

Can Lean Six Sigma be used to improve the Specimen Sample Process Flow within the NDTC Laboratory?



By

Paul Thomas Murray

Student's No: 11266831

Supervisor: Gaye Stephens

Health Informatics

Trinity College Dublin

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Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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SUMMARY

The use of Business Process Management Systems (BPMS) to improve the continuity of service has been shown in industry, service and health care environments. The purpose of this research paper is to investigate the possible benefits of applying a BPMS such as Lean Six Sigma (LSS) in the National Drug Treatment Centre (NDTC) Laboratory.

The current challenges the NDTC Laboratory face are a moratorium on the recruitment of new staff, so none of the existing staff can be replaced, if they leave or take a career break. An increased number of Specimen Sample testing requests (over one million routine tests conducted in 2012), with an average increase of 37.49% from 2012 to 2013 and the pressure of sustaining a 48 hour Turn-Around Time (TAT), these and the constant pressure of maintaining an accredited Laboratory are having a negative effect on staff morale.

A series of interviews were conducted with the Senior Laboratory Team, consequently ten processes were defined where it was believed that LSS could be used to improve the Laboratory Specimen Sample Process Flow. A template was developed using a selection of LSS tools which could be reused on different Laboratory process problems. The template was divided into five different stages Define, Measure, Analysis, Implement and Control, this LSS methodology is known as DMAIC and allowed for the problems in the ten processes to be identified.

The project was divided into two Phases; Phase I was completed in July 2013 and Phase II is currently in the Analysis stage and is scheduled to be completed in January 2014.

The process improvements demonstrated a 50% reduction in time for some of the processes, a complete reduction in transcriptions errors, as several of the process improvements are now fully automated and controlled by the Laboratory Management Information System (LIMS). Based on figures in 2012 for the offsite storage and retrieval of Laboratory reports, which are now no longer paper based, the Laboratory will make substantial cost savings this year and exponentially over time as shown by similar projects carried out by the Mayo Clinic (Mayo Clinic, 2007) and the Louisiana State Police Crime Laboratory (Richard, Kupferschmid, 2011).

A survey in the form of a questionnaire was conducted to examine the attitudes and perceptions of the Laboratory staff and to measure the user acceptance of the LSS interventions. Overall the findings indicated the staff did believe the implementations were an improvement to the process work flow, they rated the efficiency of the proposed solution as high or very high.

The Implementation of LSS has demonstrated that a coherent approach to continuous improvement (Pepper, Spedding, 2010) has been achieved within the NDTC Laboratory. By reducing and eliminating waste and identifying the value streams, the NDTC Laboratory can provide an effective framework for producing systematic improvements with a reduction in effort (de Koning, 2006) and costs.

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ABBREVIATIONS

5S's	Sort, Straighten, Scrub/Shine, Standardise, Sustain
BPR	Business Processing Re-engineering
CODIS	Combined DNA Index System
COPQ	Costs of Poor Quality
CSF	Critical Success Factors
CTS	Critical To Success
CTQ	Critical To Quality
DAIS	Drugs and Aids Information System
DMAIC	Define, Measure, Analyse, Improve, Control
DNA	Deoxyribonucleic Acid
DFSS	Design For Six Sigma
DTCB	Drug Treatment Centre Board
EDDP	2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine
HSE	Health Service Executive
ICT	Information Computer Technology
IDT	Informed Decision Toolbox
IEQAS	Irish External Quality Assessment Scheme
ISMS	Information Management Security Systems
ISO	International Standards Organisation
IT	Information Technology
LCMS	Liquid Chromatography Mass Spectrometry
LER	Laboratory Electronic Reporting
LIMS	Laboratory Information Management Systems
LSPCL	Louisiana State Police Crime Laboratory
LSS	Lean Six Sigma
MScHI	Masters in Health Informatics

NDTC	National Drug Treatment Centre
NIJ	National Institute of Justice
NWA	Northwest Analytical
PCI	Payment Card Industry
PDCA	Plan, Do, Check, Act
PDF	Protected Document Form
PDSA	Plan, Do, Study, Act
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management Systems
RIM	Records and Information Management Systems
SAMHSA	Substance Abuse and Mental Health Services Administration
SLA	Service Level Agreement
SOP	Standard Operating Procedures
SPC	Statistical Process Control
TAT	Turnaround Time
TPS	Toyota Production System
TQM	Total Quality Management
UKNEQAS	United Kingdom National External Quality Assessment Scheme
UOM	Uncertainty Of Measurement
VAT	Value Added Tax
VSM	Value Stream Mapping
VTC	Voice of the Customer

Chapter One: Introduction

1.1 The NDTC Laboratory

The National Drug Treatment Centre (NDTC) formally known as The Drug Treatment Centre Board (DTCB) provides a drug analysis service to the Health Service Executive (HSE) addiction services, general practitioners, hospitals (general, psychiatric and maternity), juvenile detention centres, the Dublin Drug Court, the Probation and Welfare Services and voluntary agencies (Addictionireland, 2012).

The NDTC laboratory performed approximately 1,020,257 routine tests in 2012, for 269 Clinics on approximately 11,425 patients. These figures do not include non-routine tests (pH, Glucose, Pregnancy test – HCG, Ethyl Glucuronide – ETG) and confirmatory Analysis, of which there were approximately 31,573 tests in 2012 on 5,885 specimen samples received in 2012. The majority of the laboratory testing is done by a urine screening method known as immunoassay. These screening assays look for groups of drugs such as opiates, benzodiazepines, cannabis, cocaine, amphetamines, EDDP (methadone metabolite) and 6-acetylmorphine. Immunoassay is a qualitative method which indicates only the presence or absence of a drug/drug class in a sample.

Each test by immunoassay has a defined cut-off level, above which the test is deemed positive indicating that the presence of a drug/drug class was detected above the cut-off level. If a test result falls below the cut-off level, the result is deemed negative indicating that the drug/drug class was not detected above the cut-off level. Screening assays are not always 100% specific, i.e. a drug that has a similar structure can cause a false positive on the assay (cross reactivity). In this case the sample can be subjected to further Analysis by a technique known as Mass Spectrometry; this can then confirm the presence or absence of the specific drug or compound in the sample. In order to perform this confirmatory Analysis the sample must be compared to a reference standard for the drug. Many of the drugs being confirmed are controlled substances. These controlled drug reference standards are normally ordered from a supplier in the UK.

1.1.1 Problems in the Value Stream Process Flow

The issues identified from initial interviews conducted with the Senior Laboratory Team highlighted several problems in the Value Stream. The Value Stream is used to track the flow of materials and information throughout the process flow (Richard, Kupferschmid, 2011), which

included areas where there was duplication of effort and the risk of transcription errors. There were issues with the tracking and reporting systems deployed by the laboratory at the time of the interviews. These systems were a combination of paper based forms, MS Excel spread sheets, and MS Word documents, some of which were stored in a document management application called Paradigm II, while others were stored in various locations on the File Server (CHEOPS) and the Laboratory Information Management System (LIMS) which is referred to as Labware LIMS.

These data repositories were found to be cumbersome when retrieving information and the data was not automatically linked to a specimen sample or batch of specimen samples that had been tested. These largely paper based processes required the printing of reports and generated copious amounts of paper which had to be indexed, managed and eventually stored securely off-site for accreditation purposes. This amounted to a significant cost in both staff time and the NDTC finance budget.

It was possible to utilise some of the features of Labware LIMS to improve the tracking and reporting systems currently used by the NDTC. The possibility to digitally save documentation and store reports addressed the need to print and store documents off-site.

The Laboratory's main avenue of reporting has changed over the last six years from paper based reporting to mostly electronic reporting systems today. The Laboratory has several different types of electronic reporting requirements. The Laboratory Labware LIMS server communicates directly with the NDTC Electronic Patient System (EPS) and creates a view of the results for the clinical staff within the NDTC. A similar approach is in place for the HSE Drugs and Aids Information System (DAIS); results are encapsulated in Extended Mark-up Language (XML) and are sent via a secure Virtual Private Network (VPN) connection. The Laboratory also has its own Internet based reporting system known as the Laboratory Electronic Reporting (LER), this system allows registered users in clinics to login remotely and check results. The current trend to move away from paper based records and reporting, including the faxing and posting of reports, to electronic reporting via Electronic Health Records (EHR) was highlighted by Vest, Yoon, Bossak, (2012) in their paper in the British Medical Journal (BMJ).

1.1.2 NDTC Quality Control (QC) and Quality Assurance (QA) standards

A Laboratory Quality Control (QC) is a statistical process used to monitor and evaluate the Analysis that produces results. The NDTC Laboratory adheres to strict QC and Quality Assurance (QA) standards. Approximately 3% of all samples run in the Laboratory are quality controls. In order to assess performance and to ensure the highest confidence in test results,

the laboratory is involved in two external Quality Assurance schemes, the United Kingdom National External Quality Assessment Scheme (UKNEQAS) and the Irish External Quality Assessment Scheme (IEQAS) (NDTC, 2013).

1.1.3 Laboratory Accreditation

The NDTC Laboratory is accredited by the Irish National Accreditation Board (INAB) to ISO/IEC17025. The ISO/IEC 17025 standard is the main standard used in testing and calibration laboratories.

The ISO/IEC 17025 standard is aimed at improving the ability to consistently produce valid results and it has management and technical requirements.

Management requirements are primarily related to the operation and effectiveness of the quality management system within the laboratory, while technical requirements address the ICT Services, competence of staff, methodology and test/calibration equipment.

The Laboratory is audited annually by a team of Irish and international external auditors from Irish National Accreditation Board (INAB), to maintain the ISO/IEC 17025 standard. In 2012, the Laboratory successfully applied to extend the scope of accreditation to include drugs of abuse in oral fluids, Ethyl Glucuronide in urine and Cannabis confirmatory Analysis in urine. The NDTC Laboratory is classed as a Category A: (Figure 1.1) type Laboratory by INAB.

Testing and Calibration Categories:

- | | |
|--------------------|--|
| Category A: | Permanent laboratory calibration and testing where the laboratory is erected on a fixed location for a period expected to be greater than three years. |
| Category B: | Site calibration and testing that is performed by staff sent out on site by a permanent laboratory that is accredited by the Irish National Accreditation Board. |
| Category C: | Site calibration and testing that is performed in a site/mobile laboratory or by staff sent out by such a laboratory, the operation of which is the responsibility of a permanent laboratory accredited by the Irish National Accreditation Board. |
| Category D: | Site calibration and testing that is performed on site by individuals and organisations that do not have a permanent calibration/testing laboratory. Testing may be performed using |
| | (a) portable test equipment |
| | (b) a site laboratory |
| | (c) a mobile laboratory or |
| | (d) equipment from a mobile or site laboratory |

Figure 1.1: INAB Testing and Calibration Categories (NDTC, 2013)

The Laboratory successfully completed its annual audit in May 2013. The current scope of the NDTC Laboratory accreditation (Figure 1.2) can be viewed at www.inab.ie/pdf/169T.pdf (NDTC, 2013).

Clinical Chemistry Testing Laboratory

P9 Classification Number	TEST	METHOD	POSITIVITY CUT - OFF	POSITIVITY CUT-OFF SOURCE (NOTE)	UNITS	SOP Reference	
771.21 Drugs and Drug Metabolites	Benzodiazepines	Immunoassay CEDIA	200	2	ng/ml	TP8	
	Cannabis Metabolites	Immunoassay CEDIA	50	2	ng/mL	TP8	
	Cocaine	Immunoassay CEDIA	300	2	ng/mL	TP8	
	.99 Other substances in Urine	Creatinine	Immunoassay DRI	2 - 20 = dilute <2 = abnormal	3	mg/dL	TP8
		EDDP*	Immunoassay CEDIA	100	1	ng/mL	TP8
		Amphetamine/ Ecstasy	Immunoassay CEDIA	1000	4	ng/mL	TP8
		Ethyl Alcohol	Immunoassay DRI	30	4	mg/dL	TP8
		Opiates	Immunoassay CEDIA	300	2	ng/mL	TP8
		6-Monoacetyl Morphine	Immunoassay CEDIA	10	1	ng/mL	TP8
		DRI pH -Detect Test	Immunoassay DRI	3-11		N/A	TP8
		Ethyl Glucuronide	Immunoassay DRI	500	1	ng/ml	TP8
		Confirmation of THC_COOH by LC - MS	In-house	10	3	ng/ml	CFP16
.99 Other substances in Oral Fluid		Opiates	Immunoassay CEDIA	40 (neat)	3,6	ng/ml	TP48
	6-Acetylmorphine	Immunoassay CEDIA	4 (neat)	6	ng/ml	TP48	
	Benzodiazepines	Immunoassay CEDIA	20 (neat)	1	ng/ml	TP48	
	Methamphetamine	Immunoassay CEDIA	50 (neat)	3	ng/ml	TP48	
	Amphetamine	Immunoassay CEDIA	50 (neat)	3	ng/ml	TP48	
	Cannabis	Immunoassay CEDIA	4 (neat)	3	ng/ml	TP48	
	Cocaine	Immunoassay CEDIA	20 (neat)	1	ng/ml	TP48	
	Methadone	Immunoassay CEDIA	50 (neat)	6	ng/ml	TP48	

Positivity Cut-off (source):

1. Recommended by manufacturer.
2. United Kingdom Laboratory Guidelines for legally Defensible Workplace Drug Testing.
3. Mandatory Guidelines for Federal Workplace Drug testing Program.
4. Arbitrary.
5. In-house confirmatory method.
6. European Workplace Drug Test Society Guidelines in oral fluid for screening tests.

Figure 1.2: NDTC Laboratory Accreditation (NDTC, 2013)

1.1.4 Legal Requirements

The NDTC Laboratory is required to obtain a controlled drug license and a license for precursor chemicals. To obtain a controlled Drugs license the NDTC were required to demonstrate compliance to the requirements for security, storage and documentation, as set out in the regulations of the Misuse of Drugs Acts 1977 and 1984.

Controlled drugs are any substance listed in the Misuse of Drugs Acts 1977 and 1984, they are defined as a substance with a potential for misuse and or abuse. Controlled drugs Licenses are issued under the Misuse of Drugs Acts and are legally required before controlled drugs can be Imported/Exported or used for calibration or Quality Control (QC) purposes by a Laboratory.

A Precursor chemical is a substance that is used in the illicit manufacturing of a controlled drug and in 2010 the Irish Medical Board was nominated as the authority for Licensing, registration and Import/Export Authorisation for Precursor chemicals (Irish Medicines Board, 2013).

The NDTC are also required to comply with other Irish, European and International Legislation listed in table 1.1.

Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors (internal trade within the Community)
Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors
Commission Regulation (EC) No 1277/2005 of 27 July 2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.
EU Regulations on Drug precursors: European Commission (http://ec.europa.eu/taxation_customs/customs/customs_controls/drugs_precursors/legislation/index_en.htm)
Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (managed by DG TAXUD).
Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (managed by DG ENTERPRISE).
Commission Regulation (EC) No 297/2009 of 8 April 2009 amending Regulation (EC) No 1277/2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors.
Commission Regulation (EU) No 225/2011 of 7 March 2011 amending Commission Regulation (EC) No 1277/2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors was published in the OJEU L 061/2011 of 8 March 2011.
International Narcotics Control Board (http://www.incb.org/incb/convention_1988.html) 1: United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988 Reference: International Narcotics Control Board (http://www.incb.org/incb/convention_1971.html) 2: Convention on Psychotropic Substances Reference: International Narcotics Control Board (http://www.incb.org/incb/convention_1961.html) 3: Single Convention on Narcotic Drugs, 1961
Irish Statute Book (http://www.irishstatutebook.ie/1982/en/si/0321.html) Misuse of Drugs (Safe Custody) Regulations 1982

Table 1.1: Controlled Drugs and Drug Precursors Irish, European and International Legislation

1.2 Overview of Dissertation

Chapter Two of this dissertation looks at the evolution and the current state of Business Process Management Systems (BPMS) and the current trends in Healthcare and Clinical Laboratories to adopt a Lean Six Sigma (LSS) type of intervention to improve performance.

Chapter Three explores the Methodology used in answering the research question. Can Lean Six Sigma be used to improve the Specimen Sample Process Flow within the NDTC Laboratory?

Chapter Four examines the research processes used in the implementation of Phase I of the LSS Case Studies in the NDTC Laboratory.

Chapter Five provides an Analysis of the results of the LSS interventions used in the Case Studies for this dissertation.

Chapter Six discusses the results of the LSS implementation and the limitations of the research, the on-going and possible future work.

1.3 Rational behind the Proposed Lean Six Sigma Interventions

The Implementation of Lean principles and Six Sigma methodologies introduces the possibility of identifying a coherent approach to continuous improvement (Pepper, Spedding, 2010). To correctly implement a quality improvement implementation, a holistic approach is required one which optimises the process for the whole system by putting the right interventions in the correct place (Pepper, Spedding, 2010), by reducing and eliminating waste and the identification of value streams which when implemented within the NDTC Laboratory provided an effective framework for producing systematic improvements and a reduction in effort (de Koning, 2006).

With the current budgetary restraints placed on the public sector spending and in particular the health services, interventions like those detailed in this dissertation could only be realised by the use of in house resources. In the past funding was available for the procurement of outside business process analysts to complete these tasks.

- Under the Public Service Agreement 2010-2014 (Croke Park Agreement) there is a moratorium on recruitment, which means that any member of staff who leaves is no longer, replaced. The processes in place prior to the LSS project where implemented when there was a full contingency of Laboratory staff and a reduced amount of specimen sample testing requests. These processes put increased pressure on the

Laboratory staff, by implementing the LSS initiatives it reduced some of the workload for the laboratory staff and reduced the “wasteful steps” (Lean Principles) within the Laboratory value stream.

- The implementation of the LSS interventions will reduce costs over time within the NDTC by recording information electronically and thus eliminating the production of paper reports which had to be stored off-site indefinitely and at a significant cost.
- “The laboratory is accredited to the ISO 17025 standard and it is important that all of tracking systems used maintain detailed records for all chemicals and reagents used in testing. This includes LOT numbers, expiry dates and certificates” (Addictionireland, 2012). It was commented on by INAB during their annual audit in 2012, that the Laboratory was “heavily reliant on paper based systems” and that it should strive to move towards electronically recording its current tracking and reporting systems, this maybe a future requirement for INAB accreditation.
- For accreditation purposes INAB have highlighted that it now requires that stock control systems must be fully auditable (the process used by the NDTC was not) this would lead to a non-conformance and needed to be corrected before the next INAB audit, which took place on the 21st of May 2013.

1.4 Project Goals

The aim of the NDTC Laboratory’s LSS project was to help to facilitate the Laboratory with implementing process changes that could, where possible lead to a paperless environment, improve efficiency by streamlining the process flow of a specimen sample through the Laboratory and to increase the Laboratory’s operational effectiveness.

To enable the Laboratory to sustain and possibly improve the level of service it currently provides to its customers at a time when demand and expectations are perennially increasing.

By applying a LSS multi-faceted implementation in a Clinical Laboratory environment, using new technology, available resources and personnel, it is believed that this substantially increased the operational effectiveness of the NDTC Laboratory and where possible met the requirements set out by the customer (Senior Laboratory Team), to reduce costs, increase production and improve staff morale.

Chapter Two: Literature Review

2.1 Introduction

Quality improvement management and Business Process Management Systems (BPMS) have for a long time been conceived of as important strategies for maintaining competitive advantage by improving process performance, enhancing client, or customer satisfaction and allowing for the generation of more revenue or reducing costs (Snee, 2010).

The use of BPMS have successfully gained acceptance in industry throughout the world (Nonthaleerak and Hendry, 2005). Their application has been varied in terms of location and the quality improvement implementation needed to address the problem (Vest, Gamm, 2009; Richard, Kupferschmid, 2011). Their use in healthcare and laboratory services is relatively new (Taner, Sezen, Antony, 2007; Richard, Kupferschmid, 2011). When they have been applied successfully in healthcare and laboratories they have led to a reduction in costs, increased patient satisfaction, a reduction in scheduling delays and a reduction of waste (Taner, Sezen, Antony, 2007; Mayo Clinic, 2007).

The NDTC laboratory is interested in improving their processes. The author's motivation to research and apply BPMS methods is based on the Mayo Clinic Laboratories report in 2007 and the Louisiana State Police Crime Laboratory in 2011. Both of these laboratories successfully applied the BPMS methods called Lean and Lean Six Sigma (LSS) in their laboratories.

The goals of the Mayo Medical Laboratory were to improve operational performance by reducing costs, faster testing times for customers and improve quality in the laboratory. They reduced variability in performance, improved staff safety, and morale, reduced the production times for developing new tests and also reduced errors during the development and implementation of new tests (Mayo Clinic, 2007). Similarly, the Louisiana State Police Crime Laboratory (LSPCL) aimed to reduce problems such as backlogs, extended turnaround times (TAT) that exceeded a year and low productivity (Richard, Kupferschmid, 2011).

For the purpose of this literature review I will refer to these process changing methodologies as "Business Process Management Systems (BPMS)", as there are many different terms used to describe these methodologies, for example Snee, 2010 refers to them as a "Business Improvement Methodology", Nonthaleerak and Hendry, 2005 talk about "Quality management", Chakrabarty, Kay, 2007 use the phrase "Quality Improvement Program" and Vest, Gamm, 2009 refer to the use of process changing methodologies as "Transformation Strategies".

Initially in this literature review there is a description of various BPMS methods which have evolved over the years leading to LSS that is in use today. The BPMS methods discussed here were selected because of a connection to LSS or Healthcare.

Business Process Management Systems

- The Origins of Business Process Management Systems
- Henry Ford's Mass Production System
- Lean
- Just-In Time
- Total Quality Management (Deming's PDCA)
- Business Process Reengineering
- Six Sigma
- StuderGroup's Hardwiring Excellence
- Evidence-Based Management
- Boeing Lean Production System
- Lean Six Sigma

The review concludes with a description of the tools, challenges, and success factors for the LSS method which was the BPMS method of choice for this research.

2.2 Search Strategy

The methodology used to conduct this literature review involved searching publication databases such as the Trinity College Dublin (TCD) Library, Google Scholar, The International Journal of Lean Six Sigma, PubMed, BioMed Central and Emerald Insight for literature that examined the evolution, adoption and current use of LSS and other business process management methodologies in healthcare and the public sector, and in particular laboratory services.

The initial search was restricted to the phrase "Lean Six Sigma and Laboratories", but these database searches produced poor results. Expanding the search to include Quality Management, Quality Laboratories, Six Sigma, Lean, Lean Laboratories, Lean Principles, Total Quality Management, and Lean Six Sigma, proved more productive.

2.3 Business Process Management Systems:

The manufacturing industry have since the 1930's used structured scientific methods to streamline production, reduce variability in outcomes and have used statistical methods to measure quality and standardise production (DelliFraine, et al., 2010).

There have been many different BPMS used in manufacturing over the last one hundred years, such as Lean, Just-In-Time, Total Quality Management (TQM), Business Process Reengineering, StuderGroup's Hardwiring Excellence, Evidence-based management, Six Sigma and Lean Six Sigma (DelliFraine, et al., 2010; Chiarini, 2011; DelliFraine, et al., 2010; Snee, 2010).

2.3.1 The Origins of Business Process Management Systems

The origins of BPMSs are largely based on the automobile industry and in particular the evolution of Lean manufacturing in post-World War II Japan. Initially the automobile industry was a craft based production system, which relied on a highly skilled workforce to produce exactly what the customer requested, one item at a time and at great expense. To make automobiles available to the mass populous another alternative had to be initiated, this gave birth to mass production (Walmack, et al, 1990).

Mass Production used purpose built machines manned by semi-skilled workers and produced standardised products in large quantities. To ensure the production systems ran smoothly extra safeguards had to be in place. This included extra workers, large inventories of stock and large areas for the storage of produced cars to ensure that there were always supplies ready to meet demand (Walmack, et al, 1990).

The Mass Production systems where expensive to run, prone to breakdowns which would halt the entire production line and staff morale was low as the semi-skilled workers found the work to be repetitive and monotonous as the products produced were of similar type. Today most of the automobile industry production systems are based on the Lean Toyota Production System, which allows for the efficient production of highly crafted products without the added expense and rigid products produced in a standard Mass Production line (Walmack, et al, 1990).

The methods can be broadly classified as Top-down or Bottom-up approaches. Top-down concerns mainly improving processes whereas Bottom-up concentrates on solving process flow problems. The need for BPMS is usually initiated because the business goals within the organisation are not being realised, this type of approach to finding a solution to a business problem is usually approached using a top-down process methodology. BPMS improvement projects can also be initiated because performance gaps have been identified in production.

The type of approach used to resolve these shortfalls would be classed as a bottom-up process methodology. When developing a business improvement process solution, the question that should be considered is should the problem be approached from a top-down or bottom-up business solution design (Snee, 2010).

Business process or process flow types of problems can be addressed using a BPMS such as Lean Six Sigma, Lean, Six Sigma, Total Quality Management, StuderGroup's Hardwiring Excellence or other types of BPMS. Six Sigma for example can be used for solving complex business process problems. To find the wasteful steps in a process the use of a Value Stream Mapping tool is required, these are usually associated with Lean and can help identify where the business goals or performance gaps in a system are located (Snee, 2010). For a holistic approach a combination of Lean and Six Sigma methodologies can be used. Lean can be used to identify non-value added activities, or may uncover more complex problems. It is when Six Sigma and Lean are combined that a more complete solution is presented, one which addresses the problems discovered in badly designed business process systems or delays or waste identified in production flow systems. These will be discussed later in the LSS section (Snee, 2010).

To understand how LSS has evolved into the state of the art BPMS that is in use today, it helps to examine some of the other types of BPMS that have been used in the past, some of which are still in use today.

2.3.2 Henry Ford's Mass Production System

Henry Ford understood the limitations of the craft production system; two of the main issues were the workforce had to be highly skilled and craft production system yielded very low production volume, about 1,000 models a year.

The Ford Model T car allowed Ford to produce a product that was user friendly, easy to repair and was easy to manufacture, the interchangeable parts, simplicity and easily assembly of the Model T were the innovations that made the assembly line possible.

This allowed Ford to reduce costs; he no longer needed the skilled craftsmen and replaced them with semi-skilled assemblers who would stay in the same assemble area all day and parts would be delivered to them. Ford realised that this was not very efficient and changed the process by having the workers become proficient in one part of assembly and then moving the workers from one assembly point to the next assembly point and building the Model T in stages, this innovation reduced the task cycles. Ford realised that this change although more productive still had its problems as some workers worked faster than others and this could create bottle necks and the constant movement of workers from one assemble point to the next created a lot of wasted time. In 1913 Ford introduced the moving assembly production line; this meant that the cars would move

from one assembly point to the next until the car reached the end of line fully finished (Womack, Jones, Roos, 1990).

2.3.3 Lean

Lean process methodologies are based on the Japanese car industry and in particular on the Toyota Production System (TPS). The term “Lean thinking” was first coined by Womack and Jones in 1996 in reference to Toyota’s improvement production processes used in the manufacture of cars.

The Toyota Production System (TPS) started after World War II and was pioneered by Taiichi Ohno. Japan was faced with a shortage of raw materials and finances for its manufacturing production industries, so for these industries to have a competitive chance with their western counterparts the employees at Toyota were charged with reducing waste where possible and developed a business process methodology based on this concept.

In Lean production the term waste was defined as “anything other than the minimum amount of equipment, materials, parts, space and time which are absolutely essential to add value to the product” (Russell, Taylor, 2000). The Toyota Production System (TPS) eventually became the prominent car manufacturing production methodology at the time (Pepper, Spedding, 2010).

2.3.4 Just-In Time

One of the influencing factors for the adoption of Lean production methodology in the West was the publication of the book “the Machine that changed the world” by Womack, et al., 1990. The European and US car manufacturing industries began adopting and adapting the Japanese car production process methodologies and by changing these methodologies to suit western culture they could remain competitive with the Japanese car manufacturing industry. The new western methodology was known as Just-In-Time and was modelled on the Japanese Toyota Production System (TPS), these systems led to the development of the Lean principles methodology (Womack, et al., 1990; Pepper, Spedding, 2010).

2.3.5 Total Quality Management (Deming’s PDCA)

Dr Edward Deming created the Plan Do Check Action (PDCA) cycle during his lectures in Japan in 1950 and 1951. He developed the concept of plan-do-check-action or PDCA cycle, Deming based the PDCA cycle on Walter Shewhart's scientific method, Specification Production Inspection Cycle (SPIC) developed in 1939. Deming's PDCA cycle was adopted by the Japanese and developed into a management tool and became an integral part of the Japanese Quality Control (QC), Total Quality Control (TQC) and business process activities.

In 1986 Deming developed the PDCA model for the USA, the new abbreviated version was used as a learning and improvement tool and was based on the original Shewhart model and was known as the Plan Do Study Act (PDSA) cycle. This was updated in 1994 and 2009 to include methods that would support improvement and change, this version of the PDSA cycle was known as the “Model for Improvement” (Moen, Norman, 2006).

2.3.6 Business Process Reengineering

Business Process Reengineering was popular in the 1990’s but has decreased in recent years with only the term reengineering remaining (Osayawe, Ehigie, McAndrew, 2005). It was a methodology designed to leverage Information Technology and to downsize companies while sustaining performance, Hammer and Champy, 1993 are credited with developing the first complete implementation design for Business Process Reengineering. Business Process Reengineering was based on a top down implementation design driven by senior management and delivered improvements to quality, cost, service and speed by focusing on the processes. Business Process Reengineering also focused on the Voice of the Customer (VTC) and in the latter stages the employees and the empowerment of the individual (Chiarini, 2011). The five stages of Business Process Reengineering methodology (Table 2.1) were summarised by Muthu et al, 1999.

The five stages of Business Process Reengineering

1:	Preparing for Business Process Reengineering
2:	Define the current processes
3:	Design the new processes
4:	Implement the reengineered processes
5:	Continuous Improvement

Table 2.1: The Five Stages of Business Process Reengineering (Muthu et al, 1999)

2.3.7 Six Sigma

Initially Six Sigma was created for use in the electronic industry, but over the last 20 years Six Sigma has spread to many other sections of industry, the financial services, service providers, the public sector, including hospitals, healthcare and local government (Tjahjono, et al., 2010).

The Motorola approach to manufacturing was different to that used by Toyota and was based on mathematical, statistical and scientific methods used to define Sigma (σ) or more accurately Six Sigma (6σ). Although Motorola are credited with creating the Six Sigma quality improvement methodology, it is actually based on Deming’s Total Quality Management (TQM) methodology (Brady, Allen, 2006).

Motorola discovered that it was more cost effective to eliminate or reduce defects than it was to repair them. The acceptable level was defined by a Motorola engineer Bill Smith by using the

statistical equation Six Sigma (6σ) which equates to 3.4 defects per one million units. Six Sigma is the point where the cost of eliminating/repairing the defect is greater than the cost of living with the defect; it was the acceptable point of imperfection or defects in Motorola's production line. It is estimated that the implementation of the Six Sigma quality improvement methodology in Motorola has saved the company over \$16 billion (Brett, Queen, 2005).

Six Sigma was designed to improve processes by focusing on quality and reducing defects. As a statistically based methodology which improves quality by eliminating variance, Six Sigma relies on creating a near perfect process and repeating it a million times with as little deviation or variance as possible, regardless of whether it is a process performed on a factory production line or a service that is being provided in a financial institution or in healthcare. Six Sigma methodologies are about finding things that are Critical to Quality (CTQ) and focusing on reducing variance in processes that affect customers. This approach can have the negative result of slowing down processes and making them more rigid and resistant to change (Devane, 2003).

2.3.8 StuderGroup's Hardwiring Excellence

StuderGroup's Hardwiring Excellence is different from other business process management projects in that it was not developed within a manufacturing environment but in contrast was developed in a healthcare environment by Quint Studer. Unlike most of the other business process management methodologies it was designed from a healthcare service improvement perspective as opposed to production improvement objective. The StuderGroup transformation strategies and techniques focus on taking a customer-focused and employee-centred approach to service problems. They incorporate the training of staff and adopting leadership behaviour modelling, eliminating variance among leaders resulting in a better quality of service and financial benefits for Hospitals where it is successfully deployed (Vest, Gamm, 2009).

The StuderGroup's Hardwiring Excellence is focused on management concepts such as motivation, building social networks within the organisation, objective and evidence based management, user feedback and learning (Spaulding, Gamm, Griffith, 2010).

Studer proposes that by adopting the StuderGroup's Hardwiring Excellence methodology there are five ways (Table 2.2) to reduce variance in leadership.

The Five ways to reduce variance in leadership

1:	Use a common agenda format for all meetings across the organisation, based on people, service, quality, finance and growth.
2:	The Goals of your organisation should be aligned to the critical success factors and based on measurable results.
3:	The information that each department head disseminates to members of their departments is the same so that throughout the organisation each employee hears the same information.
4:	Choose a common selection method when recruiting new employees.
5:	Leaders throughout the organisation should be trained to respond uniformly to questions raised by members within their departments.

Table 2.2: The Five ways to reduce variance in leadership (Studer, 2005)

By incorporating the reduction of variances in management and providing training that promotes leadership competencies this can promote successful health care organisations (Studer, 2005).

The limitations of successfully measuring the effects of StuderGroup's Hardwiring Excellence methodologies were highlighted by Vest and Gamm in 2009, in their review of the effectiveness of transformation strategies in healthcare. Based on a multi-site study of the implementation of the StuderGroup's Hardwiring Excellence project undertaken by Meade, Bursell and Ketelsen in 2006, which looked at the effectiveness of nurse rounding, bed side visits, patient light usage, patient falls and patient satisfaction, Vest and Gamm suggested that no firm conclusions could be made as to the effectiveness of this methodology (Vest, Gamm, 2009; Meade, Bursell, Ketelsen, 2006). Alternatively, Spaulding, Gamm and Griffith, 2010, suggest that there is evidence that human resources-focused quality improvement implementations in particular StuderGroup's Hardwiring Excellence can have significant benefits when promoting organisational change in hospitals (Spaulding, Gamm, Griffith, 2010).

2.3.9 Evidence-Based Management

Evidence-based management was described by McDaniel and Lanham, 2009 as ". . . the idea that managers should adopt practices that scientific inquiry has shown to be effective". There is now a drive within healthcare, for managers to use evidence-based management tools to increase the quality and accountability of the services they provide and to increase operational efficiency (DelliFraine, et al., 2010).

To assist healthcare managers to overcome the issues identified by Evidence-based management, Rundall, et al., 2007 developed the Informed Decisions Toolbox (IDT), which are a set of tools arranged into six steps (Table 2.3) that help healthcare managers make informed decisions by taking control of the decision making process (DelliFraine, et al., 2010).

The Informed Decisions Toolbox (IDT)

Step 1:	Framing the question
Step 2:	Finding sources of information
Step 3:	Assessing the accuracy of the evidence
Step 4:	Assessing the applicability of the evidence
Step 5:	Assessing the "actionability" of the evidence
Step 6:	Determining if the information is adequate

Table 2.3: The Informed Decisions Toolbox (IDT) (Rundall, et al., 2007)

2.3.10 Boeing Lean Production System

Boeing created their Lean Production system (Figure 2.1) by combining their production systems with their quality management systems to achieve a LSS process management methodology which delivers customer satisfaction. Boeing believes that it is everyone's responsibility to ensure that they never create, accept or pass on a defect to the customer (Arkell, 2003).

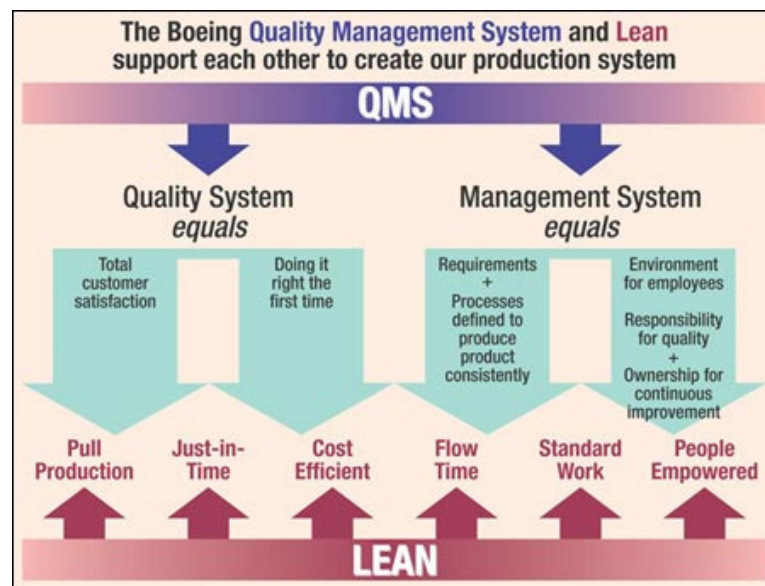


Figure 2.1: Boeing Quality Management System and Lean (Arkell, 2003)

2.3.11 Lean Six Sigma

By combining both Lean and Six Sigma methodologies (Figure 2.2), results have shown that more significant benefits can be gained, than by using these methodologies by themselves. If Lean is combined to a Six Sigma process design, it can introduce a more streamlined workflow to an otherwise slow static process and help identify other Six Sigma improvement opportunities. Likewise when Six Sigma is introduced to a system where a Lean methodology has been applied Six Sigma adds structure to the process flow. These methodologies when combined worked so well together that they formulated the basis of a new holistic methodology which has been adopted by many leading organisations. The LSS integrated approach provides a much more streamlined process flow that focuses on increasing quality and speed, reducing variance and waste by listening to the Voice of the Customer (VTC) (Brett, Queen, 2005), as Aristotle suggests “The Whole is Greater than the Sum of the Parts” (Mulgan, 1974).

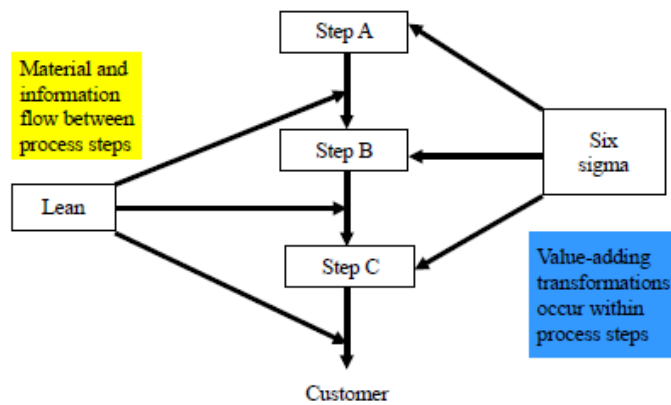


Figure 2.2: Improvement opportunities can occur within the processes (Six Sigma) or between the processes (Lean) (Snee, 2010)

Toyota’s Lean methodology was about speed, process flow and just in time manufacturing principles whereas Motorola’s Six Sigma methodology was more focused on eliminating defects. By combining Lean and Six Sigma methodologies seven principles (Table 2.4) which are the basis of the LSS methodology were created (Richard, Kupferschmid, 2011; Brett, Queen, 2005).

The Seven Principles of Lean Six Sigma:

1:	Listen to the Voice of the Customer (VTC)
2:	Identify the processes and the steps required in the process flow
3:	Improve the process flow
4:	Remove waste and non-value steps from the process flow
5:	Eliminate Variance
6:	Seek to improve the elements of the process by involving people and improving technology and equipment
7:	Use a systematic improvement framework when implementing change

Table 2.4: The Seven Principles of Lean Six Sigma (Richard, Kupferschmid, 2011; Brett, Queen, 2005)

LSS can be applied to virtually any process, when it is applied to paper or electronic documentation or a Records and Information Management (RIM) system; it can lead to improvements in customer service, reduced costs, more efficient response times and overall greater total quality management (Brett, Queen, 2005).

There are many Business Process Management Methodologies in use in healthcare today, but LSS although being a relatively new BPMS, is proving to be popular in healthcare and DelliFraine, et al., 2010 suggest that by the number of articles on the application of LSS in healthcare, that this trend is rising (Figure 2.3).

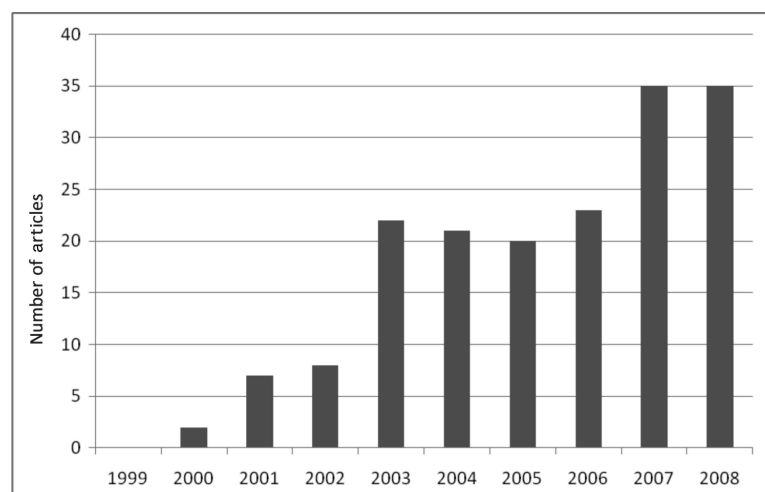


Figure 2.3: Lean and Six Sigma diffusion in healthcare, articles over time (DelliFraine, et al., 2010)

After reviewing and considering the various BPMS methods described above and their application to various domains, the LSS method was deemed the most suitable one to use in the research

described here. In the following sections some of the LSS tools are reviewed, how Lean and Six Sigma can be used in a Laboratory environment and the relevant challenges and success factors are described.

2.4 Lean Six Sigma Tools

2.4.1 DMAIC Problem Solving

The **DMAIC** structured problem-solving methodology is used as top down approach, starting at Senior Management level it is generally used in most LSS projects and is an iterative process that once completed may be repeated again to add another level of improvement. By using a DMAIC approach it allows LSS projects to be structured, clearly defined and provides standardised results when implemented correctly (Keller, Pyzdek, 2005).

- **Define** the problem
- **Measure** the Problem
- **Analyse** how the problem can be resolved
- **Implement** the solution
- **Control** the intervention and look for improvements

2.4.2 Spaghetti Diagram

A spaghetti diagram (Figure 2.4) is one of the tools used for measuring in a LSS project. It is used to track the movement in a process flow and for identifying waste or non-value steps in a process flow (Richard, Kupferschmid, 2011).



