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Applications of quality management in pathology laboratories

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APPLICATIONS OF QUALITY MANAGEMENT IN PATHOLOGY LABORATORIES

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CERTIFICATE

I certify that the substance of this thesis has not already been submitted for any degree, is not currently being submitted for any other degree, and was undertaken or published since the time of my Application and Candidature for this degree,

Where multi-authored published works or manuscripts submitted are included as Chapters of this Thesis, I certify that I am the senior and corresponding author for such works and publications.

Leslie Burnett

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It is a pleasure to acknowledge the assistance of my many colleagues and co-workers with whom I have had the opportunity to work on various aspects of this project. In particular, I would like to single out the following of my colleagues, with whom a particular rapport has developed and new and valuable ideas have arisen:

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- Mark Mackay, Ann Webber, Dick Groot Obbink and other members of the PaLMS Management Team, at Pacific Laboratory Medicine Services (PaLMS), Northern Sydney Area Health Service.
- Doug Chesher, Gabe Hegedus Mark Mackay and Anné Proos, at both ICPMR and again at PaLMS.
- Colin Mills, of the Australian Quality Awards Foundation, and Lindsey Hamilton, of the Total Quality Management Institute, at the Australian Quality Council (now part of Standards Australia).

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ABSTRACT

Objective: To assess the feasibility of applying Quality Management philosophies and techniques to pathology laboratories.

Design: Series of case studies.

Setting: Two tertiary referral pathology laboratories in Australian University teaching hospitals.

Intervention: Application of Continuous Quality Improvement techniques to complex laboratory processes; Implementation of formal Quality Systems into laboratories; Introduction of a new Laboratory Information System.

Measurement: Measurement of changes in key performance indicators.

Results: Statistically significant improvements in a variety of key performance indicators, reduction in frequency of incidents, and improvement in surrogate clinical outcomes were achieved using Quality Management approaches in pathology laboratories. Comparison of environments associated with introduction of a new Laboratory Information System identified the presence of a formal Quality System as a key factor associated with superior laboratory performance.

Conclusion: Quality Management can be applied successfully to a variety of pathology laboratory environments, and can result in significant improvements in product and service quality. A key success factor in implementing Quality Management may be the introduction of a formal Quality System.

ABBREVIATIONS

The following non-standard abbreviations are used in the text of this Thesis:

AACB	=	Australasian Association of Clinical Biochemists
ACHS	=	Australian Council on Healthcare Standards
CAP	=	College of American Pathologists
CQI	=	Continuous Quality Improvement
ISO	=	International Standards Organisation
KIMMS	=	Key Incident Monitoring and Management System
LIS	=	Laboratory Information System
PT	=	Proficiency Testing
QA	=	Quality Assurance
QASEC	=	Quality Assurance, Scientific and Education Committee
QM	=	Quality Management
RCPA	=	Royal College of Pathologists of Australasia
TQM	=	Total Quality Management

Other specialised abbreviations contained within the various research Chapters of this Thesis are introduced and defined in the research manuscripts and/or publications forming those Chapters.

TABLE OF CONTENTS

1 INTRODUCTION AND LITERATURE REVIEW:

DEFINING THE RESEARCH QUESTION

This Thesis describes work undertaken by me, or under my supervision and direction in my pathology laboratories, over the 12-year period 1990-2002. The format of the Thesis consists of various peer-reviewed, published papers, linked by a narrative that describes the relationship between the papers. These included papers focus on work during the latter half of this period 1996-2002, during which time I applied for and became a candidate for the degree of Doctor of Business Administration.

Ten years ago Quality Management (QM) * was in its infancy in Healthcare[1], and was virtually unknown in Pathology Laboratories. While it was then generally accepted that QM may be applied to good effect in industrial processes, there was scepticism whether QM was applicable in Healthcare, for medicine was "different".[2] Medicine was considered a "qualitative" discipline, with few parallels or analogues to engineering and industrial processes.

In 1990-91, at a Sydney conference of the Australian Council on Healthcare Standards, I presented initial case studies that suggested QM could be applied in a

* Throughout this Thesis, I will use the term "Total Quality Management" (TQM) to refer to overall management philosophy, and I will use the term "Continuous Quality Improvement" (CQI) to refer to the various tools and processes commonly used to implement procedural improvements. I will use the term "Quality Management" (QM) as the generic term to refer to the eclectic approach encompassing (TQM+CQI).

pathology laboratory[3, 4]. Our laboratory was a Clinical Chemistry laboratory, where Clinical Chemistry is a specialised part of the broader area of Pathology. This laboratory was a Department within a large tertiary-referral university teaching hospital pathology organisation. These preliminary studies were followed by a series of other studies arising from our laboratory[5, 6], all of which clearly demonstrated the successful application of Continuous Quality Improvement (CQI) techniques to bring about dramatic improvements in laboratory performance.

Our work resulted in considerable discussion within the Clinical Chemistry/ Clinical Biochemistry discipline of the Australian pathology profession and industry, and extending from that to the broader Australian Healthcare and International pathology industry as a whole[7, 8, 9, 10, 11, 12, 13]. It was becoming clear and was now becoming accepted that these TQM philosophies and CQI techniques were able to deliver dramatic improvements in product and service quality within the pathology laboratory environment. However, it was not so clear whether the techniques that had been developed in my laboratory were sufficiently generic to be applied to other branches of pathology. It was also questioned whether these techniques and approaches would be sufficiently portable to be regarded as the only, or even the optimal, way of pursuing quality improvement across entire organisations, or between different organisations.

Internal discussion within my own laboratory considered these questions, and also focussed on the more fundamental question of whether the improvements we had achieved and demonstrated would be sustainable. While significant improvements in

product and service had been achieved, each existed in isolation. There did not exist as yet a systematic framework able to ensure that gains made would be held. There also did not exist a management framework that would ensure that similar gains lying elsewhere and not yet discovered or made would be systematically discovered and addressed.

The next phase of our work consisted in defining, developing and describing this needed framework.

Firstly, we developed a model Quality System for Total Quality Management (TQM) in the pathology laboratory[14]. Publication of this paper was encouraged and supported by the Australasian Association of Clinical Biochemists ("AACB"), the peak laboratory organisation representing Clinical Chemistry/ Clinical Biochemistry, and one of the peak laboratory organisations in Australia and New Zealand. I was also invited by the Australian Quality Awards Foundation (later to become part of the Australian Quality Council, and more recently part of Standards Australia) to contribute these concepts towards the development of the Health Services criteria for the Australian Quality Awards (later to become the Australian Business Excellence Awards)[15].

The Introduction above has briefly described the rapid and progressive development of a TQM framework, and application of CQI tools, to a single laboratory Department within a large and complex pathology organisation. This phase resulted in the definition of a proposed generic Quality System that could be applied to single or to

multiple laboratory disciplines. This Thesis will describe the next phase in development of these ideas.

My Thesis consists of asking the research question of whether one can apply the above framework to various complex, and often multi-disciplinary projects in a large pathology organisation. Successful application was to be assessed by statistically significant changes in various quantitative laboratory outputs and outcomes (described in the next section of this Thesis).

As will be described in the Chapters of this Thesis, I have been able to show that this framework can, indeed, be applied successfully in large pathology organisations. Application of these techniques has led to improvements in product, service and business quality previously considered unobtainable. The work of this Thesis has contributed in large part to a change in the culture prevailing in contemporary Australian pathology laboratories, and has now become an accepted part of modern pathology practice.

Figures 1, 2 and 3 (following pages) illustrate the relationship between the various studies described in this Thesis.

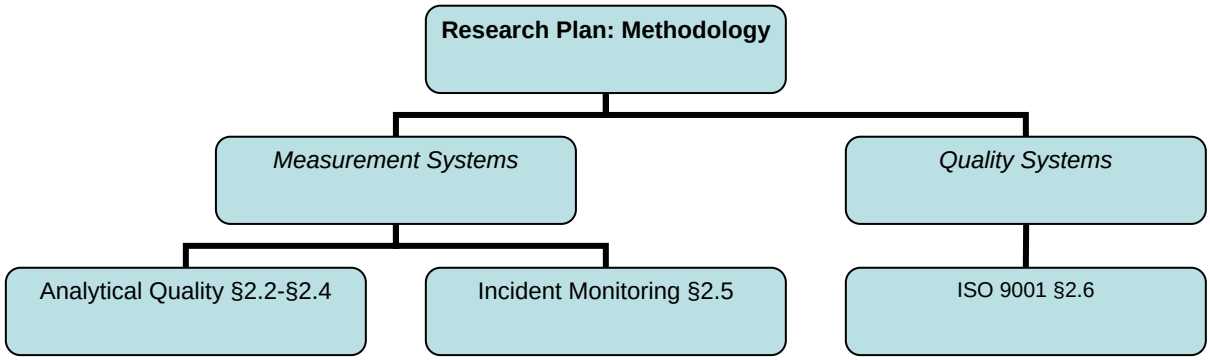


Figure 1: Relationship between the Methodologies described in §2.

