statistically significant improvement to the appropriateness of laboratory test utilisation in the management of patients with AMI. The number of tests per confirmed AMI admission was reduced by 43.5% (p<0.0001), from 69.7 tests (pre-CQI) to 39.4 tests (post-CQI). Similarly, non-clinically indicated tests were reduced by 81.7% (p<0.0001) over the period of investigation. Overall, there was a 10.6% increase in the number of clinically recommended tests requested by clinicians as a function of the introduction of the CQI strategies.

It was observed that the introduction of a TQM environment had provided a more committed, integrated and motivated clinical care effort towards improving the appropriateness of test ordering. Such team efforts were accompanied by demonstrated customer satisfaction at various aspects of the laboratory service and further benefits to patient care. Patient care benefited greatly from the highly significant changes towards more appropriate timing of blood collections for cardiac enzyme testing (p<0.0001). Other benefits included overall improvements to the turnaround time of test results, reductions in specimen delivery delays, more appropriate use of clinical laboratory tests, a streamlined
distribution of printed reports and marked improvements in communication between staff involved in the process of test ordering.

Of major importance was the finding that the CQI strategies resulted in substantial savings of 23.0% of the overall cost of pathology services. The costs of pathology services for confirmed AMI were reduced from $177.95 per admission to $136.57 per admission. Following a cost analysis it was estimated that if the CQI strategies were to be directed at the entire pathology service of the experimental group, and not just suspected AMI, an annual saving of $371,073 would result. Similarly, if the strategies were to be introduced successfully throughout all hospitals in Australia, it would potentially result in an annual projected major saving of $112.7M.

Adoption of the TQM approach appears to be a strategy worthy of exploration by laboratory directors and health administrators interested in improving patient care while at the same time reducing expenditure.
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