Was Lean Implemented Effectively and Sustained in Irish Histopathology Laboratories?

Dissertation submitted in part fulfilment of the requirements for the master of

Business Administration

at Dublin Business School

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DECLARATION

Declaration: I, Kate Thompson declare that this research is my original work and that it has never been presented to any institution or university for the award of Degree or Diploma. In addition, I have referenced correctly all literature and sources used in this work and this work is fully compliant with the Dublin Business School’s academic honesty policy.

Signed: Kate Thompson (10351816)

Date: 20/08/2018
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Finally my deepest thanks have to go to Robert. You are my rock, my constant support and I wouldn’t have made it without you.
ABSTRACT

Dissertation Topic:

To investigate if Lean was implemented effectively and sustained in Irish Histopathology laboratories.

Objectives of Study:

To examine the Lean implementation process in Irish Histopathology laboratories. Examine if Lean transformation only focuses on Processes, or if Philosophy, People and partners, and Problem-solving have also been embraced. To investigate if management support, and lead Lean. To examine how Histopathology laboratories provide customer value. To examine how Lean processes implemented have been sustained. To explore if automation is a necessary element of Lean. To examine variations in implementation and sustainability between ROI public and private Histopathology laboratories.

Nature and Scope of Research Undertaken:

An inductive, double-phased, mixed-methodology approach was applied in this study. Primary qualitative data was collected in the form of semi-structured IDIs. Three Laboratory Managers were interviewed providing expert opinion on Lean across Pathology departments. The data was coded and analysed, meaning was derived from the interviews, and the questionnaire was developed. This focused specifically on Lean in Histopathology and was distributed to the entire population of Histopathology CMSs in the ROI and NI constituting a census.

Results:

Lean has been led from within in the 57% of cases. Philosophy, Process, and Problem-solving have all been embraced to varying degrees, but People and partners is the most poorly implemented “P”. Balancing workflow seems at present unachievable due to large, unscheduled sample deliveries and work-creep from outpatient departments. Architectural limitation is the biggest impediment to achieving optimal flow design. Automation while necessary for the improvement of certain processes, is not considered a necessary element of Lean. This study found little variation between Lean in public and private Histopathology laboratories in the ROI. Instead it indicates a united profession striving to provide high-quality service while facing common challenges.

Contribution Made to the Knowledge of the Research Topic:

There is a notable absence of published information on Lean in Histopathology services in Ireland. This research aims to fill that knowledge gap, providing current information on the opinions and experiences of those working in the profession. It will also serve as a platform for further research and will be of interest to the HSE as it provides insight into the challenges faced by Histopathology departments nationally in sustaining Lean.
RESEARCH CONTEXT

1.1.1 WHAT IS PATHOLOGY?

Royal College of Physicians of Ireland (2017) defines Pathology as “the study of the nature and causes of diseases.” Pathology plays a vital role in patient care as it’s incorporated in every aspect of medicine from the diagnosis of disease and monitoring chronic conditions to the pursuit of new and innovative treatments through genetic research. There are six key Pathology disciplines in Ireland; Histopathology, Microbiology, Biochemistry, Haematology, Immunology, and Blood Transfusion.

1.1.2 WHAT IS HISTOPATHOLOGY?

Histopathology is the study of diseased body tissue, e.g. a breast lump may be removed from a patient due to a suspicion of cancer. Scientific methods are applied to determine if disease is present in the sample including adding specialised dye-stains to thin slices of tissue allowing pathologists to view different cellular structures microscopically, thus aiding in a diagnosis (The Royal College of Pathologists, 2017). This scientific discipline consists of a mixture of manual and automated techniques.

There are 35 Histopathology Chief Medical Scientists (CMSs) in hospitals laboratories across the Republic of Ireland (ROI); 24 in public (HSE and voluntary HSE) laboratories, and 11 in private laboratories. Some laboratories may not have a CMS but will instead have a Senior in Charge (SIC) but for the purpose of this study CMS will refer to Chief or SIC. Also, when I refer to CMS throughout this study I am referring specifically to Histopathology CMSs only.

It is a complex discipline with several subdivisions including, but not limited to; immunohistochemistry, special stains, non-gynae cytology, neuropathology, electron microscopy, and renal pathology. Unlike other Pathology disciplines, Histopathology does not provide a comprehensive 24/7 service. This is due to overnight processing procedures needed to ensure tissue samples are permanently preserved. This is important because unlike, e.g. Biochemistry where blood samples are quickly analysed and easily repeated, the specimens received in Histopathology are one-off specimens.

Histopathology, according to Clarke (2016, p.5), resembles the manufacturing industry more closely than other areas of healthcare because the delivery of an efficient service is dependent on producing high quality products. These products include specimens permanently embedded in wax blocks, and stained slides produced from these blocks. Providing a timely and consistently high-quality product, and matching capacity to demand are manufacturing issues that are mirrored in Histopathology. Histopathology laboratories are increasingly turning to Lean methodologies to tackle these issues. (Zarbo and D’Angelo, 2007), (Raab et al, 2008), (Clarke et al, 2013).

1.1.3 WHAT IS LEAN MANAGEMENT?
Lean is a continuous quality improvement (CI) system based on the Toyota Production System (TPS), comprising of two fundamental components. Firstly, a systematic approach to process improvement through the waste removal, resulting in the realisation of optimal value for the end user. Secondly, the creation of a culture of CI; achieved by investing in, and developing the people in the organisation (Clark et al., 2013, p.638).

There is growing evidence that lean management systems deliver superior results (Clark, 2016, p.5), however sustaining these results seems to present a greater challenge. While implementation is vital it is necessary to realise that implementing new processes for improvement is not a one-off activity, but a process of CI in which one aims to sustain high standards of quality and performance (The Carter Review, 2016).

1.1.4 WHY IS THIS TOPIC IMPORTANT?

Globally, all healthcare budgets are experiencing ever-increasing pressure to reduce costs and eliminate inefficiencies whilst striving to continually improve standards. Laboratory medicine is no exception. In the UK, laboratory testing costs the NHS approximately £2.5bn annually (The Carter Report, 2008).

Due to population increase, demand for Laboratory Medicine is on the rise. (ESRI, 2017). In Beaumont Hospital alone, demand for laboratory services increased by 5-10% annually since 1999. In 2016 in excess of 1 million General Practitioner (GP) laboratory orders were processed from 100,000 different patients. A total of 5.4 million tests were performed in 2016 across the 800 different tests on offer (Beaumont Hospital Annual Report, 2016).

Nationally, the number of specimens received in Histopathology laboratories increased 6.4% from 2016 to 2017, blocks by 3.35%, and slides by 5%. From 2013-2017 the national volume of specimens has increased by 18%, blocks by 18% and slides by 23% (Faculty of Pathology, a, 2018). All indications show that demand for laboratory services is only increasing.

The Histopathology National Quality Improvement Programme (HQI Programme) was developed in 2009 by The Faculty of Pathology. The programme aims to produce strong evidence of the quality and standard of Histopathology services in Ireland based on international standards, and importantly, “to assure the enhancement of patient care with timely and complete pathology diagnoses and reports” (Faculty of Pathology, b, 2018). With demand for Histopathology services increasing yearly all processes must work efficiently and effectively to continue to provide optimal care and a high quality service for patients.

The Irish health budget for 2018 (budget.gov.ie, 2018) increased by €685m to €15.29bn, however no breakdown exists to show how much is spent in each department, so it’s unclear if spending on Pathology, specifically Histopathology, will reflect the ever-increasing demand for services. With such limited published data on Pathology, or Histopathology services available, it’s necessary to look to the last available figures. These are from 2011 and show that €370m of a €13.7bn budget, or 2.7%, was spent on Pathology services (Health Manager, 2011). However, nothing indicates what’s spent on Histopathology annually. The only report produced that looked at Pathology services on a national level was The Carter Report (2008), and The Carter Review (2016). It
was an extensive independent report that reviewed laboratory services in England at that time and made improvement and cost saving recommendations. While no such study has been performed in Ireland, The Carter Report is recognised as a benchmark for assessing Pathology services on a national level.

With an ever-increasing workload and an undetermined investment in the service it is necessary for Histopathology to embrace and sustain Lean processes that enhance efficiency, and productivity, thus maintaining the standards set out by the HQI Programme (Faculty of Pathology, b, 2018).

### 1.2 RATIONALE FOR CHOOSING THIS TOPIC

According to the latest ESRI figures (ESRI, 2017) the Irish population is projected to increase by 14-23% by 2030. The largest increase will be seen in those aged 80 and over who will increase by 89-94% in that same timeframe. An ever-increasing, aging population, will increase the pressure on an already stretched health service. The level of specimens received in Irish Histopathology laboratories increased by 18% from 2013-2017 and with this projected increase in population it is obvious that demand for services will only increase. With a lack of evidence suggesting investment in the service will increase, it will fall on the Histopathology service to implement and sustain Lean processes that will allow departments to cope with an increasing workload while still maintaining current quality standards.

However, while implementation of Lean processes can be achieved, long term sustainability of changes presents a greater challenge (Clark, 2016, p.5). Speaking to professionals in the industry there is a general feeling that plans are regularly made to introduce new techniques or changes in work practices. Time is spent on Management projects planning change that will benefit the department but the changes are not implemented. Others feel that change is only implemented in a crisis then quickly forgotten about. Why is this happening? In under resourced departments valuable time is spent away from business as usual to complete projects that lead nowhere. Is it a bureaucratic box ticking exercise instead of an actual desire to introduce effective change or do departments lack the upper management support necessary to implement and sustain these improvements?

Personal experience in the profession has highlighted the fact that many departments are outdated and no longer fit for purpose, as the increase in workload has long-since outgrown the space allocated for the department. Recruitment of qualified staff is also an ongoing challenge for Histopathology as most graduates gravitate towards disciplines like Microbiology or Biochemistry that offer opportunities to increase their salary with on-call out-of-hours services. These challenges, as well as many others, can impact a departments ability to become Lean and to sustain change.

There is as yet no study assessing Lean experiences and opinions across Irish Histopathology laboratories. This study aims to fill that gap in the knowledge. It will provide interesting insights into how Histopathology as a profession have embraced Lean, the challenges faced in sustaining change and the benefits it can provide.
1.3 RESEARCH QUESTION AND OBJECTIVES

The research question being asked is as follows:

“Was Lean implemented effectively and sustained in Irish Histopathology laboratories?”

The research objectives are as follows:

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Table 1: Research Objectives

This research is SMART: specific, measurable, achievable, realistic and can be completed within the 12-week timeframe.

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<th>SMART Objectives</th>
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<td>Specific</td>
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<tr>
<td>Measurable</td>
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<tr>
<td>Achievable</td>
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</table>
### Realistic
Small Histopathology community, should get good response.

### Time
12 weeks, Summer 2018

Table 2: SMART Objectives.

#### 1.4 SUITABILITY OF RESEARCHER FOR THE RESEARCH

The researcher is a Senior Medical Scientist specialising in Histopathology with 12 years of experience working in this busy, evolving discipline in Beaumont Hospital. Having previously received an MSc in Biomedical Science, commitment to the profession was demonstrated by examining its current practices and exploring if it’s possible to continuously improve the high quality service provided under incessantly strained circumstances. Medical Science is a small community in Ireland. The researcher’s position gives her access to CMSs and Laboratory Managers (LMs) across the country so access to information will not be an issue.

#### 1.5 CONTRIBUTIONS OF THIS RESEARCH

The researcher proposes to examine if Lean has been implemented effectively and sustained in Irish Histopathology laboratory services. As there are currently no publications examining this topic in an Irish context this research will fill the knowledge gap. It will be of interest to Histopathology laboratory staff across the country as the questionnaire will allow them to examine and highlight successes and gaps in their own Lean processes.

The study will also present the first comparison between Lean experiences in ROI public and private laboratories.

However, while this study will focus on the Histopathology laboratory, the research question and the methodology developed will be easily transferrable to any scientific discipline within the laboratory directorate or any hospital department for that matter.

This research will also be of interest to the HSE as it will present a snapshot of current opinions and experiences of Lean in Histopathology nationally. The information obtained can be used to identify strategies for improving Histopathology services as demand continues to increase.
1.6 TIME, COST AND PROJECT MANAGEMENT

1.6.1 TIME

This research was conducted over a defined 12 week period from the 28th May to 20th August 2018. Due to the defined timeline and the snapshot approach, a cross-sectional study was most appropriate (Saunders, 2016, p.200). It was done in the researcher’s own time, outside of work. Annual leave was used when necessary. A Gantt chart was developed highlighting all the major tasks to be performed and the timeframe for completion in order to finish within the strict 12 week period (Appendix 1). The in-depth interviews (IDIs) were conducted over the course of 1 week. This was identified as a limiting factor to the study as the second phase of the research, the questionnaires, could not be developed and released to participants until the IDIs were completed and analysed.

1.6.2 COST

There were no substantial costs accrued during this study. The IDIs were performed in person in Dublin or by telephone if the interviewee was outside the city. The only purchase here was a digital Dictaphone costing €49.

The questionnaires were produced on Outlook Forms provided free by the college and were sent electronically to all participants. Statistical analysis was performed using RStudio which was available at work.

As all submissions are electronic, no printing or binding costs were accrued.

1.6.3 PROJECT MANAGEMENT

With a strict 12 week timeframe it was necessary to plan and execute this project efficiently. Using the tools and techniques learned in the Project Management module the tasks were divided into manageable units and worked through in a logical process (Table 3), leaving extra time for each task in case of unexpected delays. A Gantt chart was produced outlining these tasks and the time allotted to each (Appendix 1).

<table>
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<tr>
<th>Project Management Plan: Activities and Resources</th>
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<tr>
<td><strong>Time:</strong> 12 weeks (28 May-20 August 2018)</td>
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<tr>
<td><strong>Sequence of activities:</strong></td>
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<tr>
<td>Schedule IDIs. Contact CMSs. Write chap 3, submit for review. Write chap 1, submit. Develop questions for IDIs. Conduct IDIs. Write chap 2, submit. Analyse IDIs. Develop questionnaire. Send to CMSs. Make recommended changes to chap1-3. Analyse data. Write chap4-6. Submit. Make recommended</td>
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**Resources:**

Table 3: Project Management Plan

<table>
<thead>
<tr>
<th>1.7 LIMITATIONS OF THE RESEARCH</th>
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<td><strong>1.7.1 LIMITED POPULATION:</strong></td>
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<td>For this research to be successful it was necessary to identify potential limitations and develop strategies to tackle them. The main limitation identified was the limited population size available for the study, with only 25 CMSs in public and private laboratories nationally. A low response rate would be a concern and could jeopardise this study. To counteract this, the questionnaire was also sent to the CMSs in the 11 private hospitals in Dublin as well as those in the 5 Northern Ireland CMSs.</td>
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This approach was multi-functional. Firstly, it increased the numbers for the census. Secondly, it provided an interesting comparison between the opinions and experiences of those in the public and private hospitals in Ireland. Identifying this limitation allowed the researcher to develop and expand the research population adding extra depth to this study.

To encourage a high response rate every CMS was personally contacted to explain the study and ask them to participate. Keeping the questionnaire to a reasonable length, 10 minutes, also encouraged a high response rate.

<table>
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<th><strong>2. TIME MANAGEMENT:</strong></th>
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<td>Time was identified as another limitation. This study took place over a strict 12 week period during the Summer of 2018. During this time the researcher was in full-time employment, provided an on-call out of hours service, and sustained a personal life, all while researching and writing a dissertation. Time management skills developed during the course of this MBA were utilised to good effect. Again the Gantt chart produced helped me maintain a strict schedule (Appendix 1).</td>
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<th><strong>3. LIMITED PUBLICATIONS:</strong></th>
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<tr>
<td>During the research it became obvious that very little published work existed on Histopathology in Ireland and none on Lean in Irish Histopathology laboratories. However this further highlighted the need for this research as there was an obvious gap in the knowledge.</td>
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**CHAPTER 2: LITERATURE REVIEW**

### 2.1 INTRODUCTION

Pathology plays a vital role in patient care as it’s incorporated in every aspect of medicine from the diagnosis of disease and monitoring chronic conditions, to the pursuit of new and innovative treatments through genetic research (Royal College of Physicians of Ireland, 2017). Histopathology is the study of diseased body tissue and is a critical Pathology discipline. With the Irish population expected to increase significantly by 2030 (ESRI, 2017), demand for Irish Pathology services, including Histopathology, will only increase. There is no published evidence to suggest that investment in Histopathology is increasing to meet this elevated demand, so it will be incumbent upon Histopathology services to implement Lean processes that will allow departments to cope efficiently and effectively with an increase in workload, while still maintaining current quality standards. However, once changes have been implemented, sustaining these improvements becomes the real challenge. A departmental cultural change in attitude towards CI, and strong Lean leadership are essential to Lean sustainability in Histopathology laboratories, otherwise, improvements will be superficial and short-lived.

Other than a 2007 independent report examining the potential to centralise Irish Pathology services (Teamwork Management Services, 2007), there has been no literature examining Pathology services in Ireland on a national scale. There is currently no literature reviewing or examining the challenges faced by the Histopathology services in Ireland, and as yet no study assessing Lean implementation and sustainability across all Irish Histopathology laboratories. This research aims to fill that gap in the knowledge. By identifying and adapting an appropriate model for assessing Lean, this study will examine how Lean was implemented in Irish Histopathology laboratories, the challenges facing this profession and any impediments to successfully sustaining Lean. We will begin this journey by examining and understanding what Lean is, and identifying an appropriate model to base this research on.

### 2.2 WHAT IS LEAN MANAGEMENT

Lean is a CI system based on the Toyota Production System (TPS). It is a management philosophy rather than a set of management tools consisting of two fundamental components. Firstly, it’s a systematic approach to process improvement through waste removal (Clark *et al*, 2013, p.638) producing optimal value for the end user. Secondly, it involves the creation of a culture of CI. This is achieved by investing in and developing the employees within the organisation. (Clark *et al*, 2013, p.638). (Spear, 2005, p.78).

There are many descriptions of Lean (Spear and Bowen, 1999), (Womack, Jones and Roos, 2007) all focusing on the need to identify and remove waste, and to adopt a department-wide approach to CI. For the purpose of this study, Liker’s (2004) description has been considered the most appropriate as his 14 principles are easily related to the complex process of CI in healthcare. Liker divides the 14 principles of TPS into 4 distinct domains, the 4Ps; *Philosophy, Processes, People and partners, and Problem-solving* (Fig 1). This 4P model is the foundation upon which this research dissertation was developed. These principles are applicable to the ethos of a Histopathology...
laboratory, but reviewing the available literature around Lean in Histopathology it is evident that there is a disproportionate emphasis on applying Lean *Processes* to improve workflow. Liker (2004) agrees, highlighting that companies who fail to implement Lean effectively focus too heavily on *Processes* and fail to understand the importance of incorporating the other elements of the 4P model (Liker, 2004).

Adopting long-term thinking even at the expense of short-term financial goals is the *Philosophical* foundation that all other *P’s are built on* (Figure 1). From this researcher’s perspective, this seem a little idealistic and perhaps unrealistic as all public healthcare facilities are dependent on, and constrained by, yearly budgets. So, it is not easy to forego financial obligations in-lieu of long-term *Philosophy*. However, the significance of Philosophy must be acknowledged because if a department is to implement Lean effectively, and sustain it, there must be a shared purpose that becomes the foundation upon which all other Lean principles are built (Fig. 2). This argument is convincing and the practical application of it has been demonstrated by The Virginia Mason Medical Centre (VMMC) that embodies the Lean *Philosophy* and has embedded it into the culture of their department (Spear, 2005, p.78), (Zarbo and D’Angelo, 2007, p. 1015), (D’Angelo and Zarbo, 2007, p. 423).
The principle behind Lean Processes is that by applying the right process to the right task at the right time, will produce the right result, thus eliminating waste. While literature relating to Lean and Histopathology is far from abundant, the significance of Processes is evident as the majority of established work focuses heavily on it. From this researcher’s scientific experience, huge emphasis is placed on Processes, as reproducibility of results is a fundamental component of providing a high-quality service. Evidence of the importance of Lean Processes is seen in several studies, with many reporting increased efficiency and quality (Raab et al, 2008, p. 1193), significant decreases in reported errors (Smith et al, 2012, p. 367) (Yörükoglu et al, 2017, p. 47), and reduced turn-around-times (TATs) (Cankovic et al, 2009, p. 390). Lean can also be used effectively to identify unproductive processes such as an unevenness of the workflow or bottlenecks in the process. (NHS Improvement, a, 2014), (NHS Improvement, b, 2014). Additionally, it can identify areas where equipment or employees are overwhelmed or overburdened along the production process. This researcher can confirm, from 12 years of experience in a Histopathology laboratory, huge improvements in quality and reproducibility of results have been achieved through the application of Lean processes. However, it’s important to understand Lean is not a quick-fix solution, dependent only on the Processes applied. Clarke (2016, p.5) argues sustained improvements result from small CI in daily work-processes over time.

The importance of developing People and Partners for long-term Lean success is well demonstrated by Cankovic et al (2009, p. 390) who based their departmental improvements on TPS and Henry Ford Production System (HFPS). Their integrated process of change resulted in empowered employees who could sustain improvements with minimal intervention from management. This point is significant and highlights this researcher’s own personal experience that inclusion and encouragement of the staff, and their abilities, results in the creation of confident, happy, and well-trained employees.

Finally, Problem-solving, according to Liker, is the process of CI and learning through the ability of the employees to identify waste and resolve problems (Liker, 2004). In this researcher’s opinion, Problem-solving is linked to investing in the abilities and strengths of the People and Partners. In order to identify and resolve problems, it is necessary to develop employees, ensuring they are confident in their abilities to tackle challenges on a daily basis.

Reviewing the principles of Lean (Liker, 2004) it can be concluded that “Lean is about helping people to work smarter, not driving them to work harder” (Clark et al, 2013, p.638). Spear (2005, p.78) agrees and believes what sets organisations that have successfully implemented and sustained Lean apart from the rest, is their ability to do their work while simultaneously learning how to do it better. This concept of CI and smarter working has resulted in the expansion of Lean from manufacturing to other industries, including healthcare.
Lean was developed for the manufacturing industry but is now applied to an ever-increasing number of healthcare services globally. The implications of which are improvement of quality of service and a decrease in costs (Spear, 2005, p.78). In this researcher’s experience while investment is required for large scale improvements, a lot of improvements that have been implemented have been low cost or, in many cases, free. This has also been highlighted by Spear (2005, p.78) and NHS Improvement (2017) who considers Lean valuable as it can save an organisation money. To optimise the benefits seen from Lean implementation it is necessary to implement the process in an effective and inclusive manner.

When healthcare services adopt Lean, it tends to be in one of the following ways.

1. The first is when an executive decision is made to apply Lean methodologies to all their management processes (Clark et al, 2013, p.638). This requires a large-scale cultural change, with long-term commitment, because all patient pathways and processes have to be redesigned. (Kotter, 2007, p.96). To be successful, staff engagement is vital (Zarbo, 2010, p.361). According to some, this tends to be the most successful method of Lean adoption in the health sector (Spear, 2005, p.78), (Zarbo and D’Angelo, 2007, p. 1015) (D’Angelo and Zarbo, 2007, p. 423), the implication being that as the commitment was led from above, long-term, sustainable change is achievable (Kotter, 2007, p.96), (Clark et al, 2013, p.638). However, in the researcher’s experience, hospitals consist of complex, insular Directorates. It is more reasonable to assume if Lean were applied to an individual Directorate then the chance of success would be greater.

2. If Lean is applied to a particular department or service, it is usually led from within the department but continued success however, is dependent on ongoing support from the lead Pathologist and the head of the department (Zarbo, 2010, p.361), (Clark et al, 2013, p.638). This argument is important, however, long-term sustainability requires more than just support. In order to succeed, it is necessary to recognise CI is a long-term process consisting of several stages (Kotter, 2007, p.96). This point is valuable because by-passing steps only creates the illusion of success, and the end result will ultimately disappoint. While this may not be considered the optimal implementation process for Lean, given the evidence (NHS Improvement, a, 2010), (NHS Improvement b, 2010), (NHS Improvement a, 2014), (NHS Improvement b, 2014) it can be concluded when a department endeavours to commit to change, real and lasting improvements to patient services can be achieved (Smith et al, 2012, p. 367). Success in these cases can, in part, be attributed to the fact that the changes were led from within by employees who understood the Processes and the challenges that their departments faced. From this researcher’s experience this level of internal knowledge results in more effective changes than those imposed by external consultants who may not fully understand the day-to-day workings of the department.
3. Commonly, Lean can be regarded by those in senior management positions as a waste removal Process. Lean is not led from within but instead external Lean ‘experts’ are brought in as part of a short-term improvement project. Initial improvements may be seen but the failure to develop a CI culture means improvements are short lived (Clark et al., 2013, p.638). This can have a negative effect on the department’s ability to embrace Lean because it’s often misrepresented as a staff-reducing process rather than a CI strategy. Identifying these situations is important because the implication is CI is superficial, heavily focused on Lean tools, and characterised by a real lack of understanding of Lean as an entire system. This argument is convincing, however, this researcher must acknowledge that an external viewpoint can be helpful at times, questioning processes in a way that laboratory staff may not have considered previously. Experience has shown this researcher that external feedback is not always a bad thing, and can rejuvenate staff interest in CI when things have stagnated.