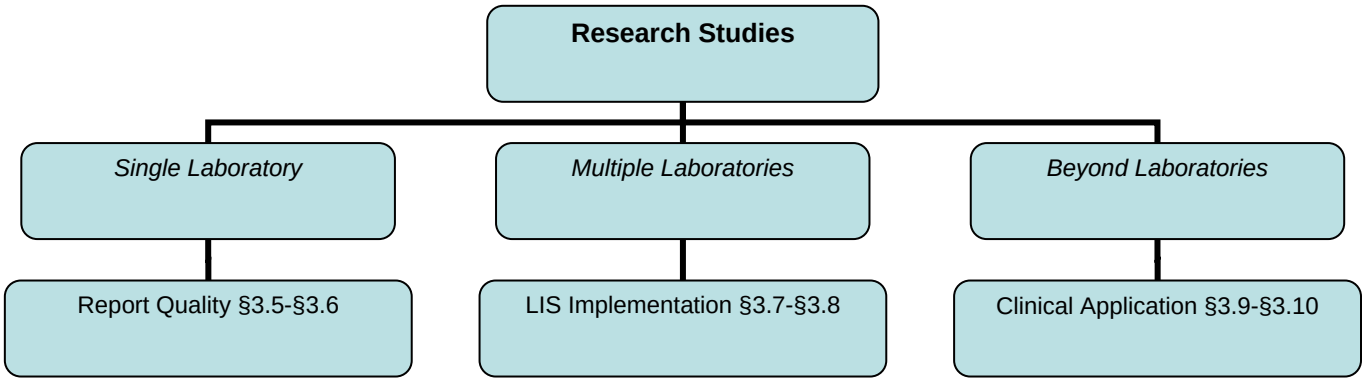


Figure 2: Relationship between the Research Studies described in §3.

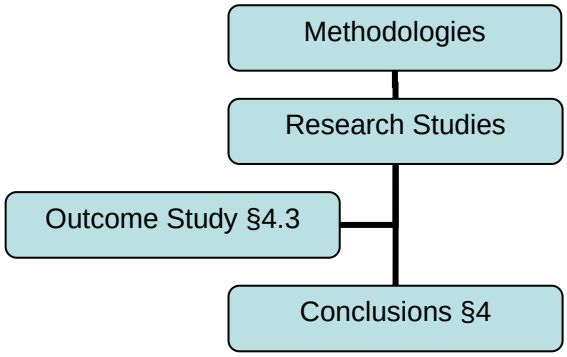


Figure 3: Relationship between Methodologies (§2), Research Studies (§3) and Conclusions (§4).

As the field is still very young and immature, it was always considered likely that each research study might lead to a number of collateral discoveries. A subsidiary research outcome was therefore expected to be the discovery of a number of additional organisational improvement strategies or outcomes revealed by the core study.

2 METHODOLOGY:

DEFINING THE MEASUREMENTS SYSTEMS

2.1 Introduction

As described in the Introduction, we developed a model Quality System for TQM in the pathology laboratory. Using this new framework, it has become possible to tackle increasingly more complex and ambitious projects in laboratory medicine. In order to demonstrate the effects of our CQI interventions, and to monitor and maintain the improvements arising from these interventions, it was necessary to have quantitative measurement systems.

Appropriate measurement systems for medical interventions require measurement of improvements in patient outcomes. However, in pathology and laboratory medicine, it is uncommon for the pathologist to be in direct patient contact. In pathology, it is more usual to define a series of "surrogate" patient outcomes, which represent key outputs of pathology with capacity or potential to influence actual patient outcomes.

The three generic key outputs of a generic pathology laboratory are:

- Product quality
- Service quality
- Cost of production, or other measurements of productivity

Product quality is synonymous with "analytical quality". This is monitored by laboratory participation in various external Proficiency Testing ("PT") or Quality Assurance Programs[16]. The largest PT program in Australasia is RCPA Quality

Assurance Programs Pty Ltd†. While details differ between the sub-disciplines of Pathology, in general the PT program distributes a “blind” sample to the laboratory for analysis, the laboratory performs the analysis as if it were a true patient specimen, and the laboratory’s results are analysed and compared to the “true” result, as well as being compared with the actual results returned by other participants. Current statistical analysis of PT data is well suited to detecting and measuring short-term changes in laboratory analytical performance, but is not designed to measure long-term trends in laboratory analytical performance. Although not the core focus of this Thesis, we found it necessary to develop new measurement tools to assess these long-term trends in laboratory analytical performance. We developed new statistical tools to enable the laboratory’s analytical performance to be measured over extended periods of time, so as to be able to detect changes in the underlying level of analytical quality. These techniques have subsequently also found application in basic pathology, unrelated to QM. These new measurement systems are presented as Chapters 2.2, 2.3 and 2.4 of this Thesis.

Service quality relates to all non-analytical aspects of the patient encounter with the pathology service, the specimen collection, speed of delivery, accuracy of transcription of patient identification information, timeliness of the analysis and result reporting, occurrence of any adverse incidents, and the satisfaction of both the patient and the referring doctor with the entire professional experience.

† http://www.rcpaqap.com.au (May 2002)

There is currently no universally accepted methodology for measuring or comparing service quality.

The College of American Pathologists ("CAP")‡ offers a "Q-Probe" program, which investigates specific aspects of service quality on an intermittent and *ad hoc* basis. While there are a few Australian laboratories participating in Q-Probes, it is not in common use in Australia.

The Australian Council on Healthcare Standards ("ACHS") provides a variety of products and services for accreditation and quality improvement for the full range of health care organisations§. One of these services is to conduct a survey of "Clinical Indicators", some of which are relevant to Pathology. Only a small number of Australian pathology services (and then mainly those associated with ACHS-accredited hospitals) currently participate in this program. The program is currently being reviewed to improve the selection, relevance and definitions of the service indicators.

The Royal College of Pathologists of Australasia ("RCPA"), through its Quality Assurance, Scientific and Education Committee ("QASEC"), is developing a program to measure "adverse incidents" in pathology. The program, to be known as the Key

‡ http://www.cap.org (May 2002)

§ http://www.achs.org.au (May 2002)

Incident Monitoring and Management System ("KIMMS"), is currently undergoing pilot testing, but is also not yet in widespread use in Australia.

As there is no standard methodology for measuring service quality, it was necessary to either adapt one of the existing systems, or to develop my own measurement systems. As I am either on the management committee, or else involved with the review, of all of the service quality programs described in the previous paragraphs, I was ideally placed to assess whether any of these programs would be suitable for this research role. The following measurement systems were to be employed in this research study:

1. Transcription and Patient Identification Error Rates could not be assessed at the necessary level of detail by any of the above measurement systems. It was therefore necessary to develop my own measurement systems. Chapter 2.5 consists of a paper that surveyed Australian pathology laboratories to determine baseline levels of Transcription and Patient Identification error rates[17]. This paper was selected for an Editorial in the Medical Journal of Australia[18] and attracted considerable international media interest. Selected dimensions of these measures (and especially transcription and identification error rates) were then used in Chapters 3.5 and 3.6.

2. Incidents could be assessed by using an adaptation of the RCPA QASEC KIMMS data set.** This measurement system was used in Chapters 3.7 and 3.8.
3. Cycle time ("Turn-around time", or "TAT" in pathology jargon) could be assessed by adapting the data set used in one of the ACHS Clinical Indicators. This measurement system was used in Chapter 3.8.

The third output of laboratories relates to their efficiency and productivity. This dimension is not the current focus of my Thesis, although is being addressed in a separate research study of mine through the RCPA Quality Assurance Programs' Benchmarking in Pathology Program††.

The above focus on the development of measurement systems contains an implicit assumption: that the laboratory is sufficiently well organised and managed to implement the measurement systems in a disciplined and robust manner. As described in the Introduction, I have defined the generic requirements for implementing a Quality System in a pathology laboratory, so as to support QM and its constituent CQI activities. In Chapter 2.6, I have described the process of successful

** To be precise, the KIMMS project was developed by me and arose from the measurement systems described in this Thesis. Development of KIMMS occurred contemporaneously with the research studies described in this Thesis.

†† http://www.rcpaqap.com.au (May 2002)

implementation of ISO 9001[19] in my laboratory‡‡, to enable the necessary measurement infrastructure to be assured.

The relationships between the various Chapters in the Methodology section are diagrammatically illustrated in Figure 1 (shown earlier, and reproduced again here):

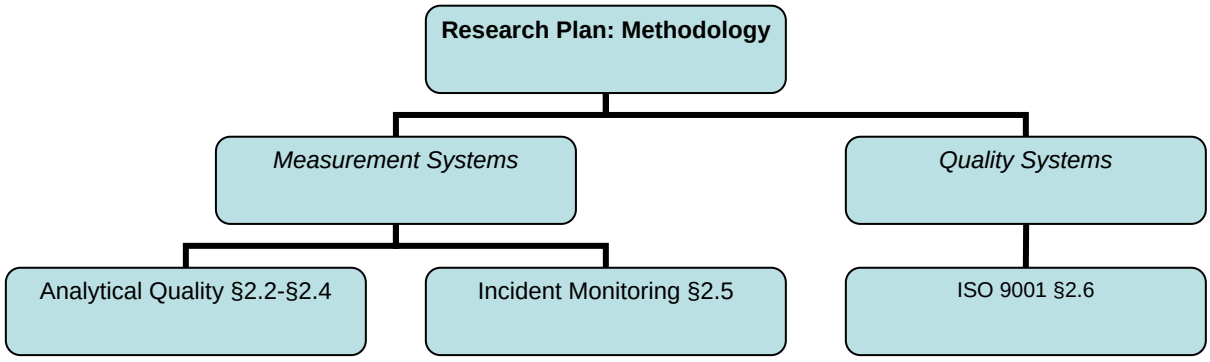


Figure 1: Relationship between the Methodologies described in §2.

‡‡ At the time of publication of this paper, my laboratory was the first laboratory in Australia to be certified and accredited to ISO 9001. Since that time, accreditation to an international Quality System standard has not only become accepted, accreditation to ISO/IEC Guide 25, and more recently ISO/IEC 17025:1999, has become mandated by law for all Australian medical laboratories seeking eligibility for participation in the Medicare payment system.

2.2 Research Methodology: Using Shewhart p control charts of external quality-assurance program data to monitor analytical performance of a clinical chemistry laboratory

Background: Techniques of statistical process control are widely used by the manufacturing industry to detect and eliminate defects during production. More recently, these techniques have been applied to a variety of processes within the clinical laboratory.

