Utilisation of LEAN Start Up Methodology for the Identification, Development, and Pilot of Novel Services that Red Cell Immunohaematology can Provide Hospital Transfusion Laboratories.

M J HAZELL

2022

Utilisation of LEAN Start Up Methodology for the Identification, Development, and Pilot of Novel Services that Red Cell Immunohaematology can Provide Hospital Transfusion Laboratories.

A thesis submitted in partial fulfilment of the requirements of the Manchester Metropolitan University for the award of Doctorate in Clinical Science.

Matthew J, Hazell

Department of Life Sciences Manchester Metropolitan University, in Collaboration with NHS Blood and Transplant and the University Hospitals Bristol and Weston NHS Foundation Trust

Submission Date – 2022

Abstract

Introduction

Service development is improved by customer input. LEAN Startup streamlines collective idea creation in extreme uncertainty, providing collaboration to match a service to customer wants. Uncertainty brought by pathology networks prompted Red Cell Immunohaematology (RCI) to use LEAN Startup to develop services beyond its traditional testing role with the Bristol Royal Infirmary (BRI).

Methods

The Value Proposition Canvas (VPC) Customer Profile, Kano model and the Business Model Canvas (BMC) identified themes and attributes for new service provision. The VPC Customer Profile identified the BRIs jobs, pains, and gains. Process mapping gathered data relating to: (i) ISO15189 vertical audit training and completion; (ii) Sample verification, automation, and manual crossmatch processes. Online Miro based events allowed redesign of processes.

Results

Three themes were identified (i) Quality assurance – Enables a self-sufficient laboratory, provides centralised document control, facilitates compliance; (ii) LEAN Laboratory – Part of daily practice, (iii) Training – Demonstrates effectiveness of a cross-organisational platform for competency. The VPC Value Map and BMC resulted with the Laboratory Solution Development Platform to support hospital partner service provision. The Build-Measure-Learn cycle resulted in three options: (1) The hospital partner bespoke service; (2) The hospital and RCI full partnership bespoke service (3) RCI led generic template service. Option 2 targeted two job themes: (i) Vertical audit training and completion to meet ISO15189 accreditation requirement. New training material was created. A new audit process allowed planning, process observation and report generation; (ii) Improve process flow. The laboratory layout was sub-optimal. A new layout reduced process waste, improved patient safety and blood readiness.

Conclusion

LEAN Startup principles and related business tools allowed identification, development, and pilot of a service beyond RCIs traditional testing role. Benefits were related to: A better understanding of the current market; An improved relationship between RCI and hospital; Empowerment of the HTL; improved patient safety and treatment times.

For my Family,

You are my world.

Acknowledgments

I have been fortunate enough to have been given the opportunity to write two doctoral theses' during my career to date. I am grateful to God that I have been gifted such opportunity. Being at different stages of my adult life, each came with their own set of challenges to overcome. Without your support throughout my Higher Specialist Scientific Training, the time to undertake the practical aspects to support this thesis, and the time to write its contents; I could not have finished… Thank you!

Special Thanks

Mark Williams and Nina-Dempsey Hibbert in their roles of Internal and External Supervisor, your encouragement, guidance, support, and feedback has been instrumental for my completion of this work.

Vanessa Winfield for always having an open door to listen to my questions, provide expert advice and on many occasions have a good chuckle.

Ulrike Paulus in her role as Clinical Supervisor, you have instilled in me the importance of being thorough to ensure I produce work of which I can be proud.

Sara Wright, Shane Grimsley, Tom Bullock, Josephine McCullagh, Peter Wright, Wayne Vietri and many more friends I have made during my Higher Specialist Scientific Training, you have made the hard days easier.

Tracey Tomlinson for supporting my earlier training requirements on the Higher Specialist Scientific Training, but more importantly for your unwavering friendship, tea times and guidance.

Stephen White and Laura Reyland for the time and support you gave the project, allowing it take place in your laboratory setting.

Stephen Bassey, Julie Staves, Andrew Fletcher, Nicola Svenson, Tim Wreford-Bush, Mike Herbert and Garry McDowell for the time to take part in the face-to-face hospital partnership event.

The National School of Healthcare Sciences and NHS Blood and Transplant for the funding my higher Specialist Scientific Training.

Agnes, Jeno, Laszlo, Rachel, Jerome, Susan, Craig, Moses and Daniel for the happiness and welcome break you have provided me during my studies.

Mum, Dad, Gareth, Ana, Douglas, Sophia, and your respective families, I would not have achieved so much without your understanding, love, and unending encouragement. I look forward to spending time with you.

My beautiful family, Pearl, and Harlow Hazell, for making my life whole with endless love, support, and happiness. You have given me the strength to reach this point and made the journey meaningful.

Declaration

No material contained in the thesis has been used in any other submission for another academic award and that any material which has been used for any other award or qualification is detailed. This includes any published material submitted by any other student of Manchester Metropolitan or any other institution

Table of Contents

List of Figures

List of Tables

List of Appendices

List of Abbreviations

Abbreviation	Full text
BMC	Business Model Canvas
BML	Build-Measure-Learn
BMS	Biomedical Scientist
BMSST	Biomedical Scientist Specialists in Transfusion
BSH	British Society for Haematology
CPA	Clinical Pathology Accreditation
EI	Electronic Issue
FMEA	Failure Mode Effect Analysis
HbF	Haemoglobin Fetal
HCPC	Health Care Protection Council
HSST	Higher Specialist Scientific Trainee
HTL	Hospital Transfusion Laboratory
ISO	International Organisation of Standardisation
JPAC	Joint Professional Advisory Committee
LIMS	Laboratory Information Management Systems
MHRA	Medicines and Healthcare Products Regulatory Agency
MVP	Minimal Viable Product
NHS	National Health Service
NHSBT	National Health Service Blood and Transplant
NSHCS	National School of Healthcare Sciences
PDSA	Plan-Do-Study-Act
PESTLE	Political Economic Societal Technology Legal Environmental
QMS	Quality Management System
RCI	Red Cell Immunohaematology
SHOT	Serious Hazards of Transfusion
SMT	Senior Management Team
UKAS	United Kingdom Accreditation Society
UKTLC	United Kingdom Transfusion Laboratory Collaborative
VPC	Value Proposition Canvas

Chapter 1 – Introduction

1.1 Pathology Services and Transfusion

Pathology services are a group of 19 clinical sciences that are strategically valuable for patient diagnosis and directing treatment (NHS Choices., 2016; The Royal College of Pathologists[1]., 2017; Lindsell., 2017). Professional registration of healthcare workers with the Royal College of Pathologists underpins the authority of all pathology services (The Royal College of Pathologists[2]., 2017). This is important for maintaining service user confidence by setting standards that healthcare workers must adhere with to practice e.g. education, training, and conduct (HCPC., 2019).

Transfusion services are critical for patient care, assuring safe blood product provision for chronic conditions (e.g. anaemia) and acute situations (e.g. massive haemorrhage resulting from trauma) (Retter *et al.*, 2013; Hunt *et al.*, 2015; Kotzé *et al.*, 2015; NHS Choices., 2015). Effective care is achieved by utilising guidance from national bodies such as – The Joint Professional Advisory Committee (JPAC); Serious Hazards of Transfusion (SHOT) and British Society for Haematology (BSH) (BSH., 2017; JPAC., 2017; SHOT[1]., 2017). Assurance of the best standards, practice and service quality is assessed by regulatory and licensing bodies such as – The Medicines and Healthcare products Regulatory Agency (MHRA); United Kingdom Accreditation Service (UKAS) (MHRA., 2017; UKAS., 2017). Transfusion services deliver high-quality, safe services, even in the face of changes that are implemented to control National Health Service (NHS) budgets (National Audit Office., 2017). For these reasons, this report aims to:

- Evaluate the status of national transfusion services by discussing:
    - The financial pressure on the NHS and its impact on capability and patient care related to transfusion.
    - Pathology networks and how they might improve the delivery of transfusion services.
    - The role NHS Blood and Transplant's (NHSBT) Red Cell Immunohaematology (RCI) department should play in pathology networks.
- Introduce LEAN Startup and business development tools that can be utilised to build services RCI can use to support networked transfusion laboratories.

1.2 Financial pressure on the NHS

The NHS is described as always undertaking exceptional measures, to provide a service free at the point of care, of the highest quality and efficiency (Beastall., 2008; Darzi., 2008; Carter., 2016). NHS delivery of healthcare occurs in the face of constant organisational restructure, resulting from changes in Government, accompanied policies and financial pressures, as well as patient expectation (Beastall., 2013; Osaro and Chima., 2014; Sull, Harland and Moore., 2015). At present, the financial position of the UK has resulted in Government reductions in public expenditure, including NHS funding restrictions (Figure 1-1) (Osaro and Chima., 2014; NHS England.,

2017). The COVID19 pandemic has certainly created even greater pressures on the NHS with longer wait times, slower admittance, and discharge rates as well as lower overall activity compared to pre-pandemic levels (Fisher and Scobie., 2022; Gov.UK., 2022). Despite recognition as one of the best value health systems in the world, the NHS is expected to deliver 10-15% cost savings by improving efficiencies of 2-3% per year (Carter., 2016; Schneider *et al*., 2017). By 2015 the NHS was expected to have made £20 billion efficiency savings, £500 million yearly by pathology services, without undermining the quality of patient care (Carter., 2016; Osaro and Chima., 2014; Linsdell., 2017). It has been suggested that spending should be increased because the demand for pathology services is increasing, which is not matched by scientist numbers and the current treatment backlog caused by the COVID-19 pandemic (Alonso-Cerezo *et al*., 2009; Osaro and Chima., 2014; Linsdell., 2017; Serious Hazards of Transfusion Steering Group., 2021).

1.3 The Effect of Financial Pressure on the Capability of the Blood Transfusion Laboratory

Reduced spending on NHS pathology services impacts on the capability of hospital transfusion laboratories (HTL) by affecting staff numbers, pay bands and training (Figure 1-1) (Osaro and Chima., 2014; Carter., 2016; Lishman., 2017). The 2017 and 2019 UK Transfusion Laboratory Collaborative (UK TLC) survey identified poor capacity planning of HTL staff to cover core working hours in the face of increased workload (Osaro and Chima., 2014; Mistry, Bolton-Maggs and Rook., 2017; Bolton-Maggs *et al*., 2019). Capacity planning is complicated by the lack of clarification from governing bodies concerning benchmarks that HTLs can utilise to ensure capability (Osaro and Chima., 2014). This has been identified and an example of a model hospital has been presented to demonstrate “what good looks like” (Carter., 2016; Model Health System., 2022). This model uses real data, allowing a single reference point for trusts to benchmark and align with good practice (Carter., 2016; Model Health System 2022). More recently capacity planning has been impacted by the COVID-19 pandemic as members of staff are absent isolating, sick or simply leave the healthcare profession because of burnout (Deakin., 2022).

1.3.1 The loss of the Biomedical Scientist Specialist

The lack of clarification on benchmarks is causing difficulty for HTLs to define skill sets required of new staff (Mistry, Bolton-Maggs and Rook., 2017). Advertisement of roles with broad skill requirements has resulted, which laboratories cannot fill, leaving them understaffed or with scientists who do not meet the advertised skill set (Osaro and Chima., 2014; Mistry, Bolton-Maggs and Rook., 2017; Bolton-Maggs *et al*., 2019). A reduction of Biomedical Scientist Specialists in transfusion (BMSST, ≥Band 6), often due to reduced budgets, has made this noticeable, where they are replaced with band 5 scientists with a broad yet shallow knowledge across multiple disciplines (Mistry, Bolton-Maggs and Rook., 2017). Reduced scientist numbers lead to overworked teams, reduced morale, burnout and eventually resulting in a higher staff turnover (Osaro and Chima., 2014; Mistry, Bolton-Maggs and Rook., 2017; Bolton-Maggs *et al*., 2019). BMSST loss is inconsistent with an increased need for provision of specialist advice and support, especially outside of core hours (Mistry, Bolton-Maggs and Rook.,

2017). The development of multidisciplinary staff skill into the transfusion specialism cannot be achieved via training, because of the lack of BMSST to act as mentors (Mistry, Bolton-Maggs and Rook., 2017; Bolton-Maggs *et al*., 2019).

1.3.2 Capability and Automated Equipment

The reduction of skilled and registered scientific staff is facilitated by the introduction of automation (Plebani and Lippi., 2010). Deskilling reduces the HTL capability to resolve the most complex cases it encounters (Plebani and Lippi., 2010; Williams[1]., 2017). The focus for the HTL is to load samples for automated result generation, rather than conduct manual investigation and interpretation (Williams[1]., 2017). Automation can also improve the capability of a service by supporting audit, reduced scientist numbers in routine investigations and re-establishing laboratory sample capacity (Alonso-Cerezo., 2009). Automation has financial burdens, where HTLs may not hold a budget for its procurement, maintenance, or upgrade (Bajpai, Kaur and Gupta., 2012). Sites where automation and registered staff numbers cannot be maintained may be incapable of running a service and be forced to refer samples to HTLs or reference laboratories that can absorb increased workloads (Williams[1]., 2017). Financial pressures result in a greater reliance on multidisciplinary scientists, often locum or agency, requiring support from expensive automated equipment due to reduced knowledge of transfusion science compared to the BMSST (Osaro and Chima., 2014; Mistry, Bolton-Maggs and Rook., 2017; Williams[1]., 2017).

1.4 The Effect of Service Capability on the Quality of Patient Care

HTL capability to provide safe and efficient services, which meet guidelines or recommendations and legal or regulatory requirements is dependent upon successful identification and achievement of quality objectives (Chaffe *et al*., 2014; Osaro and Chima., 2014). This relies on compliance with, and maintenance of its accreditation status, as well as good management of employee resource and utilisation of automation and Laboratory Information Management Systems (LIMS) (Chaffe *et al*., 2014; Osaro and Chima., 2014; Tzankov and Tornillo., 2017).

1.4.1 Accreditation and Compliance

Accreditation and compliance to accepted quality standards is a useful and important measure of service quality (Barnes., 2014; Carter., 2016; Long-Mira *et al*., 2016; Tzankov and Tornillo., 2017). Long-Mira *et al* (2016 pp 49), states:

> "Accreditation is not a goal, but a tool to reach an important goal: good professional practice in a pathology laboratory."

UK laboratory accreditation is achieved through externally led assessments against standards maintained by the International Organisation of Standardisation (ISO) (Tzankov and Tornillo., 2017). UK Accreditation was introduced more than 20 years ago and until 2010 was undertaken by the Clinical Pathology Accreditation (UK)

LTD (CPA) (Beastall., 2008). The United Kingdom Assessment Service (UKAS), an independent body appointed by the UK government, now owns the CPA and national accreditation has transitioned from the CPA to UKAS (UKAS[1]., 2017; UKAS[2]., 2017). At the time of this report, accreditation was against ISO15189:2012 – Medical Laboratory Accreditation standard (Tzankov and Tornillo., 2017; UKAS[1]., 2017). The CPA restricted accreditation to the technical competence of laboratory staff, whereas UKAS emphasises continuous improvement, patient care and that the methods used are suitable for diagnosis (Barnes., 2014; Stennett., 2017). Under ISO15189:2012, The current aspects addressed are:

- Laboratory environment
- Personnel management
- Sampling systems
- Validity and appropriateness of methods
- Management of patient feedback
- Internal audit of quality management systems
- Methods of controlling documents and records
- Management of equipment

Taken from (ISO.,2016; Stennett., 2017; Tzankov and Tornillo., 2017

ISO15189:2012 allows laboratories to conduct investigations for the international community under a recognised accreditation scheme (ISO., 2012; Long-Mira., 2016; Stearn., 2017). UKAS allows laboratories across a service network, that share a quality management system, to 'merge' together under one accreditation application (Stearn., 2017). A HTL or network can voluntarily suspend parts of its service, deemed to impact on successful accreditation (Stearn., 2017). That UKAS only recognises one legal entity for accreditation, not each site in a network, can be a problem because the addition of tests to a HTL scope requires full assessment, even if voluntarily suspended to undertake improvement to meet ISO15189 (Long-Mira., 2016; Stearn; 2017). Another problem is that while accredited procedures meet ISO15189, there may be differences between service providers (Long-Mira., 2016; Stearn; 2017). UKAS accreditation gives greater capability to provide service to a wider referral audience e.g. international customers, than available under CPA accreditation, increasing scope and allowing their accredited testing capability to remain intact (Stearn., 2017). Accreditation is suggested to improve capability, as it provides independent assurance of processes and through standardisation it reduces risks, improves turnaround time, controls costs, and enhances the quality and value of patient care (Long-Mira *et al*., 2016; Stearn., 2017; Stennett., 2017; Tzankov and Tornillo., 2017). It must be highlighted that the process of accreditation has a charge cost that is expensive (Williams[2]., 2022). In the presence of accreditation requirements that are seen in the UK, failure in compliance poses a risk to capability where the activity of a service could be suspended if accreditation is not achieved (Long-Mira *et al*., 2016).

1.4.2 Employee Resource

To maintain a safe and high-quality service, HTLs ensure the presence of adequate staff numbers that meet laboratory capacity plans; who are trained; certified; competent, undergoing continuing professional development and regular appraisal (Chaffe *et al*., 2014; Osaro and Chima., 2014). To meet quality objectives, the

HTL must have effective employee resource and capacity planning, aligned to benchmarks (Osaro and Chima., 2014). This parallels Carter (2016, p4), who states:

> "The provision of high-quality clinical care and good resource management go hand in hand".

Varying degrees of quality in healthcare are observed throughout the UK, demonstrating the HTL cannot easily safeguard service quality and ensure patient's needs are met* (Osaro and Chima., 2014; Public Health England., 2017). Carter (2016, p8) identifies this by stating:

> "The mix of qualified and unqualified staff varied from trust to trust and was inconsistent with trust activity".

This is demonstrated in the current HTL environment where there is a greater requirement for evidence-based practice, which is increasing workload (Alonso-Cerezo., 2009). Still, there is a dependence upon fewer, less specialised, and sometimes unregistered scientists, who lack mentorship from BMSST and rely more heavily on automated investigations (Chaffe *et al*., 2014; Osaro and Chima., 2014; SHOT[2]., 2019). The UK TLC identified this, where:

- 38.5% of HTL staff lacked any formal transfusion qualification
- 34.9% of laboratories may have no staff with transfusion qualifications working on a given day
- Greater than 50% knowledge and competency assessment was only achieved by 16% of HTL staff within the previous 12 months
- 62% of laboratories had agreed their 'ideal' staffing levels and skill mix, however, 12.4% state the plan is in progress
- 33% of laboratories have staff that work an extra 20 hours per week to address the shortfall in staff

(Taken from SHOT[2]., 2019)

The annual SHOT report captures reductions in capability of HTL and its impact on patient care. SHOT is an independent, professionally led hemovigilance scheme, which collects and analyses anonymised information on adverse events, reactions and near misses related to UK blood transfusion (SHOT[1]., 2017). Data identifies trends in national transfusion service capability, where the most recent report identified reductions through increased errors reported (Serious Hazards of Transfusion Steering Group., 2021). It should be noted that there was an increased capability to prevent more serious events, seen by an increased level of reported near misses (Serious Hazards of Transfusion Steering Group., 2021).

*There was no report that specifically focused on the provision of blood transfusion.

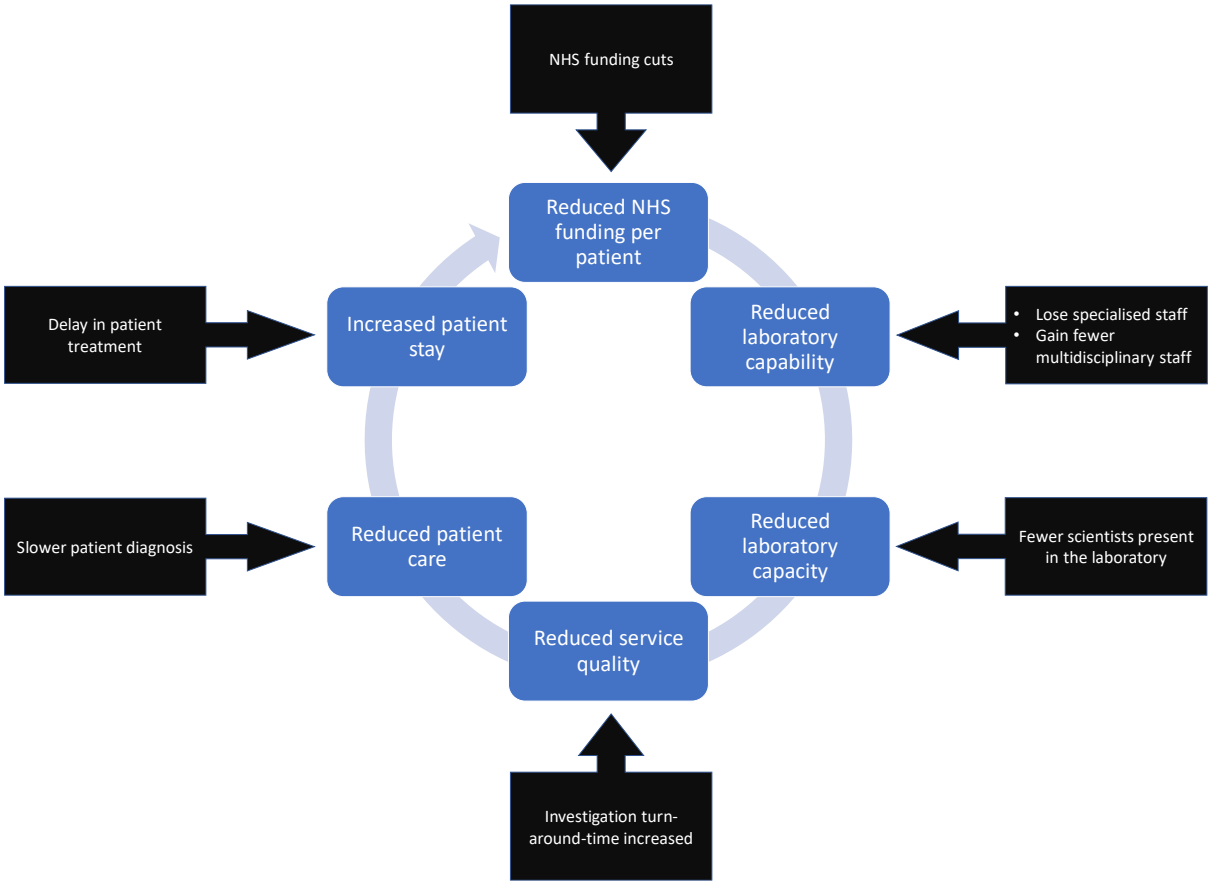


Figure 1-1: The impact of NHS funding cuts upon patient hospital stay.
1) Reduced NHS funding per patient results in the replacement of higher band, single specialism senior scientists with fewer, newly qualified multidisciplinary scientists. 2) Fewer scientists working across multiple areas of hospital pathology at the same time leads to a reduction in the laboratory's capacity. 3) A reduced capacity impacts on result turn-around-time and service quality. 4) Slower diagnosis of a patients' condition results from a reduction in service quality. 5) Slower diagnosis causes a delay in patient treatment, increasing their stay in hospital. 6) An increase in the time the patients stay in hospital increases the financial burden for the hospital. 7) Increased financial burden further reduces hospitals' funding per patient.

1.4.3 Automation and Laboratory Information Management System

Automation and an effective LIMS support the capability of laboratories and service quality (Alonso-Cerezo., 2009; Chaffe., 2014; Tzankov and Tornillo., 2017). In the HTL automated blood analysers undertake routine sample investigations e.g. blood grouping and antibody screening (Milkins *et al*., 2013). The analysers are mechanical instruments programmed to investigate blood samples and electronically transfer results to an organisations LIMS (Milkins *et al*., 2013; Jones *et al*., 2014). Patient identifiers on samples e.g. barcodes, link results automatically with the patient's electronic file, removing risks of transcriptional errors (Milkins *et al*., 2013). The LIMS assures that incompatibilities between patients and blood products are not mistakenly overlooked, by restricting release that would cause adverse events e.g. blood group incompatibilities (Milkins *et al*., 2013). The improved level of quality introduced to blood product issue because of automation and the LIMS is reflected in national guidelines (Milkins *et al*., 2013). They recommend blood can be provided without physical

investigation, instead, by electronic issue (EI), where, so long as all the guideline criteria are met, eligibility is determined by an organisations LIMS (Table 1-1) (Milkins *et al*., 2013).

Table 1-1: Eligibility criteria for the provision of blood by electronic issue.

Factors	1. Having the recommended quality management system and laboratory processes in use. 2. Having LIMS control of the issue of blood components as recommended in the BSH IT guidelines. 3. The specific patient's transfusion and antibody history and serological status of the current sample.
Process	1. Testing and result entry of the group and antibody screen are fully automated. 2. Reagents, cells, and technology used for grouping and antibody screening meet the criteria as outlined in BSH pre-transfusion compatibility procedures in blood transfusion laboratories. 3. Samples and reagents are registered and identified within the analyser via a unique barcode or equivalent. 4. Results are transmitted electronically from the analyser to the LIMS. 5. The LIMS controls the suitability of patients and their samples for EI. 6. The LIMS enables permanent exclusion of patients from EI in the presence of antibodies of likely clinical significance. 7. The LIMS enables temporary exclusion of patients from EI, e.g. limited period exclusion for 3 months following transplantation of solid organs. 8. Stock entry of unique donation number, blood group, component code and expiry date from the unit(s) is by barcode reader or other electronic means.
Patient and Sample	1. Blood group interpretation on the current sample is identical to the historical record. 2. No manual amendments have been made to automated results. 3. The current antibody screen is negative. 4. The patient's group and antibody screen results are complete and fully authorised in the LIMS. 5. The patient does not have a previously known antibody of likely clinical significance. 9. Patient is not excluded on clinical grounds according to BSH pre-transfusion compatibility procedures in blood transfusion laboratories. 10. The current sample meets the sample timing and storage requirements detailed in BSH pre-transfusion compatibility procedures in blood transfusion laboratories.

(Taken from Milkins et al., 2013)

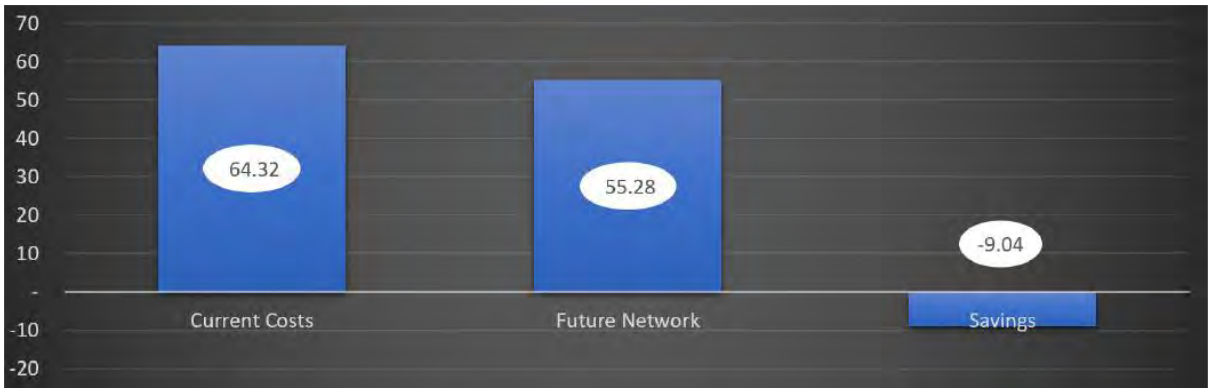
Even though HTL automation and the LIMS support capability and quality, increases in workload and reduced understanding by staff can still have a negative impact (Chaffe., 2014). If the number of test requests goes beyond capacity of the automated equipment, or, HTL scientists lack understanding of information systems, the capability of the laboratory suffers (Chaffe., 2014). Investigation delays will result, increasing turn-around-time of results and negatively impacts patient care (Figure 1-1) (Linsdell., 2017).

1.5 Pathology Networks – What are They?

Pathology networks are present throughout global healthcare and in many UK regions they have been established as part of the Pathology Modernisation Programme e.g. Viapath (Beastall., 2008; Lippi and Simundic., 2012). While some networks remain intact, others failed, a suggested cause being the lack of a designated appointment of individuals to drive their creation (Beastall., 2008). Laboratories from separate hospitals form a hub and essential service network that can employ a variety of different or identical testing methodologies (Carter., 2016; NHS Improvement[1]., 2017). This gives a network greater scope to meet general investigation requests required for patient diagnosis and have greater flexibility than a single laboratory to continuously improve the quality and efficiency of services (Beastall., 2008; Carter., 2016; NHS Improvement[2]., 2017). A hub and essential service model consists of at least one large hospital and many smaller ones to form a network (Figure 1-2) (Lippi and Simundic., 2012; NHS Improvement[1]., 2017). Networked laboratories can unify procurement of equipment, reagents, procedures, staff pool and accreditation under a single quality management system (Beastall., 2008). Larger hospitals act as a hub, having the capability and capacity to provide general and specialised tests that will be required (Beastall., 2008; NHS Improvement. 2017). Hubs undertake investigations for networked essential service hospitals, but smaller hospitals that form the essential service laboratories undertake a smaller range of critical investigations (Beastall., 2008; NHS Improvement[1]., 2017). Essential service laboratories ship samples to the network hubs and results are provided via the shared LIMS (Beastall., 2008).

Figure 1-2:An example of a hub and essential service network
The hub is classified with a red circle and the essential services are presented as green or yellow (outsourced public) circles, services are rationalised relative to the capacity and capability of the centre (Taken from NHS Improvement1., 2017).

Improvements to the quality of prevention and care, staff productivity and better procurement are suggested as benefits of increased efficiency of the delivery of healthcare (Beastall., 2008; Darzi., 2008; Carter., 2016). NHS Improvement has been working with pathology service providers to collect data to understand how to optimise delivery of better value, high quality care for patients (NHS Improvement[2]., 2017). This has led to the publication of how 105 individual pathology services within NHS England will form 29 networks, consolidating those who must work together to deliver services (NHS Improvement[1]., 2017). NHS Improvement and the Carter report present the financial benefit of networks, but also highlight the importance of good IT provision and standardisation of test requesting (Figure 1-3) (Carter; 2016; NHS Improvement[2]., 2017; Royal College of Pathologists[3]., 2017).



Cost of Current Ops	Cost of Hub Future	Cost of Referrals to Hub	Cost of Spoke Labs	Cost of Consolidated Service	Consolidation Saving
29,066,465.00	26,274,166.00			26,274,166.00	2,792,299.00
5,547,000.00		3,445,717.17	1,561,932.60	5,007,649.77	539,350.23
15,006,749.88		8,522,273.80	3,152,150.87	11,674,424.67	3,332,325.21
5,741,000.00		3,488,667.13	1,450,182.27	4,938,849.40	802,150.60
8,957,000.00		5,656,717.67	1,729,822.19	7,386,539.86	1,570,460.14
64,318,214.88	**26,274,166.00**	**21,113,375.77**	**7,894,087.93**	**55,281,629.70**	**9,036,585.18**

Figure 1-3: An example of the financial benefit of a proposed pathology network.
Original cost was ~£64 million and is proposed to drop to ~£55 million, saving ~£9 million.

1.6 The Impact of Pathology Networks on Transfusion Services in England

1.6.1 What was Expected from Pathology Networks

Networks allow benefits from the economy of scale, collaboration, and workforce planning (Beastall., 2008). No alterations in access to investigations from the implementation of the 29 new networks was suggested, as core services would remain in hospital laboratories (NHS Improvement[2]., 2017). Implementation was identified to deliver faster patient care and outcomes through better utilisation of clinical expertise; more advanced and reliable techniques; as well as equipment e.g. genetics based (Carter., 2016; NHS Improvement[2]., 2017). Delivery of the networks were highlighted to lead to savings of 200 million pounds by 2020-21 (Carter., 2016; Lishman., 2017).

Pathology networks established hospitals that were required to refer their transfusion workload to a networked HTL. Reductions in workload for the referring HTL could result in downsizing or closure, leading to a decrease in BMSST numbers (Osaro and Chima., 2014). Even so, efficiency and quality improvements that national collaboration and coordination of services offers were recognised (Carter., 2016). If planned inadequately, a negative impact on service capability and quality for both the referring and networked hospital may have been observed (Lippi and Simundic., 2012). Networked HTLs required structured capacity planning if they were to support increased workloads and added risks of inter-hospital sample transportation (Lippi and Simundic., 2012).