Implementation process is important in Lean sustainability, however several other factors and challenges also impede sustainability

2.4 CHALLENGES FACING HISTOPATHOLOGY SERVICES

Histopathology is concerned with the study of diseased body tissue. E.g. a breast biopsy is removed from a patient due to a suspicion of cancer and a range of scientific methods are applied to determine if disease is present (The Royal College of Pathologists, 2017). Histopathology consists of a mixture of manual and automated techniques. With a rapidly growing and aging population the Irish Histopathology services will continue to face challenges in the future as it continues to provide high-quality service in a time of stagnating investment.

The Irish population is projected to increase by 14-23% by 2030 with the largest increase seen in those 80 years and over who will rise by 89-94% (ESRI, 2017), intensifying pressure on an already stretched health service. In Beaumont Hospital alone, demand for all laboratory services has increased by 5-10% annually since 1999. Histopathology has not escaped this trend. Nationally, the average number of specimens received in Histopathology laboratories increased by 6.4% from 2016 to 2017, blocks by 3.35%, and slides by 5%. From 2013-2017 the national volume of specimens increased by 18%, blocks by 18% and slides by 23% (Faculty of Pathology, a, 2018). The significance of this and how it will impact on Histopathology services cannot be over-emphasised as all indications show demand for laboratory services is only increasing, further highlighting the need for efficient processes to counterbalance this growth.

Given this obvious increase, it could be assumed that investment in the service is also increasing to meet demand, however, there is little evidence to suggest that budgets are reflecting this increase. Global healthcare budgets are experiencing ever-increasing pressure to cut costs and eliminate inefficiencies (Fryer and Smellie, 2013). In the UK, laboratory testing costs the NHS approximately £2.5bn annually (The Carter Report, 2006) however, while the Irish budget for 2018 (budget.gov.ie, 2018) increased by €685m to €15.29bn there is no breakdown provided to show how much is invested in this growing service. With such limited published data on
Irish Pathology or Histopathology services available, it is necessary to look to the last available figures. These are from 2011 and show that €370m of a €13.7bn budget, or 2.7%, was spent on Pathology services (Health Manager, 2011). There is nothing to indicate what is spent on Histopathology annually.

In a time of stagnating resources, the argument for Lean adoption has never been stronger. In Ireland, Pathology laboratories adhere to ISO15189 standards (International Organisation for Standardisation, 2012), and compliance is monitored by the Irish National Accreditation Board (INAB). Lean may be the solution to maintaining high quality standards. Laboratory medicine has looked to Lean for over a decade to streamline processes, and increase quality and efficiency. In this researcher’s experience a lot of Lean has been enveloped by the quality management system (QMS) over the last number of years as the HQI Programme aims “to assure the enhancement of patient care with timely and complete pathology diagnoses and reports.” (Faculty of Pathology, b, 2018). This is also seen in the UK where “Lean is the method of choice for improving processes in Pathology services.” (NHS Improvement b, 2010). When speaking to colleagues in the profession, some intimated they don’t have an official Lean process in place, but in fact they do use Lean regularly, it’s just under the guise of quality.

Lean workflow is characterised by a continual-flow process made up of small evenly distributed batches of work that use employees and resources at the right time, in the right place producing a product that is easily distributed (Zarbo et al., 2010, p.71). A laboratory however, receives unscheduled deliveries in unpredictable batch sizes, so balancing workflow can be problematic, and value can be hindered. This is one of the major challenges faced in this researcher’s department. While it’s a fundamental component in Liker’s description of Lean (2004), it is not always possible in a healthcare facility where flow is dependent on so many variables. One-piece flow, as described by Liker (2004) is also challenging for Histopathology. While it lends itself well to the more automated departments, it is not necessarily suited to a more manual discipline like Histopathology in which the processes are compartmentalised. It makes this researcher wonder if Lean can ever be fully realised in Histopathology.

Lean functions on the principle that the aim of a business or organisation is to create value for the customer (Clark et al., 2013, p.638). Establishing how this is created can be challenging. In Histopathology the customer, for the purpose of this study, is the Pathologist or Clinician. According to the literature, value is delivered by following regulated, reproducible processes that result in a desired outcome. This could be applicable to Histopathology. If there is continuous effort to understand the customer needs, processes could be redesigned to remove any value-inhibiting waste (Clark et al., 2013, p.638).

2.5 LEAN IN HISTOPATHOLOGY

Histopathology, according to Clarke (2016. p.5), resembles the manufacturing industry more closely than other areas of healthcare. This he feels is because the delivery of an efficient service is dependent on producing high quality products. In the case of Histopathology these products are specimens permanently embedded in wax blocks, and stained slides produced from these blocks. This argument is convincing as providing a timely and
consistently high-quality product, and matching capacity to demand are manufacturing issues that are mirrored in Histopathology. However, if this manufacturing blueprint were applied to Histopathology, certain impediments would need addressing.

A ‘one size fits all’ approach to Lean adoption is not practical in Histopathology. Many departments are constrained by architecture and resources, and so will implement Lean principles in their own way dependent on space, resources, staffing levels, and equipment (Clarke, 2016, p.5). While the Smith et al (2012, p.367) argument that to achieve an optimally functioning one-piece flow model, pull systems and the ability to balance workloads must be in place is convincing, in Histopathology, daily workloads are unpredictable, and are dependent on theatre lists for that day, patient activity in outpatient departments, and the level of specimens delivered from GPs. Nonetheless, the implications of not balancing workload cannot be ignored as it can be a major contributor to error rates within a department (Smith et al, 2012, p.367).

While labelling errors in Histopathology laboratories occur frequently in the literature (Layfield and Anderson, 2010, p. 466), (Nakhleh et al, 2011, p. 969), (Smith et al, 2012, p. 367), Lean methodologies are being utilised to identify and tackle these issues in an effort to improve process flow and the quality of the service provided. Improving productivity (Smith et al, 2012, p.367), (Smith and Raab, 2011, p.1436), (Sugianto et al, 2015, p.259), and TATs are also regularly the focus of Lean improvement studies (D’Angelo and Zarbo, 2007, p.423) (Zarbo and D’Angelo, 2007, p.1015). Reading the literature, it can be concluded that Lean has a role to play in Histopathology, although it should also be noted that these articles, as stated previously, focus heavily on Processes. Implementing Processes, however, is only part of it, the real challenge lies in sustainability.

2.6 LEAN SUSTAINABILITY

As mentioned, studies show Lean has been implemented with great effect in Histopathology laboratories, but consistent analysis is needed to sustain improvements made (Clarke et al, 2013, p.638). This argument is important because it reiterates the need to implement all elements of the 4P model. It is not enough to establish the Processes and expect them to sustain themselves, lasting change requires a leader.

According to Liker (Netland, 2015), most lean transformations fail because they don’t “understand the power of Lean leadership”. Liker observed that companies were taking what was essentially a philosophy at Toyota and transforming it into a bureaucratic exercise in which they “administered programs of tools for implementing Lean”. They confuse the implementation of Processes with “deep Lean thinking” as they fail to grasp the deep and extensive transformation of culture required to emulate TPS (Liker, 2004). The significance of Lean leadership is reiterated by Zarbo (2010, p.361) who found 90% of organisations that attempt to introduce Lean fail because it is difficult for a ‘Japanese style’ management system to succeed in a ‘Western’ management culture. It seems a little defeatist but the point of a ‘one size does not fit all’ is well noted and as mentioned previously, true of Histopathology. However, it is essential, particularly in healthcare, to try to continually
improve the quality of the care provided. This can be achieved through good Lean leadership as a strong leader will create a constancy of purpose that will drive the department forward.

This could be applied to Histopathology where the leader, whether it be is a CEO, LM, or CMS, must create an organisational structure that supports and encourages a bottom-up approach to change. It will involve CI led by the workers. This point is valuable because without this kind of initiative, the only outcome is occasional management led projects initiated in a time of crisis, instead of the sustained and significant change seen at Toyota (Netland, 2015). This researcher agrees with the sentiment and, as mentioned earlier, has found including staff in decisions, and involving them in departmental improvements, boosts moral and increases the confidence of employees who may otherwise feel overlooked and under-appreciated. This is a slow process that requires commitment so it’s easy to see why sustainability becomes an issue if long-term commitment to the Lean Philosophy starts to wane.

### 2.8 CONCLUSION

Histopathology services in Ireland will continue to face increasing healthcare challenges in the coming years. If left unchecked, the quality of patient care could be diminished. It is evident from the research that Lean offers a Philosophy and a methodology by which Histopathology departments can face this challenge, while continuing to provide high-quality customer value.

Complete adoption of the 4P model is an important factor in Lean sustainability. The researcher agrees with Kaplan et al (2014, p. 970) who highlighted that to achieve successful, sustainable Lean in a Histopathology laboratory the focus cannot simply be on implementing Lean Processes, instead these Processes must be incorporated into a management system that thrives in an inclusive and supportive culture, and is driven forward by strong Lean leadership (Kaplan et al, 2014, p. 970). If Histopathology is to make real sustainable improvements Lean cannot be considered a quick-fix solution in a moment of crisis. Implementing this requires substantial investment in time, money, resources, and people.

Automation, while not embraced fully by Histopathology does have a role to play in CI. However, if one-piece flow is a fundamental component of Lean, can a discipline like Histopathology, where processes are so segregated, ever be truly Lean?
3.1 INTRODUCTION

This research focused on the implementation and sustainability of Lean in Irish Histopathology laboratories. To ensure rich, interesting information was received, and the research question was answered it was important to select an appropriate methodology. The research philosophies of Pragmatism and Interpretivism were applied in an inductive approach for this study. Mixed-methodologies of qualitative analysis, using IDIs, followed by quantitative analysis, in the form of a questionnaire was used to gather the primary research. This chapter will present the research question and objectives. It will also explore the various methodologies available, and present and justify the most appropriate choices for this study.

3.2 RESEARCH QUESTION

The research question being asked is as follows:

“Was Lean implemented effectively and sustained in Irish Histopathology laboratories?”

Due to increasing population, demand for Laboratory Medicine is rising (ESRI, 2017). As previously discussed in chapter 1 demand for Histopathology services is increasing yearly. To cope with this increase, all processes must work efficiently and effectively to continue to provide optimal care and a high quality service for patients. There is lack of evidence to suggest investment in the service will increase. It will fall on the Histopathology service to implement and sustain Lean processes that will allow departments to cope with an increase in workload while still maintaining current quality standards. However, from speaking to professionals in the industry there is a general feeling that plans are regularly made to introduce a new technique or a change in work practices that are ultimately never implemented. Others feel that change is only implemented in a crisis then quickly forgotten about. Drawing on this information research objectives have been developed.
The research objectives are as follows:

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<th>1. Research Objectives</th>
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<td>1. To examine the Lean implementation process in Irish Histopathology laboratories.</td>
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<td>2. To examine if Lean transformation only focuses on Processes, or if Philosophy, People and partners, and Problem-solving have also been embraced.</td>
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<td>3. To examine if management support, and lead Lean.</td>
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<td>4. To examine how the Histopathology laboratories, provide value for their customers.</td>
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<td>5. To examine how Lean processes implemented have been sustained.</td>
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<td>6. To examine if automation is a necessary element of Lean.</td>
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<tr>
<td>7. To examine variations in implementation and sustainability between ROI public and private Histopathology laboratories.</td>
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Table 1: Research Objectives (Repeated)

3.3 THE RESEARCH ONION

The methodologies available to researchers are not just impartial devices selected for particular tasks but instead, present philosophical commitments that will impact significantly upon the whole research process and the ability to understand what this researcher is investigating (Gill, 2010, p.6). When developing a research plan, the ‘Research Onion’ (Saunders, 2016, p.124) was used to divide the methodology into distinct progressive categories (Fig. 3). It consists of six distinct layers, as each is ‘peeled away’ a rational sequence is revealed leading to the onions core, data collection and analysis (Saunders, 2016, p.124).
3.4 RESEARCH PHILOSOPHY

Philosophy is the first layer. According to Saunders (2016, p.124), ‘the term research philosophy refers to a system of beliefs and assumptions about the development of knowledge.’ There are five main research philosophies; positivism, critical realism, interpretivism, postmodernism, and pragmatism (Saunders, 2016, p.136).

This researcher can relate to elements within all, but Pragmatism best represents the researchers beliefs and approach. This aims to bring together facts and values of individuals by assessing knowledge in conjunction with different experiences of the same process (Saunders, 2016, p.143). However, elements of Interpretivism also apply as it focuses on narratives, perceptions and interpretations of an experience (Saunders, 2016, p.138). Those who adhere to the philosophy of interpretivism acknowledge that the research procedures applied in the natural sciences are not necessarily appropriate when studying the social world (Bryman and Bell, 2015, p.17).

This study relates well to these philosophies as the assessment looks at varying experiences of the same process, i.e. experiences of Lean in Histopathology. Both philosophies are relevant, particularly to the quantitative element of this study where the IDIs are examined as a complete unit looking for themes and different interpretations of similar experiences.

An Epistemological viewpoint links well to pragmatism (Bryman and Bell, 2015, p.16) and it fits well with this research. Its focus is on narratives, opinions, perceptions, and interpretations that create a social reality (Saunders, 2016, p.127).
3.5 RESEARCH APPROACH

The second layer is concerned with the approach to theory development. There are two main approaches; deductive and inductive. Coming from a scientific background, this researcher is familiar with the deductive approach in which theoretical proposals are presented and research is conducted to prove or refute those theories (Bryman and Bell, 2015, p.11).

Alternatively, a theory can be developed after the collection and analysis of research data. This is an inductive approach (Bryman and Bell, 2015, p.11). A knowledge of existing research is still required to develop a comprehensive research question and a structured research plan. Failure to do so results in a “totally unstructured manuscript” (Suddaby, 2006, p.633).

An inductive approach is most suitable to this research project. Unlike the rigid research structure observed in deductive approaches, the flexible nature of an inductive approach allows the researcher to draw alternative explanations for the research findings. An inductive approach lends itself well to smaller sample numbers (Saunders, 2016, p.147) and as there is a limited population available for this study an inductive approach is appropriate. Glaser and Strauss (1967, cited in Suddaby, 2006, p.633) presented grounded theory (an inductive methodology) as a practical research tool for interpretive situations making it an appropriate approach when using qualitative analysis.

3.6 RESEARCH STRATEGY

Methodological choice and research strategies are the focus of the third and fourth layers of the onion. Quantitative research is primarily associated with experimental and survey strategies (Saunders, 2016, p. 168) which are “designed to produce statistics about a target population” by examining the relationships between variables (Fowler, 2013, p.8). Quantitative research is more commonly associated with a deductive approach (Bryman and Bell, 2015, p.28) but it can also be utilised in an inductive research strategy (Saunders, 2016, p.168). However quantitative data can be limited in scope and “the more the research situation reflects the complexity of the real world the less control the researcher has over the situation” (Wienclaw, 2013).

In a mixed-method study, qualitative and quantitative techniques are used in a variety of combinations to produce rich, complex information. (Saunders, 2016, p.170). Pragmatists employ a range of data-collection methods. Qualitative research can be used to capture the details of particular experiences, while quantitative analysis can be subsequently applied to detect discrepancies (Silverman, 2017, p.14).

Mixed methods were applied in this study. The methodology was a double-phased research design, consisting of a sequential exploratory approach in which qualitative IDIs were conducted. Following this, themes were gathered and pre-existing quantitative questionnaires (Malmbrandt and Åhlström, 2012, p.1131), (Kaltenbrunner et al, 2017, p.1) were developed making it suitable for this research population. This approach
worked best with this study due to the specific population being assessed. The qualitative interviews provided rich, in-depth background information regarding Lean in pathology services and the subsequent questionnaire focused in on the limited number of CMSs in Ireland.

3.7 TIME HORIZON

The fifth layer establishes the time horizon for the research to be undertaken. Studies can be cross-sectional or longitudinal. This research assessed Lean in Irish Histopathology laboratories as it is now, so this snapshot approach was appropriate. It was conducted over a defined 12-week period and a cross-sectional study is best suited to research with a strict time constraint. (Saunders, 2016, p.200).

3.8 DATA COLLECTION

Reaching the centre of the onion, a clear strategic methodology is in place for data-collection and analysis. As stated above a double-phased, mixed-methodology approach was applied in this study. Primary qualitative data was collected in the form of semi-structured IDIs followed by quantitative data-collection using questionnaires. Coding and analysis was then carried out as appropriate.

3.8.1 PRIMARY QUALITATIVE DATA COLLECTION

Experiences of participants can be best assessed by collecting and analysing their interviews as complete stories, rather than collecting them as bits of data from specific questions (Saunders, 2016, p.197). A semi-structured IDI technique was applied for this process. The questions were developed around the research question and objectives, and were designed to address various themes associated with Lean in Histopathology (Appendix 2). This will be discussed in more detail in section 3.9, Sampling.

Pathology LMs were interviewed, and in the relaxed environment of a semi-structured interview, thoughts and experiences of Lean in Pathology services were teased out. When interviewing participants, it was necessary to build a rapport putting the interviewee at ease. Using concise questions with unambiguous language enhanced the quality of the information received (Saunders, 2016, p.388).

As it was a semi-structured IDI there was a list of thematic questions for discussion. The interview contained a mixture of open and probing questions. Each participant was asked the same questions, in the same order. The structure allowed for the possibility that the answer to more than one questions could be covered in the course of a single answer (Saunders, 2016, p.391).

A list of the questions to be discussed was provided to the participants in advance of the interview. (Appendix 2). This allowed them to review any item that may be considered too sensitive to discuss in an interview, and
gave them the opportunity to prepare and review their departments current Lean status, increasing the quality of the information provided. The interviews were recorded using a Dictaphone. It was tested in advance to ensure both questions and answers were discernible on the recording regardless of whether the interview was conducted in person or by telephone.

The interviews were reviewed and examined for common themes and relationships. The information gathered was used to develop a conceptual framework (Saunders, 2016, p.570). Using this framework, the questionnaire was developed making it appropriate for quantitative data collection.

### 3.8.2. PRIMARY QUANTITATIVE DATA COLLECTION

The continued popularity of questionnaires is due to their “versatility, efficiency, and generalizability”, measuring numerous variables at little cost and time. However, producing a good questionnaire can be difficult. It needs to be designed in a way that the data sought is captured efficiently using unambiguous language. Proper design minimises the chance of errors of observation, and errors of non-observance (Schutt, 2011, p.160), (Fowler, 2013, p.10). The rate of response depends greatly on questionnaire design (Saunders, 2016, p.439).

For this study, the analytical tools produced by both Malmbrandt and Åhlström (2013, p.1131) and Kaltenbrunner et al (2017, p.1) were used as a foundation and guide for developing the questionnaire. The information gathered from the IDIs determined the topics and themes to further explore through the quantitative element of the research. The development of the questionnaire is discussed in more detail in section 3.9, Sampling.

The completed questionnaire was distributed to all CMSs nationally, via email. They were contacted personally to explain the research and asked them if they would be interested in participating. As Histopathology is such a small community the time was taken to make individual telephone calls rather than simply email as speaking to them directly enhanced the chance of a high response rate. With such a small population, there was little room for non-respondents.

The quantitative data gathered through this process was analysed using a statistical analysis package, RStudio. This data was used to suggest possible relationships between variables. Coding and analysis will be discussed further in section 3.10. Sampling will be discussed in the following section.

### 3.9 SAMPLING

Semi-structured IDIs were carried out to aid development of the theory around Lean in the Irish Histopathology laboratory services. Liker’s description of Lean and the 4P model (2004) were used when designing the framework for the IDIs and subsequent questionnaire. Three LMs were interviewed providing expert opinion on
Lean across Pathology departments (Appendix 5). One represented a NHS Pathology Department in the UK renowned for Lean workflow in Histopathology. The second represented a private hospital in Dublin and the third was from a public HSE hospital in Cork. Information gained from these IDIs informed the subsequent questionnaires that focused specifically on Lean in Histopathology across Ireland. These were sent via email to all CMSs nationally.

### 3.9.1 QUALITATIVE RESEARCH: INDIVIDUAL INDEPTH INTERVIEWS

To enhance the quality of the information collected in this study it was important to choose an appropriate instrument. (Guillernin, cited in Kaltenbrunner et al, 2015, p.3).

#### 3.9.1.1 Theoretical Development of the IDI Questions

Malmbrandt and Åhlström et al (2012) developed a 34-item questionnaire for assessing Lean in the service sector. Based on Liker’s description, it covered the 4P model of Lean. The themes in Malmbrandt and Åhlström’s questionnaire are in keeping with this research question and objectives so drawing on it, the IDI questions were developed to address various themes associated with Lean in Pathology. (Appendix 2). The broad range of items allowed this researcher to develop questions and create a structure for the IDIs that would cover the 4P model (Table 4).

#### 3.9.1.2 Pre-testing: Assessment of the IDI Questions

To validate the IDI questions a Senior Medical Scientist working within Histopathology in Beaumont Hospital was interviewed. This interview was held privately and the participant was provided with the information sheet (Appendix 3), consent form (Appendix 4), and the list of questions (Appendix 2) to be covered in advance of the interview as every effort was made to simulate the real process.

This process allowed the researcher to practice the interview technique and identify any ambiguity within the questions. It was highlighted that two of the questions were repeated, albeit phrased differently. Other than that, all language and phraseology were easily understood. Adjustments were made to the questions as suggested. Following amendments, interviews with appropriate participants were finalized. The final tool consisted of 28 questions and was estimated that the interviews would take 45-60minutes to conduct.

#### 3.9.1.3 Testing: Primary Qualitative Data Collection

Three IDIs were conducted with LMs. The first was with the LM from a busy NHS Histopathology department in Lincolnshire that has an excellent Lean reputation. Due to distance, this interview was conducted by telephone. The second interview took place in person with the LM of a busy Pathology Department from a private Dublin hospital. The final interview was also conducted by telephone, due to distance, and was with the LM of a Pathology Department from one of the largest HSE hospitals in the country. All participants have several years’ experience with Lean and are considered experts in their fields by this researcher.
The researcher chose to interview LMs and not CMSs because they would be better able to interpret Lean across all disciplines. In the hierarchy of the Laboratory Directorate the laboratory discipline Chiefs report to an overall LM (Fig. 4). The LMs were able to draw comparisons between fully-automated disciplines like Biochemistry and Haematology with the less-automated and more interpretive disciplines like Histopathology and Microbiology.

The interviews were typed (Appendix 5) and analysed deductively. Codes, 54 in total, were developed and assigned to portions of text throughout the interviews. (Appendix 7). The data was analysed repeatedly to identify commonalities, variations, and themes. Analyses was also conducted to identify relationships between various themes (Appendix 8). The findings will be discussed further in chapter 4, Data Analysis/Findings. Following this process, the quantitative data-collection tool was developed.

![Laboratory Directorate Hierarchy](image)

**Figure 4. Laboratory Directorate Hierarchy.**

### 3.9.2 QUANTITATIVE RESEARCH: CENSUS USING QUESTIONNAIRES

#### 3.9.2.1 Theoretical Development of the Questionnaire

When developing this questionnaire, the 34 items in Malmbrandt and Ählström’s (2012, p.1131) tool were reduced using theoretical reasoning and the data collected from the IDIs to determine what items could be excluded (Schutt, 2011). The items relating to the most commonly occurring themes were extracted and adapted for this study. Words and phrases mentioned by the participants were used when amending the questionnaire (Kaltenbrunner et al. 2017, p.1). The research question and objectives were also carefully considered when selecting appropriate items for inclusion. Automation was considered too complex to comprehensively assess using this questionnaire so was discussed in great-length during the IDIs and assessed in this context only. Questions were selected to cover all elements of the 4P model (Table 4).
Eighteen questions were developed, the first of which identified the type of institution participants worked for. Both previous studies had adopted a Likert-type scale which advantageously allows for statistical analysis. This method also applied here as it allowed the researcher to measure maturity of Lean implementation in a graded-scale from essentially “no adoption” to “complete adoption” of a process easily and effectively (Malmbrandt and Åhlström et al, 2013, p.1131). Like Kaltenbrunner et al (2015) respondents were asked to select the option that best represented their department.