Methods: We have investigated the application of Shewhart's *p* control charts in our laboratory's external quality assurance program to monitor the long-term performance of our laboratory's analytical quality. We have explored methods for interpreting these charts as well as some of their limitations, which include minimum subgroup size and dependence on constant specification limits.

Results: The *p* control charts have been able to detect long-term changes in our laboratory's analytical performance that would have been difficult to detect by more-conventional techniques.

Conclusion: These charts may be not only a simple method for the long-term monitoring of analytical performance of a laboratory, but also of use to the organizers of external quality-assurance programs.

This paper has been published[20] as:

Chesher D and Burnett L (1996) Using Shewhart '*p*' Control Charts of External Quality Assurance Program Data to Monitor the Analytical Performance of a Clinical Chemistry Laboratory. *Clin Chem* **42**:1478-82.

2.3 Research Methodology: Application of Process Capability to Quality Control in a Clinical Chemistry Laboratory

Background: In the manufacturing industry, the concept of process capability has been used to quantify the relationship between product specification or tolerance and the measured process performance. The capability ratio (C_p) is the most fundamental of the indices used to measure this relationship.

Methods: We evaluated the use of C_p to select quality control algorithms for various clinical chemistry analyses.

Results: Following introduction of this quality control strategy, there was an immediate, significant and sustained improvement in the analytical quality of the laboratory.

Conclusion: We have developed a simple scheme for classifying clinical chemistry analytical processes on the basis of their C_p.

This paper has been published[21] as:

Burnett L, Hegedus G, Chesher D, Burnett J and Costaganna G (1996) Application of Process Capability to Quality Control in a Clinical Chemistry Laboratory. *Clin Chem* **42**:2035-7.

2.4 Research Methodology: Equivalence of Critical Error Calculations and Process Capability C_{pk}

Background: The concept of process capability has been used by the manufacturing industry to quantify the relationship between product specification and the measured process performance. In contrast, clinical chemistry laboratories have used the approach of selecting Quality Control algorithms based on the concepts of medically important critical systematic error (ΔSE_c) and critical random error (ΔRE_c).

Methods and Results: We have demonstrated that the approaches used in calculating process capability, and that used in calculating critical systematic error and critical random error are mathematically equivalent.

Conclusion: A unification of approaches based around process capability and those around medically important critical errors is now possible. There is now available a common language between clinical chemistry and quality professionals in the manufacturing industry.

This paper has been published[22] as:

Chesher D and Burnett L (1997) Equivalence of Critical Error Calculations and Process Capability C_{pk}. [Letter] *Clin Chem* **43**:1100-1101.

2.5 Research Methodology: Error rates in Australian chemical pathology laboratories

Objective: To measure transcription and analytical errors made by Australian chemical pathology laboratories.

Design: Retrospective data collection covering the period 1 November 1993 to 1 April 1994.

Main outcome measures: Error rates in transcribing information from request forms to computer record systems, and laboratory performance on chemical analysis.

Results: Pathology laboratories had a transcription-error rate of up to 39% and an error rate of up to 26% for analytical results. The worst-performing laboratory had errors (of patient identification or results of analysis) in 46% of requests. The three best-performing laboratories achieved 85% error-free reporting, with one achieving 95%.

Conclusions: Error rates in Australian pathology laboratories vary widely, but may be as high as 46% for all specimens in some laboratories. The types of error reported were under the control of the laboratory, and would affect the accuracy of reported pathology test results, with potential adverse outcomes for patient care and inefficient use of health-care resources. There is a need to establish broader quality assurance programs and performance requirements to reduce these types of errors.

This paper has been published[23] as:

Khoury M, Burnett L and Mackay M (1996) Error rates in Australian Chemical Pathology Laboratories. *Med J Aust* **165**:128-130.

This paper was selected to be the subject of an Editorial in the above journal.

2.6 Research Methodology: Implementation of ISO 9001 in a medical testing laboratory

Background: A Clinical Chemistry Department implemented ISO 9001-1987 and ISO 9001-1994.

Methods and Results: Practitioner Report that describes the Quality System developed for accreditation, and which has been maintained since accreditation.

Conclusion: ISO 9000 Quality Systems can be applied to medical testing laboratories, and can be implemented with minimum resource costs. However, implementation of ISO 9000 at the level of individual Departments is not ideal. Greater improvements are possible when this process is undertaken at the level of the entire organisation.

This paper has been published[24] as:

Burnett L, Rochester R, Mackay M, Proos A, Shaw W and Hegedus G (1997) Implementation of ISO 9001 in a medical testing laboratory. *Accred Qual Assur* **2**:76-81.

3 RESEARCH STUDIES:

QUALITY MANAGEMENT IN PATHOLOGY LABORATORIES

3.1 Introduction

In the Introduction and Methodology sections of this Thesis, I have described the background development and evolution of QM theory and practice in my laboratory. We had demonstrated that TQM “works” in a pathology laboratory, and we had abundant evidence that improvements previously considered unachievable could be achieved for defined processes within a single Clinical Chemistry laboratory department. The next phases in development were to be the application of QM to more complex processes within a single Department, to multi-departmental processes, and to systems that extended beyond pathology.

The research studies in this section of the Thesis thus fall into three distinct themes:

1. More complex processes within a single pathology laboratory
2. Complex processes spanning multiple pathology laboratories within an overall pathology organisation
3. Systems that extended beyond the boundaries of pathology laboratories.

The relationships between the various Chapters in the Research Studies section are diagrammatically illustrated in Figure 2 (shown earlier, and reproduced again here):

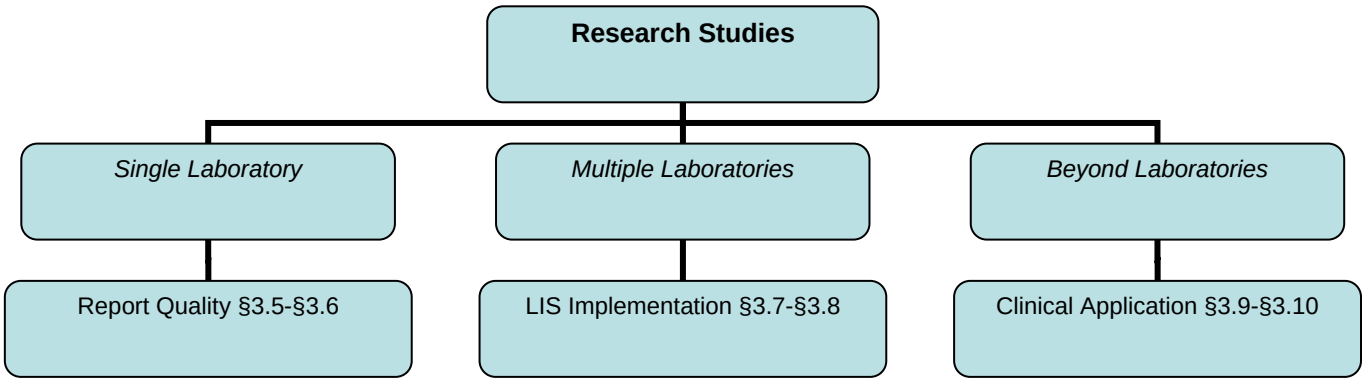


Figure 2: Relationship between the Research Studies described in §3.

3.2 Complex processes within a single pathology laboratory

In the Introduction to this Thesis, I cited several of our studies in which we had applied QM approaches to address laboratory improvements. Many of these were undertaken to improve generic business processes rather than specific laboratory or clinical processes.[3, 6] In this section, I describe the application of TQM approaches to more complex clinical processes.

Chapter 3.5 describes a CQI project in which we sought to reduce the number of errors in incorrectly addressed pathology reports. This paper is a particularly elegant demonstration of the power of integrated application of CQI tools to a clinical problem. Although not a core part of the study, the measurement system is defined and described[§§]. The outcome of the study is that we successfully demonstrated the effectiveness of CQI tools in producing a statistically highly significant reduction in the number of errors in pathology reports. It should also be noted that this reduction in error rates occurred in a fully-computerised environment (the significance of this will be clearer in the next section of this Thesis, see Chapter 3.3).

Chapter 3.6 is a continuation of the above case study. It uses the same measurement system, and investigated whether the improvements made in Chapter 3.5 can be held and maintained over an extended period of time. It should be noted that the loss of improvement described in the final study period occurred with the introduction of a

[§§] The measurement system described in Chapter 3.5 overlaps in part with that described in Chapter 2.5.

new Laboratory Information System (LIS) (the significance of this will be clearer in the next section of this Thesis, see Chapter 3.3).

3.3 Complex processes spanning multiple pathology laboratories within an overall pathology organisation

In the previous section of this Thesis (Chapter 3.2), we demonstrated the application of CQI techniques to bring about significant improvements in the quality of the result reporting process arising from a pathology laboratory. These improvements were of large magnitude (Chapter 3.5) and of sustained duration (Chapter 3.6). The improvements occurred in an environment of a formal Quality System (Chapter 2.6) and in the presence of a fully computerised laboratory environment. It was therefore disappointing to see the loss of all achieved improvements occur with the introduction of a new laboratory information system ("LIS") (see Chapter 3.6).

This stimulated an analysis of and search for the reasons for the loss of quality.

It was self-evident that the collapse in quality and return to pre-CQI baseline levels of service quality coincided with introduction of the new LIS. The LIS transferred control of this key process from within the scope of the formal Quality System, and externalised this control into a non-Quality System environment. In effect, this is what had existed prior to the commencement of the study described in Chapter 3.5, so it was not surprising to see the outcome of this change, with the loss of all improvements.

This suggested that it might be the presence or absence of a formal Quality System which was playing a major permissive role in enabling quality improvement. I

therefore designed a study to determine whether it was the lack of a Quality System at the time of the change in LIS, or the change in LIS *per se*, which was primarily responsible for the deterioration in quality. This study is described in Chapter 3.7.