Figure 2.4: Spaghetti diagram showing the steps travelled to complete a process, (Richard, Kupferschmid, 2011)

2.4.3 Value Stream Map

The last input of the define stage is the Current State Value Stream Map (Figure 2.5). The Value Stream was developed as a Lean tool and is used to track the flow of materials and information throughout the process flow. In the example below the rectangles represents a process that needs to be completed and the triangles represent areas where a process can stop and work can build up.

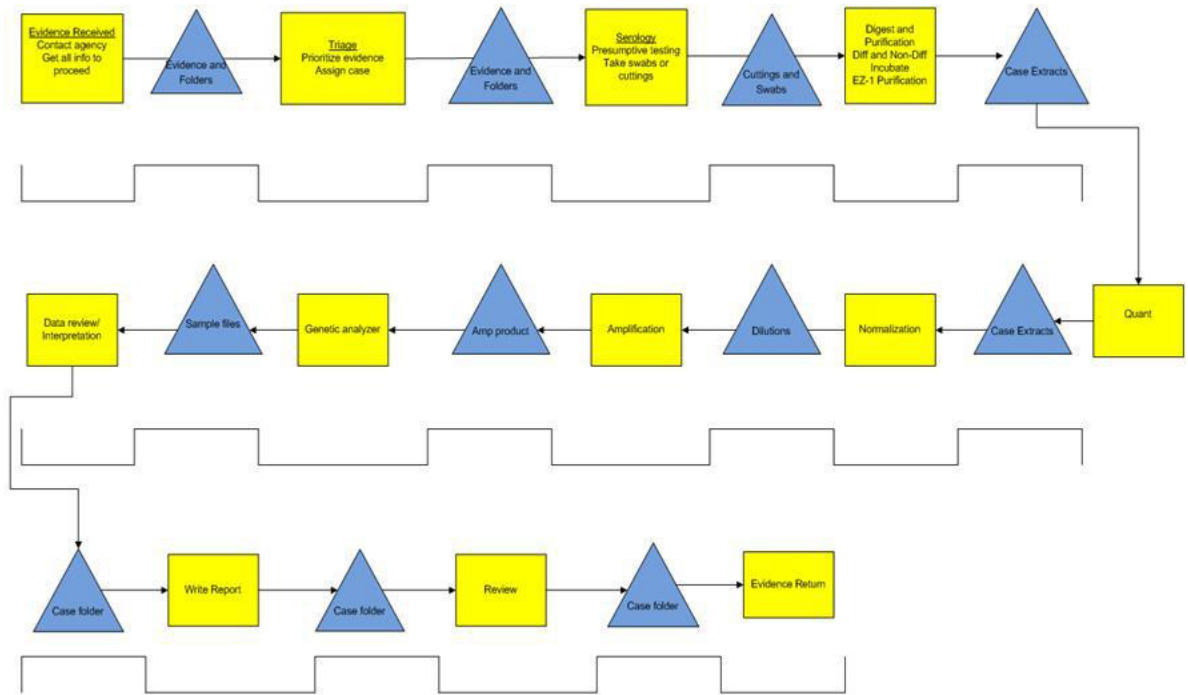


Figure 2.5: Value Stream Map (VSM) of the LSPCL DNA Process (Richard, Kupferschmid, 2011)

2.4.4 Project Selection Diagram

Project selection process diagram (Figure 2.6) is an effective tool to identify a process problem, decide on what type of improvement implementation is required and the best tool to use to provide the solution to the process improvement (Snee, Hoerl, 2007).

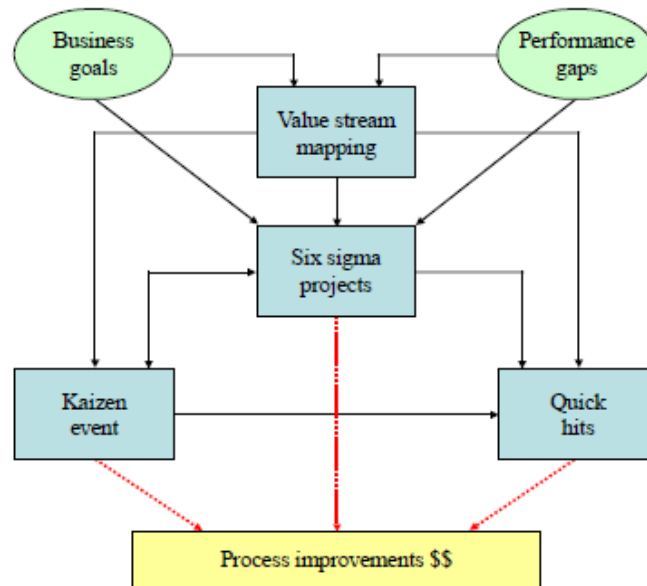


Figure 2.6: Project Improvement implementation selection diagram (Snee, Hoerl, 2007)

2.4.5 Workflow Diagram

A process flow or process map diagram is an important element during the Define and Analysis stages of DMAIC and these are best represented using workflow diagrams. A level 1 Process Map is used to present a high level view of the process flow and a level 3 Process Map (Figure 2.7) is used to define a detailed or low level representation of a single process (Richard, Kupferschmid, 2011). The meaning of the symbols used in these diagrams can be found in Appendix II.

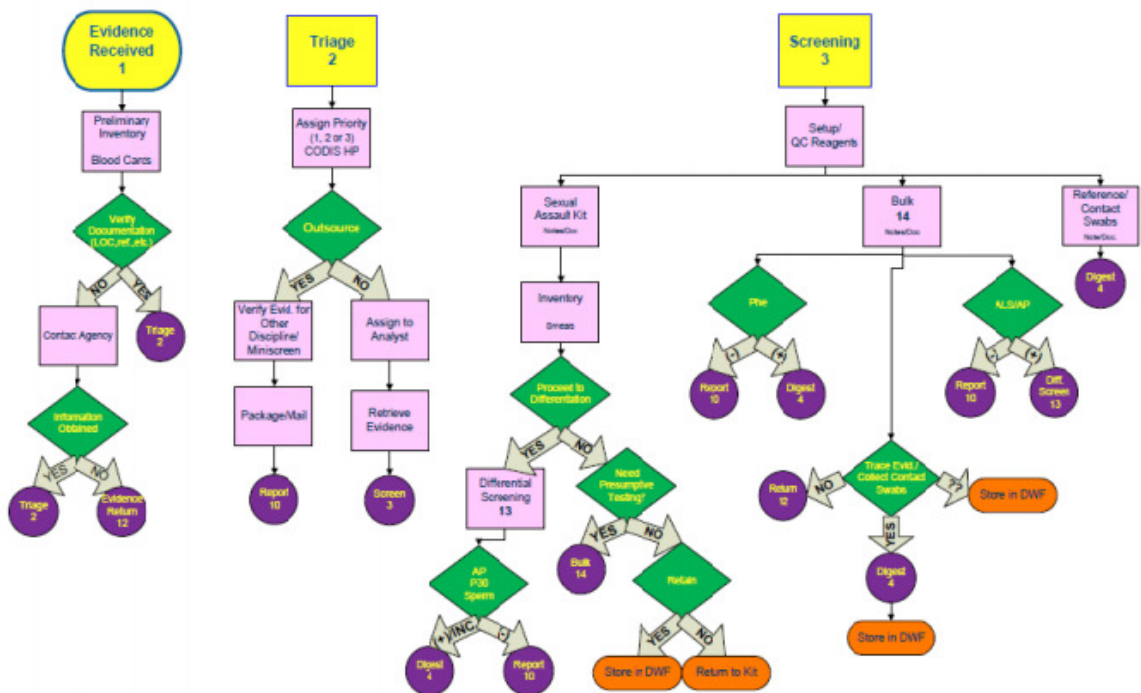


Figure 2.7: Part of a Sample process map (using Workflow diagrams) showing the last 4 process steps (level 1) and the corresponding detail under each step (level 3) (Richard, Kupferschmid, 2011)

2.5 Lean Six Sigma in Laboratories

By applying a BPMS such as LSS in a laboratory environment, it is possible to deliver and maintain quality laboratory results, reduce costs, introduce faster turnaround times on testing results, while maintaining quality of service and customer satisfaction (Mayo Clinic, 2007; Richard, Kupferschmid, 2011).

The use of Lean Principles (Table 2.5) and how they can be applied in a laboratory environment can be broken down into five main areas, these are:

Lean Principles in a laboratory environment

The Value principle which can be defined as having the value attributes of a control system process such as quality, speed, cost, it is something that is important to the client, something that a customer would pay for.
The Value stream for each value process identified is used to identify and eliminate the wasted steps used in these processes.
The Flow principle is used to enable the process or service to continuously flow through process steps once the waste has been removed.
The Pull Principle is used to enable a continuous flow of the processes by identifying when a task is completed or when an intervention is required allowing the process to become as fully automated as possible.
The final principal is an iterative process , one of continuous improvement, looking at ways to reduce the number of steps in a process, increase the quality, or reliability of the process for the client.

Table 2.5: Lean Principles in a laboratory environment (Mayo Clinic, 2007)

2.5.1 Lean Six Sigma Case Study

LSS has been successfully deployed to laboratories for the purpose of managing problems such as backlogs, extended turnaround times (TAT), and low productivity. The Louisiana State Police Crime Laboratory (LSPCL) undertook such a project in 2008 to address issues such as poor productivity, severe backlogs, and turnaround times that exceeded a year. In 2008 the LSPCL was awarded a National Institute of Justice (NIJ) efficiency improvement grant of \$600,000, with the following goals to provide solutions that could be adopted nationally.

1: Reduce DNA testing turnaround times by 50%

2: Double productivity.

3: Reduce the DNA case backlog 50%

4: Increase the number of Combined DNA Index System (CODIS) National DNA Database hits.

By adopting a LSS Methodology all of the targets were achieved.

1: DNA testing turnaround times were reduced from 258 days down to 129 days within 3 years and down to 59 days in 2011.

2: Productivity was increased to 100 requests completed a month and increased further to 175 in 2011.

3: These quality improvement implementations help reduce the backlog of requests initially down to 850 requests and eventually down to 152 requests in 2011.

4: The Increased DNA information on the CODIS database has increased the number of hits on CODIS database to 748 in 2011.

LSS enabled the LSPCL to create an efficient business like structure within a laboratory environment, one that could deliver timely and accurate DNA analyses for their customers.

The LSPCL not only achieved the goals set out by the National Institute of Justice (NIJ), they achieved their own departmental goals by completely eliminating backlogs, completing 100% of all DNA forensic casework submitted each year and reduced DNA turn-around-time to 60 days.

The LSPCL LSS project focused on three levels of improvement.

Level 1: Communication

Develop better, more efficient communication between the LSPCL and other agencies. This was achieved by cancelling unneeded tests, prioritising backlogged cases. The LSPCL created electronic DNA test request forms to equip agencies for easier future submissions. The DNA test request forms could only be processed if they were completed correctly, by adopting a culture of reducing Costs of Poor Quality (COPQ), they ensured that all the submissions received were completed correctly.

Level 2: Outsourcing

To reduce the backlog of forensic casework, the LSPCL temporarily outsourced some of the backlogged DNA Analysis casework to outside agencies. They outsourced training of new technicians and analysts to external agencies. All quality control and validation of laboratory

equipment was outsourced, these changes allowed the LSPCL to purchase technology to help reduce DNA Analysis time.

Level 3: Improve DNA forensic Analysis Workflow

By applying LSS business management principles to the laboratory allowed the LSPCL to improve productivity and increase Analysis capacity. The introduction of new technology to automate processes and the outsourcing of clerical administration tasks, allowed the DNA staff to concentrate on casework and Analysis.

The success of this LSS quality improvement implementation has led to other laboratories conducting similar LSS projects and has been adopted by the Department of Public Safety Services and the National Institute of Justice (NIJ) as a template for similar productivity challenges in DNA forensic laboratories.

An example of how spaghetti diagrams can be used in a LSS project to identify waste in a laboratory, can be seen in Figure 2.8, which shows the process flow before LSS and Figure 2.9 which shows the process flow after LSS initiatives were applied. The diagrams show the steps involved in the Analysis of a sexual assault case, they are used to scrutinise the system from end to end, and this technique is called Value Stream Mapping (VSM) (Richard, Kupferschmid, 2011).

Spaghetti diagrams from the Louisiana State Police Crime Laboratory (LSPCL) LSS project in 2008:



Figure 2.8: This Spaghetti diagram shows the steps travelled (approximately 12,687 feet or 2.4 miles) before the LSS implementation (Richard, Kupferschmid, 2011)



Figure 2.9: This Spaghetti diagram shows the new process flow (approximately 7879 feet or 1.5 miles) the LSS implementation (Richard, Kupferschmid, 2011)

In the diagrams above, the different steps of the process are represented by different colours and one step equals approximately to two feet and takes one second to travel. The total distance travelled before the LSS improvement phase was 12,687 feet which would equate to a time of 106 minutes of time spent travelling (the length of time of the process flow) per sexual assault case. The new process flow for a sexual assault case after the LSS quality improvement implementation was reduced to approximately 7879 feet or 1.5 miles (Figure 2.9). The LSPCL deals with an average of 400 sexual assault cases a year, this means that the motion waste from this process before the LSS improvement phase was 42,400 minutes a year or 34% of an employee's time (based on an employee working 40 hours a week for 52 weeks) (Richard, Kupferschmid, 2011).

2.6 Challenges to Lean Six Sigma Projects

There is very little literature detailing implementation failures of LSS projects. This could lead one to conclude that LSS is an effective BPMS and provides the desired quality improvements.

Alternatively the lack of such articles could indicate a publication bias towards successful business process management quality improvement projects (DelliFraine, Langabeer II, Nembhard, 2010).

Some of the bias and resistance towards LSS methodologies are based on how the quality improvement was executed, if for example stock was reduced in a highly intensive production environment, this could expose the organisation to greater risk while putting unnecessary pressure on staff and in turn alienating them from the quality improvement implementation (Pepper, Spedding, 2010).

The new software tools developed for use in LSS can be counterproductive for example Value Stream Mapping (VSM) software, limits the detail of the process flow collected and detracts from the system Analysis, as compared to the traditional pencil and paper approach as Value Stream Mapping (VSM) should be quick and simple (Sheridan, 2000).

Resistance to change is another factor that should be taken into consideration when undertaking any BPMS project. Atkinson 2013 claims that research in organisational development show that 90 per cent of cultural change programmes fail to reach or maintain their goals. Furthermore new organisational changes resulting from mergers or acquisitions have poor success rates with between 56% – 70% failing to achieve the objectives they initially planned for, stating that the main reason for failure was resistance to cultural change. It is important to realise that in some cases a person's first reaction to change is to personalise it "How will this affect me?", "Will I be able to use the new system?" (Atkinson, 2013).

BPMS's such as Lean, Six Sigma, and Lean Six Sigma have been deployed in healthcare over the last 15 years. There have been claims that these initiatives have led to improvements to the quality of healthcare services by improving clinical outcomes, quality of care and financial performance. DelliFraine, Langabeer II and Nembhard, 2010, conducted a comprehensive literature review of Lean, Six Sigma and Lean Six Sigma in healthcare to assess what empirical evidence existed in the literature published between 1999 and 2009 to support such claims. They suggest that there are significant statistical and analytical gaps in the BPMS literature and that the evidence is very weak to support claims that healthcare quality actually improved. Of the 177 articles reviewed they found that only 34 articles reported outcomes and of these only 11 articles used statistical Analysis to test if there had been any improvement to the quality of the healthcare services after the project was completed.

DelliFraine, Langabeer II and Nembhard, 2010, propose that a better demonstration of the effectiveness of business process management quality improvement implementations could be demonstrated by conducting a detailed statistical Analysis on specific areas highlighted for improvement before and after the BPMS is deployed. This would help provide evidence that the quality improvements were due to the BPMS project and no other factors.

In conclusion the literature suggests that it is unclear that these Business Process Management improvement projects actually improve the quality of the healthcare services and that more studies on the failure to effectuate LSS projects in healthcare should be conducted. The literature produced from these publications could be used as valuable teaching aids to healthcare professionals undertaking future business process management improvement projects (DelliFraine, Langabeer II, Nembhard, 2010). To correctly execute a LSS quality improvement implementation, a holistic approach is required one which optimises the process for the whole system by putting the right interventions in the correct place (Pepper, Spedding, 2010).

2.7 Success Factors for Lean Six Sigma

The introduction of a BPMS has been shown to successfully improve the tracking of specimen samples and stock, reduce the number of non-conformance due to human error by incorporating error proofing. The Mayo Clinic, 2007, achieved this by identifying areas during the initial analyses phase where value stream breakdowns occurred and removing non value added steps and replacing these with mistake proofing processes or flows and making continuous improvements where needed (Mayo Clinic, 2007).

LSS has the benefits of the business philosophy of the Toyota Production System (TPS) and Motorola's process improvement paradigm, which has seen it successfully deployed in healthcare, laboratories, financial services, industry, the public sector, local government and the U.S. Department of Defence. When Lean and Six Sigma are combined together they offer an extremely powerful tool which offers sustainable and continuous improvements in efficiency, waste elimination, quality and customer service (Pepper, Spedding, 2010; Richard, Kupferschmid, 2011).

The argument against deploying a LSS BPMS to a services environment is based on the belief that within the services environment it is hard to identify processes, as many are unseen and intangible and are very hard to measure. This presumption has been shown to be unfounded, as LSS has been successfully deployed in healthcare, financial services and local government (Hensley, Dobie, 2005).

By deploying a BPMS like LSS to a healthcare environment it has been shown to lead to improved resource utilisation, reduce redundancies, bottle-necks in services have diminished and has led to the removal of wasteful processes. Overall Total Quality Management (TQM) has been shown to improve, resulting in improved working conditions and greater patient and physician satisfaction and a reduction in costs (Chakrabarty, Tan, 2007).

Vest and Gamm, 2009 from their studies have concluded that the implementation of a variety of BPMS's have been successfully deployed improving both healthcare and services. Improvements seen after BPMS's such as LSS were deployed in Laboratory environments have also produced quantifiable results, such as reduced batch sizes, improvements in staff scheduling reorganisation in correlation with the arrival of samples. These improvements were achieved by using tools like DMAIC and Value Stream Mapping (VSM) (Vest, Gamm, 2009; Mayo Clinic, 2007).

Snee, 2010 argues that LSS success can be contributed to the use of the DMAIC improvement tool which he states "is arguably the best (improvement framework) available today" and also how LSS can be used to focus on finding the variables that account for the variation in a process. When these key variables are identified the process can be effectively altered.

The Critical Success Factors (CSF) to successfully deploying and sustaining improvement initiatives lies in strong leadership, using the best people and a holistic improvement methodology. The supporting infrastructure should be put in place at the beginning of the project and the improvement implementation should be treated like any other business process within the organisation. It should have a budget, strategy, management reviews, communication, and a reward system. The infrastructure in place should be sustainable, to ensure a culture of continuous improvement (Snee, 2010).

Snee, (2010) suggests that there are a number of principle critical success factors that contribute to successfully deploying a business process management methodology and that all these principles can be found within the LSS paradigm.

- A sense of urgency
- Leadership
- Think in terms of processes (all work is a process)
- Recognise variation and eliminate where possible
- Improvement in performance
- Focus on the most important issues
- Financial Benefits
- Sustainability
- Celebrate the successes

The Critical Success Factors (CSF) subscribed to by Snee, 2010, are similar to those of Chakrabarty, Tan, 2007, who suggested that for a Six Sigma methodology to be successful the following Critical Success Factors (CSF) should be considered.

- Management commitment
- Training
- Cultural change
- The Voice of the Customer (VTC)
- Improvement in Performance
- Financial Benefits
- Understanding the processes

By comparing the Critical Success Factors suggested by Snee 2010, and those suggested by Chakrabarty, Tan, 2007, it can be shown that the lists are nearly identical. Chakrabarty, Tan, 2007, further more suggest that based on the results of their literature review, that the most import Critical Success Factors (CSF) from the articles reviewed were.

- Management commitment
- Training
- Cultural change
- Financial benefits

Richard and Kupferschmid, 2011, also suggest that both the commitment of the management team and cultural change were Critical Success Factors (CSF) for their LSS improvement implementation.

The key success factors for the NDTC LSS project included a combination of those suggested by Chakrabarty, Tan, 2007 and Snee, 2010, but not exclusively all those listed.

1. Management commitment
2. Listening to the Voice of the Customer (VTC)
3. Understanding the processes to identify the most important problems
4. Improvement in performance
5. Training and managing resistance to change (Cultural change)
6. Financial Benefits
7. A need to initiate change (not necessarily, "a sense of urgency")

As stated earlier LSS methodologies have been successfully deployed across a full spectrum of industries and services, companies and organisations including, The U.S. Department of Defence, the Louisiana State Police Crime Laboratory, General Electric, Merck, Du Pont, Johnson & Johnson, W.R. Grace, Honeywell, Boeing, Bank of America, Rolls Royce and many more (Snee, Hoerl, 2003; Snee, Hoerl, 2005; Richard, Kupferschmid, 2011; Arkell, 2003).

2.8 Conclusions

The key factors to the successful completion of a LSS project suggested by Richard and Kupferschmid, 2011, is the willingness to accept change by the participants of the improvement implantation and the commitment of the management team to the project and to the completion of the project.

Although both Lean and Six Sigma methodologies have evolved separately, Pepper, 2007 suggests that a more amalgamated methodology with closer integration between the two methodologies must be achieved, one that should be based on a theoretical and scientific foundation (Pepper, 2007). Improvement opportunities are developed by identifying the business process deficiencies and not looking at which is the best approach to solving the problem (Lean or Six Sigma) as this is unproductive, improvement is the issue. A holistic approach using both Lean and Six Sigma methodologies is needed to effectively solve these problems, "Improvement opportunities occur between and within process steps" (Snee, 2010). Pepper and Spedding, 2010, concluded from their research that the findings showed evidence that there was no clear framework for the implementation of LSS and a new approach needs to be used, one that optimises Lean and Six Sigma methodologies as a whole.

Richard and Kupferschmid, 2011, following their successful LSS project stated that although their LSS process improvement implementations were conducted by LSS experts, a standard framework of tools could be custom defined from the lessons learnt, depending on the intervention required. One of the project requirements requested by the U.S. Department of Justice was that the improvements to the process flow could be replicated to other forensic DNA laboratories. Richard and Kupferschmid, 2011, suggested that the tools and concepts used successfully by the LSPCL could be used and replicated as needed, which would allow for the use of a standard methodology for similar laboratories.

To address the needs of the NDTC it was decided from the evidence provided in the Literature Review that Lean Six Sigma would be the BPMS most in line with the requirements of the NDTC. Lean Six Sigma tools like Value Stream Mapping, Spaghetti Diagrams, and Process Flow Diagrams were used effectively to identify defects and waste in the process flow as well as listening to the VTC. The approach adopted by the project team was to use these diagrams and the DMAIC tool as a template on the processes identified and selected for improvement by the customer (Senior Laboratory Team).

Chapter Three: Methodology

3.1 Introduction

The methodology used for this dissertation was to conduct a literature review on current and past BPMS's focusing in particular on LSS. A series of interviews with the key stakeholders within the NDTC Laboratory was undertaken to identify processes within the Laboratory where significant improvement could be made by the implementation of a LSS intervention. A Value Stream Map (VSM) of the specimen sample process flow within the Laboratory was created (Figure 4.4) and the processes were identified within the specimen sample process flow. A template was designed and a series of case studies based on the areas of the process flow where the customer believed significant improvements to the NDTC Laboratory could be achieved by using a BPMS such as LSS to improve productivity, reduce paper based reports and forms, reduce costs and reduce transcription errors.

3.2 Choice of Methodology

To achieve some of the requirements identified during the initial Waste Walk and interviews conducted as part of the LSS intervention required the building of several prototype development modules by a System Analyst in Labware for the current Labware LIMS application used by the NDTC. All of these prototype modules have been fully tested and successfully deployed to production by the NDTC ICT Department and the NDTC Senior Biochemists as part of Phase I of the LSS Project.

Qualitative and quantitative measurements of the current processes identified in the case studies of the before and after states of the LSS implementation were conducted where possible, to evaluate the errors introduced by the current paper based processes and to highlight the true benefits of pursuing continuous improvement activities (Tran, Thang. 2011). To better demonstrate the effectiveness of a BPMS quality improvement, as suggested by DelliFraine, Langabeer II and Nembhard, 2010, a statistical Analysis on specific areas highlighted for improvement was conducted, measuring the before and after states following the LSS process changes, with the purpose of providing where possible evidence that the quality improvements were due to the BPMS intervention and not other factors. Non-structured feedback interviews were conducted with the Senior Biochemists responsible for the production systems and process flow within the Laboratory and the Laboratory Quality Control Manager. A questionnaire was conducted with the NDTC

Laboratory staff to rate the level of satisfaction with the process improvements and to determine if the initial aims of the BPMS project had been addressed.

3.3 Purpose of Literature Review

A literature review was undertaken to examine the existing research done in this area and to identify where these BPMS's have been successfully deployed or have failed and to help identify possible pitfalls that may be encountered when such methodologies are deployed to the NDTC Laboratory. The literature review examined how other Laboratories conducted similar interventions and at how they adopted LSS methodologies and the approach they used to meet their objectives. Current and past BPMS's and in particular LSS Laboratory Quality Management systems were reviewed

3.4 Methodology used in Case Studies

The approach used by the author was to map the current Value Stream of the specimen sample process flow within the NDTC Laboratory. Once the Value Stream was mapped the individual processes within the specimen sample process flow were identified and areas where LSS could be used to eliminate waste, identify bottlenecks in the process flow and reduce errors were discussed with the Senior Laboratory Team.

A template for the design of the Case studies (see Section 3.4.1) was developed based on the Design, Measure, Analysis, Implement and Control (DMAIC) Methodology used in LSS and the steps below were used to populate the template for each of the Case Studies.

The first step in the LSS project used within the NDTC Laboratory was to gather baseline data and to start mapping the current process flow of a specimen sample through the Laboratory and identify the different processes which occur within the Laboratory (4.3 Overview of Specimen Sample Value Stream).

The second step was to measure the individual processes identified for the LSS interventions within the process flow, this involved measuring how the tasks were performed within a process, the time taken to complete the process or the quality of the process in relation to the number of transcription errors in the urine specimen sample process flow through the Laboratory. LSS was also used to identify gaps which occur within the different processes and also within the process flow (between the processes) and create a plan that would allow for the implementation of process improvements.

Thirdly an Analysis was conducted of the processes identified for improvement by the Senior Laboratory Team, where the process could be improved by leveraging Information Technology (IT), eliminating deviations or reducing errors by deploying a LSS intervention.

The next step was to deploy the identified improvements either within the process flow, within the processes, or both, using the resources available.

After the implementation phase, the Laboratory Quality Control team were assisted with the creation of Standard Operating Procedure (SOP) documentation, and training. Measurements of the new process were taken and compared to the process prior to the LSS process improvement, to identify the benefits of the process change and to validate that the interventions had improved the process flow.

3.4.1 Template Used in Case Studies

The Template used in the case studies is based on the LSS methodology of Design, Measure, Analysis, Implement, and Control (DMAIC).

3.4.1.1 Define

Conduct a Waste Walk (observing the process while in production and identifying the waste in the process) (Mayo Clinic, 2007)

Motivation – Why is this Case Study Important?

Voice of the Customer (VTC) – Interviews

What necessitates the intervention, cost, time, or to reduce waste

What objectives are to be achieved?

3.4.1.2 Measure

Document the system/process flow from start to finish (Mayo Clinic, 2007)

Define the current “As is” Process

Produce a Value Stream Map

Measure – The time a process takes to complete and the process flow

3.4.1.3 Analysis

Analysis the “As Is” and document how to correct problems

Define future state and envision how the process will function when the waste has been removed (Mayo Clinic, 2007).

3.4.1.4 Implementation

Implement the LSS intervention and measure the Key Performance Indicators (Mayo Clinic, 2007).

3.4.1.5 Control

Once the project is effectuated a review of the new process should be undertaken periodically (Mayo Clinic, 2007), with new Implementations – It is not always possible to introduce a total process change in the first instance (Figure 4.1). Some interventions must be performed in iterations (different stages) before they can be fully deployed (Mayo Clinic, 2007).



Figure 4.1: Develop a plan of action, which will manage performance while the Lean Six Sigma intervention is being implemented (Mayo Clinic, 2007)

3.5 Interviews and Data Selection Requirements

A key component that LSS methodology emphasises, is the need to listen to the Voice of the Customer (VTC) (George, George, 2003), to achieve this, a series of interviews were initially conducted with the Senior Laboratory Team.

Once a process was identified where a LSS intervention (Case Study) could be used to make significant improvement to specimen sample Value Stream, a Case Study was undertaken and a member of the Senior Laboratory Team was assigned to the individual Case Study.

Interviews were conducted with the Biochemists responsible for that particular process, throughout the lifecycle of the Case study to insure that the Voice of the Customer (VTC) was always heard.

3.6 Limitation of Research Methodology

LSS as a Business Process Management System can be deployed very quickly and effectively when adequate resources are available. Due to the timeframe set out for this Masters in Health Informatics (MSc HI) Dissertation and the limited resources available within the NDTC as discussed in the introduction, this project was divided into two Phases. Phase I was conducted between March 2013 and July 2013 for the inclusion in this Dissertation and Phase II is planned to be conducted from August 2013 to January 2014, the define stage for some of the processes in Phase II have been included in Appendix I. The five process issues selected for Phase I from the initial ten processes highlighted by Laboratory Senior Management team have been resolved and solutions to the process problems have been fully deployed to production. It was deemed that these five processes selected for Phase I would yield substantial benefits within the Laboratory and that they should be used as Case Studies for the purpose of this Dissertation.

Chapter Four: Research

4.1 Introduction

The approach adopted to address issues faced by the NDTC in regards to, reduce costs, the increased number of specimen sample requests received, staff shortages (due to the current moratorium on recruitment) and extended turn-around times (TAT), was to use a BPMS approach to address some of the issues. The goal was to create interventions that would allow the services provided to be conducted in a timely, accurate manor and meet the needs of the customer.

To achieve these goals LSS was used to identify areas within the main Value Stream process flow where changes could be leveraged to enhance the processes and process flow and eliminate waste.

4.2 Research Design

Listening to the Voice of the Customer (VTC) through a series of interviews conducted with the NDTC Laboratory Principle Biochemist and Senior Biochemists, four key requirements became apparent for the success of the project (see 4.2.1 below). During the course of these interviews 10 processes were identified (Table 4.1 and Table 4.2) where if a LSS intervention were initiated it was believed that significant improvement to the specimen sample Value Stream would be realised.

The project was split into two different phases, Phase I of the project would be run over five months from February 2013 to July 2013 and would aim at resolving the first 5 of the 10 process improvement areas identified by the customer and Phase II of the project would be run over the following five months August 2013 to January 2014 and would focus on improving the remaining five processes identified by the customer.

4.2.1 Four key requirements

1. Reduce paper by developing a paperless environment.
2. Improve process performance.
3. Reduce human errors.
4. Create processes that can cope with the increasing number of specimen sample requests.

4.2.2 Phase I: The First Five processes Identified for Improvement by the Laboratory Senior Management Team

Process	Information	Case Studies
Sample Reference Log	The Sample Reference Log is a record of a Batch of urine specimens known as samples prepared by the Laboratory staff for Analysis.	Process 1 – Page 48
Sample Disposal Log	Sample trays are currently stored in the Laboratory Cold Room awaiting disposal. The current process is to update a MS Word document "The Sample Disposal Log" and store the documents on the Server.	Process 2 – Page 58 No Longer needed due to the implementation of Process 1
NWA Statistical Reports	A North West Analytical (NWA) statistical Analysis is conducted on an Analyser when one of the following states occurs. 1: A new LOT of Calibrator is used on one of the Analysers. 2: A new LOT of Reagent is used on one of the Analysers. 3: A new LOT of Quality Controls (QC) are used on one of the Analysers. 4: If a Quality Control (QC) is failing.	Process 3 – Page 59
Electronic Reporting	Reporting Section - all reports are printed and after 4 months are stored securely offsite, at considerable expense. By storing these reports electronically it is hoped that this will negate the need to print off paper based reports.	Process 4 – Page 67
New Stock Tracking and Reporting	When New Stock is used in the NDTC Laboratory each box is examined and checked against the Delivery Docket. Stock may consist of individual assignments of Reagents, Calibrators and Quality Controls or a combination of them. A stock taking exercise is conducted each month.	Process 5 – Page 75

Table 4.1: The First Five Case Studies identified during Interviews.

4.2.3 Phase II: The Second Five processes Identified for Improvement by the Laboratory Senior Management Team

Process	Information	Case Studies
Controlled Drug Tracking	Controlled Drugs Tracking requirements and the control system processes used by the NDTC Laboratory to meet the legal requirements for the use of these drugs.	Process 6: Appendix I – Page 125 In Development Phase
Instrument Maintenance	All analysers must be checked and calibrated each morning. At present this process is recorded in a TF3 form which is generated by Pardigm II and stored on the Server.	Process 7: Appendix I – Page 130 Not Initiated at Present
Analyser Calibration	At the end of each day details of what has happened on the Analysers must be recorded. The analyser software does not facilitate the export of this information into the (LIMS).	Process 8: Appendix I – Page 133 Not Initiated at Present
Laboratory Telephone Enquiries	The current process is to record telephone queries by hand on a printed MS Word document form (LR04). These forms are collated on a MS Excel Spread sheet and a monthly Analysis performed by the Laboratory Customer Service Department.	Process 9: Appendix I – Page 134 Not Initiated at Present
Confirmatory Analysis	Testing for example confirmatory Analysis list of samples, currently these reports are printed off, it is hoped that these could go back into Labware LIMS.	Process 10: Appendix I – Page 135 Not Initiated at Present

Table 4.2: The Second Five Case Studies identified during Interviews.

4.3 Overview of Specimen Sample Value Stream

The first step in the LSS intervention used in the NDTC was to identify the specimen sample Value Stream in the Laboratory. Once the process flow of the specimen sample was identified a process flow chart was created (Figure 4.2) to map the process flow of a specimen sample through the Laboratory. The Value Stream map (Figure 4.4) is used to identify the processes that add value to the process flow and also to highlight areas of waste within the process flow. The Senior Laboratory Team selected 10 processes where a change could bring substantial benefits in cost, time and staff morale within the Laboratory. These processes were then examined using the LSS DMAIC tool to measure the existing processes and define how they could be changed.

4.3.1 Process Map of the NDTC Laboratory Specimen Sample Journey

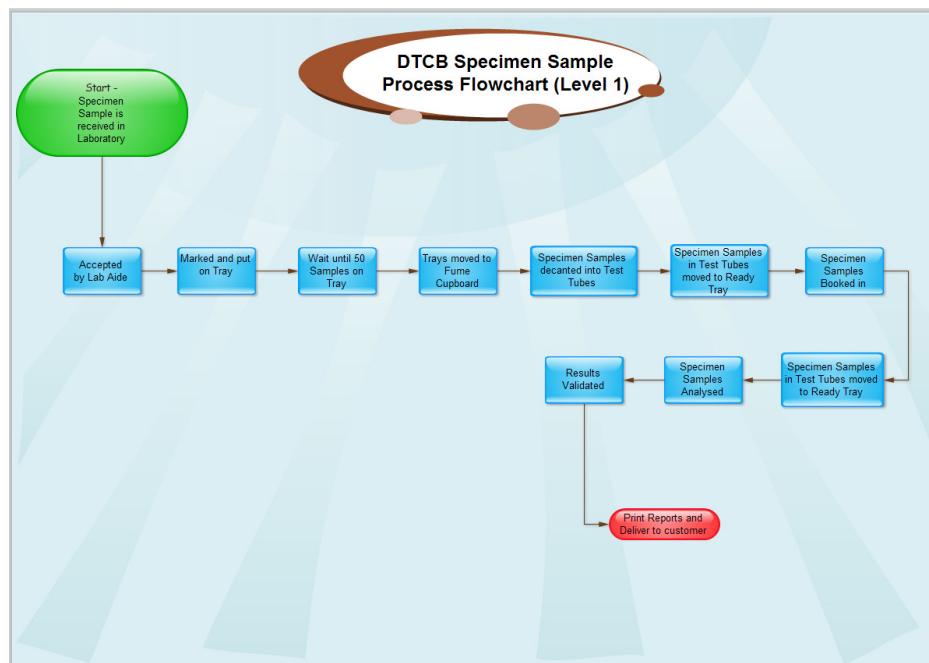


Figure 4.2: Level 1 - Process Flowchart Laboratory Specimen Sample Journey

4.3.2 Spaghetti Diagram - NDTC Laboratory Specimen Sample Journey

The specimen samples journey is mapped out on a Spaghetti Diagram (Figure 4.3) from when it arrived at the delivery hatch to when it was moved to the cold room awaiting disposal.

- 1: Samples arrive in vials, either via the lift and are delivered by a courier (External Samples) or via a pneumatic shoot (Internal Samples).
- 2: The samples are unpacked at the delivery hatch.
- 3: Samples are sorted onto trays (approximately 50 samples per tray).

4: The trays are then moved to a counter beside fume hoods where they are stored before decanting.

5 – 5a: The samples are decanted into test tubes and two identical barcodes are used one is placed on the Vial (step 5) and one is placed on the test tube (step 5a).

6 – 6a: The trays of Vials are taken to the Book-in Laboratory and the Sample information is inputted into Labware LIMS (step 6). The test tubes are placed in racks which hold 10 Test Tubes and these are moved to the not for processing counter (step 6a) and wait there until the Vials have been booked into Labware LIMS by the Lab Aides.

7 – 7a: Once Booked-in the trays of Vials are moved to a trolley (step 7) and the Test Tubes are moved to the ready for processing counter (step 7a).

8 – 8a: The trolley containing the trays of Vials is moved the cold room and kept for 2 weeks before being disposed of (step 8). The test tubes are placed in one of the two AU2700 Analysers and the required tests are carried out on the samples (step 8a).

9: When all tests have been run and the results validated the test tubes are disposed of.

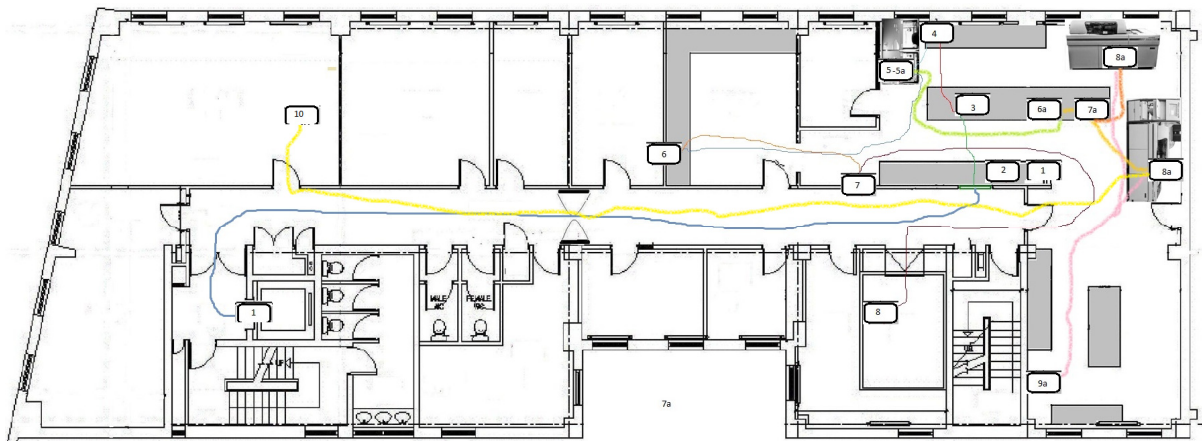


Figure 4.3: Spaghetti Diagram – NDTC Laboratory Specimen Sample Journey.

10: Once the tests are completed, checked and validated the Laboratory sends the results via Clinic reports to its customers. The Laboratory prints a hardcopy of every Clinic report and these printed Clinic reports are kept indefinitely and are eventually moved to offsite storage. If a customer requires a faxed Clinic report or mailed Clinic report another copy of the report is printed and sent to the customer.

The Laboratory has several electronic methods in which their customers can receive Clinic reports. For a customer to access their Clinic reports electronically they are required to register their Clinic with the Laboratory and an account for that Clinic will be created by the Laboratory. Once the customer is a registered user of the NDTC Laboratory Electronic Reporting (LER) application they can securely login and check results over the Internet.

If the customer has access to the Health Services Executive (HSE) network and is a registered user of the HSE's Drugs Aids Information System (DAIS), they can access their Clinic reports or if the customer has access to the NDTC network and is a registered user of the NDTC's Electronic Patient System (EPS), they will have access to their Clinic reports electronically.