Ms. Kaltenbrunner and Ms. Malmbrandt were contacted via email to request permission to utilize and further develop their questionnaires for the purpose of this study. They both graciously consented. (Appendix 9 and 10).

<table>
<thead>
<tr>
<th>4P Model</th>
<th>Questionnaire Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Philosophy</td>
<td>Q2. Lean Implementation</td>
</tr>
<tr>
<td></td>
<td>Q4. Staff Commitment</td>
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<tr>
<td></td>
<td>Q6. Chief Commitment</td>
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<tr>
<td></td>
<td>Q7. Time Allocation</td>
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<tr>
<td></td>
<td>Q18. Sustaining Improvements</td>
</tr>
<tr>
<td>Processes</td>
<td>Q10. VSM</td>
</tr>
<tr>
<td></td>
<td>Q11. Flow Design</td>
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<tr>
<td></td>
<td>Q12. Standardised Procedures</td>
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<tr>
<td></td>
<td>Q13. Balance Workload</td>
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<tr>
<td></td>
<td>Q14. Visual Management</td>
</tr>
<tr>
<td>People &amp; Partners</td>
<td>Q3. Lean Training</td>
</tr>
<tr>
<td></td>
<td>Q5. Staff Understanding</td>
</tr>
<tr>
<td></td>
<td>Q8. Change Agent</td>
</tr>
</tbody>
</table>
3.9.2.2 Pre-testing

To validate the questionnaire, a test run was performed using a collection of Medical Scientists across various Pathology disciplines. All effort was made to emulate the real process. An information sheet was provided via email and as the questionnaire is web-based, a link was provided to gain access to it. The purpose of this pre-test was to assess the construction of the questionnaire, to determine length-of-time for completion, to identify ambiguity in language, and to ensure the web-link functioned appropriately. It was originally created using Google Forms, however in pre-testing it was discovered the researcher’s hospital firewall prevented participants opening the link. It was reproduced in Outlook Forms which opened successfully. This also allowed the researcher to copy the questionnaire into a Word document that could be distributed to any hospital in which Outlook Forms might have been blocked (Appendix 11). After this change, all participants responded positively and no further issues were identified.

3.9.2.3 Testing: Primary Quantitative Data Collection

The developed questionnaire was distributed to appropriate participants. The criteria for inclusion in the study were as follows:

1. CMSs across the 24 public Histopathology laboratories in the ROI. Beaumont Hospital, has 1 Chief over Histopathology, however, Neuropathology is an independent, self-contained, sub-specialty so the SIC was included as it was felt they would contribute interesting and varying insights for their department.
2. CMSs in the 11 private hospital laboratories across the ROI. This provided an interesting cultural comparison between public and private work practices. Also, one of these laboratories is purely Cytopathology orientated, but as Cytopathology is a subdivision of Histopathology it was included in this study.
3. CMSs across the 4 NHS Histopathology laboratories in Northern Ireland (NI) and the 1 private facility.
As the questionnaire was distributed to the entire population of CMSs in the ROI and NI this constitutes a census rather than a sample.

Participants were given 3 weeks to respond, allowing for the busy holiday season. A Word Document version of the questionnaire was requested by 4 participants who were unable to open the link due to hospital firewalls. Once returned, these results were added to Outlook Forms manually. One gentle reminder and a final thank you email were sent. The recommended minimum response rate is 30 for statistical analysis (Saunders, 2016, p. 305). The response rate was 32 out of a possible total of 40, representing an 80% response rate. The quantitative data gathered through this process was analysed using a RStudio. This will be discussed further in chapter 4, Data Analysis/Findings, and chapter 5, Discussion.

### 3.10 CODING AND ANALYSIS

Qualitative data cannot be quantified or analysed numerically (Tayler-Powell and Renner, 2003, p.1), instead raw data from the IDIs was analysed and examined by assigning codes to certain words, phrases or themes. Coding of the qualitative data related to the research question and objectives. Two coding techniques were used. Firstly, open coding was used to assign codes to words or phrases in the text (appendix 7). Secondly, axial coding was applied to categorise the coded phrases into themes (Appendix 8) (University of Kent).

The IDIs conducted during this study were reviewed and examined using thematic analysis. The application of coding allowed the researcher to categorise data with similar meanings (Tayler-Powell & Renner, 2003, p. 5), (Saunders, 2016, p.580). The data was reviewed looking for common themes and relationships (Tayler-Powell and Renner, 2003, p.5), (Zhang and Wildemuth, 2016, p.5). There were no pre-conceived themes in mind when analysis began, instead themes presented themselves as the interviews were re-read. A conceptual framework was developed from the information (Saunders, 2016, p.570) from which the questionnaires previously created by Kaltenbrunner et al (2017, p.1) and Malmbrandt and Åhiström (2013, p.1131) were adapted specifically, with the research question and objectives in mind.

The adapted questionnaire was distributed via email to CMSs in all hospitals across the ROI, it was also distributed to CMSs in NI. The raw data collected was assessed and described using RStudio. Data was numerically coded allowing easy entry and comparison of variables (Saunders, 2016, p.505). The information is presented visually in Chapter 4. The Likert-type scale adopted in the questionnaire facilitated easy numerical coding and analysis.
3.11 ETHICAL ISSUES

According to Saunders (2016, p.249), ethical issues can arise when requesting access to information. It’s important not to apply pressure on participant’s to grant access to information that may be considered sensitive. This was addressed in both stages of the primary research. Firstly, potential interviewees were contacted and asked if they would like to participate. An information sheet about the study and a consent form informing them of their rights were provided. A list of the questions was also provided to the interviewees before the IDIs allowing them the opportunity to raise any queries they had regarding the content, and to consult their hospital confidentiality policies regarding the release of such information. None of the participants raised any concerns.

Secondly, those participating in the census were contacted to request their participation. Participation was voluntary. Their rights were explained in the information sheet accompanying the questionnaire and consent was implied by the subsequent completion of said questionnaire. Questions focusing on issues such as employee numbers and workload were avoided as these topics can be quite sensitive and controversial, and were likely to dissuade participation. No other ethical issues were identified.

3.12 LIMITATIONS TO THE RESEARCH

3.12.1 LIMITED POPULATION:

For this research to be successful it was necessary to identify potential limitations and develop strategies to tackle them. The main limitation identified was the limited population size available for the study, with only 25 CMSs in public hospital laboratories across the ROI. A low response rate was a concern and could jeopardise the study. To counteract this, the questionnaire was also sent to the CMSs in the 11 private hospitals in the ROI as well as to the CMSs in the 4 Northern Ireland NHS laboratories and the 1 private facility.

This approach was multi-functional. Firstly, it increased the numbers for the census. Secondly, it provided an interesting comparison between the opinions and experiences of those in the public and private hospitals in the ROI. Identifying this limitation allowed the researcher to develop and expand the research population adding extra depth to this study.

To encourage a high response rate all CMSs were personally contacted to explain the study and ask them to participate. Also, the questionnaire was kept to a reasonable length, 10 minutes, to encouraged a high response rate (Fan and Yan, 2010, p.132).

3.12.2 TIME MANAGEMENT:

Time was identified as another limitation. This study took place over a strict 12-week period during Summer in 2018. During this time the researcher maintained full-time employment, provided an on-call out of hours service, and sustained a personal life all while researching and writing a dissertation. Time management skills developed
During the course of this MBA were utilised to good effect. Again, the Gantt chart produced helped me maintain a strict schedule (Appendix 1).

3.12.3 LIMITED PUBLICATIONS:

During the research it became clear that little published work existed on Histopathology in Ireland and none on Lean in Irish Histopathology laboratories. However, this further highlighted the need for this research as there was an obvious gap in the knowledge.
CHAPTER 4: DATA FINDINGS AND ANALYSIS

4.1 INTRODUCTION

The findings from the primary qualitative IDIs and the quantitative census will be analysed here. The IDIs, as discussed in chapter 3, were carried out with the participation of 3 hospital LMs. The first from the United Kingdom (UK), the second from a private hospital in the Republic of Ireland (ROI private), and the third from a public hospital in the ROI (ROI public). The IDIs were analysed and coded to identify themes. Following this, an 18-item questionnaire was developed and a census was distributed to all CMSs in public and private hospital across the ROI, and NI. This data was analysed using RStudio statistical analysis package.

This chapter aims to analyse the information provided during the IDIs and examine the themes identified. The data gathered from the census was also analysed to identify any significant statistical relationships between variables. Additionally, any similarities or differences between public and private institutions in the ROI were identified. As this chapter contains original primary research, references were not utilised here.

4.2 QUALITATIVE ANALYSIS: DATA-CODING, THEMES, AND HIERARCHICAL ARRANGEMENT

The three IDIs were transcribed to allow analysis, (Appendix 5) Following this, rigorous, analytical examination of the answers was undertaken to identify suitable codes, as discussed in section 3.9.1. A full list of codes and their meanings are available in (Appendix 7) While specific questions were prepared for the interviews, there were no pre-conceived themes in mind when the data was analysed. Instead themes emerged from the data as the interviews were re-read. Fifty-three codes were identified through open-coding (Appendix 7). Axial coding was then applied to categorise these codes into themes, 7 themes resulted from this process. From this level of analysis, meaning was derived from the IDIs (Appendix 8).

4.3 QUANTITATIVE ANALYSIS

Following the IDIs an 18-item questionnaire was developed as discussed in section 3.9.2. Questionnaires were sent to the 40 CMSs across the entire island of Ireland, the breakdown can be seen in Table 5 and 6. It should be noted that, as previously stated, for the majority of questions the answers were expressed in a Likert-type scale with level of Lean maturity increasing from 1 (essentially, no) up to 5 (what could be considered the optimal Lean implementation). As the options are quite long they are represented as 1-5 in the tables and histograms. This is intended to prevent the graphs from looking cluttered. The meaning for the numeric coding can be identified in the Word document version of the questionnaire in (Appendix 11) The census data was then analysed using RStudio (version 1.1.183 in combination with version 3.4.2).
## Quantitative Census Response Rate

<table>
<thead>
<tr>
<th>Institution</th>
<th>Total No. of CMSs</th>
<th>No. of Responses</th>
<th>% Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>ROI Public</td>
<td>24</td>
<td>20</td>
<td>83%</td>
</tr>
<tr>
<td>ROI Private</td>
<td>11</td>
<td>10</td>
<td>91%</td>
</tr>
<tr>
<td>NI NHS</td>
<td>4</td>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>NI Private</td>
<td>1</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>32</strong></td>
<td><strong>80%</strong></td>
</tr>
</tbody>
</table>

Table 5: Quantitative Census Response Rate

### Institution Response Breakdown

- **ROI Public:** 31% of responses
- **ROI Private:** 63% of responses
- **NI:** 6% of responses

Table 6: Institution Response Breakdown
4.4 DATA FINDINGS:

4.4.1 LEAN IMPLEMENTATION PROCESS

Qualitative Findings with Respect to Lean Implementation Process:

As discussed in chapter 2, the literature review, Lean implementation is most successful when it is led from within, with continued support from the head of department and head Pathologist necessary to facilitate ongoing success. In two of the three IDIs, Lean was implemented by an external company that reviewed the departmental structures and processes making recommendations accordingly. The ROI public hospital was the only institution in which the change was led from within. In this case one of the discipline Chiefs had a black belt in Lean. He drove the process. He organised courses, encouraged staff to attend them, providing time and resources for the development of a Lean team. While the other two interviewees may have had external companies implement Lean, they were both champions of the process and instrumental in its implementation. The UK site also had a Head Pathologist driving the process.

The importance of a Change Agent has been highlighted in chapter 2. That importance is mirrored in the IDIs. For the first number of years the UK site had a prominent Change Agent driving improvement work but at present that role is not occupied. In ROI private, that function is incorporated, like many Lean functions, into the Quality Manager role. They drive any required quality improvements. The ROI public site has a department project manager in place leading change. The department Chiefs drive change in their own laboratories. Also, all interviewees have several years of experience in Lean, promoting and championing it continuously.

Quantitative Findings with Respect to Lean Implementation Process:

In the census, participants were asked if Lean was implemented by an external company, an internal member of staff, or the third option was “unsure”. This third option was meant to be used by those who may not have been there when Lean was introduced, but speaking to some colleagues who completed the questionnaire, they intimated that they selected this option because they don’t have an official Lean project. However as discussed in chapter 2, many colleagues feel they don’t partake in Lean practices when in fact they do, just under the guise of quality. This was ambiguous on my part, highlighting that this question made the assumption Lean was already established. The results for this showed that of the 32 responses, Lean was led from within in 56% of cases. It was led externally in 9% of cases and 31% were unsure.

From the census results we see that 66% of respondents highlighted that they do not have a change agent in place driving improvements (Table 7).
4.4.2 STAFF DEVELOPMENT

4.2.2.1 Staff Training

Qualitative Findings with Respect to Staff Training:

Developing staff, as previously discussed, is a core principle of a successful Lean environment because they will be relied upon to adopt and support the processes required for CI. All interviewees revealed that some of their employees have received Lean training of varying levels from in-house training up to one black belt in the ROI public hospital. In this hospital, a large number of staff have been trained as courses pop up on a continuous basis and staff are encouraged to attend.

Quantitative Findings with Respect to Staff Training:

Quantitatively however, we see that 47% of respondents say their staff have not received Lean training, while the remaining 53% have received training but that level of training varies (Table 8).

4.2.2.2 Staff Understanding of Lean

Qualitative Findings with Respect to Staff Understanding of Lean:

When discussing staff understanding of Lean, two of the interviewees said that staff understanding varies. More experienced, established staff understand the concepts of Lean because they went through the transition and had formal training, while with staff turnover, the newer staff members just accept “that’s the way we work.” For the third interviewee, the level of understanding varies interdepartmentally. Where the Lean ethos is strong the staff definitely understand it, but in other areas it’s not as prominent.
Quantitative Findings with Respect to Staff Understanding of Lean:

Reviewing the census data, staff understanding of Lean is fairly evenly distributed across all options. While 23% of respondents stated their staff understand Lean in terms of “how we do things here”, the remaining respondents highlighted at least a basic level of understanding of Lean in terms of housekeeping, right up to being able to identify the ideal Lean flow. A marginally higher response (25%) is seen in those who can identify Lean in terms of providing efficiency (Table 8).

4.2.2.3 Staff Commitment

Qualitative Findings with Respect to Staff Commitment:

Staff commitment to the process was also reviewed. In the UK site, the Laboratory Manager found that initial groundwork was difficult and time-consuming for the staff but once they went ‘live’ with continuous flow, they could see the benefits of the work they had been doing. Staff commitment increased when they realised that work quality improved, and the number of defects reduced. Likewise, ROI private found that involving staff in the value stream mapping (VSM) process increased staff commitment because they could see the benefits of the improvements they were implementing. For ROI public, they find that in the departments with a good Lean ethos, the staff buy into it. As discussed in chapter 2, it is important to have someone driving Lean for it to be successful. This third site found that in the laboratory disciplines that don’t have anyone driving Lean, it’s harder to convince staff to buy into it.

Quantitative Findings with Respect to Staff Commitment:

According to the census data, staff commitment varies with 34% saying their staff support it and engage in developing improvement ideas but they don’t take an active role in problem solving. In 22% of cases the staff see Lean as a temporary project to which they are willing to dedicate limited time and energy. A further 28% say staff actively participate in improvement work, follow problems through to completion, and drive Lean adoption (Table 8).

4.2.2.4 Staff Involvement in Improvement Work

Qualitative Findings with Respect to Improvement Work:

As discussed in chapter 2, staff involvement in improvement work enhances both their understanding of Lean processes and their commitment to the Lean journey. Staff partake in improvement work across all three sites, but the level of involvement varies. In the UK site, staff are involved in improvement work but not as much as he would like them to be, while in the ROI public site all staff are encouraged to make suggestions on the QMS. If there are big changes that require a team, they try and share it around and encourage people to be involved.
Quantitative Findings with Respect to Improvement Work:

The IDI results are mirrored in the census, as we see all staff are involved in improvement work to some extent. The highest response (41%) indicating that most staff participate in improvement work, but at varying levels (Table 8).

![Lean Training](image1)

![Staff Understanding](image2)

![Staff Commitment](image3)

![Improvement Work](image4)

Table 8: Staff Development

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4.4.3 MANAGEMENT SUPPORT OF LEAN

4.4.3.1 Management Involvement, and Support of Lean

Qualitative Findings with Respect to Management Involvement, and Support of Lean:

Management involvement, and support of Lean was also examined. All three interviewees take a proactive role in promoting and encouraging Lean. However, two of the respondents revealed they can no longer personally commit as much time as they would like, or that they used to, due to increasing workload. For both of these sites a lot of previous Lean work has been incorporated into the department QMS so there is a sense that all
that good work has not been wasted. For the third site, ROI public, the LM encourages and promotes Lean training and is actively leading a large internal Lean project at present.

As highlighted in chapter 2, management buy-in on Lean projects is an important component of their success. The UK interviewee intimated that they had complete buy-in from their Trust from 2012-2013 but the economic slump meant resources were more limited and the first things to go are the CI teams. For the two ROI sites hospital management support is necessary for large scale changes such as architectural or equipment changes. According to one, this buy-in is essential to keep those involved in Lean motivated. However, they both highlighted that a lot of Lean is “just do it philosophy” and with limited resources they “try their best with what we have.” It is obvious from speaking to these managers that they themselves promote and lead Lean.

Quantitative Findings with Respect to Management Involvement and Support of Lean:

Most participants answered quite highly when asked about their Lean commitment, with 25% indicating they support it and actively engage in developing improvements, but they don’t take an active role in problem-solving or adoption of new processes. A further 28% said they follow problems through to completion and drive Lean, and 31% see improvements as an important part of daily work, focusing equally on developing new solutions and sustaining changes. However, 16% of participants see Lean as a temporary project (Table 9).

Table 9: Management Support of Lean
4.4.3.2 Time and Resourcing

Qualitative Findings with Respect to Time and Resourcing:

Time and resourcing are important factors in continuous improvement, however, two of the three interviewees feel that adequate time and resources are not given. Both feel that improvements are not planned but rather implemented in a crisis. ROI private believes this kind of improvement work is “rushed, panicked, and the negative association with this type of implementation remains for a long time.” The UK interviewee has found that due to staffing issues their department is being instructed to prioritise certain work which goes against one of the key Lean ethos’ of “first in, first out.” This he feels is introducing more waste as their “good work is slowly being unpicked by NHS Improvement micromanagement.” In contrast, the ROI public site try to free up staff as much as they can to plan and implement change. They also give time to training but they do concede that everything is finite.

Quantitative Findings with Respect to Time and Resourcing:

These results are mirrored by the census in which 44% said that time was not specifically allocated for this purpose. Only 9% said time was regularly allocated, while a further 13% said improvement work was part of their daily routine, and a necessary element of quality healthcare provision (Table 9).

4.4.4 VALUE FOR, AND COMMUNICATION WITH CUSTOMERS

Qualitative Findings with Respect to Value for, and Communication with Customers:

The interview also addressed the provision of customer value. In this instance “customer” was defined as the immediate customer, i.e. Pathologists and Clinicians. For all, communication with the customer is important. All send out user satisfaction surveys to identify areas for improvement. The UK site educate their customers on lab processes and they set KPIs. In ROI private, engagement with the wards is also important, and they feel that partaking in Internal Quality Control (IQC) and External Quality Assurance (EQA) programmes increases the quality of the service they provide. In ROI public, Lean projects will also include a measure of the benefits of the project, and they see the removal of waste as also increasing value for customers. This reiterates the important role of Lean, as discussed in chapter 2, in providing value for customers.

Qualitative Findings with Respect to Value for, and Communication with Customers:

We see from the quantitative results that creating customer value is something that all departments strive for. They all address customer value to some level. In 44% of cases customers are often asked for feedback that is subsequently used for improvement work. They also use this feedback to challenge current processes. A further 22% have evidence of innovative solutions that were developed from customer feedback, and this information is then fed back to customers (Table 10).
4.4.5 APPLICATION OF LEAN PROCESSES

Qualitative Findings with Respect to Application of Lean Processes:

The next series of interview questions focused on the Lean processes applied in each hospital Pathology Department. As discussed in chapter 2, most published data on Lean and Histopathology focuses heavily on Processes. All three interviewees use a variety of methods to identify waste including VSM, audits, and spaghetti diagrams, etc. Architectural limitations are the main limiting factor for all interviewees in achieving optimal flow. Flow improvements were made by the staff as they try to “work around with what we have.” Visual management is utilised by all three departments. The UK and ROI public sites employ a broad range of visual management techniques, while the ROI private hospital acknowledge that while they use some visual management, it’s not sufficient, but again, architectural limitations play a part here as they have limited wall space. Every procedure is standardised across all three sites and quality standards have been built in to all daily routines and processes as all sites adhere to ISO15189 guidelines.

An important principle of Lean, as highlighted in chapter 2, is the ability to balance and level workloads. This is a limiting factor for all interviewees. For the UK site, new clinics are added but the laboratory is not informed resulting “work creep”. The ROI public interviewee said that over half of their workload comes from GPs and the Pathology department has no control over delivery times of these specimens, so ultimately, they’re delivered in large batches making balancing workloads impossible.

Table 10: Providing Customer Value
Quantitative Findings with Respect to Application of Lean Processes:

Examining the census data, we see in the majority of cases (47%) VSM is not used to identify waste, with only 13% indicating that all processes are mapped, visualised in the department, and updated regularly. Looking at visual management we see that 31/32 participants (97%) utilise it in some form, with 56% saying there is systematic visualisation in appropriate areas, based on need (Table 11).

When asked if their laboratory is designed for flow, 44% agreed that they facilitate flow by ensuring information and resources are located based on when and where they are needed in the process, however ultimately optimal flow is hindered by architecture. While a further 16% went a level further and confirmed that the laboratory has a strong approach to flow where the most commonly occurring processes can be identified by looking at laboratory lay-out, and location of the resources and information. Only 1 respondent (3%) said the department was disorderly and not designed for flow (Table 11).

Perhaps the most definitive result relates to standardised procedures, with 75% saying they have standardised tasks for all processes. For them the standard procedure is seen as the gold standard and is referred to when there are variations in quality, etc. All other participants use standard procedures to varying degrees. As discussed in chapter 2, Histopathology laboratories adhere to ISO15189 guidelines, and most are accredited and inspected regularly. Standardised procedures are a basic requirement of such accreditation (Table 11).
The IDI findings regarding balancing workflow is further reflected in the census, 63% of respondents said they can plan and balance workloads to some extent but it’s mostly out of their control. A further 34% said they can plan resources to a certain extent in advance if they know to expect an increase in patient activity on a certain day (Table 12).
4.4.6 PROBLEM-SOLVING

Qualitative Findings with Respect to Problem-solving:

The importance of problem-solving, and staff involvement in this is another principle of Lean discussed in Chapter 2. For the three sites a lot of problem-solving functions have been incorporated into, and are managed through the QMS. This is a structured process. Staff involvement in solving problems is also encouraged across all sites but the level of involvement can be dependent on training level. In most cases pro-active problem-solving is done by the staff on the ground.

Quantitative Findings with Respect to Problem-solving:

IDI results are reflected quantitatively, we see that 28% of institutions have strong problem-solving structures in place, while 31% have said they are starting to implement a structured approach to improvement work, and are starting to use problem-solving tools to do it. Only 6% of cases said that improvement work is unplanned and only done in a time of crisis to tackle the symptoms rather than the cause (Table 12).

As indicated earlier, staff in 41% of cases are involved in improvement work but at varying levels (Table 8). The focus of that improvement work, in the majority of cases (38%) is on the laboratory environment, however, process improvements are starting to occur. In 25% of cases, process flow and value are becoming the focus of improvements (Table 12).
4.4.7 LEAN SUSTAINABILITY

Qualitative Findings with Respect to Lean Sustainability:

Implementing Lean is only half the battle. As discussed in chapter 2, sustaining improvements can be challenging. All sites interviewed sustain their improvements by monitoring and refining them over a period of time. For ROI public, they often wait for the pressure point to build up again before implementing the next change. While they may all have structures in place to sustain improvements, they all find that inadequate resources are allocated to sustaining the change. Staffing is an issue so routine work is prioritised over improvement work regularly.