This study suggested that the presence of a formal Quality System improved the operational outcome of a change in LIS. It also was consistent with the notion that quality improvement is best managed and pursued within an overall TQM environment, of which a formal Quality System is an important part.

The study in Chapter 3.7 suggested the presence of a formal Quality System was an important element in enabling and supporting systematic quality improvement. However, there are a number of different Quality Systems available, with at least two (ISO 9001 and ISO 17025) being in wide-spread use in Australian laboratories. I therefore designed a study to compare whether there were significant differences between these two Quality Systems in their permissive contributions to quality improvement. Chapter 3.8 describes a further development of the study in Chapter 3.7. I compared three different laboratory environments:

- No formal Quality System
- ISO 9001 certified Quality System
- Quality System to ISO 17025

and from this was able to confirm that a formal Quality System improved the quality outcomes of pathology during the process of introducing a new LIS. Furthermore, it did not appear to matter which Quality System was used (ISO 9001 or ISO 17025),

consistent with the notion that it is the presence of a Quality System which is important in a TQM environment, not *which* Quality System is used.

Finally, an interesting and unexpected incidental observation arose from the study in Chapter 3.8. The number of “incidents” (see definition in Chapter 3.8) that are able to be resolved during LIS implementation appeared to plateau approximately six months after implementation date of the LIS, with no further improvement or resolution of reported incidents after that date. Presumably, steady-state equilibrium is reached, at which the rate of resolution of reported incidents is balanced by the reporting of new incidents. This suggests that, during implementation of a major new LIS, incidents not resolved after six months are unlikely to be resolved, and management should seek alternative solutions to these problems, rather than assuming they will be addressed as part of the LIS implementation project plan.

3.4 Systems that extend beyond the boundaries of pathology laboratories

Two final research studies are presented. These two papers address systems in which a change within the laboratory environment can be shown to directly affect clinical outcomes.

In Chapter 3.9, I describe a study in which CQI tools were used to identify the root cause of “needlestick injuries”, a major occupational hazard in Healthcare environments. Using data gathered from within the laboratory, we were able to identify a practice in the hospital clinical environment that greatly increased the risk to laboratory staff of their suffering a needlestick injury. By a simple redesign of the clinical procedure, a significant reduction in risk of needlestick injury for laboratory staff was achieved. This paper attracted considerable interest amongst clinical epidemiologists, and was selected as the subject of an editorial in the Journal in which it was published.[25]

The final research study, presented as Chapter 3.10, describes how the judicious selection of CQI tools, combined once again with a formal Quality System, can be used to improve access to and availability of clinical services within a fixed cost of service. This paper is particularly interesting as it includes consideration of the contributions of introduction of a new LIS, and of the contributions of introducing a formal Quality System. By comparing various intervention strategies, it is possible to

see the relative importance of CQI, Quality Systems, and LIS, within a broader TQM environment.

3.5 Research Study: Reduction of Errors in Laboratory Test Reports using Continuous Quality Improvement (CQI) Techniques

Background: The techniques of continuous quality improvement have been applied to the problem of wrongly addressed clinical laboratory test reports.

Methods: Over a 6-month period, flow charts of the process of producing test reports were created, the error rates of incorrectly addressed test reports established, and the root causes of these errors were identified and progressively removed.

Results: A 17-fold sustained reduction in the rate of incorrectly addressed test reports was achieved with faster turnaround time, no significant expenditure of funds, and no changes in staff, equipment, or the laboratory information system.

Conclusions: TQM (and its CQI techniques) is a powerful and exciting tool for a clinical laboratory. Improvements in productivity are orders of magnitude higher than have been achieved by introducing new technology. These improvements can often be implemented immediately without the necessity for ever purchasing this technology.

This paper has been published[26] as:

Banning J, Brown J, Hooper L, Hamilton J, Burnett J and Burnett L (1993) Reduction of Errors in Laboratory Test Reports using Continuous Quality Improvement (CQI) Techniques. *Clin. Lab. Management Rev.* **7**(5): 424-437.

3.6 Research Study: Reduction of Errors in Laboratory Test Reports- Comparison of Continuous Quality Improvement Techniques with Laboratory Information System Techniques

Background: We have compared two different strategies for minimising the number of addressing errors on clinical laboratory test reports over an extended period of time.

Methods: One strategy consisted of the application of continuous quality improvement (CQI) techniques involving manually implemented control charts. An alternative strategy consisted of implementation of an integrated laboratory system with electronic data interchange of a hospital patient master database.

Results: The manual CQI techniques utilizing manual control charts resulted in error rates 16-fold lower than that achieved using fully computerised procedures. The lower rate of errors was maintained at minimum levels for two years

Conclusion: We have found using CQI techniques resulted in error rates 16-fold lower than that achieved using fully computerised procedures.

This paper has been published [27] as:

Burnett L and Banning J (1995) Reduction of Errors in Laboratory Test Reports: Comparison of Continuous Quality Improvement Techniques with Laboratory Information System Techniques, in “Quality Assurance and TQM for Analytical

Laboratories” (Ed. M. Parkany) The Royal Society of Chemistry, Cambridge UK. pp. 97-101.

3.7 Research Study: ISO compliant Laboratory Quality Systems and Incident Monitoring improve the implementation of Laboratory Information Systems

Background: Quality Systems can provide a means of measuring the rate of occurrence of defined incidents and non-conformities.

Methods: We have studied the application of laboratory Quality Systems to monitoring the implementation of Laboratory Information Systems (LIS) in two similar size tertiary hospital pathology laboratories in Australia. At one site, one Department implemented a Quality System accredited to ISO 9001-1987 and ISO 9001-1994 while the rest of the organisation did not have a formal Quality System; this site implemented the Cerner PathNet LIS. At the other site, the organisation was in the process of implementing ISO/IEC Guide 25-1990 and ISO/IEC 17025-1999; this site implemented the PJACC AUSLAB LIS. The rate of Quality System incidents and non-conformities was used to track the progress of implementation of the LIS.

Results: We found that different Quality Systems appeared equally useful in monitoring the rate of occurrence of incidents. However, the presence of a formal Quality System greatly improved the proportion of incidents that could be investigated and resolved at root cause level.

Conclusion: Incident monitoring, as part of a formal Quality System, proved to be a useful tool in monitoring and managing the implementation of these Laboratory Information Systems.

This paper has been published [28] as:

Burnett L, Chesher D, Groot-Obbink D, Hegedus G, Mackay M, Proos A, Rochester C and Shaw W (2002) ISO compliant Laboratory Quality Systems and Incident Monitoring improve the Implementation of Laboratory Information Systems. *Accred Qual Assur* **7**:237-241.

3.8 Research Study: Managing the implementation of Laboratory Information Systems using Quality Systems and Incident Monitoring

Background: Implementation of a Laboratory Information System (LIS) is a major operational change to a medical laboratory. We used incident monitoring to track the frequency, nature and time course of problems arising during LIS implementation.

Methods: We used a formal Quality System to document incidents occurring during the implementation of a LIS in two tertiary hospital pathology laboratories in Australia.

Results: The number of incidents peaked during the first two months after implementation. Root cause analysis of incidents showed that the majority of incidents were operational in nature. Incidents resolution plateaued four to six months after implementation, with minimal further resolution of incidents after this time. Quality indicators had still not returned to baseline after one year.

Conclusions: The peak number of incidents occurred during the first two months after implementation. Incidents that were not resolved within six months of LIS implementation were unlikely to be resolved after twelve months. The majority of incidents occurring during LIS implementation were operational and not directly related to the LIS. The presence of a formal Quality System improves the proportion of incidents that can be resolved at root cause level.

This paper has been submitted for publication[29] as:

Burnett L, Chesher D, Groot-Obbink D, Hegedus G, Mackay M, Proos A, Rochester C and Shaw W (submitted) Managing the implementation of Laboratory Information Systems using Quality Systems and Incident Monitoring. *Clin Chem.*

Please note that this Study has been included in the format of the manuscript "as submitted".

INTRODUCTION

Medical testing laboratories are highly dependent on their Laboratory Information Systems (LIS) for daily operations, and these LIS are commonly interfaced with third-party analytical equipment, Hospital Information Systems, and revenue and accounting systems. Implementing a new LIS is a major operational challenge for a medical laboratory.

Although some literature is available for describing optimal strategies for managing implementation of LIS in the medical laboratory environment ([30]), this tends to be anecdotal and not evidence-based. In other industries, complex environments are managed with the assistance of organisational Quality Systems. We have previously described several studies of the application of formal Quality Systems to the medical testing environment ([31], [32], [33]) and to medical LIS ().

In the present study, we have explored whether Quality Systems can be used to monitor and assist in management of the implementation of medical LIS. Through fortuitous circumstances, two similar-sized organisations serving similar markets in the same city independently chose to implement two different LIS. We studied the nature and rate of occurrence of “incidents” (defined in terms of Quality System non-conformities) that occurred during the three months prior to, and the twelve months immediately following, the implementation of the two LIS in these two medical testing laboratories.

METHODS

Description of the two organisations

The Institute of Clinical Pathology and Medical Research (ICPMR) and Pacific Laboratory Medicine Services (PaLMS) are similar sized tertiary referral pathology and medical testing laboratories in Sydney, Australia. Both operate multi-campus laboratories serving populations of some 750,000 people, and both are centred on a University teaching hospital, with associated major metropolitan hospitals and community referrers. Both organisations have annual turnover of ~$AUD30-40 million and both employ some 300-400 staff.

Laboratory Information Systems (LIS)

In 1993, the ICPMR implemented the Cerner PathNet LIS (Cerner Computer Corporation, http://www.cerner.com). Following extensive project planning over several years, this LIS was implemented over a period of a few days concurrently in all laboratory Departments across the entire ICPMR organisation at Westmead Hospital.

