

**Investigating the Effectiveness and Efficiency of
Forensic Pathology Practice in Western Cape, South
Africa**

by

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Abstract

Introduction: In South Africa (SA), the forensic sector faces significant challenges including how to meet increasing public expectations for high quality, reliable and valid scientific and medico legal results, whilst dealing with increasing caseloads and restricted resources in a developing country. Internationally, lean six-sigma and/or business-based frameworks have been developed to define, measure and analyse the efficiency, effectiveness and output of forensic laboratories, so as to assess performance to meet such challenges.

Aim: This pilot project aimed to investigate the effectiveness and efficiency of forensic pathology practice at Salt River Mortuary (SRM) by applying lean six sigma principles (define, measure, analyse and improve) and FORESIGHT metric analyses to retrospective case and staffing data, as well as prospective observational analyses.

Methods: A retrospective analysis of cases admitted to Salt River Mortuary in 2015 was conducted to define and measure a snapshot of forensic pathology practice in Cape Town. In addition, observations of autopsy processes were conducted to identify bottlenecks in the system and provide suggestions for improvement.

Results: An analysis of post-mortem report turn-around for 3567 cases admitted to SRM in 2015 showed that approximately 10% of cases were closed (cause of death was determined) on the day of the post-mortem, 65% within 14 days and 80% closed within a 30 day period. Certain requested ancillary investigations delayed the finalisation of cause of death; for example, only 8.33% of carbon monoxide testing and 30.31% of histological examinations were completed within the year. A process map outlining autopsy practices at SRM was generated through observational data, which also identified key bottlenecks in the process (e.g.: equipment issues). Preliminary financial data suggested that it cost on average R16 155.03 per case. Staff data demonstrated a lack of pathologists compared to other staff categories and high case load requirements.

Discussion: This pilot study investigates the utilization of metrics and strategic frameworks to assess forensic pathology processes in Cape Town. This study offers a cross-sectional insight into financial performance, efficiency and effectiveness of post-mortem investigations at SRM,

highlighting bottlenecks and inefficiencies, and providing suggestions for improvement. The findings will assist in forming a basis for future work into the development of a framework for monitoring performance and progress, and developing benchmark standards for the death investigation system in South Africa

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There are no conflicts of interest to declare.

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Abbreviations

CO:	Carbon monoxide
DMAIC:	Define, Measure, Analyse, Improve and Control
FACT:	Forensic Anthropology Cape Town
FPO:	Forensic Pathology Officer
FCL:	Forensic Chemistry Laboratory
FSL:	Forensic Science Laboratory
FTE:	Full Time Employee
FPS:	Forensic Pathology Services
KEXP:	Capital expense
LEXP:	Labour expense
NAME:	National Association of Medical Examiners
NHLS:	National Health Laboratory Service
OPEXP:	Operational expense
PM:	Post-mortem
PPE:	Personal protection equipment
RTA:	Road traffic accident
SA:	South Africa
SAECK:	Sexual Assault Evidence Collection Kit
SIDs:	Sudden, unexpected and unexplained infant deaths
SQM:	Square meters
SUDA:	Sudden unexpected death of adult
SUDI:	Sudden unexpected death of infant
SUDJ:	Sudden unexpected death of juvenile
SWGMDI:	Scientific Working Group for Medicolegal Death Investigation
TOTEXP:	Total expense
UCT:	University of Cape Town
USA:	United States of America
WC:	Western Cape
WVU:	West Virginia University

Chapter 1. Literature Review

1.1. Introduction

1.1.1. Modern history of forensics in the international courtroom

In 1960, approximately 1 percent of all cases going to court in the United States (US) were presented using forensic evidence. A paper by Peterson et. al. (1987) investigated the effect of forensic science evidence in the courtroom via interviews with court employees (such as judges, and attorneys) and jurors, as well as reviewing thousands of retrospective case files for which forensic science samples had been examined. They found that in two thirds of cases other evidence was seen as more significant than forensics (eyewitness identifications or confessions being the most highly regarded). However, scientific evidence did influence the severity of sentences passed following conviction, with an average of 30 percent increase in sentence length when forensic evidence was indicated in conviction (Peterson et al. 1987).

In 1985, a new technique called DNA fingerprinting was presented in a paper by Jeffreys (1985). By applying restriction enzymes to DNA isolations from forensic samples, DNA strands present would be cut at specific points. Due to the variability of DNA sequence in different individuals it was hypothesised that, except in cases involving identical twins, a unique set of cut strands would be created. These could then be separated by size and stained to create a DNA fingerprint (Jeffreys 1985). This technique would be re-examined and improved upon over the following years, changing the location examined on the DNA strand and methods used to create and display resulting patterns, until it was accepted as the “gold standard” for individual identification in the 1990’s. Today short tandem repeat analysis, in non-coding regions, is used. Since the number of tandem repeats at each site varies per individual so does the length of the amplified DNA when the region is copied through polymerase chain reaction techniques. This creates a similar fingerprint-like ladder when separated on a gel, however, modern instruments use colour probes and detection of fragments to create an electropherogram instead (Lynch 2003). Alongside this increase in specificity and sensitivity of forensic techniques came an increase in public awareness of the potential use and

evidential value of forensic science evidence in the courtroom. DNA evidence is now widely used in the courtroom, having become one of the most relied upon forensic techniques.

In South Africa the legal system is not jury based, decisions of guilt or innocence are made by judges. There have been no studies to date on how these professionals are affected by the use of forensic evidence, this is another area for future study.

1.1.2. The CSI effect

One way this was apparent was the increase in crime television series focussing on forensic techniques in investigation and conviction of the offender. An example being the show “Crime Scene Investigation” (CSI). A study by Schweitzer and Saks (2007) examined episodes of CSI aired to date and concluded that approximately 40 percent of the techniques used were fictional. The remaining 60 percent of procedures were valid only in their rough methods (for example only in the use of accurate names for analysis, but not in the actual techniques). The portrayal of the job of forensic investigators was also unrealistic. For example a single investigator would be assigned to a single case and be involved from the crime scene through all analysis and the inevitable confession by the suspect. This creates an unrealistic expectation for a forensic witness to be an expert in all fields when they generally specialise in one. When examining the conclusions made by jurors in a simulated trial, who were asked if they watched CSI, 29% of the group that did not view CSI regularly would have convicted versus 18% that did. It seemed that regular watching CSI created scepticism in the jurors, leading to them being less persuaded by forensic evidence not up to the same (impossible) standard as the show. They noted however that this was only a single mock case and the results could not be said to be statistically significant. It was also unknown if societally this trend would be a negative effect, with CSI exposed jurors disbelieving reliable evidence, or a positive one, in which these jurors were more cautiously sceptical of potentially unreliable evidence (Schweitzer & Saks 2007). This potential trend was investigated further over the following years.

Ferguson (2013) compiled information from these studies and explored the possible effect of such shows on the public, and in turn he termed the trend the “CSI effect” (Ferguson 2013). He concluded that the effect was three fold; in that it had the potential to cause an increased interest amongst students in pursuing a career in criminal science, the potential to increase

awareness amongst criminals on how to get away with crimes and an increased expectation by jurors and the public when it came to the use, validity, and effectiveness scientific evidence and related expert testimony. It is this last potential effect that will be focussed on in this dissertation chapter due to its possible influence on the expectations placed on forensic laboratories (Ferguson 2013). In recent years the CSI effect has been expanded to include the effect of the media on the public perception and expectations of forensic science (Cole 2015).

A 2015 paper by Cole examined the effects of the media and CSI type programs on the public. His paper focussed on the ways the media and CSI type shows distort the reality of the situation of forensic science. This study involved an examination of 397 media articles on forensics through 2002 to 2011. Falsities included matters of time, it was estimated that what is expected to take days would in reality require six months for a forensic laboratory to process, capacity, wherein a single team of investigators focussed on one case at a time when in reality they would have to work up to 30 cases con-currently in the US, and technology, again highlighting fictional techniques and technology designed for aesthetic rather than functional reasons (Cole 2015). In a court setting this ultimately means that jurors put increased pressure on the prosecution to meet higher standards than are practical, or in many cases possible.

1.1.3. Challenges facing forensic science

In order to meet these high expectations the forensic services must overcome many challenges. In 2009, the National Research Council (NRC) published a report on the challenges faced by forensic science in the US (NRC 2009). They identified four key areas: “resources, research, standardization, and education”, which were succinctly explained by the statement of Peter M. Marone to the Subcommittee on Crime, Terrorism and Homeland Security (Marone 2009).

In terms of resources, one of the major problems highlighted, was funding of the forensic sciences. It was explained that often funding was determined by the government based more on political reasoning than the actual situation in the forensic laboratories. An example of this being 2007 financial crisis that saw many US states reduce funding in all areas. Funding was also not allocated to various fields in the suggested appropriate ratios, with a disproportionate amount being spent of DNA analysis (Marone 2009).

Not enough funding was allocated for research either, however there was a government demand that all forensic methods be validated and new methods be developed, which could only be done through further research (Marone 2009). It was also highlighted that a broader research base was required. There were more research scientists working in the biological and chemical fields, in which methods have already been validated, versus field that still require validation such as tool mark or fingerprint examination. This may also be attributed to disproportionate funding, focusing on the biological and chemistry fields, whilst not paying more attention others (Marone 2009). This lack of validation has also contributed to a lack of standardization within certain forensic fields.

Also contributing to a lack of standardization was the lack of fixed guidelines for lab accreditation, qualification of employees and standard methods and report formats. Marone stated that quality education programmes in the forensic sciences could rectify this by providing personnel training in the field of work and on laboratory standards and accreditation (Marone 2009).

1.1.5. Forensics in South Africa

In South Africa similar challenges may face the forensic community due to an increased crime rate, lack of funding and training. However the law and process of investigation differ, for example a judge not a jury system. The process of unnatural death investigation in South Africa is governed by the South African Inquests Act of 1959.

According to the South African Inquests Act of 1959, all suspected non-natural deaths have to be investigated in order to determine the identity of the deceased, cause of death, date of death and whether or not someone could be charged with an offence (South African magistrates court 1959). In this case, suspected non-natural deaths are defined as any death suspected to possibly be due to physical or chemical factors, suspected criminal commission or act of omission. This includes cases such as murder, in which someone can be held responsible for the death, to more subtle cases such as sudden deaths or procedure related cases in which any possible blame needs to be confirmed or ruled out. In all of these cases pathologists are required to examine the body in a post-mortem examination (PM) (Inquests Act 1959). Figure 1 puts this

information into more context by comparing the ratio for each cause of death in the city of Cape Town.

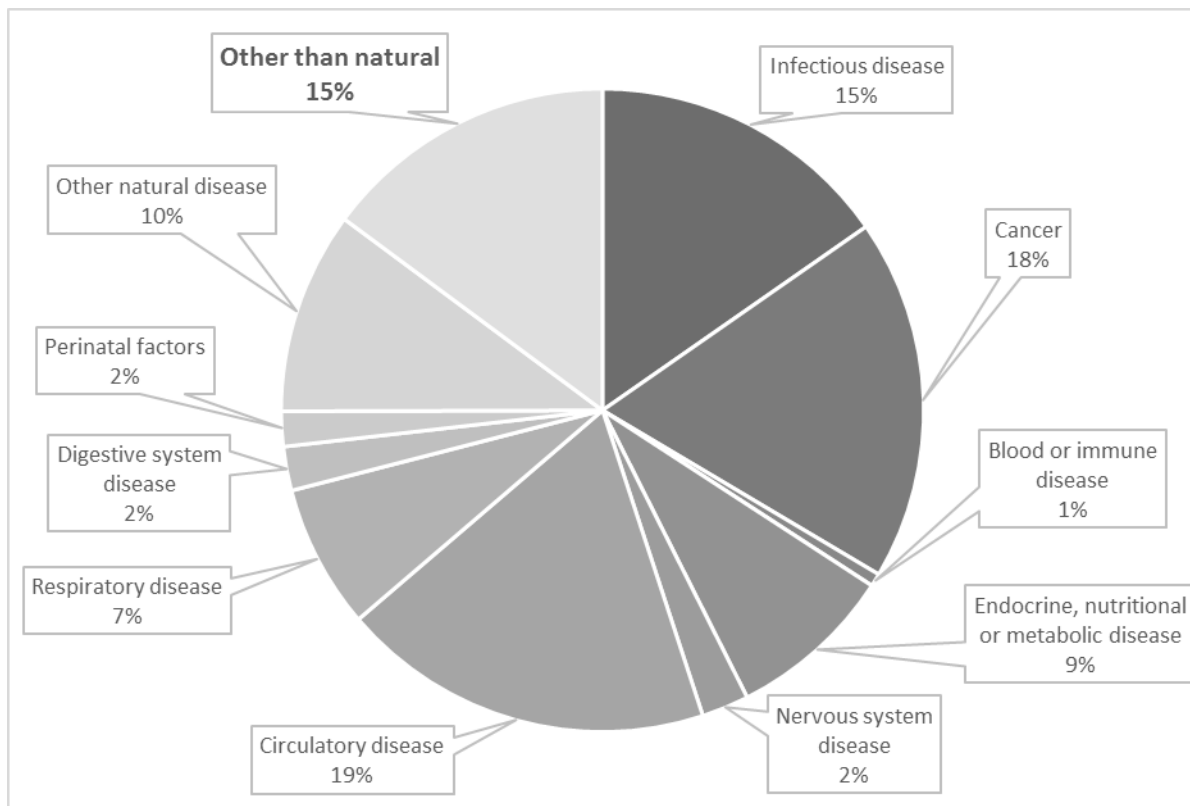
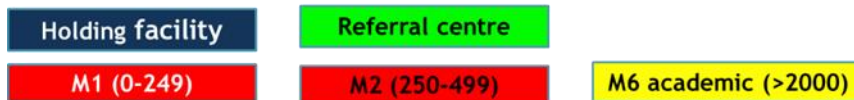


Figure 1: Percentage of each documented cause of death for all recorded deaths in the city of Cape Town, 2014 (Statistics South Africa 2015)

As figure 1 illustrates, other than natural deaths tied with deaths due to infectious disease as being the third highest cause of death in 2014 at 15%, with circulatory disease being the most frequent cause (19%) and cancers the second most (18%) (Statistics South Africa 2015). The bodies for the non-natural cases (15% of total deaths) are sent to forensic pathology centres for post-mortem (PM) examinations.

There are 18 pathology facilities currently in the Western Cape, an idea of their location can be observed in figure 2. Figure 1 shows the location of facilities:



Number of cases by facility in ascending order:

Swellendam	66
Riversdale	79
Laingsburg	107
Beaufort We	113
Mosselbay	137
Vredenburg	165
Wolseley	171
Oudtshoorn	173
Knysna	182
Malmesbury	205
Vredendal	237
George	313
Hermanus	382
Paarl	424
Worcester	524
Stellenboch	534
Tygerberg	3263
Salt river	3695

Figure 2: Pathology centres in the Western Cape and the number of cases for each, in 2015 (Western Cape Government 2015)

As can be seen above of there were eighteen forensic pathology facilities in the province, five being holding facilities and three referral facilities, at which autopsies are not performed. Of the remaining ten facilities four were M1 level (able to process up to 249 cases annually) and two were M2 level (processing up to 499 cases annually). This leaves the bulk of cases to be examined at Tygerberg and Salt River Mortuary (which process over 3 500 unnatural death cases each annually) (Western Cape Government 2015). This high caseload (associated with death investigation analyses) is an added challenge that South African mortuaries and forensic facilities face as well as the four main challenges previously identified for international forensic facilities (resources, research, standardization, and education) along with other issues. This may have been further affected by the closure of the Stellenbosch and Swellendam facilities in 2016.

South Africa also faces the challenge of standardisation of forensic practices. A 2011 paper by du Toit-Prinsloo et. al. focussed on the investigation of sudden, unexpected and unexplained infant deaths (SIDs deaths) and showed a lack of a comparable strategy in investigating cases. The retrospective study analysed data from infant fatality cases (younger than one year old) in two forensic pathology centres, one in Pretoria and one in Cape Town from 2000 to 2004. Over 12 000 cases per centre were recorded, giving the study a large data pool from which to draw reliable statistics. Out of these cases, 512 were identified as possible SIDs deaths however only 171 of these had been classified as such upon the initial investigation (du Toit-Prinsloo et al. 2011).

There was also a statistically significant difference in the percentage of cases declared as SIDs between the two centres, 9.17% of the sudden unexpected deaths in infants (SUDI) were classified as SIDS cases in Pretoria, whilst in Cape Town, 40.25% were classified as such. This was attributed to the fact that investigation protocol differed between centres and cases, with no standard procedure set in place, particularly in the definition of these cases. In Pretoria, 18.35% of SUDI cases underwent a partial autopsy to verify the diagnosis of SIDs, whilst 0.24% (a single case) was confirmed as such. Without such a national protocol, data from different centres was not comparable and some information may have been missed (du Toit-Prinsloo et al. 2011). It is also important to note that because SIDs is a diagnosis of exclusion a partial autopsy may not be sufficient to justify its diagnosis.

1.1.4. Summary

It can thus be seen that the advancement of forensic techniques has resulted in more weight being placed on forensic science as timeous and reliable evidence in the courtroom. This, along with the CSI effect and increasing public awareness of forensic science, has led to an increase in what is expected of forensic laboratories. However there are many challenges faced by laboratories that prevent such high quality results from being produced in the timely manner expected. These include a lack of resources, which in turn affects areas of research for future method development and validation, a lack of standardization and an increasingly high case load. The question is then how efficiency and effectiveness be increased to match expectations in light of minimal funding? Previously published strategies will be examined in this literature review in an attempt to answer this question and provide a point of reference for the research of this study. This review will focus on the challenges of reducing costs and increasing efficiency and effectiveness. This will be done with a mind to identify gaps in this research in a South African context. Finally the context of the research study will be explained relevant to these discussed papers.