4.3.3 Value Stream Map - NDTC Laboratory Specimen Sample Journey (AS IS)

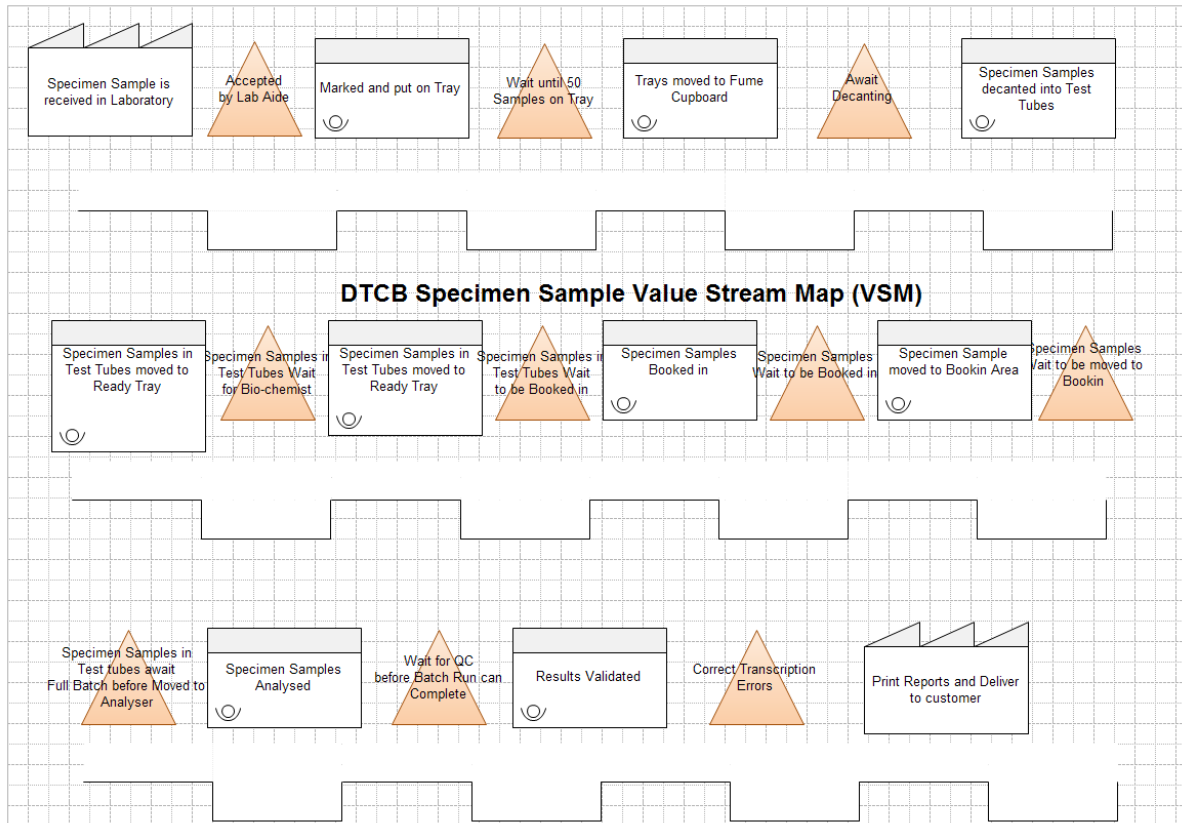


Figure 4.4: NDTC Laboratory Specimen Sample Value Stream Map

The above stages were the Define (D) and Measure stages (M) of the DMAIC methodology, the next stage was to Analyse (A) the process flow to show areas of waste, errors, deviations within the processes and non-productive activities. These were highlighted to the Senior Laboratory Team using a Value Stream Map (VSM) Figure 4.4 and a plan for improvement undertaken. The Implementation (I) phase of the project is where the improvements and process changes identified during the Analysis (A) phrase of the DMAIC process are implemented. The final part of the DMAIC process is the Control (C) phase which concentrates on continuously improving the process, that may have not been possible to carry out earlier because the initial implementation phase needed to be in place first. The Control (C) stage of the project is where Standard Operating Procedures (SOP) are defined and put in place; it is the phase of constant revisiting the activities performed within the process and improving them.

4.4 Phase I: Process 1: TF4 Form used to Record Specimen Sample Reference logs

The Sample Reference Log is a record of a batch of urine specimens known as samples prepared by the Laboratory for Analysis (Figure 4.5). A batch can contain up to three trays and each tray contains up to 50 urine samples. The trays are sorted by clinics and can contain several samples from different clinics. When a sample or a group of samples are received into the Laboratory they are arranged on trays and grouped together by clinics, sometimes the samples from one clinic may spread across several trays.

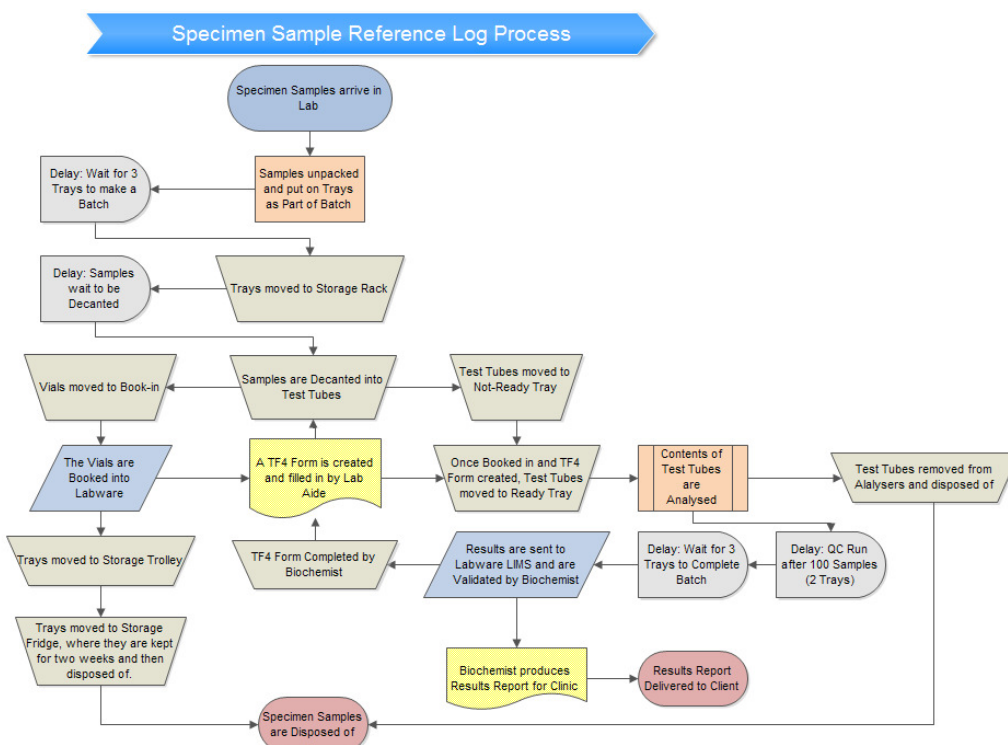



Figure 4.5: Specimen Sample Workflow Diagram before LSS

To record which samples were processed in a batch, a TF4 form (Figure 4.6) is generated by the Lab Aide responsible for booking in that batch of samples. A TF4 form is a word document template that is filled in by the Lab Aide to record what samples are being processed in a batch. The TF4 form (Sample Reference Log) contains details of which Trays are being used, what samples are being processed on that Tray, the clinic the samples belong too, and the number of samples that are being tested for that clinic.

Once the Lab Aide has completed the initial part of the TF4 form, the form is then saved to the Laboratory document server in a shared folder. When a Batch has been completed and the Quality

Control checks have been conducted for the batch of samples tested, the TF4 form is reviewed by a Biochemist. The Biochemist then generates Clinic reports from within Labware LIMS for each of the clinics based on the results of tests carried out on that batch and prints a copy of Clinic reports for each Clinic. The TF4 form is checked for transcription errors against the Clinic reports and once all errors have been corrected the batch is validated as complete by the Biochemist. The Biochemist then completes their section of the TF4 form and saves the completed version of the TF4 form to the Laboratory document server and also prints a hard copy of the TF4 form. A hardcopy of the reports are printed and the TF4 form is signed by the Biochemist and attached to the reports which are stored in the Laboratory for six months and are then sent offsite for long term storage.

 Feidhmeannacht na Seirbhíse Sláinte Health Service Executive	LÁRIONAD NÁISIÚNTA CÓIREÁLA DRUGAÍ NATIONAL DRUG TREATMENT CENTRE DRUG ANALYSIS LABORATORY	Form Ref: TF4
		Page No.: 1
TF4 - Sample Reference Log		Version: 1.11
		Issued Date: 26/03/2013
		Issued By: Quality Manager

Batch: 5
 Date: 05/04/2013
 Page: 1 of 1

Tray No.	Code	Barcode Sequence	No.	Reported			Initials	Comment
				Time	Date	Method *P/F/D/E/R/ML		
05/04/2013-07	AD	13056681-13056709	29	15:24	05/04/13	L	SP	
05/04/2013-07	CLAC	13056710-13056721	12	15:55	05/04/13	L	SP	
05/04/2013-07	SJC	13056722-13056728	7	15:24	05/04/13	L	SP	
05/04/2013-11	SJC	13056729-13056742	14	15:24	05/04/13	L	SP	
05/04/2013-11	GRAN	13056743-13056765	23	15:47	05/04/13	P	SP	1 NR (13056754)
05/04/2013-11	MCMP	13056766-13056770	5	15:47	05/04/13	P	SP	
05/04/2013-11	COST	13056771	1	15:28	05/04/13	P	SP	
05/04/2013-11	RIAL	13056772-13056775	4	15:28	05/04/13	P	SP	

* P=Post; F=Fax; D=DAIS; E=EPS; R=Retained; I=Internal Post; L= Laboratory Electronic Reporting

Initialed by Lab aide: GG & MH
 Signed by Biochemist who completed the batch: _____
 Date:

Figure 4.6: TF4 Form – Sample Reference Log

4.4.1 Define: TF4 Form used to Record Specimen Sample Reference logs

- 1: Samples are delivered in Vials at delivery hatch in main Laboratory.
- 2: Samples unpacked and sorted onto Sample trays. Each Sample tray contains approximately 50 samples.
- 3: Sample trays are moved to storage trolley waiting decanting.

4: Sample trays are moved into fume cupboards and are decanted into test tubes (Process 5a in the Spaghetti Diagram, see Figure 4.8) which are held in racks, each holds ten test tubes. Both the Vials and the test tubes are bar-coded with matching barcodes when they are decanted (Figure 4.7).

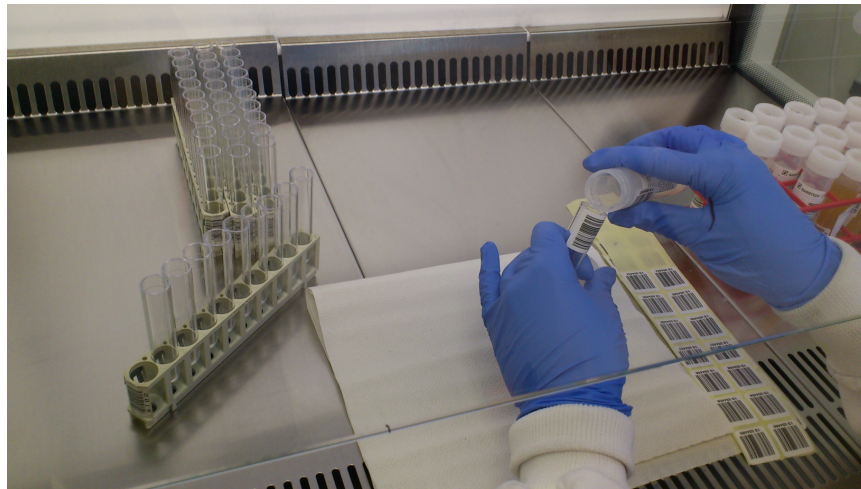


Figure 4.7: Decanting barcoded Vial into barcoded Test Tube

5: The Vials are moved to the book-in area, where the information relating to the samples is entered into Labware LIMS. The information includes the Client name, date of birth, Clinic requesting test and the barcode on the Vial is scanned into Labware LIMS using a barcode scanner.

5a: The Test Tubes are moved from the fume cupboards to the counter where they are stored in the Not-Ready tray. They are stored there until all the Vials on the Sample tray are booked into Labware LIMS.

6: The Vials are taken to the book-in area, where the Barcodes are scanned into Labware LIMS and the information about the sample is recorded i.e. Clinic, Client details, tests requested, tray and batch ID. Once a batch has been booked in, a TF4 Form (Figure 4.6) is created.

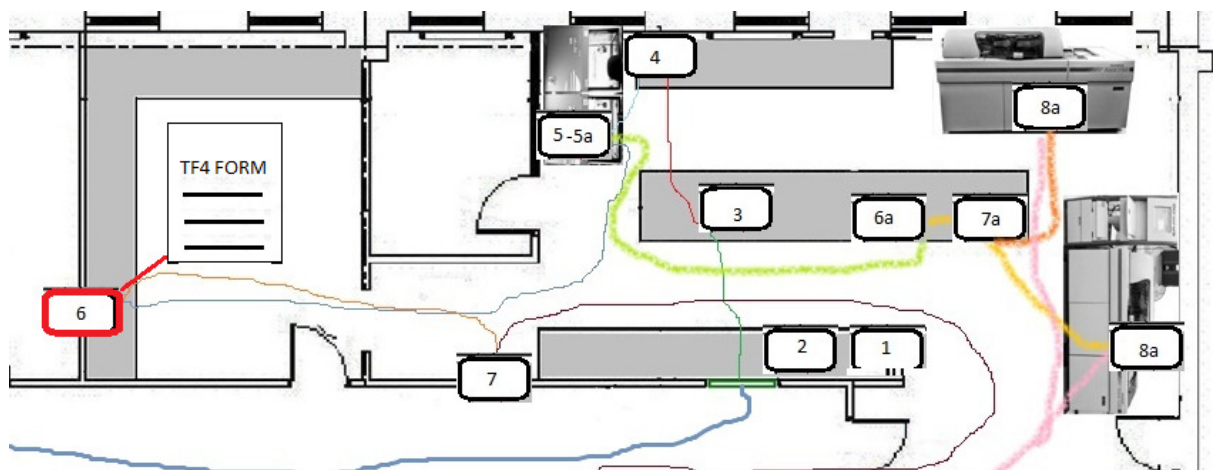
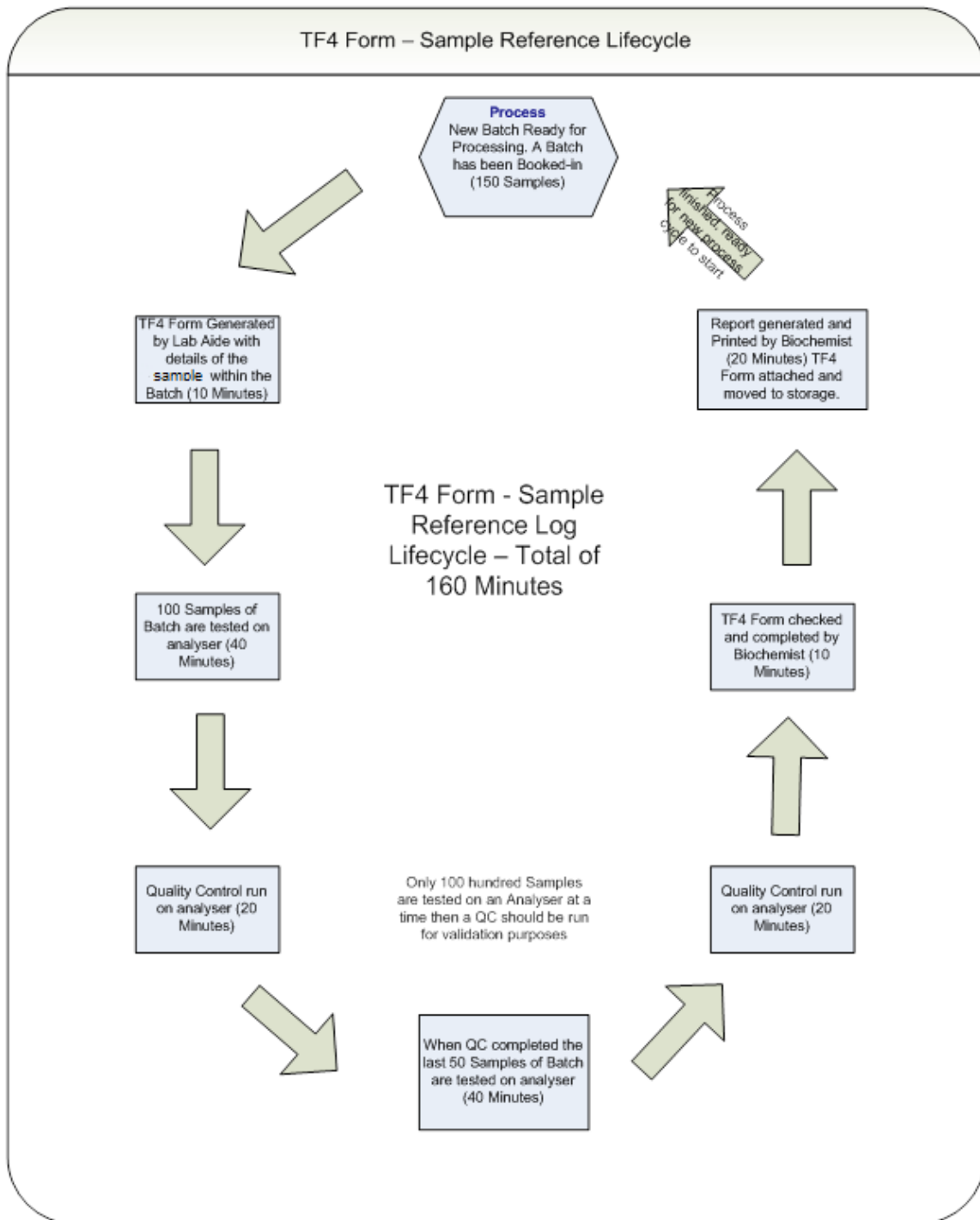


Figure 4.8: NDTC Spaghetti Diagram of Specimen Sample Journey

4.4.2 Measure: TF4 Form used to Record Specimen Sample Reference logs

- 1: A batch consists of approximately 150 samples or 3 trays, each tray can hold up to 50 samples. The amount of time it takes for three trays to be filled, creating a batch, can take anywhere between 20 minutes and 2 hours and depends on the amount of samples delivered.
- 2: A TF4 form is generated by the Lab Aides after all samples in a batch are Booked-in and requires all information to be entered manually, this takes approximately 10 minutes.
- 3: Each analyser runs approx. 100 samples at a time (this process, depending on how many different tests are required per sample, takes approximately 40 minutes).
- 4: After each process of 100 hundred samples are run a QC check must be analysed to validate the results of the previous Samples, each QC check takes approximately 20 minutes to run.
- 5: The remaining part of the batch (up to 50 samples) must wait for the QC results to be approved and these Samples are then processed taking approximately 40 minutes to complete.
- 6: Once again a QC check is run to validate the results (approximately 20 Minutes).
- 7: The TF4 form is compared to the Clinic reports and checked for transcription errors by the Biochemists and if there are no errors the results are validated, this takes approximately 10 minutes to complete.
- 8: Clinic reports are generated on the Labware LIMS application and then printed (approximately 20 minutes).
- 9: The TF4 form is attached to the printed results report and these files are stored in a storage folder and eventually moved to offsite storage after six months (Figure 4.9).

TF4 form (Sample Reference Log) Lifecycle (Before Lean Six Sigma Intervention 160 Minutes)



Fig

ure 4.9: TF4 Form – Sample Reference Log Lifecycle before LSS

4.4.3 Analyse: TF4 Form used to Record Specimen Sample Reference logs

Issues Identified: TF4 Form used to Record Specimen Sample Reference logs

1: A tray or 2 trays maybe fully tested, that is, they have been analysed and a QC check has been run on the analyser, but the results cannot be processed as completed because the whole batch has not been run (a batch usually contains 3 trays (150 samples)), this creates a bottleneck and the Biochemist must wait an average of 60 minutes extra before they can start validating results.

2: The information recorded in the TF4 forms is entered manually by the Lab Aides after the book-in process is complete. Because the information is entered manually there is always a risk of transcription errors being made by the Lab Aides and not being identified by the Biochemists during validation. This can lead to result reports being sent to customers with errors and omission of results.

3: All of the information that the TF4 forms contain exists electronically in Labware LIMS in several different locations.

4: A bottleneck will always be created by a batch which contains over a hundred samples as the analysers run 100 samples between each QC run.

5: If a clinic has less than 50 samples to be tested, the process will take over 160 minutes before a Clinic report can be generated because reports cannot be generated until the entire batch is completed.

4.4.4 Implement: TF4 Form used to Record Specimen Sample Reference logs

The new LSS process flow required making changes to the process flow and removing waste. In this instance waste within the process flow could be defined as unnecessary time spent waiting for a batch run to complete before the validation part of the process could be completed (Figure 4.10). Waste was also defined within the process by the need to check for transcription errors, as the TF4 forms could be generated by Labware LIMS and require no manual data entry by the Lab Aides.

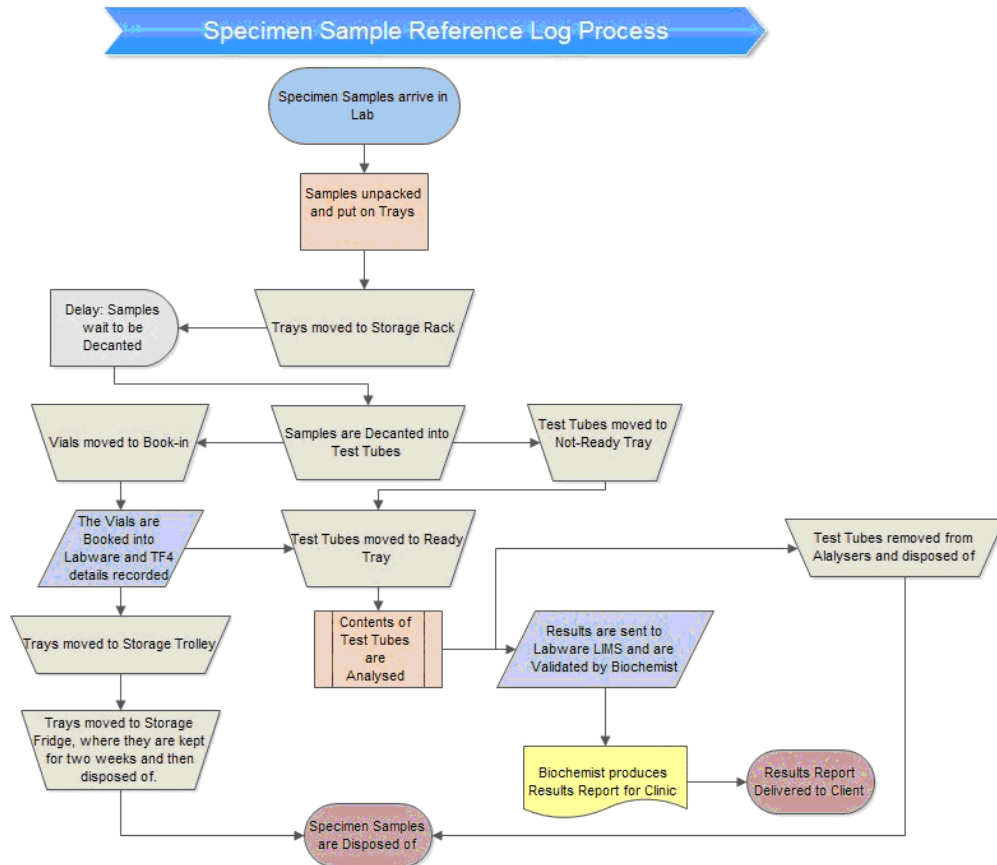


Figure 4.10: Specimen Sample Workflow Diagram after LSS

Process Change 1: Lab Aides now process Samples in trays (50 Samples per tray) and no longer use a batch (3 trays) system.

Process Change 2: A module was developed within Labware LIMS that would take the information entered by the Lab Aide during the Book-in phase and the validation information entered by the Biochemist and generate a completed TF4 form (Figure 4.11) eliminating transcription errors that may have occurred when the TF4 forms were completed manually.

HSE - National Drug Treatment Centre Laboratory Form Ref: TF4, Version 1.13, Effective Date: 03/11/2011 Time: 13:00

Batch: _____ Please Note: * indicates Non Compliance Sample
 Tray ID: 26042013-08 Page 1 of 7 Date: 26/04/2013

No.	Barcode	Barcode & Time	Clinic	Chart Number	Sampled Date	DOB	Forename	Surname	Sex	Dist Number	Analysis requested
1	13099671	26042013 11:30	TRY		24/04/2013	07/11/1971			M		AMPH AMPH BENZ BENZ COCA COCA EDDP EDDP OPA OPA OPAM ALCO ALCOM CANN CANM OREA OREA
2	13099672	26042013 11:30	TRY		24/04/2013				M		OREA OREA ALCO ALCOM BENZ BENZ CANN CANM COCA COCA OCAM EDDP EDDP OPA OPA
3	13099673	26042013 11:30	TRY		24/04/2013				M		OREA OREA ALCO ALCOM BENZ BENZ CANN CANM COCA COCA OCAM EDDP EDDP OPA OPA
4	13099674	26042013 11:30	TRY		24/04/2013				M		OREA OREA ALCO ALCOM BENZ BENZ CANN CANM COCA COCA OCAM EDDP EDDP OPA OPA
5	13099675	26042013 11:30	TRY		24/04/2013				M		OREA OREA ALCO ALCOM BENZ BENZ CANN CANM COCA COCA OCAM EDDP EDDP OPA OPA
6	13099676	26042013 11:30	TRY		24/04/2013				M		OREA OREA ALCO ALCOM BENZ BENZ CANN CANM COCA COCA OCAM EDDP EDDP OPA OPA
7	13099677	26042013 11:30	TRY		24/04/2013				M		OREA OREA ALCO ALCOM BENZ BENZ CANN CANM COCA COCA OCAM EDDP EDDP OPA OPA
8	13099678	26042013 11:30	TRY		24/04/2013				M		OREA OREA ALCO ALCOM BENZ BENZ CANN CANM COCA COCA OCAM EDDP EDDP OPA OPA

Tray ID: 26042013-08 Page 7 of 7 Date: 26/04/2013

No. Barcode Barcode & Time Clinic Chart Number Sampled Date DOB Forename Surname Sex Dist Number Analysis requested

HSE - National Drug Treatment Centre Laboratory Form Ref: TF4, Draft Version 1.0

Batch: 26042013-08 Date: _____

Code	Barcode Sequence	Number	Time	Date	Reported Method	#	Initials	Comment
MHC	13099685 - 13099688	14	14:50	26/04/2013	Post	460		
MPS	13099719 - 13099719	2	14:51	26/04/2013	Fax & Post (one)	461		
SRB	13099712 - 13099718	7	14:52	26/04/2013	Fax	462		
QMS	13099699 - 13099709	11	14:52	26/04/2013	Fax	463		
TRY	13099671 - 13099684	14	14:53	26/04/2013	Post	464		

Signed by Lab Aide: _____ Signed by Biochemist who completed the batch: _____ Date: _____
 Checked By: _____ Date: _____

Figure 4.11: Screenshot of Labware LIMS TF4 Form

Sample Reference Log Specification Requirements for Labware LIMS Development

Create Report (TF4 Form) that will highlight the following, see Figure 4.12 for Crystal Report Design of Main Report and SubReport.

- All the samples on a tray
- Summary at the end of each report
- The Summary should contain
 - Clinic:
 - Barcode Range:
 - Number of Samples:
- The Report should contain a section for reporting
 - Time & Date reported:
 - Method of reporting:
 - Report unique number:
 - Username of biochemist who performed the reporting:

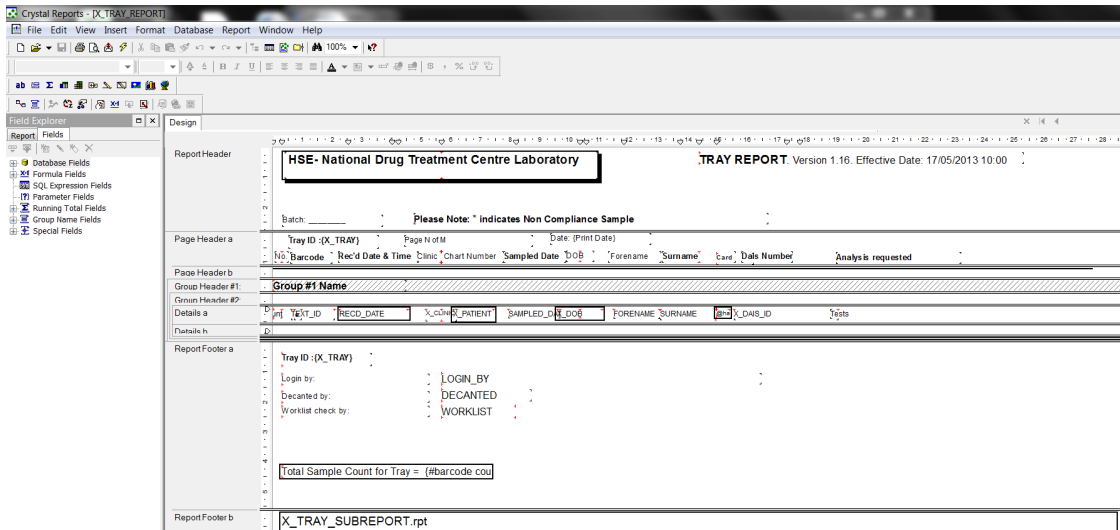


Figure 4.12: Crystal Report Design of Main Report and SubReport for TF4 Form

Process Change 3: All TF4 forms are now signed electronically by the biochemist and their credentials are verified by Labware LIMS.

Lean Six Sigma Stage I - TF4 Form – Sample Reference Log Lifecycle (80 Minutes) After Lean Six Sigma Interventions

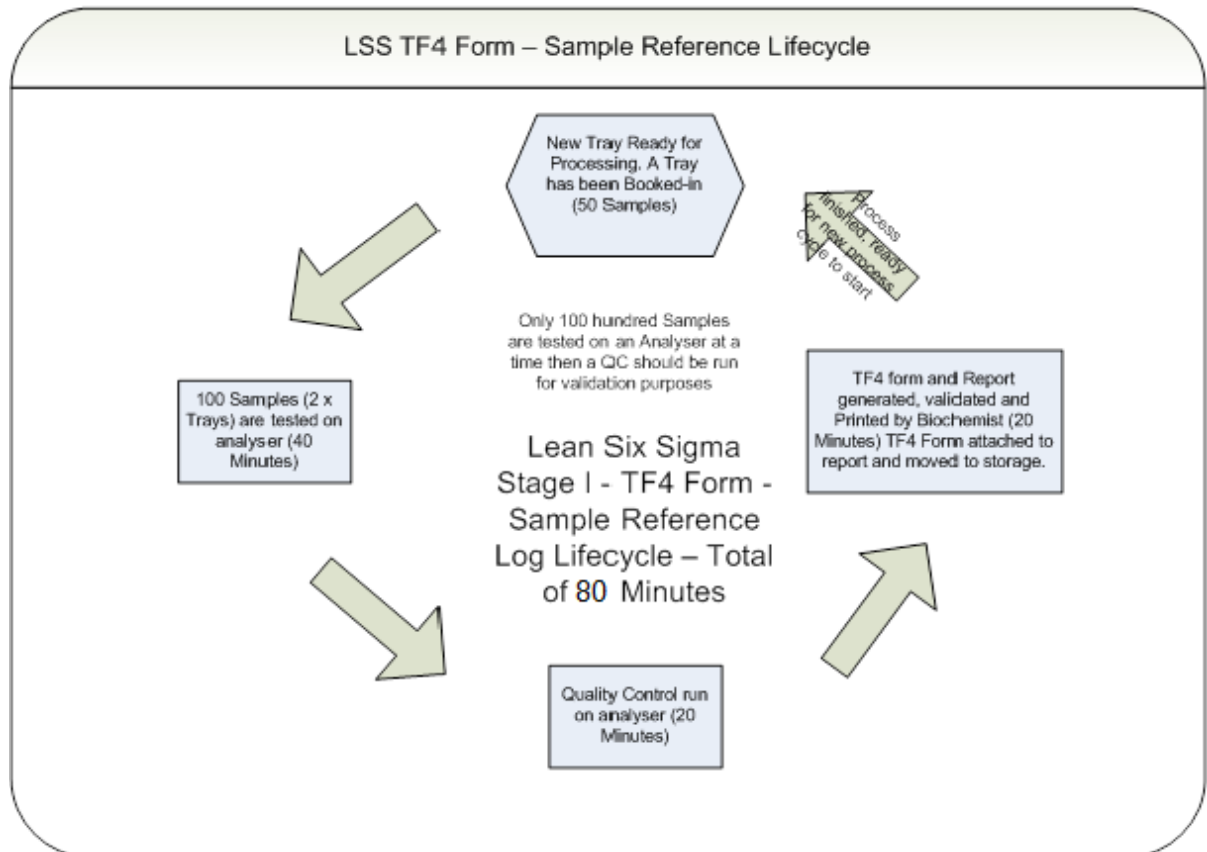


Figure 4.13: TF4 Form – Sample Reference Log Lifecycle after LSS

4.4.5 Control: TF4 Form used to Record Specimen Sample Reference logs

The Clinic reports are accessible to the NDTC customers depending on what the customer requirements are and what services they subscribe too. It is envisioned that in the near future the generation of hardcopy reports will no longer be needed and that all customers (including the HSE DAIS users) will access the results online via the NDTC’s Laboratory Electronic Reporting (LER) application (Figure 4.14). The TF4 forms currently generated by Labware LIMS will no longer need to be printed off as these will be stored electronically on the file and print Server (CHEOPS).

System Log Out

Clinic Log Out

Main Menu

Update Profile

REPORTS Urine*

1: Patient Report (Urine)

2: Clinic Report (Urine)

REPORTS Oral Fluids (OF)**

3: Patient Report (OF)

4: Clinic Report (OF)

Input Start date: 30 Apr 2012

Input End dates: 30 Apr 2013

Select Patient: TEST Creatinine, Test Test, TEST TEST

Patient Report (Urine)

LÁRIONAD NÁISIÚNTA CÓIREÁLA DRUGAÍ
NATIONAL DRUG TREATMENT CENTRE
DRUG ANALYSIS LABORATORY

An tSaotharlann
FSS LÁRIONAD NÁISIÚNTA CÓIREÁLA DRUGAÍ
Láiríonad Mhic Cárthaigh
30-31 Sráid an Phiarsaigh, Baile Átha Cliath 2
Teleafóin: +353 1 648 8719
Facs: +353 1 648 8618
Ríomhphost: laboratory@dtcb.ie
Láithreán: www.addictionireland.ie

The Laboratory
HSE NATIONAL DRUG TREATMENT CENTRE
McCarthy Centre
30-31 Pearse Street, Dublin
Telephone: +353 1 648 8719
Fax: +353 1 648 8618
e-mail: laboratory@dtcb.ie
Website: www.addictionireland.ie

LAB__LABORATORY TEST CLINIC
Toy Lane
Toy Town

User:
Clinic ID: LAB | Sampled between : 30/04/2012 - 30/04/2013
Chart No.: 19 | Patient date of birth: 25/04/2013

Patient:

Barcode	Date sampled	OPIA	6-AMOR	BENZ	EDDP	CANN	ALCO	AMPH	COCA	Comment
13060117	24/04/2013									
13060099	24/04/2013									

Statistical Information

Figure 4.14: Screenshot of the Laboratory Electronic Report (LER) Application

4.5 Phase I: Process 2: The Sample Disposal Log

The LSS intervention outlined for Process 2: The Sample Disposal Log was never actuated. As discussed in the literature review earlier, when using a BPMS like LSS as opposed to Lean or Six Sigma or another BPMS, it can help identify other improvement opportunities (Brett, Queen, 2005) and in this instance Process 1: (TF4 Form used to Record Specimen Sample Reference logs) incorporated the solution to the issues defined in the initial interviews with the customer (the Senior Laboratory Team) for this process.

A request was made by the Senior Laboratory Team to design an application or develop a module in Labware LIMS that could be used to effectively manage the process of recording and tracking analysed specimen samples which were queued for disposal.

4.5.1 Define: The Sample Disposal Log

A urine specimen sample is only regarded as being valid for testing purposes up to two weeks after the specimen sample has been analysed. The current process is to update a MS Word document "The Sample Disposal Log" and store the documents on the Laboratory file server (CHEOPS).

4.5.2 Measure: The Sample Disposal Log

Lab Aides manually track and record the batch of samples that are moved to a storage fridge awaiting disposal. Because the information was entered manually there is always risk of transcription errors being made by the Lab Aides.

4.5.3 Analysis: The Sample Disposal Log

Develop a module in Labware LIMS that would facilitate the recording of the movement of specimen samples through the Laboratory. A hand held device (barcode scanner) could be used to record or update the sample trays; these trays are stored in the Laboratory cold room.

4.5.4 Implementation: The Sample Disposal Log

The changes made to the new Labware LIMS module implemented as part of the LSS improvements for Process 1, allowed the Lab Aides to use Labware LIMS to track each tray through the Laboratory and this process is now part of the Book-in lifecycle of Process 1 and required no further development.

4.5.5 Control: The Sample Disposal Log

This process of manually recording the disposal of specimen samples is now part of process 1 and the process of recording the disposal of specimen samples is now fully incorporated into Labware LIMS.

4.6 Phase I: Process 3: North West Analytical (NWA) Statistical Analysis

The North West Analytical (NWA) statistical Analysis conducted in the NDTC Laboratory is used for control studies of statistical records to set limits of pass or fails and QCs. The QC systems used in the NDTC Laboratory and in other clinical laboratories are based on the Westgard rules (see 5.2.1 Laboratory Quality Control Management Methodologies), these rules enable the Biochemist to ascertain if the tests they are performing are "in control" and reportable or are "out of control"(Carroll, Pinnick, Carroll, 2003).

North West Analytical provide Statistical Process Control (SPC) software that integrates with major manufacturing systems including Labware LIMS and over 3,000 manufacturers world-wide use NWA analyse plant data for certification, regulatory compliance and cost reduction (North West Analytics, 2013).

4.6.1 Define: North West Analytical (NWA) Statistical Analysis Process

A NWA statistical Analysis is conducted on an analyser when one of the following states occurs.

1: A new LOT of calibrator is used on one of the Analysers.

A calibrator is a standard level of a drug and is used to verify the +/- cut off detection levels for that drug type. Calibrators are stored in the Laboratory refrigerators in bottles, the bottles are taken from the refrigerators each morning, and a calibrator for each drug type is decanted into an aliquot which is then placed on the Analyser (Figure 4.15). QCs are then run on the analyser to establish the calibration level of this drug type on the analyser (Figure 4.16).



Figure 4.15: Calibrator for each drug type is decanted into an Aliquot which is then placed in the Analyser

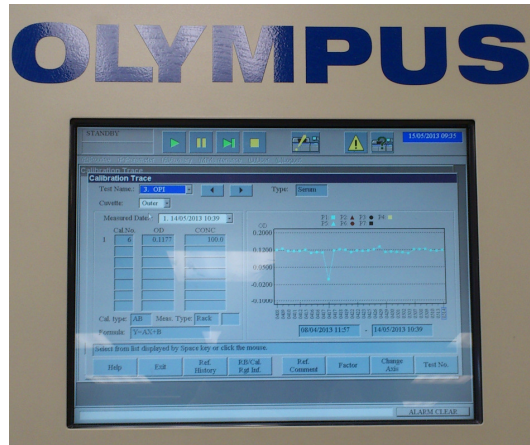


Figure 4.16: QC's are then run on the Analyser to establish the system is within control

2: If a QC is failing.

QCs are run on the analysers first thing in the morning following the calibration of the analysers and a QC is run after approximately 100 specimen samples are tested on the analysers.

3: If a new LOT of reagent is used on one of the analysers.

A reagent is an Assay (a type of test). Reagents are stored in refrigerated units inside of the analysers; these are changed only when needed.

4: A new LOT of QC is used on one or both of the analysers.

QCs are similar to calibrators, but the concentration of drugs is +/- 25% of the cut off for each assay (i.e. 75% or 125% of the calibrator). They are included with the specimen samples during a specimen sample run. QCs produce the mean standard deviations (SD) above or below the mean. A failure is recorded when a result is three standard deviations (3'S) above or below the mean. A warning is recorded when a result is two standard deviations (2'S) above or below the mean.

4.6.2 Measure: North West Analytical (NWA) Statistical Analysis Process

Stage 1:

Each time a new NWA statistical Analysis is run for one or both of the analysers a new TF12 form must be completed. The TF12 form contains details of the results of a statistical Analysis which is calculated on a CF3 Microsoft (MS) Excel spreadsheet which is generated in Labware LIMS. To perform a statistical Analysis on the CF3 Microsoft (MS) Excel spreadsheet, a selection of 30 QC results are selected from Labware LIMS, these QCs must contain no failures (a failure is any QC with a +/- 3'SD result). If one of the QCs is a failure, this QCs must be manually removed, Labware LIMS is once again requested to return 30 QCs and this process continues until 30 QCs without any failures are returned.

Stage 2:

The following statistical analyses are carried out on the 30 QCs using the CF3 Microsoft (MS) Excel spreadsheet.

- Calculation of the Mean
- Calculation of the Standard Deviation

Stage 3:

The statistical Analysis information generated in a MS Excel Spreadsheet, based on the 30 QC results is then entered into the CF12 form manually and can contain transcription errors.

Stage 4:

The statistical Analysis results are entered into a section of Labware LIMS called Product Specification and details three standard deviations (3'S) below the mean and the three standard deviations (3'S) above the mean are recorded (Table 4.3). Likewise the reason for the change e.g. a new control LOT has been added, is recorded.

Product Specification	Reason for new Control LOT
Minimum (Mean -)	-3 Standard Deviations
Maximum (Mean +)	+3 Standard Deviations
Low Control (Mean -)	-2 Standard Deviations
High Control (Mean +)	+2 Standard Deviations
Average	Mean

Table 4.3: Information for Statistical Analysis entered into Labware LIMS Product Specs Module

Stage 5:

The CF3 Microsoft (MS) Excel spreadsheet is then printed and attached to the TF12 form (see Appendix III).

Stage 6:

The statistical Analysis values (mean and SD) are then entered into the analysers.

4.6.3 Analyse: North West Analytical (NWA) Statistical Analysis Process

The statistical Analysis is manually carried out on an Microsoft (MS) Excel spreadsheet CF3 form (Figure 4.17) this could lead to calculation errors.