1.6.2 An update of Pathology Networks – 2018

In 2018 an update highlighted that since starting the implementation of the 29 pathology networks there was a high level of engagement (91%) and almost as high-level agreement on a local partnership operating model (80%) (NHS Improvement[3]., 2018). Even so, a considerable amount of variation had been shown in terms of pay and non-pay cost (NHS Improvement[3]., 2018). Hospital size and the type of speciality did not have an influence on this finding, but it was thought to be linked to best practice and innovative ways of working (NHS Improvement., 2018). For blood sciences, which would likely include transfusion, maximum efficiency was suggested to be achieved if the hub was central to the network (NHS Improvement[3]., 2018). This resulted from a central location having a higher concentration of workforce, but only when blood sciences had more than 50% direct access activity of the total pathology workload (NHS Improvement., 2018).

1.6.3 An update of Pathology Networks - 2019

In a 2019 update engagement with NHS Improvement and NHS England remained high (97%) and agreement on a local partnership operating model had continued to be achieved (84%), however concerns were highlighted for the number of networks that were on track (76%) (NHS Improvement and NHS England., 2019). Even so, positive impacts relating to network formation were being identified with an average cost per test drop by 20% and contractual savings of as much as £18 million over 5 years through joint equipment purchase (NHS Improvement and NHS England., 2019). As well as financial savings, staff shortages had been tackled through greater access to a wider pool of consultants, and in particular to blood transfusion adoption of a new approach to training, recruitment, retention and adopting new technologies (NHS Improvement and NHS England., 2019)

1.7 Red Cell Immunohaematology and its Future in Pathology Networks

RCI is an ISO15189:2012 and ISO13485:2016 accredited reference service, provided nationally through 7 laboratories and supported by Medical and Clinical Scientist Consultants (ISO., 2012; ISO., 2016; Winfield., 2022). HTLs are mandated to be accredited to ISO15189:2012, RCI also has ISO13485:2016 accreditation allowing it to produce reagents (NHSBT., 2018). These are used by RCI, other UK transfusion services and by HTLs e.g. antibody screening cell panel (Winfield., 2022). RCI are accredited to undertake testing that is also performed by the HTL (Table 1-2) (Winfield., 2022). RCI scientists are trained to undertake more detailed investigations of patient samples, as well as provide advice to support the HTL when they are unable to obtain results required to select

blood products (Table 1-2) (Winfield., 2022). RCI investigations can be more time consuming and hands on per case, than those in the HTL (Winfield., 2022). HTL scientists could undertake these investigations with the availability of the correct equipment, consumables, and training (Anonymised Stakeholder Interviews., 2017). Even so, the RCI service is important to the HTL because there are very few cases relative to an individual hospitals' daily workload where more detailed investigation is required (Anonymised Stakeholder Interviews., 2017). If the HTL scientist's focus was drawn to investigate these 'troublesome' samples, there would be a negative impact on the laboratory's ability to turnaround its routine investigations, impacting patient care (Anonymised Stakeholder Interviews., 2017).

Table 1-2: Differences in transfusion laboratory techniques undertaken at the hospital and red cell immunohematology

Technique	Identifies/purpose	Undertaken by
ABO Rh and K group	ABO group, Rh and K phenotype	Hospital and RCI
Antibody Screen	The presence of a RBC antibody	Hospital and RCI
Antibody Identification	RCI antibody specificity	Hospital and RCI
Crossmatch	Compatibility between blood product and patient	Hospital and RCI
Monospecific direct antiglobulin test	The presence and class of antibody on the surface of the RBC in the patients' circulation as well as the presence of compliment	Hospital and RCI
D positive flow cytometry	The presence of D positive cells in the circulation of a D negative women	Hospital and RCI
Elution	Removes antibodies from the surface of RBCs from the patient's circulation so specificity can be determined	Hospital and RCI
Antibody titration	Determines risk of HDFN, clinical significance of cold reacting antibodies or impact on solid organ transplant.	Hospital and RCI
Red cell phenotype	The RBC phenotype of a patient	Hospital and RCI
Electronic Issue	Issue of RBC units without bench work so long as criteria in Table 1-1 is met.	Hospital
Acid elution	The presence of RBC containing HbF in a patients' circulation	Hospital
Anomalous ABO and D investigation	A more detailed investigation to understand grouping issues – involves specialist grouping /serological reagents and genotyping	RCI
Allo/Auto Adsorption	Removes pan-reactivity to enable identification obscured clinically significant results	RCI
Continuous flow anti-D and c quantification	Measures the level of antibody in a patient's circulation relative to a clinical standard	RCI
Red cell genotype	The potential RBC phenotype of a patient	RCI
Drug associated haemolysis	The potential for drug treatment to cause haemolysis	RCI
Bi phasic haemolysin (Donath-Landsteiner)	Detects the presence of active haemolysins at 37°C but rely on cold temperatures to bind RBCs.	RCI
IgA deficiency	Investigation of IgA level and presence of anti-IgA	RCI

The role of reference services in pathology networks is not defined by NHS improvement, however, network introduction presents the opportunity for RCI to review its own service provision (Anonymised Stakeholder Interviews., 2017). RCI could identify novel service propositions that align with reduced expenditure and give the service greater integration with the HTL (Anonymised Stakeholder Interviews., 2017). Opinion was that the introduction of pathology networks will have an impact on the service RCI provides, potentially gaining work from some trusts who look for a third-party provider (Anonymised Stakeholder Interviews., 2017). There is a risk to RCI that larger hubs will begin to setup specialised services that compete with the RCI model (Anonymised Stakeholder Interviews., 2017). This risk is increased, as RCI does not currently offer a routine 24-hour service provision, but an on-call out of hours service, for an increased charge (Anonymised Stakeholder Interviews., 2017). The lack of IT connectivity between RCI and hospitals poses another risk, restricting industry norms such as electronic test requesting and reporting (Anonymised Stakeholder Interviews., 2017). The consensus is that RCI will resolve these issues, but potentially begin to make a move towards an advice service for networks, seeing testing occurring in the HTL, rather than the reference service (Anonymised Stakeholder Interviews., 2017).

1.8 Business Development

1.8.1 The Kano Model

The Kano model is a tool developed in 1984 by Noriaki Kano that can be used to understand the expectation that a customer has for a new service. (Verduyn., 2014; Harijith and Naduthodi., 2017; Tufail *et al., 2021)*. Attributes of a service are identified through understanding the customers wants and needs (Verduyn., 2014; Harijith and Naduthodi., 2017; Tufail *et al*., 2021). Assessment of attributes takes place by positioning them on the model against category ranges that are assigned to each axis (Figure 1-4) (Harijith and Naduthodi., 2017; Tufail *et al*., 2021). A level of fulfilment for the customer is assigned to the X axis, whereas the level of satisfaction is related to the Y axis (Verduyn., 2014). For the model to work well, it is critical to assign a third category within the model space, allowing a greater depth of understanding for the service attributes (Figure 1-4) (Tufail *et al*., 2021). The finished Kano model can be used to define basic attributes of the service, to attributes that are required to deliver a high-level service (Verduyn., 2014; Harijith and Naduthodi., 2017; Tufail *et al*., 2021). If basic attributes are not included in the service, this would likely cause customer dissatisfaction (Harijith and Naduthodi., 2017). Features of a higher-level service are not required for service implementation, and if not included, do not decrease customer satisfaction, but if included improve the perceived quality for the customer (Harijith and Naduthodi., 2017; Tufail *et al*., 2021). An example often used for the Kano model is that of a hotel service, where attributes related to a night's stay are defined on the model (Figure 1-4) (Winfield., 2019). Attributes of such a service will include must have features for the customer to be fulfilled e.g. Bed, mattress, pillows and covers (Figure 1-4) (Winfield., 2019). Additional features that improve the customers experience e.g. Tea and coffee making facilities and a shower (Figure 1-4) (Winfield., 2019). Attributes that delight the customer,

but are not critical for implementation e.g. Sea view, ensuite bathroom and free mini bar (Figure 1-4) (Winfield., 2019).

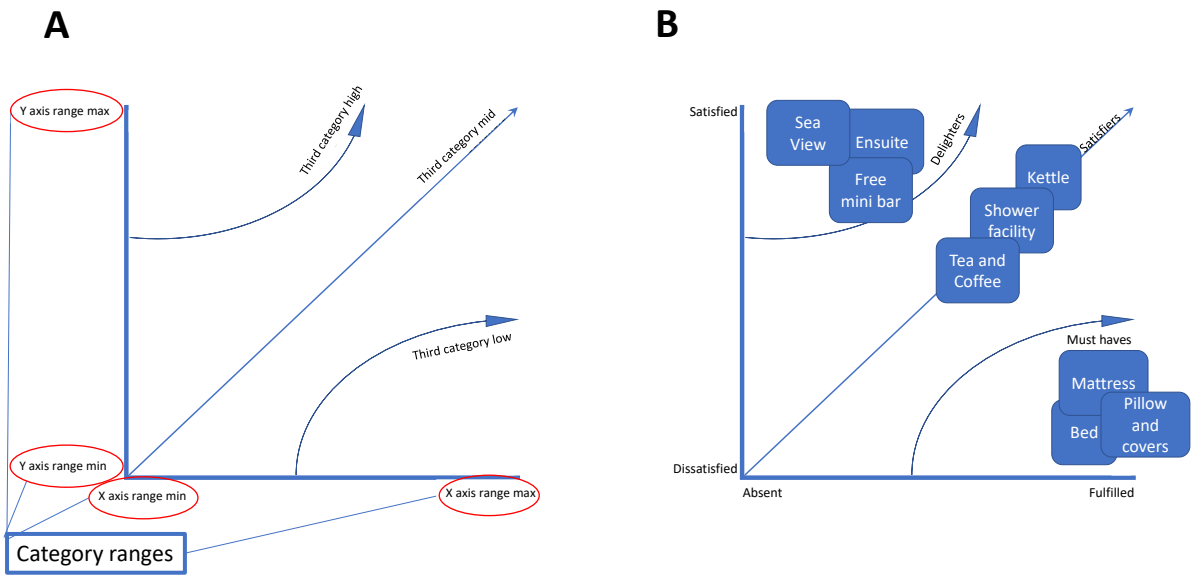


Figure 1-4: Basic representation of the Kano model and example
A) Category ranges are highlighted on the X axis and Y axis in red bubbles; the third category is present in the model space in areas defined by blue arrows. B) An example of a hotel service highlighting must have attributes that result in the customer feeling fulfilled, attributes that improve the customers satisfaction and attributes that delight a customer, leaving them completely satisfied with the service.

1.8.2 LEAN Startup

A Startup has been defined by Ries (2012; pp 17) as:

> "A human institution designed to create new products and services under conditions of extreme uncertainty"

LEAN is a set of principles originally introduced by Toyota and used by NHSBT to streamline manufacturing processes (NHSBT[1]., 2018). The principle is that a cycle is used to continuously improve and create value for the customer and minimise waste (NHSBT[1]., 2018). The cycle has five principles (1) Identify value from the customers perspective; (2) Map the value stream used to bring a product or service to the customer, identifying areas of value and non-value; (3) Establishing a flow that continuously produces for the customer; (4) That is pulled by customer need downstream in the process; (5) All carried out in the perfect way (NHSBT[1]., 2018) (Figure 1-5).

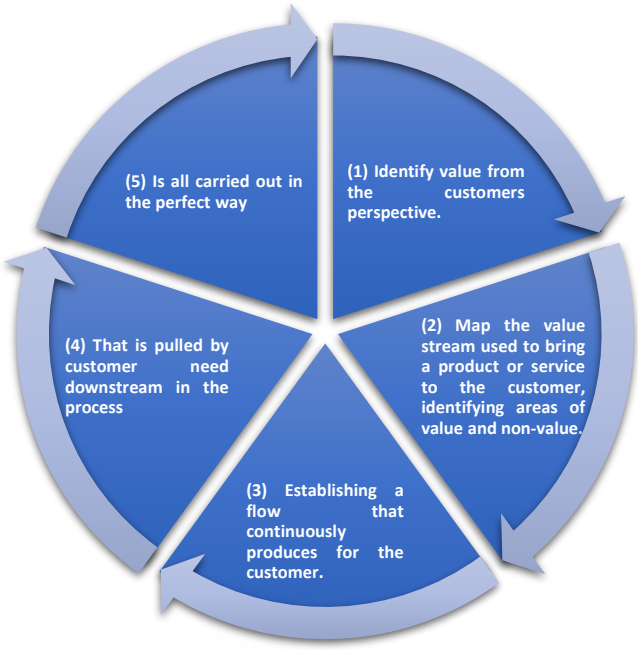


Figure 1-5: The five principles of the LEAN manufacturing
(1) Identify value from the customers perspective; (2) Map the value stream; (3) Establish a flow; (4) Controlled by pull downstream in processing; (5) Achieve perfection. Once the cycle is complete, continuous improvement can be achieved by moving repeatedly through the cycle to add further value (Adapted from the LEAN Enterprise Institute., 2018).

The aim of LEAN Startup is to streamline new ideas businesses wish to introduce to a market under conditions of extreme uncertainty (Ries., 2012; Hazell., 2017). LEAN Startup has been defined by York and Danes (2014; pp21) as:

> "An approach to entrepreneurial and innovative activities that emphasises placing resources into the creation of customer value, viewing all other activity as waste until a fit is found between the product and the intended market".

It draws on LEAN and other ideologies, such as Design Thinking and Agile Development, used for continuous innovation (Ries., 2012; York and Danes., 2014; Hazell., 2017; Lizarelli *et al*., 2021). LEAN Startup separates value from waste in a new idea, focusing on its development at a time of maximum flexibility, to understand and produce what customers really want (Ries., 2012). This negates a situation of poor fit, where an innovation is:

Designed → Built → Released → Customer doesn't want it → Innovation dream abandoned

(Adapted from Ries., 2012; Hazell., 2017)

Creating a system where the business:

Conceives an idea → Figures out what the customers want and what they will pay for → The final innovation is created and adopted quickly

(Adapted from Ries 2012; Hazell 2017)

Analogous to LEAN manufacturing, five principles guide the LEAN Startup philosophy, where: (1) Entrepreneurs are everywhere; (2) Entrepreneurship is management; (3) It is dependent on validated learning; (4) It relies on the creation of innovation through the Build-Measure-Learn loop; (5) Improved outcomes are achieved by Innovation accounting (Figure 1-6) (Reis., 2012).

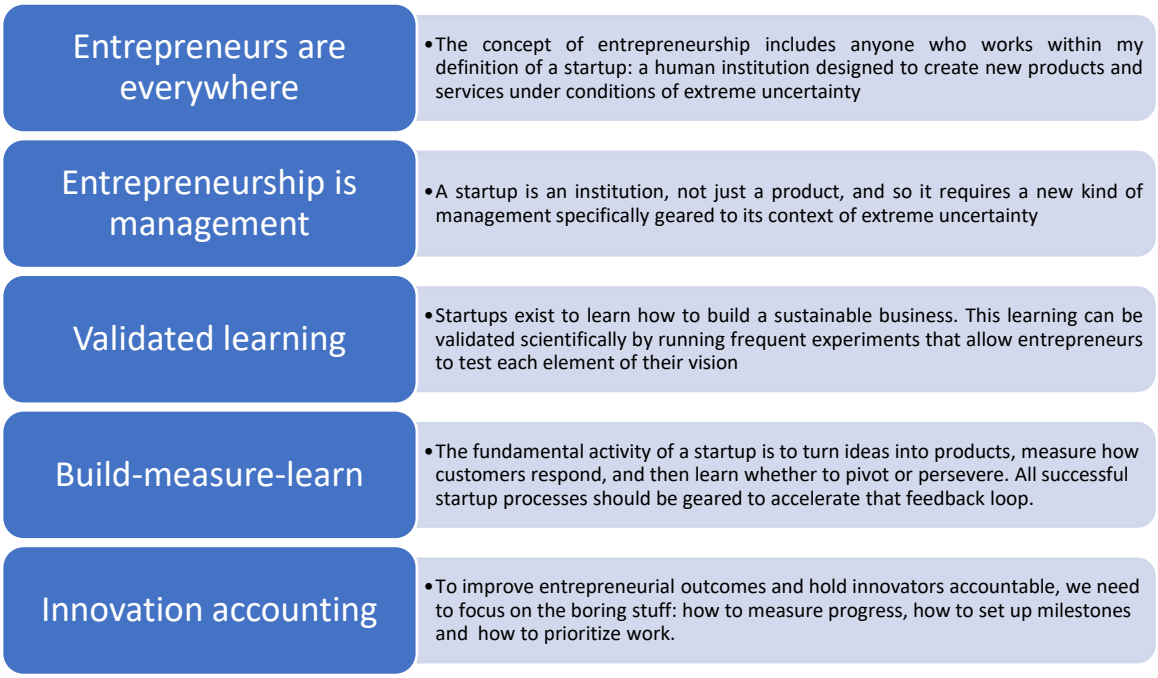


Figure 1-6: The five principles of LEAN Startup
(1) Entrepreneurs are everywhere; (2) Entrepreneurship is management; (3) It is dependent on validated learning; (4) It relies on the creation of innovation through the Build-Measure-Learn loop; (5) Improved outcomes are achieved by Innovation accounting (adapted from Ries., 2012).

Although all principles of LEAN Startup are important to its philosophy, the most important is the Build-Measure-Learn (BML) method cycle of idea development (Blank., 2013; Silva *et al*., 2013; Ries 2012). This is a cycle that resembles the plan-do-study-act (PDSA) method utilised in LEAN to undertake continuous improvement of manufacturing processes (Figure 1-7) (Blank., 2013; Silva *et al*., 2013; Ries 2012). Both are simplistic methods allowing the progression of ideas (persevere) with the option to continuously improve them if necessary (pivot) (Reis., 2012; York and Danes., 2013; Hazell., 2017). Three stages make up the BML cycle, whereas four make up the PDSA (Silva., 2013). Both are utilised to design, test and analyse the effectiveness of an idea, which is measured by the level of value for the customer and reducing waste in the process (Ries., 2012). Being cyclic,

they have the potential to run continuously (Silva *et al.*, 2013). This is normally the case with the PDSA cycle, aimed at continuously improving processes, whereas the BML cycle has the potential to end if success is accomplished and a desired minimal viable product (MVP) is identified (Ries., 2012; York and Danes., 2013). Design of the MVP relies on customer consultation, potentially through repetition of the BML cycle (Ries.,2012). It is more likely that the BML cycle would continue to be repeated beyond the post launch phase of the MVP to continue achieving good market fit (Ries., 2012; Blank., 2013; York and Danes., 2013; Hazell., 2017).

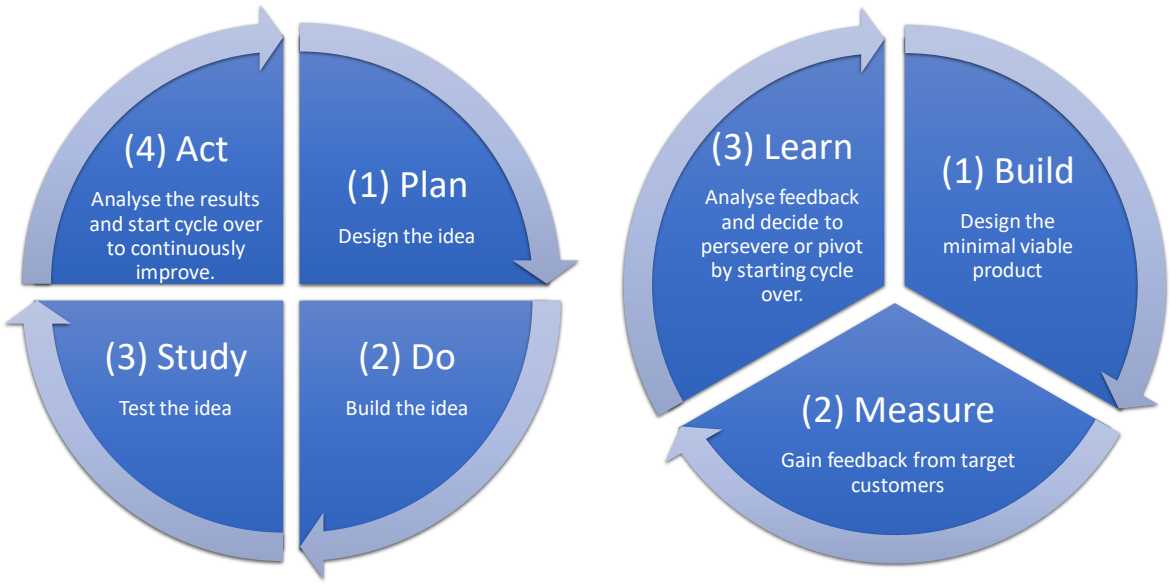


Figure 1-7: A side by side representation of the LEAN manufacturing PLAN-DO-STUDY-ACT cycle and LEAN Startup BUILD-MEASURE-LEARN cycle of continuous improvement.

1.8.3 LEAN Startup in the Healthcare Setting

LEAN Startup has been used across a range of business levels and sectors, from Startup enterprise, through to large established companies (Silva., 2013; Ghezzi., 2015; Yordanova., 2018; Euchner, 2019; Ghezzi., 2019; Shepherd and Gruber., 2020). The use of its principles has resulted in both success and failure, but general opinion is believed to be positive in the business community (Bieraugel., 2015; Edison *et al.,* 2015; Still., 2017; Ghezzi., 2019). For academic communities there is believed to still be a level of uncertainty for its usefulness in business development and future success (Ghezzi and Cavallo., 2020; Shepherd and Gruber., 2020; Lizarelli., 2021). More generally, LEAN Startup has been used in the software development community where rapid changes can be made to code and trialled (Neyem *et al.*, 2016; Risso *et al.*, 2016; Ghezzi 2019).

There is little evidence for the use of LEAN Startup in the healthcare setting, and as such can be considered novel for the provision of new services (Blank., 2013 York and Danes., 2013; Hazell., 2017). A review of the literature identified that LEAN Startup had only been used to develop and implement three new services in the healthcare setting (Hazell., 2017). One service was unsuccessful due to the projects inability to meet regulatory requirements (Nirwan and Dhwanto., 2014; Hazell., 2017). Two services were successful, seeing the implementation of a cloud based mobile system to support patient monitoring (Neyem *et al.*, 2016; Risso *et al.*,

2016). The level of output of healthcare related services resulting from the use of LEAN Startup is yet to be realised or understood (Silva *et al*; York and Danes., 2013; Hazell., 2017). Its use has the potential to allow faster service development, which meets the customers' needs more efficiently and has a greater chance of being effective (Silva *et al*., 2013).

1.8.4 The Business Model Canvas

Several definitions have been provided to explain a business model (Pourabdollahaian and Copani., 2014). Osterwalder and Pigneur (2010; pp14) describes a business model as:

> "A description of the rationale of how an organisation creates, delivers and captures value".

Tools have been developed to allow creation of a business model to better understand the dynamics of its products or services (value propositions) and the market it supplies (Osterwalder and Pigneur., 2010; Osterwalder *et al*., 2014). The business model canvas (BMC) is constructed from the nine building blocks defined in Table 1-3 and presented in Figure 1-8. These are populated to identify how a business creates, delivers, and captures value (Osterwalder and Pigneur., 2010).

Table 1-3: Definition of the nine building blocks that form the business model canvas

Building Block	Definition
Customer segments	No Company can survive without customers; they may be grouped in this area by common needs, behaviours, or other attributes. Once complete a company can decide which segments to serve and which to ignore allowing the business model to be designed around specific customer needs.
Value propositions	This is where products and services are laid out, which cater to the wants and needs of the customer segments. These can be innovative propositions, or they can be like those existing on the market, with extra components.
Channels	How the business interacts with its customer segments are documented here. These can be communication, distribution, or sales, but they are points of interaction that are important to the experience of the customer.
Customer relationships	This block outlines the type of relationship wanted between the business and the customer segments. Motivations for these relationships could results from them being already in place (retention), to gain more customers (acquisition) or to grow a market (upselling).
Revenue streams	The generation of cash from each customer segment is represented by this block and they can be generated from one-time customer payments or repeat payments (gated stages in a value proposition or continued customer support). The pricing scheme for the same value proposition may be the same (fixed) or vary (Dynamic) for each customer.
Key resources	Key resources are elements that are integral to value propositions, allowing customer contact, their design, creation, and delivery. Any company resources can be identified as key to a value proposition, whether they are physical, financial, intellectual, or human. Key resources can be owned by the company, leased, or acquired from key partners.
Key activities	These are akin to key resources but are actions undertaken by the company to operate successfully. The actions that form key activities can include production, problem solving, platform use or networking. Those viewed by the company will depend on the value propositions that company holds.
Key partnerships	This defines a company's supplier and partner network which is created for strategic, competitive and development reasons. This segment also identifies supplier relationships that are important to the company's business model. Identification of this network allows targeted interaction with the network to influence economy, reduce risk and uncertainty and acquisition of particular resources and activities.
Cost structure	Running the business model incurs costs from creation of value propositions, their delivery to customers, maintenance of relationships and driving revenue streams. Cost structures are viewed on a scale with one end defined by cost driven factors and the other by value driven

(Adapted from Osterwalder and Pigneur., 2010)

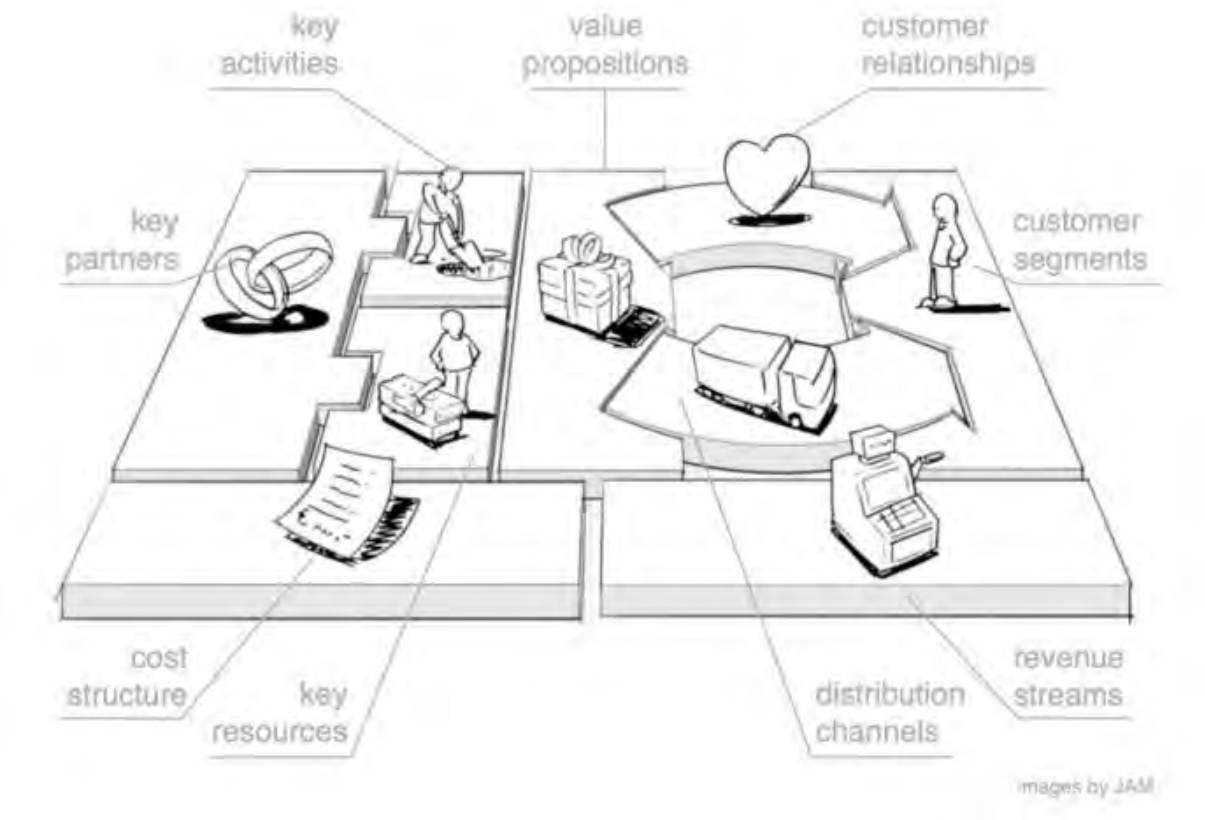


Figure 1-8: The Business Model Canvas
Constructed from the nine building blocks: Customer segments; Value propositions; Channels; Customer relations; Revenue streams; Key resources; Key activities; Key partnerships; Cost structure that are used to map out how an organisation creates, delivers, and captures value (Taken from Osterwalder and Pigneur., 2010).

1.8.5 The Value Proposition Canvas

The value proposition canvas (VPC) is paired with the BMC, expanding two of the nine building blocks to better understand how an organisation's value propositions meet the customer's expectations (Osterwalder *et al*., 2014). The value proposition and customer segment building blocks of the BMC are expanded to create the VPC, dividing each block into the three new segments defined in Table 1-4 and presented in Figure 1-9 (Osterwalder *et al*., 2014). Population of these segments allows a business to accelerate idea formation, in line with the customer's needs (Osterwalder *et al*., 2014; Hazell., 2017).

Table 1-4: Definition of the six segments of the value proposition canvas

Building Block	Segment	Definition
Value propositions	Products and services	A list of all the products and services that a value proposition is built around.
	Gain creators	How the product and services provide gains for the customer.
	Pain relievers	How the products and services alleviate pains the customer is experiencing.
Customer segments	Customer jobs	Customer descriptions of what they are trying to get done in their work activities.
	Gains	Good outcomes the customer wants to achieve, or they are seeking
	Pains	Bad outcomes, risks and obstacles related to the customers jobs.

(Adapted from Osterwalder and Pigneur., 2014)

A literature search found little published evidence for use of the BMC and VPC in healthcare. It is suggested that business modelling and identification of value propositions that are tailored to meet the customer's needs are crucial in a quick evolving sector such as healthcare (Pourabdollahaian and Copani., 2014). There is the potential for these tools to be used to map the RCI business and develop new service ideas that are tailored to meet the needs of the HTLs that form networks in the NHS England.

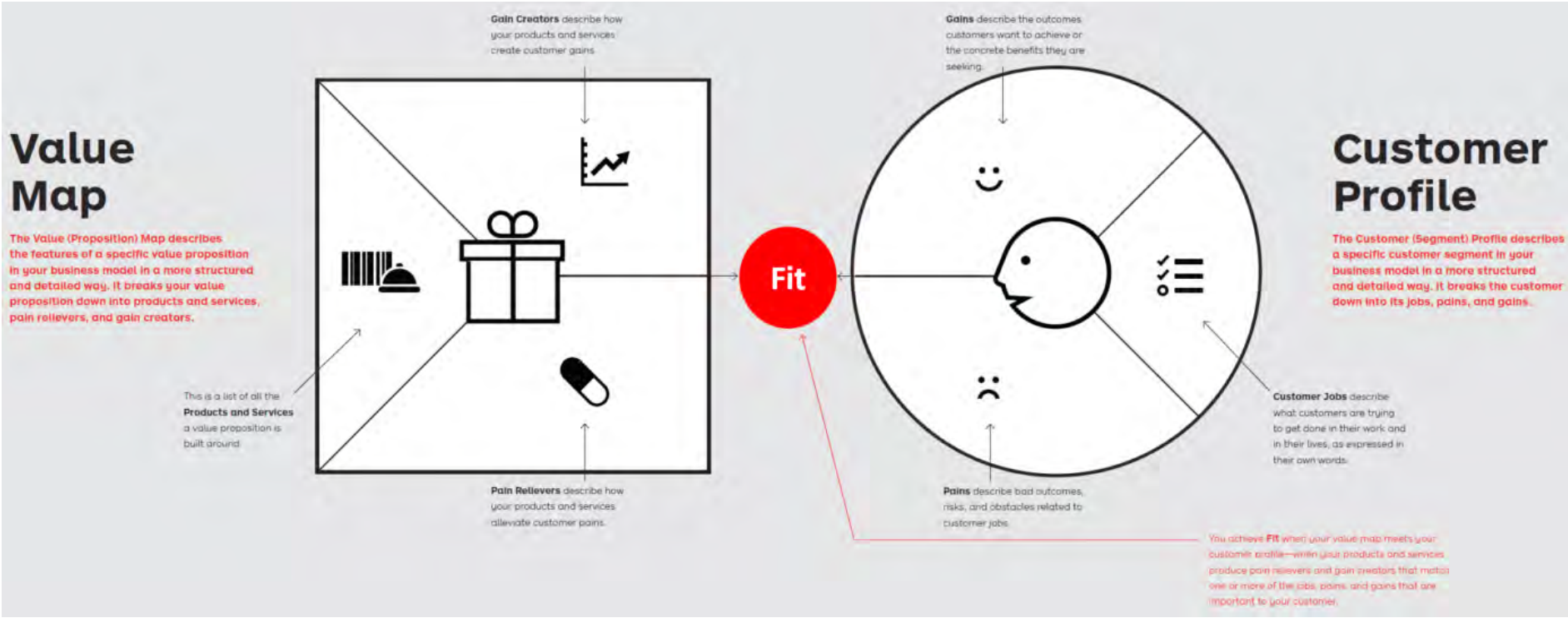


Figure 1-9: The Value Proposition Canvas
An expansion of the Value propositions and Customer Relationships blocks of the Business Model Canvas. Both blocks are further segmented to map the fit of the products and services created with the customers profile by comparing the customers pains and desired gains to the products pain relievers and gain creators (Taken from Osterwalder et al., 2014).