1.3. Literature Search strategy

A systematic search of the literature using google scholar, PubMed and Science direct was done using key terms such as “criminal forensic efficiency” or “challenges to forensics”. The first round of literature was read and further key search terms developed from it.

Papers were included in this review if they were deemed to provide insight on the challenges faced by forensic fields internationally and in South Africa or ways that they could be resolved. A focus was made on papers identifying how to increase efficiency and effectiveness since during research it was decided to confront this area for the research project.

Although no specific time frame was used and no papers would be excluded for being too old, more recent papers were included (7 years since publishing and less) and the time frame from 2009 onwards was emphasized.

1.4. Strategies for addressing challenges in the forensic sector

1.4.1. Financial issues: Outsourcing and privatisation

In 2010, the United Kingdom (UK) privatised its forensic services, moving from partial outsourcing to entirely closing down its government run forensic laboratories and outsourcing all operations (McAndrew 2012). This was done since the government was incurring a loss of up to 2 million pounds per day (McAndrew 2012). A paper by McAndrew (2012) critically analysed the benefits of a private business based model for forensic service provision. He stated that in a free market the price of a service is more likely to reflect its value since prices reflect the market, which fluctuates more regularly than government funding is re-examined and changed (McAndrew 2012).

Since price and profit vary regularly, he went on to explain that an open market provides different incentives than government funding. With government funding, even in cases of partial outsourcing, tenders are given out for a fixed period and a large sum is paid for certain broad results to be met. Profit and personal benefits such as salaries and bonuses are thus not as market dependant. For example, a manager's goals under a government system may be to gain status since salary is assured. Thus focus on production (e.g.: more tests done) may lead to an unnecessary spending of resources, rather than in a business setting where minimal spending and work for maximal results is often the way to profit. However this emphasis on profit can also have negative consequences (McAndrew 2012).

To begin with, it has been argued that a forensic service motivated solely by profit may not produce as reliable results due to not emphasising accuracy or reliability or the use of inferior, cheaper, materials or equipment. However such a problem may be overcome if laboratories are required to obtain accreditation and conform to ISO or other standards with regular quality testing and inspections (McAndrew 2012).

Whilst this may prevent quality from slipping, there is still the ethical question of having a public service in the hands of the private sector. Much forensic data can be considered confidential, for example, access to the DNA database. Whilst at the present time only report

generation is done privately (e.g.: generating a profile not matching it) there is the question of what data should be confidential and what can be seen (or even claim to be owned) by private companies. This becomes a further problem when one considers the possibility of a monopoly arising in the forensic market in which a single company is responsible for all analysis and has access to all reports arising (McAndrew 2012). The major advantage of privatisation is the competition factor between different private companies, but this may be achievable through other means.

Koppl (2005), suggested a program of “competitive self-regulation” in which evidence would be equally divided amongst forensic laboratories capable of processing it. Laboratories’ quality would be carefully monitored through random selection of cases for duplicate testing. There would also be an emphasis on cost reduction, with expense between laboratories being compared (e.g.: cost per case). Laboratories that performed well would receive additional funding and their methods be adopted by other laboratories. Those that do not perform well would be closed (Koppl 2005).

Whilst this method may have some benefits it would be difficult to implement. The locations of forensic laboratories may not be ideal for an equal division of cases (those in a highly populated city versus those servicing several smaller cities for example). If a laboratory had to be closed it may cause a backlog at other laboratories. The author’s description of employing the best methods however, can be done through other means, at least for quality, by accreditation of facilities to international standards.

1.4.2. ISO accreditation

An international standard adopted by many forensic laboratories is the ISO17025 for testing laboratories, and outlines the general requirements for monitoring and ensuring competence, covering testing and calibration performed using standard methods, laboratory-developed methods and non-standard methods. It explains how to validate methods, monitor performance, identify performance and quality issues and correct them. If applied and correctly implemented and accredited, it may allow for different laboratories with the same accreditation to be able to perform equally well and their results are equally reliable. However it is not a step by step

guide for laboratory methods, these must be designed by the laboratory itself or adopted from previous ISO17025 validation studies (ISO 2005).

An example of such a validation study can be seen in a DNA assay for typing 52 single nucleotide polymorphisms (SNPs) for human identification by Borsting et. al. (2009). When the method was previously tried in different laboratories the results seem comparable and the method easy to implement, however some discrepancies were noted, specifically that some peaks heights were too high. Using the laboratory's internal guidelines it would have been acceptable to adjust the peak height ratio after testing. However for ISO accreditation the method had to be redesigned. By testing the method on 50 paternity cases and 33 twin sets to ensure statistical validity and meeting all ISO criteria an internationally accepted method was created. It would now be possible to transfer this method for use in any other laboratory, with the permission of the researchers involved and an internal methods validation to ensure its accuracy and applicability of use. This way only one laboratory need develop a standard technique that is proven to provide quality results, instead of each creating taking the time to create their own standards (Borsting et al. 2009).

1.4.3. Process mapping

Once a method, procedure or process has been decided upon it must be displayed in an easy to understand and implement manner. Process mapping, in which a method or process is displayed in a flow chart, can help with this. It can also be used to record simply and visually a larger part of the workflow, or even the entire workflow, of a laboratory (SWGDMI 2013a). Figure 3 gives a brief example of what a process map may look like for when a case is reported to a forensic pathology service or medico legal investigation service. This may include, the reporting of an unnatural death, which may require investigations such as on the scene or a hospital, performance of an autopsy, and other ancillary investigations.

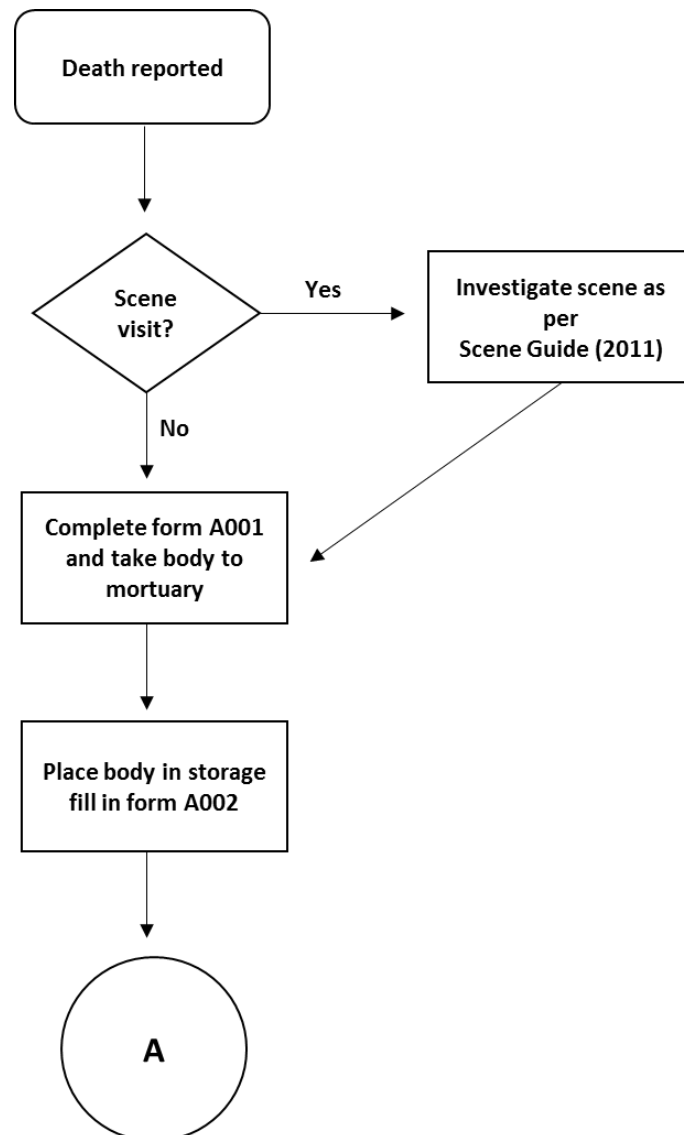


Figure 3: Fictional example figure of a process map when a death is reported

Figure 3 helps to highlight some of the generally accepted trends in designing process maps. The start of a map is indicated by a box with rounded corners. A decision box uses a diamond shape with “yes” flowing to the right and “no” directly down. Forms and guides to be referred to can be included so as to simplify the map, whilst still providing extra detail if required. A continuation of the map onto another page is given by a circle with a letter in it, which is repeated at the point of continuation on the next page. By using a standard method in their design, process maps can be read easily by any other speaker of the language they were made in (Abubakker 2013). If a process map were detailed for forensic pathology practice it may be a simple way of illustrating the workflow as well as provide a way to identify where challenges or backlogs are lying by investigating each step in the process.

1.4.4. SWOT matrices

Whilst these methods may help ensure standard practices are used there is also the competition advantage to privatisation mentioned earlier that requires consideration. A way to do this, apart from Koppl’s methods discussed previously (Koppl 2005), is through the application of business analyses in government-run forensic laboratories with an aim of increasing efficiency and effectiveness. Thus the techniques that would be used by private businesses are used by the state or public entity instead. One of the simplest of these techniques is the SWOT (strengths, weaknesses, oppotunities and threats) matrix.

Newman et. al (2011) provided a basic example of how technique can be utilized by through the analysis of the internal strengths and weaknesses of a laboratory and the external threats and opportunities that affect its running. These factors are then displayed in a simple table as per Figure 4 (Newman et al. 2011).

	<u>Strengths:</u> List internal factors that give your laboratory an advantage	<u>Weaknesses:</u> List internal factors that may cause issues in your laboratory's performance
<u>Opportunities:</u> Identify external opportunities that your laboratory can take advantage of	Use these strengths to better utilise opportunities	Limit these weaknesses by using available opportunities
<u>Threats:</u> Identify external factors that may threaten your laboratory's performance	Use these strengths to minimise threats	Try to limit these weaknesses and still minimise threats

Figure 4: Example of how to fill in a SWOT matrix by stating and cross referencing strengths, weakness opportunities and threats (Newman et al. 2011)

Figure 4 shows what would be filled into each section of a SWOT matrix. By listing strengths, weakness, opportunities and threats and seeing how they interact, allow for suggestion to be made on how to use strengths and opportunities, whilst minimising weaknesses and reducing threats (Newman et al. 2011). Whilst the SWOT matrix highlights the beginning of the application of business principles and metrics to improving public forensic services, many studies have been performed and alternative advances to investigating and improving efficiencies have been subsequently reported.

1.4.5. Lean Six Sigma and the DMAIC approach

Lean Six Sigma (LSS) is a business-based strategy based on the “Lean philosophy”: that the time needed to deliver a product to the customer should be reduced as much as possible by identifying and eliminating waste (Shaffie & Shahbazi 2012b). In LSS, this is achieved through a Six Sigma approach consisting of five steps: define, measure, analyse, improve and control, also known as the DMAIC approach (Shaffie & Shahbazi 2012). The ‘define’ step involves identifying the problem to be investigated and developing a problem statement highlighting the

critical area for improvement, outlining the business case (why the project makes good business sense, its scope and benefits), defining standard terms and drawing up a process map showing the workflow involved in the entire process (Shaffie & Shahbazi 2012b). This is followed by the 'measure' step, involving pin-pointing variables in the process map that can be measured, deciding on an appropriate benchmark for comparison, data collection and validation of the system. The 'analyse' step that follows consists of calculating current performance through metric analysis, comparing it to the benchmark standards, and determining how performance must change to meet that benchmark. In the 'improve' step, this data is used to suggest ideas for improvement to be able to meet the benchmark, which are then implemented in the control step and monitored to identify any further problems and/or improvements that may develop (Hahn 2011, Shaffie & Shahbazi 2012). Whilst this technique originated from, and is usually applied in, the business field; studies have been performed to determine how best to apply it in a forensic setting.

Two pivotal studies investigation the application of LSS to forensic practices were those of QUADRUPOL and FORESIGHT (Houck et al. 2009, Speaker 2009). QUADRUPOL took place in Europe in 2003 and analysed data across four participating forensic facilities. Data on casework, financial, and personnel was analysed for each investigative area, such as pathology, toxicology and DNA analysis. The study aimed to develop standards that could be compared between facilities of differing size, with different resources and caseloads. It was found that ratios were most effective in these cases, for example the cost per case or number of items processed per case, to permit relative comparison. FORESIGHT was intended to be a replication of the QUADRUPOL study comparing 15 participating laboratories in the United States (US). However, this study also added further key performance indicators (KPI) that were found to be necessary in a US setting, for example cases per square foot. A further result of these studies was the development of a list of defined terms that could serve as a benchmark for future studies, a necessity for the 'define' step (Houck et al. 2009, Speaker 2009).

Some of these key performance indicators were published in an article by Speaker (2009) and can be summarised below in table 1:

Table 1: Key performance indicators devised by Speaker (2009)

Efficiency measures		
Tests and reports per full time employee (FTE)	Cases, items, samples and tests per FTE	
Quality measures		
Errors per test, sample and case	Tests per item, sample and case	
Production measures		
Capital expense/total expense	Operational expenses/total expenses	Capital expense/labour expense
Casework hours/total hours worked	Courtroom hours/total hours worked	Support staff/total staff
Operational staff/total staff	Scientists/operational staff	
Return on investment		
Items processed/total costs	Samples processed/total costs	Tests completed/total costs
Reports completed/total costs	Backlog cases/total costs	

Another example of this type of study was performed by Louisiana State Police Crime Laboratory, who performed a LSS study to improve the efficiency of their DNA services (Richard & Kupferschmid 2011). The final progress report was published in 2011, showing a 134% increase in the completion rate of sample processing. This allowed laboratories to process more samples than they were receiving and they could thus process backlog samples as well. This study also highlighted the importance of the control step in monitoring the implementation of suggestions for improvement so that any resulting problems can be fixed. For example, when a bottle neck was removed upstream, DNA extraction showed a new bottleneck, which was rectified by purchasing further equipment and increasing the number of extractions that could be conducted at once. It is thus advisable that after implementing changes, one continues to study the process and does not assume the problem has been fixed (Richard & Kupferschmid 2011).

The Louisiana study cost a total of approximately \$600 000, however it is now possible for a laboratory to conduct self-analyses using FORESIGHT metric analyses, a service offered by

the West Virginia University (WVU) College of Business and Economics for free, with consultation from the WVU experts. Through this comparison areas for improvement can be identified and staff of WVU can suggest ways to improve throughput, minimise waste and increase efficiency and performance (WVU 2007, Houck et al. 2009). This process requires a Laboratory Reporting and Analysis Tool (WVU 2007a) spread sheet to be completed and submitted. Relevant terms have been standardized and defined to limit errors based on personal experience. The analysis is conducted by comparing the data on this form to that of other participants (West Virginia University 2012). This is currently applicable more so to the U.S. Forensic laboratories, and has not been applied to South African practice, which is different and requires its own level of standardization.

1.5. The role of this study

The four major challenges faced by forensic practices internationally involve “resources, research, standardization, and education” as mentioned previously (NRC 2009). Whilst resources are a responsibility of the government and research and education are roles of universities and other establishments, forensic laboratories may have the resources and capabilities to be able to tackle the issue of standardisation. Examples of methodology that may assist are described in the studies discussed under section 1.4.

These cited studies illustrate what has been done internationally when applying business metrics to forensic practices in order to increase efficiency and effectiveness. However, no such study (Like QUADRUPOL or FORESIGHT) has been completed in South Africa. It is also recognized that these studies largely focus on forensic science laboratory practice. It may also be found that different challenges are faced in this country that are identified through this research, and may open avenues for further research in South Africa.

An example of how international standards could be compared to local standards can be derived from a report by the Scientific Working Group for Medicolegal Death Investigation (SWGMDI) in 2013, which used data on medicolegal autopsy and death investigation centres collected by the National Association of Medical Examiners (NAME) over the previous 15 years to draw up standards for forensic pathology centres in the United States (US) (SWGMDI 2013b).

As previously mentioned some areas, such as SIDs cases, lack standard definitions of terms that can lead to differing diagnosis of cause of death at different mortuaries. WVU provides some ideas of terms to standardise on their free LabRAT form, for example from what an “item” to what constitutes alcohol testing and other investigation areas. Setting these definitions in context will be an essential first step so that Lean Six Six metrics (via the DMAIC approach) can be applied with minimal confusion.

It is hoped that this project will provide a basis for forensic efficiency analysis and improvement in South Africa and set a benchmark that other studies can improve upon.

In conclusion, forensic science is becoming an increased focus of investigation and a larger part of court evidence. In order to provide exceptional service and accurate results and meet public demand it is wise to investigate laboratory and forensic practices and optimise them, which can be done through business based practices such as the DMAIC approach and LSS. This study will be focussing on examining the efficiency and effectiveness of forensic pathology practice in South Africa with an eye to showing how these business based approaches may be used here.

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Chapter 2: Methods

2.1. Study approach and design

This study was intended as a pilot study and aimed to highlight how Lean Six Sigma and DMAIC methods could be used to analyse and improve efficiency and effectiveness in forensic pathology practise, and whether use of these metrics are applicable to a developing country. It was conducted at the University of Cape Town during the course of 2016. It consisted of two parts: a retrospective cross sectional and quantitative component and an observational component. Both sections focussed on cases and practises at Salt River mortuary in Cape Town, South Africa. This is one of the two largest of 17 mortuaries in the Western Cape.

The examination of these practices included investigation into processes from the receipt of a body at the mortuary, through examinations and analyses, until finalization of the cause of death (the function of Forensic Pathology Services) and generation of the required reports by forensic pathologists. Salt River mortuary was chosen to examine in this study as it is one of the busiest in Western Cape receiving over 3500 admissions per year.