The UK site intimated that the inability to attract staff has brought them right back to where they started. Their centralised Pathology department was established to tackle the shortage of Pathologists and laboratory staff, now years later they’re in the same position and to him it seems that lessons have not been learned. He also found from experience that in economic downturns when budgets are constrained, the CI teams are the first to go or, are redeployed to crisis management.

According to all participants, the results of Lean implementation may not be as visible as it once was, but the evidence is still there. According to ROI private, to an outside person looking in the improvements may not be obvious, but changes are obvious to those who went through the process. ROI public said, “not every lean project works, and not every lean project sticks, but the ones that worked are definitely still there.”

Quantitative Findings with Respect to Lean Sustainability:

The quantitative findings show us that all participants make an effort to sustain improvements. For 34%, all improvements are monitored to ensure sustainability. If they are not, the reasons are discussed, and changes of work standards based on these discussions are documented. In the majority of cases (81% in total), the improvements are added to the standard procedures (Table 13).
4.4.8 LEAN AND AUTOMATION

Qualitative Analysis Only:

Unlike the fully automated Blood Sciences, Histopathology is a mixture of manual and automated techniques. It was important to examine if automation, in the interviewees’ opinions, is a necessary element of successful Lean implementation, and if they recognised a difference in the level of Lean implementation between automated laboratories and the more manual disciplines. Regarding level of implementation, the UK site found there was more engagement with Histopathology than with the blood sciences. This he feels is because the key change agent was a Histopathology Consultant. There was more scepticism and cynicism within the blood sciences while there was consensus in Histopathology that improvement was needed.

ROI public believes there’s more scope for Lean in manual laboratories, as you look to relieve issues like repetitive strain injury (RSI), or peaks. An automated machine can “work at the pace it can work at”, there’s little room for enhancement and so often, work-arounds are created. In these cases, you’re tied to what the machine can do so improvements are difficult. In a manual lab, “there is more scope, and more flexibility to think outside the box.”

ROI private highlighted that when looking at Lean in an automated laboratory you’re looking at Leaning out the entire process. This, due to the nature of Histopathology, is difficult as Histopathology is fragmented around the different processing stages.

When asked if automation was a necessary element of process improvement all interviewees agreed that it is not. ROI private felt that it is necessary to reach a critical specimen mass before automation becomes a consideration. According to ROI public, it depends on what you’re looking to address, automation could be implemented to tackle issues like RSI, but it’s not essential. The UK site felt that while certain technology is
required to improve processes, it can also become a hindrance and create bottlenecks. He believes it’s more important to get the process right and then introduce appropriate automation.

4.6 VARIABLE CORRELATIONS

Quantitative variables were then compared to identify any interesting correlations. As mentioned in chapter 2, internally led Lean implementation results in a more sustainable Lean environment. This study suggests a correlation between these 2 variables as a larger proportion of those who led Lean from within (n=9) also answered higher in the Sustaining Improvements question (Table 14).

<table>
<thead>
<tr>
<th>Lean Implementation Vs Sustaining Improvements</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<td>1</td>
<td>7</td>
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Table 14: Lean Implementation Vs Sustaining Improvements
We also see a correlation between those whose staff have not received Lean training and those who do not use VSM to identify waste (n=12) (Table 15).

<table>
<thead>
<tr>
<th>VSM Waste Vs Lean Training</th>
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Table 15: VSM for Waste Vs Lean Training

This study also suggests a higher correlation between those who implemented Lean internally and those who answered higher regarding their laboratories flow-design (n=10). As discussed in chapter 2, when Lean is led from within it is more successful because it is being led by those who perform the work and understand the flow required for the department to operate optimally (Table 16).

<table>
<thead>
<tr>
<th>Lean Implementation Vs Flow Design</th>
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Table 16: Lean Implementation Vs Flow Design
Interestingly, those who answered low for Lean Training also answered highly for Standardised Procedures (n=10, n=11). However, as mentioned in chapter 2 adherence to ISO15189 guidelines is important for any department wishing to provide a high-quality service, regardless of whether Lean is a prominent feature in a department or not (Table 17).

<table>
<thead>
<tr>
<th>Lean Training Vs Standardised Procedures</th>
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Table 17: Lean Training Vs Standardised Procedures
This study also appears to suggest a correlation between Lean Implementation and use of Standardised Procedures. We see that a greater number of those who implemented Lean internally, also answered highly for the use of Standardised Procedures (n=14). Again highlighting, as discussed in chapter 2 that when Lean is led from within there is a greater understanding of the processes and procedures that need to be optimised (Table 18).

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<thead>
<tr>
<th>Lean Implementation Vs Standardised Procedures</th>
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Table 18: Lean Implementation Vs Standardised Procedures
4.7 ROI PUBLIC VS ROI PRIVATE

When reviewing ROI public and ROI private responses to the census, slight variations were only observed in 2 areas: training, and allocating time for improvement work. It is evident that in 70% of ROI private cases staff have not received Lean training compared to 35% of ROI public respondents. It is also observed that the overall level of Lean training is greater in ROI public (Table 19).

![Lean Training: ROI Public Vs ROI Private](image)

Table 19: Lean training: ROI public Vs ROI private

Again, we see that 70% of ROI private respondents say that time is not allocated for improvement work compared to 35% of ROI public. ROI public display a marginally higher response to allocating resources across the board.

![Lean Time Allocation: ROI Public Vs ROI Private](image)

Table 20: Lean time allocation: ROI public Vs ROI private

The results will be discussed further in the following chapter.
CHAPTER 5: DISCUSSION

5.1 INTRODUCTION

This research is founded on the question “Was lean implemented effectively and sustained in Irish Histopathology laboratories?” The rational for choosing this particular question is discussed in chapter 1. In this chapter, the research question and objectives will be reviewed and discussed in relation to the findings from chapter 4, and literature previously discussed in chapter 2.

This researcher found that employing mixed methods to this study produced a level of depth that would not have been captured with a mono-method. The expert opinions presented by the LMs in the IDIs was supported or refuted by the subsequent census of Irish Histopathology CMSs producing interesting, insightful findings. This is the first study to investigate Lean in Irish Histopathology laboratories, and the first national census capturing the opinions and experiences of this specialised profession. The findings are evaluated below in relation to the research question and objectives, and the literature review.

5.2 RESEARCH OBJECTIVE 1: EXAMINING THE LEAN IMPLEMENTATION PROCESS IN IRISH HISTOPATHOLOGY LABORATORIES

As discussed in chapter 2, there is no literature examining the implementation of Lean in Irish Histopathology laboratories and one of the primary objectives of this study was to examine the way in which Lean was implemented. In healthcare Lean, as discussed previously, often tends to be applied to a specific department (Zarbo, 2010, p. 361), (Clarke et al, 2013, p. 638). Implementing Lean to a department can be successful if there is commitment to change (Smith et al, 2012, p. 367) and it is led from within (Zarbo, 2010, p. 361), (Clarke et al, 2013, p. 638). This, in the authors experience is the most common Lean implementation process in Pathology departments.

From the 3 IDIs conducted the code for Lean Implementation was mentioned at a frequency of 10 times (F10) highlighting its importance. Lean was led from within in 1 case, ROI public. They had a strong Lean leader driving the process, organising courses and encouraging staff attendance. In the experience of the other interviewees, external Lean consultants were invited to review the departments and suggest improvements. According to Clarke et al (2013, p.638), implementing Lean this way can result in immediate improvements that are short-lived because a CI culture is not developed when Lean is not led from within. Externally-led Lean can alienate staff, therefore effective communication (F8) with relevant stakeholders is important if it’s to succeed. Clarke et al (2013, p.638) highlighted that these short-lived improvements can negatively affect a department’s ability to embrace Lean because it can often be misconstrued as a staff reducing process. ROI private highlighted that in his previous position as LM in another hospital, external consultants were invited to present Lean to the Heads of departments, this meeting however “descended into chaos” because Finance couldn’t grasp that this process would not result in job losses.
When it is led from within there is a sense that those leading it have a better understanding of the processes, and perhaps a better grasp of the changes needed for effective implementation. However, for departments that are just starting their Lean journey, external help may be prudent as the skills required to lead such a change may not be present within the department. The UK interviewee said that when embarking on their Lean journey, there were no role models in England to follow, so they turned to industry, examined the methods they used and suitably replicated them for a laboratory environment. They had a very structured externally-led process when implementing Lean. It is interesting to note that the 2 sites that utilised external Lean experts are also the 2 that currently, due to a host of factors, are struggling to dedicate adequate time and resources to Lean, while the internally led, ROI public, are still actively training and encouraging staff involvement.

We see that the implementation trend in the IDIs does not correlate with the census (Table 7). Lean was led from within in 57% of cases and externally in only 9%, and a correlation was noted between those that led from within and those who answered highly for sustainability. This low rate of external implementation is interesting and could suggest that, as much of Lean has now been incorporated into Quality (F15) and the QMS (F9), Lean is being controlled from within as departments adhere to ISO15189 guidelines (2012). It could also suggest that the profession is embracing Lean Philosophy of long-term planning and not just focusing on Processes as the literature has suggested.

5.3 RESEARCH OBJECT 2: EXAMINING IF LEAN TRANSFORMATION ONLY FOCUSES ON PROCESSES, OR IF PHILOSOPHY, PEOPLE AND PARTNERS, AND PROBLEM-SOLVING HAVE ALSO BEEN EMBRACED

As discussed in the chapter 2, Liker (2004) believes companies that fail to implement Lean effectively focus too heavily on processes and don’t grasp the importance of incorporating all elements of the 4P model. Reviewing the limited literature on Lean in Histopathology, a disproportionate emphasis on Processes is evident.

Processes (F23) was the most frequently occurring theme in the IDIs highlighting the importance placed on them by the interviewees. The items in the questionnaire were developed to cover and examine the 4Ps (Table 4). The graphical results while presented in chapter 4, have also been reorganised into the 4P categories in Appendix 12 for easy visual comparison.

This study has presented some interesting findings. Liker’s description of Lean Philosophy promotes adopting long-term thinking for the organisation. From the census results we see that the all Philosophical variables (Table 4) with the exception of Time allocation, have in most cases been implemented. Liker (2004) highlighted that to implement Lean effectively and sustain it, there must be a shared purpose that becomes the foundation that all other Lean principles are built on. It appears, from the data collected during this study, that in the majority of cases long-term thinking in terms of commitment to quality, implementing from within, and sustaining changes are important to the Histopathology profession in Ireland.
Interestingly, adoption of Processes is complex. While standardised procedures and visual management have been well adopted, optimal flow-design, and balancing workflow are more difficult to achieve. It is obvious that for both, great effort has been made to improve flow, and balance workload but several external factors impede optimal implementation. Architecture is the greatest impediment to flow-design. Balancing workflow as discussed previously, seems unachievable for Irish Histopathology laboratories at present, as it is subject to several external obstacles. From this researcher’s experience, huge emphasis is placed on Processes as reproducibility of results is fundamental component of providing a high-quality service and from this we again, see the commitment to quality. However, it’s noted that VSM is under-utilised, but this is unsurprising as analysis of the data highlighted a correlation between those who do not use VSM and those whose staff have not been trained in Lean.

As discussed in chapter 2, developing human capital within an organisation is desirable if they wish to promote a productive, inclusive, and respectful work environment (Liker, 2004), however, reviewing People and partners, we see that this is the most poorly implemented “P”. Lean training is low, most do not have a Changes Agent, and there is variability in Staff Understanding of Lean. Creating Customer Value is the only variable that all institutions have embraced to some degree. These results could be attributed to, as previously discussed, Increasing workloads, and staff-turnover. In the IDIs it was highlighted that staff understanding of Lean varies between more established staff who received Lean training, as they went through initial Lean implementation, and the newer staff who just accept it as “the way we do things here.”

Clarke et al (2013, p.638) said “Lean is about helping people to work smarter, not driving them to work harder” and this is achieved by promoting a culture of CI and learning, in which staff can identify waste and resolve problems (Liker, 2004). The census data indicates that this element of Lean is evolving. While most staff participate at varying levels in Improvement Work, we see that for the majority the Focus of Improvement Work is starting to move towards process improvements, with most starting to use Problem-solving tools to do it. In this researcher’s experience, encouraging staff to identify, and resolve problems creates confident, enthusiastic employees. This collaborative process, and exchange of ideas can lead to innovative solutions. It’s encouraging to see the development of this area.

While a one-size-fits-all approach is not practical in Histopathology, the literature would suggest that cherry-picking parts of Lean hinders sustainability. Liker (2004) said that it’s easy for companies to implement Lean Processes and confuse it with “deep Lean thinking” because they fail to understand the deep transformation of culture required to emulate Toyota’s success. Remarkably, what we see here is a wide-level of implementation of Philosophy, Processes, and Problem-solving. People and partnerships appears to be overlooked in comparison, but it’s interesting and encouraging to see that as a profession we are not just favouring Processes as the literature would suggest.
5.4 RESEARCH OBJECTIVE 3: EXAMINING IF HISTOPATHOLOGY LABORATORIES CAN BALANCE WORKFLOW

Balancing workflow (F9), Lean Flow (F9), and Architectural Limitations (F4) are codes that commonly occur together throughout the IDIs. All interviewees have problems balancing their workflow due to architectural limitations and external factors. As discussed in the chapter 2, many departments implement Lean principles in their own way because they are constrained by architecture and resources (Clarke, 2016, p.5). This issue is mirrored in this study as according to the UK interviewee “One of the things with cellular pathology, is that you are tied to things like the extractors and plumbing and so you can only do so much with the environment you inherit.” ROI private used to be a convent, and ROI public occupies an old building so neither are designed for flow. Any changes to flow were led by the staff and according to the UK, with investment, they could do so much more.

Balancing workflow is challenging for all. While this is a fundamental component of Liker’s description of Lean (Liker, 2004) this is not always possible in Histopathology, where flow is dependent on so many external factors. The UK site say they cannot balance workflow as he believes the NHS has a “silo mentality” where they “don’t care what our problems are, they just want to get their patients through the door.” “Work creep” is an issue for them as new clinics are often added, but the Histopathology laboratory is not informed. This is an issue regularly faced in this researcher’s department, and presumably, in many others. It further highlights the important role communication (F8) plays in an efficiently run service and the impact a lack of communication (F4) can have on a department’s ability to balance workload.

As previously discussed, pull systems and the ability to balance workloads must be in place to achieve an optimally functioning one-piece flow model. However, ROI public said they tried to implement push/pull systems to level off peaks but still get bottlenecks. A large portion of their work comes from GPs. Balancing workflow is difficult because they have no control over sample delivery times so, often they receive large batches, but according to Zarbo et al (2010, p. 71), small evenly distributed batches are essential for optimal lean workflow. These challenges are universal as confirmed by the census (Table 13). While 63% plan and balance their workload to some extent, they admit that it is mostly out of their control. A further 34% said that with advance notice of an increased workload on a particular day, they can plan resources accordingly. However, at present, without serious investment, and open communication with all relevant stakeholders, long-term balancing of workloads does not appear to be achievable for Histopathology in Ireland.

5.5 RESEARCH OBJECTIVE 4: EXAMINING IF MANAGEMENT SUPPORT, AND LEAD LEAN

Chapter 2 highlighted the importance of Lean leadership. According to Liker (Netland, 2015), most lean transformations fail because the stakeholders don’t “understand the power of Lean leadership.” All interviewees agree that upper-hospital management support (F4) is essential if implementing large-scale projects, but as
highlighted by the UK site, this support can dwindle during economic slumps. While ROI private feels management buy-in is necessary to keep those involved in Lean motivated, he also believes that a lot of Lean is “just do it philosophy” reiterating the point made in the literature review, that Lean can deliver quality improvements with little need for capital investment (Spear, 2005, p.78).

Management support and Lean leadership does not apply solely to upper-management, it also incorporates LMs and CMSs. From the IDIs it’s evident that all 3 LMs have several years of experience leading and promoting Lean (F6). It is this level of departmental leadership that promotes sustainability. However, 2 interviewees (ROI private & NHS) intimated that due to ever-increasing workloads, and staffing shortages they don’t have the time to commit to Lean (F6) that they once had. The increasingly busy workloads that departments are facing is highlighted by the 16% of CMSs that feel Lean is a temporary project (Table 9). As workloads continue to increase but investment and resourcing stagnate it’s unsurprising that many see Lean as a short-term, quick-fix solution, or in some cases, a necessary evil to get them through Accreditation. Encouragingly, the CMS support for Lean as indicated by all other participants, could be construed as discipline-wide understanding of the important role Lean has played, and will continue to play in the future.

However, while according to the census, CMS commitment to Lean is high, their ability to allocate time for improvement work is limited as 44% do not allocate time for it and only 9% are in a position to allocate time regularly (Table 9). These 2 variables seem to be at odds, but working in the profession this researcher can understand the complex situation. While many are committed to Lean the increasing workload and diminishing resources make it increasingly difficult to allocate time to anything other than routine work. It could also be considered that years of improvement work was conducted over the last 10-15 years as laboratories embraced ISO15189 (2012). Improvements were made, procedures standardised, and it is perhaps these long-standing improvements that the respondents are committed to on a daily basis. This inability to allocate time was also revealed during the IDIs as ROI private and the UK site are in a situation now where improvement work (F9) is only considered in a crisis (F4). As previously mentioned, ROI private believes improvement work conducted under these conditions is “panicked, it’s rushed and the negative association with that remain for a very, very long time” so leading and supporting Lean in a crisis is best avoided if possible.

5.6 RESEARCH OBJECTIVE 5: EXAMINING HOW HISTOPATHOLOGY LABORATORIES PROVIDE VALUE FOR CUSTOMERS

As discussed in the LR one of the principle aims of Lean is to provide value (F5) for the customer (Clark et al, 2013, p.638). For Histopathology, establishing how value is created can be challenging. For the purposes of this study the researcher defined “customer” as the immediate customer, i.e. the Pathologist or Clinician. While many processes were mentioned, communication (F8) for all, is key. All 3 interviewees send out user-satisfaction surveys and amend their processes, if possible, based on this feedback.
This exchange of ideas and regular communication echoes the Clarke et al (2013, p. 638) belief that the value stream is continuously improved by understanding the customer’s need, and redesigning the process to remove all value-inhibiting waste. The IDI results are also mirrored in the census in which all participants attempt to provide customer value (Table 10). Customer feedback, in 44% of cases, is used for improvement work and as a basis to challenge their current processes. While the focus here is on the immediate customer, providing value for them ultimately provides value for the patient which is the driving force behind all quality improvement.

5.7 RESEARCH OBJECTIVE 6: EXAMINING HOW IMPLEMENTED LEAN PROCESSES ARE SUSTAINED

During the IDIs, Lean Sustainability was the second most frequently reoccurring theme (F21) indicating its importance. Promoting and implementing Lean is a complex and involved process, but sustaining Lean is the real challenge. From personal experience this researcher agrees with Kotter (2007, p.96), ‘until changes sink deeply into a company’s culture, a process that can take 5-10 years, new approaches are fragile and subject to regression.’ To sustain changes over this period of time requires strong Lean leadership. If Histopathology leaders are to replicate the sustainability seen in Toyota they must follow suit and create an organisational structure that supports and encourages a bottom-up approach to change. This involves empowering the workforce, involving them in improvement work and allowing them to solve process problems as part of the daily routine. During the IDIs it was highlighted that, while it depends on the level of training, anyone who identifies an issue can stop the process and solve it. This level of staff-involvement in problem-solving is a very important element of Lean, but it is also an essential component of good leadership. As mentioned in chapter 2, this researcher has found that including staff in decisions, involving them in departmental improvements, and giving them the freedom, and encouragement to solve problems boosts moral, and increases the confidence of employees who may otherwise feel under-valued. Experience has highlighted that enthusiastic employees are more open to change and are more likely to feel satisfaction from a job well done. Employees like this are likely to sustain improvements and this is facilitated through good leadership.

From the census it can be seen that staff involvement and commitment to Lean varies (Table 8). All sites indicated their staff partake in improvement work, but level of involvement differs. It also highlights that while there is generally staff commitment to Lean, in 22% of cases the staff see it as a temporary project, while a further 6% don’t engage with it at all. It is also clear that 28% of respondents have strong problem-solving structures in place, and encouragingly a further 31% are starting to implement a structured approach to improvement work and utilising problem-solving tools to do it. While the focus of improvement work is currently mostly on the laboratory environment, it’s promising to see that in 25% of cases process flow and value are becoming the focus (Table 13). These statistics highlight the positive work that departments are doing as they implement and try to sustain their improvements, but also underline the challenges some departments will have sustaining improvements in the long-term.
Zarbo (2010, p.361) believes that cultural transformation of all work practices is required if Lean is to be truly successful, and while some respondents clearly encourage and support staff involvement in Lean, for those departments that see Lean as a temporary project it is clear that this cultural transformation has not occurred. So one can only assume that sustainability will be a constant struggle for them.

Sustaining Lean according to Liker (2004) is dependent on implementing all elements in the 4P model. As discussed above this research indicates that Histopathology has embraced Philosophy, Processes, and Problem-solving as the census shows a wide-level of implementation, albeit varying levels of implementation, the implementation is evident. In contrast People and partnerships appears to be implemented to a lower-degree, and while this must be addressed, surely embracing the other Ps will go a long way to safeguarding sustainability.

5.8 RESEARCH OBJECTIVE 7: EXAMINING IF AUTOMATION IS A NECESSARY ELEMENT OF LEAN

Histopathology, unlike the fully automated Blood Sciences, is a mixture of manual and automated techniques. An interesting objective of this study was to determine if automation (F10) is a necessary element of Lean and if without it, Histopathology could ever be truly Lean. Interestingly, all 3 interviewees felt that automation was not a necessary element of Lean. From the IDIs it could be construed that the 2 elements are independent as the level of engagement and openness to change are more essential to Lean. The UK site found a greater level of engagement with Histopathology than with the Blood Sciences, this he admits could be related to the fact that their main Change Agent was a Histopathology Consultant. The level of scepticism was higher in the automated departments while in Histopathology there was a general consensus that a change was needed. Getting this level of buy-in from the staff is surely a more valuable element of Lean success than an automated process.

When examining it technically, ROI private said that when you look at Lean in an automated laboratory you are looking to “Lean-out” the entire process, but due to the fragmented nature of Histopathology processes, it’s not that straightforward. In this case it’s necessary to look at mapping the individual processes to make them as efficient as possible.

This was further emphasised when ROI public highlighted that an automated machine can “work at the pace it can work at.” This, while an obvious point is well made, because we have a tendency to assume any process can be improved with automation when in fact, in terms of Histopathology, as pointed out, it depends on what a department wants to achieve. If alleviating RSI, or peaks in workflow is the aim then there is scope to implement automation. However, with manual techniques “there is more scope and more flexibility to think outside the box” unlike with an automated process where you are confined to what the machine can do. This sentiment is echoed by the UK site that believes while certain technology is needed to improve processes, it too can present problems and create bottlenecks ultimately hindering the flow.
Another interesting objective of this study was to review, and compare the implementation, processes and, sustainability of Lean in ROI public and ROI private Histopathology laboratories. There was no literature to draw on, so this is the first time the 2 have been compared scientifically. A total of 20 responses were received from the public laboratories, and 10 responses from private facilities representing an 83% and 91% response-rate respectively, so it is assumed this is a good representation of the profession. Data analysis of the census indicated there is little significant variation between public and private. There were only 2 areas of note: Lean training (Table 20), and time allocation for improvement work (Table 21). From the census, it’s evident that 70% of private CMSs say their staff have not received Lean training compared to 35% of public CMSs. Also, 70% of private facilities do not allocate time for improvement work, again, compared to 35% of public sites. Overall for both categories the public seemed to engage at a marginally higher rate than the private.

However, what’s important here are the similarities not the 2 differences. This census indicates a united profession, united in both the good and the bad. All strive to provide high-quality healthcare utilising Lean as best they can, while simultaneously, all seem to share the challenges of resourcing, time, the inability to balance workflow, and the architectural limitations of their environment, etc. Investment is also a struggle for both public and private facilities.