1	A	B	C	D	E	F	G	H	I	J	K	L	M
2	STOCK TY#	TEST	NAME	BARCODE	KIT LOT#	LOT#	EXPIRY	DATE IN USE/ON INSTRUMENT (CAL, REA)	DATE LOT IN USE	PREPARED DA	PREPARED	ONBOARD BY	AU2700 BARG
3	CALIBRATOR	Alcohol	URI Alcohol Negative	H130125	same as lot#	59635879	2014 04	04/04/2013	06/02/2013	N/A	N/A		C0000003
4	CALIBRATOR	Alcohol	URI 100mg/dL Alcohol	H130117	same as lot#	59750398	2014 11	28/03/2013	04/02/2013	N/A	N/A		C0000008
5	CALIBRATOR	Opiate	CEDIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
6	CALIBRATOR	Amphetamine	CEDIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
7	CALIBRATOR	Cocaine	CEDIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
8	CALIBRATOR	EDDP	CEDIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
9	CALIBRATOR	6-Acetylmorphine	CEDIA Heroin Metabolite	H130137	same as lot#	59708473	2013 08	11/04/2013	23/09/2012	N/A	N/A		C0000005
10	CALIBRATOR	Creatinine	URI 2mg/dL Creatinine-Detect	H130025	same as lot#	59845664	2013 05	01/02/2013	01/02/2013	N/A	N/A		C0000006
11	CALIBRATOR	Creatinine	URI 20mg/dL Creatinine-Detect	H130025	same as lot#	59845664	2013 05	01/02/2013	01/02/2013	N/A	N/A		C0000007
12	CALIBRATOR	Benzodiazepine	Secondary Cut-Off	H130143	same as lot#	59848061	2014 01	18/04/2013	18/04/2013	N/A	N/A		C0000010
13	CALIBRATOR	Cannabis(THC)	CEDIA THC 50	H130106	same as lot#	59827548	2014 03	22/03/2013	31/01/2013	N/A	N/A		C0000011
14	CALIBRATOR	pH	URI pH3.0	H130099	same as lot#	59795769	2013 06	20/03/2013	02/01/2013	N/A	N/A		C0000020
15	CALIBRATOR	pH	URI pH11.0	H130100	same as lot#	59795774	2013 06	20/03/2013	02/01/2013	N/A	N/A		C0000021
16	CALIBRATOR	EG	URI Alcohol Negative	H130125	same as lot#	59635879	2014 04	04/04/2013	06/02/2013	N/A	N/A		C0000100
17	CALIBRATOR	EG	URI EG 100ng/mL	H130081	same as lot#	59670676	2013 07	07/03/2013	19/09/2012	N/A	N/A		C0000101
18	CALIBRATOR	EG	URI EG 500ng/mL	H130092	same as lot#	59807121	2014 03	15/03/2013	11/10/2012	N/A	N/A		C0000102
19	CALIBRATOR	EG	URI EG 1000ng/mL	H130093	same as lot#	59670716	2013 07	15/03/2013	30/07/2012	N/A	N/A		C0000103
20	CALIBRATOR	EG	URI EG 2000ng/mL	H130074	same as lot#	59670719	2013 07	04/03/2013	13/09/2012	N/A	N/A		C0000104
21	QC	Negative check	Drug free urine	N/A	same as lot#	E13418	2013 06	N/A	13/03/2012	23/02/2012	N/A		Q0000001
22	QC	Positive check	Urine detectabuse control	N/A	same as lot#	MC4073	2015 12	N/A	16/04/2013	N/A	N/A		Q0000002
23	QC	Creatinine	13mg/dL Creatinine	N/A	same as lot#	59817685	2013 05	N/A	03/09/2012	N/A	N/A		Q0000003
24	QC	Creatinine	20mg/dL Creatinine	N/A	same as lot#	59817688	2013 05	N/A	02/01/2013	N/A	N/A		Q0000004
25	QC	Opiate	Clinical Low	N/A	59737676	59737663	2013 11	N/A	26/11/2012	N/A	N/A		Q0000023
26	QC	Cocaine	Clinical Low	N/A	59737676	59737663	2013 11	N/A	26/11/2012	N/A	N/A		Q0000023
27	QC	EDDP	Clinical Low	N/A	59737676	59737663	2013 11	N/A	26/11/2012	N/A	N/A		Q0000023
28	QC	Opiate	Clinical High	N/A	59737676	59737665	2013 11	N/A	26/11/2012	N/A	N/A		Q0000030
29	QC	Cocaine	Clinical High	N/A	59737676	59737665	2013 11	N/A	26/11/2012	N/A	N/A		Q0000030
30	QC	EDDP	Clinical High	N/A	59737676	59737665	2013 11	N/A	26/11/2012	N/A	N/A		Q0000030
31	QC	Benzodiazepine	Select Low	N/A	59670231	59670225	2013 11	N/A	20/11/2012	N/A	N/A		Q0000031
32	QC	6-Acetylmorphine	Select Low	N/A	59670231	59670225	2013 11	N/A	20/11/2012	N/A	N/A		Q0000031
33	QC	Benzodiazepine	Select High	N/A	59670231	59670223	2013 11	N/A	20/11/2012	N/A	N/A		Q0000032
34	QC	6-Acetylmorphine	Select High	N/A	59670231	59670223	2013 11	N/A	20/11/2012	N/A	N/A		Q0000032
35	QC	Amphetamine	Primary Low	N/A	59657545	59657525	2013 11	N/A	04/12/2012	N/A	N/A		Q0000033
36	QC	Amphetamine	Primary High	N/A	59657545	59657531	2013 11	N/A	04/12/2012	N/A	N/A		Q0000034
37	QC	Alcohol	50mg/dL Alcohol	N/A	same as lot#	59899074	2015 06	N/A	21/12/2012	N/A	N/A		Q0000035
38	QC	Alcohol	300mg/dL Alcohol	N/A	same as lot#	59899074	2015 06	N/A	21/12/2012	N/A	N/A		Q0000036
39	QC	Cannabis(THC)	THC 50 Low	N/A	59829739	59785004	2014 02	N/A	23/04/2013	N/A	N/A		Q0000037
40	QC	Cannabis(THC)	THC 50 High	N/A	59829739	59785005	2014 02	N/A	23/04/2013	N/A	N/A		Q0000038
41	QC	pH	URI pH3.0	N/A	same as lot#	59768690	2013 06	N/A	02/01/2013	N/A	N/A		Q0000041
42	QC	pH	URI pH7.0	N/A	same as lot#	59774428	2013 06	N/A	02/01/2013	N/A	N/A		Q0000042
43	QC	pH	URI pH10.0	N/A	same as lot#	59774437	2013 06	N/A	02/01/2013	N/A	N/A		Q0000043
44	QC	EG	URI EG 375ng/mL	N/A	same as lot#	59801821	2014 02	N/A	06/03/2013	N/A	N/A		Q0000101
45	QC	EG	URI EG 625ng/mL	N/A	same as lot#	59805634	2014 02	N/A	22/04/2013	N/A	N/A		Q0000102
46	REAGENT	Creatinine	URI Creatinine- Detect	H130140	same as lot#	59820638	2014 04	16/04/2013	26/11/2012	N/A	N/A	SP	N/A
47	REAGENT	Opiate	CEDIA Opiate	H130154	same as lot#	59614938	2014 04	26/04/2013	22/11/2012	23/04/2013	SP	SP	N/A
48	REAGENT	Cocaine	CEDIA Cocaine	H130136	same as lot#	59678740	2014 07	11/04/2013	20/09/2012	10/04/2013	LL	SP	N/A

Figure 4.17: CF3 MS Excel Spreadsheet

There was also the possibility that multiple statistical Analysis processes would have to be performed on the analysers over a relatively short period of time, for example if LOTs of calibrators had to be changed on day 1, an NWA statistical Analysis would have to be conducted. If on day 2 a new LOT of QCs had to be added then a second set of NWA statistical Analysis would have to run and so forth.

Issues Identified: North West Analytical (NWA) Statistical Analysis Process

1: The system is a manual paper based system prone to human error and generating unnecessary forms and Microsoft (MS) Excel spreadsheets which have to be stored offsite.

2: Statistical Analysis is not conducted on a regular basis and the analysers must reach a stage where the QCs are failing or new LOTs are being used before a new statistical Analysis is conducted, i.e. mean and SD do not reflect the current conditions.

3: During a recent audit by the Irish National Accreditation Board (INAB) the Laboratory was advised to change its current statistical Analysis process, as statistical Analysis may not have been performed on an analyser for a long period of time. The auditor pointed out that if such a case occurred, then the statistical Analysis for that analyser could not be considered valid.

4: The current manual calculation for the statistical Analysis process is prone to calculation and transcription errors.

5: The process for obtaining 30 QC results without failures can take a Biochemist a consider amount of time to generate.

4.6.4 Implement: North West Analytical (NWA) Statistical Analysis Process

To address some of the issues identified with this process, several different solutions needed to be put in place to eliminate waste and streamline the process.

Process Change 1: Was to change the parameters for carrying out an NWA statistical Analysis, rather than waiting for an event to occur that would initiate a NWA statistical Analysis, it was agreed that an NWA statistical Analysis would be carried out each month and a TF12 form updated once a month regardless of LOT changes.

This action was based on recommendations from the INAB auditors who pointed out that an analyser could run for six months without having a NWA statistical Analysis conducted, depending on the batch of calibrators, QCs or reagents being used. They deemed it better to update monthly on scheduled basis and incorporate changes made during the month if necessary.

Process Change 2: Labware LIMS was programmed to have the option to exclude failed QCs, that is where a QC is 3 or more standard deviations (3σ) outside the norm, this change makes it possible

for the Biochemist to get 30 QCs returned in the first instance as opposed to the old system of querying Labware LIMS repeatedly until 30 QCs were returned without any fails.

Process Change 3: Once Labware LIMS returns the 30 QCs, the Biochemist has the option to update the QC specs within Labware LIMS automatically. The Biochemist can select one or both analysers to run a NWA statistical Analysis on and the statistics are calculated by Labware LIMS, removing the possibility of human error in calculating the results (see Appendix IV for Source Code used). The Biochemist enters the reason for conducting the NWA statistical Analysis into Labware LIMS and completes the TF12 form.

Process Change 4: The new NWA Labware LIMS Module records the date and time when the NWA was carried out and has a search facility function.

Process Change 5: Labware LIMS will save the automatically generated NWA Analysis TF12 form to the QC_PROJECT folder on the (CHEOPS) Server.

To achieve the process changes required software specification requirements were sent to Labware and a senior Labware system Analysts was assigned to develop the Labware LIMS application to the NDTC requirements.

4.6.4.1 NWA Specification Requirements for Labware LIMS Development

- Design Method for sending QCs across to NWA, 30 QCs required with option to exclude failures. QC results are similar to samples and results should be compiled into folders according to QC type.
- Calculate the Mean and Standard Deviation for each QC.
- Labware LIMS to Create Charts – Warning limits set at 2 Standard Deviations (2SD) limits and Control limits set at 3 Standard Deviations (3SD) which is failures.
- An update note needs to be added when updating the statistical Analysis (Free text) this is to use for recording the reason for updating e.g. “New Reagent or New Quality Control (QC) has been applied”. Create a Crystal Report to record QC updates.
- Charts in NWA need to be checked and relevant rules added – i.e. Westgard Rules can be applied if required.
- The Date Range should be incorporated into the NWA so that a Biochemist can search for samples which only run on a certain date e.g. 01/02/2013
- Only compile statistical Analysis updates to QCs that are within the control limits, no 3SD (failures), see Figure 4.18.

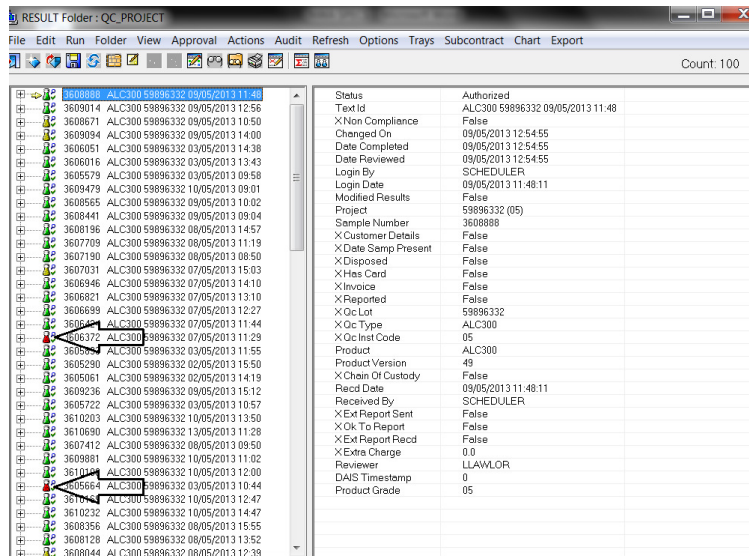


Figure 4.18: Exclude failed Quality Controls (QC) from Statistical Analysis

4.6.4.2 NWA Specification Requirements for QC_PROJECT folder on the Server

- A filter needs to be created for showing only open projects (QC LOTs) in Labware LIMS
- Query Tag feature needed see Figure 4.19 for folder template.

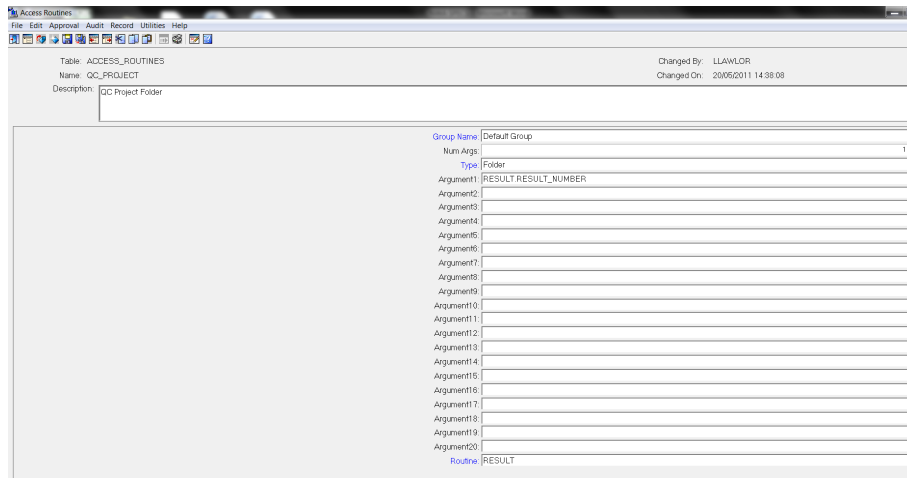


Figure 4.19: Template for QC_PROJECT folder

4.6.5 Control: New Lean Six Sigma North West Analytical (NWA) Statistical Analysis Process

The NWA statistical Analysis is now fully deployed to the production environment and like all LSS projects is subject to review and enhancements where possible. In the near future the next process change will involve the TF12 form which will no longer be printed, instead it will be generated by Labware LIMS and many of the fields that are currently filled in by hand will be populated with data from Labware LIMS, the TF12 forms will be automatically stored as PDF documents on the (CHEOPS) Server.

4.7 Phase I: Process 4: Electronic Reporting Section

All specimen sample result reports are currently printed and after six months are stored securely offsite. The Laboratory is required to keep a printed record so that the principles of measurements in use on the day the specimen sample was analysed are captured.

4.7.1 Define: Electronic Reporting Section

The different parameters for each tray or batch are recorded with details of the barcode used, the chain of custody, unique ID, the clinic, the Biochemist who ran the report, the client details, and the type of assay carried out (urine or saliva testing).

The Cut-Off levels for positive and negative results are set in accordance with the guidelines of the Substance Abuse and Mental Health Services Administration (SAMHSA). The reports also record the UOM (uncertainty of measurement); each Laboratory is responsible for these levels).

4.7.2 Measure: Electronic Reporting Section

4.7.2.1 Level 3 Process flows for NDTC Laboratory Reporting

To understand the process flow for reporting it was necessary to examine the different types of reports generated and the processes in the production of each report.

4.7.2.2 All Reports Are First Printed

1: Before reports are printed, the Biochemist must cross-check the number of sample results for each clinic on a TF4 form against the numbers for that clinic on the tray work list provided with the batch.

2: If there are samples for a clinic being reported which were logged into the Labware LIMS system but did not run, these samples have an un-received status, if the un-received sample(s) were booked-in the day before Analysis of the other samples this date is included when printing the clinics results report (Figure 4.20) .

3: The report appears in a preview format before printing. Select print, to print the report.

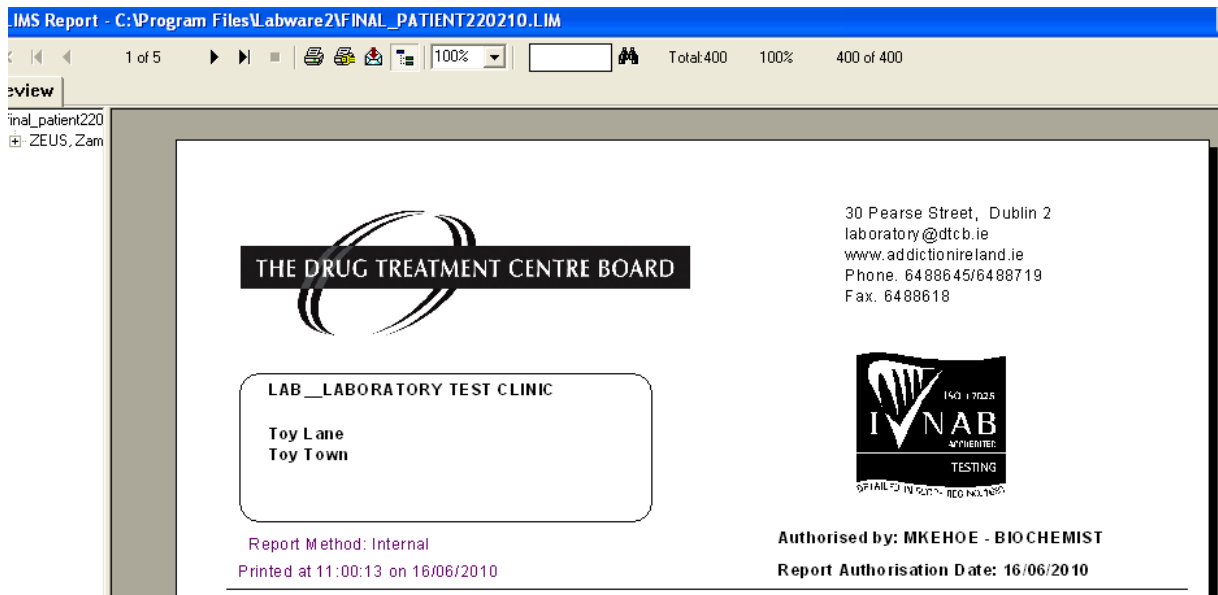


Figure 4.20: Print Preview of Report in Labware LIMS

4: The results print in a report format which is generated with a unique identification number.

5: The biochemist checks each report sheet for the clinic. The Biochemist then ensures the client samples are booked into the correct clinic, all tests/non-conformances are included in the clinic report.

6: Non-conformance forms are only issued for samples which could not be booked into the Labware LIMS system and/or samples from DAIS clinics. The biochemist also checks the final statistics for each clinic on the last page to ensure the number of tests analysed is correct.

4.7.2.3 Process for Fax Reporting

1: The reporting method (F) for Fax is recorded on the TF4 form. Before faxing, the report is checked against the Results Reporting List (AR4) to ensure that the report is being sent to the correct agreed fax number and that the report has been printed correctly, i.e. multiple client results per page or separate client per page report.

2: Fax the report and await confirmation / transmission verification report. Once a fax confirmation receipt has been received, the Biochemist checks the details are correct by marking the time which the fax was received by the recipient, the clinic name and the fax report result are marked as "OK".

3: When the confirmation(s) have being received only then will the biochemist attach the fax confirmation sheet to the report. The time, date, and Biochemist initials are entered on to the TF4 form with the date and stored on server.

4: If the secure fax number on AR4 is not working or is busy, the report and the fax sheet are stapled together and placed with the batch. The clinic reports are reprinted in duplicate or a copy made of the original report. The original report is posted to the clinic and the copy of report is stored in the batch file.

4.7.2.4 Process for Posting Reports

1: The reporting method (P) for Post is recorded on the TF4. The report is printed twice, one copy of the report is posted to the relevant clinic, and the second copy of the report is retained with the batch documentation. The date and time are recorded as the time the report was printed. The time, date and Biochemist initials are entered on the TF4 form and stored on the (CHEOPS) Server.

2: If results on a specific client have been requested by a clinic to which the results have already been reported, a copy of the existing report is made and posted. The copied report is stamped with the copy and date stamp.

4.7.2.5 Process for the Electronic Patient System (EPS) Reporting

1: The reporting method (E) for EPS is recorded on the TF4 and Internal NDTC clinics are automatically reported into the EPS system once the results have been authorised in Labware LIMS.

2: The reports for these clinics should be printed out and filed with the relevant batch. There is no requirement to send hard copy reports to the internal clinics unless hard copies have been requested or as stated in AR4 form. The time, date and Biochemist initials are entered on the TF4 form and stored on the (CHEOPS) Server.

4.7.2.6 Process for Drugs and Aids Information System (DAIS) reporting through Labware LIMS

1: The reporting method (D) for DAIS is recorded on the TF4. DAIS results are sent automatically through Labware on the Labware Scheduler, currently located on the (ARTEMIS) Server.

2: Once the samples have been authorised the Scheduler will pick up the result automatically and send them to the DAIS system electronically.

3: In the Labware LIMS TRAY folder each sample should each have a light green star beside it once the reports have been printed and the samples should each have a light green star beside them to indicate that the result was successfully sent electronically to DAIS (Figure 4.21).

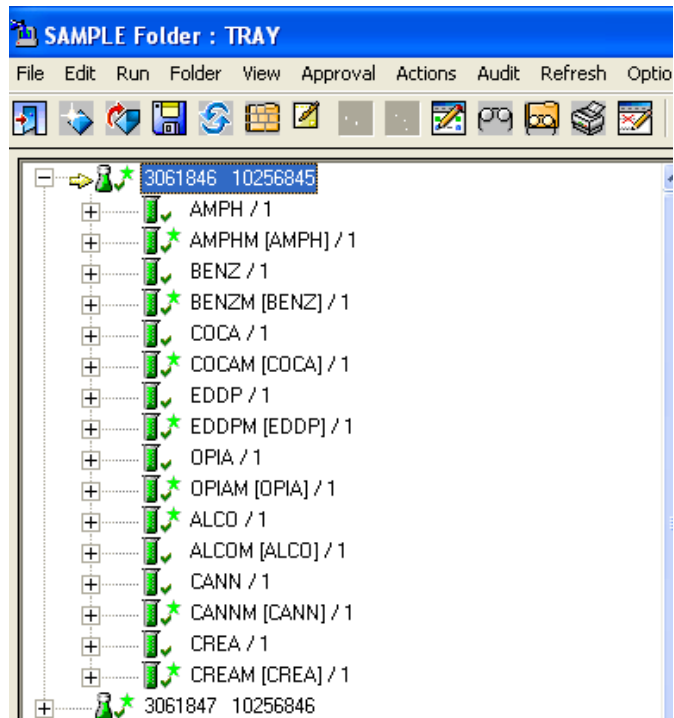


Figure 4.21: Tray folder in Labware LIMS

4: The time, date and Biochemist initials are entered on to the TF4 form which is stored on the (CHEOPS) Server.

4.7.2.7 Process for using the Laboratory Electronic Reporting (LER) Application

1: The reporting method (L) for LER is recorded on the TF4 form. The clinic results report is printed from Labware LIMS for the LER and retained with the batch.

2: The time, date and Biochemist initials are entered on to the TF4 form which is stored on the (CHEOPS) Server.

4.7.2.8 Process for Drug Court Results Reporting

1: Results for Drug Court clients are reported to their attending clinics as normal. The Drug Court Nurse sends a fax request on a Thursday evening for the clients attending court the following week. A one month's cumulative report for each client is faxed to the Drug Court when requested.

4.7.2.9 Process for Chain of Custody & Probation reporting

1: All positive samples require confirmatory Analysis.

All samples which have been assigned Chain of Custody or Probation status are reported by Post.

4.7.2.10 Process for Filing Reports once they have been sent to Customer

1: Once the TF4 form has been completed, it is printed and the biochemist signs and dates the form on the day it was completed.

2: All the documentation (see Appendix III) is filed into a brown batch folder with date and batch id (see Appendices XI)

- TF4 form,
- TF11 form (externals)
- Tray ID sheets
- NCF's
- Clinic reports
- Copy of Chain of Custody form where relevant
- AF30 forms where relevant

3: The brown batch folder is filed into the next available archive box in date order.

4: The electronic documentation is stored by date in folders on the on the (CHEOPS) Server for example *\\Daily_Batch_Documentation\2011\September\28\TF4_28_11_2011.xls*.

5: The senior Biochemist responsible for routine testing checks the TF20 form, when satisfied all the information is correct, it is stored on the (CHEOPS) Server.

4.7.3 Analysis: Electronic Reporting Section

A copy of all result reports are printed filed and stored for six months in the Laboratory office. After six months these reports are then stored in storage boxes and shipped off site to a storage company where they are stored indefinitely in case they need to be retrieved.

If result reports need to be posted or faxed to a clinic then a second copy of the report are printed for this purpose.

The challenges to implementing an Electronic Reporting solution required significant changes to the Laboratory technical infrastructure, to accommodate the storage of such large amounts of data.

The Biochemist is required to print a TF4 form to check and validate that all the result reports are correct and contain the correct amount of specimen samples for the correct clinics. The Biochemist manually fills in the form and this form is then checked by a senior Biochemist to insure that the information is correct; this process can be prone to transcription errors depending on the amount of specimen sample requests and the number of Lab Aides, Biochemists and their workload.

Issues Identified: Electronic Reporting Section

1: Large amounts of paper and printer supplies used.

2: Storage requirements for the printed reports will exponentially increase as the reports that are printed (all reports) must be stored offsite.

3: The time and cost involved with printing, filing and searching reports make this process a good candidate for a LSS intervention.

4: Requests for hard copies of reports can take days to reach the Client.

4.7.4 Implementation: Electronic Reporting Section

Process Change 1: The Laboratory Information Computer Technology (ICT) infrastructure was moved from Physical Servers to Virtual Servers. This allowed ICT department to allocate resources such as processing power, Random Access Memory (RAM) and storage space to any of the Laboratory Servers as needed. The virtualisation of the Servers allows for the future expansion of the capacity and resources for the Laboratory infrastructure with little or no downtime to the production environment.

Process Change 2: The implementation of redundant Laboratory Virtual Servers which would allow the Laboratory to stay operational in the event of a failure of the production servers.

Process Change 3: All result reports will be generated automatically in Labware LIMS. This negates the need to print any result reports other than those that need to be sent by fax or post.

Process Change 4: The TF4 reporting form is automatically completed with the clinic, barcode range, no. of samples, unique report ID, method of reporting, time & date reported and user ID of the reporting Biochemist. The information is now generated by Labware LIMS and is no longer manually completed by hand, reducing transcription errors and time.

This project was deployed to production on the 31/05/2013 and was initially tested and monitored and ran in parallel with the existing electronic reporting system, until the 21/06/2013 when it was fully deployed to production.

4.7.4.1 Specification Requirements for Electronic Reporting

- 1: Labware LIMS to generate a Protected Document Form (PDF) for all result reports and this file to be stored on a secure location on the Laboratory (CHEOPS) Server.
- 2: All PDF result reports generated in Labware LIMS should have a unique filename which should contain the client reference number, tray, clinic and the date the report was initially generated.
- 3: All PDF result reports should be automatically saved once the result report has been generated in Labware LIMS.
- 4: All PDF result reports should be retrievable through a Search mechanism within Labware LIMS and searches can be conducted by date, tray, clinic and/or barcode.
- 5: Labware LIMS will now automatically generate a TF4 reporting form with the TRAY check list once the reports have been generated.
- 6: The generated TF4 reporting form will automatically fill with the clinic, barcode range, no. of samples, unique report ID, method of reporting, time & date reported and user ID of the reporting Biochemist.

Below is a list of the Sections in Labware LIMS where changes were made to complete the specification requirements (see Appendix V, for full list of code).

Changes made/ additions to Labware system

Table Name	Record Name	Record Version	Changed On	Changed By	Group
ACCESS_ROUTINES	ORAL_CLIN		31/05/2013 18:05:10	SNELLI	DEFAULT
CONFIG_SYS	STRUCTURE_UPDATED		31/05/2013 16:58:32	SNELLI	
QUERY_TAG	FINAL_CLINIC_PDF		31/05/2013 11:36:48	SNELLI	DEFAULT
SUBROUTINE	AS_MM_OPEN		31/05/2013 15:52:07	SNELLI	DEFAULT
SUBROUTINE	REP_CLIN_C_S		31/05/2013 16:14:05	SNELLI	DEFAULT
SUBROUTINE	REP_CLIN_PDF		31/05/2013 15:53:26	SNELLI	DEFAULT
SUBROUTINE	VAL_FIND_PDF		31/05/2013 16:26:03	SNELLI	DEFAULT
SUBROUTINE	VAL_REP_ORAL_CLIN		31/05/2013 18:04:09	SNELLI	DEFAULT
SUBROUTINE	VAL_REP_PDF		31/05/2013 15:39:46	SNELLI	DEFAULT
TABLE_MASTER	X_REPORTS		31/05/2013 16:58:32	SNELLI	DEFAULT
USER_DIALOG_TEMP	FIND_PDF		31/05/2013 16:49:06	SNELLI	DEFAULT

4.7.5 Control: Electronic Reporting Section

The Laboratory is currently trying to encourage all its customers to switch to Internet based LER system, they are setting up a process where individual Court Reports can be made available on the LER for use by the Courts. The current practise of printing reports and sending them by registered post is expensive. This is a slow process of change and as some GP practices do not have Internet access, this may not be realised fully in the near future.

4.8 Phase I: Process 5: Stock Tracking and Reporting Process

Requirements Statement

When New Stock arrives into the NDTC Laboratory each box is examined and checked against the Delivery Docket. Stock may consist of individual assignments of reagents, calibrators and QCs or a combination of them. This process is completed manually and the data is not captured in Labware LIMS. The stock taking process is carried out monthly and can take up a substantial amount of time and resources in the Laboratory. It was requested that a more automated process be put in place to monitor the stock, alert when stock is low and be fully integrated into Labware LIMS (Figure 2.2).

4.8.1 Define: Stock Tracking and Reporting Process

New Stock is checked against the delivery docket to verify that the quantities correspond. The stock details are recorded in a Microsoft (MS) Excel spreadsheet called Kit Stock.xls. The details recorded consist of LOT Numbers and the manufacturers Barcode. LOT Numbers are generated by the manufacturers and used as reference to track which batch a particular LOT came from. Many boxes may arrive with the same Manufactures Barcode and LOT numbers and so a unique NDTC Barcode and Number are generated for each box and recorded in the CF3 (Table 4.4) Microsoft (MS) Excel Spreadsheet.

The expiry date is recorded and the State type of the Stock. Stock may arrive in two different states either ready or not-ready. A ready LOT of stock can be used in the analyser while a not-ready LOT of stock must be prepared for usage in the analyser, once the stock is prepared it is issued a new Barcode and expiry date as prepared solutions then expire sooner than the non-ready LOT of stock. The details of the prepared stock are recorded in the CF3 form.

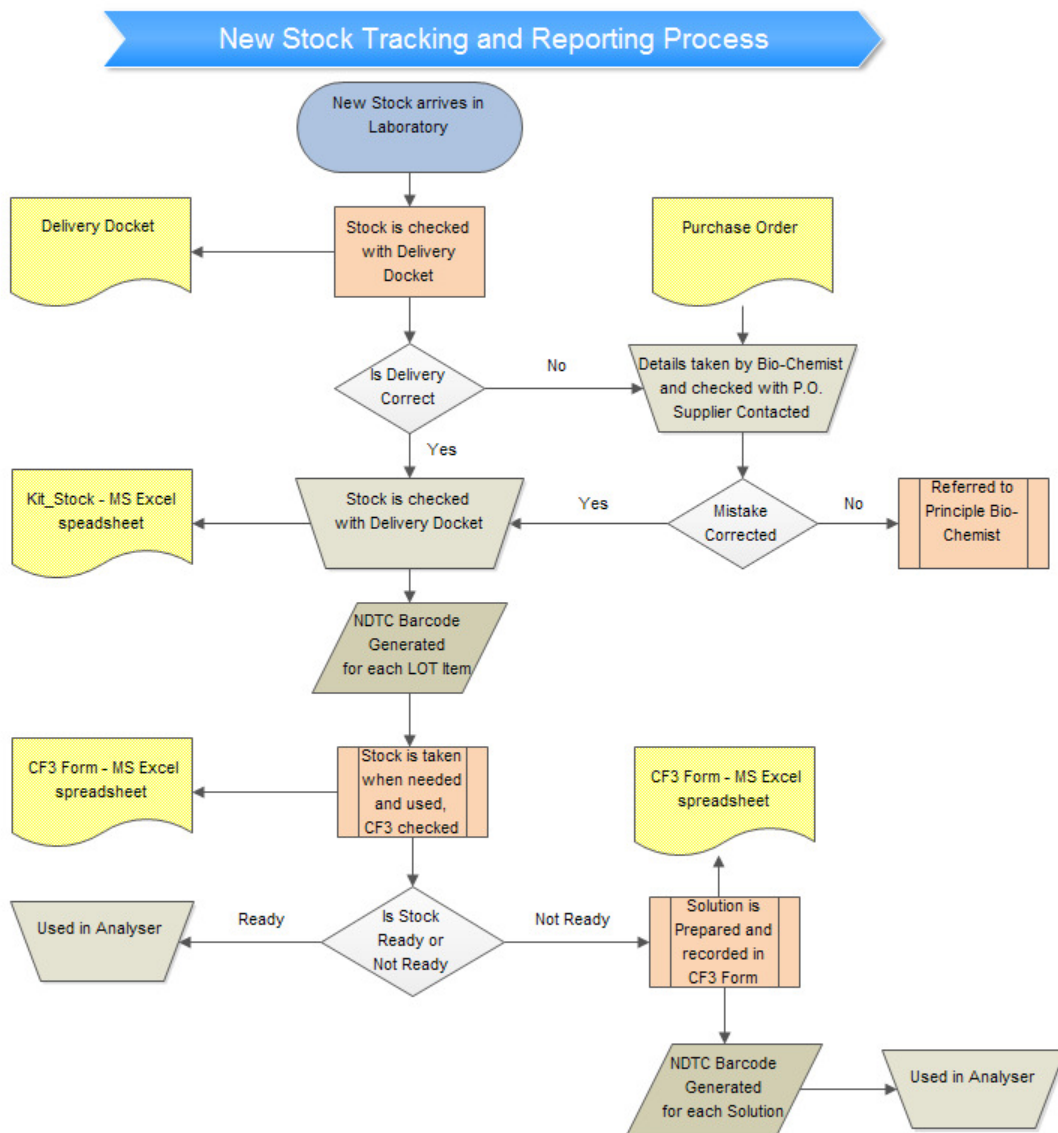


Figure 4.22: Workflow - New Stock Tracking and Reporting

Test	Name	Barcode	Kit Lot#	Lot#	Expiry	Date in Use	Date Lot in Use	Prepared Date	Prepared By	AU2700 Barcode
Type of test recorded e.g. alcohol, cocaine etc.	Type of Reagent, QC or calibrator used	Lot# Barcode, e.g. H120049	Can be the the same as Lot# or new NDC Barcode for solutions	Lot# Number from supplier	Supplier Expiry date of Lot#	Date the Calibrator or Reagent was in use	Will be different for not-Ready Solutions	Date Solution prepared for not-Ready Lot#	If not ready who prepared Solution	Barcode for Analyser e.g. C0000003

Table 4.4: MS Excel Spreadsheet CF3

4.8.2 Measure: Stock Tracking and Reporting Process

Once a month a full inventory of stock is taken before new stock can be ordered and a list of all the stock in storage is created in a Microsoft (MS) Excel spreadsheet. This inventory process can take up to two days depending on who is conducting the audit and how many people are assisting. Once the inventory process is completed the information is then entered into a Microsoft (MS) Excel spreadsheet known as a TF3 form and this is then printed off.

The Biochemist responsible for stock control that month checks the TF3 form and judges what stock will need to be ordered to ensure that there is enough stock available for the next month and that the stock has not expired and will not expire before the next inventory of stock. Ordering of stock is based on experience and not on the levels used in previous months.

There is no audit trail on the usage of stock during the month.

When new stock arrives in Laboratory it is checked against delivery docket and once the Biochemist has been confirmed that the order is correct it is entered into the Kit-Stock Microsoft (MS) Excel spreadsheet. If there is a problem with the order the details are passed on to a senior Biochemist who contacts the supplier to get the error corrected. A barcode is then generated for the new LOT of stock and the information is recorded in the TF3 form. The stock is then stored in the cold room and is used when needed.

4.8.3 Analysis: Stock Tracking and Reporting Process

Once a month a full inventory of stock is taken and a list of all the stock in storage is created in a Microsoft (MS) Excel spreadsheet. There are a several problems with this method of stock control.

Issues Identified: Stock Tracking and Reporting Process

1: It requires the Biochemist to be aware of the current stock in storage during the month as all the stock for certain reagent or calibrator maybe used up or may have exceeded its expiry date before the monthly inventory of stock is completed.

2: The manual system relies on the experience of the Biochemists knowing what tests have been performed that month and what stock may be required or should be ordered before the monthly inventory of stock take.

3: If too much stock is ordered and not used the stock can go out of date, this can be very expensive and also leads to the risk of out of date stock being used in the analysers by junior staff, these errors might not be realised until the QC stage of the specimen sample process flow and may require the reprocessing of one or many batches of specimen samples.

4: For accreditation purposes INAB have highlighted that it now requires that stock control systems must be fully auditable (the current process is not) this would lead to a non-conformance and needed to be corrected before the next INAB audit in May 2013.

The goal of this LSS intervention was to look at improving the quality assurance systems within the Laboratory and not necessarily the performance time of the stock tracking and reporting process.

4.8.4 Implementation: Stock Tracking and Reporting Process

To best facilitate all the requirements of the customer (the Senior Laboratory Team) it was deemed necessary to develop the LSS intervention within Labware LIMS. The development of the Inventory Management module within Labware LIMS was used to complete this task.

The specification requirements for this process change were given to Labware and a senior system Analysis was assigned to the NDTTC to provide a solution that would meet these requirements.

4.8.4.1 Specification Requirements for Inventory Manager

1: Alerting function should be in place for when stock has expired or is nearing expiration date.

2: The Inventory Manager should keep a detailed audit trail and track what stock has been added, what stock has been taken away or used, when it was used, by whom it was used and all entries must be time stamped.

3: The Inventory Manager must be able to generate a current stock report when required.

4: Replace the Microsoft (MS) Excel spreadsheet and record the information relating to new stock directly into Labware LIMS.

4.8.4.2 Code used to make changes to the Inventory Manager Module

Expiry check

' Expiry Checks

'=====

status = CanAccessFunction("NDTC_QCexpiryChecks")

IF (status=true) THEN

 gosub as_check_inst_pm

ENDIF

' Inst PM Date Checks

'=====

status = CanAccessFunction("NDTC_InstPMChecks")

IF (status=true) THEN

 gosub as_check_qc_lot_exp

ENDIF

' See how many users are already logged in...

gosub usage_in

Stock code

Inventory filters

/* Select stock of a particular inventory type */

invType = SELECT Inventory_Item.Inventory_Type

q = ""

q = q & "select distinct ii.stock, ii.stock + ' - ' + s.description "

q = q & "from inventory_item ii, stock s "

q = q & "where ii.stock = s.name "

IF (isEmpty(invType)=false) THEN

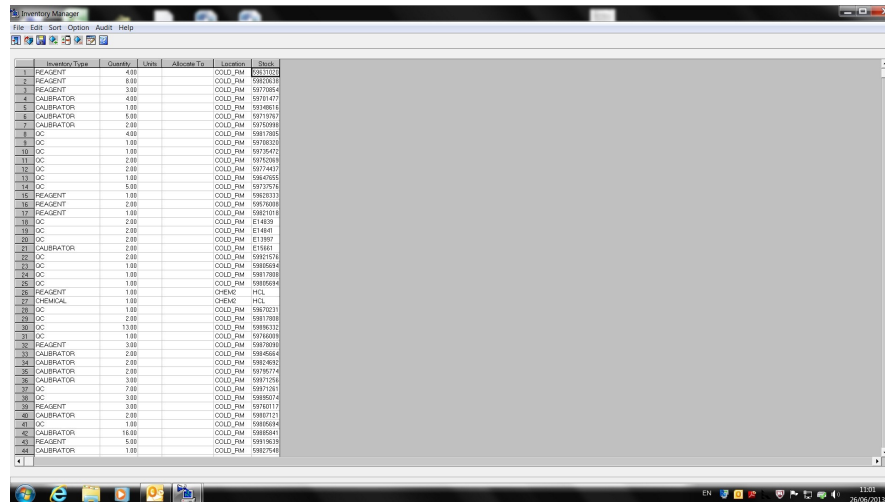
 q = q & " and ii.inventory_type = " + invType + ""

ENDIF

status = SQL(q, "stockArray")

Return stockArray

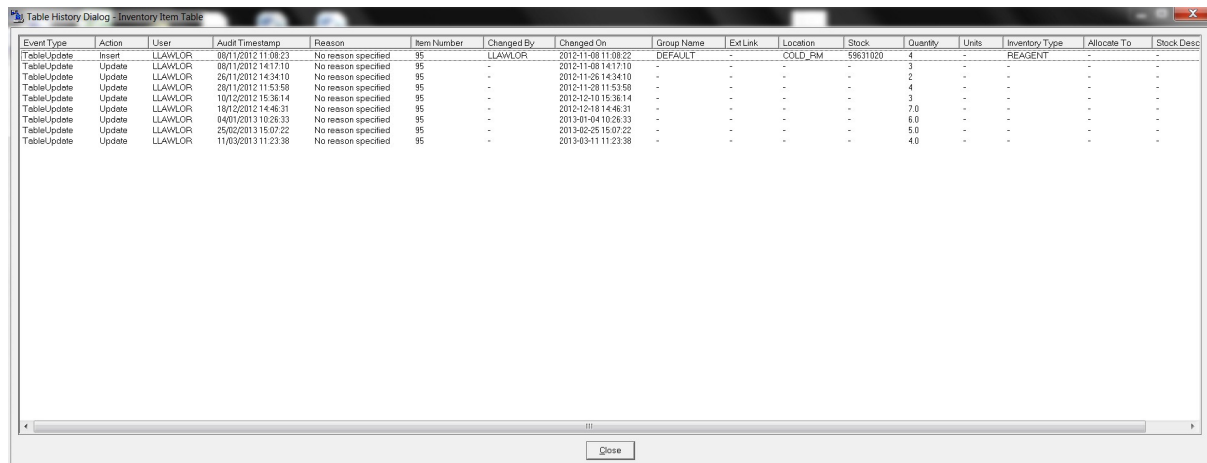
Process Change 1: The Inventory Manager Module was developed within Labware LIMS, this is now used to record all inventory activity (Figure 4.23), and this new module replaced the Microsoft (MS) Excel spreadsheet used to record the stock each month.