For the retrospective component all the cases from 2015 in which decedents were examined by a pathologist employed by Salt River mortuary and for which a post mortem examination report (FPS007 report) was available for data collection were sampled. Case files for pathology are different to police files as they are aimed at providing information used to determine cause of death and a report stating this cause. In some cases, a preliminary report stating cause of death is undetermined at autopsy or is under investigation, the pathologist may have collected specimens for ancillary investigations (Inquests Act, 1959) and the test results may still be required. An amended FPS007 or docket opinion report may subsequently be completed by pathologists upon receipt of the results, however some results such as toxicology can take months to be returned. It was decided to use case data from 2015, along with financial data for the 2015 year, obtained from the Department of Forensic Pathology and Salt River mortuary.

For the observational component the work of the pathologists was observed. There were ten pathologists employed by Salt River Mortuary at the time of this study. Each was asked if they were willing to participate, and all agreed and signed informed consent forms. A typical work day at Salt River mortuary (from arrival of the pathologist through autopsies to clean up) was observed for each pathologist for approximately three autopsies per pathologist (28 total observations).

2.2. Data collection and analysis

Since this study was based on the use of the DMAIC approach; data collection and analysis are best described in sections as follows:

2.2.1. Define

The first step in a DMAIC approach is to define key terms for standardisation (Shaffie & Shahbazi 2012a). In this case, terms important for understanding the process in forensic pathology and for collecting data in an accurate and systemic fashion were identified. These terms came from three main sources: the LabRAT form available from West Virginia University's website (a form for FORESIGHT analysis that can be populated by a client and sent to them for analysis) (WVU 2007a), a 2009 study by Speaker that described "Key performance indicators for managerial analysis" (Speaker 2009) and terms that were identified as relevant for data collection in this project after reading multiple case reports. These terms and their sources are summarised in table 2. Definitions identified and proposed can be found in Appendix A.1.

Table 2: Key terms requiring definitions in this study

From LabRATT form					
Alcohol testing	CO testing	Court time	Full time employee	Item	Sample
Test					
From "Key performance indicators"					
Capital expense	Casework hours	Labour expense	Facilities area	Operational staff	Operational expense
Scientist	Support staff	Total expense	Total hours		
Terms needed for this project					
Accident	Autopsy	Cause of death	Closed case	External examination	Final FPS007
Histology	Homicide	Hospital report	Lab27 form	LODOX X-ray	Manner of death
Microbiology	National Health Laboratory	Non-natural death	Odontology	Open case	Organ cut
Pathologist	Pathology	Pharmacology	Physical	Post-mortem examination	Post-operative
Preliminary FPS007	Report date	Request	Road traffic accident (RTA)	Sexual assault	Sudden unexpected
Suicide	Toxicology	Virology			

These terms were defined by reading and citing literature or as project specific terms for this study so as to standardise data collection. For example a closed case specifically in this project was defined as when a “finalized cause of death is determined by the forensic pathologist”. All definitions can be found in Appendix A.1.

2.2.2. Measure

2.2.2.1 Retrospective case data

Case data for the year 2015 was first preliminary reviewed on the Office Autopsy Database (HREC R036/2014) for included cases. Cases included were then reviewed in more detail (post-mortem reports and available ancillary investigations) in hard copy and digital format from The Division of Forensic Medicine and Toxicology (UCT). Data was captured using EpiData (version 3.1, available at <http://www.epidata.dk/download.php>). In total 3567 cases were captured.

The data captured can be best explained in three main categories: dates, factors and requests/tests. ‘Date’ data included the date on which any significant events occurred (for example receipt of the body) or reports were generated (Table 3). This was used when analysing time intervals for various processes, for example the time taken to close a case would be from the date of body receipt to the date of final autopsy FPS007 report commissioning (stating cause of death). Turnaround time was recorded in days from PM to report return.

The recording of ‘factors’ involved noting whether or not a certain factor was associated with the case (e.g.: if it was a road traffic accident (RTA)) (Table 3). The ‘requests/tests’ category involved recording if a test was done or a request was made at the PM and if so how many items, samples and tests were involved (Table 3).

The definitions of items, samples and tests have been modified from the LabRATT template to be as follows for the purpose of this project (Appendix A.1.):

Item: A single object given for laboratory examination, e.g.: a tube of blood or single bullet, single item of clothing or a single body (WVU 2007b).

Sample: An item or part of an item that is used for testing and produces a result published in a report, e.g.: tissue piece or blood sample from a collected tube (WVU 2007b).

Test: Analyses of a sample taken from an item or the entirety of the item, not including reviews of previous data. The test results are included in a report (WVU 2007b).

For example in histology an item would be a tissue specimen, a sample would be a piece of the original specimen taken to make a slide and a test would be the analysis on the slide.

Bearing these definitions in mind, Table 3 gives a summary of the various areas falling under each data category and the division or person responsible for each request/test:

Table 3: Categories for which data was collected and the person/division involved with

them

Dates	Factors	Requests/tests
On the scene (by FPOs):	Accident	Pathologists at Salt River:
LAB27 report	Homicide	Post mortem examination
On the scene by hospital staff:	Post-operative	LODOX x-rays
Hospital report	RTA	Autopsies
FOs at Salt River:	Sexual assault	FCL:
Body arrival at Salt River	SUDA or SUDI or SUDJ	Alcohol testing
Pathologists at Salt River:	Suicide	CO testing
PM examination	Other	Toxicology
SUDI/SUDA form		UCT pharmacology:
Forensic Chemistry Laboratory (FCL):		Pharmacology
Alcohol report		UCT histologists:
Carbon monoxide (CO) report		Histology
Toxicology report		Pathologists at UCT with histologists:
UCT pharmacology:		Organ cut
Pharmacology report		NHLS:
UCT histologists:		Microbiology
Histology report		Virology
Pathologists at UCT with histologists:		Blood chemistry
Organ cut report		Independent analysts:
NHLS reports:		Odontology
Microbiology report		State forensic genetics laboratory:
Virology report		Genetics
Blood chemistry report		SAECK
Independent analysts:		Others:
Odontology report		Physical evidence
Others:		Other
Other reports		

2.2.2.2 Observational data

The observational section of the study consisted of a non-participatory observation of a typical work weekday at Salt River Mortuary for each of the ten pathologists who currently perform autopsies (7 consultants (fully qualified consultant forensic pathologists), 1 medical officer and 2 registrars (in forensic pathology residency)). This observation spanned from the pathologist's arrival to the mortuary, through post-mortem examinations and clean up, and their departure. It must be noted that the pathologists complete the autopsies at Salt River Mortuary and return to the University of Cape Town, a separate location, for the remainder of the working day. Observations were only made at the Salt River mortuary. Typically this consisted of a 1.5-5 hour observation during which the observer made notes on any procedures done and their times (e.g.: 08:45- Case 1 X-rayed, 08:50- Case 1 taken back to PM area, etc.) as well as any major problems that occurred (e.g.: 08:50- Gloves have run out with no replacements).

2.2.2.3 Financial and staff data

In order to conduct efficiency calculations as laid out in "Key performance indicators" (Speaker 2009), the following financial and staff data was collected:

- Number of full time employees (operational, reporting pathologist and support)
- Total expenses
- Operational expenses
- Capital expenses
- Labour expenses
- Total work and case work hours (support, operational and scientists)

This data was obtained for the 2015 year from both the Division of Forensic Medicine and Toxicology and Salt River Mortuary and pooled, since staff (such as pathologists) and analyses (e.g.: histology) are all within the FPS West-metropole (Salt River) service and work occurs at both locations.

2.2.3. Analyse

2.2.3.1 Retrospective case data

Retrospective case data was only collected if human remains were examined by a pathologist employed by Salt River mortuary and an autopsy (FPS007) report was available. A flow chart showing the inclusion and exclusion of cases was drawn up to better show this and the sample size (Figure 5). Cases were excluded if the remains were non-human or if the remains were examined by someone other than a Salt River employed forensic pathologist.

Data collected in EpiData was exported into Excel 2013 for analysis. The number of times a request was made for each ancillary investigation area was totalled, these areas being:

- Alcohol (ethanol analyses)
- CO (carbon monoxide)
- Genetics
- Histology
- Microbiology
- National health laboratory services (NHLS) testing
- Odontology
- Organ cuts (organ pathology)
- Pharmacology
- Physical (forensic evidence)
- SAECK kit
- Toxicology
- Virology
- Other (eg.: fingerprint analysis)

Collection of samples for processing by staff in an investigation area was considered an acceptable indication of a request for analysis. A bar graph displaying the number of requests per area and their percentage out of the total requests was created to better show this data. This data was also represented in table format, divided by the type of case (based on the cause or alternatively the manner of death e.g.: RTA or accidental).

The date data was used to determine if a report had been published (it would have a date listed in the exported excel data). A stacked histogram showing the number of reports returned and outstanding for each test area was drawn up, a second histogram excluding alcohol test data for scale concerns was also included.

Date data was also used to determine the amount of time in days for these reports to be returned. For each investigation area the minimum number of days, upper bound ($Q3+1.5IQR$) and quartiles between them (Q1, Q2 or average, Q3) were determined. This data was used to compile two box plots describing the time interval for the return of reports: one for tests done by UCT, Pharmacology Division and FSL and a second for tests by the NHLS and odontology analysts. This was done to due to a large difference in the times between the two groups.

2.2.3.2 Observational data

Common steps in the post mortem and autopsy procedures were noted between pathologists from the observations (for example LODOX x-ray of a body) and the time taken in each case for these was recorded in Excel 2013. This data was used to draw up a process map outlining the general work flow involved in a post mortem examination.

Recorded time data was then used to determine the length of time spent on each case at the mortuary during observations. This data was separated based on cause of death and stacked histogram showing the amount of time taken per case of each type.

During observations any issues were noted, these were classified as time specific concerns (timing issues such as mortuary opening times), equipment issues, mortuary design issues, process concerns (concerns in the actual workflow) and interpersonal conflicts. A bulleted summary was given for each section.

2.2.3.3 Financial and staff data

Some of the business calculations did not lend themselves to clear graphical representation. For these reasons the number of cases, reports, items, samples and tests per full time employee (FTE) were placed in a table alongside the cost per case, report, item, sample and test.

By examining the time taken in each retrospective case for a final cause of death to be determined (the time for a final autopsy FPS007 report in days), a graph of the percentage of cases closed over a 30 day period could be drawn up. This was done through analysing the cumulative frequency of cases closed after each day they were open for and plotting day versus percentage cases closed. This graph was expanded upon in a second plot of closed cases over a 30 day period, with data divided into case type.

Using the financial and staff data, the ratio of capital to labour to operational expenses were compared using a pie chart (for combined data from the Division of Forensic Medicine and Toxicology and Salt River Mortuary). Likewise the ratio of the number of full time employed staff in each category (support, reporting pathologists and operational) were displayed in a second pie chart.

2.2.4. Improve

2.2.4.2 Retrospective case data

This data was intended to postulate current standards for the various investigation areas (e.g.: how long on average does it take for toxicology results to be returned?) and how these affect FPS practise and can be improved. A backlog case has been defined by the LabRAT form and Speaker (2009) as being a case open for longer than 30 days (Speaker 2009, WVU 2007a). This was extrapolated to report generation times to identify possible areas of investigation in which backlogs might be present, as definitions of ‘backlog’ from external agencies were not available. Suggestions of areas where backlogs were observed as well as where standardization is required were suggested. Further research on how to improve these areas of practise was suggested.

2.2.4.2 Observational data

The bottlenecks identified on the process map were analysed in terms of how they could be reduced or prevented based on the observational data. For example, if a queue developed to use the X-ray machine a possible suggestion could be better scheduling or a second instrument. Challenges foreseen to be associated with suggestions made for improvements were also considered. Some suggestions were also made based on what other published studies have done, for example automated note taking based on voice recognition for post mortems (Al-Aynati & Chorneyko 2003).

2.2.4.3 Financial and staff data

Spending ratios were compared to that found in international laboratories, for example as indicated in the “key performance indicators” paper by Speaker (Speaker 2009). However most of this data, such as staffing data, was meant to help postulate a benchmark for Salt River mortuary that could be compared to other mortuaries in Western Cape, and eventually South Africa, hence comparisons to current practise in other mortuaries was not performed in this study. Suggestions were made as to where standardization is required and whether application of these international metrics studies can be successfully applied in a South African setting. Determining an ideal benchmark for FPS practise in Western Cape and South Africa should be the subject of future research.

2.3. Ethics

Ethical approval was obtained from the Human Research Ethics Committee (HREC) of University of Cape Town (HREC REF: 177/2016) (Appendix A). Consent was obtained from all pathologists observed in this study. They were informed that there is no remuneration for the study, that their participation would be kept confidential, and that they were free to withdraw from the study at any time without needing to give an explanation, upon which any data obtained from their observation would be destroyed.

All retrospective and financial data was kept confidential, contained no specific identifying information, and was stored on a flash drive that did not leave the Division of Forensic Medicine and Toxicology, UCT, during the course of the study, which was stored securely when not in use. All data was anonymised so as to not identify any participants or sensitive data.

Chapter 3: Results

3.1. Retrospective case data

In total, 3695 cases were admitted to Salt River Mortuary throughout 2015 (Figure 5). Overall, 3567 cases were included in the investigation, based on the definitions established (Figure 5) (Appendix A.1.). It was from these cases that a more detailed retrospective analysis was conducted. This aimed at documenting and analysing numerical data associated with these cases and their ancillary investigations (including associated items, samples and the like) with the goal of assessing efficiency.

3.1.1. Included cases

A total of 128 cases (3.46%) from the 2015 files were excluded from this study. These excluded cases comprised of: non-human remains (n=1), anthropological remains (bones) analysed by Forensic Anthropology Cape Town (FACT) (n=5), hospital autopsies (n=37), the pathologist findings had not yet been dictated (n=70), the report had not been finalised (n=3) or cases not located due to unknown factors (n=12). Figure 4 summarises this data in a flow-chart format.

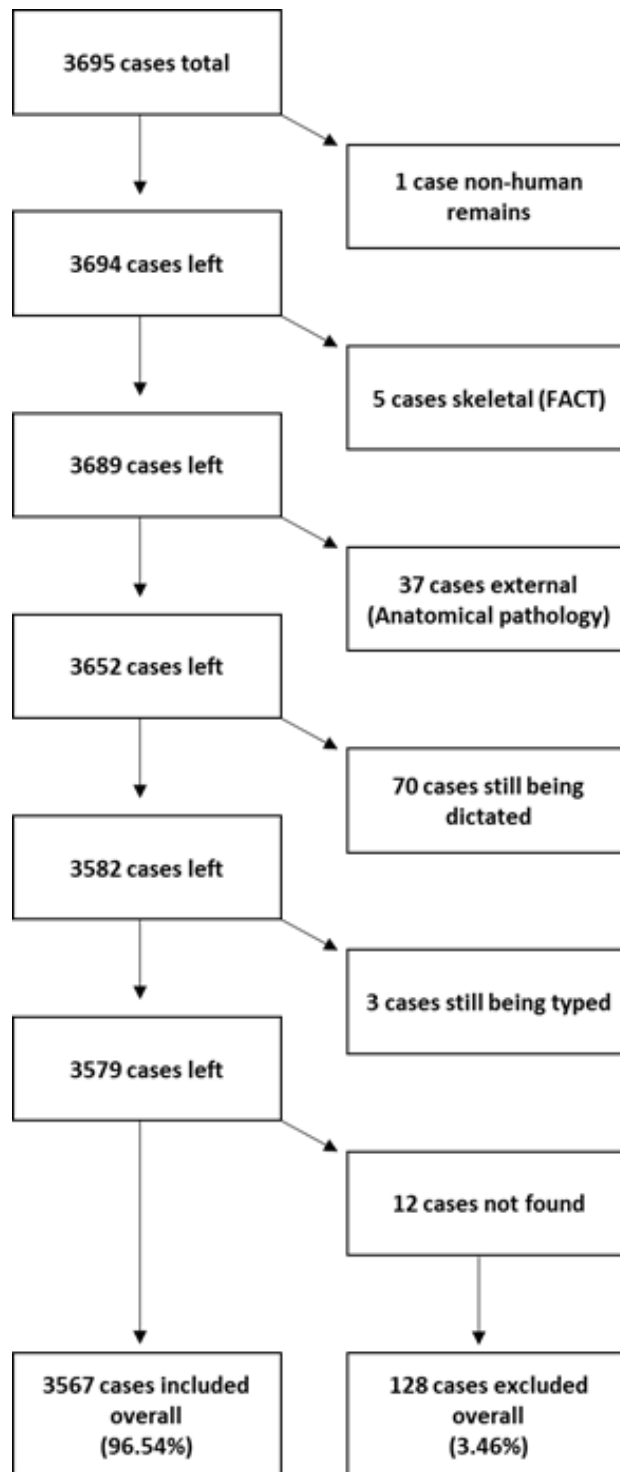


Figure 5: Flow diagram of Salt River mortuary case reports from 2015 included in the study and reasons for exclusion (remaining cases on left, excluded cases on right)

Figure 5 shows that overall 96.54% of admitted cases (n=3567) to Salt-River mortuary were investigated further in this study. These cases were used in retrospective analysis of report

turnaround times and related to staff and financial data. This large case pool provided a large sample size from which to draw statically useful conclusions.

The total report turnaround time from PM to finalisation of cause of death was recorded, but will be represented in a later figures (Figures 14 and 15) and related to the time for case closure (finalisation of cause of death hence releasing of the final PM/autopsy report).

3.1.2. Post-mortem Ancillary Investigations

Out of the 3567 cases of all-cause mortality 2234 cases (62.63%) had requests for ancillary investigations. The number of requests made and for which types of analyses are illustrated in Figure 6.