1.9 Summary of Key Points in the Introduction

The changing environment of the pathology services in the NHS has been presented, with a focus on the impact on the HTL environment and the introduction of 29 pathology networks in England. It is not clear how the RCI reference service fits into these new pathology networks, however, they are viewed by the reference service as an opportunity for RCI to review its own service provision. It is suggested that the use of the BMC and VPC have the potential to map the RCI business and develop new service ideas. Combined with the principles of LEAN Startup, these services can be refined to better meet the needs of the wider NHS transfusion community and allow greater integration of RCI into the pathology network model.

Chapter 2 Principal Research Question and Aims of Thesis

2.1 Principal Research Question

Can RCI provide services beyond its traditional testing role, to the wider transfusion industry (using LEAN Startup)?

2.2 Aims of Research

The aims of the project were to:

1. Identify novel services that the RCI department could provide Hospital Transfusion Laboratories.
2. Develop novel services for RCI using LEAN Startup principles and methodology
3. Pilot novel services and identify criteria relevant to expansion beyond pilot e.g. cost.
4. Identify the benefits of the novel services to NHSBT; RCI; User (NHS/Private) and the patient

2.3 Rationale and Justification for the Research

The rational for this Professional Doctorate is that the healthcare environment has a high level of uncertainty due to its link to government funding and policies, population dynamics, disease status, treatment availability, desire, and cost (Martin., 2013; Fiorio *et al.,* 2018; Nilsen *et al*., 2020). For RCI, there is an increase in uncertainty due to the lack of inclusion of reference services in the planning and implementation of pathology networks (Cavanagh., 2021). Even so, Transfusion 2024 highlights a need for closer integrated partnership working between NHSBT and HTLs (Allard., 2021). This closer working could result from changes introduced through pathology modernisation that can drive a requirement from the HTL for the provision of new service themes beyond RCI's standard catalogue (Section 1.7). LEAN Startup was developed to support new service development in an environment of extreme uncertainty, but there is very little evidence to support its use in the healthcare environment (Section 1.8.2 and 1.8.3). This justifies the use of LEAN Startup principles in this Professional Doctorate to identify and develop new services for RCI beyond its traditional testing role. The findings will add to the limited body of evidence for the use of LEAN Startup principles in the healthcare environment.

Chapter 3 Methods

The following chapter describes the methods used to gain greater insight of the understanding that hospital partners had in relation to pathology modernisation, service development and related LEAN Startup tools. It also describes how LEAN Startup tools were used to create a business model that identified customer jobs and attributes of services that RCI could provide to assist in their resolution. Finally, it describes all other methods used for the generation of results documented in this thesis.

3.1 Project Ethics

To understand if the project required ethical approval the Medical Research Council/NHS Health Research Authority ethics tool questions were completed (Available at http://www.hra-decisiontools.org.uk/ethics/).

The questions were as follows:

- Are the participants in your study randomised to different groups? – NO
- Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved? – NO
- Are your findings going to be generalisable? – NO

Ethics approval was not required (Appendix 1)

3.2 Hospital Partnership Meeting

Hospital partners (Hospital Laboratory Manager (x5), Transfusion Lead (x1), Haematology Consultant (x1) and Consultant Clinical Scientist Trainee (HSST) (x2)) from five trusts attended a face-2-face meeting with members of the RCI department (Head of RCI (x1), National Process Improvement Manager (x1), Head of Laboratory (x1) and Consultant Clinical Scientist Trainee (x1)). The agenda for the meeting was to utilise the LEAN Startup and business model tools to understand how RCI could support hospital trusts with services beyond its current scope of provision.

3.2.1 Pre-Event data Collection

An online survey (Jisc., 2019) was created to collect data anonymously from hospital partners and RCI members invited to attend the hospital partnership meeting. The aim of the survey was to identify information related attendees' knowledge of the following categories:

- Pathology modernisation: NHS improvement's pathology modernisation project, the categorisation of the hospital the partner was employed with (Hub or Essential service), stage of implementation and how/by who it was being implemented.

- Hospital transfusion laboratory staffing: Ability of the hospital to employ/retain staff, as well as related problems and any actions taken to overcome difficulties.
- Understanding of RCI involvement in pathology modernisation: Opinion on RCI inclusion in models, perceived impact of pathology modernisation on RCI, scope and direction for new service development by RCI.
- Participant experience of service development: role undertaken, and difficulties experienced.
- Knowledge of LEAN Start-up.

Attendee opinion was gathered using polar questions (yes/no – some with don't know option); multiple choice questions (single answer, with 'other' option and multi-answer, with 'other' option).

3.2.2 Open forum discussion of new service development ideas

Service ideas identified in the online survey were defined as topics of open discussion for the meeting attendees. Meeting facilitators (Project Lead and National Process Improvement Manager) captured service-related attributes with sticky notes, then grouped them into potential service themes for later discussion with the attendees.

3.2.3 The Value Proposition Canvas

The customer profile section of the value proposition canvas was used to identify additional service ideas that could be of value to a hospital partner. Attendees of the hospital partner meeting were asked to identify activities that they were trying to get done within their service alongside their daily laboratory case load that could be provided as a service by a third party. These were defined as customer jobs. Discussion then took place to identify any bad outcomes, risks, or obstacles (pains) related to the hospital partner's jobs and the benefits (gains) they were seeking from their completion. Conversation was initiated in the following order with the associated description of each section:

1. Customer jobs – What is the customer trying to get done in their work? What tasks, problem solving, and needs is the customer trying to accommodate? These may be critical or trivial.
2. Customer pains – The negative aspects for the customer when trying to complete their work and what they would like to avoid. Anything that annoys or troubles the customer (this can be before, during or after completing a job. Costs, emotions, and risks can be captured here. Information may be severe or light
3. Customer gains – The positive outcomes and benefits for the customer when they complete their work or that they would love to have. What would make it easier for the customer? Items identified may be required, expected, desired, or surprised by. Consider functional utilities, social gains, positive emotions, and cost savings. Items identified may be relevant.

(Figure 3-1)

All identified items were affixed to the relevant section on the value proposition canvas. Attributes that were identified during the discussion of the customer jobs that did not relate to the value proposition canvas were grouped with those identified in the open discussion (Figure 3-1).

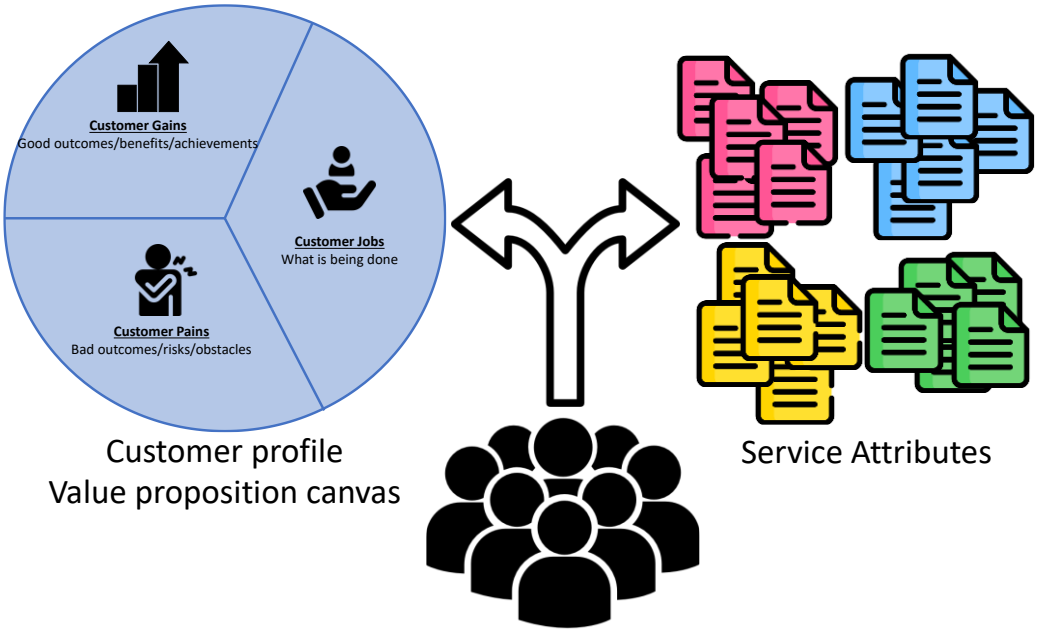


Figure 3-1: Overview of the VPC customer profile section completion in the hospital partnership meeting
Attendees of the meeting identified activities that they were trying to complete. These were written on sticky notes and assigned to the value proposition canvas.

3.2.4 Kano Model

The Kano model is used to understand the expectation that a customer has for a new service by placing attributes in positions relative to category ranges on each axis and a third scale within the model space (Section 1.8.1). Service attributes identified from the open discussion and customer profile section of the value proposition canvas were affixed to Kano models that related to identified service areas. Category ranges utilised to assess customer expectations of each service attribute were:

- Absent to fulfilled (X-axis)
- Dissatisfied to satisfied (Y-axis)

(Figure 3-2)

The third category assigned identified how critical the attributes were perceived by the meeting participants for a customer to take up a service with NHSBT RCI. These were categorised as:

- Must haves – these are attributes that a service can't do without
- Satisfiers – these improve the service use for the customer
- Delighters – these improve the customer perception of the service being offered but aren't necessary to provide the service.

(Figure 3-2)

The aim of this exercise was to give insight into what attributes must be included as part of a minimal viable service for a hospital partner. It also allows greater understanding of what attributes could be classed as additional items (satisfiers or delighters) that could be added extras in a service and provided at additional cost.

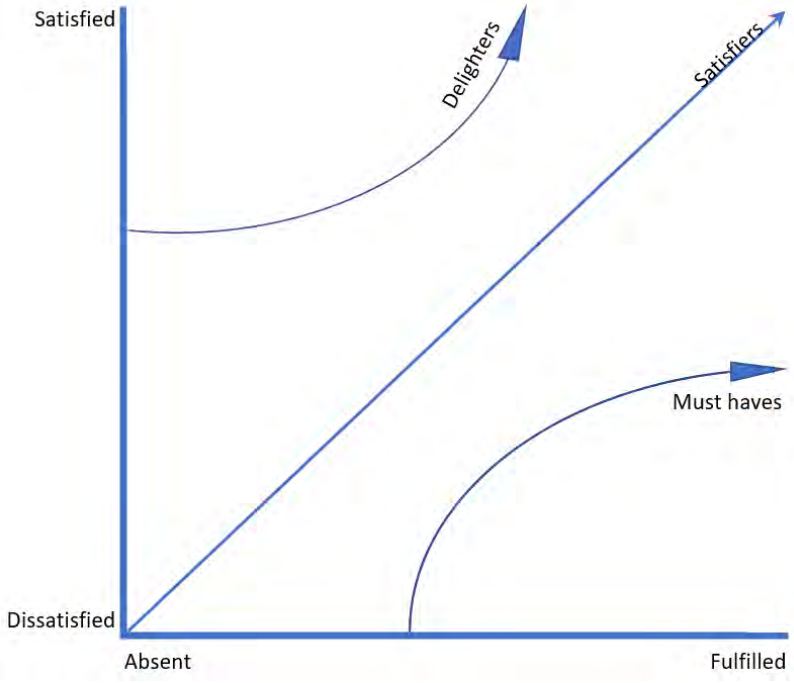


Figure 3-2: Representation of the Kano model used to define service attributes and customer expectation for their inclusion. Attributes were added to the Kano model based upon being defined on a scale of importance (X-axis – Absent to Fulfilled) or scale of customer satisfaction (Dissatisfied to Satisfied) and categorised into either Must haves, Satisfiers, or Delighters.

3.2.5 The Business Model Canvas

The BMC is used to summarise a business through the completion of its nine building blocks: Key partners; Key activities; Key resources; Value propositions; Customer relationships; Channels; Customer segments; Cost structure; revenue streams. Population of the BMC blocks allows the identification of how a business creates, delivers, and captures value (Section 1.8.4). In the hospital partnership meeting the BMC building blocks were discussed in the following order and conversation facilitated with the associated descriptions:

1. Value propositions – How RCI help; What is the value you are delivering to you customer? Which of your customer's problems are you helping to solve? What is the customer need that your value proposition addresses? What is your promise to your customers? What are the products and services you create for your customer?
2. Customer segments – Who RCI help; For whom are you creating value? What are the customer segments that either pay, receive, or decide your value proposition?

3. Customer relationships – How RCI interact; What relationships does each customer segment expect you to establish and maintain?
4. Channels – How they know RCI and how RCI deliver; How does your value proposition reach your customer? Where can your customer buy or use your products and services?
5. Key resources – Who RCI are and what RCI have; What are the resources you need to create and deliver the value proposition?
6. Key activities – What RCI do; What are the activities you perform every day to create and deliver your value proposition?
7. Key partners – Who helps RCI; Who are your most important partners? Which key resources do you acquire from partners? Which key activities do your partners perform?
8. Revenue streams – What RCI get; How do customers reward you for the value you provide to them? What are the different revenue models?
9. Cost structure – What RCI give; What are the important costs you make to create and deliver your value propositions?

Information from the discussion related to each block was captured on sticky notes and added to the BMC in the relevant location.

3.2.6 Post-Event Data Collection

An online survey (Survey Monkey®., 2019) was created to collect data anomalously from the meeting attendees. The aim was to identify:

- How beneficial/enjoyable/relevant attendees found the day.
- Should future service development take this form and if attendees would attend a future RCI service development day of this format.
- Areas for future service improvement related to patient care.
- Participant opinions (likes/dislikes/ease of use/future use) and participant understanding of the business development tools post event.

Attendee opinion related to questions was gathered using a scale scoring system (low/negative score = 1; high/positive score = 5) and where possible, free text fields to collect individual opinions (Appendix 2).

3.3 PESTLE Analysis

PESTLE stands for political, economic, societal, technology, legal and environmental. These topic areas were used to structure an analysis of factors that have the potential to impact a new service RCI could provide to a HTL (Parera., 2017). To undertake the PESTLE analysis, a remote meeting (Microsoft TEAMS) was held with the Head of Service for RCI. Microsoft Power Point was used to document factors, as well potential threats and opportunities related to each topic area of the PESTLE analysis (Figure 3-3). The aim for the output of the PESTLE

analysis was to allow the identification of opportunities and threats to a service; understanding of the environment of a new service and avoidance of failure by mapping factors related to the changing environment relating to the service provider and potential user (Parera., 2017). The completed output of the analysis was discussed with the service user following their agreement to take part in the research.

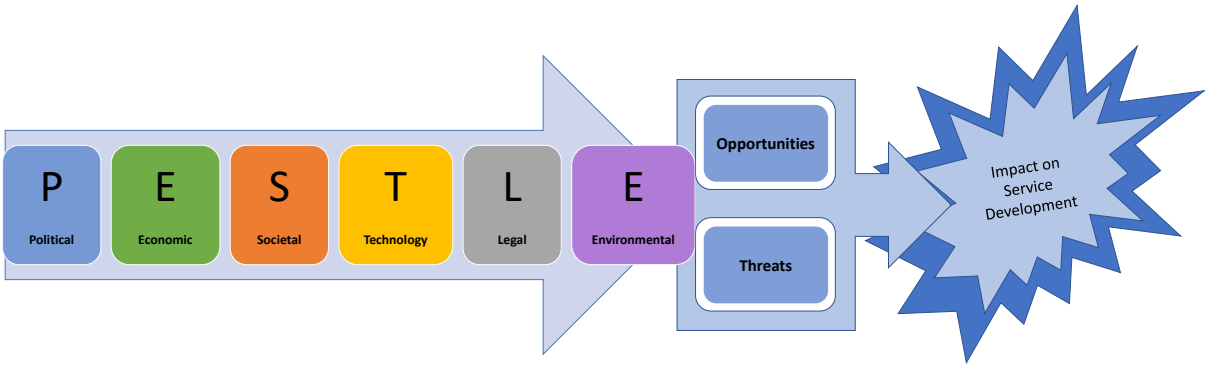


Figure 3-3: Political, Economic, Societal, Technology, Legal and Environmental (PESTLE) analysis.
This allows the identification of factors that have the potential to positively (opportunities) or negatively (threats) impact the provision of a new RCI service developed for a hospital transfusion laboratory.

3.4 Competitor analysis

During the development of a new service, it is important to undertake a competitor analysis to understand who is in competition with the service idea and what the competitor is offering their customer (Hatzijordanou *et al*., 2019). This gives a unique perspective for the service being created, allowing the service developer to include must-have components, as well as identify unique attributes that can be offered that will be of interest to the target market (Hatzijordanou *et al*., 2019). Competitors were identified via Google search.

For LEAN manufacturing training/implementation the following search terms were used: Medical laboratory; Support, Service, Consultant, LEAN, Continuous improvement.

For vertical witness audit the following search terms were used: Medical laboratory, Support service, Consultant, Audit, Assessment, ISO15189, BSQR, Operational impact group.

Following the search, information related to the companies that offered a related service was either identified on their website or they were contacted and engaged in discussion relating to the service they offered. The following information was recorded:

- Service overview
- Country of operation
- Company business type, size, and number of staff
- Target market
- Service price
- Service accreditation
- Bespoke service offering
- Post contract completion support
- Provision of resource materials and training
- Provision of an output meeting, summary report and summative or formative feedback
- Company market strategy
- Perceived market share
- Provides services that relate to the customer's service provision
- Employs HCPC registered scientists or equivalent

Any information provided outside of the defined criteria was documented as additional notes. From the information provided in the discussion, a threat level relative to RCIs new service provision was assigned to each competitor.

3.5 Identification of a Hospital Partner

Implementation of the project was impacted by the COVID-19 pandemic, limiting the pool of potential hospital partners to the Bristol region where the Project Lead was based. RCI were approached through the local pathology network by the Hospital Transfusion Laboratory Manager for the Bristol Royal Infirmary and Weston General Hospital. The Transfusion Laboratory Manager was new in post and was tasked as part of Pathology Modernisation to create a single transfusion service under a new trust banner - The Bristol Royal Infirmary and Weston Trust. This led to the request for support from RCI in this endeavour, as well as identifying areas of improvement for the current Transfusion service at the Bristol Royal Infirmary. Due to the fortuitous link between the request from the Transfusion Laboratory Manager and the Professional Doctorate, the Project Lead pitched the project idea, which was accepted with a material transfer agreement in place (Appendix 3).

3.6 The Value Proposition Canvas

The value proposition canvas expands the customer segments and the value proposition blocks of the BMC to allow greater understanding of how an organisation can meet the customers expectation (Section 1.8.5).

3.6.1 The Customer Segment

The customer profile section of the value proposition canvas was distributed to staff at the hospital partners' laboratory for a fortnight. Additional paper copies were supplied that could be taken away and completed.

The following instruction was given to the transfusion laboratory staff:

1. Identify current activities that needed to be completed alongside daily laboratory case load where support from a third party would be useful:
    - Write a description of the identified activity on the customer jobs section of the customer profile.
2. Identify any bad outcomes, risks, or obstacles the identified job causes in the laboratory:
    - Write a description of the identified items on the customer pains section of the customer profile.
3. Identify any benefits that would be achieved from the completion of the jobs:
    - Write a description of the identified items on the customer gains section of the customer profile.

Following completion, copies of the canvas were collected, and ideas collated. Discussion took place between the Project Lead, Hospital Laboratory Manager and Head of RCI to understand which jobs were perceived to be most important. All jobs identified were then assessed against those previously identified in the hospital partnership meeting for common themes (Section 4.1.3.1).

3.6.2 The Value Map

A meeting was held between the project lead and the Head of RCI to reflect on and discuss the items populated on the value proposition canvas – customer segment by the hospital partner. This allowed identification of counter items/services or products that alleviate problems (bad outcomes, risks, or obstacles) and deliver the wants for the customer.

3.7 The Business Model Canvas

The BMC is constructed from nine building blocks that are populated to identify how a business creates, delivers, and captures value (Section 3.2.5). The Project Lead and the Head of RCI held a meeting to discuss how the BMC related to the completed Value Proposition Canvas. Identified items were recorded on sticky notes and added to the relevant section of the BMC.

3.8 Miro Based Event

Miro (Miro©. (2022). Miro Board. Miro Enterprise. Miro.com) is an online visual collaboration platform that can be used as a space to bring project team members together virtually to co-create in real time using an infinite

canvas and its digital tools (Miro., 2021). Miro has built in templates, but also allows users to embed documents, paste in images, create tables, and add virtual sticky notes to content (Figure 3-4). This project was impacted by the COVID19 Pandemic meaning face-to-face meetings were not recommended by the UK government. Miro was used to hold team events related to service development.

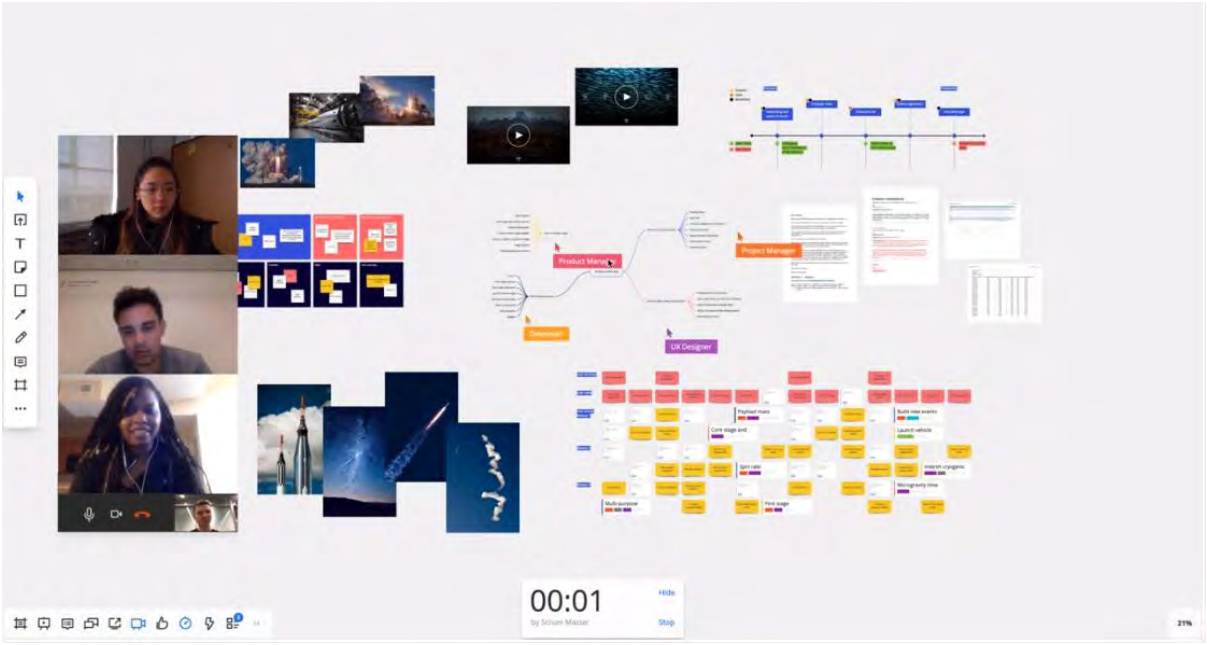


Figure 3-4: Example of a MIRO board (taken from https://miro.com/online-whiteboard/)

3.9 Vertical Audit Training and Execution Service

An online event to review current processes and create improvements to the HTL vertical audit service was chaired by the Project Lead and attended by the Hospital Transfusion Manager, RCI National Improvement Manager, NHSBT Quality Project specialist, Continuous Improvement Facilitator and the Operations and IT Manager IBGRL. The following methods describe pre-event data collection, event related activities and post event data gathering.

3.9.1 Process Mapping

The Project Lead, RCI National Improvement Manager and the Hospital Laboratory Manager reviewed documentation (copies not included) related to vertical audit (training and process) and mapped the current state by adding key steps to sticky notes and adding them to a board in sequential order. Each step was then given a criticality score, using a scale system (not critical to process = 1; critical to process = 5). A new process was then created during the online event. This was based upon the current process at the hospital partners laboratory but drawing on the experience of the process from NHS Blood and Transplant.

3.9.2 Historic Audit Output Review

A board was created that had three sections – What's good; What's not so good; and Areas for Improvement. The five most recent vertical audits performed were reviewed together by the Project Lead, RCI National Improvement Manager and Hospital Laboratory Manager. Items that were identified by the discussion were assigned to an appropriate section on the board.

3.10 LEAN Laboratory Service

An online event to understand and reduce waste in the HTL system was chaired by the Project Lead and attended by the Hospital Transfusion Manager, Hospital Senior BMS (x2), RCI National Improvement Manager, RCI Consultant Clinical Scientist, Senior Clinical Scientist (x3), RCI National Training Manager and Continuous Improvement Lead Specialist. The following related methods describe pre-event data gathering, event related activities and post event data gathering.

3.10.1 Process Mapping

The layout of the laboratory was documented, and maps created in relation to the following processes:

- Sample verification
- Work carried out using the laboratories automation
- Manual crossmatch was mapped, and data were collected

Data were collected relative to each process that included: Process start point; Process end point; Distance travelled in steps; Flow time; Touch time; How many people were involved in the process, Percentage yield (right first time – this was an estimate by staff); Number of interruptions; Work in progress (batch size/number of samples waiting); Problems/flow stoppers. Process mapping was repeated post event to understand areas of improvement.

3.10.2 LEAN Eight Waste Assessment

During process mapping of sample verification, automation and manual crossmatch, any observation of the following LEAN continuous improvement wastes was documented:

1. Transport – Moving items related to the process around unnecessarily
2. Inventory – Holding too many items or items are not available
3. Motion – People moving around more than required for the process
4. People – Individuals carrying out jobs that do not relate to their potential
5. Waiting – Process stalled because of external impact
6. Over production – Excess items or activity related to the process
7. Over processing – Additional activity performed that isn't required for the process
8. Defects – Rework, errors that must be put right, controls failures.

3.10.3 Failure Mode and Effects Analysis

Process steps where risk exists were identified through open discussion of the sample verification, automation, and crossmatch process maps and related data. These were documented and added as virtual sticky notes to the MIRO board. The event group scored each risk step on a scale of one to five for the impact the risk would have on the process (5 = high), the likelihood that the risk would happen (5 = likely) and the ease of detection of the risk (5 = no controls). A Failure Mode and Effect Analysis (FMEA) score was defined by multiplying the three scores together. Once scoring was completed the group brainstormed possible solutions to the risks and then repeated scoring each risk step with the possible solution in place. The FMEA score was repeated. The five top scoring risk steps were defined as items that must be considered as high priority for change in the new laboratory layout.

3.11 Service Development and Implementation Costs

A meeting to identify the activities that had been undertaken during the development and implementation of services with the hospital partner that could be charged for by a business took place between the Project Lead and Head of RCI. An excel spreadsheet was created to capture all related cost data (Figure 3-5). Activities identified were captured in column A and estimated time relative to each activity in column B. To capture multiple NHSBT employees that were involved in an activity, separate rows were created for an activity relative to the number of employees involved. Column C was used to capture the NHSBT employee pay band involved in the activity, allowing more accurate cost representation of each employee's time. The completed sheet was reviewed by the RCI Business Development Manager, who gave understanding and justification of activities and timings that truly reflected the service development and implementation undertaken. Final review took place by the Clinical Services Senior Commercial Accountant, who added columns (D, E, F, H and J) and formulae (Figure 3-5 and Appendix 4) to allow more accurate break down of employee pay band (top, middle and bottom of band scale) and formulae to calculate the total cost of the service development and implementation.

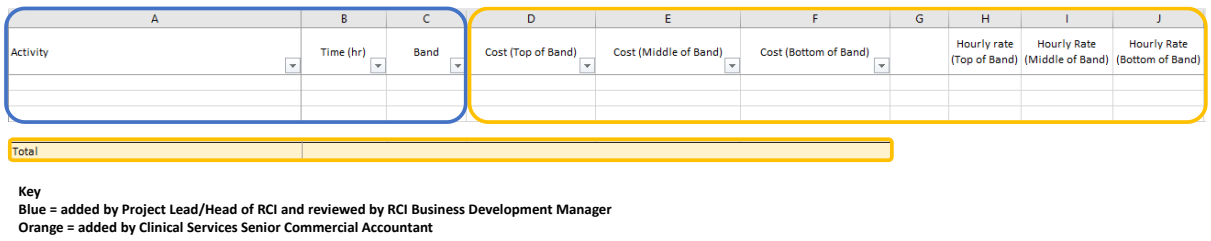


Figure 3-5: The spreadsheet used to capture data related to the cost-of-service development and implementation of services with the hospital partner.
The blue box represents areas where information was added by the Project Lead/Head of RCI and reviewed by the RCI Business Development Manager and the orange box represents areas where information was added by the Clinical Services Senior Commercial Accountant.

Chapter 4 Results

4.1 The Hospital Partnership Meeting

The hospital partner meeting was held to gain an understanding of the knowledge and experience of LEAN Startup principles in the transfusion/haematology discipline. Through open discussion and the use of service development canvases, it aimed to understand the types of services that could be provided to the wider NHS beyond the RCI department's standard provision (Section 1.7 and 3.2). Attendees were Senior Biomedical Scientists and Clinicians from NHS Blood and Transplant, Oxford John Radcliffe Hospital, Royal Cornwall Hospitals NHS Trust, Hull University Teaching Hospitals, North Bristol NHS Trust, Royal United Hospitals Bath NHS Foundation Trust, Barts Health NHS Trust, and The Royal Wolverhampton NHS Trust.

4.1.1 Pre-Event Data Collection – Survey Results

A survey was produced to collect data anomalously from the hospital partnership meeting invitees about pathology modernisation, hospital transfusion laboratory staffing, an understanding of RCI involvement in pathology modernisation, invitee experience of service development, and knowledge of LEAN Startup. Answers from questions relating to each category are presented in the following sections (4.1.1.1 to 4.1.1.5).

4.1.1.1 Answers Relating to Questions Focused on Pathology Modernisation

All participants of the survey were aware of the pathology modernisation project that was taking place across pathology services in NHS England (8/8) (Figure 4-1A). Most survey participants were employed at a Hub (6/8), but there was a minority employed by hospitals that provided essential services (2/8) (Figure 4-1B). Half of the survey participants identified that integration of the transfusion laboratory of their hospital had not moved beyond the planning stage (1/8 = not begun; 3/8 = in planning). One participant's laboratory was in the process of integrating with their network, and one had completed their integration. Two participants did not know what stage they were at related to integration at the time of the survey (Figure 4-1C). For the integration that was taking place, most participants identified that there was a designated person taking a lead role (5/8 = lead person in place Vs 1/8 = no lead person). Two survey participants did not know if there was a lead individual for integration of their laboratory into the local pathology network (Figure 4-1D). Where the lead person was known, knowledge of running a transfusion laboratory was identified as not essential by some individuals (3/5 had knowledge of running a transfusion laboratory, 2/5 did not) (Figure 4-1E). There was an even split for participants involved (4) Vs not involved (4) in the integration process at their hospital, one of which was the lead (Figure 4-1F).