These similarities could be explained by the fact that it is a small community. Most will have attended the same few colleges that offer the Biomedical Science Degree and so have been trained together. Movement of staff between the public and private facilities could also account for this. Also, problems, and solutions are regularly discussed at professional meetings so information becomes communal. All facilities have adopted ISO15189 standards (2012) over the last decade and most facilities are accredited by INAB, so a high level of standardisation between both public and private is to be expected. It is encouraging perhaps, to see from this study, that we’re all in it together.
6 CONCLUSIONS AND RECOMMENDATIONS

6.1 CONCLUSION

The research question asked is “Was Lean implemented effectively and sustained in Irish Histopathology laboratories?” In chapters 1&2 it was highlighted that there was a paucity of published literature on Irish Histopathology services. As demand for Histopathology increases, planning and sustaining the growing needs of laboratories nationally is inhibited by this lack of data. This research aimed to fill the knowledge gap by identifying the key factors affecting Lean in Histopathology laboratories. The conclusions for the research objectives are discussed below.

➢ Research Objective 1: To examine the Lean implementation process in Irish Histopathology laboratories.

Lean was led from within in 56% of cases, and externally in 9% of cases. A correlation was identified in the data between internal Lean Implementation and Lean Sustainability, reiterating Zarbo’s (2010, p.361) point that Lean implementation can be more successful if led from within. The low level of externally led Lean could suggest that the profession is embracing the Lean Philosophy of long-term planning and not just focusing on Processes as the literature has suggested.

➢ Research Objective 2: To examine if Lean transformation only focuses on Processes, or if Philosophy, People and partners, and Problem-solving have also been embraced.

Liker (2004) highlighted that cherry-picking parts of Lean would inhibit Lean sustainability as implementing Processes is often confused with “deep Lean thinking”. Interestingly, in the majority of cases, Philosophy, Processes, and Problem-solving have been embraced positively by Irish Histopathology laboratories, albeit to varying degrees. People and partners appears to be the most poorly implemented ‘P’. Staff training in Lean is low, most do not have a change agent in place, and there is wide variability in staff understanding of Lean. Increasing workloads and staff-turnover have been suggested as possible reasons for this, as newer staff have yet to be trained in Lean.

➢ Research Objective 3: To examine if Histopathology laboratories can balance workflow.

Clarke (2016, p.5) highlighted that many departments implement Lean in their own way because they are constrained by architecture and resources. This is mirrored in this dissertation as architectural limitation is the main challenge affecting flow-design in Irish Histopathology laboratories. Enhancements to flow have been made by the staff but investment is required for further improvement. Balancing workflow seems unachievable at present in Irish Histopathology laboratories mainly due to “work creep”, and large specimen deliveries at irregular times.
Research Objective 4: To examine if management support, and lead Lean.

Upper management support is necessary for large-scale Lean projects but a lot of Lean is “just do it philosophy.” According to Liker (Netland, 2015), most lean transformations fail because the stakeholders don’t “understand the power of Lean leadership.” In Histopathology, the importance of Lean leadership is understood. However, increasing workloads, and staffing shortages mean LMs cannot dedicate enough time to Lean. The effects of this increasing workload is seen in the 16% of CMSs that see Lean as a temporary project. The CMS commitment to Lean as indicated by all other participants could be construed as discipline-wide understanding of the important role Lean has to play in the future. However, their ability to commit time to improvement work is limited as 44% do not allocate any time and only 9% do so regularly.

Research Objective 5: To examine how Histopathology laboratories provide value for customers.

Communication is identified as a key element to providing customer value. User-satisfaction surveys is the most commonly applied tool. Customer feedback, in 44% of cases is used for improvement work and to challenge current processes, reiterating the need to understand customer needs in order to continuously improve the value stream (Clarke et al, 2013, p.638).

Research Objective 6: To examine how implemented Lean processes have been sustained.

Several factors impact upon sustainability. Lean implementation in the majority of cases, was led from within, and a correlation was noted between those who led from within and those who answered highly for sustainability. Implementing all aspects of the 4P model is an important element of Lean sustainability. In Irish Histopathology laboratories the trend suggests that Philosophy, Processes, and Problem-solving have been embraced by most, but People and partners is noticeably under-employed. All respondents attempt to sustain improvements, in 81% of cases the improvement is added to the standardized procedures and monitored over time.

Research Objective 7: To examine if automation is a necessary element of Lean.

Automation, according to the LMs, is not a necessary element of Lean. Level of engagement with Lean, and openness to change are more important. The fragmented nature of Histopathology makes it difficult to “Lean-out” the entire process. Instead, individual processes must be mapped to make them as efficient as possible. Manual techniques offer more flexibility, and freedom to think creatively compared to automated processes that are confined within their own limits. Automation can alleviate RSI and improve processes, but they are also subject to bottlenecks.

Research Objective 8: To examine Lean variations between public and private Histopathology laboratories in the Republic of Ireland.

Little significant variation was identified between public and private Histopathology laboratories. There were only 2 areas of note: Lean training and time allocation. Public responses were marginally more
positive for both. The similarities indicate a united profession. All strive to provide a high-quality service, utilising Lean as best they can, while simultaneously facing common challenges of resourcing, time, the inability to balance workflow, and the architectural limitations of their environment. Adherence to ISO15189 and INAB Accreditation are likely major contributing factors to this unity.

The purpose of this dissertation was to determine if Lean was implemented effectively, and sustained in Irish Histopathology laboratories. Liker’s description of Lean, and the 4P model were used as a basis to determine this. There were numerous factors to consider. Both implementation and sustainability are linked by complete implementation of the 4P model. From analysis of the data we see that overall, Philosophy, Processes, and Problem-solving have been adopted in most cases to varying degrees. People and partners however has been poorly implemented, impacting greatly on the ability to sustain Lean. Employees must be invested in, as failure to do so could impact upon quality of service in the future as staff changes and retirements occur. A long-term approach to staff development must be considered.

Another major impediment to Lean sustainability identified was the inability of most departments to balance and level workflow. Without serious consideration, this will become increasingly problematic as current trends suggest demand for services will only increase.

However this should not negate the good work being done, under increasingly pressurised conditions, to provide a high-quality service. The issues highlighted are for the most part out of the hands of CMSs. Tackling them requires large scale government investment. With investment, the architectural limitations that constrain most departments could be addressed, and time and resources could be contributed more regularly to ensuring employees are given the opportunity to attend Lean training. This would go a long way to sustaining improvements.

6.2 RECOMMENDATIONS

6.2.1 RECOMMENDATIONS FOR MANAGEMENT

As highlighted in the LR implementation of the 4P model contributes greatly to Lean sustainability. Human capital is the greatest asset to any laboratory and this study highlighted the need to invest more in the staff. Laboratory management need to be more proactive in promoting this investment. Staff understanding and commitment to Lean would be improved with relevant training.

6.2.2 RECOMMENDATIONS FOR GOVERNMENT BODIES

The long-term sustainability of Lean in Histopathology is impeded by architecture, and the inability of departments to dedicate time and resources to employee development.
Demand for Histopathology is growing, however there is no evidence to suggest investment in the service is growing to match demand. This investment needs to be transparent. Understanding of the level of investment required to support the development of Histopathology services is impeded by the lack of National Histopathology data. A review of all Pathology services in Ireland is needed to provide a current picture of the challenges faced by the profession. The Carter Report (2008), as created in the UK, could be used as a blueprint for this review.

6.2.3 RECOMMENDATIONS FOR FUTURE STUDY

This study and the developed questionnaire could be expanded to review the implementation and sustainability of Lean across all Pathology disciplines. It would give a more comprehensive picture of Lean in Irish laboratories, and contribute in its own way to a national review of Pathology services.

Staffing and recruitment issues were mentioned often during the IDIs. In the past few years there has been an abundance of retirements but the level of entry into Histopathology has not matched this loss. A review is needed on the reluctance of Biomedical Science students to choose Histopathology, as this continued lack of new graduates will become an issue in the future.
CHAPTER 7: REFLECTION

7.1 SELF REFLECTION

7.1.1 PERSONAL PROFILE

As a Senior Medical Scientist working in a busy and constantly evolving healthcare profession, I can appreciate the need for, and the importance of personal development. Some research into the process of reflective writing has allowed me to further understand the significant role it can play in identifying and focusing personal values and goals (Cottrell, 2015) (University of Birmingham). It allows me to look back at situations and take meaning from them that will help me become a better scientist and leader in the future.

I agree with Socrates who said, “the unexamined life is not worth living.” (Plato. Apology 38a). To progress and evolve intellectually, and personally, it is important to examine one’s own personal strengths and weaknesses. I have performed a personal SWOT analysis (Appendix: Personal SWOT). Understanding myself better will positively influence my professional and personal life.

I think Kierkegaard (1843) said it perfectly, “Life can only be understood backwards; but it must be lived forwards.” For me it is impossible to reflect without acknowledging that my past, the way I was raised, and the values that were instilled in me have impacted greatly on the person I have become. Values such as integrity, honesty, determination, and dedication have all given me the good work ethic that guides me daily.

According to Gibbs (1988, p.9), if you don’t reflect on an experience, it can be quickly forgotten about, and its important lessons lost. Using the Gibbs Reflective cycle as a guide I reviewed the development process of this thesis over the last 2 years, my personal learning development journey, and the valuable lessons learned from this experience.

![Gibbs' Reflective Cycle](University of Birmingham)

Fig 5: Gibbs’ Reflective Cycle (University of Birmingham)
7.1.2 PROCESS

The idea for this dissertation topic arose from a conversation I had with a colleague who told me about wonderful project posters that were produced by colleagues in her laboratory when they had attended in-house management courses. The projects reviewed areas of the department to Lean, research would be done, lovely posters created, but the changes were never implemented. I started to wonder if this was a box-ticking exercise instead of a desire for real change and it made me reflect on my own departments experience with Lean. When I started working there in 2005 Lean was the buzz word, and I suddenly realised I hadn’t heard it mentioned in years. I began to wonder if it was a fad. From this, my research question and objectives were formed.

There were a lot of elements to this study but I found my scientific background helped me to form a very concise and structured approach. Saunders research onion really facilitated this process. It gave me a great structure through which my methodology was developed. While to some this seemed like a laborious process, this structured, methodical approach fed into my strengths. It focused me so that I could easily answer the following: What do I want to ask? Who do I want to ask? How will I ask it?

Histopathology is a small community and I was concerned that I wouldn’t get the required number of questionnaire responses. However, having identified this as a limitation I decided to tackle it head-on and spent every lunch-break over the course of 3 weeks personally calling every CMS nationally to explain my study and ask if they’d be interested in participating. I knew some of them so it was easy to call on them. But for the majority of them this was our first interaction and I admit I was nervous with each phone call, nervous I wouldn’t articulate well, nervous my study would sound silly, and nervous they’d say no. It must be noted that every single person I spoke to was kind, courteous and eager to help. Many were very interested in the outcome of this study and have requested a copy of the finished work. This process, while daunting, did allow me to connect with, and introduce myself to all CMSs nationally. It was a very positive experience.

Simultaneously, I was also conducting my IDIs. This was a challenge for me. I was interviewing professionals with several years of experience in Lean and feared I would sound unprepared and unprofessional. Preparation was key here. I am happy with the end result. All interviewees were incredibly helpful and happy to discuss their experiences and it was obvious that all were excellent candidates for this study. I also took from this the interesting experience of conducting an interview which will be a useful skill in the future.

I feel that a lot of interpersonal skills were honed during this process, and a lot of contacts were made. It was a very enjoyable and rewarding process.

7.1.3 PERSONAL LEARNING DEVELOPMENT

My education and my continuous need to learn is something that I pride myself on. I completed my previous MSc 8 years ago. I enjoyed the experience immensely but it was a necessary evil. I required it to get a promotion as per the guidelines of our professional body. I expanded on previously learned theory but it was essentially more of the same. I have for the last few years wanted to do another course but I couldn’t decide in what
context. This raised eyebrows amongst some colleagues as the general feeling is “well I’ve done the necessary MSc, so I’m done”. This attitude isn’t good enough for me. I have 30 years of working life left and I refuse to accept that I’ve finished learning. So I was faced with a decision, do I complete another MSc and see where it brings me or be brave and do something completely different? Bravery was definitely the preferred choice. So 2 years ago I applied for this MBA course. It has been the best decision I have ever made. I left class every week brimming with new knowledge and it elevated me from an intellectual stagnation I never realised I was experiencing. There was immense joy in learning something so new and unrelated from my daily routine.

It did have its challenges. I sacrificed a lot of time with my partner, family, and friends over the last 2 years but my resilience, and their constant support drove me forward. Also, most of my classmates work in a business environment so the language, the terminology and the material was familiar to them. I felt I had to work harder to understand the material, however, I found that my scientific background and my previous MSc experience gave me the edge in certain areas where analytical, reasoned thinking was required. Determination, dedication, and a desire to learn were key traits that kept me motivated throughout the 2 years.

I have learned a lot from this experience both academically, and personally. I have learned to look at my profession differently and I have been able to apply every module to my department in some way, even a subject as diverse as Marketing has allowed me to appreciate the optics of a situation. Meeting and engaging with professionals from different backgrounds and working with them in teams has been a different and enjoyable learning curve. The Project Management module was particularly important as it gave me a lot of new skills that I could apply at work as I am involved in a large national laboratory project. It also gave me ample opportunity to speak publically which was something that previously made me nervous. Overall this was a very successful learning experience that has changed my perception of my profession and myself.

7.1.4 IF NECESSARY, WHAT CHANGES WOULD YOU MAKE TO THIS PROCESS?

While the workload was challenging, and personal sacrifices were made, I actually really enjoyed this whole process. I loved going to class and making new friends. There’s really nothing I would change, it was a very rewarding experience.

7.1.5 WHAT’S THE MOST IMPORTANT THING YOU’RE LEARNED DURING THIS PROCESS?

While there is an abundance to choose from, I would have to say that my level of dedication and resilience surprised me (Appendix: Skills Inventory). According to Basso (2015, p. 13) “one of the compelling consequences of building skills and capacities is that they are critical to setting and moving toward one’s life goals.” Throughout this MBA I was constantly challenged by intense academic workload, while working in a busy and understaffed department, participating in an on-call service, all while maintaining a personal life. It was difficult, but inner strength in areas like dedication and resilience shone through.
After this experience, I strongly agree with Coutu (2002, p. 46) who highlighted “more than education, more than experience, more than training, a person’s level of resilience will determine who succeeds and who fails.” This encourages and emboldens me because I feel having succeeded at this I really could overcome any challenge and succeed at anything I put my mind to.

While some (Block & Kremen, 1996) (Tugade & Fredrickson, 2004) may see resilience as one’s ability to move forward from a negative or traumatic experience, I have more positive associations with resilience and would favour a more optimistic definition that identifies it as an ability to adjust positively to adversity. (Jackson, 2007). This may seem like semantics but personally I cannot consider this MBA a negative or traumatic experience, but rather challenges that I have encountered along this journey and have overcome to find myself a stronger person. “Resilience is something you learn after the fact” (Coutu, 2002. P. 46) and I’ve certainly learned it now.

7.1.6 CONCLUDING FROM THE EXPERIENCE

While time commitments were a challenge over the last 2 years, what I have gained academically and personally far out-weigh any challenge. I have broadened my perception of my work environment, no longer thinking of it just scientifically but also looking at the bigger picture, and the need for a level of business acumen if a laboratory is to run efficiently and successfully.

7.1.7 ACTION PLAN

While I very much enjoy my profession, and get great job satisfaction, this MBA has opened me up to the possibility of a career outside the laboratory. I’m unsure in what capacity yet, but I feel with this MBA completed if the right opportunity were to arise I am prepared to make the move. The knowledge and skills acquired during this course will be invaluable in both my current position and any future roles to come.
7.2 REFERENCES: REFLECTIVE WRITING


University of Birmingham. 'A short guide to reflective writing.' Available at: https://intranet.birmingham.ac.uk/as/libraryservices/library/skills/asc/documents/public/Short-Guide-Reflective-Writing.pdf
### 7.3 APPENDIX: REFLECTIVE WRITING

#### 7.3.1 APPENDIX 1: PERSONAL SWOT ANALYSIS

**Strengths and Weaknesses:**

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resilient</td>
<td>Can take on too much</td>
</tr>
<tr>
<td>Dedicated</td>
<td>Organised</td>
</tr>
<tr>
<td>Adaptable</td>
<td>Can let stress get the better of me occasionally</td>
</tr>
<tr>
<td>Detail orientated</td>
<td>Can be hard on myself</td>
</tr>
<tr>
<td>Time management</td>
<td>Need security</td>
</tr>
<tr>
<td>Quality focused</td>
<td>Can doubt my own abilities at times</td>
</tr>
<tr>
<td>Problem-solver</td>
<td>Find it hard to say no.</td>
</tr>
<tr>
<td>Team player</td>
<td></td>
</tr>
<tr>
<td>Articulate</td>
<td></td>
</tr>
<tr>
<td>Can analyse stressful situations</td>
<td></td>
</tr>
<tr>
<td>Organised</td>
<td></td>
</tr>
<tr>
<td>Adventurous</td>
<td></td>
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</tbody>
</table>

Completed the SWOT analysis (Cottrell, p. 99) my first observation was ‘thank God my strengths outnumber my weaknesses!’...well just about. I noticed that a lot of my strengths make me very suitable for my current work environment, i.e. detail orientated, quality orientated, team player, etc.

Another interesting observation were the contradictions between some of my strengths and weakness. For example I named ‘organised’ as both a strength and weakness. When working in a scientific environment it makes sense to be organised and structured but of course if you spend too much time tidying up before you begin a task and so time management can become an issue. I also said that I can sometimes let stress get the better of me while at the same time highlighting that I can step back and analyse a stressful situation and find a way to relieve it. I think I have developed this strength over the years of working in a stressful environment. I can have the initial panic if things are getting too intense but I have taught myself to stand back and analyse the problem.

Another contradiction I highlighted is ‘adventurous’ as a strength and ‘security’ as a weakness. The fear of losing a sense of professional security could hamper my intentions to progress.

In my SWOT weakness I see here that saying ‘no’ when I’m too busy to help can be an issue for me. This is something that I need to work on. Saying ‘yes’ when I can’t commit the time to a task can be a time management nightmare. It also leads to increased stress and worry. I feel that as part of a team environment you are expected to say ‘yes’. However I will have to believe that just saying ‘no’ because I’m swamped with other work doesn’t affect my standing as a committed team player. During this course I have learned several tips for improving time...
management and I will certainly utilise small pockets of time to sort out minor tasks. I spend a lot of time commuting by bus so this presents the ideal opportunity for drawing up lists, making call, sending emails.

Knowing where to begin a new challenge can be very daunting and I find that sometimes instead of tackling it straight on I can distract myself with any number of tasks that are less important. Writing a list of the steps to be completed seems like such a basic thing to do but for some reason I never do this. I will try to begin all tasks in this way.

Time management is such an important part of any busy schedule and it is something that I previously struggled with. However during this MBA my time management skills have increased dramatically as I juggled work, college, and a personal life.

I also find that I can be quite hard on myself if something goes wrong. I see this as accepting responsibility for my actions but perhaps I can take my mistakes to heart a little too much.

Opportunities and Threats:

<table>
<thead>
<tr>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joy of learning something new</td>
<td>Fear of change</td>
</tr>
<tr>
<td>New challenges</td>
<td>Indecision as to what direction to take professionally</td>
</tr>
<tr>
<td>Networking opportunities</td>
<td></td>
</tr>
</tbody>
</table>

Assessing my ‘Threats’ I see that fear and indecision could potentially hold me back from achieving my goals. I have tried to work on these during the course. I faced my fear of public speaking by presenting in class often throughout the MBA. It was terrifying and while I felt like I was going to have a heart attack I did it and I feel the better for it. It was just step 1 in a long process but at least I’ve taken that step. I also tackled indecision by choosing my research topic. This really was difficult and indecision is something I struggle with. I guess I’m afraid of making the wrong decisions in life. I think I will have to work on these two side by side. My outlook on life and general disposition I feel leaves me open to several opportunities.
<table>
<thead>
<tr>
<th>Academic Skills</th>
<th>Professional Skills</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent communicator</td>
<td>Resilient</td>
</tr>
<tr>
<td>Enjoys learning</td>
<td>Dedicated</td>
</tr>
<tr>
<td>Good critical thinker</td>
<td>Determined</td>
</tr>
<tr>
<td>Excellent organisation</td>
<td>Motivator</td>
</tr>
<tr>
<td>Good multi-tasker</td>
<td>Good under pressure</td>
</tr>
<tr>
<td></td>
<td>Open to change</td>
</tr>
<tr>
<td></td>
<td>Team player</td>
</tr>
<tr>
<td></td>
<td>Excellent communicator</td>
</tr>
</tbody>
</table>


University of Kent (no date) ‘Chapter 8 Coding of Qualitative Data’. Available at: https://www.coursehero.com/file/16353578/Chapter8Coding/ (Accessed:02 July 18).


APPENDIX 2: LEAN INTERVIEW QUESTIONS:

1. Do you recall when you first heard about Lean Management?
2. What was your process for implementing Lean in your institution?
3. Did you identify a role model and emulate their process?
4. Have your staff received or attended any training in Lean?
5. Do your staff understand Lean processes and flow?
6. In what way do you feel your employees are committed to the Lean processes in their daily routines?
7. As the Laboratory Manager do you take a proactive role in promoting and encouraging Lean practices and improvements within the department?
8. How vital is hospital management support when implementing new processes?
9. Is adequate time and resources allocated to improvement work?
10. Do you have a change agent driving improvement work?
11. How do you ensure you provide value for your customer, i.e. pathologists and clinicians?
12. What processes, if any, do you use to identify waste?
13. Are your workplaces designed for ‘flow’?
14. Do you have standardised practices in place?
15. Are you able to level and balance workloads to avoid bottlenecks or to deal with a sudden increase in demand for services?
16. Have quality standards been built into the daily routines and processes?
17. What ‘Pull’ systems do you have in place?
18. How does your department identify waste?
19. Is information visualised in your department? E.g. safety information, work standards, performance in relation to KPIs, etc.
20. To what extent do your employees participate in improvement work? E.g. improving work environment, process flow, entire flow, etc.
21. Does your department have structured problem solving practices?
22. How do you sustain improvements that have been made?
23. Do you feel that adequate resources are allocated to sustaining changes?
24. Are the results of Lean implementation obvious within your department?
25. Have you identified any difference in the level of Lean implementation between automated laboratories, like Biochemistry, and the more manual laboratories, like Histopathology?
26. Do you think that automation is a necessary element of process improvement?
27. How do you measure your Lean success? KPIs, etc.
28. How would you rate your level of Lean maturity?
29. Why do you think it has been so successful here?
APPENDIX 3: INFORMATION SHEET

INFORMATION SHEET

PROJECT TITLE

“Assessing Lean Management in the Irish Histopathology Laboratory Services.”

My name is Kate Thompson and I am a Senior Medical Scientist working in the Histopathology laboratory in Beaumont Hospital. I am a part-time MBA student in Dublin Business School and this dissertation will be supervised by Mr. Gary Bernie.

You are being asked to take part in a research study on Lean management in Irish Histopathology laboratories. To date no comprehensive assessment of Lean Management experiences and opinions across Irish Histopathology laboratories has been undertaken. I aim to fill this gap in the knowledge.

The research question being asked is “Was Lean management implemented effectively and sustained in Irish Histopathology laboratories?” There are two stages to this research. Firstly, qualitative in-depth interviews will be conducted with Laboratory Managers to gain a deeper understanding of Lean across all Pathology disciplines. This information will be analysed and reviewed for common themes. These themes will be used to adapt a suitable questionnaire that will be distributed to Irish Histopathology Chiefs to measure their perceptions and experiences of Lean Management within their own laboratory.

WHAT WILL HAPPEN

In this study, you will be asked to answer a series of questions designed to draw out your knowledge and experience of Lean practices within your department. The questions will be sent to you in advance so that you can get a sense of the information I wish to cover. The interviews will be recorded with a digital recorder.

TIME COMMITMENT

The in-depth interview will be conducted over a single session of approximately 2 hours.

PARTICIPANTS' RIGHTS

You may decide to stop being a part of the research study at any time without explanation required from you. You have the right to ask that any data you have supplied to that point be withdrawn/destroyed.

You have the right to omit or refuse to answer or respond to any question that is asked of you.