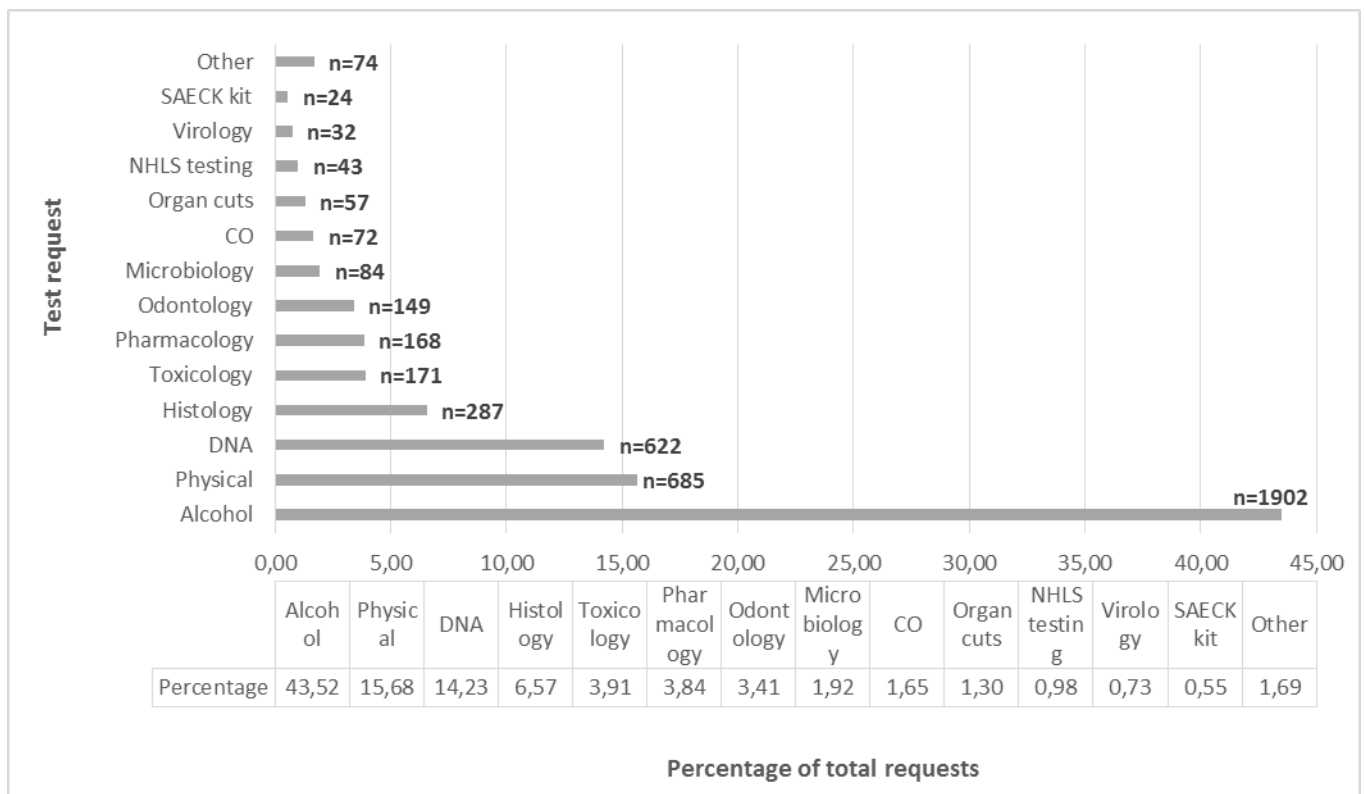


Figure 6: Comparison between different test areas (y-axis) in terms of their percentage of total tests requested (x-axis) with table summarising data below x-axis

As can be seen from Figure 6, blood alcohol analysis made up the bulk of requests at 43.5% (n=1902) in 2015. This was followed by physical evidence testing (e.g. bullets for ballistics) at

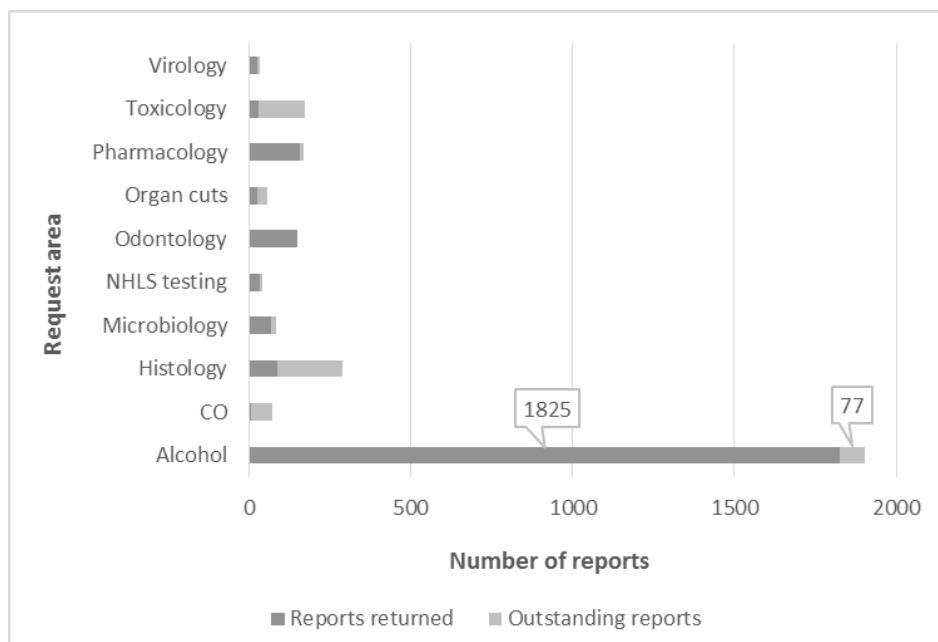
15.6% (n=685) and DNA testing for victim identification at 14.2% (n=622) requests. The least requested investigation was the analysis of a Sexual Assault Evidence Collection Kit (SAECK), made 0.55% of the time (n=24), the second and third least being virology at 0.73% (n=32) and NHLS testing (blood cell count and chemistry) at 0.98% (n=43). Overall “other” requests were made in 1.7% of cases (n=74). These included fingerprinting, identification of fingernail scrapings, tissues for evidence (not for histology or dissection), entomology and blood for private DNA testing requested by the family. Table 4 examines the requests made in more depth, linking them to different manners of death, including suicide, homicide, post-operative, accident and road traffic accidents (a separate category of investigation for the purpose of this study).

Table 4: Percentage of cases in which requests for analysis by different investigation areas were made, separated by manner of death

Test requested (percentage of cases)	Manner of death					
	Accident (n=132)	Homicide (n=1354)	RTA (n=399)	Postoperative (n=240)	SUDA/I (n=1019)	Suicide (n=216)
Alcohol	44,70	87,00	69,42	0,00	11,97	81,94
CO	0,76	0,52	0,00	0,00	0,00	1,85
Genetics	5,30	33,46	9,52	0,00	1,37	5,09
Histology	19,70	1,55	1,75	28,33	12,27	9,26
Microbiology	2,27	0,07	0,00	1,67	7,46	0,00
NHLS testing	3,03	0,00	0,00	1,25	3,04	1,85
Odontology	2,27	3,99	8,52	0,83	2,55	3,70
Organ dissection	4,55	0,81	1,75	5,83	1,18	0,93
Pharmacology	14,39	1,33	1,00	0,42	7,56	20,37
Physical	3,03	41,80	0,50	0,83	1,18	51,39
SAECK kit	0,00	1,70	0,00	0,00	0,00	0,46
Toxicology	16,67	2,36	2,01	0,00	4,81	24,07
Virology	0,00	0,07	0,00	0,42	2,94	0,00
Other	5,30	1,26	2,26	6,25	1,67	2,31
Requests per case (n/case)	1,22	1,76	0,97	0,46	0,58	2,03

The highlighted areas of table 4 show for each column the more frequent types of tests requested. For example in homicide, alcohol (ethanol) level analysis (mostly in blood but sometimes in vitreous humor) was most commonly requested (87.0%) followed by physical item analysis (41.8%) such as ballistics and genetics analysis (33.5%) for victim identification. Whilst in post-operative cases the emphasis was on histological examinations (28.3%).

Overall the highest number of requests made per case came from suicide cases (2.0/case), followed by homicides (1.8/case) and accidental deaths (1.2/case); in all these cases more requests were made than the total number of cases. In RTA (0.97/case), SUDA/I (0.6/case) and post-operative cases (0.5/case) fewer requests were made than the total number of cases however. The question is then, how many of these requests were completed? This information is described in Figures 7 and 8 and in more depth in Table 5.



Note: alcohol having 1825 reports returned and 77 outstanding, the rest shown in more detail in figure 8

Figure 7: Number of reports returned and outstanding (x-axis) for each request area (y-axis), unadjusted scale

In Figure 7 it can be seen that for alcohol testing 1825 result reports were returned from requests by October 2016, with 77 still outstanding. However due to the large amount of alcohol requests versus other test areas, a second graph focusing on other tests was drawn up to adequately compare the other areas, this is shown in Figure 8.

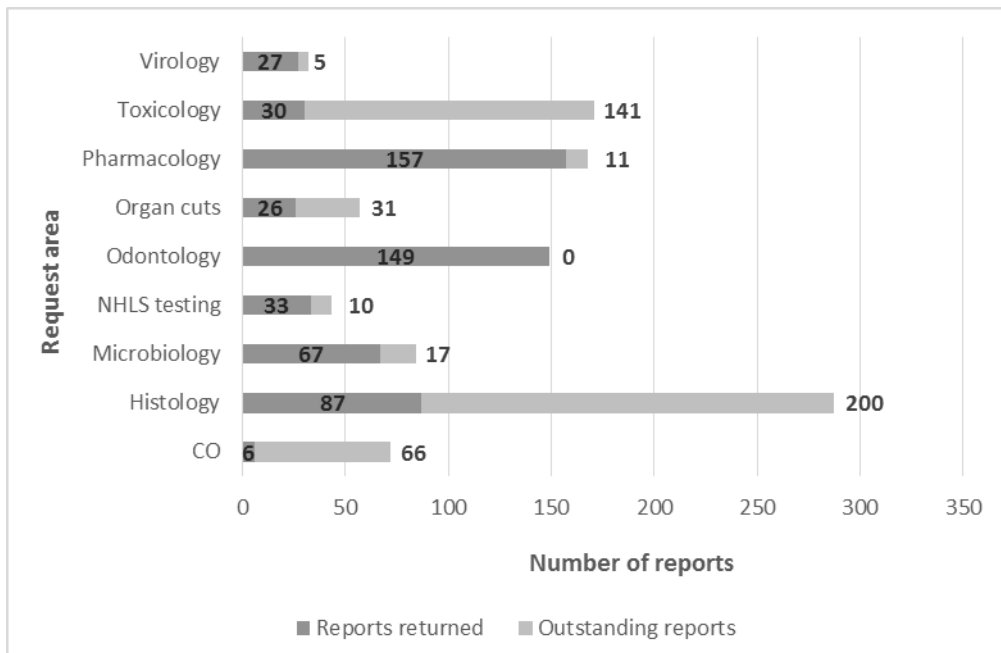


Figure 8: Number of reports returned and outstanding (x-axis) for each request area (y-axis), excluding alcohol for scale

Figure 8 illustrates that the greatest return of reports was for odontology with all requests resulting in the release of a report (n=149), followed by pharmacology with 11 reports outstanding and 157 completed. The lowest number of returned reports versus outstanding ones was for carbon monoxide (CO) testing with 6 reports returned and 66 outstanding. To aid comparisons, Table 5 displays the percentage of reports returned for requests in all test areas.

Table 5: Percentage results returned and outstanding for each test request area

Request area	Percent results returned	Percent outstanding
Alcohol (n=1902)	96,0	4,0
CO (n=72)	8,3	91,7
Histology (n=287)	30,3	69,7
Microbiology (n=84)	79,8	20,2
NHLS testing (n=43)	76,7	23,3
Odontology (n=149)	100,0	0,0
Organ cuts (n=57)	45,6	54,4
Pharmacology (n=168)	93,5	6,5
Toxicology (n=171)	17,5	82,5
Virology (n=32)	84,4	15,6

Table 5 shows that the greatest return of reports was for odontology with 100 percent of requests getting a result report submitted to the Division of Forensic Medicine. Alcohol was the second highest (96.0%), followed by pharmacology (93.5%), virology (84.4%), microbiology (79.8%) and NHLS tests (76.7%). The lowest percentage of reports finalised and submitted to the pathologists were from CO testing (8.3%), increasing to 17.5% for toxicology, 30.3% for histology and 45.6% for organ cuts. This indicates that the current most problematic area of investigation is receiving results of CO and toxicological analyses from the external laboratories. The least returned in-house investigation was histology, it is suggested that the pathologists may retain histology (which is a time consuming analysis) until toxicology results are complete in case it is shown to not be critical to the case (e.g.: if the cause of death is determined by toxicology there would be no need to spend time analysing histology samples). Because those may take very long, the histology may be significantly delayed.

The time it took for these reports to be returned was variable, and is illustrated in more detail in Table 6 along with Figures 9 and 10. The Table provides the minimum, median and other quartile data for all requested analyses. CO reports were not analysed since there were too few available (n=8) for further statistical analyses.

Table 6: Distribution of turnaround time for report generation (in days) after requests made in the various test areas, including Q1, Q2 (median), Q3, minimums and upper boundaries (Q3+1.5IQR)

Test areas	Parameters				
	Min	Q1	Q2 (median)	Q3	Q3+1.5IQR
Histology (n=87)	5	103,5	187,5	307	612
Organ cuts (n=26)	2	34	110	176	389
Alcohol (n=1825)	13	34	47	60	99
Toxicology (n=30)	7	75,5	154	276,5	578
Pharmacology (n=157)	1	7	15	24	50
Microbiology (n=67)	1	3	4	6	11
Virology (n=27)	2	3	4	6,5	12
NHLS (n=33)	1	2	4	8	17
Odontology (n=149)	1	3	8	13	28

The data from table 6 was used to draw up two box plots (Figure 9 and 10). The first was for tests performed within the Division of Forensic Medicine and Toxicology (histology and organ cuts) which are FPS internal investigations, as well as external tests performed by UCT's Division of Pharmacology (drug screen) and National Health's Forensic Chemistry Laboratory (FCL) (alcohol and toxicology) shown in figure 9.

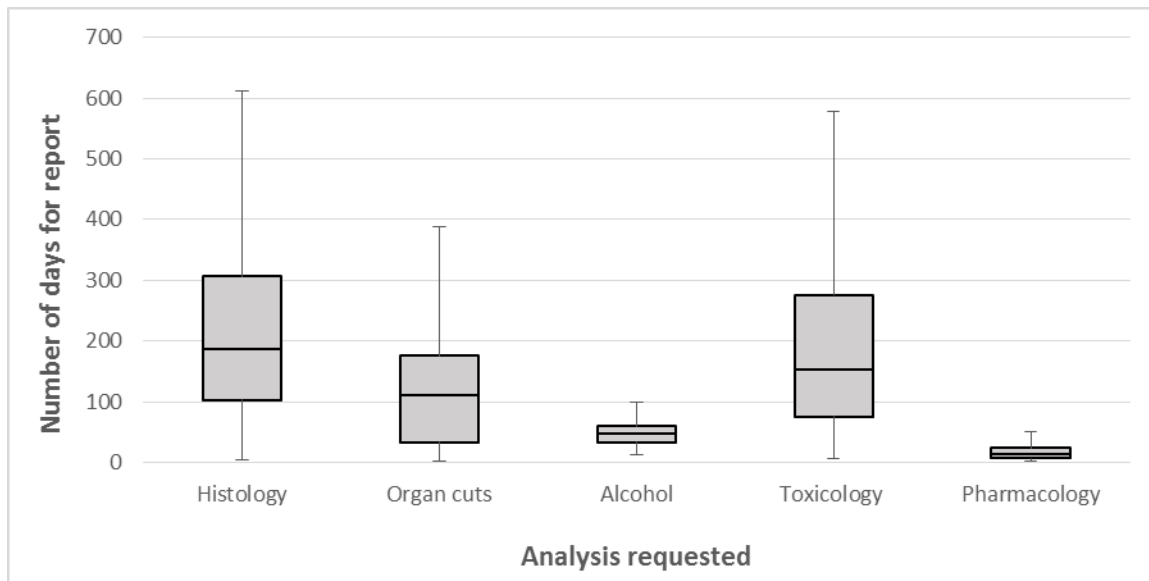


Figure 9: Box plot showing turnaround time distribution in days for reports (y-axis) for tests by the Department of Pathology UCT (histology and organ cuts), Pharmacology and FSL (alcohol and toxicology) (x-axis)

Figure 9 and Table 6 show that the median turnaround time (in days) for reports was fastest for pharmacology tests (Q2=15) and 75% of reports were available within 24 days (Q3) with an upper bound of 50 days (Q3+1.5IQR), the second fastest turnaround distribution was for blood alcohol concentration analysis (Q2=47, Q3=60, Q3+1.5=99). The slowest turnaround was for histology (Q2=188, Q3=307, Q3+1.5IQR=612, followed by toxicology (Q2=154, Q3=276.5, Q3+1.5IQR=578) and organ cuts (Q2=110, Q3=176, Q3+1.5IQR=389).

Figure 10 shows the box plot distributions for reports by the NHLS (microbiology, virology and “other” such as blood cell count and chemistry (electrolyte levels not drug chemistry, which is done by the FCL)) and independent odontologists, separated for scale concerns.