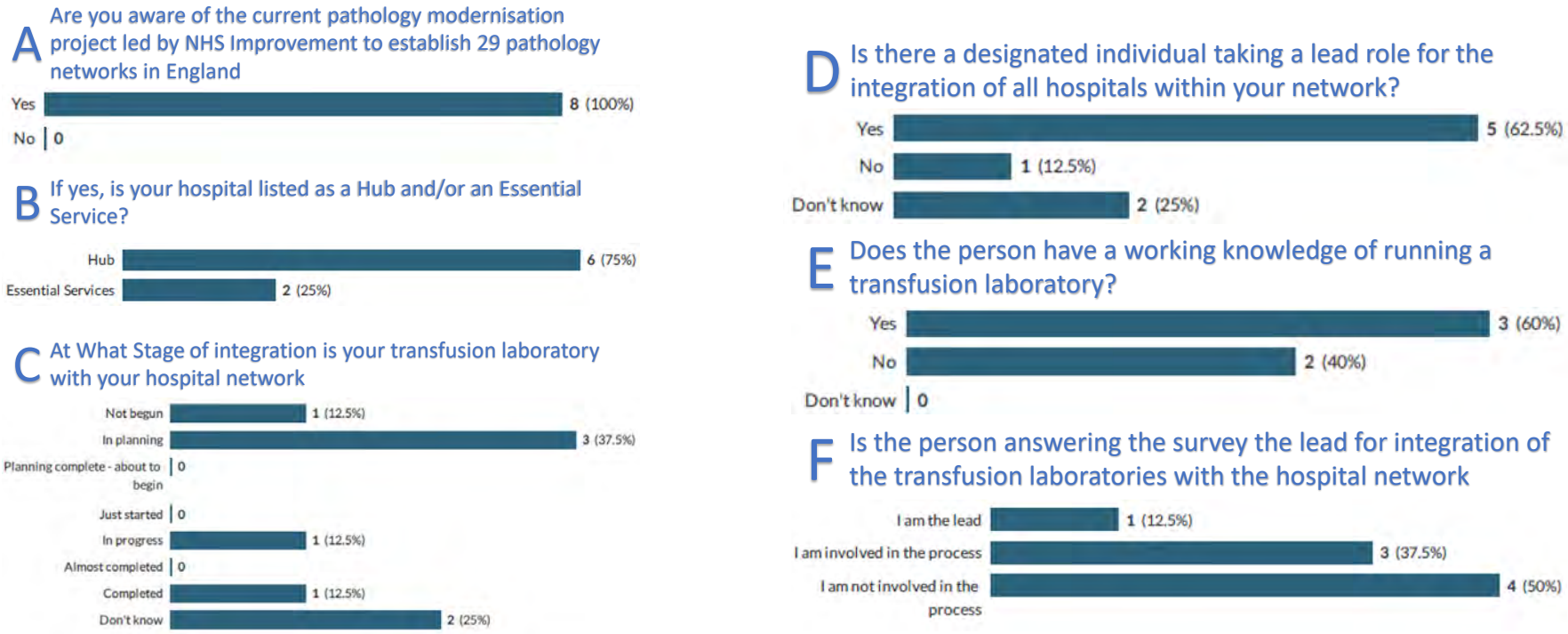


Figure 4-1: Summary of the pre-event data collection questions that related to the subject of pathology modernisation.
Eight invitees answered questions on – (A) Their awareness of the NHS improvement pathology modernisation project, all were aware;(B) The status of their hospital (B), six were a Hub, two an Essential Service provider; (C) The stage of integration with local network, one had not begun, three were in planning, one was in progress, one had completed and two did not know; (D) If there was a designated lead for the integration, five said yes, one said no and two did not know; (E) If the person had working knowledge of running a transfusion lab, three said yes, two said no; (F) If the person answering the survey was the lead for integration, one said yes, three said they were involved but not the lead, four said they were not involved in the process.

4.1.1.2 Answers Relating to Questions focused on Hospital Transfusion Laboratory Staffing

All hospital representatives completing the survey identified that there had been problems with recruitment or retention separately (2/8 and 1/8) or with both (5/8) (Figure 4-2A). Reasons for this were given as: Candidates do not meet the required skill set (7/8); The hospital location (4/8); Lack of scientific opportunities/career progression (3/8); Hospital speciality (1/8); Laboratory workload (2/8); Hospital size (1/8). Funding was not identified as an issue related to recruitment or retention of staff in the transfusion laboratory (Figure 4-2B). The actions that had been taken to improve recruitment and retention were: Employing locum support (3/8); Down grading the grade of the post advertised (2/8); Combining the post with another role (2/8); Offering current staff overtime to fill the gap (3/8). No hospital had disestablished an advertised post or been provided support for their service from another site (Figure 4-2C).

Figure 4-2: Summary of the pre-event data collection questions that related to the subject of HTL staffing numbers. Eight invitees answered questions on – (A) If their hospital had experienced difficulties recruitment and/retention of scientists, two had experienced issues with recruitment, one with retention and five with both; (B) Reasons for difficulties, seven resulted from candidates not meeting required skill set, four because of the hospital location, three due to a lack of scientific opportunities/career progression, one the hospitals speciality, two the laboratory workload and one the hospital size; (C) Measures taken to mitigate the situation were, three gained locum support, two downgraded the post level, two combined the post with another role, three offered current staff overtime.

4.1.1.3 Answers Relating to Questions Focused on the Understanding of RCI Involvement in Pathology Modernisation

Half of the participants of the survey did not know if RCI had been included in the planning of pathology networks, two participants felt they had been and two felt that RCI had not been included (Figure 4-3A). The perceived impact of establishing pathology networks on RCI was: Increased activity (2/8); Decreased activity (2/8); no change in activity (3/8). No one participant held the opinion that the introduction of pathology networks would change the type of referral that RCI would receive (Figure 4-3B). All participants felt that RCI could develop new services that could be used by the HTL (Figure 4-3C). Areas where these services could be created were Patient investigation (5/8); Quality support (2/8); Compliance support (2/8); Training (7/8); Education (7/8); Streamlining of processes (4/8) (Figure 4-3D).

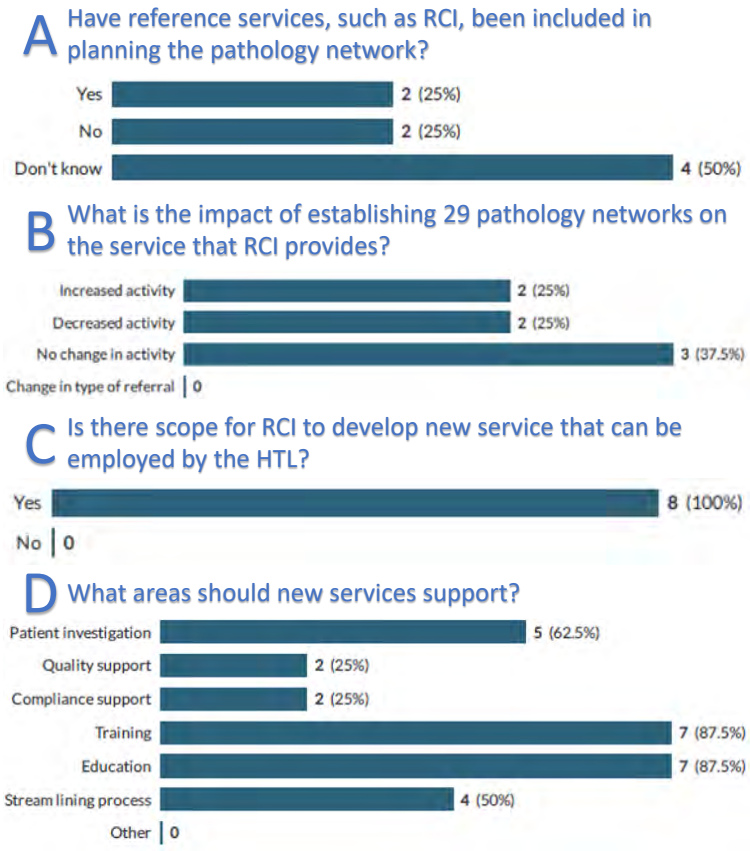


Figure 4-3: Summary of the pre-event data collection questions that related to the subject of RCIs involvement in pathology modernisation.
Eight invitees answered questions on – (A) Have reference services been included in the planning of pathology networks, two answered yes, two answered no and four expressed that they did not know; (B) the impact of pathology networks on the service RCI provides, two felt it would increase activity, two suggested it would decrease activity and four saw no change in activity occurring; (C) if there was scope to develop new services for the HTL, all eight agreed that there was scope; (D) what areas should new services support, five suggested patient investigation, two were quality support, two suggested compliance support, seven answered training, seven also education and four with streamlining processes

4.1.1.4 Answers Relating to Questions Focused on Participants' Experience of Service Development

A wide range of experience related to service development was observed, where some participants had experience of multiple types. Participants had been a project lead (6/8), Project contributor (5/8) and/or Service tester (3/8). One participant had no experience of service development (Figure 4-4A). Difficulties experienced when releasing a new or amended service included: Services(s) not meeting the customers requirement (1/8); being too expensive (1/8); there being a lack of trained individuals to deliver the service (1/8); not enough uptake of the service to maintain competency (1/8); there were various issues that were unique to the service (1/8); referring laboratories did not see contributing to the pilot as a priority (1/8) (Figure 4-4B).

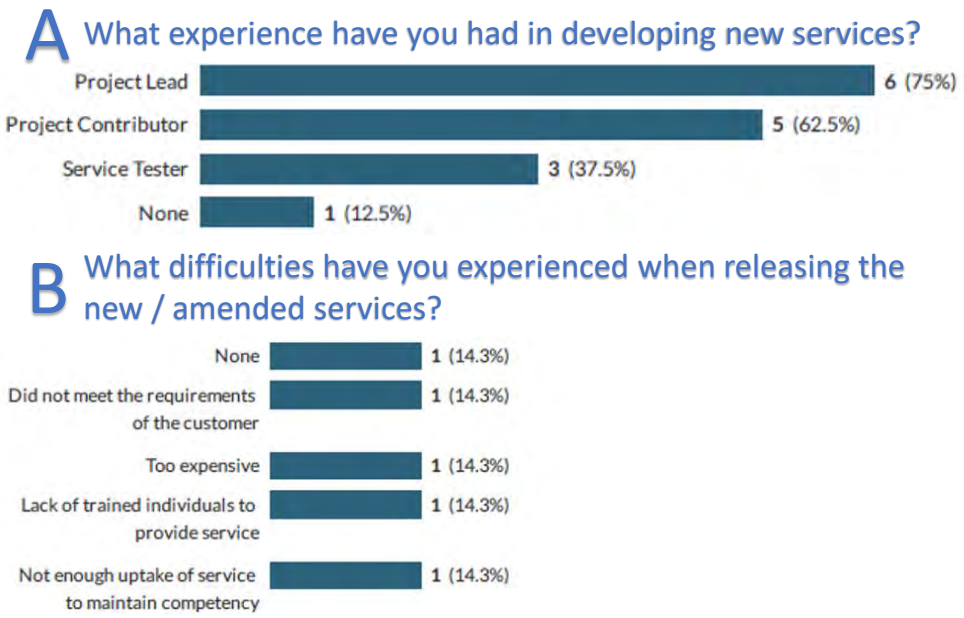


Figure 4-4: Summary of the pre-event data collection questions that related to experience of service development.
Eight invitees answered questions on – (A) What experience they have had in developing new service, six had been project lead, five had been project contributor, three had been service tester and one had no experience; (B) The difficulties they had experienced when releasing new/amended services, one had experienced no difficulties, one felt the service released did not meet the requirements of the customer, one felt it was too expensive, one had a lock of trained individuals to provide the service and one didn't have enough uptake of the service to maintain competency.

4.1.1.5 Answers Relating to Questions Focused on Participants' Knowledge of LEAN Startup

When asked about a current knowledge of LEAN Startup, participants felt they either knew of the tool, but not about it (5/8) or were confident they had an awareness (3/8). No participants felt they were fully conversant in LEAN Startup (Figure 4-5).

Figure 4-5: Summary of the pre-event data collection questions that related to the awareness of LEAN Startup. Eight invitees answered question a question on their awareness of LEAN Startup, five stated they knew of it, but not about it and three suggested they were fairly confident with their awareness.

4.1.2 Output from the Open Forum Discussion of New Service Development Ideas

Five main areas from the pre-event data collection survey were discussed openly with meeting attendees. The aim of this process was to identify attributes that could be included as part of service provision. A summary of the output is provided below.

4.1.2.1 Provision of Support to Hospital Hub and Essential Services Laboratories

All attendees felt it would be useful during pathology network integration to have a clear designated person within RCI that could offer support to the pathology hubs and essential service transfusion laboratories. This support could be via telephone, video conference or even face to face.

4.1.2.2 Provision of Educational Tools and Training

It was felt in the discussion that there are issues with the lack of practical transfusion experience and knowledge among new staff, however, this varied for each attendee's laboratory. Attendees considered educational tools to be an important area where RCI should be involved. Delivery of training materials was discussed, and the attendees identified the importance in the use of videos on specific topics, webinars for staff to join or having face to face sessions in the hospital. Examples of online tools were highlighted, such as Moodle, where all training is online. This was suggested to allow students to view resources such as videos and quizzes at a time that suits them and to ask questions to transfusion experts. The discussion identified that any training provided would need to be in bite size chunks, and where possible, rolled out on site in the hospitals or online. This would improve attendance by the HTL staff as it would overcome issues related to the release of staff to go off site or for long periods of time related to external courses.

4.1.2.3 Provision of Support for Audit Readiness and Other Quality Related Activities

All attendees felt it would be good to have RCI staff to support the HTL with performing audit activity as it would give an outside perspective of the HTL, improving their audit readiness for external accreditation. There were concerns raised by HTL attendees that quality support within the hospital is led by the haematology laboratory and any involvement would require their agreement. Attendees of the meeting from RCI supported this suggestion of assistance in audit, but this would be reliant on RCI staffing levels.

4.1.2.4 Empowerment of the Hospital Transfusion Laboratory with RCI-Centric Investigations

The range of investigations that RCI provide the HTL (Section 1.7) was discussed. A number of the tests provided by RCI were considered important enough for the HTL to provide e.g. adsorption and elution, but would require support from experienced BMSs who undertake these investigations as part of RCI routine work. The hospital attendees felt that the implementation of a wider range of tests to the hospital transfusion laboratory environment would empower the HTL BMSs, increasing their knowledge and training in the field of transfusion. The topic of remote interpretation of RBC antibody identification panels was discussed with mixed opinion. Many at the meeting believed scanning results to RCI for interpretation could cause a reduction in skill level within the hospital transfusion laboratory.

4.1.2.5 Implementation of LEAN Tools and Thinking into the Hospital Transfusion Laboratory

Discussion centred on how LEAN tools and thinking are not universally used or embedded in all hospitals. Not all laboratories carry out process mapping to see where the process is going wrong, or where wastes could be eliminated. LEAN thinking is widely used within RCI and is often learnt from those who carry out tasks frequently. Some hospitals are starting to do this, but all feel that RCI could help with introducing and embedding LEAN thinking, however, some attendees felt there were other service areas where support was required more urgently.

4.1.3 Hospital Partnership Meeting Value Proposition Canvas

This section highlights one half of the value proposition canvas – the customer profile, identifying customer jobs that could be provided as a service (Section 1.8.5 and 3.6.1). The jobs identified are described as service attributes, as well as the related pains they cause and gains that are made through their completion. To improve the ease in understanding of what was identified, information is grouped into themes in the sections detailed below e.g. Quality assurance and is also summarised in Figure 4-6.

4.1.3.1 Customer Profile – The Customer Jobs

Identified service attributes were grouped under related themes in the customer jobs section of the VPC:

- Quality assurance
    - Validation of processes or equipment
    - Completing a quality risk assessment
    - Writing documents or producing document templates
    - Capacity planning
- LEAN laboratory
    - Process map creation
    - Creating and monitoring key performance indicators
    - Formulating action plans and undertaking/overseeing their implementation
- Training
    - Basic training of transfusion laboratory staff
    - Create material for self-directed training of laboratory staff
    - Provide practical training of laboratory staff
    - Provide training on transfusion related scientific theory and clinical context
    - Maintain and sign off training records
    - Demonstrate the application of knowledge to transfusion related cases
    - Maintain staff portfolios for continuous professional development
    - Create material/infrastructure for competency assessment
    - Maintain staff competency records

Service attributes that could not be assigned to a theme were grouped as Other

- Mentor staff
- Provide staff induction to transfusion
- Provide training to standards of good laboratory practice

4.1.3.2 Customer Profile – The Customer Pains and Gains

With the service themes identified, the related pains and gains were defined and grouped in the relevant section:

<u>Quality Assurance</u>

Customer pains:

- Creating/identifying materials for validation e.g. scripts and samples
- Staff training to laboratory process

- A negative mental impact on staff
- The conflict caused between departments over quality related activity

Customer Gains:

- It increases the safety for the patient, laboratory staff members and the organisation
- Completion of quality assurance related activities contributes to compliance
- Completion of quality assurance related activities ensures there is a consistency for compliance

Lean Laboratory

Customer pains:

- Laboratory improvement activities feel forced upon staff
- There is a lack of understanding of how and why the laboratory must be made more LEAN
- There is no staff buy in to the process
- Having the time to create a LEAN laboratory is considered a luxury
- Undertaking LEAN improvement of the transfusion laboratory is seen as a concept, not a reality
- There is a lack of published evidence related to the process in a transfusion laboratory
- Staff need to be competent to undertake the process
- Its continuous

Customer gains:

- Undertaking LEAN practice in the laboratory will increase the efficiency in the laboratory processes
- There is likely to be related cost savings
- There will be a positive impact on quality in the laboratory processes
- There will be greater clarity of the processes being undertaken in the transfusion laboratory
- Standard work will be defined for the transfusion laboratory
- Undertaking LEAN will create evidence to support the practice and use in the transfusion laboratory environment

Training

Customer pains:

- Related processes are time consuming
    - Prepare material; assess material; encourage staff to complete; gain staff engagement in the process; demonstrate the effectiveness of the training
- No central platform available

- No time to develop a platform
- Lack of availability of materials
- Wasted resource training staff if they cannot be retained
- Don't have the right people with the correct knowledge to provide training
- Lack of motivation in the trainers to undertake training
- Lack of funding to provide training (staff time and consumables)
- Ensuring those who are training or have been trained meet the training requirement

Customer gains:

- The service is self sufficient
- Increases safety related to activities being undertaken in the lab and for products being issued to patients
- Creates a learning and sharing culture
- There is increased trust and assurance within the transfusion laboratory team, as well as with the service users
- More likely to retain staff if the training is of high quality
- Decreases stress as the training is being rolled out
- The laboratory environment is improved by the presence of trained staff
- Training that is managed well creates calm in the laboratory environment

Other

Customer pains:

- A lack of protected time for laboratory staff to undertake activities that are not sample investigation
- Programme design cannot suit all laboratory sizes
- Managing the expectation of the laboratory users
- No selection process to find the right individual for the work
- Defining skills for laboratory staff due to multidisciplinary rotation
- Having the freedom to act on results
- Standards that are related to the transfusion laboratory are restrictive
- A lack of availability of mentors for staff
- Loss of staff who can undertake required activities in the laboratory environment

Customer gains:

- Can break down barriers
- Allows better service provision

- Staff are better trained
- There is a bigger pool of staff for promotion
- Intra and inter departmental relationships are improved
- Allows for personal development
- There is better staff retention
- Staff feel valued
- Management of the laboratory (staff and workload) becomes easier
- Improved morale within the department

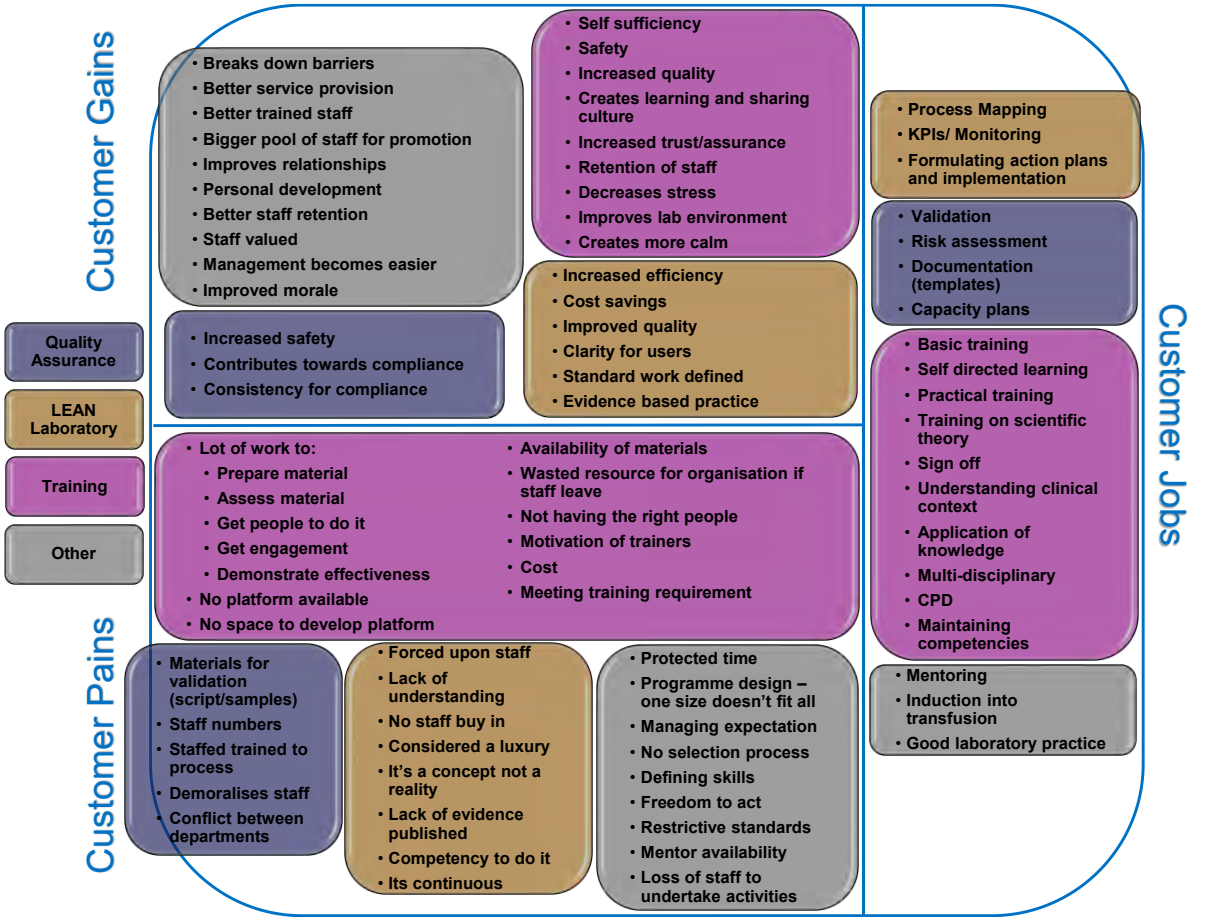


Figure 4-6: Customer half of the value proposition canvas completed in discussion with attendees of the Hospital Partnership meeting.
The three customer segments were used to identify the: i) customer jobs that are relevant to the attendees, ii) pains they cause, and iii) gains created when complete. A summary of the sticky notes that were identified by the attendees are grouped by their relationship to customers jobs (purple = quality assurance related theme; orange = LEAN laboratory related theme; iii) pink = training related theme; and iv) grey was used to group attributes that did not relate to an identified theme.

4.1.4 Hospital Partnership Meeting Kano Models

A Kano model was created for each service theme identified during completion of the customer profile of the VPC – Quality assurance; LEAN Laboratory; Training. Attributes identified in open discussion and during the customer profile creation were assigned to the associated themed Kano model to the agreed category – must

haves; satisfiers; delighters (Section 3.2.4). Information related to each Kano model is detailed in sections – 4.1.4.1 Quality Assurance; 4.1.4.2 LEAN Laboratory and 4.1.4.3 Training, as well as summarised in Figure 4-7.

4.1.4.1 Quality Assurance Kano Model

A service related to the delivery of quality assurance activities must have staff trained to perform validation of equipment, undertake capacity planning, risk assessment and the creation of document templates.

To create additional satisfaction in a service related to quality assurance, it would have to demonstrate increased safety, have a consistency in approach and maintain compliance. This would be achieved through shared practice and staff that are employed and dedicated to the service.

For the customer to be delighted in the service it would be provided by an external company that allowed centralisation of a panel of individuals to undertake related activities as well as create and manage a central library of documentation.

4.1.4.2 LEAN Laboratory Kano Model

The must have attributes identified for a service that provided a LEAN laboratory included: being able to perform process mapping and identify waste in the system; manage an event related to continuous improvement; deliver an output for the customer; check the output suggestion against current practice.

To achieve greater satisfaction for the customer the service provided would have to make the customer self-sufficient by embedding process mapping as business as usual, allowing the customer to undertake mapping of their processes. There would need to be the creation of savings and benefits at a greater than expected level, as well as improvement in activity related key performance indicators.

Delight in a service was suggested to come from process mapping being undertaken by an external multidisciplinary team. Sustainment of this process must occur to allow continuous improvement. Outputs from the provision of a service that provides LEAN related services must be published.

4.1.4.3 Training Kano Model

Must have attributes for training related activities includes delivery by a designated trainer, within a required time frame, with suitable materials, by following a pre-designed syllabus and a generic platform. The service must be affordable and provide assessment to demonstrate competency.

Greater satisfaction from a service would be achieved via the provision of training to maintain competency that integrates with professional bodies. Training completion time would be flexible but allow quick turnaround via the delivery of bite size training modules aimed at the release of staff for short periods of time. There would be

designated trainers for the delivery of material which would include pre-induction work, bench work (wet workshop), be multidisciplinary and create peer to peer interaction.

Attributes of a service that would delight a customer would be its provision at a minimal cost, through a virtual platform, which could be accessed across a range of devices that were accessible on-demand, from home as well as work. The service would provide accredited, multidisciplinary material for all learning levels and one-to-one access to trainers. Any learning completed would be recorded in a competency passport that would be accepted across NHS/private pathology laboratories.

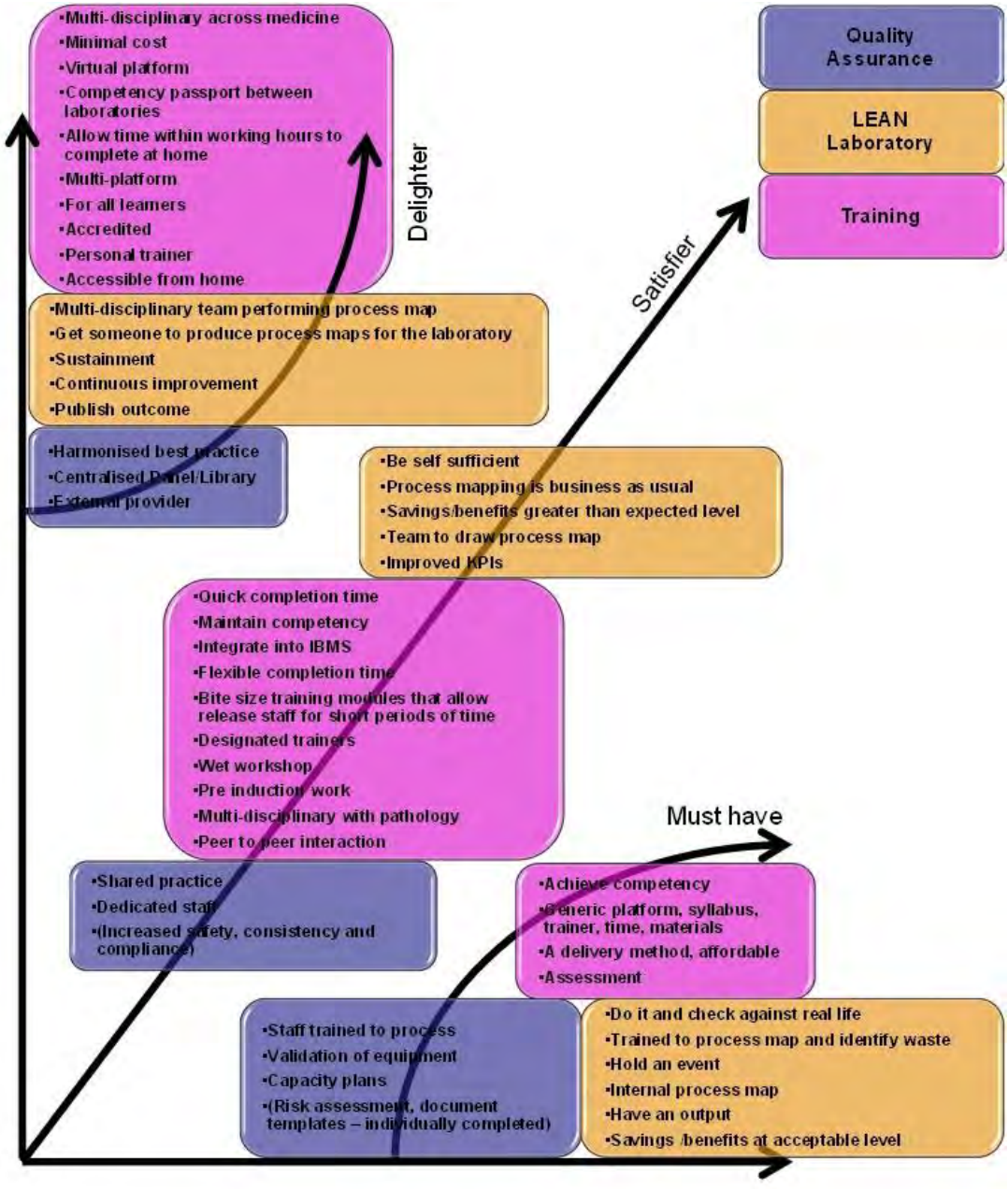


Figure 4-7: The Kano model with a summary of sticky notes that were identified in discussion with attendees. The categories – Must have, Satisfier and Delighter are used to define and position attributes along with the service themes Quality Assurance (purple), LEAN Laboratory (Orange) and Training (Pink) to group attributes on the model.

4.1.5 Hospital Partnership Meeting Business Model Canvas

Items identified in open discussion and during the BMC creation were assigned to the associated building block: Value propositions; Customer segments; Distribution channels; Customer relationships; Key resources; Key activities; Key partners; Revenue streams or Cost structure (Section 3.7). To improve the ease in understanding of what was identified, information is grouped into the building blocks in the sections detailed below and summarised in Figure 4-8.

Value propositions: There were three main themes identified in the value proposition session of the Hospital Partnership Meeting – Quality; LEAN; Training and education (Section 4.1.3.1). Attributes relating to these themes are not expanded here as they are already defined.

Customer segments: A wide range of customer segments were identified that the attendees of the hospital partnership meeting felt related to all the value propositions. These were:

- The RCI department
- Hospital laboratories (Hubs and Essential Services)
- Specialist Registrars
- Clinics and community-based services
- Accreditation bodies
- Support Staff
- Students
- Clinical trials units
- Universities
- Equipment suppliers

Distribution Channels: Attendees of the meeting felt that there were theme related components of this building block of the BMC:

- Quality service related – RCI and hospital laboratories would undertake this internally
- LEAN service related – This would be provided by RCI as a commercial bespoke venture that is on demand
- Training and education – This could be provided via a range of platforms that included: face to face, webinars, hard copy resources, software, Moodle, via facilitators, a laboratory based ‘wet workshop’, via email.

Customer Relationships: Attendees of the meeting also felt there were theme related components for this building block of the BMC, as well as components that were universal to all the value propositions:

- Quality service related – For laboratory staff this would be a continuous relationship, whereas medical staff would have an intermittent relationship
- LEAN – No relationships specific to a LEAN service were identified

- Training and education – This would range from a translational relationship to a partnership that would see trained staff able to move across organisational boundaries with their knowledge and competency
- All service themes – all services would require continual interaction between RCI and the HTL, clinics and the community; RCI and hospital labs with the accreditation organisations and trial units, this was perceived as a sporadic interaction; Equipment supplier relationship was identified as a relationship based upon demand.

Key Resources: This section was not expanded in the BMC session as the attendees felt that it had been covered in the Kano model session (Section 4.1.4).