Inventory Type	Quantity	Units	Absolute Tr	Location	Price
REAGENT	400			COLD_RM	5873333
REAGENT	800			COLD_RM	5873333
REAGENT	300			COLD_RM	5873084
CALIBRATOR	400			COLD_RM	5873147
CALIBRATOR	100			COLD_RM	5873804
CALIBRATOR	500			COLD_RM	5873197
CALIBRATOR	200			COLD_RM	5873098
OC	400			COLD_RM	5887385
OC	100			COLD_RM	5873029
OC	100			COLD_RM	5873472
OC	200			COLD_RM	5873038
OC	200			COLD_RM	5873443
OC	100			COLD_RM	5884053
OC	500			COLD_RM	5873754
REAGENT	100			COLD_RM	5883333
REAGENT	200			COLD_RM	5887898
REAGENT	100			COLD_RM	5882181
OC	200			COLD_RM	E1458
OC	200			COLD_RM	E1458
OC	200			COLD_RM	E1458
CALIBRATOR	200			COLD_RM	E1583
OC	200			COLD_RM	5893754
OC	100			COLD_RM	5885684
OC	100			COLD_RM	5887898
OC	100			COLD_RM	5885684
REAGENT	100			CHEM	HCL
CHEMICAL	100			CHEM	HCL
OC	100			COLD_RM	5887833
OC	200			COLD_RM	5887898
OC	1300			COLD_RM	5886333
OC	100			COLD_RM	5873038
REAGENT	300			COLD_RM	5887898
REAGENT	200			COLD_RM	5885684
CALIBRATOR	200			COLD_RM	5882181
CALIBRATOR	200			COLD_RM	5882181
OC	200			COLD_RM	5873754
CALIBRATOR	300			COLD_RM	5873754
OC	300			COLD_RM	5873754
OC	700			COLD_RM	5873197
OC	300			COLD_RM	5885684
REAGENT	300			COLD_RM	5873117
CALIBRATOR	200			COLD_RM	5887833
OC	100			COLD_RM	5885684
CALIBRATOR	100			COLD_RM	5885684
REAGENT	500			COLD_RM	5881963
CALIBRATOR	100			COLD_RM	5882754

Figure 4.23: Inventory Manager - Stock within Labware LIMS

Process Change 2: A full audit history of reagents, calibrators and other inventory stock is now used to record all activity of inventory stock (Figure 4.24). The Inventory Manager module can now be checked for when new stock was added.



Event Type	Action	User	Audit Timestamp	Reason	Item Number	Changed By	Changed On	Group Name	Ext Link	Location	Stock	Quantity	Units	Inventory Type	Allocate To	Stock Desc
TableUpdate	Insert	LLAWLOR	08/12/2012 11:08:23	No reason specified	95	LLAWLOR	2012-11-08 11:08:22	DEFAULT	-	COLD_RM	58631020	4	-	REAGENT	-	-
TableUpdate	Update	LLAWLOR	08/12/2012 14:12:10	No reason specified	95	-	2012-11-08 14:12:10	-	-	-	-	-	-	-	-	-
TableUpdate	Update	LLAWLOR	26/11/2012 14:34:10	No reason specified	95	-	2012-11-26 14:34:10	-	-	-	-	2	-	-	-	-
TableUpdate	Update	LLAWLOR	20/11/2012 11:53:58	No reason specified	95	-	2012-11-20 11:53:58	-	-	-	-	4	-	-	-	-
TableUpdate	Update	LLAWLOR	10/12/2012 15:38:14	No reason specified	95	-	2012-12-10 15:38:14	-	-	-	-	3	-	-	-	-
TableUpdate	Update	LLAWLOR	18/12/2012 14:46:31	No reason specified	95	-	2012-12-18 14:46:31	-	-	-	-	7.0	-	-	-	-
TableUpdate	Update	LLAWLOR	04/01/2013 10:26:33	No reason specified	95	-	2013-01-04 10:26:33	-	-	-	-	6.0	-	-	-	-
TableUpdate	Update	LLAWLOR	25/02/2013 15:07:22	No reason specified	95	-	2013-02-25 15:07:22	-	-	-	-	5.0	-	-	-	-
TableUpdate	Update	LLAWLOR	11/03/2013 11:23:38	No reason specified	95	-	2013-03-11 11:23:38	-	-	-	-	4.0	-	-	-	-

Figure 4.24: Inventory Manager - Audit history of one lot of reagent

Process Change 3: The new Inventory Manager can be searched for specific stock by a Biochemist and the Biochemist now controls all of the records for the inventory, these records are updated in real time, so there is no need for a monthly inventory stock taking exercise.

4: Process Change 4: The reporting functionality of the Inventory Manager allows for ad hoc reports to be generated by a Biochemist detailing active stock, stock due to expire and summary reports used for ordering of stock (Figure 4.25).

inventory_report_26062013.pdf

Inventory Report

Location: COLD_ROOM

CALIBRATOR	Lot No.	Expiry Date	Pres. Rx	Pres. date	QUANTITY
PH Cut-off Calibrator	5959532	01/12/2012			6.00
Alcohol 100 Cut-off Calibrator	5975998	01/12/2014			2.00
Clinical Cut-off Calibrator	5982482	01/02/2014			2.00
PH Cut-off Calibrator	5959579	01/07/2013			2.00
Creatinine Calibrator kit	5971256	01/02/2013			2.00
6-Amer Cut-off Calibrator	5982921	01/01/2014			6.00
THC 50 Cut-off Calibrator	5982758	01/04/2013			1.00
Secondary Cut-off Calibrator	5984861	01/02/2014			6.00
THC 50 Cut-off Calibrator	5982758	01/04/2013			2.00
Secondary Cut-off Calibrator	5984861	01/02/2014			2.00
Clinical Cut-off Calibrator	5982982	01/02/2014			6.00
Negative Alcohol Cut-off Calibrator	5983579	01/02/2013			6.00
DIG 500 Calibrator	5980121	01/04/2014			2.00
DIG 1000 Calibrator	5987976	01/08/2013			6.00
Alcohol 100mg/dl Cut-off Calibrator	5985941	01/08/2015			16.00
6-Amer Cut-off Calibrator	6011276	31/08/2014			2.00
PH Cut-off Calibrator	6016713	30/04/2014			2.00
Creatinine Calibrator kit	6015485	31/12/2013			4.00
6-Amer Cut-off Calibrator	6029482	01/02/2014			2.00
THC 50 Cut-off Calibrator	5999858	01/02/2014			2.00
DIG 100 Calibrator	5988283	01/04/2014			1.00
DIG 1000 Calibrator	5988281	01/04/2014			1.00
DIG 2000 Calibrator	5979460	01/08/2014			1.00
CONTROL	Lot No.	Expiry Date	Pres. Rx	Pres. date	QUANTITY
Creatinine 23 Control	5984564	01/02/2013			2.00
DIG 275 Control	5983093	01/08/2014			2.00
50 Alcohol Control	6083949	31/12/2015			9.00
Creatinine 23 Control	6016763	01/01/2014			2.00
pH 3.8 Control	5979499	01/12/2013			1.00
pH 7.8 Control	5983829	01/01/2014			1.00
pH 10.0 Control	5989544	01/12/2013			1.00
Primary Control	5985788	01/07/2014			1.00
THC 50 Control	5982979	01/02/2014			8.00
Select Control	5985489	01/07/2014			12.00
Creatinine 23 Control	5971261	01/10/2013			7.00
50 Alcohol Control	5985576	01/07/2015			2.00
pH 7.8 Control	5979424	01/07/2013			6.00
Creatinine 1.3 Control	5981785	01/02/2013			4.00
pH 3.8 Control	5978090	01/07/2013			6.00
pH 10.0 Control	5979407	01/07/2013			2.00
Primary Control	5983545	01/12/2013			6.00
Clinical Control	5973576	01/12/2013			5.00
23mg Creatinine Control	5981788	01/02/2013			1.00
Select Control	5987923	01/12/2013			1.00
300 Alcohol Control	5986332	01/09/2015			13.00
REAGENTS	Lot No.	Expiry Date	Pres. Rx	Pres. date	QUANTITY
Benzodiazepine Reagent	59815742	01/02/2015			6.00
6-Amer Reagent	59845729	01/02/2014			6.00

Figure 4.25: Inventory Manager Report – Inventory Stock Details

5: Process 5: The Inventory Manager Module in Labware LIMS has been programmed with an alerting system. This alerting system opens an alert window if stock is nearing expiration date or if stock is out of date. The new Inventory Manager alerting system should prevent out of date stock being used in an analyser as all stock must be accounted for before it is taken out of storage. By alerting the Biochemist to stock nearing expiration, allows the Biochemist to order and replace stock before it ever reaches its expiry date (Figure 4.26).

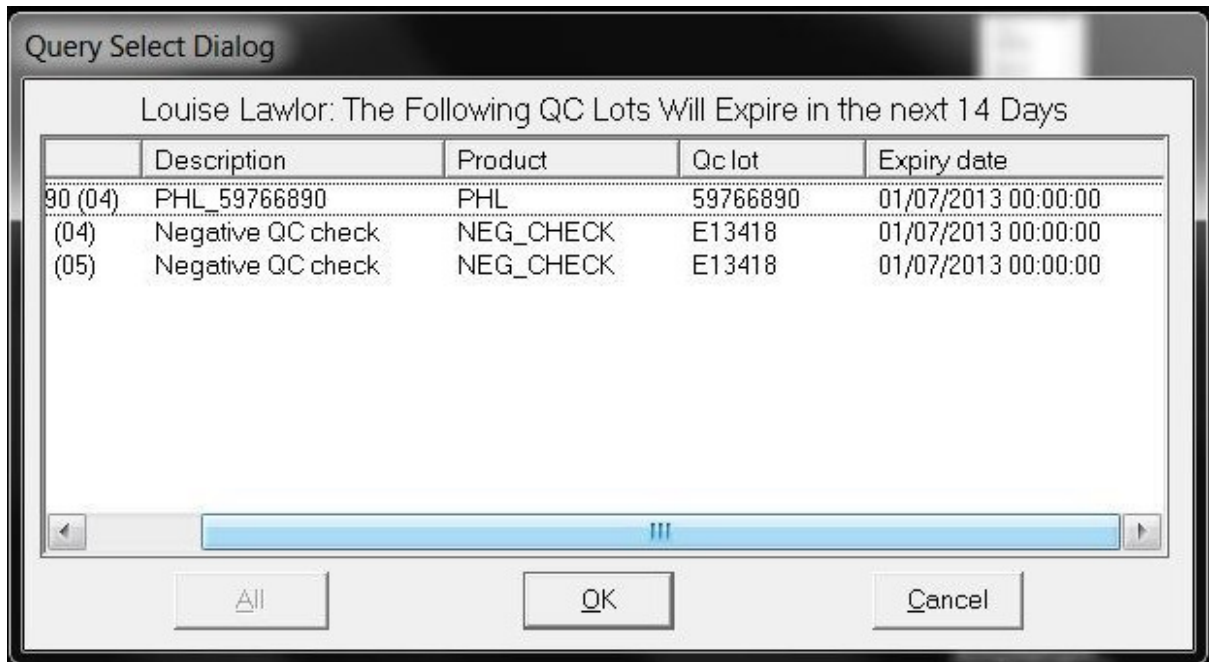


Figure 4.26: Alerting System within the Inventory Manager Module

The inventory stock taking is no longer required because the usage of all stock is now tracked electronically, the inventory stock taking each month could take up to two days and could require several members of the Laboratory staff to assist with the audit. The process of stock tracking is now recorded in real time as the stock is taken from storage and there is no longer a requirement to have a monthly inventory stock take.

4.8.5 Control: Stock Tracking and Reporting Process

This project was deployed to the Test environment on the 15/04/2013 for initial testing and monitoring. When testing was completed it was then deployed to the Production environment on the 10/05/2013. The temporary Microsoft (MS) Excel spreadsheet used during the monthly stock taking was replaced by the Labware LIMS Inventory Manager Module and all data was entered directly into Labware LIMS. The CF3 form is now stored electronically and is no longer required to be printed off and stored offsite.

The new Inventory Manager will be improved upon to give real time details of all stock usage before September 2013. A statistical Analysis section will be added to the Inventory Manager module to Analysis the usage of different types of stock and a Clinical Decision Support System (CDSS) will be used to predict the requirements for stock inventory based on past usage, these changes are currently being tested in the Phase II Process 6 (Controlled Drug Tracking) were they will also be used.

It is envisioned that once such systems are in place the task of inventory management may be out sourced to the supplies and finance department of the NDTC, freeing up Biochemists to do scientific work and reducing their current administrative duties.

4.9 Conclusions

This concludes Phase I of the LSS process improvement project; all process development improvements have been fully deployed to production and will continuously be improved upon as part of the quality improvement mechanisms of the Control stage of LSS. Phase II of the LSS process improvement project started in August 2013 and is expected to be completed in January 2014, the define stage for the processes in Phase II have been included in Appendix I.

Chapter Five: Results and Analysis

5.1. Introduction

The goal of this Results and Analysis Chapter is to evaluate and measure where possible, the outputs before and after the LSS interventions. In this section of the Dissertation the aim is to analyse the data formalised in Chapter 4, and see if these process changes achieve the objectives of the customer and the project team as discussed in Chapter 1.

This Chapter will measure comparisons, in particular, between the reductions in time the processes take to complete, costs of creating reports and the offsite storing of paper records as compared to storing the information electronically. The reduction in transcription errors, these were measured against the number of transcription errors previously recorded for non-conformance purposes. A review of the process changes made for quality control and accreditation purposes was likewise conducted.

The measurement of usability, accessibility, and audit-ability from the end-users perspective is an important element of any LSS project. Labware LIMS now has replaced several manual processes, it records who created/edited forms, reports and other system changes. User feedback on the impact that these changes have made for accreditation purposes and for tracking transcription errors were addressed by conducting non-structured interviews with the Senior Laboratory Team responsible for quality control and the production environment.

To assess the level of user satisfaction and user acceptance, a questionnaire was designed. The questionnaire asked all the Laboratory staff, to rate their level of satisfaction with the LSS strategy used and their impression of the LSS process changes. The questionnaire also asked have the initiatives deployed in Phase I of the "Improving the Specimen Sample Process Flow" aided the Laboratory team in maintaining their targets, even with the staff shortages and an increase in the number of specimen sample test requests and has morale improved because of the changes.

5.2 Factors that Influenced using Lean Six Sigma

5.2.1 Laboratory Quality Control Management Methodologies

The QC used to validate that an instrument is operating within design parameters should likewise indicate that the results produced are reliable (QCNet, 2008).

The main requirements of a Laboratory QC system are that the system is documented, understood by the people using it, that it is reliable and supports continuous improvement. The Laboratory as an entity should consist as a total system and not a series of activities and

uncoordinated processes. A quality system should be seen as a total system that can be subjected to review and audits both internal and external (Badrack, 2008).

A QC product used in a Laboratory for validation can be a liquid or a freeze-dried material and is made up of one or more analytes/drugs of a known concentration and is usually tested the same as specimen samples. QCs are run on a regular basis because a test system can fail or begin to malfunction anytime since the last QC was run (QCNet, 2008).

Quality Control (QC) Statistical Analysis

The QC statistics most commonly used by a Laboratory are the Mean [\bar{x}] and the Standard Deviation [s]. The Mean or average is the best estimate of the value of an analyte used for that control. The Standard Deviation provides an estimate of the consistency of the test and the Standard Deviation can also be used to monitor daily performance.

Westgard Rules

Dr James Westgard published an article on Laboratory QC in 1981, this was based on principles in statistical control used in industry, and this article became the basis for QC statistical Analysis in laboratories. It was based on six rules (Table 5.1) which can be used individually or in combination to determine the quality of an analytical run and are known as the Westgard Rules (Westgard, et al., 1981). Several Westgard rules are currently used in the NDTC Laboratory (Rule 1_{2s}, Rule 1_{3s}) see Table 5.1 below and NWA is used to monitor these.

WESTGARD RULES	
Rule 1 _{2s}	This is a warning rule that is violated when a single control observation is outside the $\pm 2s$ (Standard Deviations) limits.
Rule 1 _{3s}	This rule identifies unacceptable random error or possibly the beginning of a large systematic error. Any QC result outside $\pm 3s$ violates this rule.
Rule 2 _{2s}	This rule identifies systematic error only. The criteria for violation of this rule are: <ul style="list-style-type: none"> • Two consecutive QC results • Greater than $\pm 2s$ • On the same side of the mean
Rule R _{4s}	This rule identifies random error only, and is applied only within the current run. If there is at least a 4s difference between control values within a single run, the rule is violated for random error.
Rule 3 _{1s}	The criteria which must be met to violate this rule are: <ul style="list-style-type: none"> • Three consecutive results • Greater than 1s • On the same side of the mean
Rule 4 _{1s}	The criteria which must be met to violate this rule are: <ul style="list-style-type: none"> • Four consecutive results • Greater than 1s • On the same side of the mean

Table 5.1: The Six Basic Westgard Rules (QCNet, 2008)

5.2.2 Stakeholder Involvement

The reason for applying a BPMS in the NDTC was driven by the Voice of the Customer (VTC), and helping the customer (in this instance the customer was the Senior Laboratory Team) identify where significant improvements can be made to the Laboratory specimen sample Value Stream. The customer's specified areas where improvements to process flow could be made and also identified problem areas within the processes where possible changes could be of significant importance.

The moratorium on recruitment of new staff which was implemented under the Public Service Agreement 2010-2014 (Croke Park Agreement) has meant no new or replacement staff are recruited when staff leave, take career breaks or go on maternity leave, which has put increased pressure on the Laboratory team who are required to do more work, with less staff.

In May 2013 for example there were 3 members of staff on maternity leave, 1 member of staff on 3 weeks annual leave, and 1 member of the Laboratory Team on a 1 year career break from a total of 12 permanent staff.

5.2.3 Resistance to change

Resistance to change was a factor that was not anticipated at the beginning of this LSS project, as the initial interviews were with the Senior Laboratory Team and they were open to change, this did cause minor delays when implementing some changes.

Atkinson, 2013 claims that research in organisational development show that 90 per cent of cultural change programmes fail to reach or maintain their goals. Likewise new organisational changes resulting from mergers or acquisition have poor success rates with between 56 – 70 per cent failing to achieve the objectives they initially planned for, stating that the main reason for failure was resistance to cultural change (Atkinson, 2013).

Although there was very little resistance to change encountered, the adoption of some positive strategies had to be enacted to ensure that the resistance to change did not become an issue.

- Communication with the entire Laboratory team was vital. All the process changes were explained that were to be deployed and the expectations of the positive impact that would be achieved once these changes were fully implemented. Explaining what the impact of some of these changes would have on an individual basis and listening to their ideas gave them a sense of being part of the project.

- Another strategy utilised where possible resistance to change could have been an issue was to have the Laboratory team members who were committed to the success of the project, carry out the initial testing and let them find potential flaws. Once these risks had all been eliminated, the LSS intervention was put into production and ran in parallel with the old process.
- Once the process was bedded down in the production environment and was working within design parameters, the Standard Operating Procedure (SOP) documentation was created on how the system is intended to operate. The LSS intervention was presented to all the members of the Laboratory Team. If staff members had any reservations these were addressed by demonstrating that the system was already working in production.

It was important to understand that the initial reaction to change for many people is to personalise it “How will this affect me?”, “Will I be able to use the new system?”, and this should be taken into account when deploying new changes (Atkinson, 2013).

5.2.4 Legal Requirements

The NDTC Laboratory is required to obtain a controlled drug license and a license for precursor chemicals. To obtain a controlled Drugs license the NDTC are required to demonstrate compliance to the requirements for security, storage, and documentation, as set out in the regulations of the Misuse of Drugs Acts 1977 and 1984. The system and process changes adopted during this LSS project were conducted in compliance to this legislation and the process changes in both the production and the test environments were audited by INAB on the 23rd of May 2013 and where found to be compliant with Laboratory best practice.

5.3 Analysis of Results

5.3.1 Process 1: TF4 Form used to Record Specimen Sample Reference logs

This process involved changing from a batch system which relied on a process lifecycle of three trays (150 specimen samples) to be analysed before the final stage of the process could be completed and reports sent to the NDTC customer. The Sample Reference Log process lifecycle before LSS Intervention (Figure 5.1) took up to 160 Minutes to complete.

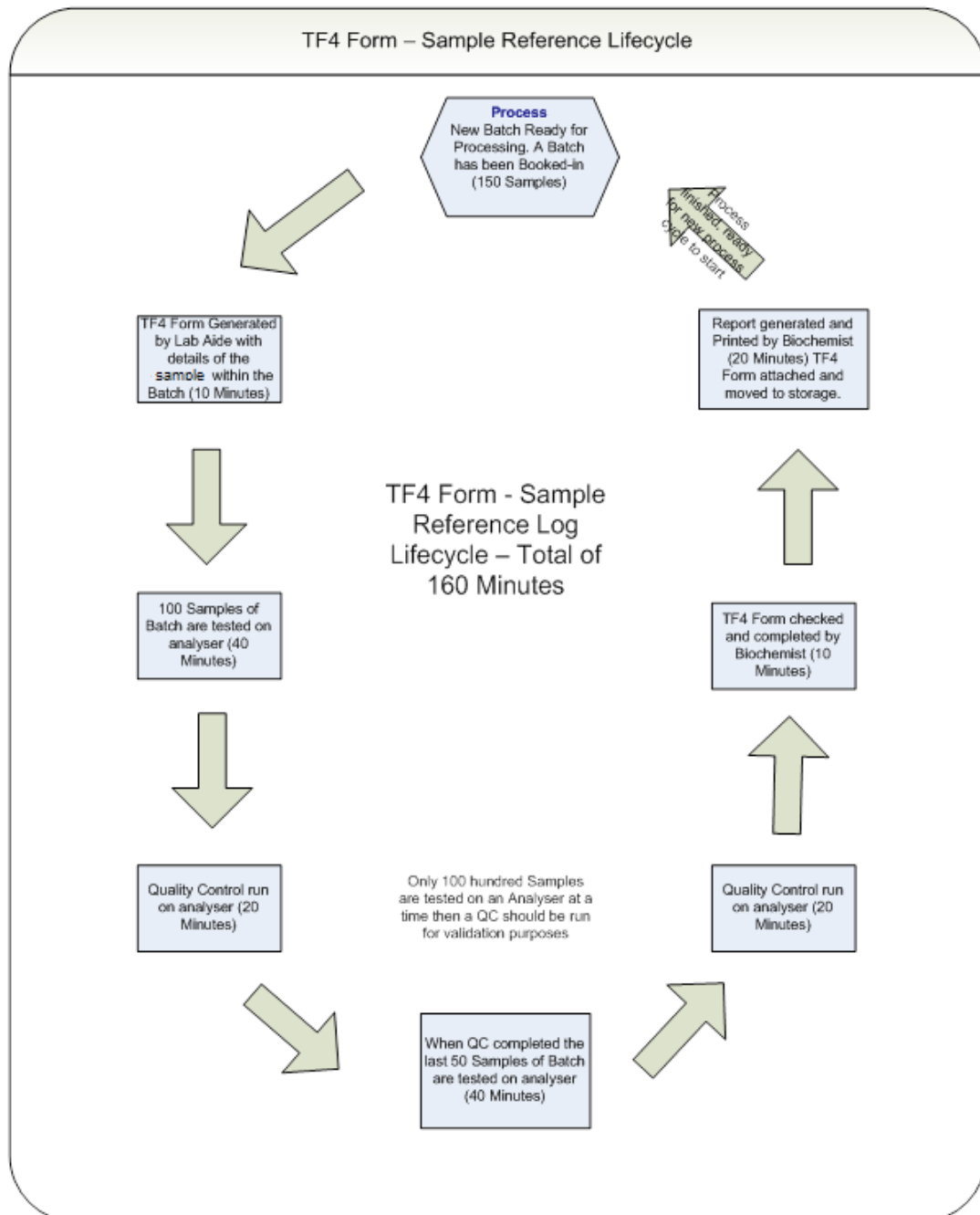


Figure 5.1: TF4 Form – Sample Reference Log Lifecycle

The new LSS intervention changed from the traditional batch process lifecycle to a tray system. This change removed unnecessary waste, by eliminating the time spent waiting for a batch to complete before results could be reported to customers. Test result reports can be reported now once a tray has been analysed. The new Sample Reference Log (Figure 5.2) process lifecycle takes 80 minutes to complete, a reduction in time of 50%.

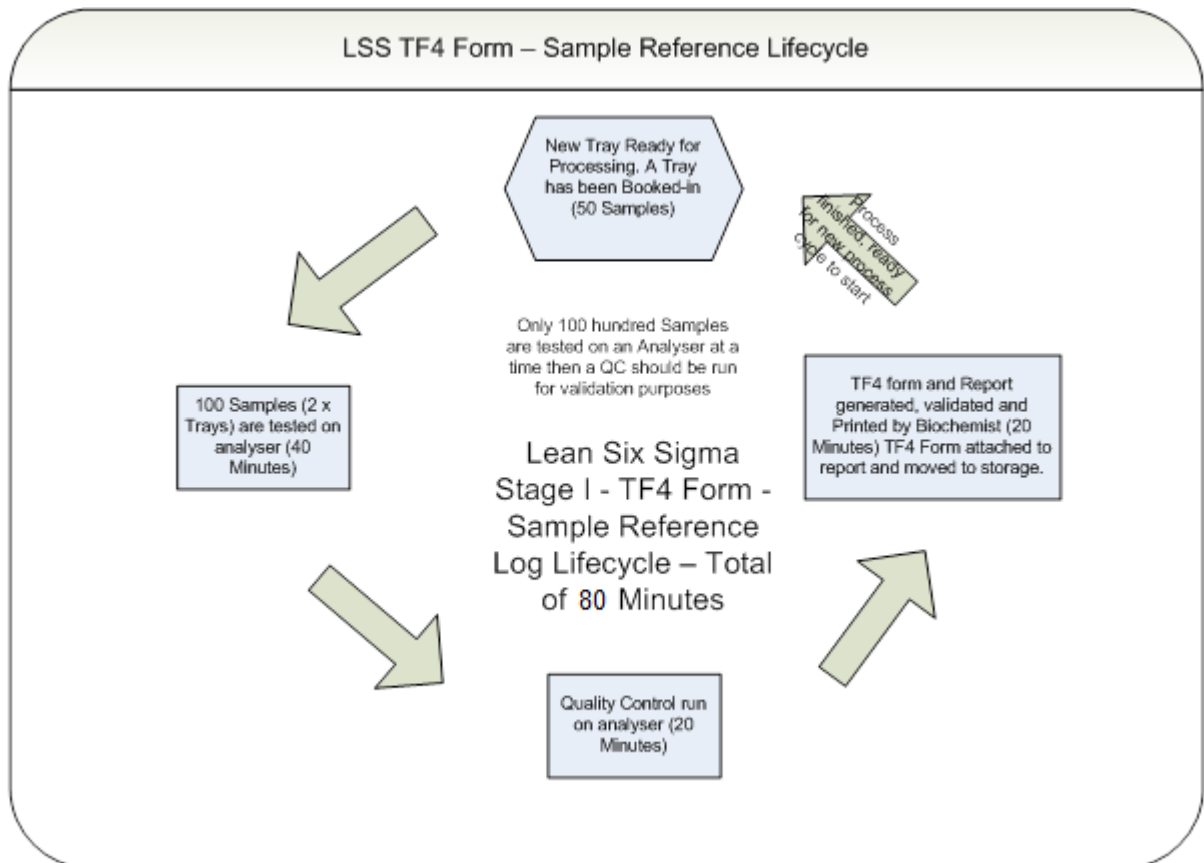


Figure 5.2: TF4 Form – New Sample Reference Log Lifecycle

In the previous batch system process, the information recorded in the Sample Reference Logs (TF4 forms) was entered manually by the Lab Aides after the book-in process was completed. Because the information was entered manually there was always a risk of transcription errors occurring. The Sample Reference Logs (TF4 forms) were then checked visually by the Biochemists. There was always a risk of errors not being identified by the Biochemists during validation, which in turn has led to reports being sent to customers with errors.

The new Labware LIMS module implemented as part of the LSS intervention generates the completed Sample Reference Logs (TF4 forms) which are then completed by a Biochemist which has eliminated transcription errors in this process.

5.3.2 Process 2: The Sample Disposal Log

Initially a request was made by the Senior Laboratory Team to design an application or develop a module in Labware LIMS that could help them effectively manage the process of recording and tracking analysed specimen samples which were queued for disposal. A urine specimen sample is classed as being valid for testing purposes for up to two weeks after the specimen sample has been received.

The changes made to the new Labware LIMS module implemented as part of the LSS improvements for Process 1, allowed the Lab Aides to use Labware LIMS to track each tray through the Laboratory. This process is now part of the Book-in lifecycle of Process 1 and required no further development, this is common in Lean projects where wasteful processes are identified and removed from the Value Stream (Mayo, 2007).

5.3.3 Process 3: North West Analytical (NWA) Statistical Analysis

A NWA statistical Analysis was performed on both Olympus AU2700 analysers to compare the QC updates for primary QC low and the primary QC high for both analysers. A comparison NWA statistical Analysis was conducted on two different processes, one before the LSS intervention and one using the LSS intervention. The test was conducted for the primary QC for both low and high on both analysers.

Test one was completed on the analysers using the Standard Operating Procedure (SOP) used in the Laboratory without the LSS intervention. Test two was completed after the using the LSS intervention on the NWA process.

The purpose of the testing was to validate that the data produced by both systems produced the same statistical Analysis results and that the new automatic updating system was working correctly within design parameters. Secondly the testing was conducted to verify the process time of each process system (Figure 5.3), that is the before LSS intervention (manual process) and the after LSS intervention (automatic process). The Bar Chart below shows the time savings with the new LSS intervention, a saving of 13:44 Minutes (approximately 50% reduction in process time).

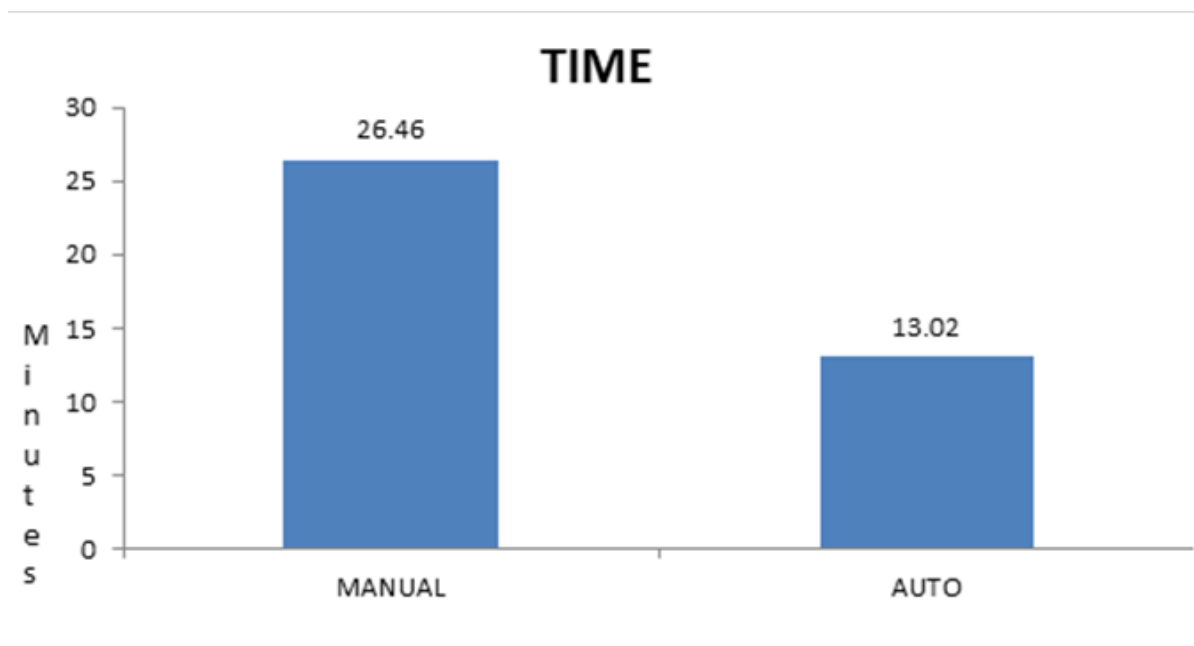


Figure 5.3: The two NWA processes, MANUAL was before LSS intervention and AUTO was after LSS intervention

5.3.4 Process 4: Electronic Reporting Section

Directly generating and storing the client reports electronically has had significant performance improvements for the Result Reporting Process (Table 5.2).

Timings for Reporting

Report Type	Old system	New System
Fax & POST	26 minutes	16 minutes
DAIS	20 minutes	12 minutes
LER	20 minutes	8 minutes

Table 5.2: The amount of time taken to generate and send a set of reports for the Client Result Reporting Process

A full cost Analysis was conducted and the details of these findings are outlined in section 5.5 Cost and Benefits below.

5.3.5 Process 5: Stock Tracking and Reporting Process

This LSS intervention was a quality process improvement initiative focusing at improving the quality assurance systems within the Laboratory and not necessarily the performance time of the stock tracking and reporting process, this process change was required for accreditation purposes. INAB had highlighted that stock control systems must now be fully auditable and that if changes were not made to the current process this would lead to a non-conformance and needed to be corrected before the next INAB audit in May 2013.

The previous manual Stock Tracking and Reporting process was based on a manual monthly stock taking protocol and this was replaced with a newly developed module for Labware LIMS which tracks all the Laboratory stock for certain reagents, QCs and calibrators in real time, and alerts the Laboratory team when stock is nearing its expiration date. This allows the Biochemist plenty of time to replenish supplies. This system was designed to help prevent Laboratory staff from inadvertently using expired stock.

There have been instances where expired stock had been used in an analyser and all the specimen samples had to be retested, likewise, instances have occurred where stock has not been available for an analyser for several days, and this analyser was offline while new stock was purchased. These types of incidents occur very rarely and would therefore not make the basis for a reasonable quantifiable Analysis study.

5.3.6 Specimen Samples Processed in 2012

The total amount of specimen sample requests received by the NDTC Laboratory in 2012 was 134,871 (Table 5.3), with an average of 11,239 samples processed per month for the year 2012.

Year	Month	Samples Received
2012	JAN	10223
2012	FEB	9253
2012	MAR	10086
2012	APR	8760
2012	MAY	10353
2012	JUN	9718
2012	JUL	11202
Subtotal	Total for Jan - July	69,595
2012	AUG	13065
2012	SEP	11438
2012	OCT	14085
2012	NOV	15054
2012	DEC	11634
2012	Total for 2012	134,871

Table 5.3: The amount of Specimen Samples received for 2012

5.3.7 Specimen Samples Processed in 2013

The amount of specimen sample requests received by the Laboratory for 2013 (January to July) was 108,168 (Table 5.4) and the average amount of samples per month was 15,452. Compared to 2012 (January to July) the Laboratory received 69,595 specimen sample requests, and the average amount of specimen samples per month was 9,942 (Table 5.3). This shows that in 2013 there has been an increase of 37.49% in the average amount of samples received per month for the periods January to July.

The NDTC took over the contract for all HSE specimen samples in October 2012; this has led to an average increase of 47.80% (Figure 5.4) since October 2012 in specimen sample requests received by the NDTC. No extra resources other than the LSS interventions have been made available to cope with the increased demand.

year	Month	Samples received
2013	JAN	17224
2013	FEB	15175
2013	MAR	14472
2013	APR	16429
2013	MAY	16993
2013	JUN	12792
2013	JUL	15083
2013	AUG	
2013	SEP	
2013	OCT	
2013	NOV	
2013	DEC	
2013	Total	108168

Table 5.4: The amount of Specimen Samples processed to date for 2013

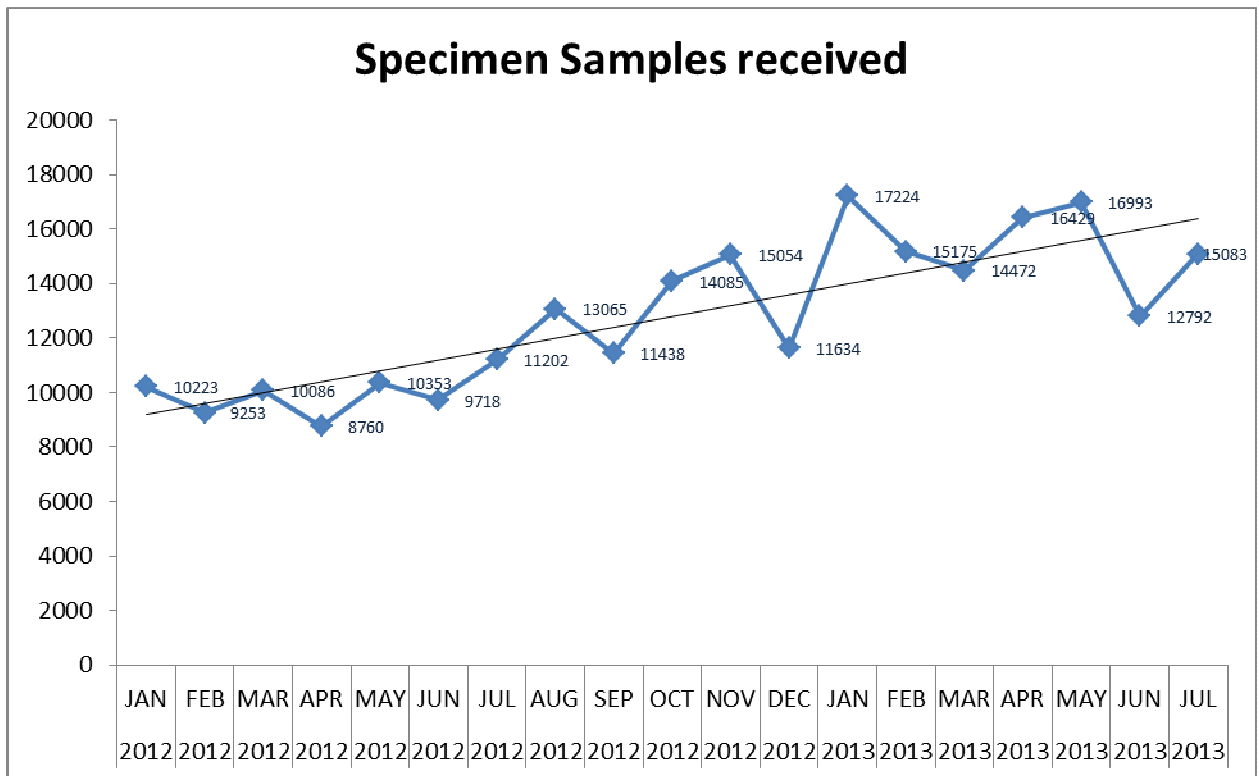


Figure 5.4: Samples received by the NDTC Laboratory in 2012 and 2013

5.3.8 Turnaround Times (TAT)

The Service Level Agreement (SLA) that the NDTC aspire to is a TAT of 48 hours. This time also includes weekends and out of hours (17:30 – 08:30 when the NDTC is closed) and may not be a true reflection of the TAT in terms of the amount of time a specimen sample spends in the NDTC Laboratory actively being processed. The TAT was classed as a non-conformance by INAB during a recent audit and it was suggested that the NDTC Laboratory should consider changing the TAT as “48 hours was not realistic with the current staffing levels”. The TAT is currently being revised as part of Phase II of this project and changes to the NDTC SLA and to how the TAT is calculated will be implemented in August 2013.

The TAT is recorded in two different stages within the NDTC Laboratory, and then the two stages are added together to create the total TAT for the specimen sample.

- The Lab Aide Stage is calculated from when a specimen sample is received and ends when the specimen sample is Booked-in to Labware LIMS.
- The Biochemist Stage is calculated from the when the specimen sample is Booked-in to Labware LIMS and ends when the results are reported.

The TAT for the available data for 2012 (Table 5.5) shows that a total of 134,871 specimen samples were processed in the Laboratory, with an average TAT of 35.17 hours per specimen sample.

WEEK	LAB AIDE	BIOCHEMIST	TAT
01/01/2012	22.11	21.87	34.38
09/01/2012	20.63	17.02	38.35
16/01/2012	20.5	29.38	51.23
23/01/2012	22.47	14.28	36.15
30/01/2012	21.48	15.7	36.97
06/02/2012	21.22	12.21	34.97
13/02/2012	19.78	12.3	32.11
20/02/2012	15.88	10.28	22.49
27/02/2012	n/a	n/a	n/a
05/03/2012	n/a	n/a	n/a
12/03/2012	n/a	n/a	n/a
19/03/2012	n/a	n/a	n/a
26/03/2012	n/a	n/a	n/a
02/04/2012	n/a	n/a	n/a
09/04/2012	n/a	n/a	n/a
16/04/2012	n/a	n/a	n/a
23/04/2012	21.98	15.27	38.16
30/04/2012	25.36	13.59	40.14
07/05/2012	23.96	20.3	44.89
14/05/2012	18.95	15.68	36.14
21/05/2012	20.27	16	37.17
28/05/2012	25.94	20.24	46.2
04/06/2012	20.15	13.75	27.76
11/06/2012	15.57	19.5	36.31
18/06/2012	11.25	23.27	35.09
25/06/2012	15.79	30.28	46.81
02/07/2012	18.98	22.96	35.47
09/07/2012	17.09	36.28	54.09
16/07/2012	19.63	14.99	31.88
23/07/2012	19.42	20.02	31.45
30/07/2012	22.35	11.36	35.28
Average for Jan - July	20.03	18.54	37.54
06/08/2012	13.03	28.2	41.93
13/08/2012	6.11	7.55	14.05
20/08/2012	10.07	7.61	18.01
27/08/2012	n/a	n/a	n/a
03/09/2012	15.12	10.24	26.22
10/09/2012	3.82	14.28	18.2
17/09/2012	12.54	18.88	31.91

24/09/2012	9.21	20.98	30.53
01/10/2012	7.03	11.76	19.06
08/10/2012	6.55	14.95	21.67
15/10/2012	4.53	15.21	19.44
22/10/2012	13.4	20.27	36.36
29/10/2012	10.56	12.07	22.93
05/11/2012	15.44	19.42	31.74
12/11/2012	19.77	26.82	41.23
19/11/2012	33.43	44.32	80.41
26/11/2012	18.9	11.65	25.27
03/12/2012	13.93	8.33	19.27
10/12/2012	12.45	12.32	25.26
17/12/2012	27.23	9.87	38.29
24/12/2012	51.86	12.91	60.97
31/12/2012	28.97	42.16	61.08
Average for 2012	18.06	18.1	35.17

Table 5.5: The Turnaround Times (TAT) for the available data for 2012

The TAT for the available data up until July 2013 shows that a total of 108,168 specimen samples (Table 5.4) were received in the Laboratory with an average TAT of 55.52 hours per specimen sample (Table 5.6). In comparison to the same period in 2012 (January 2012 – July 2012) where there was a total of 69,595 specimen samples received (Table 5.3) with an average TAT (from the available data for 2012) of 37.54 hours per specimen sample (Table 5.5).