You have the right to have your questions about the procedure answered (unless answering would interfere with the study’s outcome, A full de-briefing will be given after the study). If you have any questions as a result of this information sheet, you should ask the researcher before the study begins.
CONFIDENTIALITY/ANONYMITY

The data I collect does not contain any personal information about you except your name, professional position, and the hospital you work for. As in keeping with recent GDPR guidelines the data collected during this study will be used for my dissertation, with the potential of use at conferences and/or in publication, etc. If requested your name and hospital will be anonymized.

FOR FURTHER INFORMATION

I and/or my supervisor Mr. Gary Bernie will be happy to answer your questions about this study at any time. You may contact my supervisor at gary.bernie@dbs.ie or through Dublin Business School (01) 417 7500.
INFORMED CONSENT FORM

PROJECT TITLE:

“Assessing Lean Management in the Irish Histopathology Laboratory Services.”

PROJECT SUMMARY:

The research question being asked is “Was Lean management implemented effectively and sustained in Irish Histopathology laboratories?” There are two stages to this research. Firstly, qualitative in-depth interviews will be conducted with Laboratory Managers to gain a deeper understanding of Lean across all Pathology disciplines. This information will be analysed and reviewed for common themes. These themes will be used to adapt a suitable questionnaire that will be distributed to Irish Histopathology Chiefs to measure their perceptions and experiences of Lean Management.

By signing below, you are agreeing that: (1) you have read and understood the Participant Information Sheet, (2) questions about your participation in this study have been answered satisfactorily, (3) you are aware of the potential risks (if any), and (4) you are taking part in this research study voluntarily (without coercion).

__________________________________________  __________________________________________
Participant’s signature  Student’s Name (Printed)

__________________________________________  __________________________________________
Participant’s Name (Printed)  Student Name signature

__________________________________________
Date
APPENDIX 5: PRIMARY IDIS

IDI No. 1: Mr. Robert Hughes, Cellular Pathology Services Manager, Path Links NHS Pathology Services, Northern Lincolnshire and Goole NHS Foundation Trust, UK.

Conducted: 18/06/2018.

Do you recall when you first heard about Lean Management?

Yes, it was when I was applying for the post here in October 2006. I visited the department and it was mentioned at that time. I had to give a presentation for my interview and it orientated around Lean management.

What was your process for implementing Lean in your institution?

The Lean journey in PathLinks started around 2005 and the key driver at this point was the Clinical Director at the time, David Clarke. He picked up on Lean Management from attending a Laboratory Management conference organised by the ACD in which an international speaker gave a presentation on the benefits of utilising Lean management. I think it may have been one of the big private hospital in the States that are linked with the motor industry. Perhaps the Henry Ford Institute. He came away from that talk having bought several copied of “Lean Thinking” and passed them around to the Pathology general managers at the time. What that did at the time, it was fortunate because that was when there was still Pathology Modernisation money about, and part of the modernisation bid that went in was to fund Lean consultancy so the funding brought in Lean consultancy with a company called Argent Global. They came on site and delivered training and did a review of the processes, formulated current state/future state maps and made recommendations of what we should do with our varied Directorates to gain efficiencies from our Pathology services. They were with us between 2006 to late 2009. It was a very structured process at the beginning.

Did you identify a role model and emulate their process?

The current General Manager, the former General Manager and the Clinical Director went over to the States and visited a couple of institutes but that was very superficial. From a UK perspective, we didn’t have a key role model in the UK, there was little to be learned from other Pathology centres at the time because of the unique nature of our service but what we did look at was manufacturing industry. David visited many places but here in Lincoln we have Siemens who produce gas turbine engines. We visited the plant there and brought away various ideas so really it was recognising and looking at what we could bring from industry and apply it in Pathology. (Kate) So you essentially had no one to follow so you looked to industry? Absolutely and very much from a UK perspective, we became an exemplar site for NHS Improvement for 2-3 years at least we would have at least 1 visit a month from people coming to have a look at us to take away messages for improvement. (Kate) So essentially you guys became the role-models?

Have your staff received or attended any training in Lean?

Yes, because at the beginning, way, way back Argent delivered their training and the idea was that we would have our own PathLinks Lean team. They did deliver their 101 training. I attended that and a variety of staff went through that and received it. I actually put a bid in and got funding for band 1-4 training so a huge proportion of our laboratory support staff actually went through and got their yellow belt and we have one person that went on and got their green belt.

Do your staff understand Lean processes and flow?
Yes, a high proportion. If we were to go to the lab now and say explain Lean, at operation level because of staff turn-over level a lot of people just accept that it’s the way we work and it’s what we do. The long-standing members of staff who have been with us through that 10 year journey will understand because they received the formal training, and also they understand what it was like before and what we achieved by implementing the processes that we have.

In what way do you feel your employees are committed to the Lean processes in their daily routines?

Can I answer that in 2 ways? Commitment, talking from a historical point of view when I first came across here they had spent a lot of time doing SS and all the cold face workforce could see is “what is this going to achieve? It’s just ritualised cleaning.” There’s a quote that David Clarke still uses that one of the members of staff said, “are we going to get more people because all this SS is taking an awful lot of time you know?” He was recognising that we have to put in all those baseline changes in order to eliminate a lot of the noise so we could actually make process changes. There was really a tipping point, a lightbulb moment, in mid-2008 when we switched on continuous flow and that was when people really got the appetite for it and that was when trying to push that boulder up the hill it really changed the other way and started rolling for us so we had a successful 3-4 years where we ran multiple Kaizen events and expanded our learning. We got a huge level of commitment from our team because it really saved our neck because the work that was being carried over, the mistakes that were made on a daily basis. When I first got here it wasn’t a nice place to work and the changes we made, the improvements we made really did generate the commitment from the staff because they realised that it was about making their working lives as well as improving the quality of the work and reducing defects, it made everything better for everybody.

So, we have got a group of people that are committed on a daily basis because of the processes that we have in place. The SS mechanisms, the flow mechanisms that we have in place, we have those routines in place every day and they’re committed to it because that’s the way we work. Prior to working here, I was a Senior BMS working in a large teaching hospital doing exciting Histology, interesting stuff in Nottingham but it was time for a change for me professionally so moving back to district general type Pathology there had to be something new for me to learn and that was what attracted me to it because I was able to learn a management style rather than just becoming a conventional Chief. It was ‘adapt these tools, adapt this way of working, this is the way we want you to do things.’ We are where we’re at now, in fact what’s interesting looking at things now is that we’ve come full circle. The whole reasons that PathLinks was formed was because in the early 1990s we couldn’t recruit Pathologists, we couldn’t retain Biomedical Scientists and we’re really back to where we were. We haven’t learned from that. The NHS is really bad at learning from its mistakes and unfortunately, we’re back where we are and it’s worse now because we’ve got a far higher work load and we’re already centralised. There’s a shortage of Pathologists and trying to attract people to sleepy old Lincolnshire is extremely difficult.

As the Laboratory Manager do you take a proactive role in promoting and encouraging Lean practices and improvements within the department?

I’d say yes, but not as much as I’d like to. Unfortunately, our planned kaizen events are more limited than they used to be but what I would say is a positive thing a lot our improvement methodologies have been incorporated into our transition to ISO15189 Accreditation. So, they have been dove-tailed into QMS.

How vital is hospital management support when implementing new processes?

This is a tricky question and it’s one of the problems we have sustaining our CI program. As a pathology provider and especially Cellular Pathology directorate we’re pretty much divorced from the trust. Because we are a pathology network, the Cellular Pathology department is located at Lincoln, which is part of United Lincoln Hospital Trust and the employer for PathLinks in Northern Lincolnshire and Goole, so a lot of times we can be seen as a bit of a squatter on the ULH site. It does divorce us a bit from the main Trust management. The other issue that we have got here is that yes, the Trust are central to continuous improvement because
they have got to be that top down thread of ‘This is what we’re going to do’ and the connectivity. There was complete buy-in for a decent period of time, through to 2012-2013. However, because of the economic situation, the state of the NHS is that one of the first things that goes are the continuous improvement teams, or their roles get redeployed into crisis management. It’s not planned improvement, it is putting your finger in the hole to stop the water squirting out.

**Is adequate time and resources allocated to improvement work?**

*I would say no. It is purely now, because of the situation and the service provision that we’ve got, it is purely down to crisis management. The issue that we’ve got here is that United PathLinks hospitals in Northern Lincolnshire and Hull are unfortunately 2 of the worst performing NHS Trusts in the country. Both have huge financial problems and that dove-tailed with performance problems so both of them are being monitored closely for performance. That removes a lot of freedom but it also means that it becomes very target orientated and for us at the moment with our deficit of Pathologists we are purely being told to focus on cancer pathway samples and that removes one of the key Lean ethos’ of “first in first out,” manage the flow. All that work that was done is gradually being unpicked by micromanagement of NHS Improvement. That introduces further waste in the system because we have more sort and re-sort rather than letting the work flow out in a controlled manner.*

**Do you have a change agent driving improvement work?**

*We don’t at present. We had David Clarke and he did a lot of successful work with NHS improvement.*

**How do you ensure you provide value for your customer? (i.e. pathologists and clinicians)**

*We try to listen to them as much as possible, we try to get them to understand our processes, ultimately, we set KPIs and of course we have voice of customer exercises.*

**What processes, if any, do you use to identify waste?**

*We have something called Qtips board, so we have an operational board in the Lab which monitors quality, timeliness, productivity and safety and we have those linked in to our objective setting. We have KPIs we monitor outside of those as well. And of course, to identify waste we are also looking at audits and we do bespoke data gathering when we identify problems. It’s a case of stepping back and looking at what you are doing. Historically we would do a lot of it by identifying a problem, a workflow and perform A 3 exercises. Whereas now a lot of our improvement and our monitoring is within our ISO15189 compliance.*

**Are your workplaces designed for ‘flow’?**

*As best as we can. We could do so much, I have put many recommendations in place but of course it requires investment. It is now recognised at PathLinks management and at trust level that if they want to improve cellular pathology services anymore it will require investment. One of the things with cellular pathology is that you are tied to things like the extractors and plumbing and so you can only do so much the with environment you inherit.*

**Do you have standardised practices in place?**

*We all have our SOPs in place but it is about how strongly we control that. One of the things we learned very quickly, and I have given presentations on this including writing it up in The Biomedical Scientist, is that we recognised that our SOPs were not fit for purpose. We use A3 Sops, they are visual, short, condensed SOP’s. A SOP can comprise of multiple worksheets but it is removing as much of the compliance information that is irrelevant when you want to use an SOP on the bench there was too much depth. When I got here there we’re 19 sections of the SOP before you actually got to the procedure and there was an appendix to the Sop that was
a bench extract which was the bit people would print out and use on the bench! Again, it’s that root cause analysis; we were doing all of this but still not producing an actual document that was fit for purpose. We had to stand back and look at SOPS that we had in everyday life, the way we use procedures, the way procedures work and what we need from procedures. That was a case of learning; we saw an example of A3 SOPs in Siemens and that pushed us to look at training within industry and we very much developed that A3 SOP template which we still use now.

**Are you able to level and balance workloads to avoid bottle necks or to deal with a sudden increase in demand for services?**

No and that is the problem. The NHS works on a complete silo mentality on trust level and at clinical level. They don’t care what our problems are, they just want to get their patients true the door and shift it on to the next person in the queue so there is no chance we can deal with our demand management. Unfortunately, we still deliver our service on a Monday to Friday 9-5:30 basis, although we operate between 8 in the morning till 7:30 in the evening. The number of additional clinics that are come in to play, and we are not told about it, new initiatives come in and we are not told about it which results in a creep. The big hit for us is that there are weekend clinics which occur and bearing in mind that we are a county-wide service, we can come in on Monday morning and we can find we have anything between 25 and 50 percent extra work on a Monday than we would on any other day of the week. So, trying to shift our unload level is virtually impossible.

**Have quality standards been built in to the daily routines and processes?**

Yes, we are built-in. There are a couple of things here, implementing lean management improves the quality of the department. The quality of the department wasn’t as good as I wanted it to be when I arrived. By using lean management skills, it created the spare capacity in order to focus on those elements, that allowed us to set quality standards and establish them. However, it did create some problems, because one of the things that was pushed on to us, and we weren’t told, and this was non-negotiable at the time, that we would not require our microscope QC, the idea was that we would do a macro QC and not push but allocate the slides to a pathologist and they would let us know if they wanted rework. That was with engagement from the pathologist. That was forgotten over a five-year period. It is evident to us now that you can’t QC a microscopical product using a macro technique. The issue that we had at the time, and we are having to re-implement it now, the issue that we’ve got because of staff turnover, you lose that skill, you lose the microscopy skills and therefore it takes time to re-implement that into the system. So, its two-fold, yes, we weren’t and we implemented and put in better and more robust quality standards but there were elements where we did fail and we had to learn from that.

**Is information visualised in your department? E.g. safety information, work standards, performance in relation to KPIs, etc.**

We use a huge amount of visual management whether that be A3 Sops, whether that is workstation layout, maintenance calendars, rotas, and of course the Qtips board, which is a huge board in the laboratory demonstrating data.

**To what extent do your employees participate in improvement work? E.g. improving work environment, process flow, entire flow, etc.**

Not as much as I would like but they still do. Again, it goes back to that focus - “right we’re going to diary and we are going to kaizen this area” but we still conduct improvement work and the way we do that is by making sure it’s the operational staff that to do it but we wouldn’t badge it up and call them kaizen. It may be a root cause analysis, it may be an improvement plan because of an incident or a trend of incidents but we wouldn’t necessarily call it a kaizen event.
Does your department have structured problem-solving practices?

Yes, and they are now dove-tailed into our quality management system so they would be part of our recourse analysis. We wouldn’t necessarily do A3 improvement exercises but our favourite visual problem-solving tool is doing fishbone diagrams for when we are doing a root cause analysis.

Are the employees in each discipline ‘multifunctional’? (e.g. do they identify process issues but also follow up on these issues and observe the continued improvement of that process?)

Again, its twofold; at a lower level and an operational level people let us know when certain things aren’t working. We have a very structured rota system so staff will very quickly feedback and let us know when things aren’t working. When we implement improvements and they are not working people will feedback to us. We are now more structured. Unfortunately, it’s a bit too much command & control with regard to improvements, with regards to incidents and errors. They will trend, they will come through us in a quality management report we will then have a root cause analysis meeting but at that point what we will do is engage people on the operational rota.

How do you sustain improvements that have been made?

Monitor - If improvements have been put in place we will monitor them over a period of time. We wouldn’t expect to get it right first time either. When the improvements go in we will monitor and then refine it over a period of time.

Do you feel that adequate resources are allocated to sustaining changes?

No. If we had the resources we wouldn’t be in the situation we are in and we would be able to do so much more.

Are the results of Lean implementation obvious within your department?

Yes, they aren’t as obvious as they used to be but they are there. 5S is in place, visual management is in place, A3 SOPs are in place, workflow is in place, batch size reduction is in place. The tools are there.

Have you identified any difference in the level of Lean implementation between automated laboratories, like Biochemistry, and the more manual laboratories, like Histopathology?

You could talk about this for hours. Within PathLinks the level of engagement we had with LEAN was far greater in cellular pathology than it was in blood sciences. The key change agent, David Clarke, was of course a cellular pathologist and the key thing is that we needed something to look in cell path. Cell path wasn’t working and we needed to improve the way we delivered the service. We had consensus and we knew that we had to change, whereas there was a lot more skepticism and cynicism within blood sciences. The work that they did do and put in place? If I went into blood sciences now you can see the evidence of it. They did some good work and the evidence is that work cells are more effective than track but the pound signs are what matters and of course when it came into recruitment procurement the track systems came in a lot cheaper than the work cell type set up so that learning went out the windows and they moved over onto a track system.

Do you think that automation is a necessary element of process improvement?

No. When we talk about automation, I think we went through a really bad period where because LEAN was seen as the buzz word and because of NHS improvements in promoting it, I have a recollection of a certain company when I went to IBMS congress and I was looking at one of these huge automated staining machines,
an integrated staining machine, and I just stood there looking at it and the sales rep came up behind me and asked if I liked the look of it, he said it was a ‘truly lean platform’ and of course that just put the prickles up on the back of my neck so I said to him ‘Ok, tell me about it, why is it a truly lean platform?’ because it was bathed in high volume and was unpredictable and I think that’s the risk. We actually took a step back and we have evidence; we needed certain technology to improve our processes but certain of the automated technologies actually unhinge. So we bought a low tech staining machine, we had an integrated staining machine but as we did our improvement programme it became evident that it was the bottleneck in our laboratory. You can buy more of the equal so that you are just doubling your inefficiency and waste or you can buy a more appropriate machine. That was an example where instead of having an integrated work cell we unplugged and created a staining work cell with separate stainer, oven and cover slipper which would outstrip and provide complete predictability over staining time at a fraction of the cost of a big automated machine. Unfortunately, because we are a small voice in the market it’s not what the global market wants. We are now ten years on and that machine we got is obsolete and unfortunately, we are going to have to go down an automated route. Lean solutions are often low-cost solutions, I had to sit in on a PathLinks management board meeting and we were told there was no capital replacement money. The H&E staining machine that we have the cost is so negligible that the cost that is going to be put on our budget, because we are going to have to replace that machine, is huge. You can automate a bad process, you have to get your process right, and put the correct automation in. There are example here in the UK of when that pathology improvement came in and there was a knee jerk reaction and people went out and spent money on tissue processors that could process in an hour and they are just sitting in a corridor in bubble wrap. They were bought by a pathology improvement manager but the Histology manager wasn’t told. The money had to be spent and people just had a knee reaction, they thought they could improve the process but didn’t look at the process closely.

How do you measure your Lean success? (E.g. KPIs, financially, ability to deal with increasing demand without need for additional staff or equipment, etc.?)

We were able to generate a lot of evidence about this in the beginning with regard to error rates and so forth, but then you tend to plateau. There are certain things where you just know you need improve but unfortunately, and again this was a learning thing on our part, we just got on with it and did the kaizens but what we didn’t do was collect enough data to demonstrate the transition. That was something that NHS improvements did teach us and make us do, slow down and capture what is truly going wrong, what is the error rate, what is the defect rate and then evidence in the improvement. What we have done now and what we have in place are our KPI’s so that on a basic level on a daily basis we are measuring our rework rate at embedding, we are measuring the volume of work that we are carrying over if any work at microtomy. From a financial point of view the measurement of success is that we have been sustainable. We have been able to eliminate the waste and therefore been able to implement and adopt many improvements. The problem that we have now because of the capacity and demand problem is that the well is dry. There is no further waste so we cannot absorb any more work, any further processes without investment and it’s completely the wrong time for investment.

How would you rate your level of Lean maturity? (E.g., in its infancy, well established, etc.?)

I would say that we are well established but at the moment it is latent.

Why do you think it has been so successful here?

I think it has been successful but I don’t think it is down to one thing. Firstly, we have the change agent; we were going to do it and we were going to lead the way on it and secondly we needed to, the quality and the processes were so poor here after the centralisation of the service that something needed to change to make it PathLinks pathology rather than just a merged department that had appeared. Prior to implementing predictable flow there was no predictability with the workflow at all, cases would fall through the system which
compounded the problem because we had poor fixation, poor processing which meant that section quality was poor. Now we are able to control our processes and improve the quality of the output.

IDI No. 2: Mr. Pauric Reilly, Laboratory Manager, Bon Secours Hospital, Glasnevin, Dublin.

Conducted: 20/06/2018.

Do you recall when you first heard about Lean Management?

Yes, I first got involved in lean for lean sake back in 2006 in Beaumont. I had been running similar projects to lean but without the LEAN structure prior to that in my career both in Drogheda and in Cavan.

What was your process for implementing Lean in your institution?

In the first case I introduced LEAN through one of the supply companies that we had in one of the laboratories in Beaumont. The supply company proposed a LEAN review of the lab to essentially develop into the lab the system that we purchased and that was only partially implemented.

Did you identify a role model and emulate their process?

My own. We actually brought a team into Beaumont hospital to talk about the merits of LEAN to the assembled heads of Departments, It was quite a big meeting. The presentation descended into chaos towards the end because the financial accountant simply could not accept the concept of having a forty percent efficiency gain in the hospital without having redundancies as a result. LEAN accounting and financial accounting are two very, very different concepts. LEAN tends to look at accountancy in terms of value, accountants tend to look at accountancy in terms of cost. They are different concepts. Value is a very simple concept but you need two measurements; you need to be able to measure your outcome and you need to be able to measure your cost. Value is income minus the cost. If you are only looking at outcome or you are only looking at cost then you are essentially trying to clap with only one hand, you are not going to be successful.

Have your staff received or attended any training in Lean?

Yes, I did value stream mapping and LEAN waste identification with them and subsequently we had presentations from Peter and David, I can’t remember their surnames, from Bolton Hospital who are now out there in the market place introducing LEAN and developing LEAN concepts in hospitals. We had a number of formal presentations from them.

Do your staff understand Lean processes and flow?

My older staff do, I haven’t had the chance to go back to the value stream mapping presentations with the younger staff yet, that will be happening after accreditation this year.

In what way do you feel your employees are committed to the Lean processes in their daily routines?

Well, when we did the value stream mapping training we actually trained with live ammunition, we went straight into our own processes and value stream mapped them and made some very significant changes to some of our structures directly resulting from that. So that for instance we transferred a clerical grade job into an MLA job and transferred that function from the office into the laboratory. That ultimately meant that we could do our order entry for blood sciences in the blood science room. We eliminated a lot of walking, 3.6km, per day, per scientist. We took an hour off our TAT and we were able to turn the scientist time that was released from that project into repatriating a number of expensive send out tests that we had. We had a lot of win out of the small change we made.
In the office, we looked at the workload we had associated with referral testing results and it was extremely onerous and it consumed an awful lot of time and file space. We invested in a document scanning system that now links the referral report to the laboratory accession number and keeps a permanent record of it. We returned an office space to the hospital worth 30,000 euro and we redeployed a second member of staff to the general pool of secretaries to the hospital.

As the Laboratory Manager do you take a proactive role in promoting and encouraging Lean practices and improvements within the department?

Yes but. Workload has gone up an awful lot of the past few years and the time to to be able to step back and do LEAN is extremely marginalised at the moment. We have done nothing significant with LEAN other than a couple of war on waste projects in the last two years but the war on waste is a template that we have kept running. Accreditation takes over but we were able to use the process maps we did through value stream mapping. We were able to take them and pivot them for risk assessment of critical control points so at least we didn’t lose the work we did in value stream mapping originally.

How vital is hospital management support when implementing new processes?

There are two answers to that. An awful lot of Lean is a just do it philosophy, if you see it do it, but that only works on small improvement projects. When it comes to bigger projects that you want to do and you want to do them from a Lean perspective, management buy-in is absolutely essential. There are things that you need to do that require a lot of money being spent if it’s around architecture, knocking walls, that sort of thing. Similarly, if it’s around purchasing new equipment or changing information technology systems, that’s crucial. The management buy-in is actually essential to keep the staff involved in Lean motivated. If you appear to be the only people doing Lean on an otherwise mean street it is a very lonely and isolated place to be and the rewards for it are negative not positive.

Is adequate time and resources allocated to improvement work?

Absolutely not. Improvement work is generally considered when the wolf is at the door. Now is a time for crisis now is a time for Lean when it is actually the wrong time for Lean, its panicked, its rushed and the negative associations with that remain for very, very long time. People associate Lean like that with cuts.

Do you have a change agent driving improvement work?

Here it’s about the quality manager. The Quality manager here is running the audit, assessing us against the standards and driving the quality improvements that are required. The operational improvements are pretty much foisted on us rather than we opt into them. For instance, they were foisted on us back in 2012 when the economy crashed and he number of patients with insurance plummeted and those retaining insurance picked lesser options than they had her before so the income for the hospital plummeted as a result. We live on what we earn, we don’t get a government subsidy or anything like it, we live on what we take in on the door in income and as that fell we had to cut the cloth. There was a big impetus to change back in 2012. More recently things have improved and the organisation is investing very significantly across its six sites in the country. The next drive we are on is a margins improvement project, we basically want to increase our profitability on the work that we do, some are now back looking at efficiencies that can be extracted from the system. For instance, I have six “war on waste” projects running currently mourned changing systems that we have in place and try and make them more efficient and we are about to engage again as a group looking for laboratory efficiencies in general. We are looking to improve the efficiency of the department by 2%. It doesn’t sound an awful lot but when you are already very Lean it is an awful lot. For us it’s about finding 60,000 euros worth of efficiency.