In 1998, PaLMS implemented the PJACC AUSLAB LIS (PJA Computer Consultants, Melbourne Australia, http://www.pjacc.com.au). Following equally extensive project planning over several years, this LIS was implemented gradually over a period of some six months, one laboratory Department at a time, across the entire PaLMS organisation at Royal North Shore Hospital (and four other hospitals). The implementation described in this paper covers the central Clinical Chemistry,

Hematology and Specimen Reception Departments, representing some 70% of total laboratory activity.

Prior to the implementation of these two new LIS, both ICPMR and PaLMS had used a variety of legacy LIS from multiple and different vendors. At time of writing of this paper in 2001, both organisations continue to use their respective LIS as described in this paper.

Quality Systems

Within Australia, Pathology is highly regulated with complex Government legislation linking laboratory accreditation to eligibility for reimbursement. All pathology laboratories must be accredited by the National Association of Testing Authorities, Australia ("NATA") (National Association of Testing Authorities, Australia, Rhodes NSW, Australia) under a scheme ("RCPA/NATA") administered by the Royal College of Pathologists of Australasia ("RCPA") (Royal College of Pathologists of Australasia, Surry Hills NSW, Australia) and NATA.

Both ICPMR and PaLMS were fully accredited to RCPA/NATA standards at time of this study. In addition, at ICPMR, the Department of Clinical Chemistry (and only this one Department) was voluntarily accredited to the higher accreditation standards of ISO 9001:1987 ([34]) and ISO 9001:1994 ([35]). At PaLMS, the entire organisation was in the process of upgrading its Quality System to the higher accreditation standard of ISO/IEC Guide 25-1990 ([36]) and ISO/IEC 17025-1999 ([37]). We have previously shown (5) that these various Quality Systems are equally suitable for reporting incidents for monitoring LIS implementation.

Incident Definition and Monitoring

For the ICPMR implementation, the Department of Clinical Chemistry registered and analysed all “incidents” affecting its Quality System. All incidents were classified as being either “significant” (i.e. either having material impact on the Departmental operations, or having potential for direct patient/customer harm), or “minor” (all other incidents and observations). Incidents reported from elsewhere within the ICPMR, which affected but were otherwise outside of the scope of the Clinical Chemistry Quality System, were included in this study, while those that did not affect the Clinical Chemistry Quality System were not recorded.

For the PaLMS implementation, a single, organisation-wide Quality System and incident database was used.

Incident investigation and resolution

An incident, once recorded, was regarded as being active until it was formally investigated and closed. Closure of an incident required demonstration that the root cause of the incident had been identified and addressed.

RESULTS

Time-course of incidents following implementation of the LIS

The rate at which incidents are reported was remarkably similar between institutions and different LIS vendors. The peak rates occurred in the first two months after the launch of the LIS (Fig. 1), by which time 71% of all incidents had been reported. The rate of new incidents then fell to a lower level and remains at that lower level for at least six months after LIS implementation. The rate of occurrence of new incidents

did not return to baseline levels for more than one year after implementation (data not shown).

Resolution of incidents following implementation of the LIS

We next studied the extent to which incidents were investigated and resolved at Root Cause level. Each incident was further classified as being “significant” or “minor”. Fig. 2 shows the frequency of incidents resolved over the duration of the study at the ICPMR site. At this site, incidents were classified as “significant” or “non-significant”, and were recorded in the presence (Clinical Chemistry Department) or absence (all other Departments) of a Quality System. In the presence of a Quality System, 90% of significant incidents were resolved by the sixth month. In the absence of a Quality System, only 70% of significant incidents were resolved, and these were resolved within the first four months after LIS implementation. In both environments, after the first four to six months, negligible numbers of additional incidents were resolved. Using information obtained during resolution of these incidents, we noted where in the organisation the Root Cause of the incident lay. Fig. 3 shows a “Cause and Effect” analysis of Root Causes ([38]), from which the classifications of Root Causes shown in Figs. 4 and 5 was derived. From Figs. 4 and 5 it is clear that issues directly related to the LIS software or configuration were responsible for only a minority (10-16%, depending on classification scheme) of incidents. The majority of incidents reported arose from pre-analytical workflow issues highlighted or revealed by the LIS implementation.

Finally, we examined two surrogate markers of outcome of the laboratory testing process. Fig. 6 shows the Turn-around Time deteriorated significantly after LIS

implementation, and had still not returned to baseline levels one year later. Fig. 7 shows the number of reports ("charts") with incorrect address details, which we have previously shown ([39]) to be the result of variation in various workflow issues.

DISCUSSION

The introduction of a new LIS is one of the most potentially disruptive changes that a medical testing laboratory can experience. The fortuitous circumstances of two similar-sized medical testing laboratories in the same city and health-care system, choosing to implement two similarly specified LIS from different vendors, and in the presence of different Quality Systems environments, has provided us with a unique opportunity to study and document the impact of this change process and to derive principles to assist others manage future LIS implementations.

We have previously shown (5) that the presence of a Quality System does not affect the time-course of incidents, although it does improve the rate and extent of resolution of incidents reported. We found that the time-course of occurrence of incidents also did not appear to be dependent on the brand or vendor of the LIS.

The quality of results issued by the laboratory is likely to be affected for lengthy periods of time. While we found only a few examples of analytical problems directly attributable to the LIS implementation, effects on service delivery (Fig. 6) and service accuracy (Fig. 7) were significant and long lasting. The duration and magnitude of deterioration in service quality needs to be recognised and carefully considered in the decision whether to implement an organisation-wide LIS. While a single integrated LIS presumably provides major benefits for clinical reporting and laboratory

management, these advantages need to outweigh the costs of a prolonged period of clinical service disruption and reduced service quality.

The critical period for laboratory operations in which maximal rates of incidents occur will be the first two months after LIS implementation. The rate of new incidents will then decrease, but will continue at a higher-than-baseline level for many months. Resolution of incidents continues for four to six months after LIS implementation (depending on whether or not a Quality System has been implemented). A Quality System appears to allow a higher proportion of incidents to be investigated and successfully resolved. However, if an incident has not been resolved successfully by this time, it is unlikely to be resolved. This suggests that "work-arounds" and alternative solutions to problems should be sought if a problem has not been resolved by six months.

Only a minority of incidents reported after LIS implementation had their Root Cause in the LIS itself. The overwhelming majority (84-90%) of incidents could be resolved only by changes to laboratory operations and workflow. This suggests that organisations may need to manage the LIS implementation by focussing on review and changes to laboratory operations, rather than focussing primarily on LIS issues.

Two centuries ago, Hegel observed: "What experience and history teach is this – that people … never have learned anything from history, or acted on principles deduced from it" ([40]). This study has allowed us to document the time-course and extent of the impact on laboratory performance of the introduction of a new LIS, and to derive some general principles. We have documented the nature and timing of incidents arising during LIS implementation, and this should be of value to other institutions planning LIS implementation projects. The remarkable similarity of these effects

between different organisations, and their independence from LIS brand name or vendor, suggests that these observations reflect the change associated with the LIS implementation process itself. We also conclude that the presence of a formal Quality System improves the management, investigation and resolution of incidents over that which could be achieved in the absence of a formal Quality System. A final important message is that incidents that have not been resolved within six months of LIS implementation are unlikely to be resolved by twelve months.

ACKNOWLEDGMENTS

We thank the staff of ICPMR and PaLMS for their assistance in enabling this study to be performed.

We are grateful to Sharon Rogers for her comments and critical reading of this manuscript.

FIGURES LEGENDS

Figure 1

Time-course of incident reporting. The monthly frequency of incidents is shown for each of the three sites. The incident frequency has been expressed as the monthly proportion of all incidents recorded during the one month prior to, the month of, and the six months following the implementation of the LIS at each site. Also shown is the cumulative sum of the incidents recorded at one of the three sites; the other two sites had essentially the same cumulative frequency profile (not shown).

Figure 2

Rate of resolution of incidents. The monthly cumulative sum of proportion of all incidents that were successfully investigated and resolved is shown for various sites.

Figure 3

Cause-and-Effect analysis of potential root causes for incidents. Each incident was analysed to determine potential root causes for incidents. The Figure shows the Cause-and-Effect diagram (38) developed for the ICPMR site.

Figure 4

Location of Root Causes of incidents. For all incidents successfully investigated and resolved at the PaLMS site, the location in the analytical process of the root cause of the incident was classified into the categories shown. Note that percentages may differ slightly from those shown in Fig. 5 due to root causes lying in more than one category.

Figure 5

Classification of Root Causes of incidents. For all incidents successfully investigated and resolved at the PaLMS site, the root cause of the incident was classified into the categories shown. Note that percentages may differ slightly from those shown in Fig. 4 due to root causes lying in more than one category.

Figure 6

Turn-around Time. The turn-around time for Potassium analysis at ICPMR for specimens from Emergency ward is shown, for a baseline period covering two years prior to LIS implementation, and at various times up to one year post-LIS implementation. The Turn-around time was defined in this study as the number of minutes elapsing between arrival of the specimen in the laboratory, and the time at which the result is first released from the laboratory LIS. Shown are the mean time, the Upper Control

Limit (3σ) for samples taken from statistical control charts, and the 95th percentile of the entire population of samples.

Figure 7

Addressing errors. The proportion of all printed pathology reports/charts that did not contain the correct destination address is shown in a p control chart. The proportion of incorrect addresses is marked “p”, UCL and LCL are the Upper and Lower Control Limits (3σ), and “p_bar” is the average proportion of incorrect reports.