Although this reflects a 44.48% increase in the TAT for 2013, when it is taken in the context that the amount of specimen samples received has increased by 38.75%, the amount of downtime in the first half of the year due to ICT system changes (Figure 5.5) and the NDTC Laboratory were down 33% of their fulltime staff (from 12 to 8 members of staff during most of this period) it is not a true reflection of the TAT for 2013.

The last LSS Phase I interventions went into production in June 2013, by comparing Figures from June 2013 to July 2013 with figures from the same period in 2012, it can be seen in Table 5.11 below that there was a decrease in the average TAT for these two months of .11(0.3%).

WEEK	LAB AIDE	BIOCHEMIST	TAT
07/01/2013	18.38	13.51	32.85
14/01/2013	25.04	17.3	42.98
21/01/2013	33.98	19.53	54.57
28/01/2013	46.89	29.94	78.29
04/02/2013	82.03	14.84	100.62
11/02/2013	64.21	21.19	88.29
18/02/2013	35.04	22.24	58.22
25/02/2013	23.81	10.85	35.32
04/03/2013	15.96	12.67	27.61
11/03/2013	64.01	33.47	98.02
18/03/2013	51.35	7.4	59.78
25/03/2013	75.56	6.64	85
02/04/2013	64.38	12.85	77.36
08/04/2013	38.17	21.88	60.96
15/04/2013	19.06	20.28	39.88
22/04/2013	23.38	46.31	69.61
29/04/2013	27.09	84.89	112.3
06/05/2013	20.8	22.91	44.48
13/05/2013	24.6	32.09	56.05
20/05/2013	12.47	31.17	44.04
27/05/2013	20.22	25.63	45.76
04/06/2013	42.88	22.93	65.4
10/06/2013	14.69	30.83	45.59
17/06/2013	13.93	8.65	23.18
24/06/2013	9.8	13.01	22.57
01/07/2013	19.84	15.09	35.63
08/07/2013	13.41	17.74	31.26
15/07/2013	22.32	22.81	45.17
22/07/2013	20.07	10.09	29.16
Average for 2013	32.53	22.37	55.52

Table 5.6: The Turnaround Times (TAT) for the available data for 2013

A factor which should be considered when analysing the figures for 2013 is the impact of ICT system downtime has had on the Laboratory due to development, testing, and deployment of the new Laboratory Virtual Server environment. The Virtual Server project started in January 2013 and the final phase of deployment was finished in May 2013. The LSS Interventions were deployed to production between the end of May 2013 and June 2013. In June 2013 the TAT started to reflect a positive change (Figure 5.5).

The Line Chart in Figure 5.5 below shows the average TAT in hours per specimen sample request for each week from week beginning 07th of January 2013 to week ending the 22nd of July 2013 and is

indicated by the green line on the chart. The blue line on the chart represents the Lab Aides time spent on the Specimen Sample process flow and is measured from when a specimen sample is delivered into the Laboratory to the time when it is booked-in. The red line on the chart represents the Biochemists time spent on the specimen sample process flow and the TAT for their part of the process which is measured from when a specimen sample is booked-in until the result is validated and sent to the customer.

The peaks on the Line Chart for specimen sample TAT below (Figure 5.5) highlight the effects that ICT downtime and staff shortages have had on the TAT for the first six months of 2013.

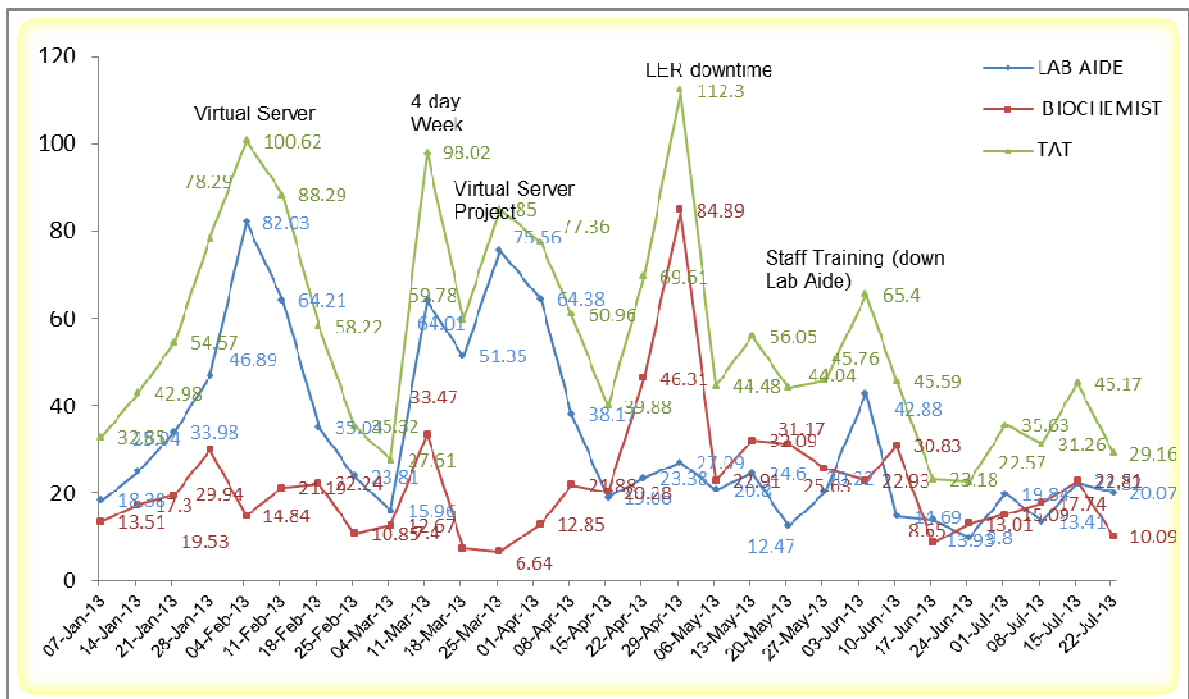


Figure 5.5: Factors Effecting Laboratory Turnaround Times (TAT)

5.3.9 Laboratory Transcription Errors

There have been 220 Transcription errors in the Laboratory between January 2012 and July 2013, of these 35 have been in relation to the processes in Phase I (Table 5.7) that were changed as part of the LSS project. Since the deployment of the LSS there have been no transcription errors with any of the processes in phase I of the LSS project.

Non Conformances	Batch Removal	Sample Disposal Log	Electronic Report	Inventory	NWA
Jan - Dec 2012	12	1	7	5	6
Jan - May 2013	2	0	1	0	1
Total	14	1	8	5	7

Table 5.7: Transcription errors in the Phase I Processes before LSS

Keeping in line with the LSS methodology of reducing waste and divergence, the processes were changed where possible from manual human entry systems to automated systems, for example the NWA statistical analysis calculations are in most part completed by Labware LIMS and in the Record Specimen Sample Logs process the TF4 form is now generated and populated by Labware LIMS. Human error is a complex subject to understand and there are several factors that should be considered when designing and implementing technology solutions (Woods, 2010). In his book *Behind Human Error*, Woods, 2010, states that the “clumsy use of computer technology” can increase the potential for human error.

5.4 User Acceptance Analysis

To access the level of user acceptance a triangulated approach was used during Phase I of the LSS Project, this consisted of interviews with the senior members of the Laboratory team, development of new process interventions and user feedback on the project in the form of a questionnaire.

The interview stage involved taking note of the Senior Laboratory Team’s comments and suggests, the building of prototype process systems and refining these systems based on user feedback. These systems, once they were refined, were later deployed to production. To complete the assessment of user acceptance and involvement, a Questionnaire was designed around gauging the level of satisfaction the Laboratory team had with the new changes to the specimen sample process flow and if they were satisfied that the LSS interventions had enabled them to manage the burden of having to process extra samples with a reduced team. The Questionnaire looked at how the Laboratory teams rated the level of morale within the Laboratory since the LSS interventions where implemented.

A series of non-structured closing interviews were also conducted with the Senior Laboratory Team to ascertain if the changes made during Phase I had met their expectations and needs, as outlined in the initial interviews that were conducted before and during the Phase I of the LSS Project.

5.4.1 Questionnaire

The questionnaire was comprised of ten Likert-like questions based on the premise of user satisfaction and following Bertram’s, 2006, guide on how to use a questionnaire using the Likert scale to analyse ordinal data. Although the Likert Scale is a highly reliable scale, there are some drawbacks with using it. Respondents may agree with questions in order to please the person conducting the study. There is the possibility that respondents will avoid using extreme responses and they may not be honest with their responses (Bertram, 2006). The questionnaire included two open ended questions allowing the users to add addition comments or suggest alternative areas of improvement (see Appendix XI).

The analysis of the data from the questionnaire was compiled using R, a language and environment for statistical computing (r-project.org, 2013). A Chi-Squared test was carried out on the data and the calculated P values were correlated using the R application to a probability of less than 0.05 (Appendix XII) indicating that the observed data is not significantly different (Higgins, Green, 2011).

Questions one to three were concerned with the participant's impression of how the LSS interventions were implemented and how they adapted to the change (Figure 5.6). Question four measured the usability of the new process changes (Figure 5.7). Questions five through seven measured the participant's satisfaction with the potential benefits the improvements made to the process flow (Figure 5.8) and questions eight to ten measured how the participant's felt the changes had impacted on the existing issues within the Laboratory, in relation to staffing, workload, and morale (Figure 5.9). Questions eleven and twelve were open ended questions and allowed the participant's to make suggestions of how LSS could be used elsewhere in the Laboratory and any addition comments the user wished to make (Table 5.8).

	Overall how would you rate your level of Satisfaction with...	Very Low	Low	Neither Low nor High	High	Very High	Median	Responses
Q1	...the levels of communication during the implementation phase of the Lean Six Sigma interventions?	0% (0)	0% (0)	25% (3)	66.6% (8)	8.4% (1)	1	12
Q2	...how the transition from the old system to the new system was implemented?	0% (0)	0% (0)	25% (3)	50% (6)	25% (3)	3	12
Q3	...your transition of moving from the old system to the new system?	0% (0)	0% (0)	25% (3)	41.7% (5)	33.3% (4)	3	12
Q4	...the usability of the new process changes?	0% (0)	0% (0)	0% (0)	58.3% (7)	41.7% (5)	0	12
Q5	...the reduction in the amount of transcriptions errors?	0% (0)	0% (0)	9.1% (1)	72.7% (8)	18.2% (2)	1	11
Q6	...the amount of time saving these enhancements have had on how you perform your daily tasks?	0% (0)	0% (0)	0% (0)	41.7% (5)	58.3% (7)	0	12
Q7	...the audit-ability of the new enhancements in relation to accreditation and the ISO 17025 standard?	0% (0)	0% (0)	16.7% (2)	66.6% (8)	16.7% (2)	2	12
Q8	...how the new process changes have helped working with reduced levels of staff?	8.4% (1)	8.3% (1)	16.7% (2)	66.6% (8)	0% (0)	1	12
Q9	...the new process changes in relation to coping with the extra specimen samples the Laboratory receives?	0% (0)	9.1% (1)	9.1% (1)	54.5% (6)	27.3% (3)	1	11
Q10	...the levels of staff morale since the new process changes have been deployed?	0% (0)	0% (0)	58.3% (7)	41.7% (5)	0% (0)	0	12
Q11	Would there be a benefit for Lean Six Sigma interventions in other areas of the Laboratory?	No 16.7% (2)	Yes 83.3% (10)				6	12

Table 5.8: Questionnaire Data Analysis

The questionnaire was conducted in August 2013 and included a description of the LSS interventions. The questionnaire was anonymous and completely voluntary and the Laboratory team understood the questions being asked. The response rate to the questionnaire was 100% with all 12 members of the Laboratory team completing the questionnaires.

In relation to the users opinion of how Phase I of the LSS project was implemented (questions one to three), 75% of all staff rated their satisfaction as high to very high and 25% said their level of satisfaction was neither high nor low. While 23.8% of Biochemists and 20% of Lab Aides claimed their level of satisfaction was very high, in relation to the communication, the change from the old processes to the new LSS processes, and the ease in which they went from using the old process to using the new LSS processes.

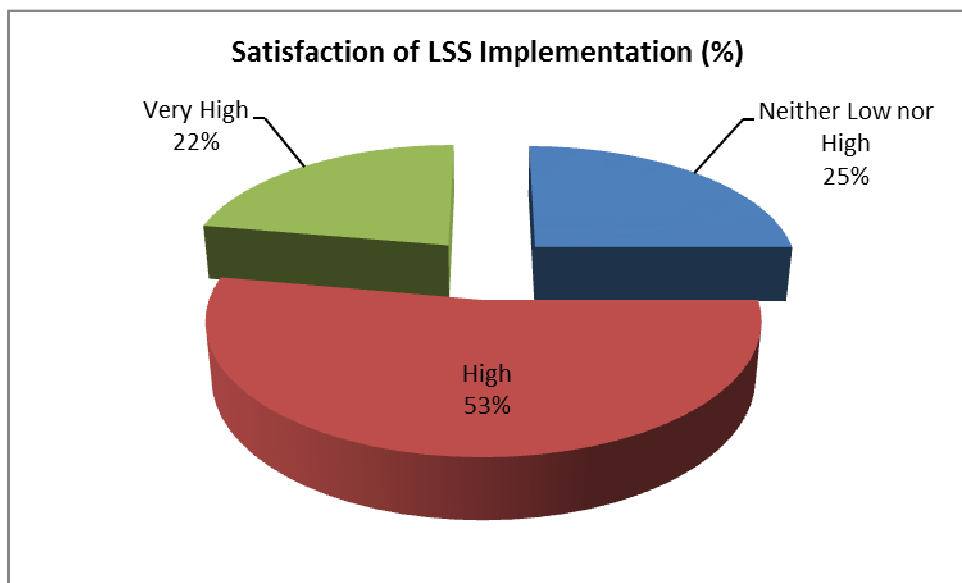


Figure 5.6: (Q1 - Q3) User satisfaction with how the LSS project was implemented (%)

Question four rated the user's level of satisfaction with the usability of the new LSS interventions, 100% of the Laboratory team rated their satisfaction as high or very high, with 42.8% of Biochemists and 40% of Lab Aides rating their satisfaction with the usability of the new processes as very high.

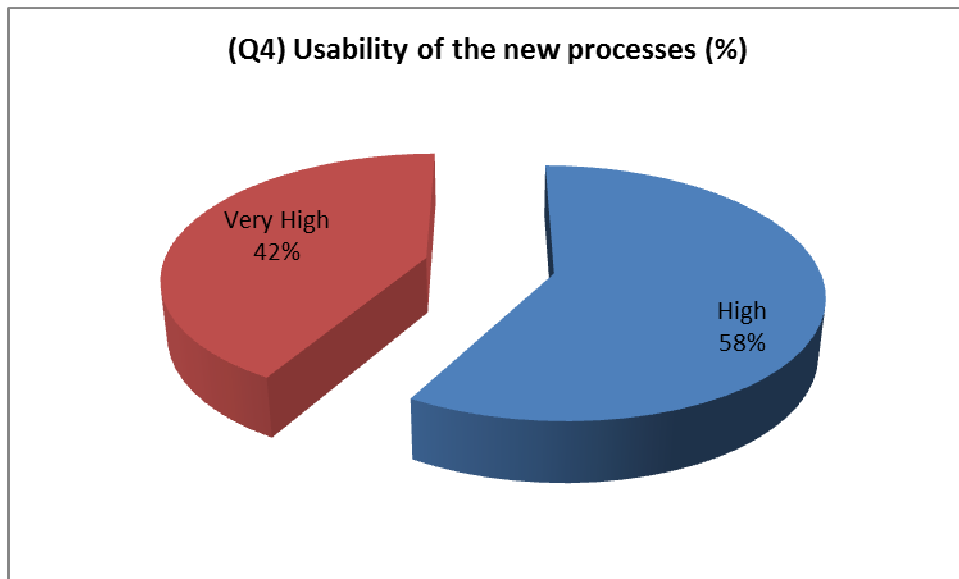


Figure 5.7: (Q4) Satisfaction with how the LSS project was implemented (%)

Questions five through seven measured the participant's satisfaction with the potential benefits the LSS process improvements may have had in relation to human error, process time and quality systems. 91% of the Laboratory team rated their satisfaction with these improvements as high or very high, with 23.8% of Biochemists and 40% of Lab Aides rating their level of satisfaction as very high (Figure 5.8).

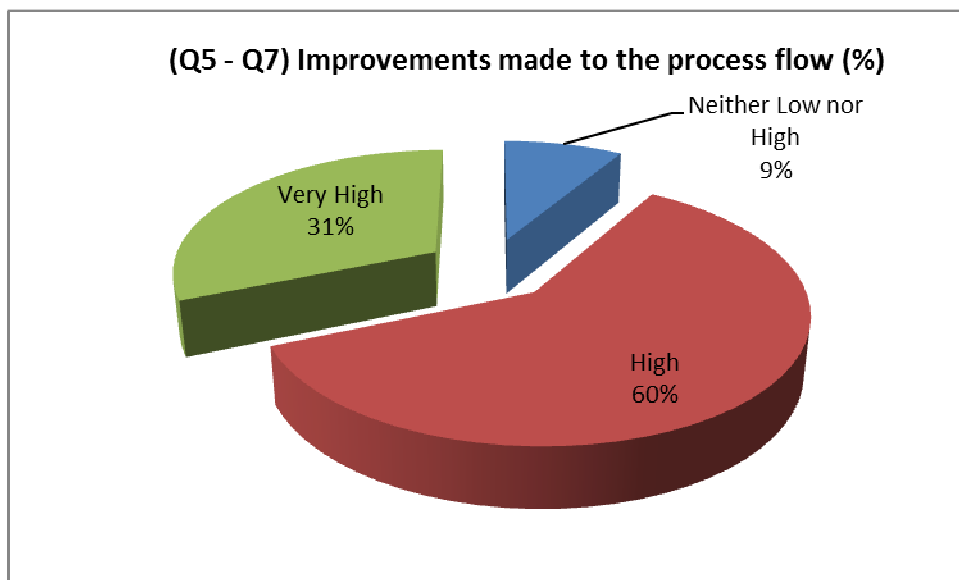


Figure 5.8: (Q5 - Q7) Satisfaction with the LSS process improvements in relation to human error, process time, and quality (%)

The final set of Likert-like questions (questions eight to ten) looked at the level of satisfaction in relation to some of the issues which had been identified in the Laboratory, staffing, the increased number of specimen samples received by the Laboratory and the level of morale of the Laboratory team after the LSS implementation. In relation to the issues in the Laboratory prior to the LSS intervention 61.1% of the Laboratory team rated their level of satisfaction as high or very high, with 4.8% of Biochemists and 13.3% of Lab Aides rating their satisfaction as very high. It is worth noting that 8.3% of the Laboratory team rated their level of satisfaction as low or very low and 27.8% rated their level of satisfaction as neither high nor low (Figure 5.9).

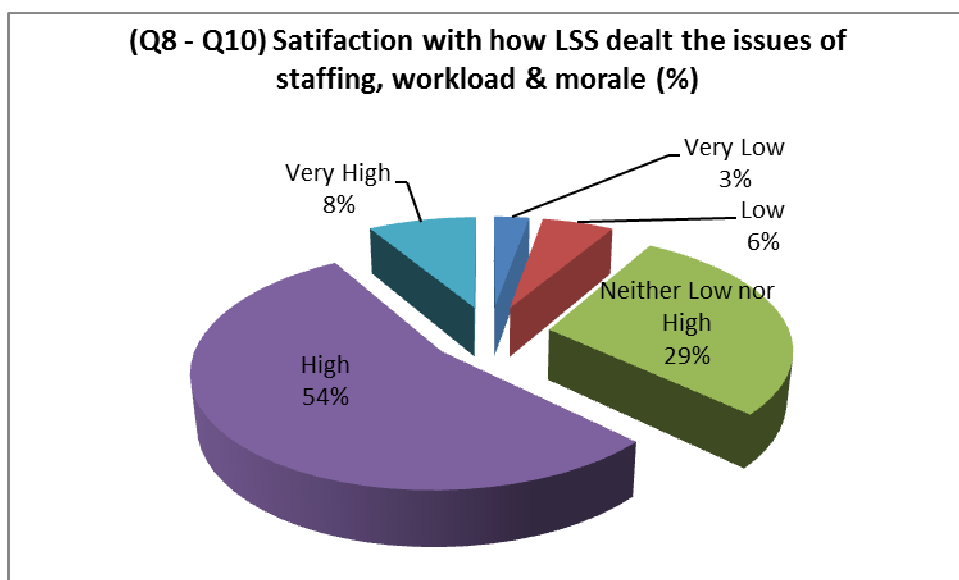


Figure 5.9: (Q8 - Q10) Satisfaction in relation to the existing issues within the Laboratory, staffing, workload, and morale (%)

On question eleven 83.3% of the Laboratory team believed that LSS interventions could be used elsewhere in the Laboratory. Some of the suggestions were in confirmatory analysis techniques, control drugs (Phase II, process 6), the stock ordering system, and the CF3 form for the reagents on AU2700 analysers.

The additional comments section (question twelve), contained some positive feedback and suggested that the systems seemed more “simplified and quicker”, “there was a good level of communication during the project”, “the improvements were positive”, “staff morale has improved slightly” and that the improvements have made “work easier”, another factor which was highlighted was “the return of staff from maternity leave”.

5.4.2 Interviews

The initial interviews with the Senior Laboratory Team provided the information needed to define the areas where significant improvement could be made and influenced the design of the proposed LSS intervention. The Senior Laboratory Team were positive about the concept and put forward the 10 scenarios where LSS could positively contribute to performance in specific areas of the Laboratory. Some of the Senior Biochemists would have been in favour of using LSS for a wider spectrum of work than was envisaged for Phase I and Phase II of this project had the resources been available.

During the course of the project some members of staff were less enthusiastic about certain LSS interventions and concerns about certain issues were raised during some of the interview sessions. Scenarios were discussed during the prototype testing and deployment stages of some of the LSS interventions, where design changes may have been useful. At the time it was deemed by the project team, that the disadvantages outweighed the advantages of implementing some of these changes at that point in the project. LSS is about constant improvement, any changes, issues or problems could always be addressed during the later Control stage of the LSS project.

The closing interviews provided mainly positive feedback, from the Senior Laboratory Team, all the team felt that the improvements had made a positive, tangible impact on the Specimen Sample Process Flow, but felt that extra resources were needed, and that the Laboratory staff were still under a lot of pressure. It was also commented that, had the LSS process changes not been in place at certain points in June, when staffing levels had been reduced even further, the Laboratory would not have been able to cope with the amount of specimen sample test requests received. The LSS had highlighted areas where new innovations could be utilised beyond Phase I and Phase II such as “electronic faxing” and “integrating the LCMS and confirmatory analysis into Labware LIMS”. The Senior Laboratory Team were positive about continuing on the work in Phase II of the LSS project.

5.5 Cost and Benefits

The costs of storage and filing of reports for the NDTC Laboratory has now been reduced substantially, if funding became available in the future the historical data which is stored offsite by the OASIS GROUP at an annual cost of approximately €3157.44 per annum (506 Boxes @ €0.52 per Month), could be scanned into the new electronic reporting system and negate the need for these services completely. The following information relates to the costs incurred for the old reporting process before the LSS intervention and most of these costs will no longer be incurred by the NDTC as of June 2013.

The NDTC store Laboratory reports which are older than six months securely offsite and use the services provided by the OASIS Group a company that specialise in the secure management and storing of both paper based and electronic data records. The OASIS Group have been accredited to the International Standards Organisation (ISO) 9001 which is the internationally recognised standard for Quality Management Systems (QMS), the ISO 27001 standard which is the international standard for Information Management Security Systems (ISMS) and the Payment Card Industry (PCI) Data Security Standard which requires the company to adherence to a set of specific security standards. The OASIS Group continually assess the integrity of their information systems and insure that they are legally compliant and achieve customer satisfaction (OASIS GROUP, 2013).

OASIS Group Pricing Services for the NDTC – Document & Management Storage

Standard Oasis Box, per Month	Rate: €0.52
Add & Track new Box	Rate: €0.75
Add & Track new File	Rate: €0.45
Handling Charge per Box or File – in/Out	Rate: €1:00
For the first 10 boxes delivered/collected	Rate: €8.00
Each additional box/file	Rate: €1.00
Special Delivery – Within 3 hours	Rate: €35:00
Out of Office Hours Delivery	Rate: €60:00
Weekend/Bank Holiday Delivery	Rate: €80:00
OASIS Standard Archive Box	Rate: €2:50

(Delivery/Collection 08:30hrs to 17:00hrs) Copy of original pricing quote can be found in Appendices X and all prices exclude Value Added Tax (VAT).

5.5.1 Costs of Consumables for Laboratory Reporting

The consumables used in the Laboratory for the year prior to the deployment of the first LSS intervention to the production environment can be seen in Table 5.9 below. This table refers to items that are directly related to Laboratory reporting and will not be required in the same quantity in the future as the majority of reports will now be dealt with electronically.

Laboratory Reporting Expenses (excluding Posting & Faxing Costs) May 2012 to April 2013			
	Quantity	Unit Cost	Total
HP 42x ink cartridges	4	€235.00	€940.00
TN3170	3	€110.00	€330.00
Brown Folders	28	€9.80	€274.40
Box Paper	65	€25.00	€1,625.00
Box small window private and confidential envelopes	7	€30.00	€210.00
Pack Connect Plastic Pockets	4	€6.80	€27.20
A4 Envelopes window + non window	2	€43.36	€86.72
HP 78A Laserjet Print Cartridge	2	€98.00	€196.00
Box A5 Sized Envelopes	2	€11.60	€23.20
TN 2120 Ink Cartridge PLUS drum for fax/printer in main lab	4	€86.00	€344.00
Non tear envelopes	6	€86.00	€516.00
Total Costs for May 2012 to April 2013			€4,572.52

Table 5.9: The Laboratory Costs of Printing and Reporting May 2012 to April 2013

5.5.2 Evidence of Cost Benefit Analysis

The final stage of the new Electronic Reporting process went Live on the 1st of June 2013 and the full benefits of the cost saving that will benefit the NDTC will not be fully realised until 2014. The following cost Analysis based on the periods of January 2012 to December 2012 (Table 5.10) and from January 2013 to July 2013 (Table 5.9) shows the potential cost savings the NDTC will achieve.

There has been a reduction in the number of new boxes containing Laboratory reports being stored offsite, 48 new boxes in 2012 (Table 5.10) and 27 new boxes in 2013 (Table 5.11). All reports are stored electronically as of the 1st of June 2013, so no new boxes of paper reports will be created for offsite storage.

Oasis Storage Boxes 2012	Unit Cost	Quantity	Total Cost
Cost of registering on Database	0.75	48	€36.00
Refill a Box	1.00	29	€29.00
Access Box	1.00	29	€29.00
Fuel Surcharge per Journey	1.11	2	€2.22
Price of Cardboard Box	2.50	48	€120.00
Storage of Boxes (See Table 5.12)	0.52	-	€2,588.04
Delivery (First 10 x €8+ €1 per extra Box)		29	€27.00
Pickup (First 10 x €8+ €1 per extra Box)		29	€27.00
Total Costs for Oasis Storage Service 2012			€2,858.26

Table 5.10: Cost Details of Oasis Offsite Storage for 2012

A total of 29 boxes were required to be returned for the yearly INAB audit in 2012 (Table 5.10) and a total of 54 boxes were required to be returned for the yearly INAB audit in 2013 (Table 5.11).

Oasis Storage Boxes - Jan - July 2013	Unit Cost	Quantity	Total Cost
Cost of registering on Database	0.75	27	€20.25
Refill a Box	1.00	54	€54.00
Access Box	1.00	54	€54.00
Fuel Surcharge per Journey	1.11	3	€3.33
Price of Cardboard Box	2.50	27	€67.50
Storage of Boxes (See Table 5.13)	0.52	-	€1,813.76
Delivery (First 10 x €8+ €1 per extra Box)	53.00	53	€51.00
Delivery (First 10 x €8+ €1 per extra Box)	1.00	1	€8.00
Pickup (First 10 x €8+ €1 per extra Box)	54.00	54	€52.00
Total Costs for Oasis up to July (7 Months)			€2,123.84
Addition 5 Months Storage: To End of Year	0.52	2530	€1,315.60
Total Costs for Oasis Storage Service 2013			€3,439.44

Table 5.11: Cost Details of Oasis Offsite Storage for 2013

Table 5.11 is a breakdown of the costs incurred for the storage and retrieval of paper based reports up to the 31st of July 2013, there will be a further 5 months storage charge for the remaining part of 2013. The new Electronic Reporting Process will mean that there will no longer be a requirement for the storing of new paper reports offsite, as all future reports will be stored electronically.

5.6 Conclusion

The Implementation of Lean principles and Six Sigma methodologies introduces the possibility of identifying a coherent approach to continuous improvement (Pepper, Spedding, 2010) by reducing and eliminating waste. Because the time frame for measurement is short (2 months, June – July 2013, when all phase I LSS interventions were deployed) it is hard to demonstrate effectively the positive differences the LSS interventions have had on the NDTC Laboratory.

What is evident when we compare the TAT from Table 5.5 (TAT for 2012) and Table 5.6 (TAT for 2013) and the amount of specimen samples received from Table 5.2 (specimen samples for 2012) and Table 5.4 (specimen samples for 2013) for the time period the LSS interventions were deployed to production which was from the 4th of June 2013 to the 22nd of July 2013. The amount of specimen samples received by the NDTC in June and July 2013 was 27,875, an increase of 6,955. In comparison to the same period for 2012, there were 20,920 specimen samples received by the NDTC, an average increase of 33.2% over the two months. The TAT for these two months has decreased in 2013, from an average of 37.36 in 2012, to an average of 37.25 in 2013 (a difference of .11). A decrease of 0.3% in the TAT may not be a substantial decrease (Table 5.12), although when taken in consideration with the fact that NDTC Laboratory were operationally down 33% of its full time staff during some of this period, it stands to reason that the TAT should improve once more staff are available.

The process improvements above were achieved by identifying key processes in the Laboratory Value Stream and designing new process changes that eliminated waste. When implemented correctly, it was found that these process changes provided an effective framework for producing systematic improvements and a reduction in effort (de Koning, 2006).

The Average amount of Samples per month from June 2012 to July 2012	10460
The Average amount of Samples per month from June 2013 to July 2013	13938
An Increase in the Specimen Samples Received in 2013	(33.2%)
The Average amount of TATS for 4 th June 2012 to 23 rd July 2012	37.36
The Average amount of TATS for 4 th June 2013 to 22 nd July 2013	37.25
An Decrease in the TAT in 2013 of .11	(0.3%)

Table 5.12: Comparison between TAT and Specimen Samples between June - July 2012 & June - July 2013

The initial stage of the new reporting process went live on the 1st of June 2013; it had been running in parallel with the manual printed reporting process in April and May 2013. Reports for customers who use one of the Laboratory Electronic Reporting systems are no longer printed and are now stored electronically and accessed when needed through the Labware LIMS system. If customers require a hard copy of a report, the reports are printed off upon request and sent to the Customer.

There is evidence to suggest that had the LSS Electronic Report process improvement not been initiated there would have been a substantial increase in the cost associated with offsite storage of paper records. In the first quarter of 2012 there were a total of 18 new boxes sent for offsite storage (Table 5.13), in the same period of 2013 there were a total of 27 new boxes sent for offsite storage, this is in line with a 33.2% increase in Specimen Sample testing requests as discussed earlier. There were a further 30 new boxes sent for offsite storage in the latter part of 2012 (Table 5.13) whereas in 2013 there were no new boxes sent for offsite storage as all reports for April, May, June and July were stored electronically. In April and May 2013 the new process improvement ran in parallel with the paper based process, all electronic reports for this period were validated and the paper reports destroyed.

As part of the continuous improvement process of LSS the outsourcing of a scanning service to scan the historical documentation will be investigated so this data can be stored electronically and the existing paper records destroyed, to avoid accruing unnecessary costs in 2014 (Table 5.15).

Oasis Storage Costs 2012			
	No. of New Boxes	Total No. of Boxes in Storage	Cost
05/11/2012	14	479	€498.16
25/07/2012	16	465	€483.60
02/04/2012	18	449	€933.92
01/01/2012	0	431	€672.36
Total 31/12/2012	48	479	€2,588.04

Table 5.13: The Details of Offsite Storage for 2012

Oasis Storage Costs 2013			
	No. of New Boxes	Total No. of Boxes in Storage	Cost
01/08/2013	0	506	€1,315.60
12/03/2013	27	506	€1,315.60
01/01/2013	0	479	€498.16
Total 31/12/2013	27	506	€3,129.36

Table 5.14: The Projected Details of Offsite Storage for 2013

Oasis Storage Costs 2014			
	No. of New Boxes	Total No. of Boxes in Storage	Cost
01/01/2014	0	506	€3,157.44
Total 31/12/2014	0	506	€3,157.44

Table 5.15: The Projected Details of Offsite Storage for 2014

Finally looking at the data from the recent Questionnaire on user satisfaction in relation to the LSS interventions, 100% of the participants rated the usability of the new LSS process changes as high or very high. On how the Laboratory team felt Phase I of the LSS interventions were implemented, 75% of the users scored this as high or very high. When asked about how they rated their satisfaction with the benefits the LSS improvements had made to the different processes, 91% of the Laboratory team rated this as high or very high, the Lab Aides being more in favour of the interventions with 40% of them rating the benefits as very high. On whether the LSS interventions improved morale and the other issues with staffing and the extra demands on productivity, overall 61% of the participants rated their level of satisfaction as high or very high.

The positive comments from the closing interviews with the Senior Laboratory Team indicated a high level of user acceptance. The new LSS processes “freed up the Senior Biochemist to manage the production system”, “the processes seem quicker and it’s easier to find stuff, as it cuts out searching through boxes of paper records”, and “the Laboratory has become more compartmentalised, with the systems working like a factory process, without interruptions”. Comments like these, three months after Phase I went into production, are good quality indicators that the system changes are still perceived as being affective and according to Davis, Bagozzi, Warshaw, 1989, perceived usefulness strongly influences people’s user acceptance of Computer Technology.

Chapter Six: Discussion & Conclusions

6.1. Introduction

One of the objectives of this dissertation was to conduct some qualitative and quantitative research analysis on the deployment of LSS BPMS in a Healthcare environment. It was likewise believed that the findings produced in this dissertation should adhere to the recommendation of DelliFraine, Langabeer II and Nembhard, 2010, who suggested that the effectiveness of BPMS could be achieved by conducting a detailed statistical analysis on the specific areas highlighted for improvement and measuring the processes before and after the BPMs improvement was implemented.

This paper contributes towards knowledge by providing a template of how LSS can be successfully implemented in a small Clinical Laboratory in a time of budgetary restraints and without the need of outsourcing to private vendors and by creating a domain specific standard that could be used as a building block by other Laboratories.

6.2 Summary of Findings and Results of Lean Six Sigma Implementation

The clinical Laboratory Value Stream is made up of many different processes which have a symbiotic relationship with the process flow as well as the other processes. Documenting and being aware of the entire Value Stream is at the centre of capturing the current “As Is” system (Mayo, 2007), so that changes can be effectively and efficiently implemented. If not enough planning has gone into the LSS Intervention this can have negative implications on the entire process flow. This was highlighted in the planning of this LSS project. By deploying the “TF4 Form used to Record Specimen Sample Reference logs” (Process 1) first, the changes introduced by this LSS intervention completely negated the need to proceed with the proposed LSS intervention “The Sample Disposal Log” (process 2).

The Sample Disposal Log (process 2) has now been removed from the Laboratory Value Stream process flow, had the decision been made to implement the Sample Disposal Log (process 2) without looking at the Value Stream in its entirety the proposed intervention would have been unnecessary. The proposed solution for the Sample Disposal Log (process 2) involved the development of a new Module in Labware LIMS, the purchasing of new handheld barcode scanners and the development of a new electronic Sample Disposal Log. This would have been an example of over production/over processing which is where a BPMS such as Lean and LSS are effective, by

identifying and eliminating these wasteful processes, as they have no value to the customer (Mayo, 2007).

The ease of access to Internet based services has put increased pressure on the NDTC Laboratory, as customer expectations have changed with the advent of Internet based services. Customers now expect the delivery of test results much sooner than they previously did with paper based systems, their expectations of the usability, quality and security of Internet based patient systems have likewise increased (Hogg, Laing, Winkelman, 2003).

Using the traditional paper based systems (Fax and Posting) for sending test reports to customers had a TAT of on average 4 days. When all of the LSS interventions identified in this research are implemented it will be possible to reduce the specimen sample TAT to 4 hours for customers using the Laboratory Electronic Reporting (LER), the NDTC Electronic Patient System (EPS) or the Health Service Executive's (HSE) DAIS application, based on the time of day of the delivery of the sample to the Laboratory. The current customer Service Level Agreement (SLA) for the NDTC Laboratory is a TAT of 48 hours.

Improvements since LSS Implementation:

- Reduced batch sizes which have reduced process time by 50%
- A reduction in Transcription errors by conducting a "Root Cause Analysis" and where possible mistake proofing the Information Technology (IT) interventions.
- Improved the NWA Statistical Analysis process for the Quality Control systems
- Introduced a new Stock Inventory Management System
- Leveraged Technology to provide an IT infrastructure that facilitated the storage of electronic documents, reducing paper and taking the Laboratory closer to a paperless reporting system
- Decrease in TATs since the first LSS intervention was deployed to production. The TATs have remained consistently under 48 hours (Figure 6.1).
- Reports are now accessible from within Labware LIMS, linking directly to the clinic by the date of test request. This allows the Biochemists to follow up on queries on results by being able to access the system and customer report simultaneously.

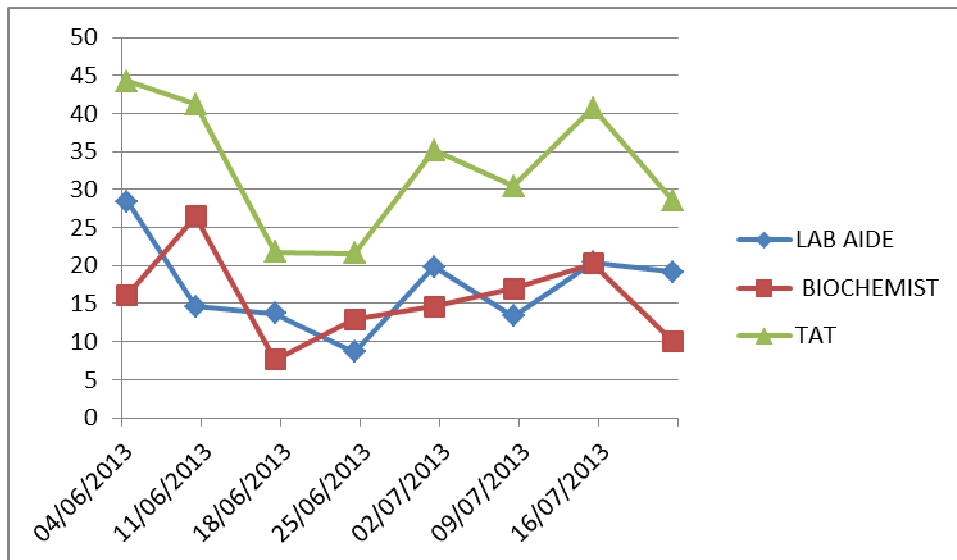


Figure 6.1: Laboratory Turnaround Times (TAT) since the deployment of the last Lean Six Sigma intervention

6.3 Limitations of Research

One of the main restraints on this project was the lack of funding available to make structural changes within the Laboratory. The only way to eliminate time wasted due to movement would be to restructure the entire layout of the Laboratory.

Unfortunately the Laboratory has evolved over many years and the location of the analysers, worktops and fume cupboards are more because of necessity rather than practicality. After the initial waste walk was conducted it was clear there were many areas where if changes could be made to the layout of the Laboratory it could lead to a massive reduction in the amount of time wasted from unnecessary movement.

The other limitation of this research was time, although I had the luxury of working in the same building as the Laboratory, I found it difficult to devote time during my normal working hours to the LSS process changes and had to spend some of my personal time implementing these interventions.

The lack of a dedicated LSS project team, had the staff resources been available to allocate staff to this project on a full time basis, we would have achieved a lot more in a much shorter time frame.

6.4 Recommendations for Present and Future Work

Some of the comments from the closing interviews for Phase I with the Senior Laboratory Team were interesting and although generally positive they highlight issues with the process of change that were not anticipated, for example it was commented that

- “The inventory management process now seemed much longer and needed to be simplified”
- “The Biochemists needed retraining on the new LSS processes which the Lab Aides use”
- “The new tray system had introduced another step for the Biochemists in the process flow, should a repeat test be required on a sample!”

Other issues were not identified when the Value Stream was being mapped.

- The inventory process required improvements to quality and control, speed and simplicity were not a requirement.
- Likewise, replacing the old batch process with the new tray process, put in error correction systems which did not take into account that requests for repeated tests can be raised if the results are not satisfactory.

These are lessons that have been learnt for Phase II of the LSS project. The issues identified by the Senior Laboratory Team are being addressed as part of the Control phase of LSS (LSS is about continuous improvement).

The NDTC has been given approval for the recruitment of a replacement Senior Biochemist for the role of Laboratory Customer Service Manager. It is envisioned that when the Laboratory Customer Service role is filled in 2013 that a new drive will be initiated as part of the continuous improvement process of LSS, to encourage our existing and new customers to move away from the traditional printed and fax report systems and towards one of the Electronic Reporting systems the Laboratory subscribe to.

The research undertaken in the literature review, would suggest that there would seem to be disparity in the choice of BPMS and there is no standard framework for the deployment of Lean, Six Sigma or LSS and this would seem to be the same in current Health sector (Pepper, Spedding, 2010).

In their literature review, DelliFraine, Langabeer II and Nembhard, 2010, claimed that there has been a gap in the demonstration of good statistical analysis to prove that a BPMS such as Lean Six Sigma

does improve the quality of healthcare services. This is not the case with this dissertation or the NDTC Laboratory LSS project, who followed the recommendations of Pepper, Spedding, 2010, in conducting a the LSS improvement project focusing on the Laboratory Value Stream as a complete system, with the aim of the project being to put the correct interventions in the right place.