How do you ensure you provide value for your customer? (i.e. pathologists and clinicians)
For us in terms of providing value we have a couple self-measures out there like user satisfaction and we do that for our patients through phlebotomy, we do that for our users through surveys at the consultants and again similarly at the wards with slightly different questions asked. We also have an array of quality indicators that we measure so we are looking at things like our turnaround time which is sort of ubiquitous in the laboratory, we are also looking at quirksier little things like specimen form issues, where forms are not filled in with detail, we report that out and measure an improvement from the time we put an initiative in so there is good engagement with the wards. We have a morning meeting here where if there are issues in pathology of phlebotomy they are put on the floor for the staff so that they know that for this day there is going to be pressure on the phlebotomy department for instance. we have several systems like that plus we have an array of measures that come through our quality management system as well, IQC, EQA, they’re all there.

What processes, if any, do you use to identify waste?

The value stream mapping is the one for us and our waste is defined into nine categories; Transport, Inventory, Motion, Waiting, Overprocessing, Overproducing, Defects, not realising people’s full potential, and Expertise.

Are your workplaces designed for ‘flow’?

Not exactly, our workplace used to be a convent, not designed for laboratory flows. We have made the best silk pure we could out of the sow’s ear that we got and certainly the value stream mapping that we did back in the past would have improved it. If I was designing a laboratory form scratch it would not look like the thing we have here, it wouldn’t look like the thing in Beaumont either. it would be setting laboratories up around individual work units that are U-Shaped. Work goes in at one end, reports come out the other and I would have my supervisors and my reporting consultants on a mezzanine floor overlooking. Immediately from supervision you would see where the blockages occur and where you need to redeploy resources

Do you have standardised practices in place?

Yes. Every procedure we have is process mapped every procedure is governed by a standard operation procedure.

Are you able to level and balance workloads to avoid bottlenecks or to deal with a sudden increase in demand for services?

No. As I said earlier, I think we are a little too Lean now. Our capacity for Kaizen activity is exceedingly limited and our capacity to deal with a crisis like somebody being out sick is also very limited. At the moment, my phlebotomy service should have four people available but it has two. One is on annual leave and another has an injury so I can’t meet all demands that require four people with two. It’s not always a question of capacity, my blood sciences are not at capacity but their ability to reach capacity is exceedingly impaired by the staff turnover that I have had and the relative inexperience of the younger staff that are there. Inexperience is a risk in laboratory systems and the answer to that is additional training and additional supervision both of which are very resource consuming.

Have quality standards been built in to the daily routines and processes?

We are ISO15189 accredited by INAB since 2007. We have recently upgraded our Q-Pulse system to incorporate risk management risk assessment within the incident module. We have suspended accreditation in three of our Labs which has again stemmed from staff turnover and the associated risk particular to on-call systems but we are hoping to have them reinstated this year.

Is information visualised in your department? E.g. safety information, work standards, performance in relation to KPIs, etc.
KPIs no. we have our quality indicators on noticeboards. Safety - we have a couple of safety posters, up couple of hand washing posters up. Is it sufficient? I would say no, but do we have the wall space - No.

**Does your department have structured problem-solving practices?**

Yes, we have an incident management module in Q-Pulse and we register our problems in and that has a stepwise work through; identify the causes, identify the risks and score them, identify the corrective actions, identify the preventive actions and then there’s oversight of all that with the quality manager. It’s a very structured process.

**Are the employees in each discipline ‘multifunctional’? (e.g. do they identify process issues but also follow up on these issues and observe the continued improvement of that process?)**

It depends on their level of training in the organisation essentially, but yes anybody who identifies a problem can stop the process and solve the problem or get somebody to solve the problem with them.

**How do you sustain improvements that have been made?**

Well again we do that through the quality management system through another workflow in it called change control change and that’s a multistep process depending on the change, the level of change. For instance, if we are looking at replacing a member of staff probably 45 steps need to be completed within that process but having completed them you are sustaining what you have done, you are not slipping back and you are not missing out on something that should have been included.

**Do you feel that adequate resources are allocated to sustaining changes?**

No. For instance I have three critical voids in my staff at the moment; I don’t have a LIS manager, I don’t have a point of care manager and I don’t have a disease surveillance scientist. So, sustaining our system in the absence of those critical functions, really and truly it has to be unsustainable because otherwise you are saying that those functions are not necessary.

**Are the results of Lean implementation obvious within your department?**

I would say to the outside person looking in; no. To those who have participated in it and made the changes themselves, yes. They aren’t as obvious as they used to be but they are there.

**Have you identified any difference in the level of Lean implementation between automated laboratories, like Biochemistry, and the more manual laboratories, like Histopathology?**

When you look at Lean in an automated laboratory you are looking at Lean for the entire system. When you look at Lean in a manual laboratory you are looking at Lean for this step or that step, or this sub process or that sub process. It’s very difficult to Lean out the entire of histology when it is as fragmented around the different stages of processing as it is. I mean, you can run a value stream mapping exercise in the tissue cut up room but that has no impact whatsoever on embedding. You have to look at embedding for embedding and then look at microtomy for microtomy and then look at staining for staining and then look at immunos for immunos. You will build up five or six projects but it only takes one person missing on the day to scupper anything you were trying to achieve.

**Do you think that automation is a necessary element of process improvement?**

Yes and no. You have to reach a critical mass before automation is a consideration. For instance, I would never consider a (inaudible) system for automation in microbiology here but I absolutely would consider a (inaudible) system for automation in Beaumont because the scale of the operation is in a different league. We are dealing...
with 2,000 specimen a month, Beaumont is probably dealing with that a day. It’s about the scale of the operation you are looking at. I would consider automation for tissue processing but I wouldn’t be prepared to consider as a small private hospital on the Northside of Dublin but I would be prepared to consider it as a project within an academic teaching hospital and from that perspective to develop it further into the actual production. It’s very difficult to lead on a very bold process automation when you do not have the backing of academic teaching hospital behind you.

**How do you measure your Lean success? (E.g. KPIs, financially, ability to deal with increasing demand without need for additional staff or equipment, etc.?)**

I am using a war on waste template. It identifies the process we want to change in its current status, identifies what we would like from the improved status, looks at the cost of implementation and looks at the cost in terms of value gained from doing the project. We then implement the project and just make sure that it has gone as we envisaged and that’s how we look at it. When we sustain that project, we count that into our war on waste on an ongoing basis, so whatever gains we made in 2012 and sustained they are accrued as cost avoidance as opposed to genuine savings.

**How would you rate your level of Lean maturity? (E.g., in its infancy, well established, etc.?)**

We are very much infancy. I don’t think that Lean of itself matures. My personal view is that LEAN works best where you are already a little over resourced and Lean identifies the resources that you are not using to their full potential and that you find alternative use for that resource, it works very well in that extent. If you are looking to bring in a new development, you have to flood the development with resources to get there. You then bring Lean in to eliminate out the excesses that resource. I don’t think Lean is a tool then to sustain that. I think SIGMA is a tool to sustain that. Six SIGMA gives to us as scientists and to the doctors as clinicians the evidential basis worked on values and empirical measurement that will satisfy their curiosity. Lean will never satisfy their curiosity. Lean is a bit too much ‘looks good - is good’.

**Why do you think it has been so successful here?**

Lean has been successful here because it was driven here. Lean was never going to be successful if the people trying to do it were passengers, they have to be drivers. Everybody has to be a driver of Lean. I can’t go down to biochemistry now and tell Ruth ‘Ruth I am going to come down now and I’m going to value stream biochemistry and Lean approve it’ - That categorically will not work, all that will serve to do is completely alienate Ruth. I have to go down to Ruth and say ‘Ruth I think we may have opportunity to improve the processes here. Will you have a look at value stream mapping with me’ The person who knows the defects best in the system is the person operating the system. The person who can find the best improvement is that same person and the person who has most to gain from making those improvements is again that same person. If you alienate them at the outset you have lost them.
IDI No. 3: Ms. Sinead Creagh: Laboratory Manager, University Hospital, Cork.

Conducted: 21/06/2018.

Do you recall when you first heard about Lean Management?

I did a Lean yellow belt course in 2010 but I would have been aware of it before then. I did a diploma in quality management around 2004/2005 and six-sigma would have been part of that, now probably not lean but definitely the idea of ‘error per million’ and that type of thing. The concepts that surround Lean from 2004 but the yellow belt course from 2010.

What was your process for implementing Lean in your institution?

When I did that Yellow belt course in 2010 I did it through CUH. At the time, I worked in microbiology so a number of staff would have done that course at the same time. Leading on from that, six of us set up a lean team and asked all the staff for suggestions and we did post-it exercises; ‘the top three things that annoyed you’ or ‘the top three things were a change would be beneficial’ or ‘where you thought something should change’ these were put up on a big notice board and we collated the data and looked at the top and highest hitting from the suggestions that the staff thought would make the most improvement and we started with them. On the back of that two of the members of that team, but not myself, would have gone on to do the green belt. The Lean project was then driven by those staff members. From the point of the microbiology laboratory the process was to train people in the yellow belt and then have them lead it.

Did you identify a role model and emulate their process?

In the microbiology lab at the time the chief had a black belt in Lean so he would have driven it. He organised the courses, encouraged us to go on them and set up the Lean team. He gave us the support and the time to meet up every couple of weeks. Whilst I wasn’t looking at other hospitals he certainly was, he visited other hospitals with Lean processes.

Have your staff received or attended any training in Lean?

There is one black belt and I have sixteen people who did a two day lean yellow belt course. Twenty-five people did in-house training, they were all from the histology department, which has a very strong lean ethos. One of their own members gave a training session on understanding their own contribution to the lean process. There was another seminar where forty-seven attended, it was called ‘Lean, Mean and in Control’. We have three green belts and I have attended a lean workshop in the last twelve months. These courses are popping up on a continual basis and people are attending them. The two green belts I spoke about are from microbiology and we have new project manager who has just completed his green belt, so that ties in very closely with project management and we would hope to see the benefit of that.

Do your staff understand Lean processes and flow?

It varies from department to department. In 2010, it was very strong in microbiology, at the moment it is very strong in histology. In other departments, there may not be much emphasis on it. So, where the ethos is strong then definitely the staff are committed and understand it but in other areas it is not as to the fore.

In what way do you feel your employees are committed to the Lean processes in their daily routines?

Where change has been implemented then staff do buy into those but where there are areas with no background then it is harder to convince people. In the labs that have a strong background in lean it is easier to convert people to the idea. They are committed in the labs where the processes are implemented but in the labs where there might not be a driver, nobody pushing it, it is harder to convince people.
As the Laboratory Manager do you take a proactive role in promoting and encouraging Lean practices and improvements within the department?

I have been in this role since September and the project manager who started after me has done a green belt, so I suggested to him that he would do that course. On the back of that we have quite a substantial project in specimen reception that he is overseeing, and it is based on lean principles of measuring. I have asked them not to come with the solution but come to it open minded and let’s measure it and see what are the possibilities. Rather than coming and saying ‘This is the answer, we know what the problem is’ I don’t want them to come with an answer because that will be very closed. There are different disciplines, different grades and skill mix involved in it and I don’t want everyone coming with their own answer.

How vital is hospital management support when implementing new processes?

It is important but like everywhere, resources are limited so even though you might have a great idea you wouldn’t necessarily have the funding to changes benches, knock walls or that sort of thing. I suppose in any that I have been involved with you have to kind of make do with what you have. If you had a great idea where there were great savings to be made, hospital management might support that. It’s not necessarily a given, it is a reality that resources are limited. We try our best with what we have.

Is adequate time and resources allocated to improvement work?

It’s difficult in a busy work environment to always have time but while I would say we mightn’t be able to fund different changes, what we can control is how much time we give to people and we do try to free people up to maybe plan, measure and implement changes and follow through with them. And training of course; we try to give as much time as we can but everything is finite.

Do you have a change agent driving improvement work?

We have project manager now and the individual chiefs in their own departments do drive change. Some of the consultants, especially in the histology department would be very interested in driving lean. From a driving change point of view; we have a very strong quality team and a quality manager and the seniors in the areas would all be very committed. The staff on the ground as well would be very committed to implement changes.

How do you ensure you provide value for your customer? (i.e. pathologists and clinicians)

With lean projects, we would include measurements of the benefit of the lean project and in all our change management we would consider what the benefit is. I suppose by their very nature lean changes are looking to remove waste which would increase value. On an annual basis, we do a service user survey in which we ask if there are any changes they require.

What processes, if any, do you use to identify waste?

When we are looking at lean projects we map the process so then you are looking at measuring waste where there is waiting or maybe batching or waste in terms of movement of staff, maybe the layout of where the fridges are, where the incubator is or where you specimen reception is, that kind of thing. We have done spaghetti diagrams as part of the projects and you can nearly see from those tools where the waste is. We also have Kanban for inventory, which should help you reduce the amount of stock you hold and therefore eliminate waste.

Are your workplaces designed for ‘flow’?

We are in an old building; this hospital has been here for 40 years so any changes to flow have been made by the staff. There hves been some changes to the structure with extensions been put on but there has been
nobody in with a sledgehammer knocking walls or that sort of thing. We try and work around what we have. If its big projects there would be structural changes made but smaller projects that come from staff suggestions there isn’t structural changes really.

Do you have standardised practices in place?

There is a procedure for everything really and we also have process maps for all of our processes as well. Be it processing a sample or any of the quality processes that are there; complaint management, auditing, document control including all the benches - we have process maps for all of those.

Are you able to level and balance workloads to avoid bottle necks or to deal with a sudden increase in demand for services?

We are different from maybe the Dublin hospitals in that maybe over half our workload would be from GPs and you are very limited by courier delivery and the couriers are employed by the GPs not ourselves so we don’t have a lot of control over it. We work with them, but we don’t have ultimate control over when the samples are delivered so we do get big batches. In some areas, we have tried to look at working under a push/pull system so that you level off peaks as much as you can but we do get bottlenecks or peaks due to delivery of the samples that come in batches.

Have quality standards been built in to the daily routines and processes?

Every lab is accredited at this stage so are bound by them really. We have a fifteen-year history of having a very strong quality management system in place.

Is information visualised in your department? E.g. safety information, work standards, performance in relation to KPIs, etc.

We have process maps for all our bench processes as well as the other ones. All our bench process maps are up on notice boards and then you would have things like turnaround time reports and EQA reports. If there was a process that was a lean process in some areas then there would be flow maps. So, for station 1, station 2, station 3 there would be maps for what station you are at now and what you are doing at that station.

To what extent do your employees participate in improvement work? E.g. improving work environment, process flow, entire flow, etc.

We would encourage people to make suggestions and we do that using Qpulse. We try and be as paperless as we can so any suggestion made through Qpulse would be considered by the chief in that laboratory and then if it is accepted then it goes through the normal change control process and we would encourage those who make suggestions to be involved. Even if there are other changes on a bench, for example if you are bringing in a new piece of instrumentation it wouldn’t just be the senior. If things only need one person then it is just the senior but if a team were needed we would share it around as much as we can and encourage as many people to be involved. Even be involved in different areas, maybe the verification report or take ownership for the SOP or they might do some of the offsite training.

Does your department have structured problem-solving practices?

For non-conforming work, we use a 5Y model for the root cause analysis and we would review trends and that kind of thing. A lot of it is structured though the quality system if there has been a non-conformance. Proactive problem solving is done by staff on the ground and any good ideas or suggestions would be captured in the quality system.
How do you sustain improvements that have been made?

We could all be better at this. You make an improvement and you think, that’s grand that’s the problem fixed. We process map them, we do have procedures and they are reviewed an annual or every two years basis. The **** ** would be every year. We often wait for the pressure point to build up again before we look at maybe implementing the next change or the next lean projects to help us. Everyone is busy. It would be great if we could sit back and say, ‘Can we see a problem coming down the road here?’ or is there something we can do in a proactive sense where there isn’t a problem yet but that often isn’t the case.

Do you feel that adequate resources are allocated to sustaining changes?

If money is needed or changes or infrastructure where you might need commitment for maintenance we try our best in those circumstances but you are in the pot with everyone else and you are trying to make your case made. On each lab level, we would try to free up as much time as we can for people. Of course, the routine work needs to be done but some days you might have to just say look that’s the day we are putting two people on that change and maybe the annual leave might be curtailed on the back of it.

Are the results of Lean implementation obvious within your department?

They are in the areas that there are implemented Yes. From my own experience, I’ve implemented projects in a couple of areas in the microbiology lab and they are still there seven and eight years later. Maybe we should go back and review it but when things are working we tend to leave them. Not every lean project works and not every lean project sticks but definitely the ones that worked are still there.

Have you identified any difference in the level of Lean implementation between automated laboratories, like Biochemistry, and the more manual laboratories, like Histopathology?

My own background is in one of the more manual labs so I would think there is more scope for lean in the manual labs. You are looking at relieving things like RSI, relieving peaks and that sort of thing as opposed to full automation. An automation can work at the pace it can work at, there is very little manoeuvring or flexibility there so even if you do implement lean (and I don’t have much experience in automated labs, so I could be wrong) where you want to implement change there you are very tied to what the instrument can do, you are working around the instrument whereas in a manual lab you have a bit more flexibility, a bit more scope to think outside the box.

Do you think that automation is a necessary element of process improvement?

It depends on what you are setting out to address. If you are looking at high areas of RSI then maybe automation is part of the solution but I don’t think its necessarily an essential part of it.

How do you measure your Lean success? (E.g. KPIs, financially, ability to deal with increasing demand without need for additional staff or equipment, etc.)

In each project, you would look at savings, staff numbers that you needed, time, can you see how much has been saved in terms of kilometres. They are not necessarily always financial and probably financial savings are not the drivers for lean changes in my own experience. Financial savings are more tied to business cases and tenders and that sort of thing. With **** you can see a financial saving but if you are looking at an actual process it is more efficiencies in staff time.

How would you rate your level of Lean maturity? (E.g., in its infancy, well established, etc.)

When I am talking about the microbiology projects they are about 2010 - 2012 and they have maybe fizzled out a bit whereas in histology it is a bit more current. In other labs, maybe they didn’t ever take off to the same
extent and we are now in a new phase with specimen reception to introduce lean ideas there. It varies across the departments.

Why do you think it has been so successful here?

If you have someone who will lead it that’s the main thing. Even if you have people on the ground who think it’s a great idea and are really pushing it, unless the person who needs to release them off the bench aren’t prepared to support it, then it becomes very difficult. I would say good leadership. There is also a driver for change, we are making improvements just to stand still. With workload increasing all the time we are in a position where we need to try and lean as much as we can just to be able to manage with what we have. What is coming in the door is increasing year on year and we have no control over that.
### APPENDIX 6: CODING FREQUENCY

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APPENDIX 7: IDI OPEN CODING

Architecture Limitations
Improvement to department limited by architecture of building.

Change Agent
Introduced, or was the key driver behind Lean implementation in department.

Communication
Exchange of ideas or information effectively within the department and externally.

Communication-Failure
Information/ideas not being exchanged effectively.

Continued Lean Improvement
Where effort is made to continually improve processes through Lean methodology.

Crisis Management

Demand Management
Managing fluctuations in workload. Controlling the volume of samples received.

Fear of Lean
Fear of the perceived negative consequences of Lean.

Hospital Management Support
Hospital management support in implementing change.

Implementation Challenges
Challenges/opposition faced early in the Lean process.

Implementation Process
Steps taken to implement Lean.

Improvement Limitations

Improvement Work
Use of Lean methodologies to improve work processes.

Initial Exposure to Lean
When interviewee was first exposed to Lean.

Investment
Financial investment in Lean.
Lean and Automation
Association between Lean and automated processes.

Lean and Cost
Costs associated with Lean.

Lean Consultancy
External consultants brought in to review processes and flow.

Lean Commitment
Commitment of staff and managers to Lean processes and change.

Lean Engagement
Engagement of staff with Lean methodology and processes.

Lean Flow
Flow of processes and equipment throughout the department.

Lean in Manufacturing
Lean in manufacturing.

Lean Justification
Justification for embracing Lean processes.

Lean Maturity
How established are the Lean processes in the department?

Lean Processes
Lean techniques/processes utilised throughout the department.

Lean in Quality
Where Lean is incorporated into the QMS.

Lean Role Model
Institution that lead the way for others.

Lean Success
Successful outcomes from Lean implementation.

Lean Sustainability
Sustaining Lean in the department.

Lean Team
Group of employees empowered to make decisions and changes that will benefit the department.

Lean Training
Formal training in Lean processes and methodologies.

**Lean Understanding-Older Staff**
Long-term staff understanding of Lean methodologies and processes.

**Lean Understanding-New Staff**
New staff understanding of Lean methodologies and processes.

**Lean Waste**
A step or a function that does not add value to a process.

**Manager Leading Lean**
Laboratory Manager takes an active role in leading and promoting Lean.

**Measuring Lean Success**
Methods for measuring the success of Lean processes and improvements in a department.

**Openness to Change**
Open to change, not in opposition.

**Problem Solving**
Identifying and solving process/methodology problems through Lean techniques.

**Process Automation**
Automating manual processes.

**Process Implementation**
Implementing Lean processes in the department.

**Process Improvement**
Improving processes through Lean methodologies and processes.

**Promoting Lean**
Promoting Lean methodologies and processes.

**Providing Value**
Providing value for our customers, Pathologists and Clinicians.

**QMS**
Quality Management System

**Quality**
Laboratory quality management system, ISO15189 Accreditation, and quality improvements through the application of Lean processes.

**Resourcing Lean**
Allocation of time and resources to implementing and sustaining Lean.
Service Improvement

Improving the service provided by the department.

Six-sigma

Lean six-sigma.

Staff Issues

Issues recruiting or retaining staff.

Standard Practices

Standard practices or procedures employed by the department in their daily functions.

Visual Management

The transfer of information through visual means.

Value Added

Value added to the system in terms of time saved, money not spent, etc.
# APPENDIX 8: IDI AXIAL CODING

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</table>
APPENDIX 9: REQUESTING PERMISSION FROM MS. KALtenBrunner TO ADAPT LEAN QUESTIONNAIRE.

Re: Requesting permission to use your Lean questionnaire.

Malin Malmbrandt <Malin.Malmbrandt@hhs.se>

In: 12:04 skrev Kate Thompson:

Dear Ms. Malmbrandt,

I am a Senior Medical Scientist working in the Histopathology Laboratory in Beaumont Hospital in Dublin. I am currently in the process of completing my MBA through Dublin Business School and am about to commence my thesis. For this I am looking at Lean Management experiences and perceptions across Irish histopathology laboratories. In the course of developing my proposal I had the good fortune to come upon your article "An instrument for assessing lean service adoption."

Would you mind if I used your questionnaire and developed it to focus specifically on Histopathology in Irish healthcare? My own research question is "Was lean management implemented effectively and sustained in Irish Histopathology laboratories?" I will be using mixed methodology of qualitative interviews followed by quantitative analysis through questionnaires. I feel your questionnaire would be invaluable during this process.

Thank you for taking the time to read this and I look forward to hearing from you.

Kind regards,
Kate Thompson (MSc)
Senior Medical Scientist,
Histopathology Laboratory,
Beaumont Hospital,
Dublin 9.
Ireland.

30 maj 2018 kl. 12:04 skrev Kate Thompson <10559198@mydbc.ie>:

APPENDIX 10: REQUESTING PERMISSION FROM MS. MALMbrandT TO ADAPT LEAN QUESTIONNAIRE.

Re: Requesting permission to use your Lean questionnaire.

Malin Malmbrandt <Malin.Malmbrandt@hhs.se>

In: 12:04 skrev Kate Thompson:

Dear Ms. Malmbrandt,

I am glad to hear that you find my questionnaire helpful, and look forward to hearing about your experience in using it.

Best regards,
Malin Malmbrandt

30 maj 2018 kl. 12:04 skrev Kate Thompson <10559198@mydbc.ie>:

Dear Ms. Malmbrandt,

I am a Senior Medical Scientist working in the Histopathology Laboratory in Beaumont Hospital in Dublin. I am currently in the process of completing my MBA through Dublin Business School and am about to commence my thesis. For this I am looking at Lean Management experiences and perceptions across Irish histopathology laboratories. In the course of developing my proposal I had the good fortune to come upon your article "An instrument for assessing lean service adoption."

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Thank you for taking the time to read this and I look forward to hearing from you.