FIGURES

Figure 1

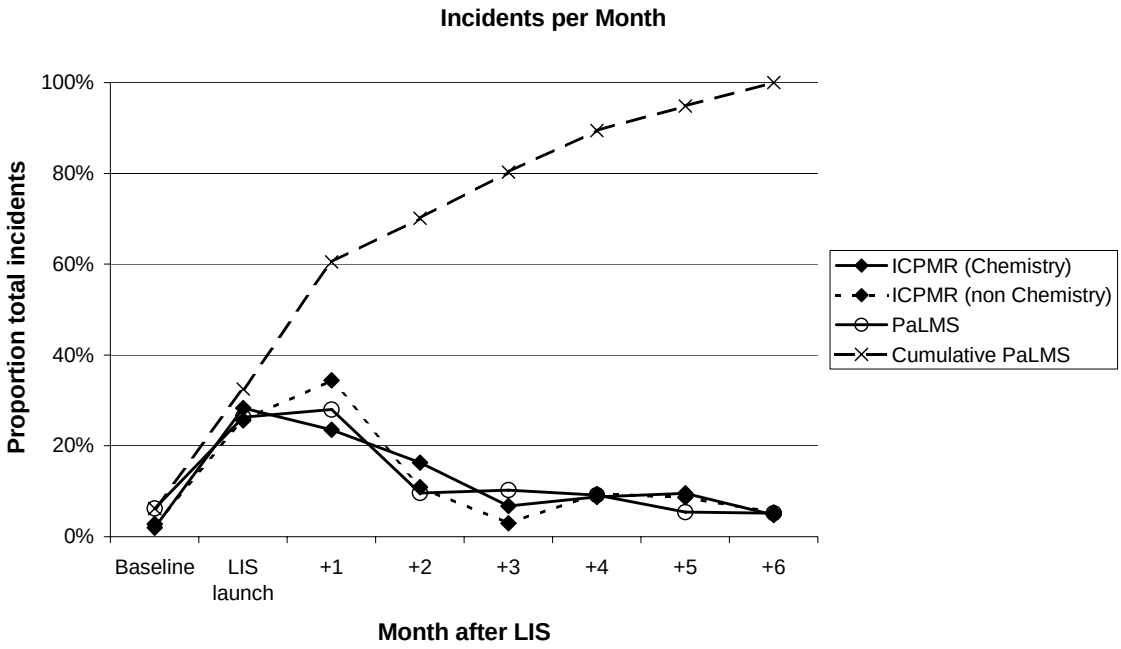


Figure 2

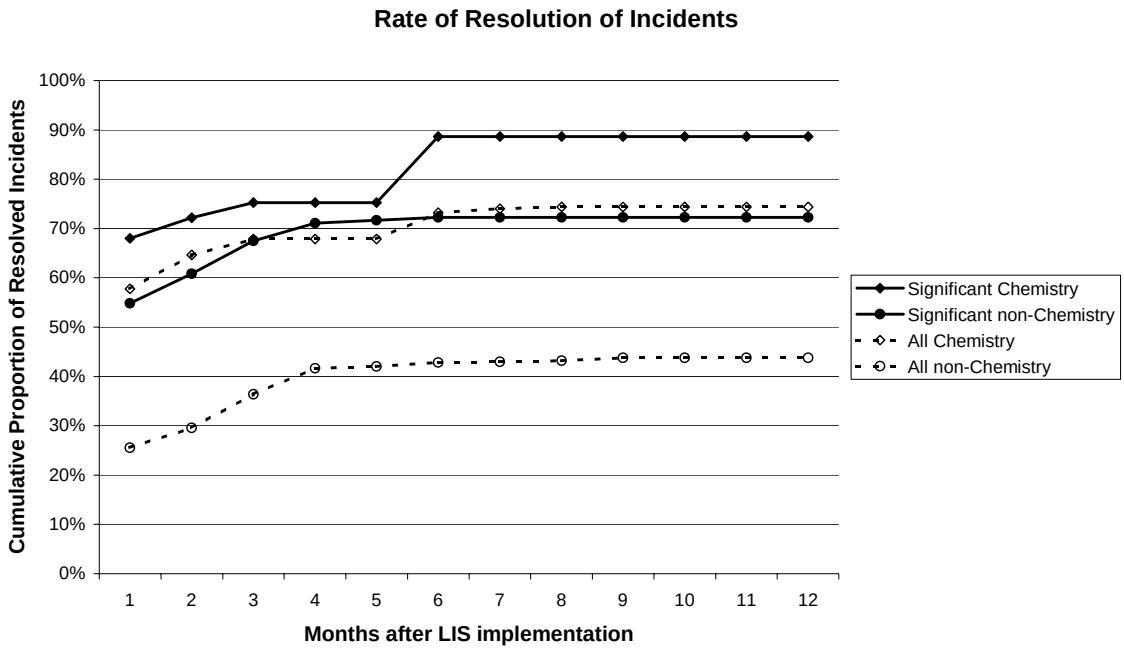

Rate of Resolution of Incidents
Cumulative Proportion of Resolved Incidents
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
1
2
3
4
5
6
7
8
9
10
11
12
Months after LIS implementation
Significant Chemistry
Significant non-Chemistry
All Chemistry
All non-Chemistry

Figure 3

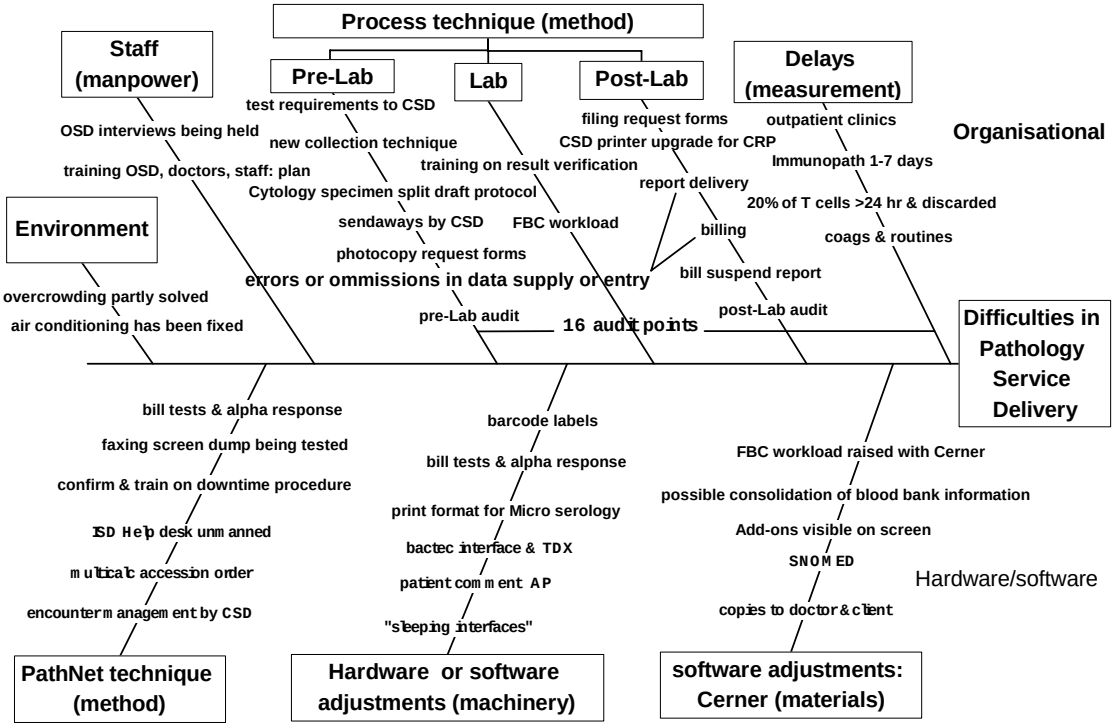

Process technique (method)
Staff (manpower)
Pre-Lab
Lab
Post-Lab
Delays (measurement)
test requirements to CSD
filing request forms
outpatient clinics
Organisational
OSD interviews being held
new collection technique
CSD printer upgrade for CRP
training OSD, doctors, staff: plan
training on result verification
Immunopath 1-7 days
report delivery
Cytology specimen split draft protocol
20% of T cells >24 hr & discarded
Environment
sendaways by CSD
FBC workload
billing
coags & routines
photocopy request forms
errors or ommissions in data supply or entry
bill suspend report
overcrowding partly solved
pre-Lab audit
16 audit points
post-Lab audit
air conditioning has been fixed
Difficulties in Pathology Service Delivery
bill tests & alpha response
barcode labels
FBC workload raised with Cerner
faxing screen dump being tested
bill tests & alpha response
confirm & train on downtime procedure
possible consolidation of blood bank information
print format for Micro serology
ISD Help desk unmanned
Add-ons visible on screen
bactec interface & TDX
multical accession order
SNOMED
Hardware/software
patient comment AP
encounter management by CSD
copies to doctor & client
"sleeping interfaces"
PathNet technique (method)
Hardware or software adjustments (machinery)
software adjustments: Cerner (materials)

Figure 4

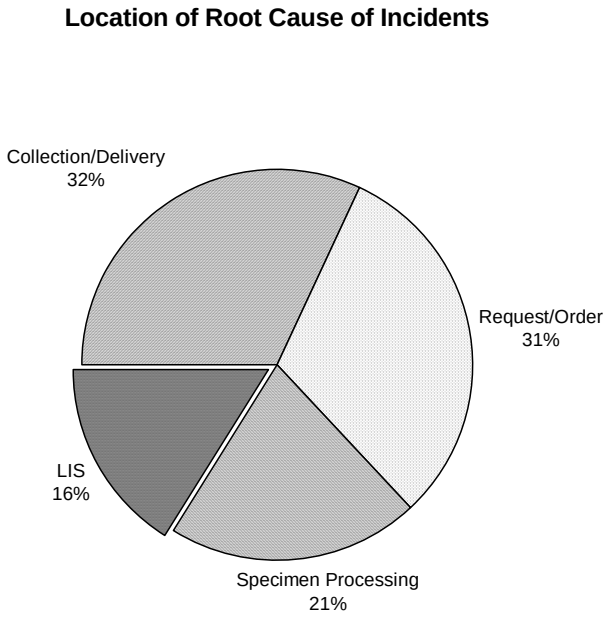

Location of Root Cause of Incidents
Collection/Delivery
32%
Request/Order
31%
LIS
16%
Specimen Processing
21%