Key activities: This section was not expanded in the BMC session as the attendees felt that it had been covered in the open discussion session (Section 4.1.2)

Key Partners: A wide range of key partners were identified that the attendees of the hospital partnership meeting felt related to all of the value propositions, these were:

- Accreditation bodies
- RCI and Hospital Laboratories
- NHSBT Quality Department
- Hospital Quality Managers
- NHS England (previously NHS Improvement)
- NHSBT Operations and Workforce Development Department
- IT (NHSBT and Hospital Trusts)
- Clinical Team (NHSBT and Hospital)
- Patient Blood Management Team
- Professional Bodies
- NHSBT continuous Improvement Team

Revenue Streams:

- All service themes could receive payment via the following suggestions:
  - RCI 60% fixed cost recharge and 40% cost per item
  - Hospital Training Budget/NHS England/Health Education England funding
  - SLAs for clinic/community services
  - Clinical trials – per trial contract
- The LEAN related service theme could recover costs as a charge per head funding from NHS Improvement

Cost Structure: The following suggestions were made by attendees and felt to cover all value propositions:

- Employee/People Salary
- Travel
- IT
- Accommodation of employees if staying away from organisation base location
- Production of material related to service
- Rental space of service base

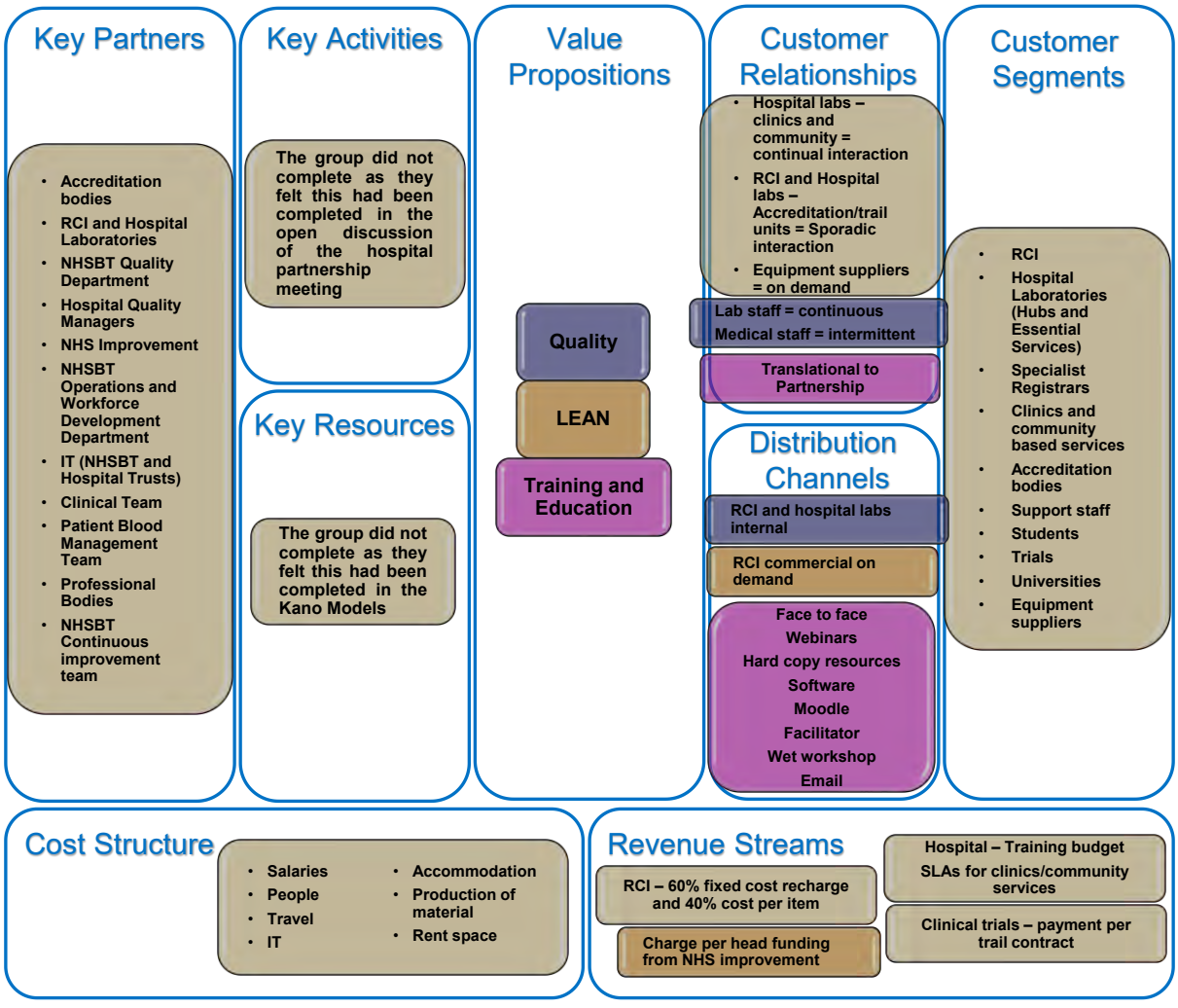


Figure 4-8:The Business model canvas and a summary of the sticky notes that were identified in discussion with attendees. The nine building blocks were used to identify information related to value propositions, customer segments, customer relationships, channels, key resources, key activities, key partners, revenue streams and cost structure of the service themes. Information relating to Quality Assurance was grouped in purple, LEAN in orange, and Training and Education in pink. Information grouped in yellow was considered by attendees to be required for all service themes.

4.1.6 Post-Event Data Collection -Survey Results

This survey was produced to collect data anomalously from the attendees of the hospital partnership meeting to understand how beneficial, enjoyable, and relevant the day was and if events of this nature should be used

in the future to develop RCI services. It also allowed an understanding of whether the participants thought there would be improvement in patient care, if services discussed in the event were developed. The survey aimed to gain attendee opinion and understanding of the business development tools, as well as their likelihood of attending a future development day. Answers from questions relating to each category are presented in the following sections (4.1.6.1 to 4.1.6.3). Engagement of the event attendees with the post event data collection survey was poor with only five out of twelve attendees of the event completing the survey.

4.1.6.1 Attendee Opinion of the Hospital Partnership Meeting

Opinions from mid-score to top-score were identified for benefit, enjoyment and relevance of the hospital partnership meeting, no scores below mid-point of the scoring scale (1 – 5, 5 = top score) were selected by attendees ([benefit – three participants = 3; one = 4 and one = 5 (Figure 4-9A)], [enjoyment – one participant = 3; two = 4 and two = 5 (Figure 4-9B)], [relevance – three participant's = 3; two = 4 (Figure 4-9C)]). Additional opinions were as follows:

In relation to the benefit of the day

- Attendee 1 – Useful to share and develop ideas on better collaboration between RCI and HTL
- Attendee 2 – I feel that RCI was already aware of the areas identified for development prior to the event
- Attendee 3 – No answer
- Attendee 4 – I found the day to be very beneficial. Particularly in sharing mutual issues, concerns, and generating new ideas for the future. I thought the day was well structured and organised and was a great opportunity to get round a table and speak openly. The use of the models helped provide structure, however I felt that by the end of the day the business model canvas was somewhat hard going and difficult to follow at times.
- Attendee 5 – It was good to get ideas down on how to improve transfusion services and discuss issues that are similar in hospital transfusion services across the country

In relation to the enjoyment of the day

- Attendee 1 – I always enjoy open and constructive discussions with transfusion professionals
- Attendees 2, 3, 4 and 5 did not offer a more detailed opinion

In relation to the relevance of the day

- Attendee 4 – I felt that LEAN was extremely important to the HTL. For some time, there has been duplication of processes between HTL and RCI with many wasteful steps ultimately leading to delays in blood provision. for example, repeating of panels which have been done in HTL are repeated at RCI. Closer working and sharing information could eliminate some of these wasteful steps and speed up the process.

- Attendee 5 – The ideas were relevant and hopefully we see some of them come to fruition in the near future
- Attendees 1, 2 and 3 did not offer a more detailed opinion

Most attendees that completed the survey acknowledged that an event of this nature should be used to develop services in the future (Yes = 4/5) (Figure 4-9D) and if this was done, all would take part in a future event of this nature (5/5) (Figure 4-9E). Personal thoughts by attendees on this matter were:

- Attendee 1 – I genuinely want to hear how RCI can support HTL in non-traditional ways
- Attendee 2 – I think that this type of event is more suited to the developmental stage of a product rather than to ID products to develop as time was spent by the hospitals requesting services which were outside of NHSBT scope
- Attendee 3 – Good to get different people from across the board in one room to discuss
- Attendee 4 – Definitely working together can only be of benefit to staff and patients.

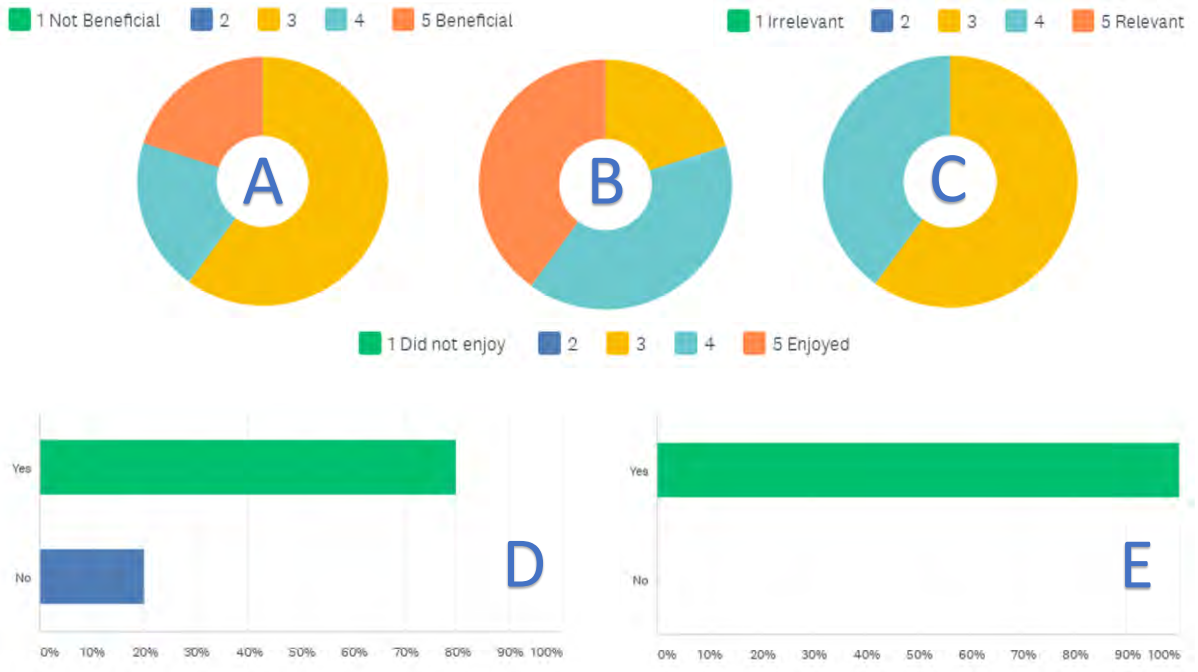


Figure 4-9: Summary of the post-event data collection questions that related to the attendee's opinion of the hospital partnership meeting
Scoring = 1 – 5, 5 = top score. Five attendees answered questions on – (A) The benefit of the day, three participants = 3; one = 4 and one = 5; (B) Enjoyment, one participant = 3; two = 4 and two = 5; (C) Relevance, three participant's = 3; two = 4; (D) If events of this nature should be used to develop service in the future, one = no and four = yes; (E) If attendees would participate in a future event of this nature, five = yes.

4.1.6.2 Attendee Opinion of the Impact on Patient Care if Services were Developed by RCI

By scoring greater than the mid-point of the scale (scoring scale = 1 – 5, 5 = top score), most attendees (4/5) that answered the post event survey believed patient care would be improved if services identified in the event were developed by RCI (three participants = 4 and one = 5). One participant did not agree with the majority opinion, scoring below mid-point of the scale (score = 2) (Figure 4-10).

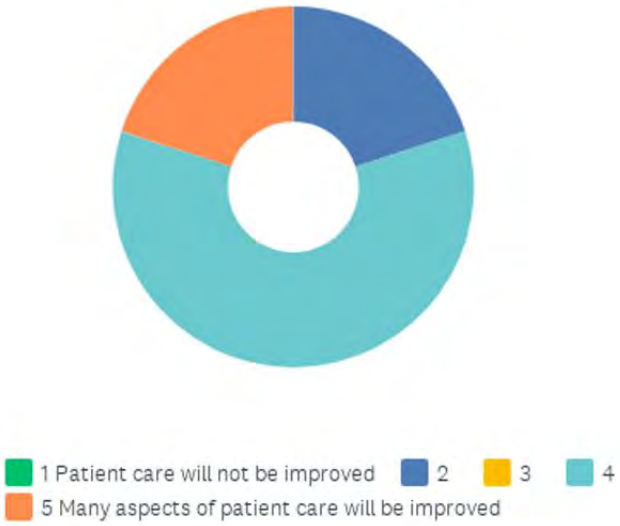


Figure 4-10: Summary of the post-event data collection that related to the perceived impact of the discussed services on patient care.
Scoring = 1 – 5, 5 = top score; One participant = 2, three = 4 and one = five.

Greater understanding relative to the scale point selected by attendees was given as follows

- Attendee 2 – I am not sure that patient care will be improved however it may empower hospital staff to be able to deal with cases more confidently
- Attendee 5 – Empowering the hospital BMS's with the sufficient knowledge and skills in blood transfusion through training and education will improve the transfusion services and have an overall positive impact on patient care - fewer delays, better informed decision making, and improved quality of the services provided.

Attendees 1, 3 and 4 did not offer a more detailed opinion

When attendees were asked to suggest three areas of patient care that could be improved by the implementation of discussed services, the answers were as follows:

- Attendee 1 – More enabled BMS who can challenge poor care decisions; Provide centralised expert support 24/7; Reducing delay in safe transfusion

- Attendee 2 – Communication between hospital and RCI BMS (this was the only area identified)
- Attendee 3 – BMS skill level increase; confidence in BMS staff to make the correct choices (no further areas identified)
- Attendee 4 – Training and Education of staff; LEANing out of existing processes; General improvement of quality on a day-to-day basis
- Attendee 5 – Holistic improvements (no further areas identified)

4.1.6.3 Attendee Opinion and Understanding of the Business Development Tools

For all survey questions relating to the VPC, BMC and Kano model a scale of 1 – 5 was used to gain the attendees opinion. The top score for each question was 5.

4.1.6.3a The Value Proposition Canvas

In relation to the VPC attendees suggested a mid-range score for enjoyment while using the tool (5 = Enjoyed; one = 2, three = 3, one = 4) (Figure 4-11A). More detailed opinion of this question was:

- Attendee 1 – This model has its uses, but it's a chore I find
- Attendee 4 – This gave a detailed investigation as to pains and gains including issues everyone encounters in a HTL and some other more specific ones.

Attendees 2, 3 and 5 did not offer a greater opinion

From scoring it was identified that attendees did not agree that they understood the goal of its use (5 = Completely understood; one = 1, two = 3, one = 4 and one = 5) (Figure 4-11B) and not all felt they were able to engage with the tool (5 = completely engaged for the entire session; one =2, one = 3, one = 4 and two = 2) (Figure 4-11C). Opinions related to the result selection were given by some attendees:

Understanding of the canvas

- Attendee 1 – I do understand this (mostly) but not convinced of its usefulness
- Attendee 2 – I really struggled to understand the purpose of this tool

Attendees 3, 4 and 5 did not offer further opinion

When asked if the goal of the canvas was achieved, only mid-range results were scored (5 = Completely met the goal; one = 2, one = 3, three = 4) (Figure 4-11D) and for how easy the VPC was to use, scores were variable (5 = Easy to use; one = 1, one = 2, two = 3, one =4) (Figure 4-11E). Attendees did not rate the VPC at top score for identifying new service ideas and related attributes, again opting for mid-range results (5 = All ideas and components identified; one =2; two = 3 and two = 4) (Figure 4-11F). When asked if attendees would use the VPC

again in the future, most results were at the mid-point of the scoring scale (5 = Definitely use again; four = 3 and one = 1) (Figure 4-11G).

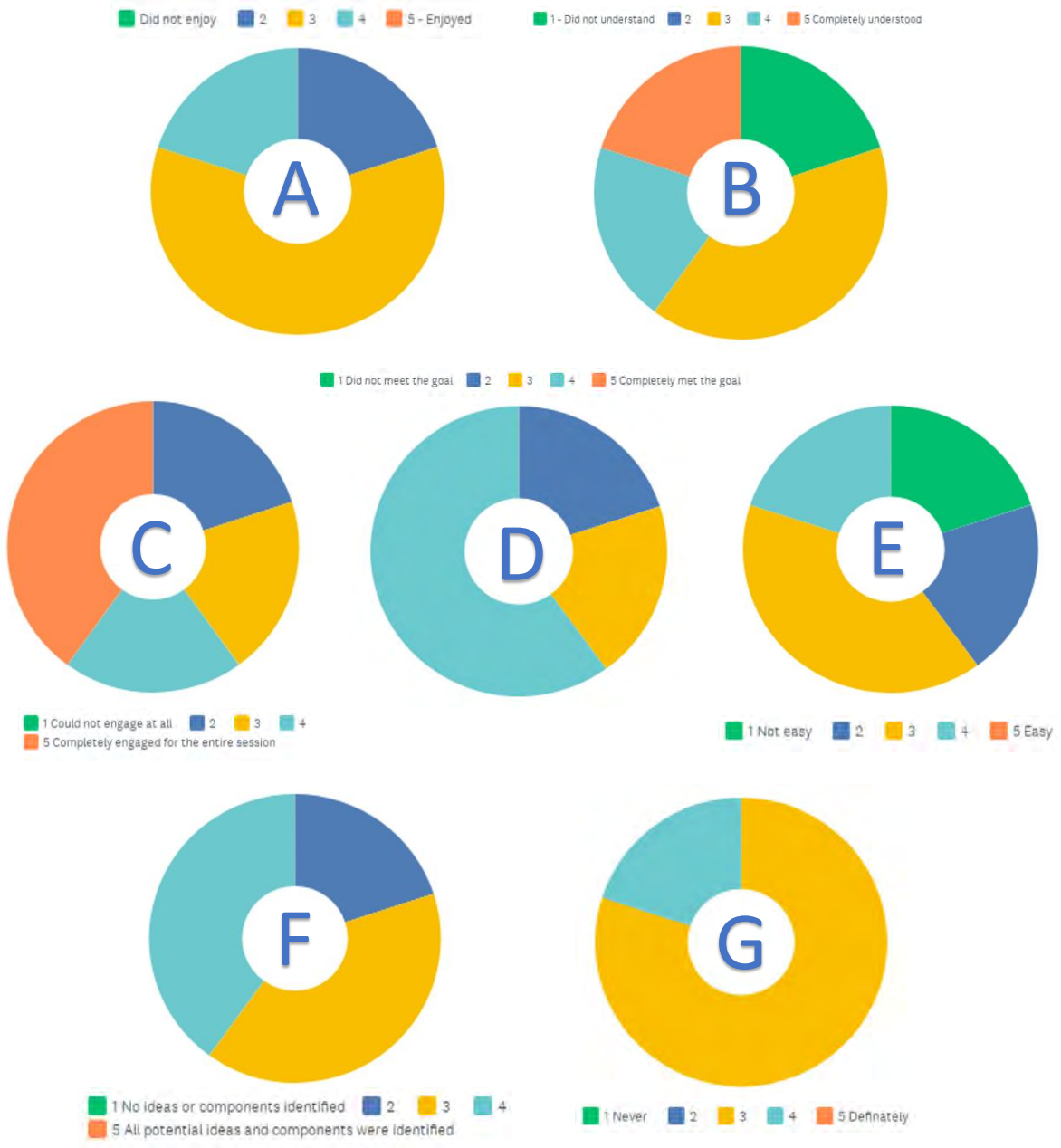


Figure 4-11: Summary of the post-event data collection questions that related to the attendee's opinion of the VPC. Scoring = 1 – 5, 5 = top score. Five attendees answered questions on – (A) The level of enjoyment felt, one = 2, three = 3 and one = 4; (B) How well they understood, one = 1, two = 3, one = 4 and one = 5; (C) The level of engagement, one = 2, one = 3, one = 4 and two = 5; (D) The goal was met, one = 2, one = 3 and three = 4; (E) How easy it was to use, one = 1, one = 2, two = 3 and one = 4; (F) what level of ideas and components of a service were identified, one = 2; two = 3; two = 4; (G) If they would use it again, four = 3 and one = 4.

4.1.6.3b The Business Model Canvas

Attendees that answered the survey identified that there was a reduced level of enjoyment when working with the BMC (5 = Enjoyed; one = 1, two =2, one = 3, one = 4) (Figure 4-12A). More detailed opinions were:

- Attendee 1 – A bit mechanical for me, but you can use it to describe the business
- Attendee 2 – I was very unsure on the purpose of this tool
- Attendee 5 – Slightly confused by the process - seems to be over complicated

A similar scoring profile was observed when asked if attendees understood the goal of the BMC (5 = Completely understood; one = 1; one = 2, one = 3, two = 4) (Figure 4-12B).

- Attendee 1 – Mostly clear, sometimes you have to be creative to find a bit of your business to meet the criteria
- Attendee 4 – I understand it's use but personally don't like this model.
- Attendee 5 – Didn't quite grasp how each section linked and which section followed on from the next

The scoring profile for earlier questions relating to the BMC was not matched when asked if the goal of the business model canvas was met (5 = Goal completely met; one = 1 and four = 3) (Figure 4-12C).

- Attendee 1 – suggested that a mid-range score was reasonable in the presence of the BMC use with a new group and the fact that it was later in the meeting day.

Attendees did not score the BMC easy to use with most results scored as three or below (Easy = 5; two = 1, one = 2 and two =3) (Figure 4-12D). Only attendee 1 offered an opinion of this:

- Attendee 1 – Sometimes the criteria for the building blocks of the BMC were a loose fit with what was identified.

A wide range in scoring related to whether the BMC identified new service ideas and related attributes (5 = All ideas and components identified; two = 1, one = 2, one = 3, one = 4) (Figure 4-12E), as well as for attendee opinion on being able to engage with the BMC (5 = Completely engaged for the entire session; one = 1, one = 2, two = 3, one = 4) (Figure 4-12F). Attendees identified that a lack of understanding (Attendee 2), the model was not easy to use (Attendee 4), and that the BMC was confusing (Attendee 5) were barriers to engagement. When asked if attendees would use the BMC in the future, most answers were towards the end of the scale that related to never (5 = Definitely; two = 1; one = 2, one = 3, one = 4) (Figure 4-12G)

Figure 4-12: Summary of the post-event data collection questions that related to the attendee's opinion of the BMC. Scoring = 1 – 5, 5 = top score. Five attendees answered questions on – (A) The level of enjoyment felt, one =1, two = 2, one = 3 and one = 4; (B) How well they understood, one = 1, one = 2, one = 3 and two = 4; (C) The level of engagement, one = 1 and four = 3; (D) The goal was met, two = 1 one = 2 and two = 3 (E) How easy it was to use, two = 1, one = 2, one = 3 and one = 4; (F) what level of ideas and components of a service were identified, one = 1; one = 2, two = 3; one = 4; (G) If they would use it again, two = 1; one = 2; one = 1 and one = 4.

4.1.6.3c The Kano Model

The Kano model session was enjoyed by all attendees that answered the survey (5 = Enjoyed; two = 4 and three = 5) (Figure 4-13A). It was felt that the goal of the business development tool was understood (5 = Completely understood; two = 4 and three = 5) (Figure 4-13B) and the goal of using the tool was met in the Kano model session (5 = Completely met the goal; two = 4 and three = 5) (Figure 4-13C). Attendee 1 offered the opinion that they could have done more with more time and preparation, but they thought it went well. Attendees found the tool easy to use (5 = Easy; two = 4 and three = 5) (Figure 4-13D), with Attendee 2 identifying they had used the tool previously. Not all attendees felt that the Kano model identified new service ideas and the components

required for their development, even so, scoring was generally mid to high (5 = All ideas and components identified; one = 1, two = 3 and two = 4) (Figure 4-13E). More detailed opinion was given:

- Attendee 2 – Helps to work out product development priorities
- Attendee 5 – I don't think it identified new ideas but made you think about which ones were essential and which would be a nice to have

Attendees 1, 3 and 4 did not offer further opinion.

All attendees that answered the survey felt that they were engaged for the entire Kano model session (5 = completely engaged for the entire session; five = 5) (Figure 4-13F). Attendee 2 highlighted that they felt a barrier to the use of the Kano model was when disagreement occurred between attendees on the levels that attributes were assigned. All attendees that answered the survey identified that they would use the Kano model in the future (5 = Definitely; five = 5) (Figure 4-13G).

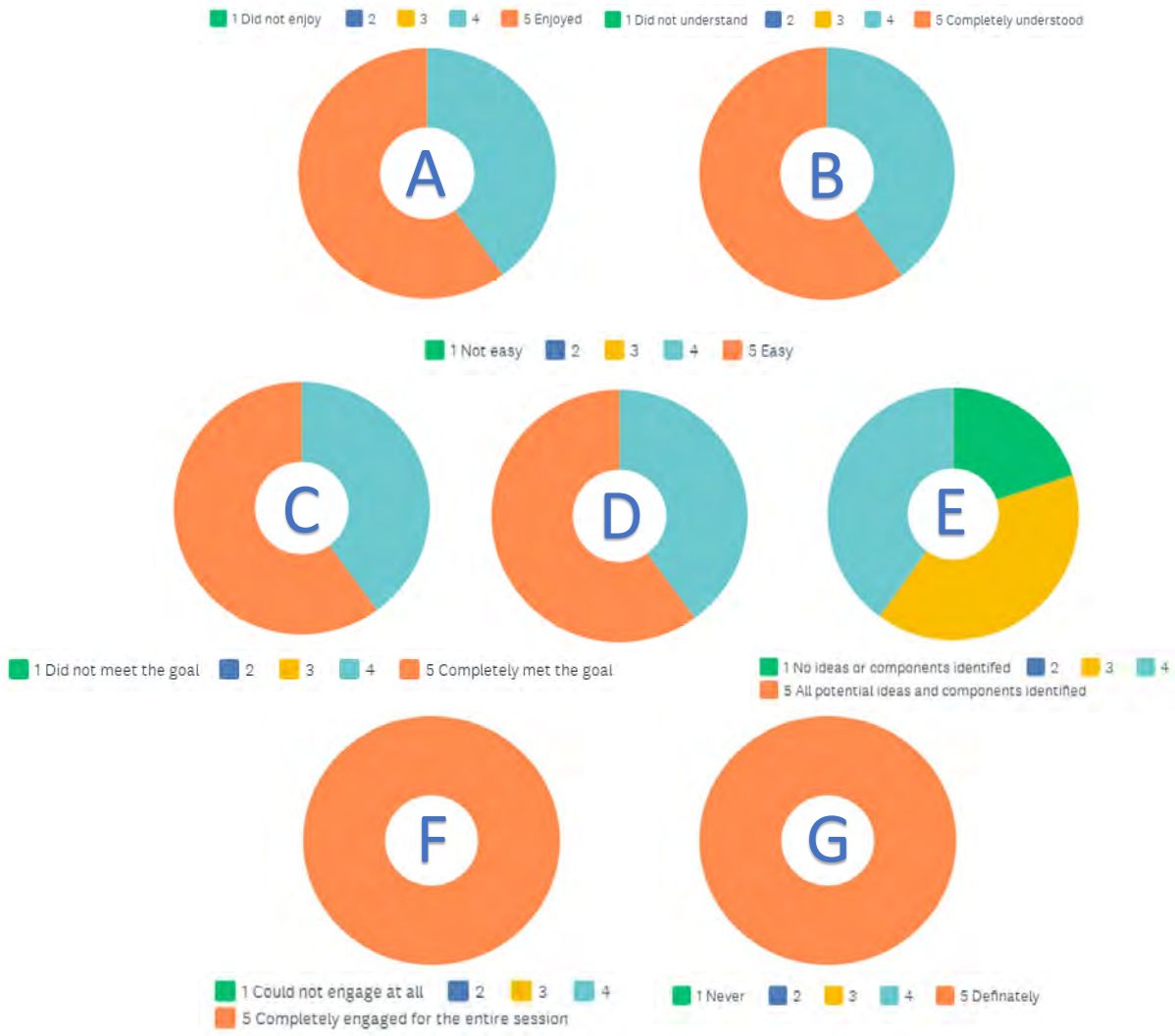


Figure 4-13: Summary of the post-event data collection questions that related to the attendee's opinion of the Kano model. Scoring = 1 – 5, 5 = top score. Five attendees answered questions on – (A) The level of enjoyment felt, two = 4 and three = 5; (B) How well they understood, two = 4 and three = 5; (C) The level of engagement, two = 4 and three = 5; (D) The goal was met, two = 4 and three = 5 (E) How easy it was to use, one = 1, two = 3 and two = 4; (F) what level of ideas and components of a service were identified, five = 5; (G) If they would use it again, five = 5.

4.2 The Laboratory Solution Development Platform

Service themes were identified in the hospital partnership meeting that were desirable to the HTL. Attendees of the meeting felt that the RCI department could support the HTL with services beyond their standard provision. From the canvas exercises that were undertaken in the hospital partnership meeting, it became clear that a future service provision wouldn't be built around one theme. Instead, much like the hospital partnership meeting, RCI could provide a platform that would facilitate the identification of the HTL partner's jobs that caused the most pains. RCI would then develop a solution with the hospital partner through the provision of expertise from wider NHSBT departments and, if required, from the wider NHS hospital network that RCI serves.

4.2.1 The Value Proposition Canvas – Product Value Map

This section highlights the completion of one half of the value proposition canvas – the value map. The canvas identified how the laboratory solution development platform could relate to the customer jobs, address the pains they cause, and create the gains wanted by the HTL (Sections 1.8.5; 3.6.2 and 4.1.3) (Figure 4-14). Three levels of the solution development platform were created and added onto the product ideas segment of the value map.

Original product idea:

- HTL led bespoke service:
    - This would be the first level of service, where the HTL would have a greater involvement in the project. This would create a stronger decision making for the HTL, which, would give them greater power and less reliance on RCI for the development of solutions to the customer's jobs.
    - To achieve this level of strength and power for the HTL in the development of solutions, RCI would support by providing guidance from experts within the department. Where there was a gap in the RCI departments expertise, RCI representatives would seek support from wider NHSBT departments.

Additional product ideas were created to support service difficulties experienced at the time of product implementation in the HTL:

- HTL and RCI full partnership:
    - This would be the second level of service, where the HTL has the same level or less involvement as RCI in the project. This means equal or less decision-making strength for the HTL, which would result in less power because of the greater reliance on RCI in the development of solutions to the customer jobs.
    - By giving up strength and power through greater support from RCI in guidance and decision making for the development of solutions, there would be a greater reliance on the RCI department as well as wider NHSBT departments.
- RCI led generic service template:
    - This would be the third level of service, where the HTL have oversight of solution development, but RCI makes all the decisions and has total control. This would mean the only power the HTL would have, is to accept or reject implementation of the solution.
    - There would be complete reliance on RCI and wider NHSBT departments.

Most of the identified gain creators for the customer were universal for each product idea and related to the pain relievers and attributes identified in the hospital partnership meeting VPC customer gains section (Figure

4-6 and Section 4.1.3.2). Association of the gain creators to each product idea is highlighted in Figure 4-14, but also in brackets in this Section as either: (1) = HTL led bespoke service; (2) = HTL and RCI full partnership bespoke service; (3) = RCI led generic template service provision. The gain creators were:

A. Expertise provided from NHSBT staff groups – This will allow multidisciplinary development of solutions that can address targets for efficiency, cost savings, quality, standard work, lab environment, safety, and compliance. Overall, improvements made in this way will lead to better service provision and patient care (1, 2, 3).
B. RCI and NHSBT brand name – RCI as a department and NHSBT as an organisation are well known for their expertise and quality, as well as the level of care they take in achieving these through staff and product support. This results in success at accreditation with a wide range of organisations allowing the provision of services that are critical to the NHS and health communities globally. For this reason, association of the products created with RCI and NHSBT increases trust and assurance in relation to the solutions created for the customer jobs. This will build into the provision of an improved and trusted service for the customer (1, 2, 3).
C. Evidence based solutions and publication – NHSBT will draw on experience of continuous improvement training and culture to provide evidence-based solutions to the customer jobs. Support from RCI staff that regularly create publication will allow for a more learning and sharing culture in the customers organisation, as well as the generation of literature and conference abstracts related to improvements (1, 2, 3).
D. Access to NHSBT meeting and development tools – This will support the development and implementation of solutions for the customer and give greater clarity of the development goal. This will lead to expedited completion of solution creation and facilitate organisational changes that will be evidence based, increasing efficiency, cost savings and improvement towards quality targets. The tools will facilitate the implementation of solutions and create an improvement in self-sufficiency that will lead to a decrease in stress felt related to customer problems. Furthermore, utilisation of these tools will support the breakdown of barriers related to customer jobs and staff interaction, because they rely on an interactive approach that encourages sharing and learning. Development occurs through teamwork and a requirement to value team members' opinion. Such interaction and involvement in the development of solutions creates an inclusive environment and allows team members to feel valued and feel self-investment in the service. They will see positive change relating to developments that they have been involved with, and are more likely to stay, improving staff retention for the customer (1, 2).
E. Improved partnership working – Interaction between RCI/NHSBT and the HTL through the product ideas will break down barriers between organisations (1, 2, 3).
F. Pricing and payment – Cost savings would be achieved for the customer. Products would need to be priced to be competitive with costs for the customer to complete the solution development on their own. Further cost savings could be made by a range of payment options (1, 2, 3).

G. Access to NHSBT meeting space – This would assist in creating calm as it would allow solution development away from the customers organisational related distraction and stress. This would also facilitate an environment for clarity as well as sharing and learning (1, 2).
H. Access to NHSBT departments – This would assist in breaking down barriers between the HTL and NHSBT. Improved relationships would allow the HTL to create new levels of self-sufficiency and improved service provision for better patient care. This would be achieved by greater access to NHSBT resource (training, equipment, instrumentation, reagents, products, and processes). Improvements made would make management of the customers' jobs easier. This interaction will also break down barriers between the HTL and NHSBT departments, creating a sharing and learning culture (1, 2, 3).