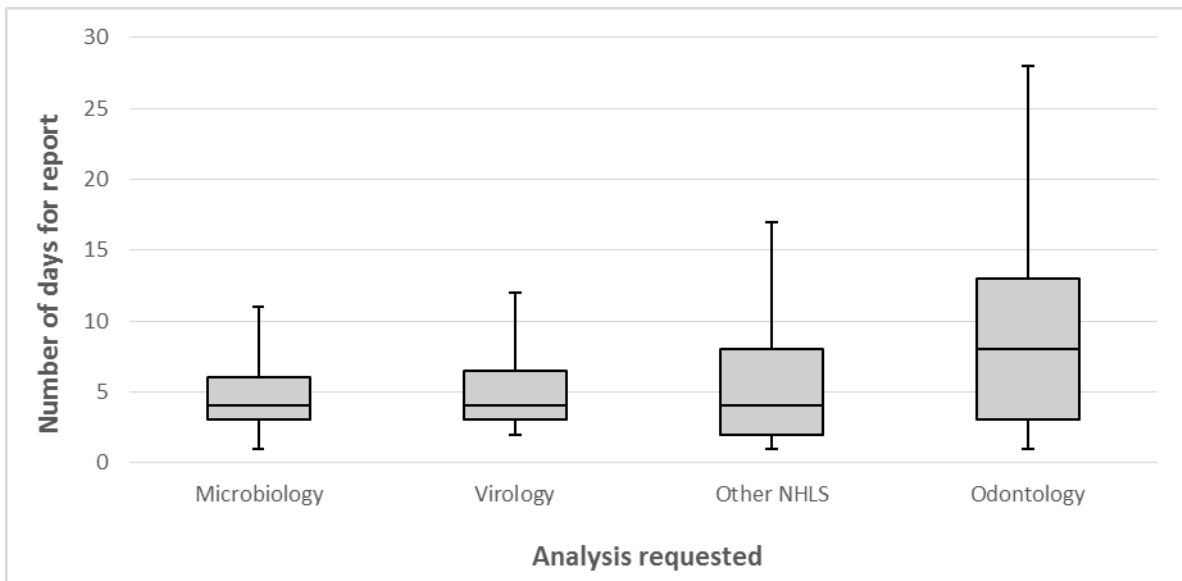


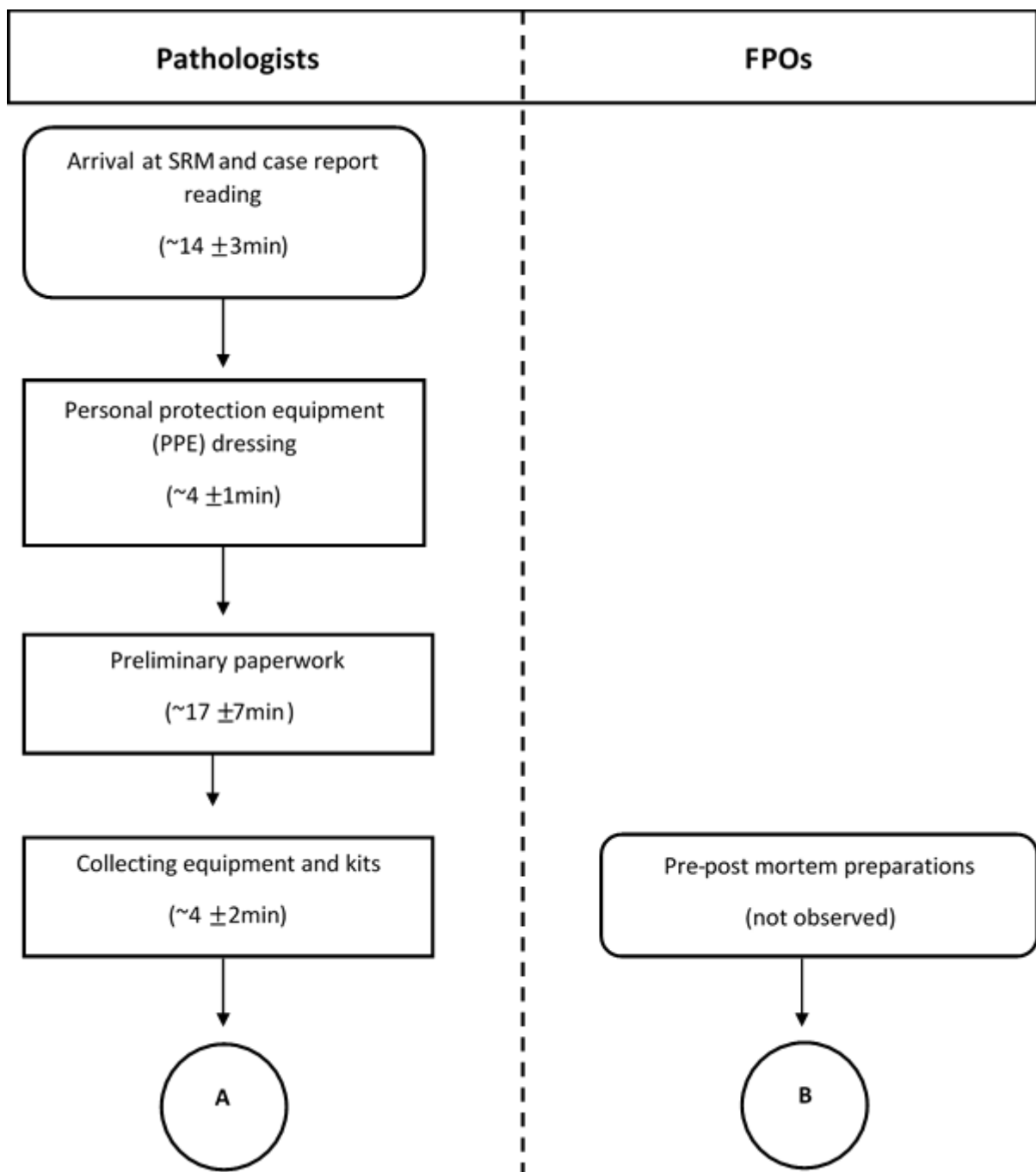
Figure 10: Box plot showing turnaround time distribution in days for reports (y-axis) for tests by the NHLS (microbiology, virology and others) and independent odontology examinations (x-axis)

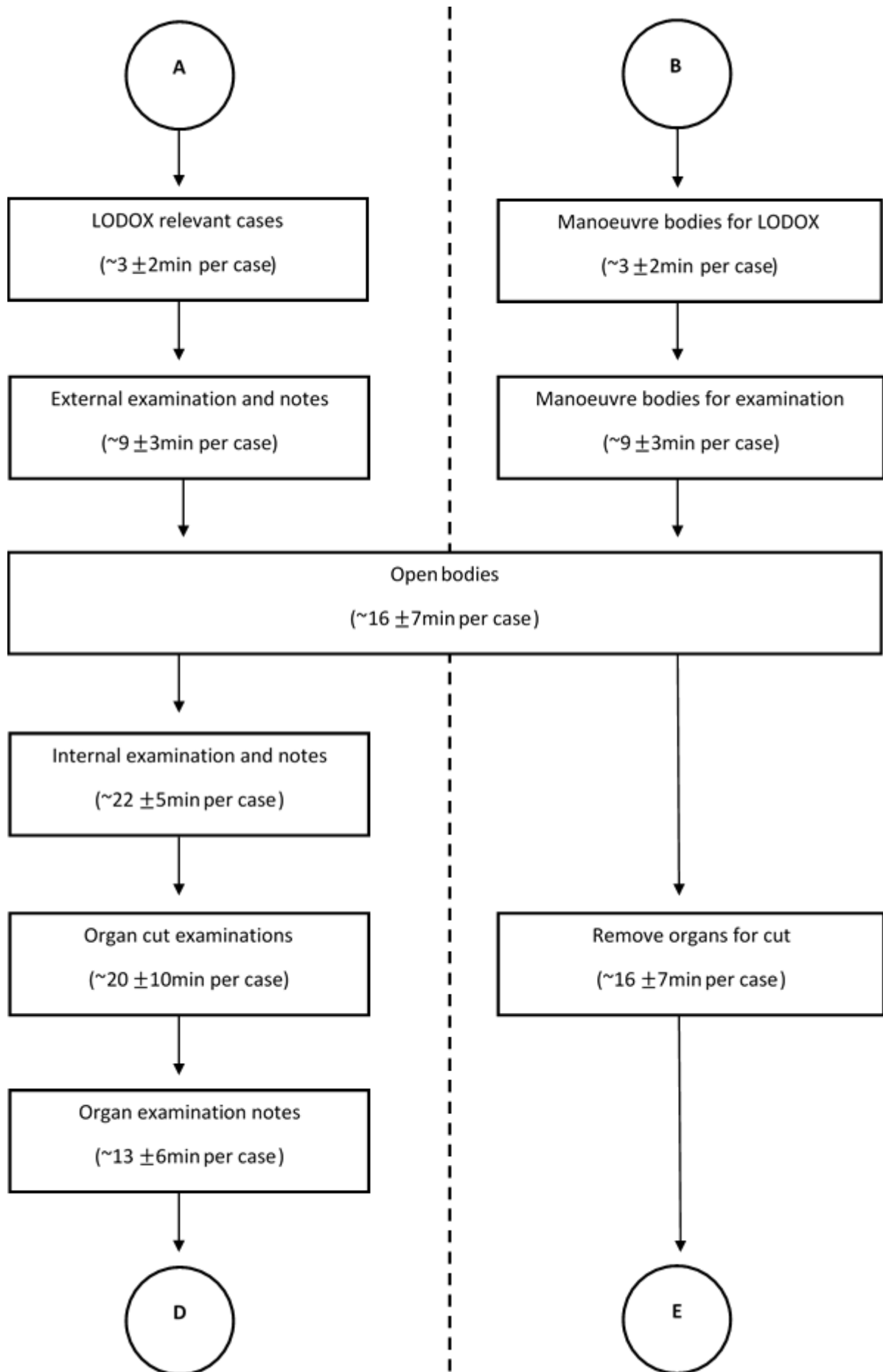
Figure 9 and table 6 show that the turnaround time for reports was fastest for microbiology tests (Q2=4, Q3=6, Q3+1.5IQR=11), followed by virology (Q2=4, Q3=6.5, Q3+1.5=12) and other NHLS tests (Q2=4, Q3=8, Q3+1.5IQR=17). Odontology examinations took the longest time for report publication (Q2=8, Q3=13, Q3+1.5IQR=28).

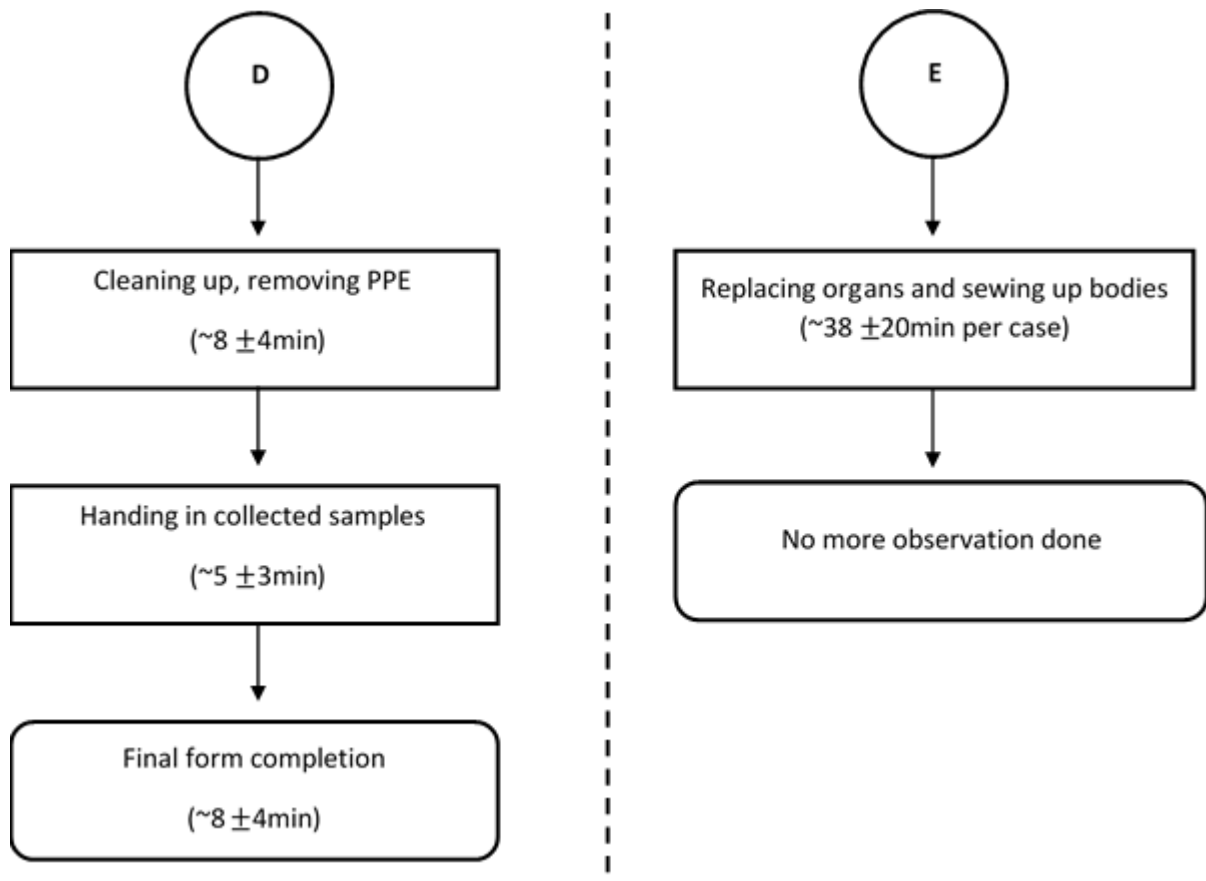
3.2. Observational data

3.2.1. Process map

The process map was developed for PM/autopsy workflow observed at Salt-River is shown in Figure 10. Note that times for each step are given in the format “~mean, +/-standard deviation” in minutes. Links to the next segment on the following page are given in circles.







Preliminary paperwork: filling it notes on the LAB27 observations form, reading case files.

LODOX: a full body x-ray, generally performed to examine suspected internal pathology visible on x-ray (such as chest infections) to reduce diagnosis time or detect foreign metallic bodies (e.g.: bullets)

Internal examination: Examining organs in situ without removing them

Organ cut: dissecting organs removed from the body for a more detailed analysis

Note that sample collection was observed, but occurred as part of other steps, example: during opening the body organ cuts, and could not be clearly separated.

Figure 11: Process map showing key steps in forensic pathology practice and their average time and standard deviation in minutes, path linked across pages through circles containing capital letters

Figure 11 shows an overview of the different steps in a general post-mortem and the responsibilities of the pathologist and FPOs during the autopsy process. It is important to note that the pathologist's work was observed and so not all steps for the FPOs' work are illustrated. The FPO is a trained assistant who assists the doctor with work such as opening and closing the body, evisceration of organs, moving the body, and also collecting the body from the scene. These are usually non-medical personnel who have been trained in-house.

In general, the pathologist is responsible for examining the body (externally and internally), dissecting organs and tissues to determine the cause of death by observing the pathology, collecting specimens for any ancillary investigations, taking notes for later report writing and completing associated paperwork. It is important to note that this is their function at the mortuary. Their other duties such as dictating their autopsies, writing reports as well as academic activities occur at the University of Cape Town. The FPOs are involved in fetching and manoeuvring the body for the pathologist (for example when X-raying using LODOX (low dose X-ray) or when doctors are examining it externally), removing organ blocks for the pathologist to examine and replacing said organs into the open body, sewing up the body then returning it to storage. They also assist the pathologist with any other concerns (such as fetching equipment or calling a second pathologist for an opinion). Some responsibilities may be shared, for example some pathologists work with the FPOs to open the body in order to speed the process.

After post-mortem examinations are complete, the pathologist returns to the University at a different location, dictates their notes and gives these to a secretary for typing into a completed report containing cause of death or stating it is as yet undetermined pending certain sample tests results. This is then signed by the pathologist and can be used as evidence in court both in criminal or inquest proceedings. The court usually uses these reports together with other police investigation reports to certify the manner of death. Pathologists can also be called to testify on these reports and their opinions about the cause and mechanism of death in a case. However this was not observed and falls outside the scope of this pilot project.

The total amount of time taken at PMs for different case types can be seen in Figure 12. Note that this is an approximation due to the small sample size (28 cases observed in total).