Figure 5

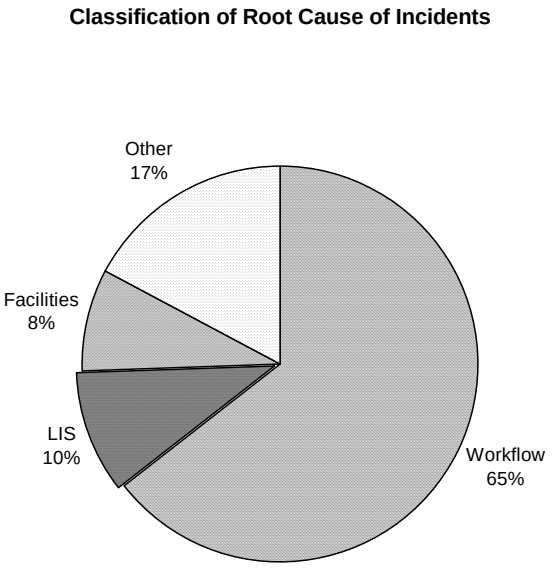

Classification of Root Cause of Incidents
Other
17%
Facilities
8%
LIS
10%
Workflow
65%

Figure 6

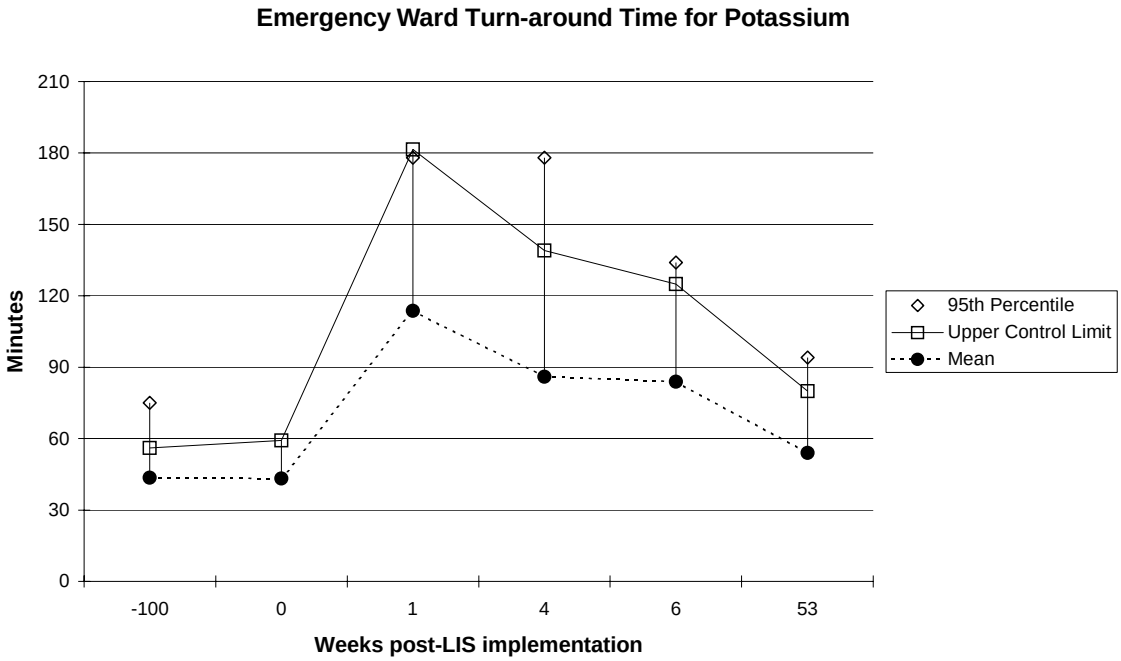
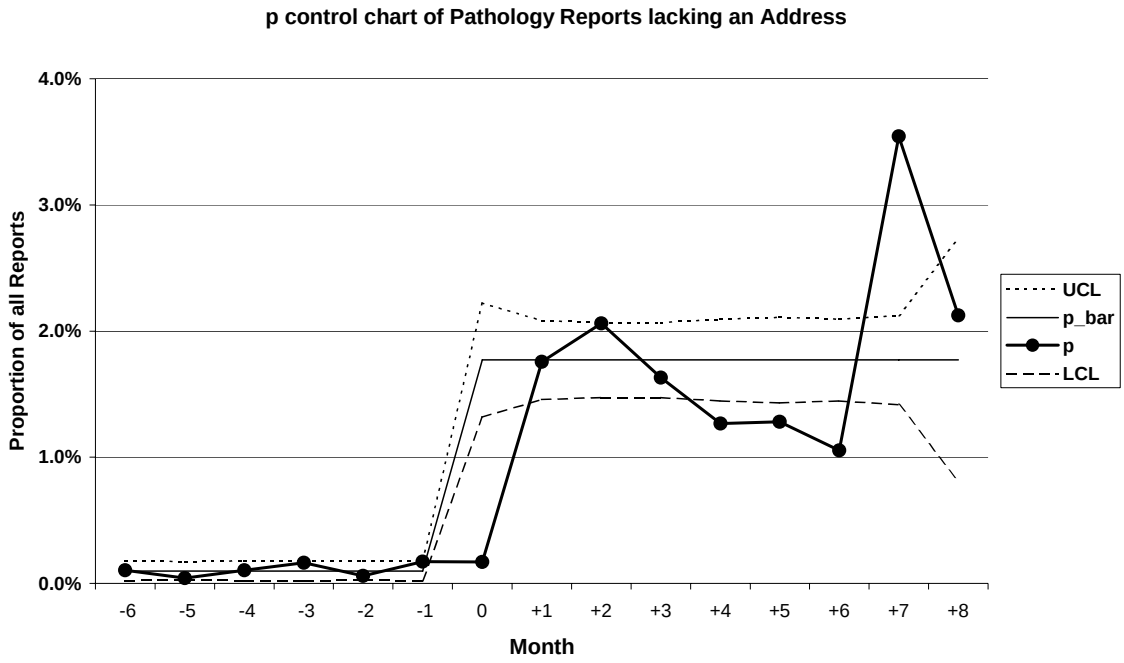

Emergency Ward Turn-around Time for Potassium
Minutes
210
180
150
120
90
60
30
0
-100
0
1
4
6
53
Weeks post-LIS implementation
95th Percentile
Upper Control Limit
Mean

Figure 7


p control chart of Pathology Reports lacking an Address
Proportion of all Reports
4.0%
3.0%
2.0%
1.0%
0.0%
-6
-5
-4
-3
-2
-1
0
+1
+2
+3
+4
+5
+6
+7
+8
Month
UCL
p_bar
p
LCL

3.9 Research Study: Application of CQI Tools to the Reduction in Risk of Needlestick Injury

Objective: To reduce the risk of needlestick injuries to laboratory workers.

Design: Continuous Quality Improvement (CQI) tools were applied to data collected on the number of blood gas syringes that arrived in the laboratory with needles still attached and to the reasons for these occurrences.

Setting: A clinical chemistry department within a 900-bed tertiary referral university teaching hospital.

Participants: Clinical chemistry laboratory staff and medical staff responsible for sending syringes with needles still attached.

Interventions: Changing to a pre-heparinized blood gas syringe that included a syringe cap within the packaging.

Results: Fivefold reduction in the number of syringes arriving in the laboratory with needles still attached.

Conclusion: The risk of needlestick injury to laboratory workers can be reduced by provision to clinical staff of pre-heparinized blood gas syringes that include a syringe cap within the packaging. The techniques of CQI provide powerful tools for the identification, solving, and monitoring of safety-related issues within the healthcare environment.

This paper has been published[41] as:

Burnett L and Chesher D (1995) Application of CQI tools to the reduction in risk of needle-stick injury. *Infect Control and Hosp Epidemiol* **16**(9): 503-505.

This paper was selected as the subject of an Editorial in the above journal.

3.10 Research Study: Optimising the availability of 'stat' laboratory tests using Shewhart 'c' control charts

Background: We describe a general strategy for optimizing the availability of 'stat' out-of-hours laboratory tests to the particular clinical needs of health care institutions.

Methods: We initially introduced a consensus menu of 'stat' tests and prospectively monitored for 5 years all additional requests for 'stat' clinical biochemistry tests in a metropolitan tertiary referral university teaching hospital. Laboratory staff triaged 'stat' requests, and clinical biochemistry consultants reviewed requests not already performed routinely. The frequency of these requests was monitored on a Shewhart 'c' control chart. A quality system certified to ISO 9001 was used to assure laboratory compliance with procedures. Various interventions were tested using the Shewhart 'c' control chart to monitor their effectiveness.

Results: Matching the timing of analytical assays with the time of sample collection had no significant effect on the number of 'stat' requests. Implementation of a hospital-wide laboratory information system also had no significant effect on the number of 'stat' requests. The most effective strategy consisted of optimization of the test menu to match request patterns, combined with the introduction of a laboratory quality system.

Conclusions: Within our institution, this strategy resulted in a sevenfold reduction in 'stat' requests, from one per 2200 specimens to fewer than one per 32 000 specimens.

This paper has been published[42] as:

Burnett L, Chesher D, Burnett JR (2002) Optimising the Availability of 'Stat' Laboratory Tests using Shewhart 'c' Control Charts. *Ann Clin Biochem* **39**:140-144.