Most of the attributes identified as pain relievers in relation to the product ideas were universal for each product idea. Association to each product idea is highlighted in Figure 4-14, but also in brackets in this Section as either: (1) = HTL led bespoke service; (2) = HTL and RCI full partnership bespoke service; (3) = RCI led generic template service provision. Attributes were targeted to mitigate the service themes and attributes identified in the hospital partnership VPC customer pains section. These were:

I. Access to NHSBT equipment, instrumentation, reagents, products, processes, and training material – These can be provided by RCI and RCI Reagents, Non-Clinical Issue, Manufacturing, Testing, IBGRL and the Scientific and Clinical Training Team. This would allow support for solution implementation for the customer (1, 2, 3).
J. Access to NHSBT training material – These can be provided by the RCI department and the wider parent organisation NHSBT e.g. The Scientific and Clinical Training team or Quality Assurance department (1, 2, 3).
K. Access to meeting space – NHSBT onsite meeting rooms or web-based meeting environment (Microsoft Teams) could be used for the development of solutions to the customers' jobs (1, 2).
L. Pricing/payment –This could be single or stand-alone, gateway or staggered, or built into a current service level agreement, whichever suits the customer (1, 2, 3).
M. Access to meeting and development tools – MIRO; Continuous improvement A3 problem solving; Process mapping. This would facilitate solution development and implementation (1, 2).
N. Peer reviewed publication – Support for publication of project outcomes would be provided by RCI staff who understand and regularly generate publications (1, 2, 3).
O. NHSBT Brand name – This would create value related to project implementation for the customer. A summary report would be provided with verification and signature from senior members of HCPC/Royal College of Pathologist registered staff e.g. The National Head of Service, Consultant Clinical Scientist, Consultant Haematologist or Senior Clinical Scientist (1, 2, 3).
P. Access to NHSBT staff resource – Experts in quality assurance, continuous improvement, laboratory management and techniques, clinical transfusion related activities, staff development and training, document control (1, 2, 3).

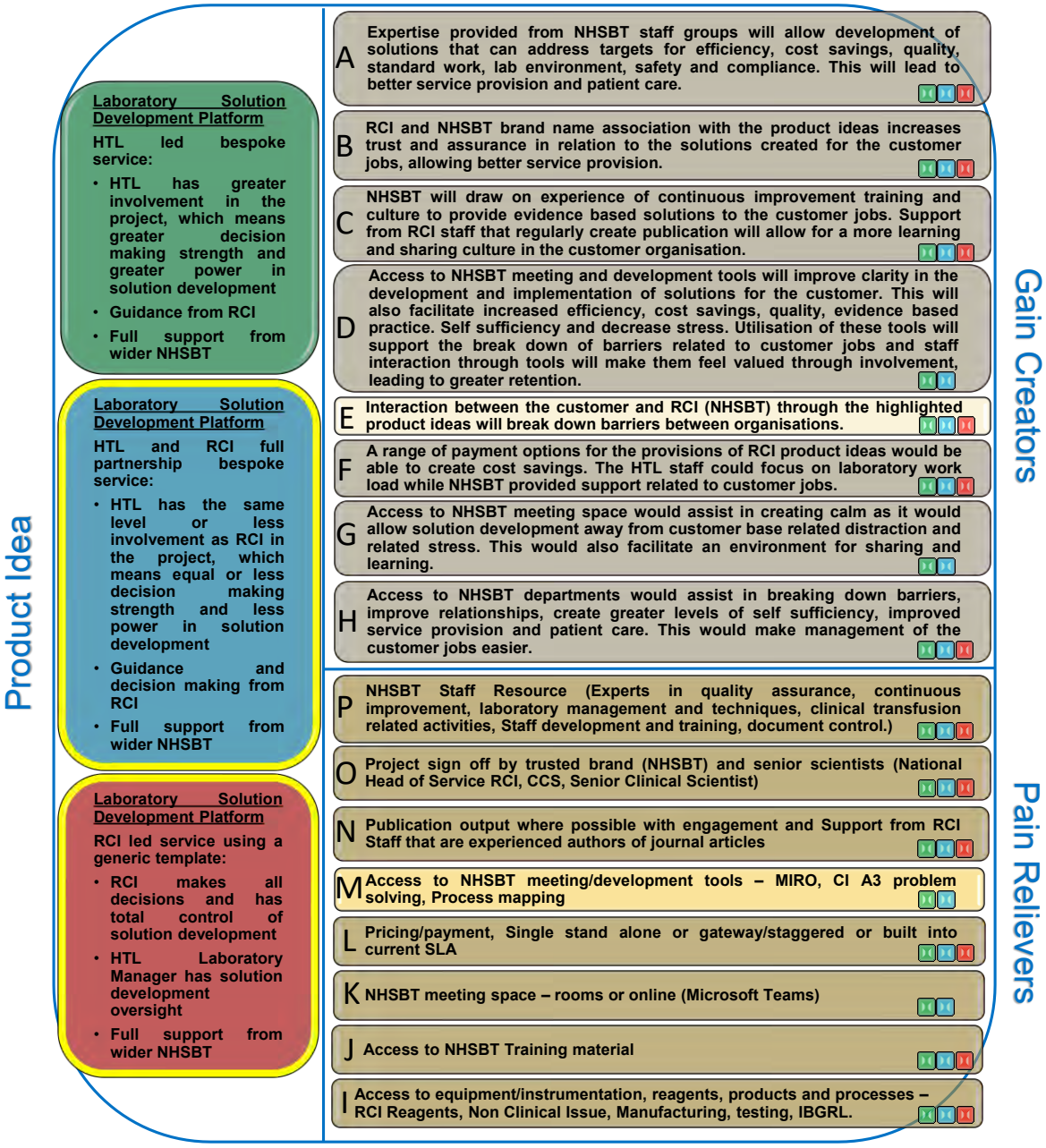


Figure 4-14: The product value map section of the value proposition canvas with a summary of the sticky notes that were identified in discussion between the Project Lead and Head of RCI.
The three product segments were used to i) identify the product ideas that could provide a solution to the customers' jobs (Laboratory solution development platform – green = HTL led bespoke service; blue = HTL and RCI full partnership bespoke service; red = RCI led generic template service provision); ii) what aspects of the product would create the customers' gains (A – H); and iii) what aspects would relieve the customers pains (I – P). The yellow outlined product ideas highlight those added beyond the original service idea. Coloured boxes (green, blue, and red) map which gain creators and pain relievers relate to each product idea.

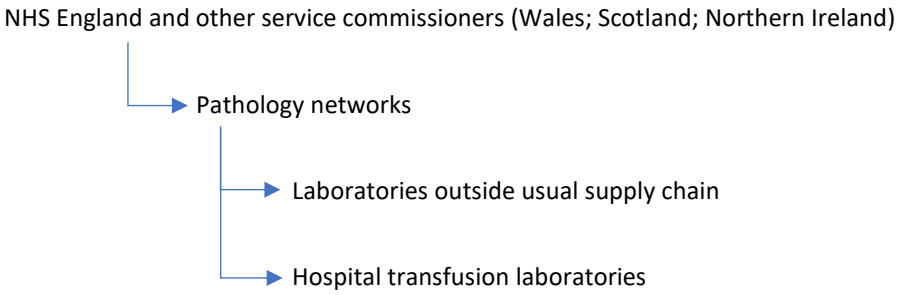
4.2.2 Business Model Canvas for the Laboratory Solution Development Platform

Discussion between the project lead and the Head of RCI in relation to the wider business aspects of the provision of the Laboratory Solution Development Platform and the Value Propositions allowed for the population of the Business Model Canvas. Items identified in the discussion were assigned to the associated building blocks: Value propositions; Customer segments; Distribution channels; Customer relationships; Key

resources; Key activities; Key partners; Revenue streams or Cost structure. These are illustrated in Figure 4-15; where possible, items are tagged to highlight if they related to the provision of the later described LEAN Laboratory or Vertical Audit service (Sections 4.2.5 and 4.2.6).

Value propositions: Three levels of the Laboratory Solution Development Platform were devised – Level 1 was a bespoke service provision led by the HTL; Level 2 was a bespoke service provision where decisions were in partnership between the HTL and RCI (NHSBT); Level 3 was led by RCI who provided a generic pre-conceived service. Greater detail of the value propositions is already described in Section 4.2.1.

Customer segments: This building block of the BMC identified various levels of the Health Service in England, but also highlighted other UK health bodies that would have transfusion laboratories:



Distribution channels: It was felt that the distribution channels between the service provider and customer were shared for all the levels of the Laboratory Solution Development Platform, these were:

- NHSBT Customer Services – This is a department in NHSBT that is responsible for being the main point of contact for customers to discuss service provision.
- Conferences – These allow dissemination of information related to the value propositions via presentations (spoken or poster) and face to face contact during the trade show or breakout sessions between speaker sessions.
- Sample referral form/phone call/Investigation reports – These are forms of regular contact between the RCI laboratory and the HTL. Information related to support or the available value propositions could be disseminated through these contact points.
- Head of RCI – HTLs may contact directly to request support that may require a bespoke service provision.
- Consultant Clinical Scientist or Trainee – Day to day activities result in regular contact with the HTL, which may result in identification of support for the HTL and advertisement of the value propositions.
- NHSBT Hospitals and Science website – HTLs consult the site to gain information related to service provision and patient management. The value propositions could be advertised to potential customers.
- Transfusion 2024 (or future plans) – Highlights key priorities for clinical and laboratory transfusion practice across the NHS (patient blood management; transfusion safety; harnessing technology;

innovation) with a five-year timeline. The value propositions can be used to support implementation and could be advertised in future versions of plans related to transfusion laboratories.

- The Update – This is a newsletter that is produced by NHSBT Customer Services for hospitals and the transfusion community. The value propositions could be advertised in a future version of The Update to improve awareness of the value propositions.
- National bodies – A greater awareness of the value propositions in the transfusion community could be driven through discussion with national bodies e.g. SHOT, UKTLC; JPAC.

Customer relationships: Two main categories of customer relationships were identified:

- Existing customers – These would accept a changed state to current service or buy into an expansion of products already available through the provision of new services.
- New customers – These would take up services that are already being provided to existing customers or would require new products to buy in to a service provision.

Key Resources: Properties identified that would be required to deliver the value propositions were:

- Established relations
- Organisation reputation
- Online and face to face meeting space
- Communication channels
- Organisational infrastructure/staffing
- Organisational expertise

Key activities: Activities that were required to deliver the value propositions were also assigned a relationship to the Audit (blue square) or LEAN Laboratory (orange square) service:

Audit and LEAN Laboratory service-related activities were:

- Continuous improvement and problem solving
- Initial state assessment and creation of a future state vision
- Process mapping
- Formative feedback

Audit service-related activities were:

- Vertical audit
- Maintaining accreditation

There were no activities that were considered to only be targeted towards the LEAN Laboratory service provision.

Key partners: A range of individuals and organisations were considered to be important to deliver the value propositions for the customer segments; these were divided by category of strategic alliance; Coopetition[†]; Joint venture; or Buyer – supplier relationship. Furthermore, these were also assigned a relationship to the Audit (blue square) or LEAN Laboratory (orange square) Service.

Audit and LEAN Laboratory service-related key partners were:

- NHSBT – other department expertise would be important in the delivery of the value propositions.
- Continuous improvement experts – The RCI National Improvement Manager was highlighted as a major contributor in relation to the project.
- Red Cell Immunohaematology – The Head of RCI was highlighted as a major contributor in relation to the project.

Revenue streams: Payment could be received via:

- Bundle pricing under a service level agreement
- Standalone pricing – gateway/staggered/urgency related

Cost structure: Finances would be required to cover:

- Staff salary
- External promotion
- Activity based costs
- Travel and hotels
- NHSBT partner time

[†] Collaboration between business competitors, in the hope of mutually beneficial results.

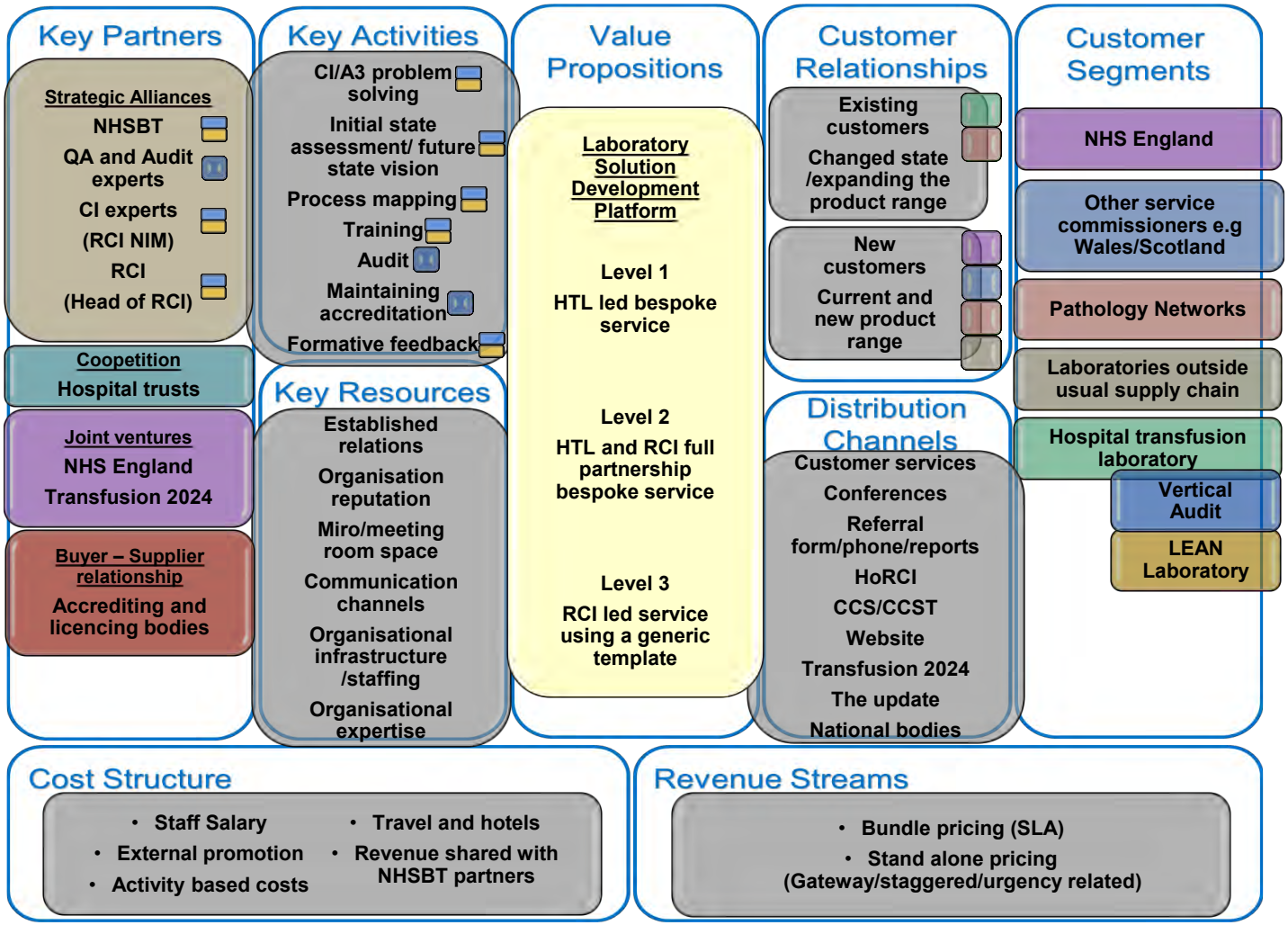


Figure 4-15: The Business Model Canvas and a summary of the attributes identified in discussion between the Project Lead and Head of RCI.
The nine building blocks were used to identify attributes that were required to deliver the value propositions for the customer segments. Attributes were positioned on the canvas in the building blocks relating to customer relationships; distribution channels; key resources; key activities; key partners; revenue streams; and cost structure. Relationships between the service themes (Vertical Audit (blue) and LEAN Laboratory (orange)) as well as customer segments were highlighted with matching colour blocks in key partners section, key activities, and customer relationship blocks.

4.2.3 Examination of the Risks and Opportunities for New Service Implementation – PESTLE Analysis

PESTLE analysis was used to identify and create a structure of factors that have the potential to impact a new service RCI could provide for a HTL. This allowed the identification of opportunities and threats related to service provision. Project development was then undertaken with greater understanding of the environment, where possible failure could be avoided by mapping factors related to the changing environment of the service provider and customer.

4.2.3.1 Political Related Threats and Opportunities

BREXIT

Threat – A change in employment law (European or UK) reduces the pool of scientists for recruitment, or there is a loss of scientists as they decide to return to their home country. This leads to:

- Fewer scientists in the laboratory
- Loss of experience and expertise in day to day running of laboratory
- Not enough team members to allow LEAN Startup development or allow training of remaining staff.

All this increases the pressure on a smaller team resulting in stress and staff sickness.

Opportunity – A reduction in staff or loss of expertise increases the:

- Requirement to understand how the HTL service can be improved or streamlined
- Opportunity for support to be provided from an external organisation

COVID19 Pandemic

Threat – Lockdowns no longer need to be in place, which results in greater attendance of patients at healthcare organisations and higher numbers of sample referrals. This reduces the time staff can attend training and LEAN Startup related events. Staff isolation (suspected and confirmed infection or vulnerable status) results in fewer staff numbers and an inability to support LEAN Startup activities. There could be a funding reduction due to cuts to cover pandemic response, this again impacts staff numbers, and the laboratory is unable to support LEAN Startup. The government COVID response could result in political change (Prime Minister, political party, legislation), which alters the environment in which pathology operates.

Opportunity – There are fewer non-seriously ill patients attending hospital, reducing sample numbers in the HTL and staff have more time to attend training and LEAN Startup events. Changes in funding of the HTL service due to the pandemic results in a requirement to understand how to improve the service and make savings. Members

of parliament experience COVID and gain understanding of the importance of an efficient and cost-effective health service.

NHS Funding

Threat – Finances may be directed away from transfusion services (staff, testing, training), impacting the support that can be provided for LEAN Startup development work.

Opportunity – Reduced funding could support the need for external support to create improvements in the HTL that result in financial savings.

Regulatory bodies

Threat – Accreditation becomes a greater focus e.g. upcoming accreditation visit (UKAS or MHRA), or accreditation cannot be maintained in:

- NHSBT – staff time (HSST or senior management) is directed to resolve issues
- HTL – Management team cannot support LEAN Startup activities as they must focus on regulation

Opportunity – RCI staff members are experienced with achieving and maintaining accreditation and a service could be built to assist the HTL based on this experience e.g. Audit training.

Pathology modernisation and networks

Threat – Merger between hospitals results in a greater workload for laboratory management and the HTL team to harmonise practice across two sites. This means there is reduced time to support LEAN Startup related development.

Opportunity – The merger allows for greater numbers of staff and increased time to support the professional doctorate. Differences in process between the laboratories requires support to create uniformity across the HTL laboratories.

NHS waiting list catch up, post COVID

Threat – NHS England has released funding that hospitals can apply to receive, to support an increase in surgeries to reduce the back log of cases that have resulted from COVID. If the BRI/Weston trust apply and are successful, this could see higher workload in the HTL that could impact the staff and time available to implement LEAN Startup related development.

Opportunity – LEAN Startup technology allows for the development of products that suit the customer in real time. Increased workload could be taken into consideration in the product development allowing the product

to still meet the customers' requirement, even with increased workload. This would support the use of LEAN Startup in service development for healthcare organisations.

4.2.3.2 Economic Related Threats and Opportunities

Economic impact of COVID (Recession /Austerity)

Threat – Reduced funding or income for hospital laboratory services and staff resulting in reduced support for service development and implementation.

Opportunity – There may be a resultant need to reduce expenditure but continue to provide a high quality of care to patients. Service development related to LEAN Startup will be at no extra cost and will empower staff to be able to identify ways for improvement to take place at low expense. An economic downturn would give a greater requirement to train staff to better manage continuous improvement. The use of LEAN Startup related development will create an environment of right first-time service provision with the aim to increase productivity.

Wages

Threats – The HTL would not be able to attract staff into the laboratory setting, or staff are drawn to leave the HTL because employment with private laboratories gives a better wage. This would mean staffing requirements in the HTL are not met and the customer is unable to release staff for LEAN Startup related activities.

Opportunities – An inability to attract staff or a reduction in staff numbers related to lower wage in the HTL compared to competitors could drive support for the implementation of LEAN Startup to gain greater understanding into how the HTL service can be improved or streamlined.

Customer drivers

Threat – Demand for service provision from NHSBT related to LEAN Startup reduces and the customer no longer invests in the project

Opportunities – New merger between hospitals identifies a need to alter the HTL laboratory e.g. process, training, thinking, teamwork. There is an increased requirement to bring staff from both sites together to generate new ideas and flow. There is a greater demand and buy in for the use of LEAN Startup for service development.

4.2.3.3 Societal Related Threats and Opportunities

Expectations

Threats – The expectation that the customer has for the project is greater than can be achieved in a specified time frame. The project is not able to progress in a timely manner or the customer stops the project before completion.

Opportunities – The customer is aware that the project is forming part of HSST professional doctorate and that there is a specified time frame for project work. Although the project is time limiting, there is the potential to form strong links between organisations and drive future collaboration for improvement activities.

Company image

Threats – The customer has a negative view of NHSBT and as a result the HTL staff may not buy into the use of LEAN Startup.

Opportunities – The manager of the HTL until recently was employed by NHSBT and left on good terms. There is a clear understanding of NHSBT continuous improvement culture and process. There is understanding of the HSST pathway and the professional doctorate requirements. The customer has the expectation that the project will be co-led with NHSBT, allowing the opportunity to help steer the use of LEAN Startup through regular weekly input sessions.

Methodology

Threats – LEAN Startup has not been employed for the development of services in the NHS. There is a low level of understanding in the Customer base. LEAN Startup tools are not used to their full potential and the developed product does not meet the need of the customer.

Opportunities – The customer has a good understanding of LEAN principles and a belief they can introduce valued change. LEAN Startup utilises LEAN principles to allow entrepreneurship for the development of new services. The customer sees the potential for benefit for the use of LEAN Startup to positively impact their work environment and formation of collaborative working between NHSBT and the HTL.

Professional Doctorate

Threats – There is a set time frame to complete the practical work of the project. The project is being conducted alongside normal work activities, which could impact the project progression.

Opportunities – The course is funded by the NSHCS. Guidelines to organisations accredited to train HSSTs require study time for the trainees to complete activities related to their training. This will allow dedicated time for the HSST to work with the customer for product development and implementation.

Staff Turnover

Threats – The project is not able to progress because the HTL has a small team and if staff leave, this impacts project development/implementation.

Opportunities – Staff turnover is common in all organisations. The use of LEAN Startup is to build a product that suits the customer. This is a chance to demonstrate how well LEAN Startup fits into the changing environment of a HTL.

Organisation links

Threats – The HTL and NHSBT are part of the NHS. The structure of the NHS results in NHSBT and HTLs considering each other as separate organisations. LEAN principles are embedded in NHSBT from very high level, whereas this may not be the case for the HTL. This may reduce the uptake of the project in the HTL. The HTL and RCI SMT/Project Lead might not have a shared vision related to the use of LEAN Startup, leading to the project not being able to progress.

Opportunities – The HTL has a new manager that has knowledge and experience of LEAN technology. This will assist in support for the use of LEAN Startup to create positive outcomes for the HTL and patients. This will build stronger links between the HTL and RCI.

RCI Senior Management Team

Threats – There is a lack of buy-in from the RCI SMT, or their own workload is too great to support progression of the project.

Opportunities – The project aligns with RCI/NHSBT goals for better integration with the HTL. The project allows RCI to test a new method of service development that fits well with the current LEAN principles embedded in NHSBT.

Location

Threats – The hospital partner may not be local to the project lead, impacting project time and increasing service charge related to travel and hotel stay (if required). In this project the HTL is split across two sites – Bristol Royal Infirmary and Weston General – 23 miles apart. NHSBT Bristol is not connected to either of these sites – 7.6 miles to Bristol Royal Infirmary and 26 miles to Weston General and neither of the HTL sites are at NHSBT

locations. This means the project lead will need to create meeting time and travel to work on site with the hospital partner.

Opportunities – The HTL and NHSBT project lead are in the same city, allowing easy project development. The pandemic has seen the introduction of a range of online tools that can be used for remote workers to interact. These can be trialled as part of the project development.

4.2.3.4 Technology Related Threats and Opportunities

Competing service

Threats – Other companies that offer service development may contact the HTL. The HTL manager, or senior management team may pursue a competing service from another company.

Opportunities – The development project can be offered at little cost from NHSBT as it forms the HSST project required for the Consultant Clinical Scientist Trainee based at RCI Bristol. It can build upon NHSBT experience ofsimilar projects and current organisation infrastructure. The work undertaken will allow for cost estimation for future provision of work to other HTLs.

Automation

Threats – Automated processing of samples and tests removes the need to develop a service that can be used to train and implement LEAN principles

Opportunities – The HTL does not employ LEAN manufacturing principles. LEAN manufacturing principles have demonstrated improvements in processes related to automated production e.g. Toyota. There will be steps in pre and post automation that have waste and will allow the demonstration of value in the service RCI can provide.

Education

Threats – LEAN Startup training may form part of the educational curriculum for BMSs. This would make the need for the proposed service redundant.

Opportunities – Training is different to activity. Undertaking of the project will allow first time learning or reinforcement of any learned LEAN related principles. The project is used to identify the needs of the customer and builds a service that meets their need. Service creation runs through the build-measure-learn cycle, this allows service development to change with the customer's needs continuously. NHSBT has LEAN principles embedded throughout the organisation, allowing experienced support for LEAN Startup service development.

Introduction of new technology

Threats – The HTL is implementing Blood Track, this will take up time from the HTL Manager who is running the LEAN Startup project with the HSST.

Opportunities – LEAN Startup has the principle to build a product that fits the customers need under extreme uncertainty. Running of the LEAN Start up based project alongside other large projects in the HTL will demonstrate the importance of external project support and the value of LEAN Startup methodology. The HTL Manager will be able to continue implementing large projects while the HSST project lead can manage development of services to alleviate the customer jobs identified in the project.

Current laboratory software e.g. Quality Management System (QMS) and LIMS

Threats – The current HTL technology does not allow for changes identified as critical for LEAN Startup solution development and implementation.

Opportunities – Successful use of LEAN Startup for solution development will create a product that considers the limitations of current laboratory software through customer involvement and the build-measure-learn cycle.

4.2.3.5 Legal Related Threats and Opportunities

Litigation

Threats – There is a growing trend in healthcare for the use of litigation. HTL – Service provision from NHSBT results in a negative impact on laboratory- environment/operation, staff members or patients.

Opportunities – LEAN Startup allows the development of a service with the customer. They will have full engagement with the tools for service development. The Project Lead will be providing the HTL manager with guidance from RCI staff members. This will allow the HTL and RCI to assess the usefulness of the LEAN Startup tools.

Inappropriate use of project data

Threats – The project can only take place with a non-disclosure agreement in place. This doesn't allow for wider dissemination of success or challenges that could not be overcome during solution development.

Opportunities – Project interaction and successful service development will allow greater levels of trust between the HTL and RCI.

4.2.3.6 Environmental Related Threats and Opportunities

Size and occupancy of HTL laboratory area

Threats – The laboratory size offers limited room for change and there are areas of the laboratory that are shared with the Haematology laboratory that could restrict idea implementation.

Opportunities – The limitations of the laboratory size in this case fits well with LEAN Startup principles to create a product where extreme uncertainty exists. It allows for the demonstration of the difference between LEAN Startup service development and LEAN Manufacturing where a service developed can look at non-physical customer jobs as well as physical. A shared location would allow success of using LEAN Startup to be viewed by a wider audience.

COVID19 Pandemic

Threats – Social distancing rules do not allow for the interaction between the HLT and RCI for the progression of LEAN Startup service development.

Opportunities – Success will demonstrate the value of service development using LEAN Startup principles where a product is built that fits the customer need under extreme uncertainty.

4.2.4 Application of the Laboratory Solution Development Platform

The level 1 Laboratory Solution Development Platform was identified by the hospital partner to meet the needs for the generation of service creation and support. Unfortunately, due to the impact of the COVID-19 pandemic on staff numbers and laboratory workload, this could not be supported with sufficient staff numbers from the hospital partner. As a result, the Project Lead in agreement with the HTL Manager made the decision to pivot and then persevere with the Level 2 Laboratory Solution Development Platform. This brought in a greater level of expertise from NHSBT for solution development, the outcomes are described in the following sections (Section 4.2.5 and 4.2.6).

4.2.4.1 Value Proposition Canvas Completed by Bristol Royal Infirmary and Weston NHS Trust

This section highlights the completion of the customer profile section of the VPC by the hospital partner. The customer jobs, related pains they cause and the gains that would be achieved if completed were identified and populated on the relevant sections. To improve the ease in understanding of what was identified, information is grouped into themes in the sections detailed below (Figure 4-16). Three main themes emerged, these were: Vertical audit training and audit process; LEAN laboratory; Pathology networks related merger of the BRI and

Weston General. When the hospital partner defined their customer jobs, they also highlighted related fears. The information provided was added to the customer jobs section of the customer profile section of the VPC:

- Vertical audit training and process:
    - The laboratory process that staff undertake to be trained to perform vertical audit and the process to conduct vertical audit does not meet service or accreditation requirement.
- LEAN laboratory:
    - There is waste present in the laboratory process.
    - LEAN methodology is not embedded in the HTL environment.
    - Turn – around – time is not optimised and potentially causes a delay in the provision of results to clinical staff for the treatment of patients.
- Pathology networks related merger:
    - There are different SOPs to undertake work at each site, calling for a need to harmonise the service.

Attributes identified as customer pains related to each theme were next defined and added to the relevant section of the canvas, these were:

- Vertical audit training and process:
    - Defined process and SOP not fit for purpose.
    - No training processes.
    - Only audit of document in a silo without observing process.
    - Unclear what is a non-conformance or an observation.
    - Availability of staff to perform audits.
- LEAN laboratory:
    - Manual serology work bench and printers positioning is poor.
    - Unable to observe automation – failures and problems go undetected.
    - Unable to observe or hear sample preparation centrifuges complete run.
    - Blood fridge positioning creates increased walking distance.
    - Walking distance during lone working is considered too large and not efficient.
    - Unable to observe activity in transfusion lab while lone working.
    - Flow of work into the transfusion laboratory is not managed efficiently due the scale of referrals and staff mix, BMS workload and laboratory flow.
    - No designated cells defined in the laboratory, so no clear responsibility for sections or workload coming into the transfusion laboratory.
- Pathology networks related merger:
    - Service not harmonised.
    - Staff don’t know each other.

  - Specialisms are different across sites.
  - Different blood group analysers at each site.
  - Different SOPs to undertake work at each site.
  - One site does not use electronic issue.
  - Different size hospitals and number of samples being referred.
  - Different ways of senior BMS undertaking work management – one site = senior BMS works across all sections; the other site senior BMS specialised to one section.

Customer gains were identified for each theme and added to the relevant section, these were:

- Vertical audit training and process
  - A training package will be available to allow staff to be ready for audit
  - Staff will see a better way to perform vertical audit, have guidance and support, as well as gain the competence to undertake an audit unsupervised
  - Clear assessment of current state and supportive build of an improved future state
  - Processes will be clearly documented
  - The audit output will be a final report
- LEAN laboratory
  - A more LEAN laboratory with less waste
  - Designated cells in the laboratory that staff will be assigned to for a shift and take ownership through management
  - Better positioning of laboratory instrumentation
  - Better layout of laboratory benching
  - Improvement to visual management in the laboratory that also allows clear message dissemination to staff and between staff
  - Staff will have a basic understanding of LEAN with the potential to gain greater experience
  - Staff will be able to lead on LEAN projects – hand holding to learn LEAN techniques
- Pathology networks related merger
  - One service across two sites
  - One set of SOPs that both sites are trained to perform
  - Team thinking – an environment where staff know each other, even across sites
  - Universal agreement of senior role working at each site
  - Understanding across sites of specialisms, referral rate and case management
  - Use of electronic issue at both sites

The scale of the project and time required to assist the hospital partner with merging the pathology services at the BRI and Weston General hospital was too great a task to be completed as part of the Professional Doctorate. Solution development focused on the vertical audit and training, and LEAN laboratory customer jobs, pains, and gains.