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APPENDICES

Appendix I: Phase II of Lean Six Sigma Interventions

7.1 Phase II: Process 6: Controlled Drugs Tracking

Controlled Drugs Tracking requirements and the control system processes used by the NDTC Laboratory to meet the legal requirements for the use of these drugs.

7.1.1 Define: Controlled Drugs Tracking

1: Currently the date the drugs were opened is not always recorded; it is hoped that this would be enforced by the proposed ICT intervention.

2: The expiry date is recorded in the excel spread sheet but there is no way of alerting the Biochemists when the drugs are out of date or when they are approaching their expiry date. It is envisioned that the proposed system would have an alerting function, either via email or the proposed integration with the alerting functions of either of the current Laboratory IT applications, Labware LIMS the Laboratory information system or Paradigm 2 the Laboratory document management system and task scheduler.

3: Not all drugs have expiry dates, some drugs have a retest date, the Laboratory is required to request a certificate of Analysis from the suppliers to verify that the batch is still stable for use in the testing of drugs. This certificate is usually emailed to the Laboratory. It is envisioned in the proposed system that this process could be automated and that the certificates are stored within the application.

4: Every drug should have a certificate Analysis form stored with it, currently these are hardcopies and stored in folder. It is envisioned that the application will store these in a live list in PDF format and these will be accessible from within the application.

5: The drugs have a finish date; this is sometimes not recorded in the Microsoft (MS) Excel spreadsheet. The new application will have an ICT intervention that will inform the Biochemist when a particular type of drug is nearing its expiry date. The application will monitor the end date of drugs and class drugs unusable if these drugs reach their finish date and alert the user. These drugs will be moved to an archive list along with licenses and certificate Analysis forms, if a user tries to check

these drugs out for testing they will be issued an alert from the ICT intervention telling them that the drugs have expired and shouldn't be used for testing.

6: Currently the drugs are moved to different fridges, these movements are not recorded on the current Microsoft (MS) Excel spreadsheet, the application should record all movement of drugs once they have been logged into the Laboratory, the person responsible for moving them and the time and date they were moved.

7: Certain drugs can only be kept out of refrigerated storage for a limited period of time, all drugs will be issued with barcodes, a workstation with a barcode scanner will be used to scan all drugs as they are checked out and in the storage facility. A proximity scanner will be used to monitor who accessed the storage areas, this data will be recorded in the application. The ICT intervention will alert the user and all members of Biochemistry team should a drug be in danger of being contaminated. If the drug is classed as contaminated it will be flagged by the system, removed from the live list and will require proof of destruction authorised by a senior Biochemist.

8: Currently the amount of drugs used are not recorded, it is envisioned that the system will require that the quantity of drugs used are recorded each time a user checks the drugs out and back in, this will also require the recording of the amounts of spillage etc.

9: The quantity of drugs that are currently in stock is not tracked, it is envisioned that the new application will have an ICT intervention that will inform the Biochemist when a particular type of drug is running low and start an automated process for the importation of a new supply of drugs when needed.

10: A reporting facility is required, that will automatically generate reports on a Daily/weekly/monthly basis as well as ad hoc reports when required.

These reports will detail information such as, the amount of drugs in stock, who has used them and when they were used, if drugs have been moved to different storage location and information on licenses and expiry dates.

It is envisioned that this reporting facility will have the ability to directly send these reports via email if required.

7.1.2 Measure: Controlled Drugs Tracking

This LSS intervention is currently in the define and measurement stage and requirements specifications have been sent to Labware LIMS requesting the requirements for the development of

a Tracking and Reporting Inventory Module and it is envisioned that the Controlled Drugs Tracking Inventory Manager will be ready for deployment to the test environment by July 2013.

1: In order to possess controlled drugs it is necessary have a licence for possession of the drug. There are three types of licences that the NDTC normally has possession of:

- 1) Licence to possess precursors
- 2) Licence to possess Schedule 1 and Schedule 2 controlled drugs
- 3) Licence to possess Schedule 3 and Schedule 4 drugs.

The licences must be applied for annually and can be applied for through the IMB's Pharmatrust Website <https://pharmatrust.imb.ie>.

2: Determine the supplier for the required drug and contact the supplier to confirm whether the drug is controlled or not controlled, including the expected time of delivery, price, carriage and cost of a controlled licence where appropriate.

3: Fill out the order as detailed in SOP AP8 for both the controlled or non-controlled drugs and send the order to the supplier according to SOP AP8.

4: A licence to import a controlled drug must be applied for through the IMB's Pharmatrust Website <https://pharmatrust.imb.ie>.

5: Log into IMB's Pharmatrust Website and add the number of vials of the preparation you are getting, e.g. if you want 1 ampoule of Anhydroecgonine Methyl ester 1mg/ml enter 1 in the quantity box (Figure 7.1)

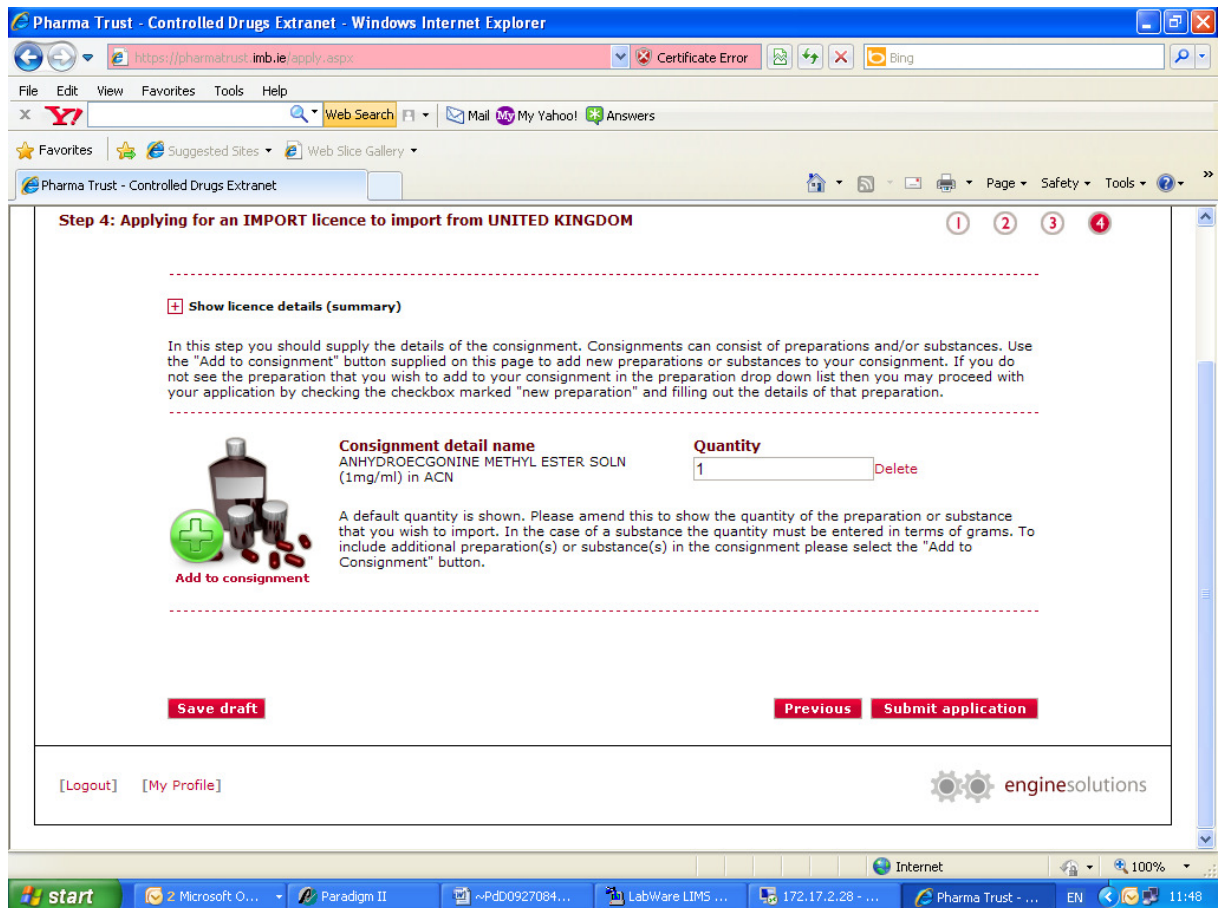


Figure 7.1: Pharmatrust Website <https://pharmatrust.imb.ie>

6: If you have more substances/preparations to apply for repeat the above again. When finished click on submit application. An email will be sent to the license holder (Principal Biochemist) when application has been successfully submitted.

7: When the application has been approved a "Certificate of Licence to Import" and the "Licence to import" will be sent to the annual Licence holder. The Certificate of Licence to import should be sent to the supplier along with a cover letter referencing the purchase order no of the controlled drug order.

8: When the controlled drugs are received into the Laboratory, the back of the Licence to Import should be filled in when the controlled drugs have been received in the Laboratory according to the instructions detailed on the back of the form.

9: The controlled drugs are recorded in the (CHEOPS) Server in the folder \Controlled Drugs\Controlled Standards Log and are stored securely and as directed.

10: Any Certificates of Analysis received with the drug substances should be filed in the Drug Substances Certificate of Analysis Folder. To find the licence numbers of annual NDTC licences, click on the “My Quotas” tab in pharmaTrust.

7.1.3 Analysis: Controlled Drugs Tracking

7.1.4 Implementation: Controlled Drugs Tracking

7.1.5 Control: Controlled Drugs Tracking

7.2 Phase II: Process 7: The Instrument Maintenance Processes for the Analysers

The successful deployment of the North West Analytical (NWA) Statistical Analysis, Electronic Reporting Section, and Sample Reference Log projects have addressed some issues initially identified by the customer in regards to this process problem and will be re-examined after the Controlled Drugs Tracking project is completed.

7.2.1 Define: The Instrument Maintenance Processes for the Analysers

All samples that are processed as part of a batch by the analysers are recorded in a TF3 form which is generated by Labware LIMS (Figure 7.2).

THE DRUG TREATMENT CENTRE BOARD DRUG ANALYSIS LABORATORY		Form Ref: TF3							
TF3 - Analyser Batch Form		Page No.: 1 of 1							
		Version: 1.17							
		Issued Date: 26/07/2012							
		Issued By: Quality Manager							

Date: 25.03.2013
Routine Analysis: Satellites

Urine Sample Barcodes	Batch	Loaded BY	AU2700 No.	QC Pass (Y/N)	QC(s) validated BY	QC validated DATE	Sample(s) authorised BY	Sample(s) authorised DATE
13050251 to 13050340	1	RS	1	Y	JH	25.03.13	PJ	25.03.13
13050441 to 13050535	2	JH	1	Y	SP	25.03/13	SP	25.03/13
13050541 to 13050550	3	JH	1	Y	SP	25.03/13	PM	25.03.2013
13050551 - 13050560	3	SP	2	Y	JH	25.03.13	PM	25.03.2013
13050561 - 13050580	3	MQ	1	Y	JH	25.03.13	PM	25.03.2013
13050771 to 13050813	4	MQ	1	Y	JH	25.03.13	PM	25.03/13
13050581 to 13050621	3	MQ	1	Y	JH	25.03.13	PM	25.03.2013
13050721 to 13050743	4	MQ	1	Y	JH	25.03.13	PM	25.03/13
13050745 to 13050770	4	MQ	1	Y	JH	25.03.13	MQ	25.03/13
13050991 to 13051000	6	PJ	1	Y	JH	25.03.13	MQ	26.03.2013
13051001 to 13051038	6	PJ	2	Y	JH	25.03.13	PJ	26.03.2013
13050891 to 13050910	5	PJ	2	Y	JH	25.03.13	PJ	25.03.2013
13050911 to 13050985	5	PJ	1	Y	JH	25.03.13	PM	25.03.2013
13051039 to 13051063	6	PJ	2	Y	JH	25.03.13	PM	26.03.2013

Repeat / Extra Test analysis

Barcode & Batch	Tests Requested	Sample centrifuged	Loaded BY	AU2700 No.	QC Pass (Y/N)	QC(s) validated BY	QC validated DATE	Sample(s) authorised BY	Sample(s) authorised DATE
13050985 BS	CREA	Y (fresh aliquots)	JH	2	Y	John Doe	25.03.13	Jane Doe	25.03.2013

Figure 7.2: TF3 Analyser Batch Form

7.2.2 Measure: The Instrument Maintenance Processes for the Analysers

The TF3 form may be incorporated into the Electronic Reporting Section project and this will negate the need for a LSS intervention as all issues initially identified will be addressed.

1: On delivery, each reagent kit box is checked ensuring the expiry date is in date and acceptable to the Senior Biochemist in Routine Testing. The reagent boxes should be initialled and dated by a Biochemist and are stored in the cold room. The delivery docket received must be given to the Senior Biochemist in Routine Testing.

2: When a new reagent is required for the analyser, both reagents labelled R1 and R2 are removed from their boxes and labelled with identical barcodes. The reagent barcodes are found on the Calibrator/Reagent barcode roll in the main Laboratory.

3: Both reagents are prepared as per manufacturer's instructions (refer to kit inserts).

4: Once reagents are prepared, the following is handwritten on the reagent bottles:

- Date prepared
- Expiry date
- LOT number
- Initials of Biochemist who prepared the reagent

5: The prepared reagents are stored in Fridge 5 located in the main Laboratory until required for use on the analysers. When the new reagents are ready to be used on the analysers the "in use" date must be recorded on the R1 and R2 reagent bottles.

6: One clean dry bottle is used for each R1 and R2 reagent. The Reagent bottles come in various sizes (30ml, 60ml, and 120ml) and the size of bottle used depends on the volume of reagent used daily.

7: The R1 / R2 reagent is poured into the corresponding R1 and R2 labelled bottles for each test. Each bottle should be filled to the maximum volume mark and NEVER above this mark.

8: Ensure the analyser is in 'Standby mode'. Remove the Reagent R1 and R2 covers. Remove any old reagent bottles and insert the new reagent R1 and R2 bottles into their assigned positions on the carousel; these are as shown in (Table 7.1).

Test	Positions
Opiate	1
Benzodiazepines	3
Cannabis	5
Amphetamine	6
Cocaine	7
Creatinine	9
Alcohol	11
6-Acetyl Morphine	10
EDDP	48

Table 7.1: Reagent bottles and their assigned positions in the Analyser Carousel

9: When the checking process is being performed the reagent status screen shows a red box indicating that checking is being performed. A blue screen appears when it has finished checking the reagents and states "Checked".

10: On the reagent status screen, click on test display icon. A test orientated screen appears which shows the position, volume of reagent in ml and number of shots available for all reagents. If a reagent is in the incorrect position, a yellow line will appear through the reagent.

11: The reagents are now ready for calibration, attach CF3 to the AU2700 Weekly Calibration and Maintenance sheet (CF1) or to the AU2700 Calibration Sheet (CF2) depending on what circumstance the reagent is being changed. Reasons for any change must be recorded on the CF2 form.

12: If the new reagent has a different LOT number from the previous reagent used refer to SOP TP23, as statistical calculations will need to be updated.

7.2.3 Analysis: The Instrument Maintenance Processes for the Analysers

7.2.4 Implementation: The Instrument Maintenance Processes for the Analysers

7.2.5 Control: The Instrument Maintenance Processes for the Analysers

7.3 Phase II: Process 8: Analyser Calibration

At the end of each day details of what has happened on the Analysers must be recorded. The analyser software does not facilitate the export of this information into Labware LIMS. The analysers contain only the past 30 days of records all older records is deleted. The information is recorded on paper forms at the end of each day.

7.3.1 Define: Analyser Calibration

There are a total of 6 forms that must be completed at the each day for each Analyser. If the forms were electronically recorded it would get negate the need for paper records, ideally if the software used by the Analyser could send the data directly to Labware LIMS it would save the need to record the data manually on paper.

7.3.2 Measure: Analyser Calibration

7.3.3 Analysis: Analyser Calibration

7.3.4 Implementation: Analyser Calibration

7.3.5 Control: Analyser Calibration

7.4 Phase II: Process 9: The Recording of Laboratory Telephone Enquiry Calls

7.4.1 Define: The Recording of Laboratory Telephone Enquiry Calls

The current process is to record these by hand on a printed MS Word document form (LR04). These forms are collated on a MS Excel Spread sheet and a monthly Analysis performed by the Laboratory Customer Service department, over 200 calls a month. A report is generated and presented to the board each month.

It is envisioned that an electronic form could be produced to replace LR04 form currently used to record information about Telephone Enquiry Calls and the results could be recorded directly into LIMS and a report Generated for the board.

7.4.2 Measure: The Recording of Laboratory Telephone Enquiry Calls

7.4.3 Analysis: The Recording of Laboratory Telephone Enquiry Calls

7.4.4 Implementation: The Recording of Laboratory Telephone Enquiry Calls

7.4.5 Control: The Recording of Laboratory Telephone Enquiry Calls

7.5 Phase II: Process 10: Confirmatory Analysis

7.5.1 Define: Confirmatory Analysis

Currently all reports are printed off for testing a Confirmatory Analysis list of samples on the LCMs or the GCMS, it is hoped that these could go back into Labware LIMS and be stored digitally.

7.5.2 Measure: Confirmatory Analysis

The successful deployment of the LSS intervention Electronic Reporting Section will accommodate the electronic recording of Confirmatory Analysis Reports.

7.5.3 Analysis: Confirmatory Analysis

7.5.4 Implementation: Confirmatory Analysis

7.5.5 Control: Confirmatory Analysis

Appendix II: Laboratory Forms and Documentation

Process 1: TF4 Form used to Record Specimen Sample Reference logs

HSE- National Drug Treatment Centre Laboratory

Form Ref: TF4, Version 1.13. Effective Date: 03/11/2011 Time: 13:50

Batch: _____ **Please Note: * indicates Non Compliance Sample**

Tray ID :26/04/2013-08 Page 1 of 7 Date: 29/04/2013

No.	Barcode	Rec'd Date & Time	Clinic	Chart Number	Sampled Date	DOB	Forename	Surname	Card	Dais Number	Analysis requested
1	13069671	25/04/2013 11:30	TRY	TRY 0217	24/04/2013				No		AMPH AMPHM BENZ BENZM COCA COCAM EDDP EDDPM OPIA OPIAM ALCO ALCOM CANN CANNM CREA CREAM
2	13069672	25/04/2013 11:30	TRY	TRY0906	24/04/2013				No		CREA CREAM ALCO ALCOM BENZ BENZM CANN CANNM COCA COCAM EDDP EDDPM OPIA OPIAM
3	13069673	25/04/2013 11:30	TRY	TRY0880	24/04/2013				No		CREA CREAM ALCO ALCOM BENZ BENZM CANN CANNM COCA COCAM FDDP FDDPM OPIA OPIAM
4	13069674	25/04/2013 11:30	TRY	TRY1008	24/04/2013				No		CREA CREAM ALCO ALCOM BENZ BENZM CANN CANNM COCA COCAM EDDP EDDPM OPIA OPIAM
5	13069675	25/04/2013 11:30	TRY	TRY0294	24/04/2013				No		CREA CREAM ALCO ALCOM BENZ BENZM CANN CANNM COCA COCAM EDDP EDDPM OPIA OPIAM
6	13069676	25/04/2013 11:30	TRY	TRY 0133	24/04/2013				No		CREA CREAM ALCO ALCOM BENZ BENZM CANN CANNM COCA COCAM EDDP EDDPM OPIA OPIAM
7	13069677	25/04/2013 11:30	TRY	TRY0891	24/04/2013				No		CREA CREAM ALCO ALCOM BENZ BENZM CANN CANNM COCA COCAM EDDP EDDPM OPIA OPIAM
8	13069678	25/04/2013 11:30	TRY	TRY0999	24/04/2013				No		CREA CREAM ALCO ALCOM BENZ BENZM CANN CANNM COCA COCAM EDDP EDDPM OPIA OPIAM

Tray ID :26/04/2013-08 Page 7 of 7 Date: 29/04/2013

No.	Barcode	Rec'd Date & Time	Clinic	Chart Number	Sampled Date	DOB	Forename	Surname	Card	Dais Number	Analysis requested

HSE- National Drug Treatment Centre Laboratory

Form Ref: TF16, Draft Version 1.0.

26/04/2013-08

Batch: _____ Date: _____


Code	Barcode Sequence	Number	Reported				Initials	Comment
			Time	Date	Method	#		
MHCC	13069685 - 13069698	14	14:50	29/04/2013	Post	460		
MPG	13069710 - 13069711	2	14:51	29/04/2013	Fax & Print one p	461		
SHB	13069712 - 13069718	7	14:52	29/04/2013	Fax	462		
SMST	13069699 - 13069709	11	14:52	29/04/2013	Fax	463		
TRY	13069671 - 13069684	14	14:53	29/04/2013	Post	464		

Signed by Lab Aide: _____ Signed by Biochemist who completed the batch: _____ Date: _____

Checked By: _____ Date: _____

Figure 7.3 New Sample Reference Log TF4 Form

Process 3: North West Analytical (NWA) Statistical Analysis

 Heilbrunnach na Scríbhne Síne Health Service Executive LÁRIONAD NAISIÚNTA OÍREÁLA DRUGAÍ NATIONAL DRUG TREATMENT CENTRE DRUG ANALYSIS LABORATORY	Form Ref: TF12
	Page No.: 1 of 1
	Version: 1.17
TF12- QC Control Study Statistics Record Form	Issued Date: 22/04/2013
	Issued By: Quality Manager

AU2700 No.: _____ Date: _____

Reason for updating statistics: _____

Details of new statistics for control(s)

QC Name	Lot Number	Nominal Value (Mean)	SD	Minimum (3σ)	Maximum (3σ)	Lo Control 1 (Warning 2σ)	Hi Control 1 (Warning 2σ)

QC Charts updated and attached? Yes Completed by (Initials): _____

CF3 attached? Yes Completed by (Initials): _____

30 QCs used in calculation? Yes Completed by (Initials): _____

QC data update checked in NWA Yes Completed by (Initials): _____

AU2700 Updated: Yes Completed by (Initials): _____

Checked By Senior Biochemist: _____ Date: _____

Senior Biochemist checked COA's are available? Yes No (see below)
 If No, give reason: _____

Figure 7.4: NWA TF12 – QC Control Study Statistics Record Form

Process 3: North West Analytical (NWA) Statistical Analysis

<p>Feidhmeannacht na Seirbhíse Sláinte Health Service Executive</p> <p>LÁRIONAD NÁISIÚNTA CÓIREÁLA DRUGAÍ NATIONAL DRUG TREATMENT CENTRE DRUG ANALYSIS LABORATORY</p>	Form Ref: TF12
	Page No.: 1 of 1
	Version: 1.18
TF12– QC Control Study Statistics Record Form	Issued Date:
	Issued By: Quality Manager

AU2700 No.: _____ Date: _____

Reason for updating statistics: _____

Details of new statistics for control(s)

QC Name	Lot Number	Nominal Value (Mean)	SD	Minimum (3s)	Maximum (3S)	Lo Control 1 (Warning 2S)	Hi Control 1 (Warning 2S)

QC Charts updated and attached? Yes Completed by (Initials): _____

QC data update checked in NWA Yes Completed by (Initials): _____

AU2700 Updated: Yes Completed by (Initials): _____

Checked By Senior Biochemist: _____ Date: _____

Senior Biochemist checked COA's are available? Yes No (see below)
 If No, give reason: _____

Figure 7.5: New NWA TF12 Form

Process 3: North West Analytical (NWA) Statistical Analysis

A	B	C	D	E	F	G	H	I	J	K	L	M	
Record for AU2700-01													
1	STOCK TYPE	TEST	NAME	BARCODE	KIT LOT#	LOT#	EXPIRY	DATE IN USE/ON INSTRUMENT (CAL. REAL)	DATE LOT IN USE	PREPARED DA	PREPARED BY	ONBOARD BY	AUS700 BARCODE
2	CALIBRATOR	Alcohol	DRI Alcohol Negative	H130125	same as lot#	59635879	2014 04	04/04/2013	06/02/2013	N/A	N/A		C0000003
3	CALIBRATOR	Alcohol	DRI 100mg/dL Alcohol	H130117	same as lot#	59750998	2014 11	23/03/2013	04/01/2013	N/A	N/A		C0000008
4	CALIBRATOR	Opiate	CECIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
5	CALIBRATOR	Amphetamine	CECIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
6	CALIBRATOR	Cocaine	CECIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
7	CALIBRATOR	EDDP	CECIA Clinical cutoff	H130156	same as lot#	59824632	2014 01	25/04/2013	18/09/2012	N/A	N/A		C0000004
8	CALIBRATOR	S-Acetylmorphine	CECIA Heroin Metabolite	H130137	same as lot#	59708473	2013 08	19/04/2013	23/08/2012	N/A	N/A		C0000005
9	CALIBRATOR	Creatinine	DRI 2mg/dL Creatinine-Detect	H130025	59845664	59817794	2013 05	01/02/2013	01/02/2013	N/A	N/A		C0000006
10	CALIBRATOR	Creatinine	DRI 20mg/dL Creatinine-Detect	H130026	59845664	59817797	2013 05	01/02/2013	01/02/2013	N/A	N/A		C0000007
11	CALIBRATOR	Benzodiazepine	Secondary Cut-Off	H130143	same as lot#	59848061	2014 01	18/04/2013	18/04/2013	N/A	N/A		C0000010
12	CALIBRATOR	Cannabis(THC)	CECIA THC 50	H130106	same as lot#	59827548	2013 03	22/03/2013	31/07/2012	N/A	N/A		C0000011
13	CALIBRATOR	pH	DRI pH3.0	H130099	59795774	59795769	2013 06	20/03/2013	02/09/2013	N/A	N/A		C0000020
14	CALIBRATOR	pH	DRI pH11.0	H130100	59795774	59795771	2013 06	20/03/2013	02/09/2013	N/A	N/A		C0000021
15	CALIBRATOR	Alcohol	DRI Alcohol Negative	H130125	same as lot#	59635879	2014 04	04/04/2013	06/02/2013	N/A	N/A		C0000100
16	CALIBRATOR	Alcohol	DRI 100mg/dL Alcohol	H130081	same as lot#	59670678	2013 07	07/03/2013	18/09/2012	N/A	N/A		C0000101
17	CALIBRATOR	Alcohol	DRI 500mg/dL Alcohol	H130092	same as lot#	59807121	2014 03	15/03/2013	11/10/2012	N/A	N/A		C0000102
18	CALIBRATOR	Alcohol	DRI 1000mg/dL Alcohol	H130093	same as lot#	59807076	2013 07	15/03/2013	30/07/2012	N/A	N/A		C0000103
19	CALIBRATOR	Alcohol	DRI 2000mg/dL Alcohol	H130074	same as lot#	59870719	2013 07	04/03/2013	13/09/2012	N/A	N/A		C0000104
20	QC	Negative check	Drug free urine	N/A	same as lot#	E13418	2013 06	N/A	13/03/2012	23/02/2012	N/A		Q0000001
21	QC	Positive check	Urine detectabuse control	N/A	same as lot#	MC4073	2013 12	N/A	16/04/2013	N/A	N/A		Q0000002
22	QC	Creatinine	13mg/dL Creatinine	N/A	same as lot#	59817805	2013 05	N/A	03/09/2012	N/A	N/A		Q0000003
23	QC	Creatinine	23mg/dL Creatinine	N/A	same as lot#	59817808	2013 05	N/A	02/09/2013	N/A	N/A		Q0000004
24	QC	Opiate	Clinical Low	N/A	59737576	59737583	2013 11	N/A	26/11/2012	N/A	N/A		Q0000029
25	QC	Cocaine	Clinical Low	N/A	59737576	59737583	2013 11	N/A	26/11/2012	N/A	N/A		Q0000029
26	QC	EDDP	Clinical Low	N/A	59737576	59737583	2013 11	N/A	26/11/2012	N/A	N/A		Q0000029
27	QC	Opiate	Clinical High	N/A	59737576	59737585	2013 11	N/A	26/11/2012	N/A	N/A		Q0000030
28	QC	Cocaine	Clinical High	N/A	59737576	59737585	2013 11	N/A	26/11/2012	N/A	N/A		Q0000030
29	QC	EDDP	Clinical High	N/A	59737576	59737585	2013 11	N/A	26/11/2012	N/A	N/A		Q0000030
30	QC	Benzodiazepine	Select Low	N/A	59670231	59670225	2013 11	N/A	20/11/2012	N/A	N/A		Q0000031
31	QC	S-Acetylmorphine	Select Low	N/A	59670231	59670225	2013 11	N/A	20/11/2012	N/A	N/A		Q0000031
32	QC	Benzodiazepine	Select High	N/A	59670231	59670229	2013 11	N/A	20/11/2012	N/A	N/A		Q0000032
33	QC	S-Acetylmorphine	Select High	N/A	59670231	59670229	2013 11	N/A	20/11/2012	N/A	N/A		Q0000032
34	QC	Amphetamine	Primary Low	N/A	59657545	59657525	2013 11	N/A	04/12/2012	N/A	N/A		Q0000033
35	QC	Amphetamine	Primary High	N/A	59657545	59657531	2013 11	N/A	04/12/2012	N/A	N/A		Q0000034
36	QC	Alcohol	50mg/dL Alcohol	N/A	same as lot#	59895074	2015 06	N/A	21/12/2012	N/A	N/A		Q0000035
37	QC	Alcohol	200mg/dL Alcohol	N/A	same as lot#	59895074	2015 06	N/A	21/12/2012	N/A	N/A		Q0000036
38	QC	Cannabis(THC)	THC 50 Low	N/A	59823739	59765004	2014 02	N/A	22/04/2013	N/A	N/A		Q0000037
39	QC	Cannabis(THC)	THC 50 High	N/A	59823739	59765005	2014 02	N/A	22/04/2013	N/A	N/A		Q0000038
40	QC	pH	DRI pH3.6	N/A	same as lot#	59766890	2013 06	N/A	02/09/2013	N/A	N/A		Q0000041
41	QC	pH	DRI pH7.0	N/A	same as lot#	59774428	2013 06	N/A	02/09/2013	N/A	N/A		Q0000042
42	QC	pH	DRI pH10.0	N/A	same as lot#	59774437	2013 06	N/A	02/09/2013	N/A	N/A		Q0000043
43	QC	EtG	DRI EtG 375ng/mL	N/A	same as lot#	59801821	2014 02	N/A	06/03/2013	N/A	N/A		Q0000101
44	QC	EtG	DRI EtG 625ng/mL	N/A	same as lot#	59805684	2014 02	N/A	22/04/2013	N/A	N/A		Q0000102
45	REAGENT	Creatinine	DRI Creatinine- Detect	H130140	same as lot#	59820638	2014 04	16/04/2013	26/11/2012	N/A	N/A	SP	N/A
46	REAGENT	Opiate	CECIA Opiate	H130154	same as lot#	59614338	2014 04	26/04/2013	22/11/2012	23/04/2013	SP	SP	N/A
47	REAGENT	Cocaine	CECIA Cocaine	H130136	same as lot#	59678740	2014 07	10/04/2013	20/09/2012	10/04/2013	LL	SP	N/A
48	REAGENT	EDDP	CECIA EDDP	H130135	same as lot#	59759166	2014 12	10/04/2013	23/07/2012	10/04/2013	LL	SP	N/A
49	REAGENT	Benzodiazepine	CECIA Benzodiazepine	H130141	same as lot#	59816742	2015 02	16/04/2013	10/03/2013	16/04/2013	SP	SP	N/A
50	REAGENT	S-Acetylmorphine	CECIA Heroin Metabolite	H130148	same as lot#	59845729	2014 04	23/04/2013	18/02/2013	23/04/2013	JH	SP	N/A
51	REAGENT	Amphetamine	CECIA Amphetamine/Ecstasy	H130162	same as lot#	59899864	2015 06	26/04/2013	18/01/2013	23/04/2013	SP	EB	N/A
52	REAGENT	Alcohol	DRI Alcohol	H130126	same as lot#	59782384	2013 09	05/04/2013	25/01/2013	N/A	N/A	JH	N/A
53	REAGENT	Cannabis(THC)	CECIA THC	H130153	same as lot#	59831020	2013 05	25/04/2013	16/08/2012	23/04/2013	SP	LL	N/A
54	REAGENT	pH	DRI pH Detect	H130119	same as lot#	59770854	2013 05	02/04/2013	07/09/2012	N/A	N/A	SP	N/A
55	REAGENT	EtG	DRI Ethyl Glucuronide Assay	H130127	same as lot#	59906535	2013 12	05/04/2013	01/03/2013	N/A	N/A	JH	N/A

Figure 7.6: New NWA CF3 Form

Appendix III: Basic Flowchart Shapes

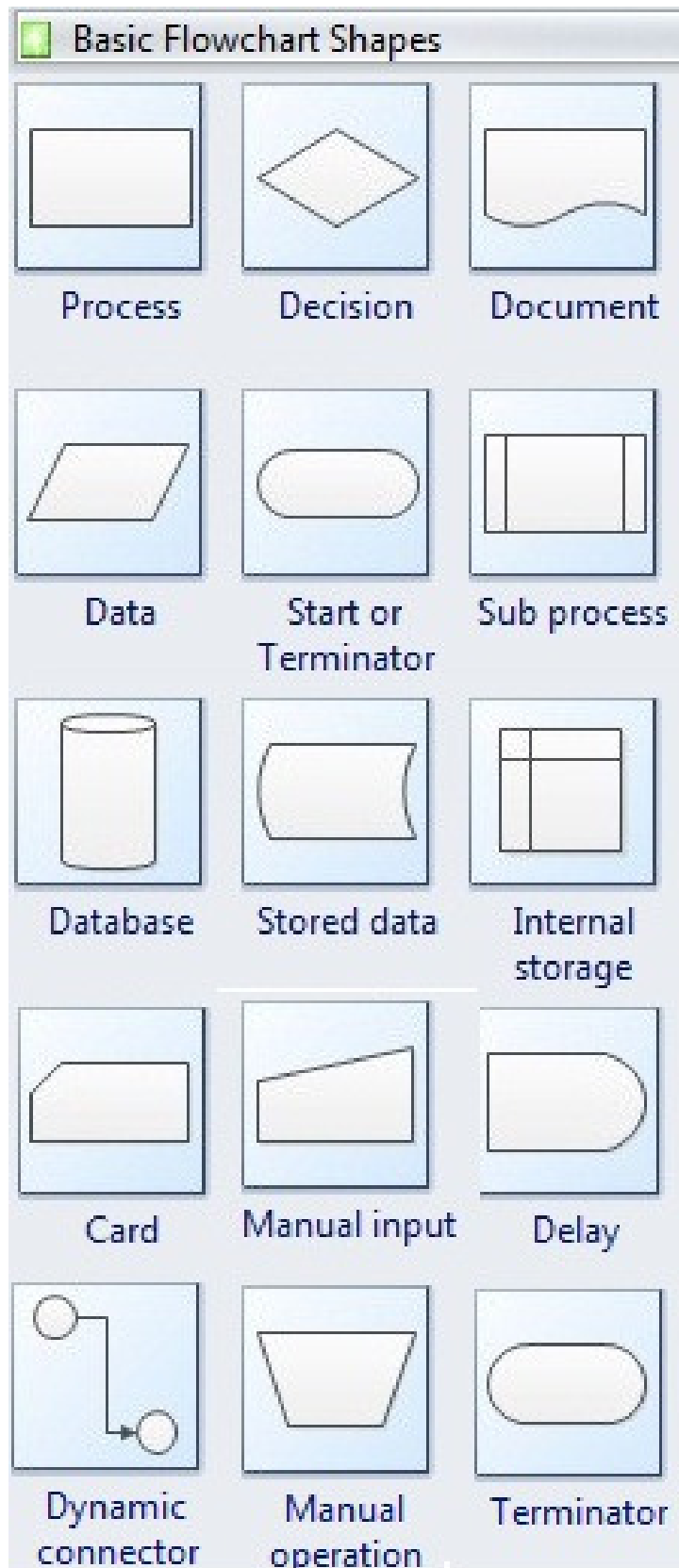


Figure 7.7: Standard Flowchart Symbols and Their Usage (Edrawsoft, 2013)

Appendix IV: Diagram of Dissertation

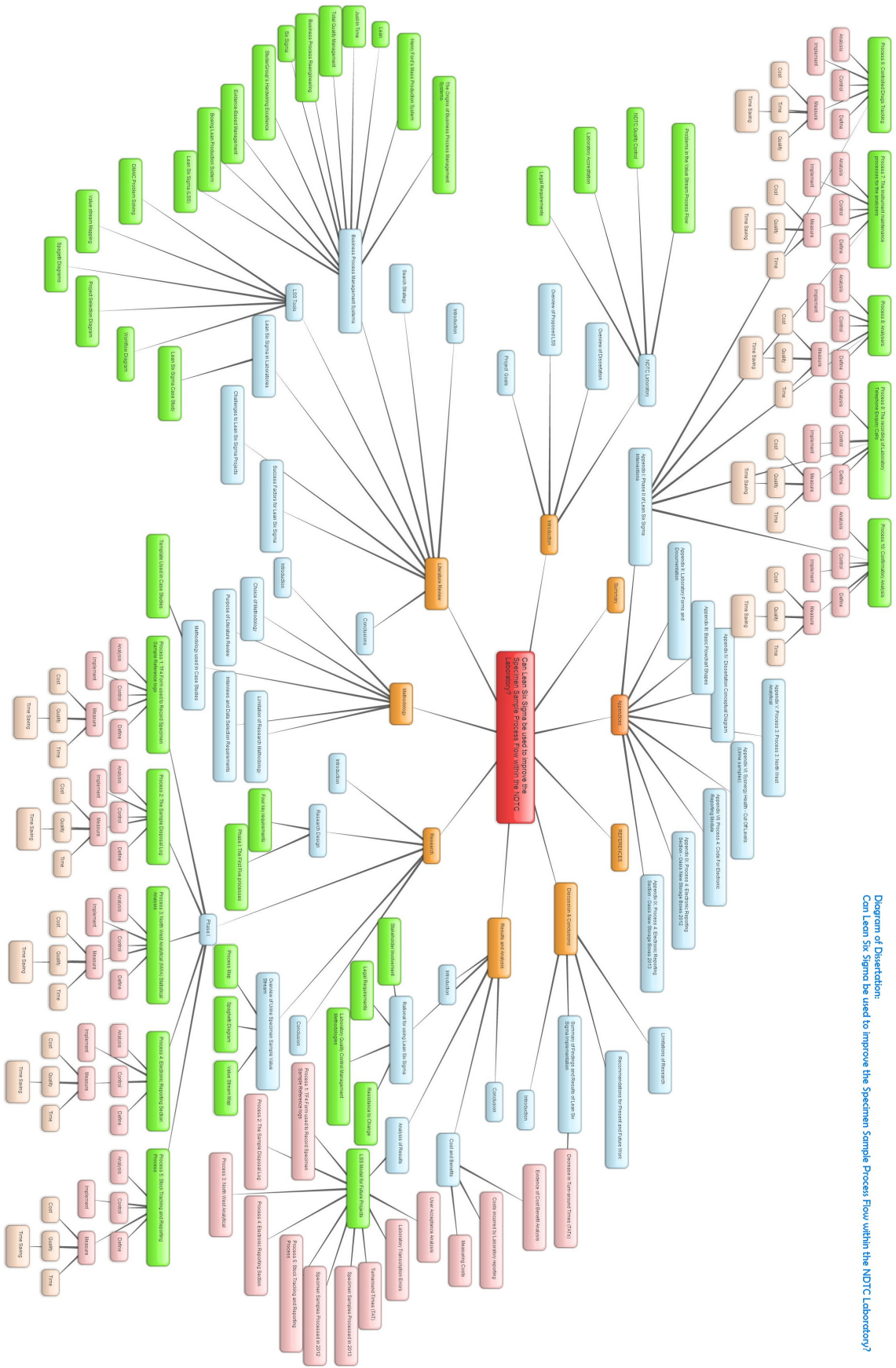


Diagram of Dissertation:
Can Lean Six Sigma be used to improve the Specimen Sample Process Flow within the NDTC Laboratory?