4 CONCLUSIONS:

OUTCOMES OF QUALITY MANAGEMENT IN PATHOLOGY

4.1 Discussion

Total Quality Management is now an accepted mainstream business strategy. Formal economic evaluation studies have demonstrated that firms which have adopted QM and gone on to win Quality Awards also have achieved superior business performance outcomes.[43] It would be highly desirable if similar improved performance outcomes could be achieved in areas of healthcare such as pathology laboratories.

In the Introduction to this Thesis, I described how early studies from my own laboratory supported the conclusion that QM could be introduced successfully into pathology laboratories. Although not the primary purpose of that Chapter, Chapter 2.2 also contains further evidence of statistically highly significant improvements in product quality arising from QM approaches. Although not formally part of this Thesis' research program, in Chapter 4.3 I have presented an outcome evaluation study of my laboratory, which clearly demonstrates significant improvement in all three dimensions of pathology laboratory performance indicators: product quality, service quality and cost efficiency. I conclude that the TQM framework developed in my laboratory "works" and achieves its intended outcome when applied to problems within the domain of a single pathology laboratory department.

The first research question I wished to address was whether one can use this same TQM framework developed in my laboratory, and apply it to various complex and often multi-disciplinary projects in a larger pathology organisation.

The research studies described in Chapter 3.5 and 3.6 addresses the issue of errors in patient identification in pathology reporting. This is a complex process, involving multiple stakeholders. These stakeholders include clinicians (who accept responsibility for identifying the patient and correctly completing the pathology request), one or more laboratories (who transcribe this information, in whole or part, into the LIS), and information technology (which may hold some or all patient demographics on-line in a hospital information system, which is itself interfaced to the LIS). We demonstrated a highly significant (§3.5) and sustained (§3.6) improvement in service quality by the application of CQI tools to this complex, multi-departmental healthcare problem.

However, towards the end of the study described in Chapter 3.6, there was a collapse in service quality. This coincided with the introduction of a new LIS, not under the control of and outside the scope of the formal Quality System operating in the Clinical Chemistry laboratory. It was necessary to consider why this collapse in quality occurred, and how it could have been prevented. Otherwise, CQI efforts in parts of a large organisation could be “derailed” by changes occurring elsewhere in the organisation.

Chapters 3.7 and 3.8 considered whether the collapse in service quality described in Chapter 3.6 could have been prevented, or ameliorated. These studies clearly showed superior outcomes in LIS project implementation in the presence of a formal Quality System, than in its absence. These studies suggest that, had a formal Quality System been in place, not only would the outcome of the LIS implementation have

been improved, but also subsidiary processes (such as those described in §3.6) would have been stabilised at known quality levels, and the deterioration in quality which was actually observed could have been prevented.

I conclude that the first research question can be answered, in part, in that the TQM framework and methodologies can be applied to complex and multi-disciplinary projects in a large pathology organisation. The framework did not appear to be unique or confined to just my laboratory. However, it would appear that, to be successful in a large pathology organisation, the presence of a formal Quality System is necessary. The study described in Chapter 3.8 suggests that it may not matter which Quality System (ISO 9000 or ISO 17025) is implemented, provided there is a formal Quality System in place.***

The final two research studies (Chapters 3.9 and 3.10) considered whether TQM could be extended into complex processes that extend beyond the boundaries of the pathology laboratory. In Chapter 3.9, we demonstrated that CQI projects initiated within and using data obtained from the pathology laboratory can be used to change clinical practice, thereby removing a significant occupation health and safety risk (in this case, needlestick injuries) from the working environment. In Chapter 3.10, we demonstrated that changes internal to the pathology laboratory (the selection and

*** Since this study was performed, the accrediting body for Australian pathology laboratories (the National Association of Testing Authorities, Australia ["NATA", http://www.nata.asn.org] has made it a condition of medical registration and accreditation that a medical testing laboratory must be accredited to ISO 17025.

availability of the analytical test menu) can be used to improve clinical access to laboratory investigations, thereby presumably improving clinical practice. Interestingly, §3.9 and §3.10 both share a similar theme: both reach the same end result (improvement in clinical practice) by identifying the changes to clinical practice needed, but both implement this change in opposite ways. In §3.9, the change in clinical practice (packaging of the syringe needle together with the syringe, rather than being delivered and stored separately) can be initiated by the laboratory and resulted in an improvement to the system such that clinical staff had no alternative but to comply. In contrast, §3.10, attempts by the laboratory to change clinical practice were unsuccessful; the successful intervention required the laboratory practice to change to match and complement that of the clinical staff. Both studies have the same theme of the need for the "customer" of the process (the laboratory in §3.9, and the clinician in §3.10) and the "supplier" (the clinician in §3.9, and the laboratory in §3.10) to work together to match their respective interfaces to a shared process or system.

Chapter 3.10 is also important because it, too, identified the presence of a formal Quality System as being an important contributor to implementing systematic improvement. It also identified the introduction of a new LIS as delivering no significant improvements *per se* to those aspects of product or service quality being measured.

From Chapters 3.9 and 3.10, I reach a similar conclusion to that arising from the earlier Chapters, *viz*. TQM can be applied to complex multi-disciplinary healthcare

processes. The scope of these multi-disciplinary healthcare processes can be across multiple sub-disciplines of pathology, or it can span the laboratory/clinical interface.

The findings described in Chapter 3.10 suggest that, once again, the presence of a formal Quality System may be an important success factor in achieving systematic and sustained quality improvement in a multi-disciplinary and complex environment.

4.2 Directions for Future Research

Before commencing the research work in this Thesis, and as described in the Introduction, I started with the premiss that QM can bring about significant improvements within a single pathology laboratory department. This is supported by §3.5 and formally demonstrated in §4.3.

In the previous section (§4.1) I reached two conclusions on the basis of the research studies described in this Thesis:

1. QM can be applied to more complex processes spanning multiple pathology departments within a larger pathology organisation. This is supported by §3.6 and by parts of the study described in §3.8.
2. QM can be applied to even more complex processes extending beyond the boundaries of the pathology laboratory, and into the clinical environment. This is supported by §3.9 and §3.10.

As discussed in the previous section (§4.1), there is strong evidence that the presence of a formal Quality System improves the implementation process of complex multi-disciplinary projects (§3.8), and improves both the quality improvement process outcomes, and their sustainability (§3.6, §3.8, §3.10). This finding is consistent with the generic experience of Quality Award winning organisations in many sectors.

In conducting the study described in Chapter 3.8, an unexpected finding was that the rate of resolution of LIS incidents (see §3.7 and §3.8) slowed by four months, and ceased by six months after implementation of a new LIS. While the rate of resolution of incidents continued for a longer period of time, and at a higher rate of resolution, in the presence of a formal Quality System than without a Quality System, in neither environment was there any progress in resolution of incidents after six months.

This is a very interesting finding. One can speculate that the reason the rate of resolution of incidents slowed, and then stopped, is that while resolution of existing incidents continued, new incidents were being reported at a similar rate, so that a steady state equilibrium situation was reached. Alternatively, one could speculate that when the steady state position was reached, while work continued on resolution of incidents, all existing incidents had already been investigated and abandoned as being “too hard to solve”, so that only newer incidents were addressed. However, whether these are, or are not, the correct explanations, the observation remains that the rate of resolution of incidents ceased by six months. This would suggest that a potential improvement strategy might be to regard any incident that had not been resolved by six months as being “insoluble” by existing strategies. Such incidents might need to be escalated for review by an alternative strategy.

It is also interesting to note that the majority of incidents reported in §3.8 arising from introduction of a new LIS were, in fact, related to non-LIS operational issues and work practices. This may well be another contributing explanation to why incident resolution ceased at six months, for the focus of incident resolution was to address

LIS-related issues. The possible strategy outlined in the previous paragraph, of escalating such unresolved incidents for review at six months, would be appropriate so that these incidents could be investigated by the powerful tools of CQI, with their capacity to bring about operational improvement, as has been amply demonstrated in the various case studies presented in this Thesis.

4.3 Outcome Study: Using National Quality Award criteria to integrate Quality Management within a Clinical Chemistry Department

This final study is an Outcome Study rather than a Research Study. The relationships between the various Chapters in the Research Studies section are diagrammatically illustrated in Figure 3 (shown earlier, and reproduced again here):

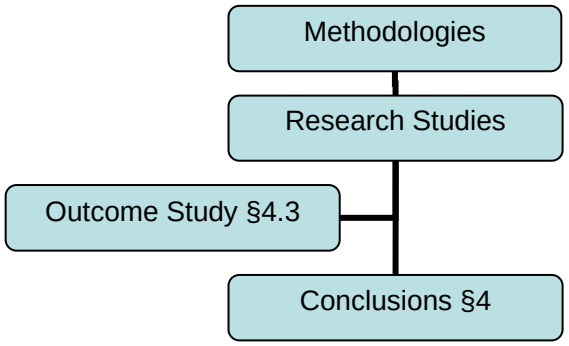


Figure 3: Relationship between Methodologies (§2), Research Studies (§3) and Conclusions (§4).

This Outcome Study is included as it provides an excellent adjunct summary of the composite contributions of the many improvement strategies contributing to the final outcome of Quality Management in the Clinical Laboratory.

Objective: To examine a comprehensive set of outcome indicators to assess the contribution of Quality Management to a Clinical Chemistry Department.

Design: Longitudinal study.

Setting: Tertiary referral pathology laboratory in an Australian University teaching hospital.

Intervention: Application of Continuous Quality Improvement techniques to complex laboratory processes.

Measurement: Measurement of changes in key performance indicators.

Results: Statistically significant improvements in a variety of key performance indicators and improvement in surrogate clinical outcomes were achieved using Quality Management approaches in a pathology laboratory.

Conclusion: Quality Management can result in significant improvements in organisation-wide product and service quality.

This paper has been published[44] as:

Burnett L (1994) Using National Quality Award criteria to integrate Quality Management within a Clinical Chemistry Department. *Quality Management in Health Care* **3**:1-15.

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