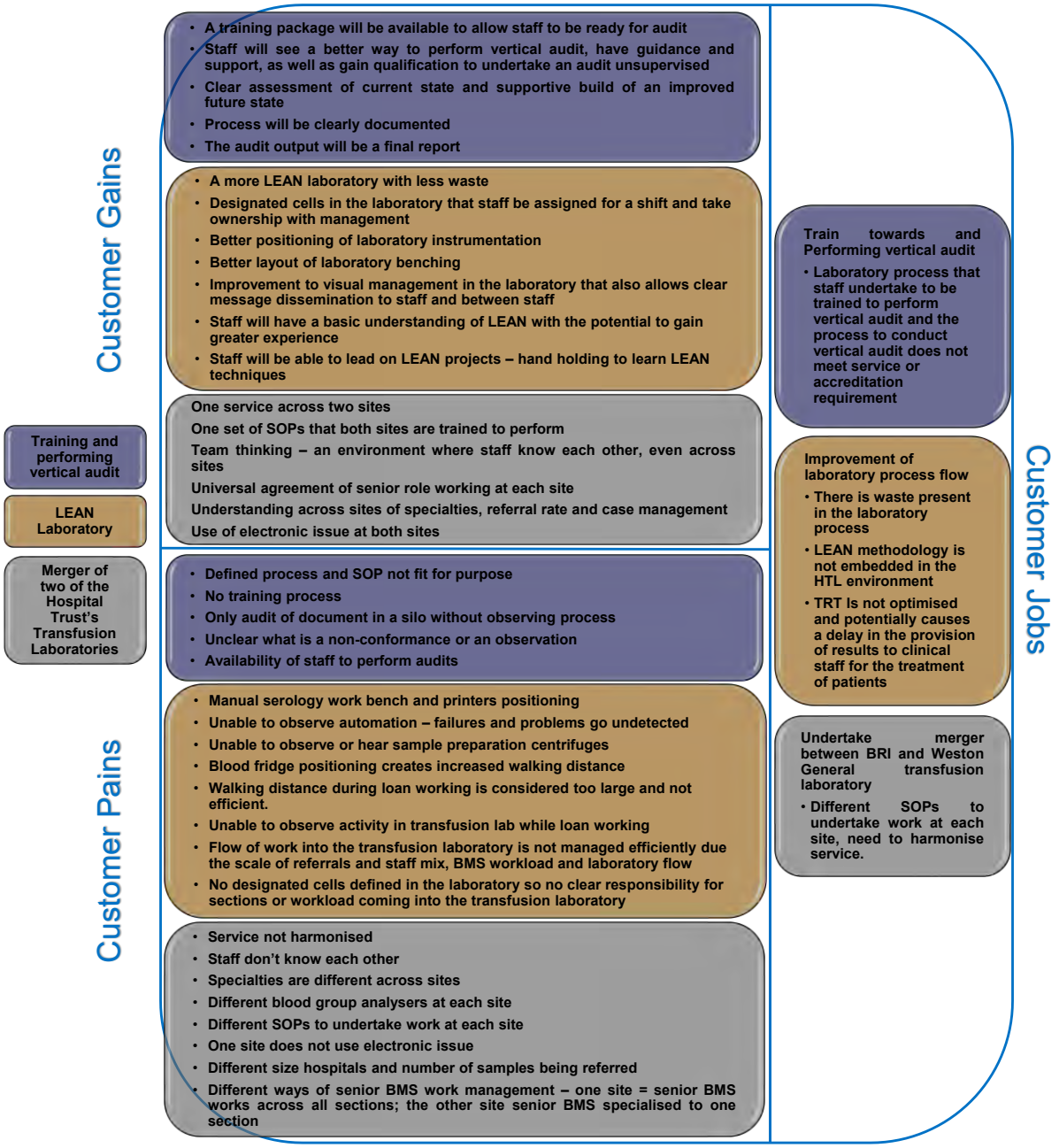


Figure 4-16: The Customer half of the value proposition canvas completed by the HTL partner.
The three customer segments were used to identify the: i) jobs that are relevant to the HTL; ii) pains they cause to complete; iii) gains created when complete. A summary of sticky notes that were identified by the HTL partner are grouped by their customer jobs (purple = Training towards and performing vertical audit; orange = LEAN laboratory; grey = Merger of two of the Hospital Trust's transfusion laboratories).

4.2.4.2 Competitor Analysis of Services that are Provided to Meet the Customer Jobs

An analysis of competitors that provide services to address the vertical audit and LEAN laboratory related customer jobs was performed. This was to manage customer expectation by better understanding service-related must haves, as well as unique attributes that can be offered as part of the Laboratory Solution Development Platform. The next two sections will summarise the competitor analysis related to vertical audit and LEAN laboratory type services.

4.2.4.2a Competitor Analysis - Audit Service Providers

Searches performed to identify audit service providers did not yield many companies. To improve the understanding of attributes related to audits, services provided by accreditation bodies as well as regulators were included. Results are highlighted in Table 4-1.

To compete with services available in the market, an audit service would need to:

- Offer advice, undertake licence application, assist in document writing, train staff to audit, implement audit processes, input into QMS development – including advice relating to governance arrangements, support for the customer in inspection processes and post inspection follow-up; perform audit against standards and codes of practice.
- Run a service that implements ISO standards within the clinical pathology laboratory environment.
- Provide a service for clinical pathology laboratories within England, but potentially the wider UK.
- Offer a bespoke service that meets the customers' requirements.
- Undertake training of the customers staff to perform audit and become self-sufficient.
- Offer formative feedback in a post-audit output meeting, report, and continued post audit support.
- Deliver the service with support from HCPC registered scientists.

Niche areas identified that could appeal to new customers are:

- Customers service provision through the service providers' own experience in the clinical pathology laboratory environment.

Table 4-1: Summary of the competitor analysis of companies that undertake vertical audit related activity.
Highlighted in the: i) green are attributes a new service provider would be required to include in their service provision to compete in the current market; ii) red are attributes considered to be a lower service offering; and iii) orange are attributes considered to be a potential gap that would interest potential customers in a new service provision.

Project ID / company size / number of staff / Business type	Service overview	Country of service	Target Market	Service Price (£)	Service accreditation	Bespoke service offering	Post audit completion support	Provide audit output meeting	Provision of summary report	Feedback: Summative / Formative / Both	Provision of training to audit	Perceived market share	Provides related services to customers service provision	Employs HCPC registered scientist (or equivalent)
Audit 1 Very small <10 Service provider	Advice, licence application, doc writing, training, implementation, QMS development, governance advice/support for process inspection & post follow-up; audit against standards/ codes of practice	UK	Human tissue	Unknown	None	Y	Y	Y	Y	F	Y	Small	N	N
Audit 2 Medium 201 – 500 Service provider	Consultancy service to assist with implantation of standards	UK	Implementation of ISO standards	Unknown	None	Y	Y	Y	Y	F	Y	Medium	N	N
Audit 3 N/A Zero Accreditation body	Government supported non-mandatory accreditation scheme against CPA standard	UK	Clinical Pathology Laboratories	Unknown	None	N	N	Y	Y	S	N	Zero	N	N
Audit 4 Medium 201 – 500 Accreditation body	Statutory government appointed accreditation body	UK	Any testing provision and calibration	Unknown	None	Auditee states scope of practice	N	Y	Y	S	N	Total	N	N
Audit 5 Large 1001 – 5000 Regulator	Executive department of health and social care - government body	Global	Pharmaceuticals*	Unknown	None	N	N	Y	Y	S	N	Total (Required)	N	Y
Audit 6 Medium 201 – 500 Regulator	Executive non-department body of the department of health	England	Healthcare providers	Unknown	None	N	N	N	Y	S	N	Total (Required)	N	Y
Audit 7 Small 51 – 200 Regulator	Executive department of health and social care - government body	UK	Human tissue**	Unknown	None	N	N	N	Y	S	N	Total (Required)	N	Y
Audit 8 Large 1001 – 5000 Accreditation body	Accreditation body	Global	Immunogenetics	Unknown	None	N	N	N	Y	S	N	Total (Required)	N	Y
Audit 9 Unknown Accreditation body	Accreditation body	Global	Stem cell and bone marrow transplant	Unknown	None	N	N	Y	Y	S	N	Total (Required)	N	Y

*Development, manufacturing, clinical trials, sale and import of medicine, wholesale dealing, medical devices and manufacture and testing of blood
**Procurement, storage, and use (clinical and research)

4.2.4.2b Competitor Analysis - LEAN Service Providers

Searches performed to identify LEAN service providers were able to recognise companies that provide training, implementation, oversight, and continued support (Table 4-2).

To compete with services available in the market, a service providing LEAN training, process mapping and implementation of improvement would need to:

- Be tailored to the customer's requirements.
- Undertake training of the customer's staff to LEAN principles and become self-sufficient.
- Provide a service for clinical pathology laboratories within England, but potentially the wider UK.
- Provide training that allows certification through the LEAN Competency System (https://www.leancompetency.org/).
- Offer a service that provides the creation and provision of resource material, a summary report and post project completion support.
- Quote a charge for a complete project, rather than offer a daily charge.

Niche areas identified that could appeal to new customers are:

- Service development that is targeted towards pathology laboratories.
- Service provision from a company that relates to the customer's service provision through the service providers own experience in the clinical pathology laboratory environment.
- Deliver the service with support from HCPC registered scientists.

Table 4-2: Summary of the competitor analysis of companies that undertake LEAN process improvement related activity.
Highlighted in the: i) green are attributes a new service provider would be required to include in their service provision to compete in the current market; ii) red are attributes considered to be a lower service offering; and iii) orange are attributes considered to be a potential gap that would interest potential customers in a new service provision.

Project ID / company size / Business type	Service overview	Country	Target Market	Service Price (£)	Service accreditation	Bespoke service offering	Post project completion support	Resource material and summary report	Market strategy	Perceived market share	Perceived threat level	Provides related services to customers service provision	Employs HCPC registered scientist (or equivalent)
LEAN 1 Very small <10 Service provider	Bespoke service covers customer wants would like - including training course; Basic information relating to LEAN; 'handholding' on the job project training.	UK	Not targeting path labs No specific target	3 days training = £1200/£1500 per day. Longer course = £600 per day. 3 years' work = £150 per day	None	Yes	By Contract	Yes	Solo operation that provides bespoke package	Very small	Low	No	No
LEAN 2 Small <50 Service provider	Standard packages, can be bespoke service, LEAN practitioner training (3 day); LEAN leader (2 days); Hand holding available; Value stream mapping course (1 day); 5 S Course (1 day); Keizen 5 S Course (1 day); Six sigma course (1 day); 600-700 courses per year.	UK	Not targeting path labs No specific target	LEAN practitioner course = £4995 (10 places). LEAN Leader = £3495 (10 places). Public course, from multiple organisations = £995 per person (£945 if virtual)	None	Yes	By Contract	Yes	Wide range of online and public courses certified by professional bodies (CQI, IRCA, IEMA, IOSH)	Large	High	No	No
LEAN 3 Small 51 -200 Service provider	Nearly always provide a bespoke package - will assess the level of intervention required, can provide project oversight or even hand holding. Generic training is available which is a standard package	UK	Not targeting path labs No specific target	For 7 labs = four sessions - 20 to 30 people with 2 facilitators per session = ~£10K. Bespoke project = £1,100 per day	None	Yes	Advice at no extra cost. New contract required for new project	Yes	Assessment of support required. imbed LEAN principles at all levels of an organisation	Medium	High	No	No
LEAN 4 Very small <10 Service provider	No training courses. Bespoke if required. LEAN education (ISO18404 - allows accreditation of customers staff). Main service = implementation via discovery. Maps of current state, working towards future state.	Global	Not targeting path labs No specific target	No daily rate. Project Charge. discovery = £7-8K; implementation (4-6 months) = £7/8K 8 people; sustained, depends on interaction.	ISO18404	Yes	By contract	Yes	Bespoke service that is charged as an entire project rather than standard price per day.	Small	High	No	No
LEAN 5 Small 51 – 200 Service provider	The business = training and consultancy - aim to develop people. give them the capability to continue building. Hand holding of the customer on products. Aim to make the company self-sustaining, hand more over to the company over time to self-perpetuate culture of LEAN.	Global	Not targeting path labs No specific target	LEAN awareness training/ assessment – 1 day = £5000. Green belt training - 6 months, 10 places = £30,000. Black belt training - 12 months, 1 person = £50,000. Also provide a consultancy service	Certification through LEAN competency system - https://www.leancompetency.org/	Yes	Advice at no extra cost. New contract required for new project	Yes	Supply modular courses that can be built on top of each other.	Large	High	No	No
LEAN 6 Very small <10 Service provider	Identify relevance to customer, offer bespoke training, help to implement LEAN (hand holding), look for waste/quality issues/ value stream map	UK and EU	Food Stores	Course for 8 people = £8K; Day rate for consultancy = £1150 plus expenses	None	Yes	By contract	Yes	Process for improvement, implement change, identify capability, create training material.	Very small	Low	No	No
LEAN 7 Small <50 Service provider	Pharma, food, forensic, viruses. Help/facilitate improvements. LEAN/process improvement, change readiness, Hardest to maintain/sustain. Work with the team to unlock improvements.	Global	Pharma, food, forensics, and microbiology labs	Entire project (28 - 29 days) = £35K or £1700 a day. This gives three consultants	Scottish Qualifications Authority accreditation (https://accreditation.sqa.org.uk)	Yes	10 days extra beyond 29-day contract term	Yes	Bespoke service, create LEAN champions for legacy of LEAN principles.	Small	High	No	No

4.2.5 Laboratory Solution Development of the Hospital Transfusion Laboratory's Vertical Audit Training and Completion Processes

4.2.5.1 Current State Assessment of Training to Perform Vertical audit

There were very few steps in training laboratory members of staff to perform vertical audit of laboratory processes (Figure 4-17). This started with identifying a person to be trained, allowing them to read the related SOP and then completing some set questions on the quality management system. Once this was complete the member of staff was signed off as competent to perform vertical audit.

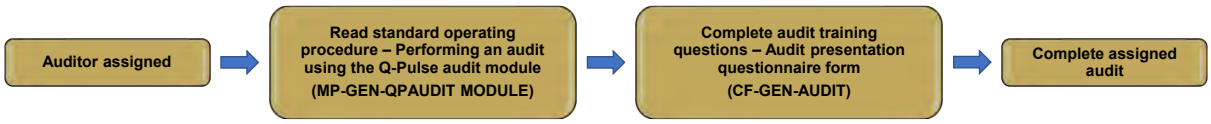


Figure 4-17: Summary of the current state process to train HTL staff to perform vertical audit.
There are four steps in the process that involves assigning the audit, reading the SOP for performing an audit, completing set of questions related to audit and then performing the assigned audit. Related documents are highlighted in the brackets.

4.2.5.2 Current State Assessment of the Vertical Audit Process

The vertical audit process was more complex than the process for training. To understand the value of each step in the process, a criticality score was assigned. The scale for the score was 1 – 5, where 5 identified that a step was critical to the process (Figure 4-18). The process began with opening the audit module in the quality management system (5), printing the audit checklist (3), and then performing the audit and recording findings (5). It was noted while assessing the vertical audit process that undertaking the audit involved printing the SOP and sitting in a silo environment away from the laboratory without witnessing the process. Findings were identified to relate to the SOP and not observations related to the process being carried out. Any findings would then be discussed by the auditor with the Head of Section and the Quality Manager (1) and given a grade (non-conformance or communication) (5). The audit is then closed in the quality management system by selecting the completion date and selecting the name of the auditor (5). A summary report is then created on the quality management system (5) and the audit findings are reviewed a second time by the Head of Section and the Quality Manager, who also accepts the findings on the quality management system (5). Next the Quality Manager and Auditor feedback to one another about the audit process (this does not form part of the current SOP but was highlighted in the conversation related to the vertical audit process) (5). Any CAPA related to the findings is completed (5) and the Head of Section closes actions and non-conformities (5). The Quality Manager will then perform a final review and closeout of the audit (no input from the Head of Section) (3) and will perform a quarterly review of all non-conformities to check for successful implementation of CAPA (This is not documented in the process) (1).

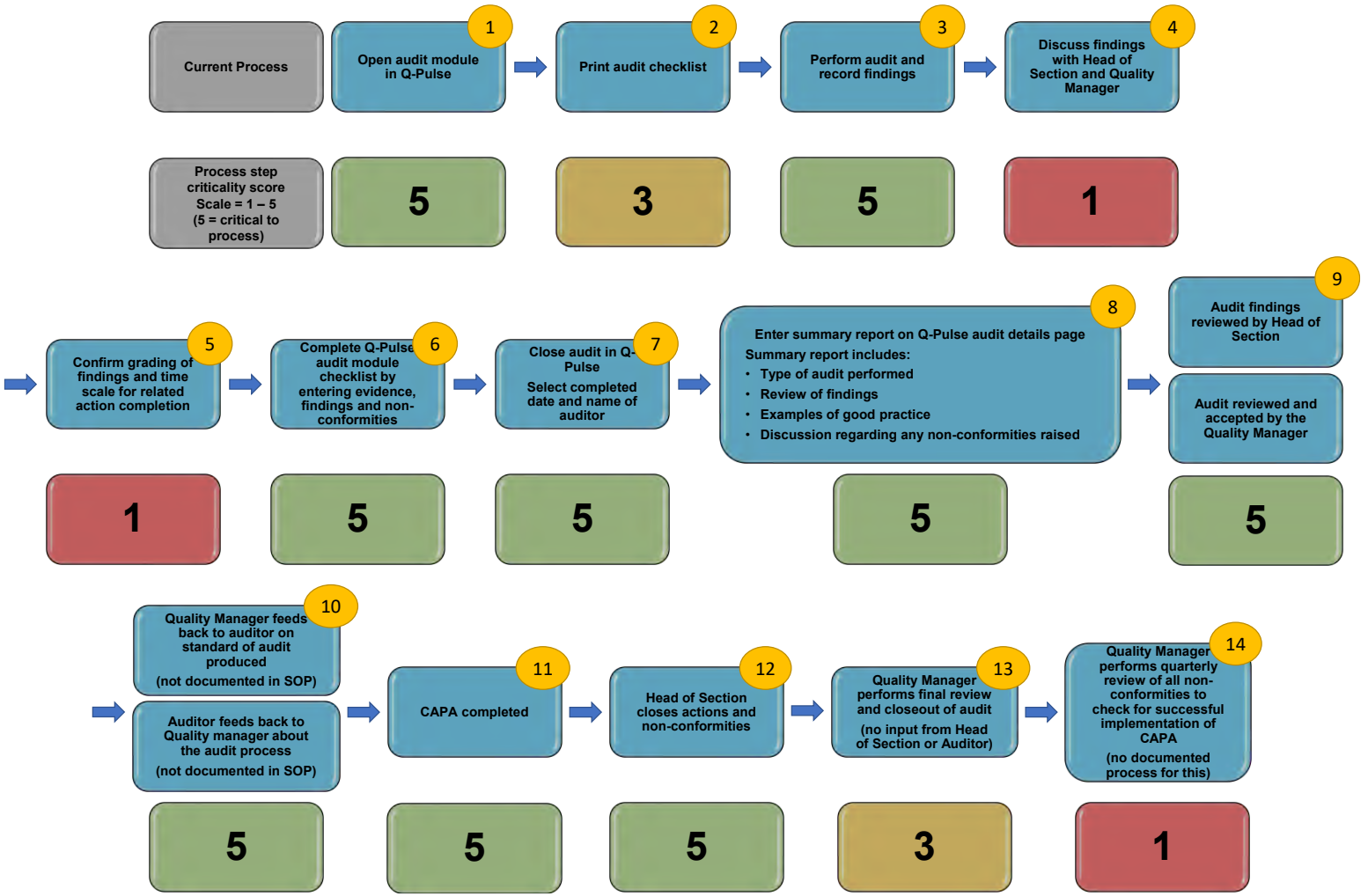


Figure 4-18: Summary of the current state process to undertake vertical audit in the HTL and criticality score for each step
Scoring = 1 – 5, where 5 identified that a step was critical to the process. There are 14 steps in the process (step number in yellow circle), three were identified as not critical to the process (Steps 4, 5 and 14; criticality score = 1); two were identified to be semi critical to the process (Steps 2 and 13; criticality score = 3); nine were identified to be critical to the process (Steps 1, 3, 6, 7, 8, 9, 10, 11, and 12; criticality score = 5).

4.2.5.3 Review of Historic Audit Output

A review of the current process was carried out by the Head of Section in Transfusion, RCI National Improvement Manager and Project Lead. The aim of the discussion was to identify what was good, not so good and needed improvement in the current audit process. The areas identified are listed below:

What's good

- Additional details box on Q-Pulse allows the Head of Section to add comments related to the vertical audit output.
- The area of standard is listed in Q-Pulse allowing the auditor to understand what they are assessing against.
- Current process adds value as it identifies non-conformances (not all are captured due to current limited live observation of vertical audit process).
- There is a standard template for vertical audit.
- Quick links on the Q-Pulse audit record joins up non-conformances to quality incident records.
- Guidance is available related to each step of the audit.
- Immediate actions can be completed in Q-Pulse to raise a document change request.

What's not so good

- At the end of an audit, full completion of required information from the auditor is not achieved. The areas that are not complete are the fields that relate to the standards and auditor actions.
- The auditor actions tab is not used in Q-Pulse.
- Some questions in the audit list on Q-Pulse aren't required.
- Standard audit template does not have the required level of detail e.g. what was seen or description of what is required from the auditor or area of standard.
- Guidance for audit step isn't descriptive enough to help with the audit.
- A quality incident is not raised if the audit goes overdue, so there is no assessment of the associated risk.
- Printout from Q-Pulse audit checklist doesn't allow space to complete notes related to the process being audited.
- No pre-population of documents to audit (pre-audit preparation doesn't take place).
- Audit completed in a silo (desktop) rather than a witness style audit (for some audits).
- No assessment of risk related to undertaking audit actions or not undertaking audit actions.
- Only transfusion staff auditing transfusion process.
- Lack of communication between the Auditor and Quality Manager.

- Non-conformances generally relate to documentation or electronic records because observation of the process does not take place.

Areas for improvement

- The vertical audit process needs to be built around a process that identifies risk related to completing or not completing actions.
- A physical document is required to write down findings related to ISO15189 as the vertical audit is taking place. This should be a template that also contains prompts on the document for information that is required to complete audit checklist on Q-Pulse. This would help to improve the understanding of the process for the auditor
- Define a process that includes desktop and witness stages of the audit.

4.2.5.4 Future State of Training to Perform Vertical Audit

The future state of the training process to vertical audit contains five steps and captures the enablers and the people required to undertake each step (Figure 4-19). The process begins with identifying the person to be trained to vertical audit. This requires trainers to manage the number of HTL staff that are required in total to be trained auditors. Next there are four parts of training that must be complete in order. Part A is a classroom-based exercise delivered by the trainer that relies on a training package, which includes department documents related to audit and a final knowledge check. Part B involves the trainee shadowing a trained auditor undertaking the future state audit process. Part C is split into two stages, if the trainee has not experienced vertical audit in previous roles, they will complete an audit, following the future state, while being shadowed by a trained auditor. The trainee will then complete a vertical audit without being shadowed. If the trainee has previous experience of completing vertical audits, they will move straight to complete a vertical audit without being shadowed. Part D will involve the trainer and Head of Section or Quality Manager assessing the output of the audit and signing off the trainee as competent if they meet the training requirements.

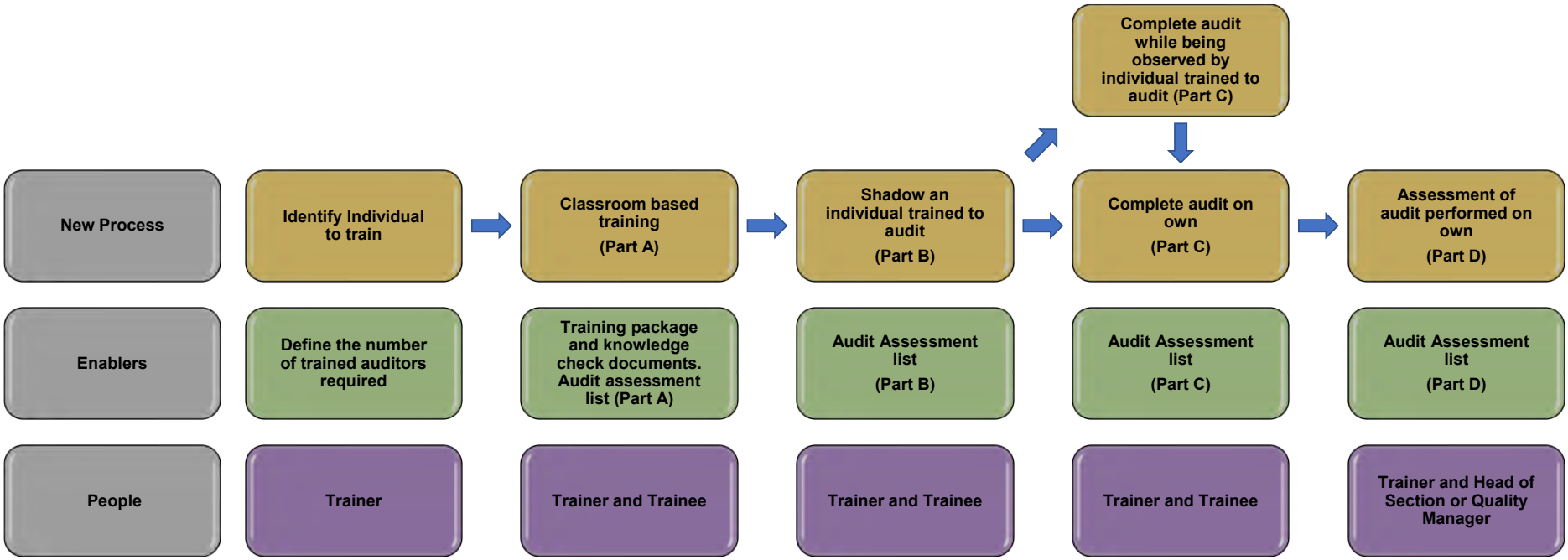


Figure 4-19: Summary of the future state process to train HTL staff to perform vertical audit.
The new process steps are presented (Yellow boxes), including enablers (Green boxes) and people (Purple boxes) that are required to undertake each step. There are either 5 steps (Trainees that have previous experience in vertical audit) or 6 steps (Trainees that do not have previous experience in vertical audit) that form the new process which is broken down into defined training parts (A, B, C and D).

4.2.5.5 Future State of the Vertical Audit Process

The future state design of the vertical audit process consists of 10 steps and captures the enablers and people required to undertake each step. The new process also maintains steps that were considered critical and semi critical in the current state vertical audit process (Figure 4-20). The process begins with the Head of Section or Quality Manager identifying in the quality management system the process that requires vertical audit (step 1). An auditor is then assigned (step 2) who undertakes a scoping meeting to identify the date and scope of the audit, as well as time for planning the audit (step 3; current state = step 1). Pre-audit planning will take place (step 4; current state = step 2) and the audit is performed (step 5; current state = step 3). If the audit cannot be performed on the assigned date, a quality incident is raised on the quality management system as well as completion of a risk and impact form related to failure to complete (step 6). An audit closing meeting is then held between the Auditor, Auditee, Head of Section, and the Quality Manager to confirm findings, assign actions and related target dates (step 7; current state = step 9). The auditor will write a summary report for the audit, upload the checklist, and assign actions in the quality management system. The audit output will be added to the quality management system (step 8; current state = 6 and 8). Next the actions will be completed, and the outcomes documented in the quality management system (step 9; current state = 11 and 12). The audit will then be reviewed in the quality management system by the Quality Manager and Head of Section and the audit will be closed when considered complete (step 10; current state = 7, 10 and 13).

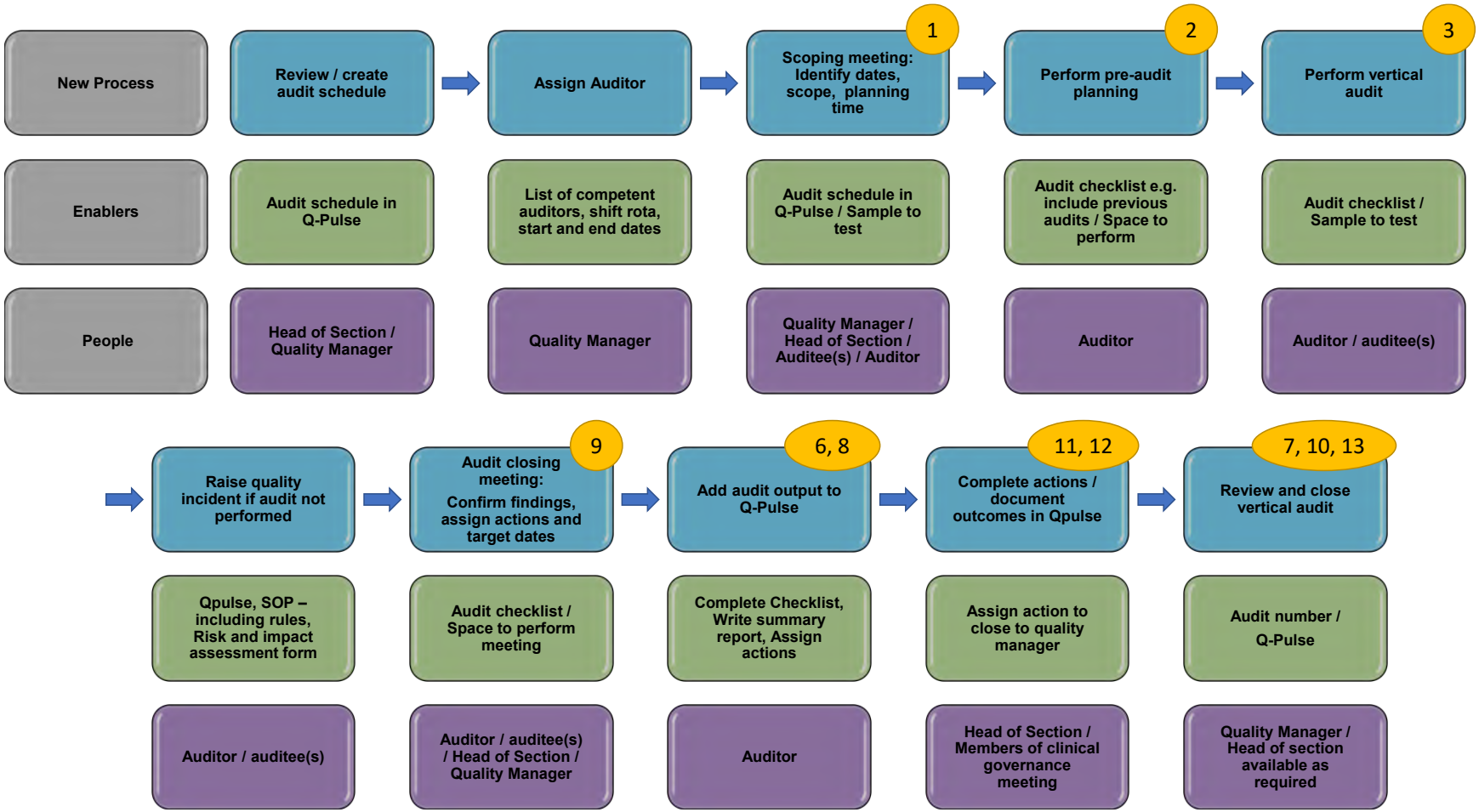


Figure 4-20: Summary of the future state process to undertake vertical audit in the HTL
The new process steps are presented (Blue boxes), including enablers (Green boxes) and people (Purple boxes) that are required to undertake each step. There are 10 steps that form the new process that include the steps considered to be critical and semi critical in the current state process map (step number highlighted in yellow circles).

4.2.6 Laboratory Solution Development to LEAN the Activity Related to the Hospital Transfusion Laboratory's Sample Verification, Automation and Manual Crossmatching Processes

4.2.6.1 Current Vs Future State Assessment of the Sample Verification, Automation and Manual Crossmatching Processes

The current state laboratory layouts with process maps overlayed, identified that the sample verification, automation, and manual crossmatch processes were not optimally undertaken in the HTL (Figure 4-21). The current state map of the sample verification process identified a long movement across the entire laboratory from the area of the lab where the laboratory computers are present to the location of the centrifuge (Figure 4-21A movement 3; Table 4-3 = 15 footsteps). The overview of the automation process identified activity that was focused on the location of the automation equipment, with repetitive movements between locations (Figure 4-21B – movements 1 and 2; movements 4, 5 and 6). The manual crossmatch process was identified to be more complex than the sample verification and automation processes (Figure 4-21Ci and Cii; Table 4-3 – Current state manual crossmatching = 16 movements; 68 and 77 footsteps Vs sample verification = 6 movements; 26 footsteps and automation = 6 movements; 24 footsteps). There were long movements present in the crossmatch process (Figure 4-21Ci and Cii and Table 4-3 – movement 4 (Cii) = 12 footsteps, 5 (Cii) = 12 footsteps; 13 (Ci and Cii) = 9 footsteps and 14 (Ci and Cii) = 9 footsteps) as well as repetitive movements within the laboratory space (Figure 4-21Ci – movements 5 and 6; 8 and 9; 13 and 14. Cii – movements 4 and 5; 6 and 7; 11 and 12; 13 and 14). The manual serology bench (Figure 4-21 – MS) and location of laboratory computers appeared to create a barrier for flow and movement in the laboratory. This forced the HTL staff to walk around the issue bench into the location to use the laboratory computers (Figure 4-21A and Cii).