Kind regards,
Kate Thompson (MSc)
Senior Medical Scientist,
Histopathology Laboratory,
Beaumont Hospital,
Dublin 9.
Ireland.
APPENDIX 11: WORD DOCUMENT VERSION OF QUESTIONNAIRE

Lean in Histopathology

The following questions have been designed to assess the extent of Lean activity in your laboratory. Please complete the questionnaire by selecting the response that best describes your workplace. Other than the first 2 questions, statements in all other questions increase in complexity as you move from 1 to 5. Please select only 1 option, if you select option 3 for example, it is assumed that option 1 and 2 also apply to your department. So, in this case it is only necessary to select 3. By completing this form, you are consenting to participation in this study.

1. What type of institution do you work for?
   - Republic of Ireland: Public (HSE/Voluntary HSE)
   - Republic of Ireland: Private
   - Northern Ireland: NHS
   - Northern Ireland: Private

2. How was Lean implemented in your department?
   - External Lean consultants reviewed our processes and flow and suggested changes.
   - An internal staff member/or team introduced and promoted Lean.
   - Unsure.

3. Have your Histopathology staff received training in Lean?
   - No, staff have not received training in Lean. 1
   - Some employees have been trained and the level of training varies.
   - All employees attended some training, but competence in improvement techniques varies.
   - All employees attended training in improvement techniques and the underlying ideas of Lean.
All employees continuously train in different aspects of improvement work and are considered highly competent in improvement work.

4. Are your Histopathology staff committed to the Lean process?

☐ No, commitment to Lean is poor, staff are openly negative to the process and do not want to engage in it.

☐ Lean is considered a temporary project, they are willing to dedicate limited time and energy to improvement work.

☐ They support Lean and actively engage in developing improvement ideas, but they do not take an active role in problem solving or adoption of new processes.

☐ They actively participate in improvement work, suggest improvements, follow problems through to completion, and they drive Lean adoption.

☐ They display an exceptional approach to the role of Lean in the laboratory, seeing improvement as an important part of daily work. They focus equally on developing new solutions and sustaining changes.

5. Do your staff understand the concepts of Lean?

☐ They cannot explain the concepts, but they accept this is just "how we do things here."

☐ They understand Lean in terms of housekeeping aspects.

☐ They understand Lean in terms of providing efficiency.

☐ They understand Lean in terms of processes and flow.

☐ They understand what the ideal flow would look like, and how they are working towards that daily.

6. As the Head of the Histopathology Laboratory, how would you rate your commitment to Lean?

☐ My commitment to Lean is poor, I am openly negative to the process and do not want to engage in it.

☐ I see Lean as a temporary project, and am willing to dedicate limited time and energy for improvement work.
I support Lean and actively engage in developing improvement ideas, but I do not take an active role in problem solving or adoption of new processes.

I actively participate in improvement work, suggest improvements, follow problems through to completion, and drive Lean adoption.

I take an strong approach to the role of Lean in the laboratory, seeing improvement as an important part of daily work. I focus equally on developing new solutions and sustaining changes.

7. Is time allocated to improvement work in your Histopathology Laboratory?
   ☐ No, time is not specifically allocated to improvement work.
   ☐ Time is allocated, but infrequently.
   ☐ Time is allocated to improvement work but only when a deadline for that work is approaching.
   ☐ Time is regularly allocated to all improvement work within the laboratory.
   ☐ Improvement work is part of the regular routine and everyone feels that improvement work is a necessary part of quality healthcare provision.

8. Does your department have a Change agent driving improvement work? (This role may have been adopted by the Quality Manager in some departments).
   ☐ No, there is no local change agent in place.
   ☐ Local change agent has been selected and appointed to the role.
   ☐ Change agent has undergone appropriate Lean training.
   ☐ Change agent is the driving force for improvement work, works closely with teams and acts as a motivator to the Histopathology laboratory.
   ☐ Change agent is seen as an expert resource for improvement teams in the laboratory.

9. How do you ensure you provide value for your customers, i.e. Pathologists and Clinicians?
   ☐ There is little or no focus on providing value for our customers.
Infrequently customers are asked for feedback, but solutions often focus on symptoms rather than root cause.

Customers are often asked for feedback, this is used for improvement work.

Customers are often asked for feedback, which is used for improvement work and also as a basis for challenging our current processes within the laboratory.

There is a strong approach to providing value for our customers. We have evidence of innovative solutions developed from customer feedback and customers receive information on improvements made.

10. Do you use value stream mapping to identify waste in your Histopathology laboratory?

No, value stream mapping is not used.

Some processes or portions of processes are mapped, but with varying quality and it may not be up to date. Non-value adding activities are identified based on recurring problems.

All major laboratory processes have been mapped, but to varying levels of quality.

We have detailed and updated process maps that are visualised in the laboratory and are updated regularly.

There is strong laboratory use of value stream mapping. Process maps are continuously updated and used to challenge processes from a customer perspective.

11. Is your workplace designed for flow?

No, the laboratory is disorderly and time is spent searching for information and the resources required to do the job.

We are in the process of organising the workplace to improve our flow.

Information and resources are easily retrieved because they are sorted and organised.

Information and resources are located based on when and where they are needed in the process in order to facilitate flow. However, optimal flow is hindered by laboratory architecture.

The laboratory has a strong approach to flow. Information and resources are organised to facilitate flow. The most reoccurring processes can be seen by looking at the organisation, and location of resources and information in the laboratory.
12. Does your laboratory have standardised procedures?

☐ No, standardised procedures are not used.

☐ There are standardised tasks in certain areas but are not necessarily documented.

☐ They are used in selected areas and are detailed and documented.

☐ They are used in most areas and are detailed and documented.

☐ We use standardised tasks for all processes in the laboratory. They are detailed and applied in all areas. When deviations in quality or turn-around-times occur, the standard is used as a guide to identify the problem. (E.g. was the procedure followed, etc)

13. Are you able to plan and balance workloads to avoid bottle necks or to deal with a sudden increase in demand for Histopathology services?

☐ No, proactive planning is not possible. Variation in specimen arrival time and resources needed make proactive planning difficult.

☐ We can plan and balance workloads and resources to some extent but it's mostly out of our control.

☐ Resources can be planned for certain areas of the lab in advance if e.g. there is an expected increase in patient clinic activity, or a designated day for non-gynae cytology work, etc.

☐ We are working with the clinics and GPs to accurately plan resources needed to cope with the workload.

☐ We take a proactive role in educating clinics and GPs, etc on our work processes to encourage them to inform us if additional clinics are opening, or if there is an expected increase in patient activity, etc.

14. Is information visualised in your laboratory?

☐ There is no visualisation of information.

☐ There is some general information such as safety instructions, etc visualised but the approach is informal.

☐ A lot of information is visualised but with no formal structure and no designated areas.
There is systematic visualisation in appropriate areas. Information visualised is diverse and based on need. (Safety, quality, etc.)

The laboratory uses innovative visualisation of general information, the information is diverse, safety, quality, KPIs, work standards, etc, and in an appropriate place so all staff can benefit from it.

15. Do the Histopathology staff participate in improvement work?

☐ No, they are not involved in improvement work.
☐ Some staff participate but in an informal way.
☐ Most staff participate in improvement work but at varying levels.
☐ All staff participate in improvement work but level of activity varies. Participation is based on knowledge of the process to be improved.
☐ There is strong participation in improvement work in the laboratory. All staff participate in improvement work for processes that they use.

16. How do you focus your improvement work?

☐ Improvement work is only carried out when necessary. There is no clear focus to the process.
☐ Improvement work focuses on improving the laboratory environment, housekeeping, etc.
☐ Improvement work focuses on improving the laboratory environment, housekeeping, etc. but process improvements are also starting to occur.
☐ Issues relating to process flow and value are becoming the focus of improvement work.
☐ There is strong and innovative improvement work in the laboratory. We are continuously improving the entire flow as part of our daily work.

17. Do you have structured problem-solving processes in place?

☐ Improvement work is unplanned and unstructured. We focus on symptoms and not the root cause. Problems are only tackled in a crisis manner and not addressed in advance.
We have started to implement a systematic approach to improvement work by looking for the root cause of problems and have started to use problem-solving tools.

Root cause analysis, etc. are used routinely. Staff are proficient in problem-solving techniques.

The staff take an experimental approach to improvement work in the laboratory. Improvements are conducted to solve problems and to further develop flow in the department.

The laboratory has a strong problem-solving structure. Improvements are made to solve problems, to enhance flow, and improve the service we provide.

18. How are improvements sustained in the Histopathology laboratory.

Earlier improvements have not been sustained.

We are educating our staff to highlight the importance of sustaining improvements over time.

Improvements will be added to the standard procedures and in most cases the improvements are monitored over time.

All improvements are monitored to ensure they are sustained. If they are not followed the reasons are discussed and there is evidence of changes to work standards based on these discussions.

Strong approach applied to ensure improvements are sustained with the discussion involving employees and managers. If the improvement is no longer in use then the reasons for this are discussed and documented.
APPENDIX 12: 4P MODEL BREAKDOWN OF QUANTITATIVE RESULTS

PHILOSOPHY:

**Lean Implementation**

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**Staff Commitment**

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<tr>
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**Sustaining Improvements**

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</table>
PROCESSES:

VSM Waste

Flow Design

Standardised Procedures

Balancing Workflow

Visual Management
**PROBLEM-SOLVING:**

![Improvement Work](image1)

![Focus Improvement Work](image2)

![Problem Solving](image3)
## APPENDIX 13: RESULTS MATRIX

<table>
<thead>
<tr>
<th>Research Objectives</th>
<th>Qualitative Findings</th>
<th>Quantitative Findings</th>
<th>Comparison to LR</th>
<th>Conclusions</th>
<th>Recommendations</th>
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<tbody>
<tr>
<td>1. To examine the Lean implementation process in Irish Histopathology laboratories.</td>
<td>2/3 used external consultants but had strong change agents championing it, consultants or LMs themselves. 1/3 lead from within (ROI public).</td>
<td>56% internal 9% external 35% unsure 66% no change agent 16% say change agent is driving force for improvement work.</td>
<td>Commonly Lean applied to particular department, etc. Usually led from within but for continued success, support of lead pathologist and LM needed (Clarke, 2013, p. 638), [Zarbo, 2010, p. 361]. May not be considered optimal implementation for Lean but when department commits to the change, real and lasting improvements to patient services can be achieved (Maxwell, 2012, p. 367). Lean considered by management as tool to remove waste. Not led from within, external Lean “experts” involved as part of short-term improvement project. Initial improvements seen but failure to develop CI culture means improvements short-lived (Clarke, 2013, p. 638). Negative affect on department’s ability to embrace Lean as often misrepresented as staff-reducing</td>
<td>Necessary to implement in effective and inclusive manner.</td>
<td>Implement changes internally. Encourage staff to get involved and lead the way on changes.</td>
</tr>
<tr>
<td>ROI private interviewee experienced alienation of staff when external group presented Lean to Heads of department in previous position he held in public hospital as finance could not grasp that this process would not result in job losses.</td>
<td></td>
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<tr>
<td>UK looked to industry to emulate their processes.</td>
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</table>
2. To examine if Lean transformation only focuses on Processes or if Philosophy, People and Partners, and Problem-solving have also been embraced

<table>
<thead>
<tr>
<th>Philosophy</th>
<th>Processes</th>
<th>People and partners</th>
<th>Problem-solving</th>
</tr>
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<tbody>
<tr>
<td>See appendix 12 for visual.</td>
<td>Adopt long-term thinking even if it hinders short-term financial goals. To implement processes successfully there must be a shared purpose that becomes the foundation that all other Lean principles are built on (Liker, 2004). (Spear, 2005, p. 78), (Zarbo, 2007, p. 1015), (O’Angelo, 2007, p. 423).</td>
<td>Philosophy, Processes and Problem-solving all appear to be embraced. People and partners the most poorly implemented. Query due to lack of resources, staffing issues, etc.</td>
<td>Must continue to invest in human capital, it’s the most valuable commodity the department has.</td>
</tr>
<tr>
<td>All Philosophical variables implemented except time allocation.</td>
<td>Processes: Companies who fail to implement Lean effectively focus too heavily on processes (Liker, 2004). Lean used to identify inefficiencies or bottlenecks (Clarke, 2016, p. 5). Literature for Histo focuses heavily on processes. (Raab, 2008, p. 1198), (Smith et al, 2012, p. 367) (Yorukoglu, 2017, p.47) (Cankovic, 2009, p. 390).</td>
<td>Processes: Standardised procedures and visual management widely adopted but flow design and balancing workflow impeded by architecture and unpredictable specimen delivery time, and work creep. Processes was code mentioned most frequently (F23), highlighting its importance.</td>
<td>Training will increase understanding and commitment to sustainability.</td>
</tr>
<tr>
<td>Standardised procedures and visual management widely adopted but flow design and balancing workflow impeded by architecture and unpredictable specimen delivery time, and work creep. Processes was code mentioned most frequently (F23), highlighting its importance.</td>
<td>People and partners: Creating customer value is the only variable adopted by all. All others poorly implemented.</td>
<td>People and partners the most poorly implemented. Query due to lack of resources, staffing issues, etc.</td>
<td></td>
</tr>
<tr>
<td>People and partners: Creating customer value is the only variable adopted by all. All others poorly implemented.</td>
<td>Problem-solving: Seems to be evolving. Most staff participate in improvement work but at</td>
<td></td>
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</table>
varying levels and most starting to use problem-solving tools to do it. The focus of improvement work moving towards process and flow improvements. 

time (Clarke, 2016, p.5).

People and partners: Investing in & developing employees within org is key to achieving culture of CI (Clarke, 2013, p. 638), (Spear, 2005, p. 78), (Liker, 2004).

Cankovic et al (2009) found that an integrated process of change resulted in empowered employees who could sustain the improvements with minimal intervention from management.

---

3. To examine if Histopathology laboratories can balance workflow.

<table>
<thead>
<tr>
<th>All have difficulty balancing workflow. All constrained by architecture.</th>
<th>All make an attempt to balance workflow.</th>
<th>Lean workflow is characterised by a continual flow process made up of small evenly distributed batches of work that use employees and resources at the right time, in the right place producing a product that is easily distributed (Zarbo, 2010, p.71).</th>
<th>Ability to balance workflow at present seems unachievable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK manage as best they can. If they want to improve Cell Path anymore, investment required.</td>
<td>63% plan and balance workload to some extent but it’s mostly out of their control.</td>
<td>Levelling and balancing workflow, while a fundamental component in Liker’s description of Lean (2004), is not always possible in a healthcare facility where flow is dependent on so many other variables. One piece flow as</td>
<td>Work creep a real issue, new clinics opened, lab not informed.</td>
</tr>
<tr>
<td>ROI private have done the best they can with the architecture they have. VSM helped.</td>
<td>34% can plan resources for a particular bench etc. in advance if they expect an increase in patient clinic activity on a particular day.</td>
<td>GP deliveries unpredictable.</td>
<td>Communication with hospital clinics and GPs necessary to alleviate pressure on the service.</td>
</tr>
<tr>
<td>ROI public said any flow changes have been made by the staff. They try to work around what they have.</td>
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</tbody>
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<td>ROI public said any flow changes have been made by the staff. They try to work around what they have.</td>
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described by Liker (2004) is also challenging for Histopathology. As mentioned previously, many departments are constrained by architecture, and resources, and so will implement Lean principles in their own way dependent on space, resources, staffing levels, and equipment (Clarke, 2016). To achieve an optimally functioning one piece-flow model, pull systems and the ability to balance workloads must be in place (Smith et al, 2012, p. 367). According to Smith et al (2012, p. 367) issues with specimen flow can be a major contributor to error rates within a department. Providing a timely and consistently high-quality product, and matching capacity to demand are manufacturing issues that are mirrored in Histopathology.

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<th>4. To examine if management support, and lead Lean.</th>
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<td>All agree for larger projects hospital buy-in is essential</td>
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<td>All participate to some extent.</td>
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<td>According to Liker (Netland, 2015), most lean transformations fail because they don’t “understand the Commitment to Lean obvious in those interviewed.</td>
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<td>Continued commitment required.</td>
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<td>31% of chiefs take strong approach</td>
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<td>Where possible time should be allocated to</td>
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UK site got complete buy-in from 2012-2013 but in economic slump CI teams first to go or are redeployed.

ROI sites believe resources limited so they try and do the best with what they have.

Also, a lot of Lean is “just do it” philosophy.

Management buy-in essential to keep those involved in Lean motivated.

All 3 have years of experience and are have bought into the philosophy.

to role of Lean seeing improvement as NB part of daily work. Also focus equally on developing new solutions and sustaining changes.

28% actively participate and suggest improvements.

25% support and in developing ideas but don’t take an active role in problem-solving or adopting new processes.

16% see Lean as a temporary project, willing to dedicate limited time to improvement work.

However, 44% said time is not allocated to improvement work.

Another 31% said time allocated but infrequently.

Only 9% said time regularly allocated to improvement work.

power of Lean leadership”.

He felt that the ever-growing number of failed implementations were down to the fact that companies were copying from other companies that had copied from Toyota instead of going back to the source and understanding the original philosophy. In these instances, there was no sustained attempt to change company culture.

To succeed it is important that leaders create an organisational structure that supports and encourages a bottom-up approach to change. It will involve continued improvement led by the workers. Without this kind of initiative the only outcome is occasional management led projects initiated in a time of crisis, instead of the sustained and significant change seen at Toyota (Netland, 2015).

Lean is so successful at Toyota, according to Liker (Netland, 2015), because in Toyota the leaders are CMSs mostly answered positively. However, they are mostly unable to dedicate time to improvement work. Possibly due to resourcing and staffing issues.
Teachers and this ethos continues up through the chain of command to the top.

Respect for people and continuous improvement are, according to Liker (Netland, 2015), two fundamental aspects of the Toyota way.

Without Lean buy-in at this level there will be no “constancy of purpose” that focuses on improvement work and creates a culture of continuous improvement (Zarbo et al., 2012, p. 321).

| 5. To examine how Histopathology laboratories provide value for their customers. |
| 3/3 send user satisfaction surveys. |
| Communication and engagement is mentioned by UK and ROI private. |
| UK also educate their users on lab processes. |
| ROI private also use quality indicators, TATs, IQC and EQA. |
| ROI public measure and highlight the benefits of Lean projects, and they increase value by removing waste. |
| All attempt to provide value. |
| 44% said customers often asked for feedback that is used for improvement work, and as a basis of challenging their current processes. |
| Further 22% have evidence of innovative solutions developed from customer feedback, the customer was also informed of these improvements. |
| Lean functions on the principle that the aim of a business or organisation is to create value for the end user or customer (Clark et al., 2013, p. 638). The value stream is continually improved by understanding the customer’s needs and redesigning the process to remove all value-inhibiting waste (Clarke, 2013, p. 638). Value created by removing waste through application of Lean processes. |
| All aim to provide value for the customer. Customer satisfaction surveys distributed and processes updated, if possible, based on feedback. Many use this feedback to challenge current processes. |
| Continuation of this is necessary to guarantee long term customer satisfaction. |
that lead to decrease in repeat testing, and dependable, reproducible results (Clarke, 2013, p. 638), (Raouf, 2015, p. 716), (Smith, 2012, p. 367), (Smith, 2011, p. 1436), (Sugianto, 2015, p. 259).

Cankovic et al (2009), in an endeavour to eliminate process defects and waste, applied Lean production principles to their pre-analytical processes and successfully reduced their TATs for tissue specimens by 44%. The most important type of waste scientists want to remove is error or issues that prevent reproducibility of results. The NHS are striving to eliminate waste and create value in their pathology services through the use of Lean in their many improvement projects as they strive to develop more reliable and advanced services for patients (NHS Improvement d, 2017), (NHS Improvement e, 2017).

6. To examine how Lean processes implemented have been sustained.

| monitored and refined over a period of time. Mostly managed through the QMS for all 3. | All attempt to sustain improvements. 19% educate staff on importance of sustaining improvements. | According to Liker (Netland, 2015), most lean transformations fail because they don’t “understand the Encouraging to see all attempt to sustain improvements, with majority adding changes to the A review of the services nationally is needed. With increasing workload, it’s necessary to ensure proper facilities and processes in place to cope. |
ROI public often wait for pressure point to build up again before implementing next change as everyone is busy and it’s hard to pre-empt problems.

All agree there is inadequate resourcing to sustain improvements.

UK could do so much more with adequate resourcing.

ROI private said recruitment is an issue and sustaining systems in the absence of critical functions is not possible. Otherwise you’re saying those functions are not necessary.

ROI public say they’re in the pot with everyone else when looking for extra resources. They try to free up time as best they can but routine work has to be done. Sometimes improvement work prioritised over AL.

For all others, the improvements are added to the SOP and monitored to varying degrees of intensity.

For the top 47% improvements monitored and if not sustained reasons are discussed with staff to uncover any issues. Shows communication with and involvement of staff.

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To succeed it is important that leaders create an organisational structure that supports and encourages a bottom-up approach to change. It will involve continued improvement led by the workers. Without this kind of initiative the only outcome is occasional management led projects initiated in a time of crisis, instead of the sustained and significant change seen at Toyota (Netland, 2015).

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Compliance with ISO 15189 and accreditation has contributed greatly to this.

However other factors affect sustainability:

Lean leadership,

Full implementation of 4P model,

Staff involvement in improvement work,

Investing in People and partners.

Good Lean leadership essential to continued sustainability as unified, common purpose.

Investment in the staff required, Lean training and providing time for improvement work will increase understanding, commitment and sustainability.

Review of staffing required, very few graduates doing Histopathology. Need to review criteria for entry into the profession to fill this gap.

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### 7. To examine if automation is a necessary element of Lean. (Qualitative Analysis Only)

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<th>N/A Qualitative only.</th>
<th>Histopathology resembles manufacturing industry more closely than other areas of healthcare (Clarke, 2013, p. 638).</th>
<th>Lean not a necessary element of Lean.</th>
<th>A review of all areas of Histopathology labs should be carried out.</th>
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<td>All agree it’s not an essential element.</td>
<td>To achieve an optimally functioning one piece-flow model, pull systems and the ability to balance workloads must be in place (Maxwell, 2012, p. 367).</td>
<td>If looking to relieve RSI or peaks it can be useful, but not necessary.</td>
<td>Enhance efficiency and flow where possible. If there is a critical mass of specimens, perhaps an automated system could be considered.</td>
</tr>
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<td>UK feel while it’s needed to improve some processes, it can actually cause bottlenecks. Lean solutions are often low-cost solutions. Essential to get your process right first, as can automate a bad process. Previous knee-jerk-rxn in UK where money spent on automated systems without looking at the process properly.</td>
<td>In manual labs, more flexibility to be creative. With automated equipment, tied to what the machine can do.</td>
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<td>However, architectural limitations of departments can limit the level and type of automation possible.</td>
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<td>ROI private said a critical mass has to be reached before automation is even a consideration. V. difficult to lead on a</td>
<td>Can’t Lean out entire Histopathology lab, need to think in terms of work cells. Make</td>
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Histopathology resembles manufacturing industry more closely than other areas of healthcare (Clarke, 2013, p. 638).
| bold process automation without the backing of a large teaching hospital behind you. | ROI public said it depends on what you want to address, if looking to tackle RSI then maybe automation is part of the solution, but not necessarily an essential part of it. |
| UK and ROI public feel there’s more scope for Lean in Histology/manual labs. | UK saw greater engagement in Histopathology because the key Change Agent was a Cellular Pathologist. General consensus that Histology needed improvement, while more scepticism and cynicism in blood sciences. |
| ROI public said more scope for Lean in manual labs if you look to relieve things like RSA, relieve peaks, etc., opposed to full automation. Automated machine can work at the pace it can work at, so v. little room for enhancement or flexibility. If you implement a change, you’re tied to what instrument can do, so end up working around it. In manual lab, more scope for flexibility and to think outside the box. ROI private said looking at Lean in automated lab, you’re looking at it for the entire system. Lean in manual lab, you’re               | them as efficient as possible. Needed to improve certain processes but can also cause bottlenecks. |
looking at it in steps. V. difficult to Lean out entire Histo as fragmented around different stages of processing. Need VSM for each area.

| 8. To examine variations in implementation and sustainability between ROI public and private Histopathology laboratories. | N/A Quantitative only. | Very little noticeable variation between public and private. Only 2 areas; Lean training in which 70% of private said their staff has not received training compared to 35% of public. Exposure to training overall marginally better in public. Allocation of time for improvement work in which 70% of private don’t allocate time compared to 35% of public. Time allocation overall better in public. | No literature regarding this. The 2 variations are not the important finding, it’s the similarities. United profession in good and bad, with common struggles. | Continue open communication across the profession. |