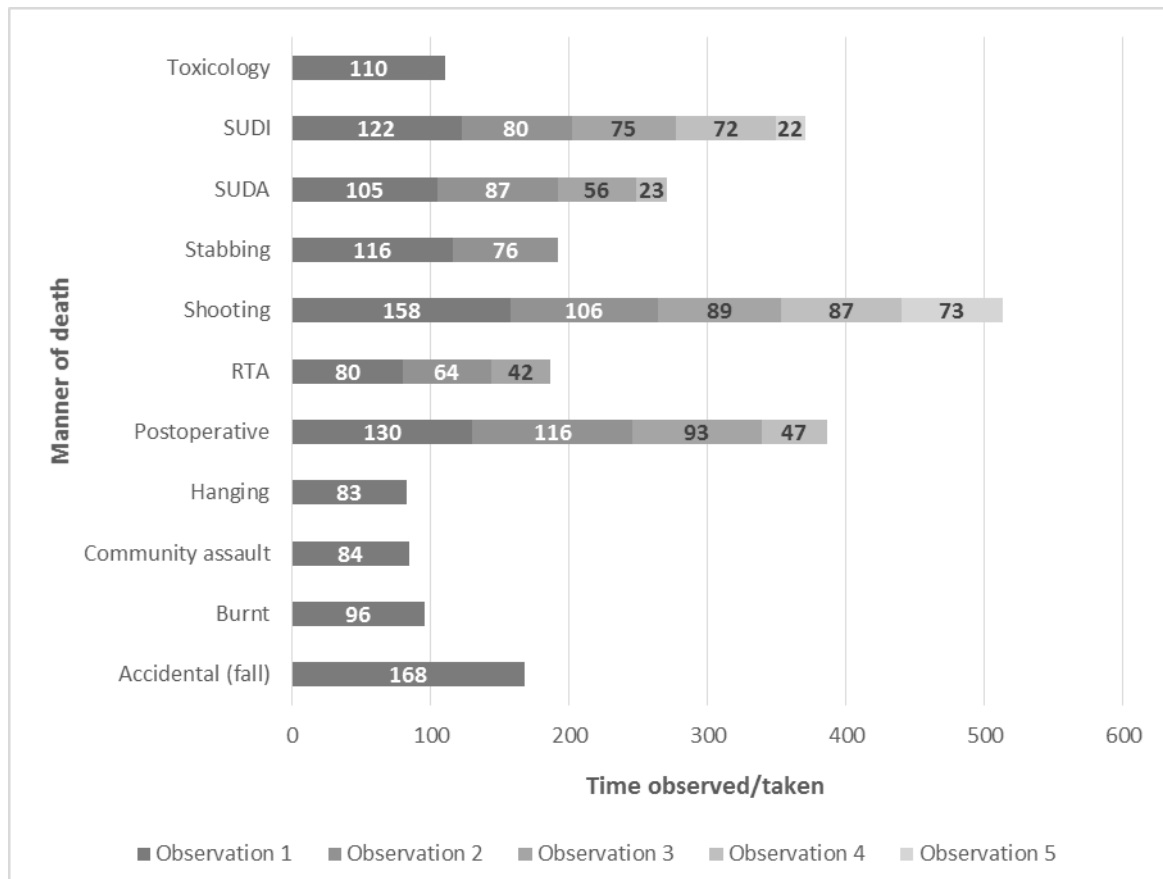


Figure 12: Amount of time observed in minutes for different known causes/methods of death (y-axis) in total (x-axis) and per case (data labels)

As can be seen from Figure 12 the longest case observed was an accidental fall (168min), however only one case of this type was observed so limited inferences can be postulated. The second longest case was a shooting (158min), followed by a postoperative case (130min). The least amount of time spent on a case was a SUDI (22min), followed by a SUDA (23min), however such cases were also highly variable in the amount of time taken (ranging from 22-122min) depending on the nature of the case and the pathologist performing the autopsy. For example the 22 minute SUDI was only LODOX'ed then declared a natural death, whilst more complicated sudden deaths (ones in which no obvious pathology was present) took longer. With shooting cases the projectile tract must be measure and recorded, which can be a more lengthy process if the victim was shot multiple times. The fact that these autopsies were carried out by different doctors also limits the interpretation of this data since factors inherent to them may have affected the time taken for investigation (e.g.: preferring more ancillary investigations).

3.2.2. Potential inefficiencies or problems noted

The potential inefficiencies noted during observations can be divided as follows:

3.2.1. Time specific concerns

- Pathologists usually arrived before mortuary officially opens: FPOs, paperwork, and equipment was not always ready.
- Use of the LODOX was often bottlenecked, and too many cases required its use at the start of the day. This can also become problematic if it breaks down.
- Office personnel (in charge of accepting samples from pathologists at the front office) may leave the autopsy before pathologists, no one to collect and ship samples taken and handed in by pathologists
- Police photographers arrived at random times after start of autopsy, and photos were not comprehensive or as accurate due to cutting of the body.
- Investigating officers arrived at random times or did not attend PMs/autopsies at all, they are theoretically required to do this to assist pathologists

3.2.2. Equipment issues

- Pathologists had their own equipment, however FPOs did not and sometimes could not locate what they needed since someone else placed it elsewhere.
- Only larger evidence bags (A3 upwards) were available on observation days, which are too large for certain specimens. For example, ballistics bullets may not be suitable to be stored in such bags, particularly multiple in one bag. In addition, specimens with biological fluids should not be collected in plastic bags.
- The forms have to be manually completed and too much information has to be repeated in writing on specimen kits and forms.
- Equipment was often missing, not appropriately available (e.g. not enough scalpels of the right size) or broken (shower head lines spraying water through cracks) or never worked (foreign plugs installed, incompatible with equipment such as scales that could not be plugged in).

- Data on forms may be smudged, contaminated with biological fluids or made dirty by the work environment. This reduced legibility and created health and safety issues for future handling of the forms.

3.2.3. Mortuary design issues

- Inadequate ventilation in one volatile poisoning case (turpentine), fumes affected pathologist and FOs
- Items for sample collection (e.g.: kits, bottles) stored away from dissection areas in three other areas (some kits near office area, others in a diagram/kit room and formaldehyde tanks elsewhere). These are not easily accessible and required that the pathologist walk around to collect items.
- Cupboards in cutting areas were too small to store all required equipment and forms
- Very few working clocks for noting times on forms, where required
- Ineffectual air fresheners, might mask subtle odours, but don't remove smell
- Passageways for moving bodies are narrow and run directly through PM areas
- Benches at cutting stations were quite high, it was difficult for shorter pathologists to take photographs directly above cut samples (to avoid distortion and obtain perpendicular angles). No small ladders available to take those photos.

3.2.4 Process concerns

- Nature, amount and packaging of samples should be standardised (e.g.: in amount, location of samples)
- Sample collection techniques, e.g.: milking of the leg for femoral blood collection, taken before or after opening body, should be standardised in terms of what is acceptable practice
- Cleaning issues: the disinfectant soap is kept outside in a “clean” area. In order to clean the cutting area one must walk in contaminated gum boots through a “clean” area to get it
- Forms difficult to keep clean when pathologist is working and trying to fill in notes at same time

3.2.5. Interpersonal conflicts

- Rotation of FPOs fortnightly makes developing a routine with a specific pathologist difficult. Different pathologists do things differently and challenges with different techniques and requirements of the two parties may lead to frustrations. In addition, some FPOs suggested that they do not want to do autopsies, would rather have other shifts, and have lower morale as a result.

3.2.3. Financial and staff data

3.2.1. Business based calculations

The first section of the preliminary business-based analyses were placed into two graphs: Figure 13 showing the distribution of expenses and Figure 14 showing the distribution of employees.

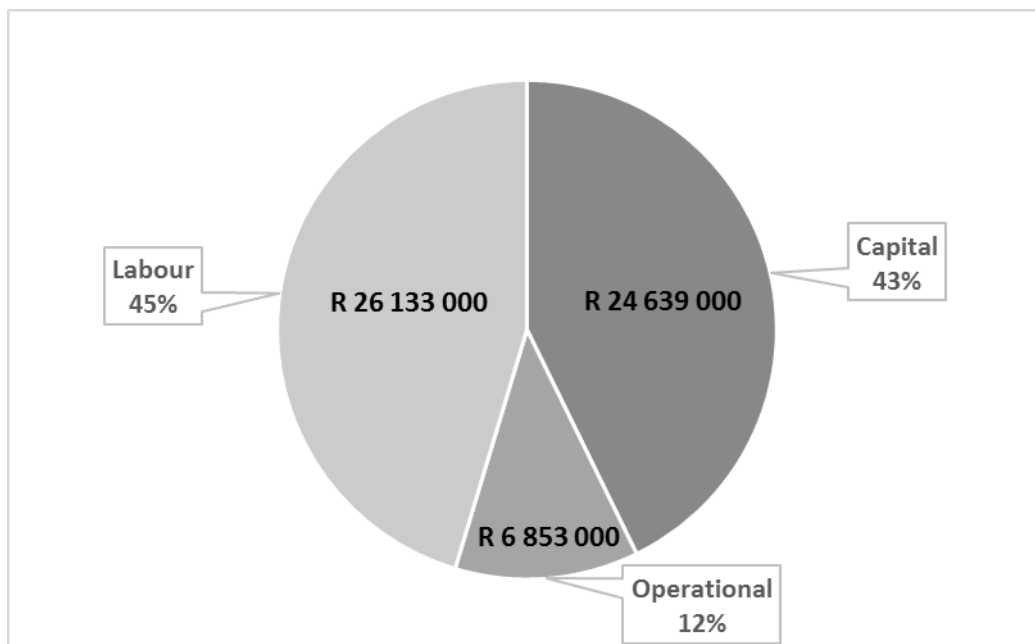


Figure 13: 2015 year spending on capital, operational and labour expenses as a percentage of total expenses

In Figure 13 it is illustrated that the highest amount was spent on labour costs at 45% (R26 133 000), with capital expenses the second highest expenditure at 43% (R24 639 000). Less was spent on operational costs which made up 12% of expenses (R6 853 000). The total cost of expenses for the year was R57 625 000. Figure 14 displays the number and ratio of operational, reporting pathologist and support staff full time employees:

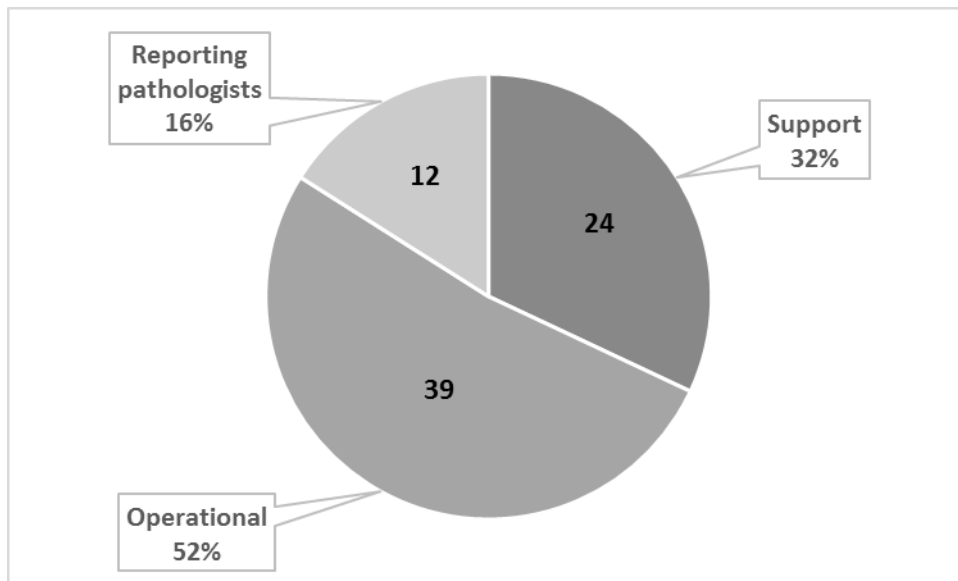


Figure 14: Comparison of operational, reporting pathologist and support staff as percentages of all FTEs

As can be seen from figure 12 in total there were 75 full time employees employed at the time of this study. Most of these are operational staff such as FPOs (n=39, 52%). There were then 24 support staff (secretaries, admin and such) employed (32% of total staff) and 12 reporting pathologists (16% of the total staff) (although one of these was the head of department and did not perform autopsies). Over the course of the year these staff put in approximately 145 000 total hours of work, approximately 95% of which was case work (around 138 000 hours). The role of pathologists in the academic environment requires that approximately 50-70% of time is spent on academic activities (depending on the pathologist).

Table 7 shows data for the calculations that were not put into graphical format, the number of cases, reports, items, samples and tests per full time employee (FTE) and the cost per case, report, item, sample and test.

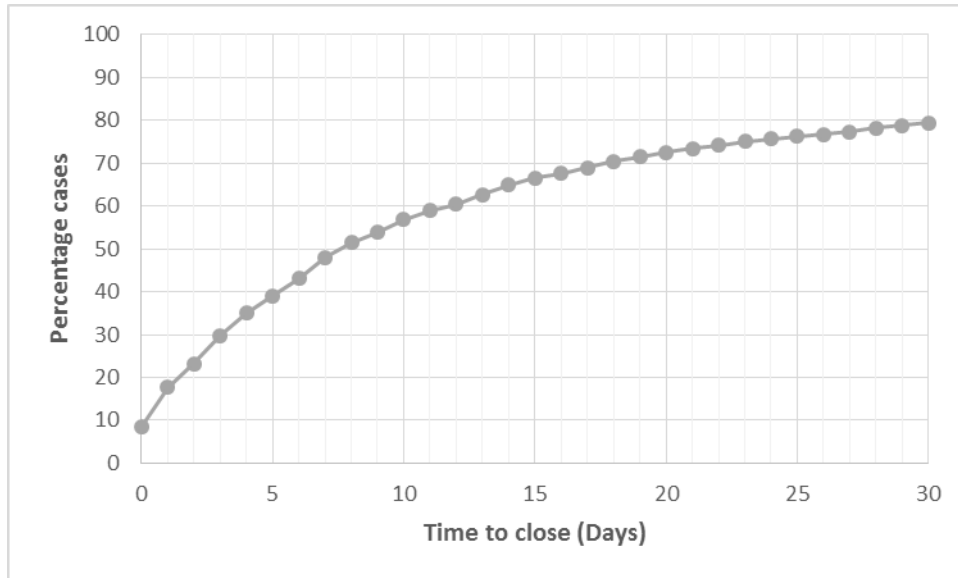
Table 7: Cases, reports, items, samples and tests per FTE and their associated costs

Per full time employee (75 FTEs):				
Cases	Reports	Items	Samples	Tests
48	49	76	93	163
Cost in rand per:				
Case	Report	Item	Sample	Test
16 155,03	15 761,76	10 093,71	8 293,75	4 720,65

As can be seen from table 7 there were 48 cases, 49 reports, 76 items, 93 samples and 163 tests per FTE. This is not to say that each FTE would have been involved with exactly 48 cases or have analysed 93 samples due to the division of labour. It cost on average R16 155.03 per case, R15 761.76 per report, R10 093.71 per item examined, R8 293 per sample taken and R4 720 per test conducted on these samples.

3.2.2. Case closure times

Figure 15 shows the time taken for cause of death to be determined and finalized (cause of death determined) in a final report (from the pathologist, including finalised cause of death) for cases overall in 2015.



Each data point indicates a single day, percentages calculated as the percentage of total reports closed after each day (cumulative)

Figure 15: Percentage of cases closed (y-axis) over a 30-day period (x-axis) for all cases types and requests

From figure 15 it can be seen that approximately 10% of cases were finalised on the day of the post-mortem (meaning that the pathologist completed a final cause of death (COD) report), 65% of CODs were finalised within 14 days (the ideal turnaround time for FPS report release according to standard mortuary practise in Western Cape (Western Cape Government 2014)) and 80% closed within a 30 day period (cut-off for backlog cases according to international studies (Speaker 2009)). Overall, 50% of cases were closed in 9 days or less. After the 30 day period displayed above (Figure 14) a further 15% of cases were closed by the end of data collection for this project (end October 2016). However 6% (n=210) of cases were still open after this time. Separating this data further allows an examination of the time for a COD to be finalised (FPS function) by case type, figure 16.

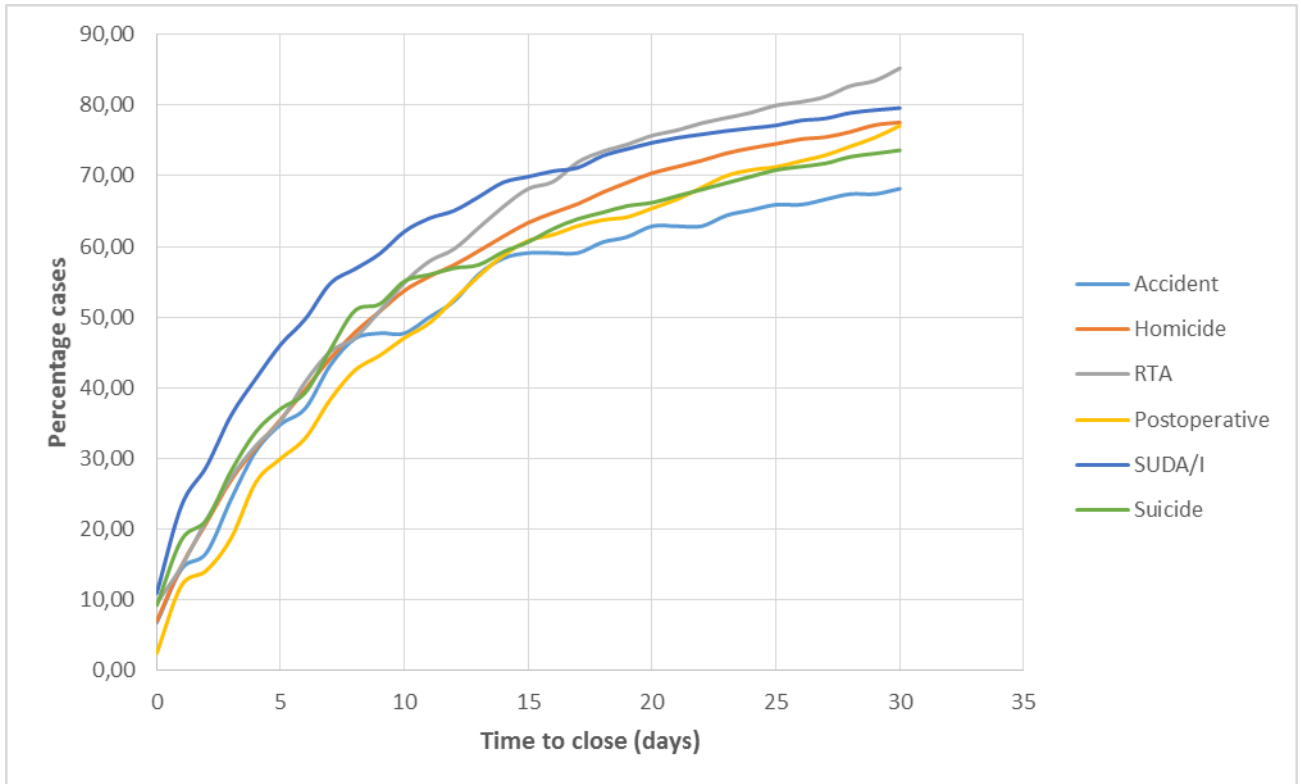


Figure 16: Percentage of cases closed (y-axis) over a 30-day period (x-axis) divided by case type

Figure 16 illustrates that sudden death cases had a COD determined fastest (50%=6days), whilst postoperative and accidental death cases took the longest time to finalise the COD (50%=11days). However in terms of total case closure RTA cases were most likely to be closed (14days=65%, 30days=85%), whilst accidental death cases were least likely (14days=58%, 30days=68%). This data is summarised in table 8 for cases closed after 0 (day of post-mortem), 14 (South African mortuary target) and 30 (international target) days.