Appendix V: Process 3: North West Analytical (NWA) Statistical Analysis Module

```
*****
***** This subroutine finds all samples and bracketing QC samples for the selected sample.
***** Its purpose is to build a folder so that the user can see the samples and its associated QCs
***** In general, QC samples are used for the samples that ran before it and for the samples that
***** run after it
*****
```

```
ClearArray("res")
```

```
'FieldArray structure:
```

```
'1  FieldName
'2  FieldLabel
'3  DataType (Text, Number, Integer, Boolean, List, File, Date, Time, Title, DateTime)
'4  DefaultValue
'5  LinkTable
'6  MaxSize
'7  ListName
'8  EntryMode (UserEntry, MandatoryEntry, DisplayOnly, TitleEntry)
'9  DependsOn
'10 FormulaSub
```

```
formName = "QC_FOLDER"
```

```
title = "QC Control Samples Selection Criterio"
```

```
width = 400
```

```
height = 400
```

```
clinicID = ""
```

```
'fieldsArray[1,1] = "PROJECT"
```

```
'fieldsArray[1,2] = "Project"
```

```
'fieldsArray[1,3] = "Text"
```

```
'fieldsArray[1,4] = ""
```

```
'fieldsArray[1,5] = "PROJECT"
```

```
'fieldsArray[1,8] = "MandatoryEntry"
```

```
'fieldsArray[2,1] = "ANALYSER"
```

```
'fieldsArray[2,2] = "Analyser"
```

```
'fieldsArray[2,3] = "List"
```

```
'fieldsArray[2,7] = ""
```

```
'fieldsArray[2,8] = "MandatoryEntry"
```

```
'fieldsArray[2,10] = "ANLYSR_LS2"
```

```
'fieldsArray[3,1] = "SHOW"
```

```
'fieldsArray[3,2] = "Show"
```

```
'fieldsArray[3,3] = "List"
```

```
'fieldsArray[3,4] = "ALL"
```

```
'fieldsArray[3,7] = "SHOW_QCS"
```

```
'fieldsArray[3,8] = "MandatoryEntry"
```

```
'fieldsArray[4,1] = "NUM_SAMP"
```

```
'fieldsArray[4,2] = "Number of Samples"
```

```
'fieldsArray[4,3] = "Integer"
```

```
'fieldsArray[4,4] = "10"
```

```
'fieldsArray[4,7] = ""
```

```
'fieldsArray[4,8] = "MandatoryEntry"
```

```
'CreateDialog(formName, title, fieldsArray, "valuesArray", "QC_FOLDER", width, height)
```

```
status = UserDialog("QC_PROJECT", "valuesArray", , ,)
```

```
IF (dialogcanceled) THEN
```

```
Return "0"
```

```
ENDIF
```

```
proj = valuesArray[ 1 ]
```

```
inst = valuesArray[ 2 ]
```

```
type = valuesArray[ 3 ]
```

```
numSmpls = valuesArray[ 4 ]
```



```

analName = valuesArray[5]

projTemp = Select Project.template
           Where Name = proj
           Order by template

q = ""
q = q + "select r.sample_number, r.result_number "
q = q + "from sample s, result r, test t "
q = q + "where s.sample_number = r.sample_number "
q = q + "   and s.sample_number = t.sample_number "
q = q + "   and t.test_number = r.test_number "
q = q + "   and r.status in ('E', 'M', 'A', 'R') "
q = q + "   and s.project = " + str(proj) + " "
IF (projTemp <> "QC_TEMP") Then
  q = q + "   and t.instrument = " + str(inst) + " "
ENDIF
if (type="OK") then
  q = q + " and r.in_spec = 'F' "
endif

if (type="EXCLUDED") then
  q = q + " and r.in_spec = 'T' "
endif

If (notEMPTY(analName)) Then
  q = q + " and t.Analysis = " + analName + ""
Endif

q = q + "order by t.prep_date desc "
SQL( q, "rLst" )

num = ubound( rLst, 1 )

oldSmp = 0
smpCnt = 0
resString = ""
for i = 1 to num
  smp = rLst[ i, 1 ]

  if (oldSmp<>smp) then
    oldSmp = smp
    smpCnt = smpCnt + 1
  endif

  if (smpCnt<=numSmpls) then
    res[ i ] = rLst[ i, 2 ]
    resString = resString + rLST[i,2] + "|"
  endif
next i

if (numSmpls>smpCnt) then
  msgbox( "Warning: Only " + str(smpCnt) + " QCs found" )
endif

return restring

```

CODE for subroutine: MNU_FM_HIS_DATA'

```

=====
'                                     - PRODUCT_SPEC.DESCRPTION ("SD = ...")
'                                     - PRODUCT_SPEC.LO_CONTROL_1 (Mean - 2SD)
'                                     - PRODUCT_SPEC.HI_CONTROL_1 (Mean + 2SD)
'
=====
status = clearArray("alst")
status = clearArray("arr")
status = clearArray("clst")
status = clearArray("gradeFields")
status = clearArray("gradeValues")
status = clearArray("iLst")
status = clearArray("parameters")
status = clearArray("prodFieldName")
status = clearArray("prodFieldValue")
status = clearArray("specFieldNameArray")
status = clearArray("specFieldValueArray")

```

```

status = clearArray("stageFields")
status = clearArray("stageValues")
status = clearArray("xValues")
status = clearArray("yValues")
status = clearArray("Values")

status = CanAccessFunction( "DTCBQCSpecUpdate" )

if (status=false) then
    txt = "You do not have access to this function." + chr(10) + chr(13) + chr(10) + chr(13)
    txt = txt + "Please contact the LIMS administrator"
    msgbox( txt )
    return
endif

if (selectedFolder<>"QC_PROJECT") then
    msgbox( "Error: Wrong folder type" )
    return
endif

class = select folder.object_class
if (class<>"RESULT") then
    msgbox( "Error: Folder must be a RESULT folder" )
    return
endif

chartNo = getIncrement( "CHART_NO" )

prod = select sample.product
proj = select sample.project

if (isEmpty(prod)) then
    msgbox( "Error: QC sample must be associated with a product" )
    return
endif

' Make sure that the selected results are stored in the folder table
' =====
performWindowMethod( , "save" )

' Get the possible Analysis
' =====
q = ""
q = q + "select distinct r.Analysis "
q = q + "from folder_objects fo, result r "
q = q + "where fo.object_id = r.result_number "
q = q + " and fo.folder = " + selectedFolder + " "
q = q + "order by 1 "
numA = SQLSelect( q, "Which Analysis", "aLst", "T" )

status = OpenProgressDialog( "Calculation Progress", "Processing", "T")
for i = 1 to numA
    anl = aLst[ i, 1 ]

    per = i / numA * 100
    status = UpdateProgressDialog( anl, per )

' Get the result records...
' =====
q = ""
q = q + "select r.result_number, t.prep_date, r.entry, t.instrument, r.sample_number "
q = q + "from folder_objects fo, result r, test t "
q = q + "where fo.object_id = r.result_number "
q = q + " and r.test_number = t.test_number "
q = q + " and fo.folder = " + selectedFolder + " "
q = q + " and t.Analysis = " + anl + " "
q = q + " and t.status = 'A'"
q = q + "order by t.prep_date, r.result_number "
SQL( q, "rLst" )

num = ubound( rLst, 1 )

ClearArray("res")
ClearArray("xValues")

```

```

ClearArray("yValues")
ClearArray("parameters")
ClearArray("values")

for j = 1 to num
    res[ j ] = rLst[ j, 1 ]
    xValues[ j ] = rLst[ j, 2 ]
    yValues[ j ] = rLst[ j, 3 ]
next j

' Sort out the chart labels etc
' =====
inst = rLst[ 1, 4 ]
SQL( "select description from instruments where name = " + str(inst) + " ", "iLst" )
instLabel = iLst[ 1, 1 ]

comment = str(instLabel) + ", QC Type: " + str(prod) + ", Lot: " + str(proj) + ", Test: " + str(ani)
parameters[ 2 ] = "yVariableDescription"
values[ 2 ] = comment

parameters[ 1 ] = "xVariableDescription"
values[ 1 ] = "Date"

' Add project comments
' =====
q = ""
q = q + "select chart_comment "
q = q + "from x_project_comments "
q = q + "where project = " + str(proj) + " "
q = q + "order by order_number desc "
SQL( q, "cLst" )
title = cLst[ 1, 1 ]

if (isEmpty(title)) then
    title = ""
endif

' Open the histogram (hidden)
' =====
inc = getIncrement( "HISTOGEN" )
histo = "CHART" + str(ani) + str(inc) ' Make sure each time we run we get a different chart object
status = HistogramChartOpen( histo, yValues, comment, , "T" )
' status = HistogramChartOpen(name,chartPoints,title,parameters,values, hide)

if (status=false) then
    msgbox( lastError )
endif

wait( 1 )

status = HistogramChartCalculations( histo )

if (status=false) then
    msgbox( lastError )
else
    lowerCapabilityLimit = RoundTo(lowerCapabilityLimit, 2)
    measurementMean = RoundTo(measurementMean, 2)
    upperCapabilityLimit = RoundTo(upperCapabilityLimit, 2)
    standardDeviation = RoundTo(standardDeviation, 2)

    ' Store the calcs in a temporary table
    ' =====
    q = ""
    q = q + "insert into x_histo_calcs "
    q = q + "(chart_no, project, instrument, Analysis, lower_limit, mean_value, upper_limit, standard_dev, num_qcs )"
    q = q + "values "
    q = q + "(" + str(chartNo) + ", " + str(proj) + ", " + str(inst) + ", " + str(ani) + ", " + str(lowerCapabilityLimit) + ", " +
str(measurementMean) + ", " + str(upperCapabilityLimit) + ", " + str(standardDeviation) + ", " + str(numberOfSamples) + " )"
    SQL( q )

    ' Store the samples used in calculating the stats
    ' =====

```

```

for j = 1 to num
  resNo = rLst[ j, 1 ]
  smpNo = rLst[ j, 5 ]

  q = ""
  q = q + "insert into x_histo_results "
  q = q + "(chart_no, sample_number, result_number ) "
  q = q + "values "
  q = q + "(" + str(chartNo) + ", " + str(smpNo) + ", " + str(resNo) + " ) "
  SQL( q )
next j
endif
next i
closeProgressDialog()

q = ""
q = q + "select Analysis, lower_limit as '-3SD', mean_value, upper_limit as '+3SD', standard_dev as 'SD', num_qcs "
q = q + "from x_histo_calcs "
q = q + "where chart_no = " + str(chartNo)
num = SQLSelect( q, "Select Tests to Update", "arr", "T" )

status = ClearArray("specFieldNameArray")
status = ClearArray("specFieldValueArray")
status = ClearArray("stageFields")
status = ClearArray("stageValues")
status = ClearArray("gradeFields")
status = ClearArray("gradeValues")

for i = 1 to num
  anl = arr[ i, 1 ]
  minVal = arr[ i, 2 ]
  nomVal = arr[ i, 3 ]
  maxVal = arr[ i, 4 ]
  standardDeviation = arr[ i, 5 ]

  ' Ian Snell 05/03/2008
  ' Round to 2 decimal places
  ' =====
  minVal = RoundTo(minVal, 2)
  nomVal = RoundTo(nomVal, 2)
  maxVal = RoundTo(maxVal, 2)

  specFieldNameArray[ i, 1 ] = "PRODUCT"
  specFieldNameArray[ i, 2 ] = "CLASS"
  specFieldNameArray[ i, 3 ] = "GRADE"
  specFieldNameArray[ i, 4 ] = "STAGE"
  specFieldNameArray[ i, 5 ] = "SPEC_TYPE"
  specFieldNameArray[ i, 6 ] = "SAMPLING_POINT"
  specFieldNameArray[ i, 7 ] = "ANALYSIS"
  specFieldNameArray[ i, 8 ] = "COMPONENT"
  specFieldNameArray[ i, 9 ] = "RULE_TYPE"
  specFieldNameArray[ i, 10 ] = "MIN_VALUE"
  specFieldNameArray[ i, 11 ] = "MAX_VALUE"
  specFieldNameArray[ i, 12 ] = "NOMINAL_VALUE"
  specFieldNameArray[ i, 13 ] = "SPEC_RULE"
  specFieldNameArray[ i, 14 ] = "X_CHART_NO"
  specFieldNameArray[ i, 15 ] = "DESCRIPTION"
  specFieldNameArray[ i, 16 ] = "LO_CONTROL_1"
  specFieldNameArray[ i, 17 ] = "HI_CONTROL_1"

  specFieldValueArray[ i, 1 ] = prod
  specFieldValueArray[ i, 2 ] = "R"
  specFieldValueArray[ i, 3 ] = inst
  specFieldValueArray[ i, 4 ] = "NONE"
  specFieldValueArray[ i, 5 ] = "NONE"
  specFieldValueArray[ i, 6 ] = "NONE"
  specFieldValueArray[ i, 7 ] = anl
  specFieldValueArray[ i, 8 ] = "Result Value"
  specFieldValueArray[ i, 9 ] = "N"
  specFieldValueArray[ i, 10 ] = minVal
  specFieldValueArray[ i, 11 ] = maxVal
  specFieldValueArray[ i, 12 ] = nomVal
  specFieldValueArray[ i, 13 ] = "MIN <= Result <= MAX"
  specFieldValueArray[ i, 14 ] = chartNo

```

```

specFieldValueArray[ i, 15 ] = "SD = " & str(standardDeviation)
specFieldValueArray[ i, 16 ] = val(nomVal) - (2 * standardDeviation)
specFieldValueArray[ i, 17 ] = val(nomVal) + (2 * standardDeviation)

stageFields[ i, 1 ] = "PRODUCT"
stageFields[ i, 2 ] = "GRADE"
stageFields[ i, 3 ] = "SAMPLING_POINT"
stageFields[ i, 4 ] = "STAGE"
stageFields[ i, 5 ] = "SPEC_TYPE"
stageFields[ i, 6 ] = "ANALYSIS"

stageValues[ i, 1 ] = prod
stageValues[ i, 2 ] = inst
stageValues[ i, 3 ] = "NONE"
stageValues[ i, 4 ] = "NONE"
stageValues[ i, 5 ] = "NONE"
stageValues[ i, 6 ] = anl
next i

gradeFields[ 1 ] = "PRODUCT"
gradeFields[ 2 ] = "GRADE"
gradeFields[ 3 ] = "SAMPLING_POINT"
gradeValues[ 1 ] = prod
gradeValues[ 2 ] = inst
gradeValues[ 3 ] = "NONE"

if (num>0) then
    status = UpdateProduct( prod, , , gradeFields, gradeValues, stageFields, stageValues, specFieldNameArray,
specFieldValueArray, "UPDATE", "T" )

    if (status) then
        txt = str(prod) + " new version created" + chr(10) + chr(13) + chr(10) + chr(13) + "Do you want to make it active?"

        ans = PromptForYesNo( txt )

        if (ans="Yes") then
            prodFieldName[ 1 ] = "ACTIVE"
            prodFieldValue[ 1 ] = true
            promptText = "Enter Audit Reason"
            status = PromptForAuditReason(promptText, "PRODUCT")
            status = UpdateProduct( prod, prodFieldName, prodFieldValue, , , , , "UPDATE", "F" )

            if (status) then
                txt = str(prod) + " is now active"
                msgbox( txt )
            else
                msgbox( lastError )
            endif
        endif
    else
        msgbox( lastError )
    endif
endif
endif

```

Appendix VI: Synergy Health - Cut Off Levels (Urine samples)

Synergy Health Product Catalogue			
Drugs of Abuse Cut Off Levels			
The cut off levels in use are those recommended by the United Kingdom Laboratory Guidelines for Legally Defensible Workplace Drug Testing.			
Drug Group/Type	Cut Off for Screening (ng/mL)	Confirmation by Drug	Cut Off for Confirmation (ng/mL)
Cannabis	50	Delta-9-THC Acid	15
Cocaine	300	Benzoyllecgonine	150
Opiates	300	Codeine	300
		Morphine	300
		6-MAM (Heroin)	10
		Dihydrocodeine	300
Methadone	300	Methadone	250
		EDDP	250
Amphetamines	300	Amphetamine	200
		Methamphetamine	200
		MDA, MDMA, MDEA	200
Benzodiazepines	200	Oxazepam	100
		Amino Nitrazepam	100
		Temazepam	100
		Nordiazepam	100
		Flunitrazepam (Rohypnol)	10
		Diazepam	10
Buprenorphine	5	Buprenorphine	5
		Norbuprenorphine	5
Propoxyphene	300	Propoxyphene	300
		Norpropoxyphene	300
Barbiturates	200	Amobarbital	150
		Butobarbital	150
		Pentobarbital	150
		Phenobarbital	150
		Secobarbital	150
Ketamine	100	Ketamine	500
		Norketamine	500

Other standards and cut off levels exist, such as the US SAMHSA guidelines, European Guidelines and Australian and New Zealand standards (AS/NZS 4308) and Synergy Health Laboratory Services can test to these cut offs if required.

Figure 7.9: Synergy Health - Cut Off Levels (Urine samples) (Synergy Health Laboratory Services, 2012)

Appendix VII: Process 4: Code For Electronic Reporting Module

SUBROUTINE REP_CLIN_C_S

This routine prompts the user for report criteria the report itself is generated in the validation subroutine for the dialog (VAL_REP_CL)

***** Created 21/12/2005 I. Snell

'FieldArray structure:

```
'1 FieldName
'2 FieldLabel
'3 DataType (Text, Number, Integer, Boolean, List, File, Date, Time, Title, DateTime)
'4 DefaultValue
'5 LinkTable
'6 MaxSize
'7 ListName
'8 EntryMode (UserEntry, MandatoryEntry, DisplayOnly, TitleEntry)
'9 DependsOn '10 FormulaSub
formName = "RE_CLINIC"
title = "Please Enter Details"
width = 687
height = 476
clinicID = ""
fieldsArray[1,1] = "CLINIC_ID"
fieldsArray[1,2] = "Clinic ID"
fieldsArray[1,3] = "Text"
fieldsArray[1,4] = ClinicID
fieldsArray[1,5] = "X_CLINIC"
fieldsArray[1,8] = "MandatoryEntry"
fieldsArray[2,1] = "PER_PAGE"
fieldsArray[2,2] = "One patient per page?"
fieldsArray[2,3] = "Boolean"
fieldsArray[2,8] = "UserEntry"
fieldsArray[2,9] = "CLINIC_ID"
fieldsArray[2,10] = "SET_PRIN"
fieldsArray[3,1] = "REP_TYPE"
fieldsArray[3,2] = "Report Type"
fieldsArray[3,3] = "List"
fieldsArray[3,7] = "REP_TYPE"
fieldsArray[3,8] = "MandatoryEntry"
fieldsArray[4,1] = "START_DATE"
fieldsArray[4,2] = "Start date"
fieldsArray[4,3] = "Date"
fieldsArray[4,4] = date()
fieldsArray[4,8] = "UserEntry"
fieldsArray[5,1] = "END_DATE"
fieldsArray[5,2] = "End date"
fieldsArray[5,3] = "Date"
fieldsArray[5,4] = date()
fieldsArray[5,8] = "UserEntry"
fieldsArray[6,1] = "STATS"
fieldsArray[6,2] = "Include Statistics?"
fieldsArray[6,3] = "Boolean"
fieldsArray[6,4] = "T"
fieldsArray[6,8] = "UserEntry"
fieldsArray[7,1] = "FIRST_ID"
fieldsArray[7,2] = "First Barcode"
fieldsArray[7,3] = "Text"
fieldsArray[7,4] = ""
fieldsArray[7,5] = "DTCB_BARCODE"
fieldsArray[7,8] = "UserEntry"
fieldsArray[8,1] = "LAST_ID"
fieldsArray[8,2] = "Last Barcode"
fieldsArray[8,3] = "Text"
fieldsArray[8,4] = ""
fieldsArray[8,5] = "DTCB_BARCODE"
fieldsArray[8,8] = "UserEntry"
fieldsArray[9,1] = "CHAIN_CUST"
fieldsArray[9,2] = "Include Chain Of Custody Statement?"
fieldsArray[9,3] = "Boolean"
fieldsArray[9,4] = "F"
```

```

fieldsArray[9,8] = "UserEntry"
fieldsArray[10,1] = "X_PRINT"
fieldsArray[10,2] = "Print"
fieldsArray[10,3] = "Text"
fieldsArray[10,8] = "DisplayOnly"
fieldsArray[10,9] = "CLINIC_ID"
fieldsArray[10,10] = "GET_PRINT_DT"
' status = CreateDialog(formName, title, fieldsArray, "valuesArray", "VAL_REP_CL_S", width, height)
status = CreateDialog(formName, title, fieldsArray, "valuesArray", "VAL_REP_PDF", width, height)
IF (dialogcanceled) THEN
  Return
ENDIF
SUBROUTINE REP_CLIN_PDF
status = UserDialog( "FIND_PDF", "void", , , "T" )
USER DIALOG find_pdf
trayDate = select find_pdf.tray_on
if (isEmpty(trayDate)) then
  return
endif
endiftDate = left(str( trayDate ), 10 )
' SQL( "select tray_id from x_trays where tray_id like " + tDate + "%' order by tray_id ", "lst" )
q = ""
q = q & "select distinct s.x_tray "
q = q & "from sample s, x_reports r "
q = q & "where s.report_number = r.report_number "
q = q & " and r.ext_link is not null "
q = q & " and s.x_tray like " + tDate + "%' "
q = q & "order by s.x_tray "
SQL( q, "lst" )
return lst
SUBROUTINE VAL_FIND_PDF
path = "\\cheops\lab_documents\"
clinic = select find_pdf.clinic
chart = select find_pdf.chart
barcode = select find_pdf.barcode
startDate = select find_pdf.from
endDate = select find_pdf.to
tray = select find_pdf.tray
IF ( isEmpty(clinic) and isEmpty(chart) and isEmpty(barCode) and isEmpty(tray) and isEmpty(startDate) and isEmpty(endDate) )
THEN
  RETURN true
ENDIF
' Find the matching reports
' =====
q = ""
q = q & "select distinct s.report_number, r.changed_on as [Printed On], r.description, r.clinic, r.ext_link "
q = q & "from sample s, x_reports r "
q = q & "where s.report_number = r.report_number "
q = q & " and r.ext_link is not null "
IF (isEmpty(clinic)=false) THEN
  q = q & " and r.clinic = " & str(clinic) & " "
ENDIF
IF (isEmpty(chart)=false) THEN
  q = q & " and s.x_patient = " & str(chart) & " "
ENDIF
IF (isEmpty(barcode)=false) THEN
  q = q & " and s.text_id = " & str(barcode) & " "
ENDIF
IF (isEmpty(tray)=false) THEN
  q = q & " and s.x_tray = " & str(tray) & " "
ENDIF
IF (isEmpty(startDate)=false) THEN
  q = q & " and r.changed_on > " & OdbcDateTimeStamp( startDate )
ENDIF
IF (isEmpty(endDate)=false) THEN
  q = q & " and r.changed_on < " & OdbcDateTimeStamp( endDate )
ENDIF
q = q & " order by 2 desc "
SQL( q, "reportArr" )
num = ubound( reportArr, 1 )
IF (num=0) THEN
  txt = "No reports found"
  msgbox( txt )
  RETURN false
ENDIF

```



```

number = SQLSelect( q, "Select a report(s) to View", "repArr", "T", "F")
IF (number>0) THEN
FOR i = 1 to number
file = repArr[ i, 5 ]
fullFilePath = str(path) & str(file)
status = ShellCommand( fullFilePath, "OPEN", "F" )
NEXT i
ENDIF
RETURN false
SUBROUTINE VAL_REP_PDF
clinicID = select re_clinic.clinic_id
repType = select re_clinic.rep_type
perPage = select re_clinic.per_page
stats = select re_clinic.stats
startDate = select re_clinic.start_date
endDate = select re_clinic.end_date
recdflag = select re_clinic.recd_flag
chncust = select re_clinic.CHAIN_CUST
' Changed IGS 17/01/2006
' =====
secs = (24 * 60 * 60) - 1
endDate = DateTimeAdd( endDate, secs )
' endDate = DateAdd(endDate, 1)
startDateODBC = OdbcDateTimeStamp(startDate)
endDateODBC = OdbcDateTimeStamp(endDate)
first = select re_clinic.first_id
last = select re_clinic.last_id
IF (repType="BARCODE") THEN
if ( isEmpty(first)=false and isEmpty(last)=false ) then
if (first>last) then
msgbox( "Invalid barcode range (last<first)" )
return false
endif
q1 = "select count(*) "
q2 = "from sample "
q3 = "where text_id between ""
q4 = str(first) + "" and "" + str( last ) + ""
q5 = " and x_clinic <> "" + str(clinicID) + ""
' IGS: 18-04-2011
' =====
q6 = " and sample_number > 0 "
q = q1 + q2 + q3 + q4 + q5 + q6
status = SQL(q,"cLst")
cnt = cLst[ 1, 1 ]
if (cnt>0) then
msgbox( "Invalid barcode range (samples from wrong clinic)" )
return false
endif
selSampQuery = "SELECT DISTINCT TEXT_ID FROM SAMPLE "
selSampQuery = selSampQuery & " WHERE text_id between "" + str(first) + "" and "" + str(last) + ""
else
msgbox( "Invalid barcode range" )
return false
endif
reportTxt = "BARCODE: " & str(first) & " - " & str(last)
ELSEIF (repType = "SAMPLE") THEN
selSampQuery = "SELECT DISTINCT BARCODE FROM REPORT_RESULTS "
selSampQuery = selSampQuery & " WHERE [Clinic] = "" & clinicID & ""
selSampQuery = selSampQuery & " AND [DATE SAMPLED] >= "" & startDateODBC
selSampQuery = selSampQuery & " AND [DATE SAMPLED] < "" & endDateODBC
reportTxt = "SAMPLED DATE: " & str(startDate) & " - " & str(endDate)
ELSEIF (repType = "TEST_INC") THEN
selSampQuery = "select distinct s.text_id, s.status "
selSampQuery = selSampQuery & "from sample s, result r "
selSampQuery = selSampQuery & "where s.x_clinic = "" + clinicID + ""
selSampQuery = selSampQuery & "and s.text_id = r.text_id "
selSampQuery = selSampQuery & "and "
selSampQuery = selSampQuery & "( (r.entered_on between "" + startDateODBC + "" AND "" + endDateODBC+ "" ) "
selSampQuery = selSampQuery & " or ( (s.status='U' ) and (s.login_date between "" + startDateODBC + "" AND "" + endDateODBC + "" ) ) "
selSampQuery = selSampQuery & " ) "
reportTxt = "TESTED DATE (inc U): " & str(startDate) & " - " & str(endDate)
ELSEIF (repType = "TEST") THEN
miniHost = false
if (miniHost) then

```

```

selSampQuery = "SELECT DISTINCT BARCODE FROM REPORT_RESULTS "
selSampQuery = selSampQuery & " WHERE [Clinic] = " & clinicID & ""
selSampQuery = selSampQuery & " AND ( "
selSampQuery = selSampQuery & " (tested_date >= " & startDateODBC & " AND tested_date < " & endDateODBC + " ) "
' Include none-compliance samples
' =====
selSampQuery = selSampQuery & " or "
selSampQuery = selSampQuery & " ( (tested_date is null) and ([Date Sampled] >= " & startDateODBC & " AND [Date Sampled] < "
& endDateODBC + " ) )"
selSampQuery = selSampQuery & " ) "
else
selSampQuery = "select distinct s.text_id "
selSampQuery = selSampQuery & " from sample s, result r "
selSampQuery = selSampQuery & " where s.x_clinic = " & clinicID & ""
selSampQuery = selSampQuery & " and s.text_id = r.text_id " selSampQuery = selSampQuery & " and r.entered_on between " &
startDateODBC & " and " & endDateODBC
endif
reportTxt = "TESTED DATE: " & str(startDate) & " - " & str(endDate)
ELSE
msgbox("No report type selected.")
' Keep the dialog open
' =====
return false
ENDIF
status = SQL(selSampQuery, "arraySampTextID", 0, "F")
numSamp = UBOUND(arraySampTextID, 1)
' Don't generate the report if there are no samples
' =====
IF (numSamp = 0) THEN
msg = "No samples."
msgbox(msg)
' Keep the dialog open
' =====
return false
ELSE
' Generate a report number and file name
' =====
path = "\\CHEOPS\LAB_DOCUMENTS\"
status = DirExists( path )
IF (status=false) THEN
status = DirNew( path )
ENDIF
reportNumber = getIncrement( "gClinicReport" )
id = "00000000" & str(reportNumber)
id = right( id, 8 )
fileName = str( id ) & ".pdf"
fullFileName = str( path ) & str( id ) & ".pdf"
clearArray( "keyFields" )
clearArray( "keyValues" )
clearArray( "fieldsArr" )
clearArray( "valuesArr" )
keyFields[ 1 ] = "REPORT_NUMBER"
keyValues[ 1 ] = reportNumber
fieldsArr[ 1 ] = "DESCRIPTION"
fieldsArr[ 2 ] = "CLINIC"
fieldsArr[ 3 ] = "EXT_LINK"
valuesArr[ 1 ] = str(reportTxt)
valuesArr[ 2 ] = str(clinicID)
valuesArr[ 3 ] = str(fileName)
status = InsertTable( "X_REPORTS", keyFields, keyValues, fieldsArr, valuesArr )
strSampIDText = ""
textIDcsv = ""
reportName = "FINAL_CLINIC"
*** CC 2005-09-04 Build string list of text_ids
for i = 1 to numSamp
strSampIDText = strSampIDText & arraySampTextID[i,1] & "|"
next i
*** CC 2005-09-04 Remove last "|"
lenSampIDText = len(strSampIDText) - 1
strSampIDText = left(strSampIDText, lenSampIDText)
status = ClearArray("argArray")
status = ClearArray("valArray")
argArray[1] = "@PrintUser"
argArray[2] = "REPORT_RESULTS.BARCODE"

```

```

argArray[3] = "@start_date"
argArray[4] = "@end_date"
argArray[5] = "@stats"
argArray[6] = "@rep_type"
argArray[7] = "@NewPage"
argArray[8] = "@firstBarcode"
argArray[9] = "@lastBarcode"
'argArray[10] = "@RecdFlag"
argArray[10] = "@showChainOfCustody"
argArray[11] = "VERSIONS.TABLE_NAME"
argArray[12] = "SAMPLE.TEMPLATE"
argArray[13] = "@reportID"
valArray[1] = USER
valArray[2] = strSampIDText
valArray[3] = startDate
valArray[4] = endDate
valArray[5] = stats
valArray[6] = repType valArray[7] = perPage
valArray[8] = first
valArray[9] = last
'valArray[10] = recdflag
valArray[10] = chncust
valArray[11] = "ANALYSIS"
valArray[12] = "DAIS|INT_LAB|ROUTINE"
valArray[13] = reportNumber
printerName = ""
status = RunReport(reportName, argArray, valArray, fullFileName, printerName )
ShellCommand( fullFileName, "OPEN", "F" )
IF (status=true) THEN
FOR i = 1 TO numSamp
txtID = arraySampTextID[ i, 1 ]
q = ""
q = q & "UPDATE SAMPLE "
q = q & "SET REPORT_NUMBER = " & str(reportNumber) & " "
q = q & "WHERE TEXT_ID = " & str(txtID) & " "
q = q & " AND REPORT_NUMBER = 0 "
IF (user<>"SNELLI") THEN
status = SQL( q, "void" )
IF (status=false) THEN
msgbox( lastError )
ENDIF
ENDIF
NEXT i
ENDIF
' Keep the dialog open
' =====
return false

```


Appendix VIII: Process 4: Electronic Reporting Section - Oasis New Storage Boxes 2012

Barcode	Alternate Code	Add Date	Status Date
538363	325	02/04/2012	02/04/2012
538364	326	02/04/2012	02/04/2012
538365	327	02/04/2012	02/04/2012
538366	328	02/04/2012	02/04/2012
538367	329	02/04/2012	02/04/2012
538368	330	02/04/2012	02/04/2012
538369	331	02/04/2012	02/04/2012
538373	335	02/04/2012	02/04/2012
538404	QR7	02/04/2012	02/04/2012
538405	QR8	02/04/2012	02/04/2012
538374	336	02/04/2012	02/04/2012
538375	337	02/04/2012	02/04/2012
538376	338	02/04/2012	28/05/2013
538391	CS21	02/04/2012	28/05/2013
538392	CS22	02/04/2012	28/05/2013
538370	332	02/04/2012	02/04/2012
538371	333	02/04/2012	02/04/2012
538372	334	02/04/2012	02/04/2012
538395	CR22	25/07/2012	25/07/2012
723554	CR23	25/07/2012	25/07/2012
723555	CR24	25/07/2012	28/05/2013
538377	339	25/07/2012	28/05/2013
538378	340	25/07/2012	28/05/2013
538379	341	25/07/2012	28/05/2013
538380	342	25/07/2012	28/05/2013
538381	343	25/07/2012	28/05/2013
538382	344	25/07/2012	28/05/2013
538383	345	25/07/2012	28/05/2013
538384	346	25/07/2012	28/05/2013
538385	347	25/07/2012	28/05/2013
538386	348	25/07/2012	28/05/2013
538387	349	25/07/2012	28/05/2013
538393	CR20	25/07/2012	25/07/2012
538394	CR21	25/07/2012	25/07/2012
538403	RR21	05/11/2012	28/05/2013
723556	353	05/11/2012	28/05/2013

723557	354	05/11/2012	28/05/2013
723558	355	05/11/2012	28/05/2013
723559	356	05/11/2012	28/05/2013
723560	357	05/11/2012	28/05/2013
723561	358	05/11/2012	28/05/2013
723562	359	05/11/2012	28/05/2013
723641	MED 11	05/11/2012	05/11/2012
723642	MED 12	05/11/2012	05/11/2012
723643	RR 20	05/11/2012	05/11/2012
538388	350	05/11/2012	28/05/2013
538389	351	05/11/2012	28/05/2013
538390	352	05/11/2012	28/05/2013

Figure 7.10: OASIS GROUP 2012 List of Document Boxes Stored offsite

Appendix IX: Process 4: Electronic Reporting Section - Oasis New Storage Boxes 2013

Barcode	Alternate Code	Add Date	Status Date
723563	360	12/03/2013	28/05/2013
723564	361	12/03/2013	28/05/2013
723565	362	12/03/2013	28/05/2013
723566	363	12/03/2013	28/05/2013
723567	364	12/03/2013	28/05/2013
723568	365	12/03/2013	28/05/2013
723569	366	12/03/2013	28/05/2013
723570	367	12/03/2013	28/05/2013
723571	368	12/03/2013	28/05/2013
723572	369	12/03/2013	28/05/2013
723573	370	12/03/2013	28/05/2013
723574	371	12/03/2013	28/05/2013
723575	72	12/03/2013	28/05/2013
723576	373	12/03/2013	28/05/2013
723577	374	12/03/2013	28/05/2013
723631	00CS24	12/03/2013	28/05/2013
723632	00CS23	12/03/2013	28/05/2013
723644	00CR25	12/03/2013	28/05/2013
723645	00CR26	12/03/2013	28/05/2013
723646	00CR27	12/03/2013	28/05/2013
723647	00CR28	12/03/2013	28/05/2013
723648	00CR29	12/03/2013	28/05/2013
723649	00RR24	12/03/2013	28/05/2013
723650	RR22	12/03/2013	28/05/2013
723651		12/03/2013	28/05/2013
723652	00CS25	12/03/2013	28/05/2013
723653	13	12/03/2013	12/03/2013

Figure 7.11: OASIS GROUP 2013 List of Document Boxes Stored offsite

Appendix X: Process 4: Electronic Reporting Section


<u>OASIS Group Pricing – Document Storage & Management</u>		
Prepared for: Fionnuala Rafferty @ DTCB - KID008	Date: 1st November 2011	
Prepared By: Paul Giles		Office Use
Storage Standard Oasis Box, per month	Rate €0.52	<input type="text"/>
Services Add & Track new Box Add & Track new File Handling Charge per Box or File – in / out	€0.75 €0.45 €1.00	<input type="text"/> <input type="text"/> <input type="text"/>
Delivery / Collection within Dublin 08:30hrs to 17:00hrs For the first 10 boxes delivered / collected Each additional box / file <small>Items requested before 12:00 hrs will be retrieved and dispatched the next working day Deliveries are within Greater Dublin area Large Deliveries / collections will be priced on application - min 48 hrs notice</small>	€8.00 €1.00	<input type="text"/> <input type="text"/>
Special Delivery Express Delivery – within 3 hours Out of Office Hours Delivery Weekend / Bank Holiday Delivery	€35.00 €60.00 €80.00	<input type="text"/> <input type="text"/> <input type="text"/>
Consumables OASIS Standard Archive Box Box / File Barcodes	€2.50 FOC	<input type="text"/> <input type="text"/>
Additional Services Etc.. Confidential Shredding Consoles (Service Charge per console) Bulk Scanning Projects Perm Out Charge, per item	€5.50 POR €1.30	<input type="text"/> <input type="text"/> <input type="text"/>

Figure 7.12: OASIS GROUP Pricing Document

Appendix XI: Questionnaire

The use of Lean Six Sigma in the NDTC Laboratory Questionnaire

Consent by subject for participation in Research Protocol

Protocol Number: _____

Subject Name: _____

Title of Protocol: *Can Lean Six Sigma methodologies be used to improve the tracking and reporting systems in the DTCB Laboratory?*

Principal Investigator: *Paul Murray*

Phone: *01 6488621*

You are being asked to participate in a research study. In order to decide whether or not you want to be part of this research study, you should understand enough about its risks and benefits to make an informed judgement. This process is known as informed consent. This consent form gives detailed information about the research study which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate.

I. NATURE OF DURATION OF PROCEDURE(S)

The study will be undertaken by Paul Murray the ICT Manager for the DTCB and the purpose of this study is ascertain your opinion of the control processes currently used in the DTCB Laboratory where Lean Six Sigma was used to improve processes, the Value Stream and reduce waste.

II. POSSIBLE ALTERNATIVES:

You may choose not to participate as participation is voluntary.

AGREEMENT TO CONSENT

The research project and the treatment procedures associated with it have been fully explained to me. All experimental procedures have been identified and no guarantee has been given about the possible results. I have had the opportunity to ask questions concerning any and all aspects of the project and any procedures involved. I am aware that participation is voluntary and that I may withdraw my consent at any time. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I, the undersigned, hereby consent to participate as a subject in the above described project conducted at the National Drug Treatment Centre. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the Principal Investigator listed above. If I have any questions concerning my rights in connection with the research, I can contact the Ethics Committee of the Nation Drug Treatment Centre.

After reading the entire consent form, if you have no further questions about giving consent, please sign where indicated.

Principal Investigator: _____

Signature of Subject: _____

Witness: _____
(circle)

Date: _____ Time: _____ am/pm

The use of Lean Six Sigma in the NDTC Laboratory Questionnaire

Below is a List of Improvements to Routine processing system that were introduced during the Lean Six Sigma Project

- TF4 Removed, 'batches' no longer require counting, catalogue clinics and write up, TF4 available at the end of the tray check report
- Trays – system now operates using trays and not batches. Samples can be processed from the analysers quicker – Tray approx. 50 samples, batch approx.: 150-200 samples.
- Batch paperwork – no longer needs to be check against tray check report by Biochemists
- All 'paperwork' saved to Server (L:\ Drive) (printed TF4, tray check no longer required). Easy access to reports for checking – no need for the recall of boxes stored offsite.
- Electronic reporting: All clinic reports automatically save as PDFs. Reports for LER are saved internally and DAIS reports do not require printing.
- All reports processed and can be searched for in Labware LIMS. The need to recall boxes for original reports not required
- NWA: Statistical updates are generated automatically. Excel sheet manual calculations & paperwork no longer required, reducing time and errors.
- System alerts when QCs are close to expiry dates
- Inventory: Recorded in Labware LIMS, audit trail available, no longer saved to MS Excel Spread sheets, transcription errors reduced.

The use of Lean Six Sigma in the NDTC Laboratory Questionnaire

Clinical Department: Laboratory
The National Drug Treatment Centre

www.Addictionireland.ie

Description: Questionnaire for the staff of the NDTC Laboratory to ascertain their level of Satisfaction with the Lean Six Sigma interventions made to the Specimen Sample Process flow.

Participant ID	No:				
Laboratory Department Role					
Agent Name	Paul Murray (ICT Manager, NDTC)				
Over all how would you rate your level of Satisfaction with...	Very Low	Low	Neither Low nor High	High	Very High
...the levels of communication during the implementation phase of the Lean Six Sigma interventions?					
...how the transition from the old system to the new system was implemented?					
...your transition of moving from the old system to the new system?					
...the usability of the new process changes?					
...the reduction in the amount of transcriptions errors?					
...the amount of time saving these enhancements have had on how you perform your daily tasks?					
...the audit-ability of the new enhancements in relation to accreditation and the ISO 17025 standard?					
...how the new process changes have helped working with reduced levels of staff?					
...the new process changes in relation to coping with the extra specimen samples the Laboratory receives?					
...the levels of staff morale since the new process changes have been deployed?					
Would there be a benefit for Lean Six Sigma interventions in other areas of the Laboratory?	Yes:		No:		
If 'Yes' Give details					
Additional comments:					

Appendix XII: Statistical Analysis

ID	Discipline	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Details	Comments
1	Lab Aide	4	4	4	4	5	5	4	4	5	3	YES		
2	Lab Aide	4	4	4	4	5	5	4	4	5	3	YES		
3	Lab Aide	4	5	5	5	4	4	4	2	3	3	YES		*
4	Lab Aide	4	4	5	5	4	5	4	4	4	3	YES		
5	Lab Aide	3	4	4	4	4	5	3	4	4	4	YES		
6	Biochemist	3	3	3	4	4	4	3	4	4	4	NO		
7	Biochemist	4	3	3	4	4	5	5	4	4	3	YES	**	**
8	Biochemist	3	5	5	5	4	5	4	3	N/A	4	YES	*	***
9	Biochemist	4	4	5	5	3	4	4	1	2	3	YES		
10	Biochemist	4	4	3	5	4	4	4	3	5	4	YES		****
11	Biochemist	5	5	4	4	N/A	4	4	4	4	3	YES	*****	
12	Biochemist	4	3	4	4	4	5	5	4	4	4	NO		

Table 7.1: Questionnaire Raw Data

R Application Data

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 1.0286, df = 2, p-value = 0.5979

Chi-squared approximation may be incorrect

```
> DisQ1=table(Discipline,Q1)
```

```
> DisQ2=table(Discipline,Q2)
```

```
> DisQ2
```

```
Q2
```

```
Discipline 3 4 5
```

```
Biochemist 3 2 2
```

```
Lab Aide 0 4 1
```

```
> summary(DisQ2)
```

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 3.771, df = 2, p-value = 0.1517

Chi-squared approximation may be incorrect

```
> DisQ3=table(Discipline,Q3)
```

```
> DisQ3
```

```
Q3
```

```
Discipline 3 4 5
```

Biochemist 3 2 2
Lab Aide 0 3 2

```
> summary(DisQ3)
```

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 2.9486, df = 2, p-value = 0.2289

Chi-squared approximation may be incorrect

```
> DisQ4=table(Discipline,Q4)
```

```
> summary(DisQ4)
```

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 0.009796, df = 1, p-value = 0.9212

Chi-squared approximation may be incorrect

```
> DisQ5=table(Discipline,Q5)
```

```
> summary(DisQ5)
```

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 4.286, df = 3, p-value = 0.2322

Chi-squared approximation may be incorrect

```
> DisQ6=table(Discipline,Q6)
```

```
> summary(DisQ6)
```

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 1.6555, df = 1, p-value = 0.1982

Chi-squared approximation may be incorrect

```
> DisQ7=table(Discipline,Q7)
```

```
> summary(DisQ7)
```

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 1.7143, df = 2, p-value = 0.4244

Chi-squared approximation may be incorrect

```
> DisQ8=table(Discipline,Q8)
```

```
> summary(DisQ8)
```

Number of cases in table: 12
Number of factors: 2

Test for independence of all factors:

Chisq = 3.771, df = 3, p-value = 0.2872

Chi-squared approximation may be incorrect

> DisQ8=table(Discipline,Q8)

> DisQ9=table(Discipline,Q9)

> summary(DisQ9)

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 3.771, df = 4, p-value = 0.4378

Chi-squared approximation may be incorrect

> DisQ10=table(Discipline,Q10)

> summary(DisQ10)

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 1.6555, df = 1, p-value = 0.1982

Chi-squared approximation may be incorrect

> DisQ11=table(Discipline,Q11)

> DisQ11

Q11

Discipline NO YES

Biochemist 2 5

Lab Aide 0 5

> summary(DisQ11)

Number of cases in table: 12

Number of factors: 2

Test for independence of all factors:

Chisq = 1.7143, df = 1, p-value = 0.1904

Chi-squared approximation may be incorrect

> matrix(Discipline,Q1)