Table 8: Percentage of cases closed per manner of death after 0, 14 and 30 days

Time (days)	Closed cases per type (%)					
	Accident	Homicide	RTA	Postoperative	SUDA/I	Suicide
0	6,8	7,0	9,5	2,5	11,0	9,3
14,00	58,3	61,4	65,7	58,8	69,1	59,3
30,00	68,2	77,5	85,2	77,1	79,6	73,6

Chapter 4: Discussion and Conclusions

4.1. Retrospective case data

Figure 5 shows the inclusion or exclusion of cases and the number of cases used in this study for retrospective data. Since more than 95% of cases were available it was decided the data obtained would be statistically useable. Cases that were still being dictated belonged to a pathologist that had fallen ill for some time. This highlights the fact that there is no fail safe for when a pathologist falls ill, particularly if hand-written notes have not yet been dictated. This highlights the problem of limited staffing and shows that the government must strategically analyses ways to invest further into staffing capacity. If this is not done then the agency could be at risk if a pathologist falls ill or resigns since there is no allowance for this currently, without having an increase in backlog of cases/autopsies. This could have negative impacts on the agency and its death investigation services to the community.

Recently there has been a shift to storing cases digitally as well as in physical file format so that they are easily accessible, and this was taking place while the project was ongoing. Currently, cases should be signed out and in by the individual, however, this relies on the person. In order to prevent cases from being untraceable (such as the 12 here) this system needs to be followed or a new one put into place. For example case files may be barcoded and scanned out by a member of staff. These suggestions were put forward and the development of a new sign-out system was piloted.

Figure 6 showed that the majority of test requests were for alcohol analysis. This is probably due to the fact that although alcohol rarely is the direct cause of death it may often be contributory to death. For example if the person was drunk can have implications for RTAs. There is also a wide use of drugs of abuse in Cape Town, so it would also be appropriate to collect specimens for toxicological investigations as well (particularly in homicides and RTAs). However, given the backlogs and challenges faced by the FCL, this is currently not standard and is not governed or specified by law except in the case of the Road Traffic Act when driving under the influence of a narcotic substance. The least used test was a SAECK analysis. This kit is commonly used in cases where sexual assault is suspected. In some cases

the time interval from the crime to PM was too long for such a kit to be of value, e.g. in decomposition cases. There may have been other cases where no history of rape before death (e.g. rape homicides) was provided or available for the pathologist at the time of autopsy.

Table 4 illustrates the different samples generally taken for different cases. It emphasises the trend for alcohol testing to be used often in a variety of cases. However in post-operative cases no alcohol requests were made, due to the setting and likelihood of any alcohol present to have been naturally eliminated from bodily systems during hospitalization. For the same reasons post-operative cases had very few requests for toxicology or pharmacology testing. Toxicology testing may however be requested in these cases if there appears to be medical negligence associated with the administration of drugs at the hospital, suspected to have caused or contributed to death.

The data in Figure 6 and Table 4 could be used when ordering stock for mortuaries, ensuring an appropriate number of sample collection kits for each area are stocked for example. There should be more blood alcohol/CO kits available (the same kit is used for collection of blood), followed by different sized bags for physical item collection and then DNA kits. A few histology buckets, toxicology kits with multiple specimen vials (although they sometimes also use blood alcohol/CO kits if only blood is collected for toxicology), tubes and swabs for microbiology/virology sample collections and SAECK kits should also be included the order. Currently, the mortuary relies on receiving certain kits from external entities, for example – toxicology kits from FCL and SAECKs from SAPS. If there is a production or delivery delay in these kits, it may result in those ancillary investigations not being performed if the autopsy has to be undertaken. It is thus suggested that internal kits are collated, particularly for toxicology, where the use of standard grey-top and red-top tubes, as well as Eppendorfs for specimen collection may be deemed appropriate. It may also be of use in development of suggested lists of samples to collect for different cases.

Figures 7 and 8 and Table 5 give insight into what investigation areas were more likely to return results. In odontology, 100% of requests resulted in a report. However these examinations were only requested 149 time throughout the year and the current individual who performs these investigations is forensic odontologist who acts only as a consultant, primarily to the mortuary. Blood alcohol, pharmacology, virology, microbiology and general NHLS tests also had high percentages of results returned. However there appear to be bottlenecks in the analysis or report

creation of histology, organ cut examinations and toxicology. While this is suggested to be an area for future studies, it may also be postulated that these are investigations that require a lot of time, particularly if comprehensive investigation was required. Histology and organ cuts are performed by the pathologists who have high caseloads and other academic requirements as well. It is suggested that other means of completing these examinations without using the time of pathologists be examined. For example the use of histology technicians specialising in the field who could return a report to the pathologist (who would only need to examine samples themselves if they deem it necessary based on the report). In addition, in 2015, in cases where both toxicology and histology were requested, histology was often delayed until toxicology results were received, which took a longer time. Alternative practice has since been put in place. The delay in toxicology results is multi-faceted in nature and requires a LSS investigation of its own within the FCL (this falls outside of the scope of the project as it is an external agency to FPS). In attempt to alleviate these challenges, FPS WC is developing their own internal laboratory for post-mortem toxicology.

The low return of CO reports was reported to be due largely to a broken instrument in the laboratory, which was delayed in being fixed. However, this does highlight the lack of a secondary method for testing such samples in case of such breakages. This also highlights issues in procurement and service maintenance, which is a challenge within the government system. It was evident that service on the instrument was significantly delayed, and that a system of sending specimens to another laboratory was available at the time (as there are only four FCL labs within the country). A system to prevent this in future should be devised, perhaps a second instrument purchased or regular maintenance budgeted for and timeously undertaken, however, this does pose challenges in a resource-limited environment.

Table 6 and Figures 9 and 10 give an idea of the time taken for ancillary investigation reports to be returned. Note that turnaround time was defined as the time from autopsy to receipt of reports from analysis. International studies have previously defined a backlog as being a time period for results longer than 30-days (P. J. Speaker 2009). The FPS identifies the ideal turnaround time for an initial autopsy report as 14 days (Western Cape Government 2015). However there are currently no legislative/laboratory requirements governing the return of laboratory reports in South Africa. There is also currently no governing body for forensic science in the country, which could provide guidelines and regulations concerning turn-around times. Microbiology, virology, other NHLS and odontology results were returned within the

14 day turnaround time target 75% of the time, whilst pharmacology produced 75% of reports within 30 days (n=24). However for histology, organ cuts, alcohol and toxicology testing under 25% of results were returned within 30 days. As only retrospective laboratory/case data was available for these calculations, examining these other test areas over longer periods of time, and in more detail to identify process and bottlenecks could form the basis of a future studies.

Pharmacology testing (a targeted screen for specific drugs of abuse) was used at the discretion of pathologists as a presumptive positive/negative test for detection, to provide preliminary information to the pathologist while waiting for FCL toxicology results. However, these results are not in an appropriate format for court and as such may cause issues if present in the docket. In these are only screening results, they need to be quantified to distinguish the causal or contributory nature of drugs to death which involves an FCL analysis. The FCL reports are in affidavit format, and are generally accepted as prima facie evidence in court, without the analyst being required to testify. However FCL is also only accredited (through SANAS) for its blood alcohol analyses, which may cause problems in court as well. It is because of these challenges that FPS is undertaking the development of a new forensic toxicology laboratory, aimed largely at post-mortem testing in unnatural death in Western Cape in attempt to assist in alleviating some of the challenges faced in the National laboratories.

4.2. Observational data

The process map (Figure 11) illustrated an overview of the general processes that occur at a PM at Salt River Mortuary. This can be used as a guide for future studies investigating the process, for example in choosing specific steps to examine the processes in more detail to identify both where process is optimal and where challenges are faced.

Figure 12 then split this process data into the time taken for each type of case observed to be processed. Since only a few of each case type were seen this data cannot be taken as standard without further investigation, however it does help to highlight trends of which cases took the most or least time, and provides a preliminary identification of processes that require further investigation for efficiency. The accidental fall that took the longest involved a large amount of paperwork and an hour was spent reading this before even beginning the investigation, leaving a period of 108 minutes for the PM, which is actually typical compared to other cases

of similar complexity (e.g.: post-operative). Shooting cases took the second longest due to bullet track marking and ballistic evidence recovery, often a body would need to be x-rayed multiple times to ensure no projectile fragments were missed. In addition, most cases of gunshot wound injuries involve multiple wounds, and with each additional wound comes an increase in time to autopsy. In other cases there was a large difference in the amount of time taken from case to case. A complicated SUDI involving the collection of microbiology and virology samples (including cerebral spinal fluid for which a lumbar puncture had to be done) took 122 minutes. Whereas in another case a chest infection was determined to have caused death after observing the x-ray, and with no opening of the body, took 23 minutes.

In order to create target times for completion of different cases a more in depth way of classifying them would be needed, for example breaking SUDI deaths into simple (unopened body) or complex (full examination and sample collection). This could be a focus of future research. It may be suggested that complex cases are assigned to consultants and that fewer cases are then assigned to the doctor who has to autopsy those cases (for example, three cases are often assigned to each doctor on the average day. When a complex case is scheduled, it is suggested that this together with an easier case is assigned only).

From the challenges noted preliminary suggestions were made for improvement as indicated below. It must be reiterated that challenges faced in South African mortuaries are extensive, particularly involving very high case-loads, limited resources and limited staffing capacity. In addition, FPS moved from the police to the Department of Health in 2006 and in the last 10 years has made great strides in the death investigation system in a developing country.

Time specific concerns:

It is suggested that fixed times for arrival of each group of staff should be determined, and no group should be allowed to leave if their work is still essential for the completion of the day's work. A staggered system could be set up so that pathologists and FO's for different PMs arrive at different times, e.g.: PM group 1 at 06:30, PM group 2 at 06:45 etc. This fifteen minute delay should allow use of the LODOX machine to proceed without bottlenecks, since only one PM group would need it at a time. Police photographers should arrive at the start of the PM group shift for which they require photos so as to get pictures before the body has potentially been cut and wounds altered. This is challenging as it relies on the SAPS individuals not FPS.

Equipment issues:

Cupboards in the PM areas should be bigger and should be able to be securely locked. A full set of equipment for the pathologist and FO/s as well as a supply of commonly required sample collection kits, evidence packaging and forms could then be kept locked in this cupboard. This would reduce time spent moving from room to room searching for equipment.

Adhesive labels could be made daily with often repeated information, e.g.: case number, date, pathologist details, to allow pathologists to easily fill in information of forms and sample kits/evidence packages. This would also increase legibility of the end results (for example having ink already dried reducing smudging in a wet environment).

Notes are also affected by the environment at PM, creating potential hygiene issues for people handling these documents at a later date (for example blood smears). One pathologist tried to remedy this by using a tape recorder, however this recorder would then need cleaning. A second used a metal tile to temporarily record data during organ cuts then transcribed this to the forms after removing dirty gloves. However this technique involved two recording steps and increased the time taken. A study by Al-Aynati and Chorneyko (2003) tried to develop an alternative to this by creating a computer programme that could recognise voices and record what was being said into a report automatically. (Al-Aynati & Chorneyko 2003) There programme had an accuracy of 93%. However a different programme unique to the languages and pronunciations in a South African setting would need to be developed before it could be used here, which could also be a topic for future study.

More appropriate packaging for ballistic samples should be available to avoid scratching when samples move around in large evidence bags and may be deformed by contact with dense objects in similar bags despite the layers of plastic between them (e.g.: a single bullet in a large bag next to a hammer in a similarly large bag on the metal floor of the back of a pathology van). This could be developed as part of a future study (e.g. foam packaging that tightly encloses items).

Mortuary design issues:

There is a need for more ventilation in the mortuary to prevent volatile substances affecting staff. This is usually combatted by the use of a biosafety hazard level three environment, which is currently not available. This may also help with the odour issues, for which the current air fresheners and ventilation are inadequate. PM areas should be restricted so that the flow of traffic does not have to pass through an occupied area, potentially getting in the way of FPOs and pathologists. The layout of the mortuary in general is very small, has limited flow (different cutting rooms in a blocked layout), and is not optimised for its specimen kit storage, which is on the other side of the mortuary from some cutting areas and requires walking back and forth to obtain necessary forms or containers. More maintenance needs to be done to fix issues, for example changing incompatible plugs out for ones compatible with equipment, fixing broken shower hoses and maintaining clocks.

These challenges will hopefully be at least partially combatted in the building of a new mortuary at a different site, set to begin in early 2017. It is important that the workflow has been designed optimally within this new mortuary so as to optimise the efficiency of performing autopsies. It is being built with biosafety hazard level 3 rooms specifically for hazardous cases so as to improve health and safety conditions of the employees.

Process concerns:

It is suggested that more studies should be undertaken to standardise the collection and packaging of samples and evidence (e.g.: if leg milking of blood is acceptable (which for toxicology is advised against), the exact amount of a sample to collect if performed). Currently, there are standard procedures for collection of evidence, such as toxicology and DNA, but this may be altered if specimen kits are to be optimised. Soap should be stored in the areas it is needed, e.g.: in liquid soap buckets in each PM room, rather than in a clean area that must be traversed in dirty Personal Protective Equipment (PPE).

Intrapersonal conflicts:

It is suggested that the relative strengths of FPOs are optimised. For example some may be better at cutting and others at administration or scene investigation. It may be suggested that instead of performing all of these function, FPOs are trained in all areas but develop greater expertise in certain areas.

4.3. Financial and staff data

Table 7 is best used as a preliminary benchmark when comparing output to other mortuaries. It was not however determined exactly how many cases each person was assigned to for example, but averages were suggested. Many employees may overlap and work on multiple samples for different cases being examined by different pathologists. Not all staff are involved in report analysis or item testing. Cost data was also calculated simply by dividing total costs by number of cases, reports, items, samples and tests. Costs are thus only estimates, and it is unknown for example exactly how much was spent on non-case related matters. However this data does serve to give some preliminary information that future studies can develop and work on further.

Spending in 2015 by SRM/UCT was highlighted in Figure 13, which shows the percentage and amount spent on capital, operational and labour expenses. The amounts shown can best be used as a benchmark when comparing this data to other mortuaries, since the setting (e.g.: purchasing power) and costs involved (e.g.: different expected wages) is not internationally comparable as it stands. In addition, because SRM has one of the highest caseloads in the country, it is important to develop on and obtain more specific and accurate representations of these metric ratios to compare to smaller mortuaries in WC. This may illustrate where resources could be better allocated, or if staff should be assigned to other mortuaries.

The ratios of spending however could be compared to an international standard. In a paper by Speaker (2009) a guideline of spending by an average US forensic laboratory was given as 80% labour, 21% operational and 5.5% capital. (Speaker 2009). From Figure 14 it appears that the 2015 spending was very different to this. However, 2015 was a year involving more capital and equipment expenditure than usual, with news development of the toxicology laboratory and purchasing of expensive instrumentation, which is a provincial investment. It is suggested to examine spending over a five year (or more) period and see how this varies. It may also be suggested that even though capital expenditure is high, that the staffing funds allocations are too low, and that increased funding into staff and their development may be an avenue worth looking into further.

Figure 15 focused on staffing data ratios. In total there were 12 pathologists employed at Salt River Mortuary in 2015, since they are the only staff that can determine cause of death and there were 3652 internal cases (excluding FACT and other external services) they would each have had to examine and report on 304 cases. With a total of 251 working days per year (excluding leave) they would have to compile at least six reports per week. There is a very high case load in South Africa and so this may be expected, however it should be analysed in more detail to determine if this work load is possible to complete. These ratios can be used as a benchmark for a high case load mortuary and may be useful when designing new mortuaries of this type.

Whilst some findings from international studies are dependent on US crime rates, certain recommendations can be carried over to the South African setting. Table 9 shows the application of these recommendations to an average annual case load at Salt River mortuary, with a minimum expected case load of 3500 annually. This mortuary experiences the highest caseload in Cape Town and is affiliated with the University of Cape Town through the Department of Pathology and is hence ideal for use in this research study.

Table 9: Application of SWGDMI (2013) findings

Parameter	Recommendation (per 1000 cases)	Calculated for 3500 cases (recommended for Salt River mortuary)	Actual Values for Salt River Mortuary
Number of pathologists	6	21	11
Number of investigators	9	32	Not determined
Number of autopsy assistants	7	25	29 (approximate)
Number of histologists	1	4	2
Number of security and attendant personnel	6	21	Not determined
Number of reception, clerical, administrative and custodial personnel	11	39	14 (approximate)

Not determined- Numbers could not be determined from staffing data obtained in this study, further data would be needed

Approximate- Since jobs are not defined the same way as overseas this data was an estimate, some employees fall into more than one category. For example FOs rotate and may also be involved in admin like duties

The data from table 9 shows that for a mortuary with a case load typical of that at Salt River mortuary only the number of autopsy assistants (FOs) match what would be expected internationally, whilst there were less than half the required number of pathologists and histologists required. This may help to explain backlogs in histology and pathology report generation. However, this information was incomplete and an approximation had to be made in some cases. It is recommended that a study focussed on the exact staffing requirements for South African mortuaries be done and guidelines published for this unique context.

Finally, figure 15 examined the number of days required for initial cause of death to be determined. Figure 15 showed that around 67% of cases closed (cause of death determined) within 15 days, 80% of cases within 30 days. It took 9 days or less to close 50% of cases, with 10% of cases being closed on the day of the post-mortem. Figure 16 then split this information up by case type. By cross examining this data with Table 4 it seems cases are more affected by their type (and possibly complexity or required comprehensiveness as a result) than the number of requests made. Sudden death cases were closed within the shortest time (50%=6 days), requests for analysis occurring 58% of the time. These were usually deemed to be natural disease (even though admitted as unnatural). However, whether drugs or alcohol contributed to these deaths (whether acutely or chronically) and contributed to natural disease is unknown. Whilst postoperative cases took longer to close (50%=11 days) fewer requests were made (46% of cases). It can be suggested to be due to the complexity of these cases involving complex surgical procedures, and distinguishing whether those cause death. RTA cases were most likely to be closed, possibly due to obvious trauma and a simpler identification of cause of death versus the least likely to be closed set of cases: accidental deaths, in which cause may not be as clear and more factors need to be ruled out. Accidents and suicides also had higher numbers of suspected drug/alcohol-related deaths and given that toxicological results were delayed, were most likely not closed by the end of this study.

4.4. Limitations

This study was intended to be a pilot project and provide a framework for analysing efficiency and effectiveness in a pathology setting. It was carried out by a single Masters student with the guidance and supervision of a single lecturer at UCT over the course of a year. Thus time and manpower were limited and the subject was not examined as in depth as it could have been, particularly as it is a minor dissertation. For example court testimony on a case can happen years after the post-mortem and it would not have been possible to view this. Due to the fact it was a pilot project data collected was still sufficient for the purposes of this study, however there were certain limitations on this information:

- Observational data was tightly focussed on the pathologist at post-mortem. The work of other staff was not observed unless the pathologist was present. Work conducted after the end of the post-mortem was not seen (such as compiling the final report).
- Not all cases for 2015 could be analysed since some were not yet in a form suitable for use in this study, e.g.: not reports dictated or typed, by the end of data collection.
- Not all investigation areas could be examined thoroughly for backlogs due to time constraints and access to information.

4.5. Future research suggestions

- Creating a medical/forensic dictionary focusing on Western Cape FPS terms and their use in a South African pathology setting. For example defining manners of death for standard classification for court.
- Observation of the entire process from crime scene to court testimony on a larger number and variety of cases over the course of a few years for several different mortuaries. This data could be used to analyse efficiency based on case type and make more tailored suggestions. It would also be useful in drawing up a fully comprehensive process map for each mortuary that could be compared to or used by other mortuaries to standardize practises.
- In depth definition of case types and development of suggested times for the PMs of each, so as to assign complex cases appropriately.

- Development of an FO rotation booking system. For example including features that allow pathologists to ask for certain FPOs. Developing FPOs in certain skills as well (scene investigation versus assistance in cutting)
- Redesigning aspects of the mortuary: staggering start of work shifts, storage cupboards, standardising procedures (e.g: LODOX or what samples to take per case type), sample collection standardisation, white boards for writing etc.
- Developing an automated voice activated record system for use during PMs. This may be a collaboration project including computer science students.
- Developing better packaging to avoid damaging ballistic samples.
- Ensuring files are traceable and a system for logging their removal from the storage room is put in place, e.g.: library style barcode scanning.
- Examining the backlogs and bottlenecks in external sample testing and the efficiency of these laboratories.
- Tracking spending over multiple years and comparing to other mortuaries in WC, SA and international standards.
- Examining workloads per employee and the ratio and number of employees in each area compared to other mortuaries.
- Benchmarking or comparing case closure time graphs for different mortuaries or over multiple years.

4.6. Conclusions

This project served as a pilot project in providing a framework for examining the efficiency and effectiveness of the Cape Town mortuary and subsequently the other 16 mortuaries in Western Cape. It lays a suggested framework for a unified definition list for these mortuaries. Through observations of pathologists' work days, numerous small inefficiencies could be noted and suggestions for improvement made. It would appear that most bottlenecks do not occur at the PM examination, but rather during ancillary investigative testing. Overall 67% of SRM cases were closed within 14 days for 2015, however these testing backlogs and bottlenecks greatly delayed those that remained with 6% cases not having been closed by the end of this projects' data collection (October, 2016). Given that the other mortuaries in Western Cape have varying staffing, case-load, equipment, process and workflow differences, it is suggested that a provincial investigation into pathology practice is undertaken. Using LSS and DMAIC approaches requires that WC FPS first standardises the terminology used by all mortuaries (for which suggestions are provided in Appendix A.1.). Following this, more structured and comprehensive investigations, together with business-based metrics analyses could be conducted. This may assist in identifying and maintaining practices that are working, and changing those that don't, so as to optimise death investigation and forensic pathology procedures and practices in an environment challenged by high caseloads and limited resources.

Future studies should be done to investigate the reasons for these backlogs identified, particularly in external entities, as well as to improve on and implement the suggestions made in this project. Studies can also be done to expand this type of research over multiple years and extend this to other provinces in South Africa.

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Appendices

A.1. Definitions

The following are the definitions that best fit key words in the forensic pathology practise at Salt River Mortuary relevant to this research. These are preliminary suggestions defined by the researcher for the purpose of this project and do not necessarily represent definitions used by pathologists or FPOs and the like.

Accident: A manner of death. An accidental death being caused by other than natural means and unintentionally.

Alcohol testing: The detection of the presence and concentration of ethanol in a sample. (WVU 2007)

Autopsy: Examination of the external and internal structures of a deceased body and collection of specimens for ancillary investigations with the aim of determining the cause of death.

Capital expense: Cost for the year of buying any equipment with an estimated lifetime longer than three years. (Speaker 2009)

Case work hours: Total hours worked excluding hours spent on research and development, education and training and external provision of support and service. (WVU 2007b)

Cause of death: Can be either a single underlying cause, defined as the factor which started the events leading directly to death or the circumstances responsible for the fatal injury, or due to multiple causes, including the underlying and other contributory factors. (Arialdi 2014)

- Closed case:** For the purposes of this study, cases were defined as closed by FPS when the finalized cause of death had been declared. A closed FPS case may still be open with the police and under investigation.
- CO testing:** The detection of the presence and concentration of carbon monoxide (CO) in a sample.
- Court time:** Time spent giving evidence in a criminal or inquest court. A sub-set of casework hours.
- External examination:** An examination of a body's exterior and any injury upon it with the aim of determining cause of death. Without introducing any further incisions.
- Final FPS007:** An FPS007 report (post mortem examination findings and cause of death report) compiled including the finalized cause of death.
- Full-time employee:** Any person employed on a full-time basis by FPS based at Salt River Mortuary and UCT Division of Forensic Medicine (e.g. joint positions such as forensic pathologists).
- Histology:** Preparation and microscopic examination of tissue samples with the aim of determining if any pathology can be described.
- Homicide:** The unlawful killing of one person by another person, whether intentional (murder) or unintentional (culpable homicide).
- Hospital report:** A form completed by hospital staff responsible for treating the deceased and declaring them dead, if the patient is admitted to hospital before death. It should provide background information on the circumstances surrounding death in hospital.

Investigation area:	An area or laboratory set aside to analyse samples of a specific type. For example toxicology or DNA analysis investigation areas. (WVU 2007b)
Item:	A single object given for laboratory examination, e.g.: a tube of blood or single bullet. (WVU 2007b)
Lab27 form:	The scene of death form for FPS. A form used by the pathologist at autopsy. It must include dates, background case information, any observations made and seal numbers of samples taken. May not be fully completed depending on the case, is used more as a guideline for the PM and report creation.
Labour expense:	Total cost associated from FTE expenses. Including salaries, benefits and training. (Houck et al. 2012)
Facilities area:	Total floor area set aside for forensic investigations, storage of samples and consumables/equipment. (Speaker 2009)
LODOX X-ray:	A low dosage X-ray used in certain cases for a full or partial scan of the body to identify trauma, pathology or foreign bodies.
Manner of death:	A description of the circumstances of death. Broadly natural or non-natural (sub-divided into accidental, homicidal, suicidal, undetermined, and procedural). (Sondik et al. 2003). In South Africa it is not the role of the pathologist to speculate on the manner of death as this is determined by the inquest magistrate [Inquests Act].
Microbiology:	Examination of PM samples for the presence of microbial pathogens that may have caused or contributed towards death.
NHLS:	The state-run National Health Laboratory Services. Performs microbiology, virology and chemical pathology (e.g.: blood cell counts and chemistry) analyses, amongst others.

- Non-natural death: Any death suspected to be due to physical or chemical factors, suspected criminal commission or act of omission (South African magistrates court 1959)
- Odontology: Examination of the dentition of the deceased with the aim of identifying unique features that may be of use in a forensic investigation (for example identification through ante-mortem dental records).
- Open case: For the purposes of this study, an open case is defined as one wherein a final cause of death has not been determined at autopsy or following ancillary investigations and remains undetermined. .
- Operational expense: Costs other than capital or labour expenses. Costs involved in upkeep and running of the pathology service. For example: maintenance and consumables. (Speaker 2009)
- Operational staff: Staff working in one or more of the following areas- casework, research and development, external services for support and education and training. This includes unit heads even if they do not create reports themselves. (Speaker 2009)
- Organ cut: Examination of an organ for pathology or trauma. For the purposes of this study it should be noted this is performed at UCT in the histology laboratory. A more in depth examination than would be done at autopsy and requiring its own report stating the findings.
- Forensic Pathologist: In South Africa, all pathologists are trained doctors and specialise in forensic pathology and conduct PM examinations with the aim of determining the cause of death, which they then put into a formalised report and present in court.

Pharmacology: For the purposes of this study, pharmacology makes reference to a drug screen on PM samples conducted by the UCT Pharmacology Division.

Physical: In this research, this category was used to refer to non-biological items and evidence sent for analysis of physical properties. For example bullets for ballistics.

PM examination: A post-mortem examination of the body by a pathologist aiming to determine cause of death. Encompasses external examinations, internal examinations (autopsies) and other techniques (LODOX etc.).

Post-operative/
procedure related: Relates to any case in which the deceased had recent surgery or was administered anaesthetic. It may be suspected that the operation was causative or contributory to death.

Preliminary FPS007: A compiled FPS007 post-mortem report that does not contain a finalised cause of death. Generally occurs when further test results are outstanding or when the pathologist's examination alone cannot explain cause of death.

Report date: The dates recorded for reports in this project were taken as the earliest date the findings were of an acceptable standard for presentation in court. For example the date FPS007 reports were signed and commissioned. If a later report was available on the same matter in would only be considered if the cause of death was altered.

Request: Collection of samples for processing by staff in an investigation area is considered an acceptable indication of a request for analysis by this project's standards.

Road traffic accident: A death resulting from injuries sustained in a road traffic accident, e.g.: accidents involving: pedestrians, cyclists, motorcycle riders, light or heavy motor vehicles and occupants, animal riders and rail

passengers or operators as well as any other form of land transport (Statistics South Africa 2009).

Sample: An item or part of an item that is used for testing and produces a result published in a report (WVU 2007b).

Scientist: Personnel that are responsible for examining items, writing a report based on their interpretations and presenting said findings in court if called to do so (Speaker 2009).

Sexual assault investigations: In terms of this project sexual assault or rape as a factor involved in a case is noted by the presence of a SAECK kit being used to collect evidence. That is not to say it definitely occurred, only that it was considered a possibly relevant factor warranting further investigation.

SUDI/J/A: Sudden unexpected death if defined as death within 24 hours of the onset of symptoms or that which is sudden, unexpected or unexplained even if it is later shown that it was natural. (Pandian et al. 2014) By South African standards adults are individuals over 18 years of age, infants below 1 year and juveniles in between this.

Suicide: A case factor when death occurs due to intentional self-inflicted injuries.

Support staff: Staff that provide internal support services. For example management and administration. Excluding operational staff such as unit/clinical heads (Speaker 2009).

Toxicology: Analysis of biological samples to detect the presence and concentrations of drugs/toxins (WVU 2007b).

Total expense: The total sum of personnel, operating and capital expenses including any other expenses not classified under these categories (Speaker 2009).

Total hours: The total amount of time worked annually by FTEs (Speaker 2009).

Test: Analytical analysis of a sample taken from an item or the entirety of the item. Not including reviews of previous data. The test results are included in a report (WVU 2007b).

Virology: Examination of PM samples for the presence of viral pathogens that may have caused or contributed towards death.

A.2. Business based calculations

Per full time employees:

Cases/FTEs: total cases for 2015/total full time employed staff at SRM and UCT pathology department

Reports/FTEs: total returned ancillary investigation reports for 2015/total full time employed staff at SRM and UCT pathology department

Items/FTEs: total items examined or collected for 2015/total full time employed staff at SRM and UCT pathology department

Samples/FTEs: total samples taken from items examined for 2015/total full time employed staff at SRM and UCT pathology department

Tests/FTEs: total tests on samples for 2015/total full time employed staff at SRM and UCT pathology department

Cost (Rands) estimates per:

Case: Total 2015 year expenses/number of cases for 2015

Report: Total 2015 year expenses/number of returned ancillary investigation reports for 2015

Item: Total 2015 year expenses/number of items examined or collected for 2015

Sample: Total 2015 year expenses/number of samples examined from items for 2015

Test: Total 2015 year expenses/number of tests on samples for 2015

A.3. Information Sheet and Informed Consent

HREC REF: 177/2016

Student: Jacqui de Jong (DJNJAC003)

Supervisor: Bronwen Davies

Department: Pathology



You are invited to participate in a study entitled “Investigating the effectiveness and efficiency of forensic pathology practice in Western Cape, South Africa”. This study has been approved by the University of Cape Town (UCT) Human Ethics Research Committee (HREC), Ref: 177/2016.

Currently in South Africa there is an ever increasing demand on the Forensic pathology service as crime rates and population increase, whilst finances available dwindle. There is thus a need to optimise the forensic pathology service’s practises in order to increase throughput, whilst maintaining a high standard of results and reducing costs. This study aims to address these issues using Lean Six Sigma, a business concept focussing on reducing waste and increasing efficiency in a service. A key step in this methodology is the compilation of process maps.

A process map is a step by step flow chart outlining the areas involved in a practise, the time taken for each and equipment or documentation required. In this case it would entail what processes occur that are associated with autopsies, in other words a typical work day for a forensic pathologist. By examining these process maps the process can be streamlined. For example it may be found that certain steps should optimally be done in a different order, some steps may be altered and some may be removed or added.

In order to see what steps need to be in the process map and to gather data on them, for example time intervals, autopsies must be observed and the workflow noted. This will be done not to note the performance or criticise each doctor, merely to get a feel for the overall practise of the mortuary.

The information obtained will provide us with an understanding of the processes involved, efficiency thereof and highlight any shortfalls in pathology practice. This project aims to come up with ways to improve efficiency and decrease waste based on what is observed.

This study focuses on Salt River mortuary, thus all pathologists working here are eligible to take part. Participation is completely voluntary and all data will be anonymous. Participation will involve being observed whilst working at Salt River mortuary. Your work will not be interfered with or disturbed in any way.

Observations will be made as to what occurs at autopsy, in what order and the time taken for each step. For example if filling out a form at autopsy it may be noted as follows:

10:24- collected form FPS007 from cupboard in document room

10:30- completed form sections 1-3

10:40- put on gloves, examined abdominal block

11:00- took off gloves

11:02- completed FPS007 form

As an example as to how this information may be used, it can be seen from the above that the form was completed in two sections, perhaps it would take less time to complete the examination and then fill in the whole form, negating the need for multiple glove changes? Or perhaps a voice recording should be taken of the autopsy so that multiple forms can be completed at the end of the day? Or maybe it is even possible for a scribe to be present, such as a medical student who needs to view autopsies anyway to learn?

There is no remuneration for this study, however the information you provide will aid in evaluating and potentially improving the practises at Salt River Mortuary. The results of this study will be shared amongst forensic professionals associated with UCT.

Your name will only appear on this consent form, which will be securely locked away. Observation data will be linked to an identifying number only (see the top right of the informed consent sheet). There will be no analysis of your individual work however, this number is only for record keeping and data collection and will not be used in analysis, results or publications.

The group of pathologists involved in this study will be kept anonymous in publications through the above and also by not recording the date of each observation. However it will be stated that Salt River Mortuary was involved.

You are free to withdraw from this study at any time. If you choose to do so then all information linked to you will be destroyed.

There are no risks associated with this study, since routine work that would have been done anyway will be observed without interference.

If you have any further questions regarding this study or wish to withdraw from it please do not hesitate to contact the researchers involved or the UCT FHS HREC offices as follows:

Student, Jacqui de Jong:

Email: Jacquidj52@gmail.com

Supervisor, Bronwen Davies:

E-mail: bronwen.davies@uct.ac.za

Work tel: 021 406 6026

UCT FHS HREC offices:

The Human Research Ethics Committee
Old Main Building of Groote Schuur Hospital,
Floor E53
Room 46
Observatory, 7925
Tel: 021 406 6346

Identifying number: _____

Declaration by participant

By signing below, I, agree to take part in a research study entitled “**Investigating the effectiveness and efficiency of forensic pathology practice in Western Cape, South Africa**”.

I declare that:

- I have read the attached information leaflet and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study (participating in the interview) is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I understand that there are no risks associated with taking part in this study

Signed at:

On (*date*) 2016.

Signature of participant.

A.4. Ethics approval letter



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • Facsimile [021] 406 6411
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

24 March 2016

HREC REF: 177/2016

Miss B Davies
Forensic Pathology
Entrance 3, Level 1
Falmouth Building -FHS

Dear Miss Davies

PROJECT TITLE: INVESTIGATING THE EFFECTIVENESS AND EFFICIENCY OF FORENSIC PATHOLOGY PRACTICE IN WESTERN CAPE, SOUTH AFRICA (Mphil-candidate-J de Jong)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 March 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the following student, Jacqui de Jong will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

Yours sincerely

Signed

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 177/2016

This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines.

The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC 177/2016