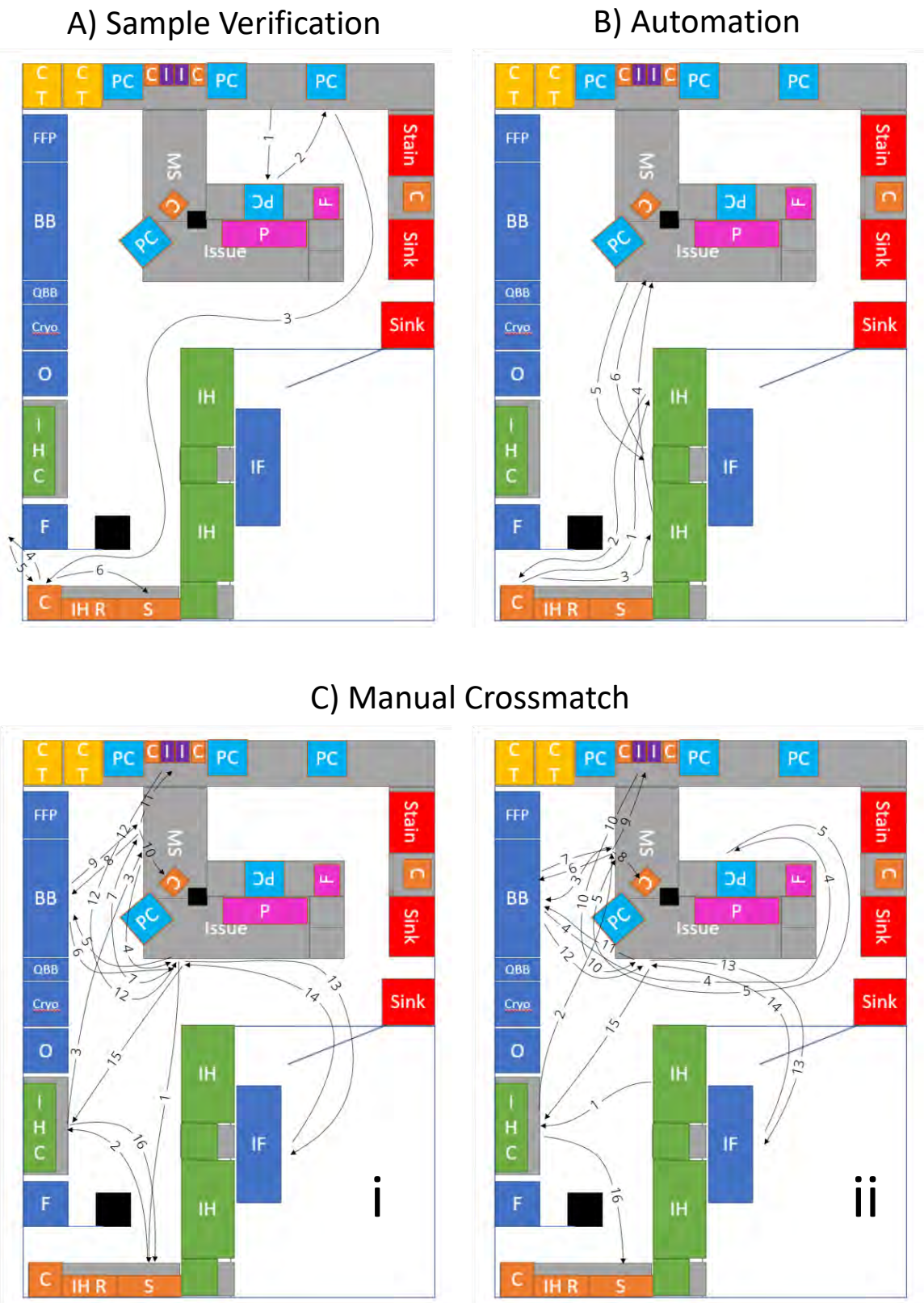


Figure 4-21: Current state layout of the hospital transfusion laboratory with overlaying process maps (Not to Scale). The Figure highlights the start and finish points of process related movements in chronological order for the sample verification (A); Automation (B) and Manual crossmatching (C). Item key = IH = Automation; IHR = Automation racks; IHC = Automation cards; C = Centrifuge; F = Fridge; Cryo = Cryo freezer; BB = Blood bank; QBB = Quarantine blood bank; IF = Issue fridge; MS = manual serology workbench; Issue = Blood unit issue bench; P = Printers; F = Fax; I = Incubator; FFP = Fresh frozen plasma; CT = Cryo thawer; O = Octoplas freezer; S = Samples.

Future state laboratory layout and overlayed process maps demonstrated better flow for the processes and greater separation of the more complex manual serology process from the shorter and simpler sample verification and automation processes (Figure 4-22A – blue manual crossmatch process arrows Vs black sample verification and red automation process arrows). This was achieved by: removal of the original manual serology workspace (1); reposition of the blood unit issue bench (2); reposition of the sample storage location, automation racks and consumables (3); a change in printer positions (4); altering the placement of the laboratory computers (5) (Figure 4-22B).

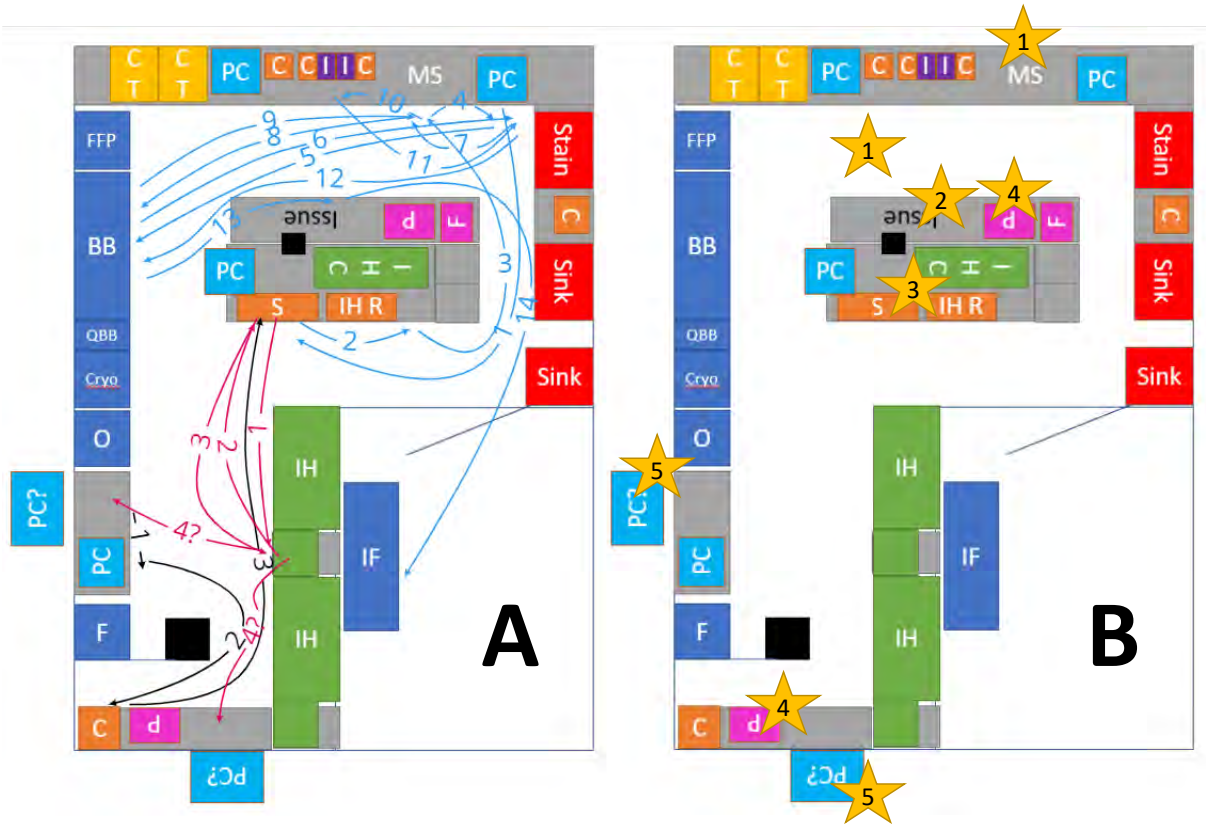


Figure 4-22: Future state layout of the hospital transfusion laboratory.
(A) Highlights the start and finish points of process related movements in chronological order for the sample verification (black arrows); automation (red arrows) and manual crossmatching (blue arrows) laboratory processes. (B) Identifies the: 1 – removal of the original manual serology workspace; 2 – reposition of the blood unit issue bench; 3 –reposition of the sample storage location, automation racks and consumables; 4 – Printer positions; 5 – positions of laboratory computers. Item key = IH = Automation; IHR = Automation racks; IHC = Automation cards; C = Centrifuge; F = Fridge; Cryo = Cryo freezer; BB = Blood bank; QBB = Quarantine blood bank; IF = Issue fridge; MS = manual serology workbench; Issue = Blood unit issue bench; P = Printers; F = Fax; I = Incubator; FFP = Fresh frozen plasma; CT = Cryo thawer; O = Octoplas freezer; S = Samples.

All future state processes demonstrated a reduction in the number of movements, but only the sample verification and automation processes were identified to have a reduction in the number of steps (Table 4-3; Number of movements/Total Steps related to the current state Vs future state – Sample verification = 6/26 Vs 3/11; Automation = 6/24 Vs 4/11; Manual crossmatch = 16/average 72.5 Vs 14/75). The long movement across the laboratory previously present in the sample verification process had seen the number of steps halved (Table 4-3; Current Vs future state = 15 Vs 7). There was a reduction in the number of repetitive motions in the automation process (Figure 4-21B and Figure 4-22; Current Vs future state = movements 1 and 2; movements 4,

5 and 6 Vs movements 1, 2 and 3). The new laboratory layout resulted in the manual crossmatch process having a greater number of long movements (Table 4-3, Figure 4-21Ci, Cii and Figure 4-22; Current Vs Future state = 4 Vs 8; future state movement 1 = 9 footsteps; 3, 5, 6. 8, 9 and 12 = 8 footsteps; 14 = 12 footsteps), but fewer repetitive movements (Figure 4-21Ci, Cii and Figure 4-22; Current state Vs Future state = 4/3 Vs 2; future state repetitive movements = 5 and 6; 8 and 9).

Table 4-3: Current and future state process related movement data.
For each process the Table identifies the number of movements/Total Steps related to the current state Vs future state. Sample verification = 6/26 Vs 3/11; Automation = 6/24 Vs 4/11; Manual crossmatch = 16/average 72.5 Vs 14/75.

Process	**Sample Verification**		**Automation**		**Manual Crossmatch**		
	Number of Steps						
Movement	Current	Future	Current	Future	Current	Current	Future
Total Steps	26	11	24	11	68	77	75
1	2	0	4	3	6	3	9
2	2	4	4	3	4	6	1
3	15	7	4	3	6	2	8
4	3		4	2	6	12	0
5	3		4		3	12	8
6	1		4		3	2	8
7					4	2	0
8					2	0	8
9					2	0	8
10					0	6	1
11					0	3	1
12					6	3	8
13					9	9	3
14					9	9	12
15					4	4	
16					4	4	

Through mapping of each of the processes current and future state, data was collected that identified the:

- Process start and end point – These were identical for current and future state.
- Flow time – All processes were shorter in the future state (Sample verification = 17 minutes 0 seconds Vs 9 minutes 30 seconds; Automation = 1 hour 30 minutes Vs 35 minutes 19 seconds; Manual crossmatch = 1 hour 5 minutes/40 minutes Vs 29 minutes).
- Touch time – The amount of time staff interacted with the process was reduced for all processes (Sample verification = 7 minutes Vs 4 minutes 27 seconds; Automation = 14 minutes Vs 5 minutes 30 seconds; Manual crossmatch = 11 minutes/7 minutes Vs 2 minutes 44 seconds).
- How many people were involved in the process – Fewer individuals were involved in the future state version of the sample verification and automation processes (Sample verification = 2 Vs 1; Automation = 2 Vs 1); but the same number (1 person) for the current and future state versions of the manual crossmatch process.
- Percentage yield – This was estimated by staff who thought there would be no difference between current and future states (Sample verification = 96%; Automation = 90%; Manual crossmatch = 95%).
- Number of interruptions – No difference in the number of interruptions was seen for the sample verification process, however, these did differ in type between current and future state (3 [Discussion with laboratory manager; Staff from outside lab came to discuss an order; Conversation with the other BMS involved in the process, not about work] Vs 3 [Discussion on three separate occasions with other laboratory BMS related to another process]). A dramatic reduction in the number of interruptions was observed in relation to the future state automation process (9 Vs 1). There was also a reduction in interruptions related to the future state for the manual crossmatching process, where no interruptions were observed (5/3 Vs 0)
- Work in progress – The current sample verification process and one of the observations related to manual crossmatch had work in progress (Current Vs future state – Sample verification = 11 Vs 0; Automation = 0 Vs 0; Manual crossmatch = 1/0 Vs 0); Problems/flow stoppers (Sample verification = 1 Vs 1; Automation = 1 Vs 0; Manual crossmatch = 1/2 Vs 0).
- Problems/flow stoppers – A range of problems and flow stoppers were identified for each process, but few were shared between processes or the current and future states. Those identified were: Staffing levels (Current state – Sample verification and Automation); Having to log into computer (Future state – Sample verification); Colleague gaining cupboard access (Current state – manual crossmatch); Additional work resulting in missed end of centrifugation (Current state – manual crossmatch); Patient ABO group not authorised (Current state – manual crossmatch).

(Table 4-4)

Table 4-4: Comparison between current Vs future state process related data.
Start and finish point (Identical for both current Vs Future state); Flow time (Sample verification = 17 minutes 0 seconds Vs 9 minutes 30 seconds; Automation = 1 hour 30 minutes Vs 35 minutes 19 seconds; Manual crossmatch = 1 hour 5 minutes/40 minutes Vs 29 minutes); Touch time (Sample verification = 7 minutes Vs 4 minutes 27 seconds; Automation = 14 minutes Vs 5 minutes 30 seconds; Manual crossmatch = 11 minutes/7 minutes Vs 2 minutes 44 seconds); Number of people (Sample verification = 2 Vs 1; Automation = 2 Vs 1; Manual crossmatch = Identical for both current and future state = 1); Percentage yield (Sample verification = identical for current and future state = 96%; Automation = identical for current and future state = 90%; Manual crossmatch = identical for current and future state = 95%); Number and type of interruptions (Sample verification = 3 Vs 3 – Interruptions were different for current and future state; Automation = 9 Vs 1; Manual crossmatch = 5/3 Vs 0) ; Work in progress (Sample verification = 11 Vs 0; Automation = 0 Vs 0; Manual crossmatch = 1/0 Vs 0); Problems/flow stoppers (Sample verification = 1 Vs 1; Automation = 1 Vs 0; Manual crossmatch = 1/2 Vs 0)

Process	**Sample verification**		**Automation**		**Manual Crossmatch**		
State	Current	Future	Current	Future	Current	Current	Future
Process step start point	Sample referral box		Loading samples onto the instrument		Receive order		
Process step end point	Samples removed from centrifuge		Authorisation of results and referral forms placed in the completed tray		Units issued and placed into the issue fridge		
Flow time	17 minutes 0 seconds	9 minutes 30 seconds	1 hour 30 minutes	35 minutes 19 seconds	1 hour 5 minutes	40 minutes	29 minutes
Touch time	7 minutes	4 minutes 27 seconds	14 minutes	5 minutes 30 seconds	11 minutes	7 minutes	2 minutes 44 seconds
Number of people	2	1	2	1	1	1	1
Percentage yield (right first time – estimate from staff)	70% of samples referred are correct and don't require clarification. After contact, 96% of samples not rejected		90% the 10% read errors on screening panel cells e.g. liquid errors.		95%		
Number of interruptions	3 Discussion with laboratory manager	3 Discussion with other laboratory BMS related to another process (x3)	9 Phone call (x5) Sample reception staff delivering samples Issue of units	1 Porter	5 Work discussion Phone call related to crossmatch	3 Phone call (x3)	None

	Staff from outside lab came to discuss an order Conversation with the other BMS involved in the process, not about work.		Manual crossmatch incubation complete Porter		BMS asked for access to cupboard under bench (x2) BMS asked for support with another investigation		
Work in progress	11 Samples waited in the sample referral box while staff were undertaking other work; waiting time was 6 minutes	None	None	None	One sample on the manual serology bench where the crossmatch is completed	None	None
Problems / flow stoppers	Below staff capacity levels	Computer logged out and had to be logged back in.	Below staff capacity levels	None	BMS gaining access to cupboard under the bench BMS did not hear the end of the centrifugation stage for the crossmatch as busy with additional work	Patient ABO group not authorised	None

4.2.6.2 LEAN Eight Waste Assessment of the Current and Future State Sample Verification, Automation and Manual Crossmatch Processes

During process mapping of sample verification, automation and manual crossmatch, any observation of the following LEAN Manufacturing wastes was documented:

1. Transport – Sample verification (current and future state) as well as manual crossmatch were identified to have transport related waste. For sample verification (current state), samples were taken to a laboratory computer and then walked back to split the workload with another member of staff. In the future state of sample verification samples were collected, but a rack was required meaning the member of staff had to return to the start location to collect the sample rack. For the manual crossmatch process, the member of staff undertook repetitive movements to carry RBC units and samples on separate occasions, but, from the same location.
2. Inventory – Waste was only observed for the current state sample verification process where the member of staff carried 11 samples and paperwork without the use of a rack or tray.
3. Motion – For all processes, except the future state of the sample verification process, waste was observed, this was: A long walk between the laboratory computers and centrifuge (current state – sample verification); Separate movements to approve, transfer and authorise groups of results (current state – automation); Extra movements to check investigation was complete and to check on the sample (Future state – automation); Long walk to collect sample and rack for sample (current state – manual crossmatch); Lots of back and fore to the blood bank fridge (current and future state – manual crossmatch).
4. People – The waste observed was that multiple members of staff were undertaking a process that could be completed by one staff member (Current state – Sample verification); Staffing was below capacity resulting in the Head of Laboratory performing work (current state – manual crossmatch).
5. Waiting – All current and future state processes were identified to have steps that resulted in waiting.
6. Over production – There was no waste observed in relation to this category.
7. Over processing – There was no waste observed in relation to this category.
8. Defects – Only the future state process for sample verification and automation presented defects, these were: Centrifuge lid would not close (sample verification); automation error (automation) and sample not suitable for testing (automation).

(Table 4-5)

Table 4-5: Comparison of the LEAN 8 wastes (Transport; Inventory; Motion; People; Waiting; Over production; Over processing; Defects) between current Vs future state process maps of the sample verification, automation, and manual crossmatch processes.
Waste was observed in the current state sample process alone for: Sample verification – inventory, motion, people; Manual crossmatch – people. Waste was observed in the current and future state process for: Sample verification – transport, waiting; Automation – motion, waiting; manual crossmatch – motion, waiting. Waste was observed in the future state process alone for: Sample verification – Defects; Automation – Defects. No waste was observed in either the current or future state process for: Sample verification – over production, over processing; Automation – transport, inventory, people, over production, over processing; Manual crossmatch – inventory, over production, over processing, defects.

Process	**Sample verification**		**Automation**		**Manual crossmatch**		
State	Current	Future	Current	Future	Current		Future
Transport	11 samples taken by one BMS, another BMS then helped so 5 samples walked back and handed over	4 items and no rack so had to collect a rack	None	None	None	Carrying red cell units to PC and samples to the PC on separate occasions	None
Inventory	11 samples in hands and paperwork. No tray or rack used	None	None	None	None	None	None
Motion	Long walk from the PCs to the centrifuge	None	Separate movements to approve, transfer and authorise batches of results (five results in a batch)	Extra movements to check investigation was complete and to check on the sample	Long walk to collect sample and rack for sample Lots of back and fore to the blood bank fridge	Long walk to collect sample and rack for sample Lots of back and fore to the blood bank fridge	Lots of back and fore to the blood bank fridge
People	Band 5 BMS (x2)	None	None	None	Lab was short staffed Laboratory manager undertaking crossmatch (band 8)	None	None

Waiting	Sample in verification box for 6 minutes waiting Centrifuge 4 minutes	Centrifuge 4 minutes Logging into computer system	Investigation run time	Investigation run time	Incubation 15 minutes Centrifuge 10 minutes Waiting for computer to be free	Incubation 15 minutes Centrifuge 10 minutes Card left in the centrifuge for 10 minutes not spinning. Group had to be authorised to complete crossmatch	Incubation 15 minutes Centrifuge 10 minutes
Overproduction	None	None	None	None	None	None	None
Overprocessing	None	None	None	None	None	None	None
Defects	None	Lid of centrifuge would not close	None	Liquid error in well Lipemic sample that was also haemolysed	None	None	None

4.2.6.3 Failure Mode Effect Analysis of Assessment of the Current and Future State Sample Verification, Automation and Manual Crossmatch Processes

The identified risk steps related to the sample verification, automation and manual crossmatch processes were assessed for their perceived impact of the risk, the likelihood of the risk, and the ease of detection of the risk (scale = 1 – 5; 5 = worst outcome for risk and likelihood; or no controls for ease of detection). The FMEA score was calculated by multiplying the impact, likelihood, and ease of detection scores together. A reduction was observed for nearly all FMEA scores if the related solutions were implemented (Table 4-6). The only risk step where a score was not reduced was risk step 13 – Routine work gets delayed due to urgent work, bottle neck created, and all results sent from automation at same time. This was unable to be impacted due to the design of the automation and its related software. Total FMEA score for all risk steps was reduced from 677 to 152 if all possible solutions were implemented (Table 4-6).

Table 4-6:Failure mode effect analysis (FMEA) of process related risk steps with and without possible solutions.
Risk steps were assessed by identifying perceived impact of the risk, the likelihood of the risk, and the ease of detection of the risk (scale = 1 – 5; 5 = worst outcome for risk and likelihood, or no controls for the ease of detection). FMEA score of each risk step was reduced by the suggested possible solution (FMEA score = impact X likelihood X ease of detection; risk step 13 FMEA score not impacted as unable to alter automation and its related software). Total FMEA score was reduced for the future state Vs current state (152 Vs 667).

	Current State				**Future State**				
Risk step	Impact	Likelihood	Ease of detection	FMEA Score (Total 667)	Possible Solutions	Impact	Likelihood	Ease of detection	FMEA Score (Total 152)
1. PC in wrong location	4	5	3	60	Redesign laboratory layout that includes a move of the PC and Centrifuge	2	2	3	12
Distractions	3	5	5	75	Agreed laboratory rules relating to distractions e.g. When staff from other hospital locations enter the laboratory. Assign a member of the team as laboratory lead e.g. The go to person in the laboratory setting. Introduce greater awareness of human factors e.g. create a specific area for porters. Create a specific area for approach, a marked area in the laboratory that staff from outside the laboratory setting can approach laboratory staff if they are within, meaning they don't disturb critical processes.	3	4	4	48
2. Lack of human factors knowledge	3	2	5	30	Introduce a greater awareness of human factors	2	1	3	6
3. Lack of flow due to manual crossmatch bench	4	5	5	100	Move the manual serology work bench, unit issue bench and the PCs	2	1	1	2
4. No defined cells	3	5	3	45	Create process specific locations in the laboratory that reduce cross process flow	1	2	2	4

5. Responsibilities, no lab lead	3	3	5	45	Introduce Laboratory and process Leads	2	2	3	12
6. PC use not optimised	2	2	2	8	Redesign laboratory layout to allows optimisation of interaction with PC related to process flow	2	2	1	4
7. Narrow walk throughs *8. Verification PCs in a one-way system with a dead end* *9. Staff walking past issue bench while issue process taking place - distraction*	4	5	5	100	Redesign layout so people aren't sitting or standing in narrow walk throughs e.g. current location of issues bench LEAN cell anticlockwise U shape consideration for layout and process flow where possible. Wider walkways	2	1	1	2
10. Urgent work could get missed or delayed	5	3	4	60	Introduce new visual management Move location of urgent work box or remove the urgent work box so that laboratory staff must be approached about urgent referrals Introduce a Laboratory Lead Create a specific area for the porter to wait	2	2	2	8
11. Lack of visibility of analysers	4	2	4	32	Redesign the laboratory layout	2	1	4	4
12. Lack of visibility of samples in centrifuge	3	4	3	36	Move centrifuge Redesign the laboratory layout	2	2	2	8

13. Routine work gets delayed due urgent work, bottle neck created, and all results sent from automation at same time	2	4	5	40	Unable to impact due to design of automation and its related software	N/A	N/A	N/A	40
14. Interruptions, cupboards not accessible	3	4	3	36	Redesign the laboratory layout or move items in the cupboards to more suitable location	1	1	2	2
			Total	667				Total	152

4.2.7 Financial Summary of the Application of the Laboratory Solution Development Platform

The financial summary for service development and implementation using the LEAN Laboratory Solution Development Platform considered 45 items of activity (31 where multiple staff were involved in the same activity) that were grouped under 14 different blocks of activity (Table 4-7). The total time associated to charging for the platform's use was 278.75 hours and utilised mostly senior level NHSBT employees (Band 7 or greater = 42/45 items of activity). Employees position on their band could vary. For the purpose of the financial summary, costs for each activity were calculated based on all employees being at the top, middle or bottom of their band. The total cost related to all 45 items of activity if all employees were at the: top of their band = £11,429.51; middle of their band = £9,853.46; bottom of their band = £9,783.56 (See Appendix 4 for full spreadsheet and related formulae).

Table 4-7: Summary of costs related to service development and implementation using the LEAN Laboratory Solution Development Platform. Summarised in the table is the: Activity undertaken; Activity block – the association of the activities with each other; Time assigned to each activity; Pay band of the member of staff involved; Cost associated to the staff members time, A = top of pay band, B = middle of the band, C = bottom of the band. The table highlights the total: Time taken to provide all activities (278.75 hours); cost if all staff members involved were at the top, middle or bottom of their associated pay band (£11,429.51; £9,853.46 or £9,783.56 respectively) (See Appendix 4 for full spreadsheet and related formulae).

Activity	**Activity Block**	**Time (hr)**	**Pay Band**	**Cost A (Top of Band)**	**Cost B (Middle of Band)**	**Cost C (Bottom of Band)**
Initialisation/advertisement	1	7.50	8b	£311.22	£267.54	£266.26
Initialisation/advertisement		7.50	8d	£441.87	£382.85	£381.47
Scoping meeting Preparation	2	3.00	8b (1)	£124.49	£107.01	£106.50
Scoping meeting Preparation		3.00	8b (2)	£124.49	£107.01	£106.50
Scoping meeting		1.00	8b (1)	£41.50	£35.67	£35.50
Scoping meeting		1.00	8b (2)	£41.50	£35.67	£35.50
Scoping meeting output		1.00	8b (1)	£41.50	£35.67	£35.50
Scoping meeting output		1.00	8b (2)	£41.50	£35.67	£35.50
Data gathering	3	15.00	8b	£622.43	£535.07	£532.52
Data analysis		15.00	8b	£622.43	£535.07	£532.52
Service development	4	22.50	8b (1)	£933.65	£802.61	£798.78
Service development		22.50	8b (2)	£933.65	£802.61	£798.78
Proposal meeting Preparation	5	3.00	8b	£124.49	£107.01	£106.50
proposal meeting		1.00	8b	£41.50	£35.67	£35.50
proposal meeting output		1.00	8b	£41.50	£35.67	£35.50
Optional redevelopment proposal Preparation	6	3.00	8b	£124.49	£107.01	£106.50
Optional redevelopment proposal meeting		1.00	8b	£41.50	£35.67	£35.50
Optional redevelopment proposal output		1.00	8b	£41.50	£35.67	£35.50
Event scoping preparation	7	3.00	8b	£124.49	£107.01	£106.50
Event scoping meeting		1.00	8b	£41.50	£35.67	£35.50
Event scoping output		1.00	8b	£41.50	£35.67	£35.50
Data gathering	8	15.00	8b	£622.43	£535.07	£532.52
Data analysis		15.00	8b	£622.43	£535.07	£532.52
Event preparation		3.00	8b (1)	£124.49	£107.01	£106.50
Event preparation		3.00	8b (2)	£124.49	£107.01	£106.50
Event Meeting		7.50	8b (1)	£311.22	£267.54	£266.26

Event Meeting		7.50	8b (2)	£311.22	£267.54	£266.26
Event Meeting		2.00	8d	£117.83	£102.09	£101.72
Event Meeting		3.75	4	£60.87	£60.77	£55.23
Event Meeting		7.50	7 (optional)	£224.39	£205.61	£194.95
Event Meeting		7.50	6 (optional)	£189.94	£166.41	£157.00
Event Output		2.00	8b	£82.99	£71.34	£71.00
Implementation training	9	4.00	8b	£165.98	£142.69	£142.01
Implementation idea		30.00	8b	£1,244.86	£1,070.15	£1,065.04
Sustainment meeting (1)	10	3.00	8b (1)	£124.49	£107.01	£106.50
Sustainment meeting (1)		1.50	8b (2)	£62.24	£53.51	£53.25
Sustainment meeting (2)	11	3.00	8b (1)	£124.49	£107.01	£106.50
Sustainment meeting (2)		1.50	8b (2)	£62.24	£53.51	£53.25
Sustainment meeting (3)	12	3.00	8b (1)	£124.49	£107.01	£106.50
Sustainment meeting (3)		1.50	8b (2)	£62.24	£53.51	£53.25
Sustainment Data gathering	13	15.00	8b	£622.43	£535.07	£532.52
Sustainment data analysis		15.00	8b	£622.43	£535.07	£532.52
Formal close preparation	14	3.00	8b	£124.49	£107.01	£106.50
Formal close		2.00	8b	£82.99	£71.34	£71.00
Report writing		7.50	8b	£311.22	£267.54	£266.26
	Total	278.75	N/A	£11,429.51	£9,853.46	£9,783.46

Chapter 5 Discussion

"The reference service provided by NHSBT RCI has been re-developed several times. Originally, the service was not led by the customer, instead RCI matched its own resources (staff, equipment, and consumables) with a leadership idea of what was required by the HTL. Once RCI had established a customer base, it entered a consultive phase to better target the customer's service requirement, becoming led more greatly by the customer. This project built upon this idea by developing a narrative with the customer to create a partnership that shaped service development and delivery. It has allowed for RCI to demonstrate it has the capability to provide services beyond its traditional testing role, to the wider transfusion industry using LEAN Startup."

(Dr Mark Williams – Head of RCI., 2022)

5.1 The Identification of New Service Ideas that the RCI Department Could Provide Hospital Transfusion Laboratories

The healthcare service environment is beset by uncertainty due to its link to state funding, policies, population dynamics, disease status, treatment availability, expectations, and cost (Martin., 2013; Fiorio *et al.,* 2018; Nilsen *et al*., 2020). Implementation of pathology modernisation in the UK introduced a further level of uncertainty for hospital pathology laboratories that were required to form new networks (Sections 1.5 and 1.6). A greater level of uncertainty was felt by reference services like RCI, because they were not included in network planning (Section 1.7) (Cavanagh., 2021). The changes introduced through pathology modernisation created insecurity that could drive a requirement from the HTL for the provision of new service themes beyond RCI's standard catalogue (Section 1.7). LEAN Startup is used to develop products that fit a customer requirement in an environment of uncertainty, so is a good fit for healthcare services at this time (Section 1.8.2). It requires customer engagement from the start of the project, to allow a successful partnership to form between provider and the customer. The partnership between RCI and the HTL in this project started with the development and distribution of a survey to gain opinions from the customer base (Section 3.2.1 and 4.1.1). For a survey to collect strong data for interpretation, the perception is to gain high participant numbers, which are from a range of backgrounds to reduce bias (Wolfe., 2016). In fact, a high level of understanding of a survey question, and of the subject matter by the survey participant is considered more important (Wolfe., 2016; Buschle., 2022). Understanding of the question can be achieved by the pre-testing of surveys, leading to better understanding for respondents, for more optimal output and helping to eliminate answer bias in final survey design (Wolfe., 2016; Buschle., 2022). The surveys utilised in this study did not undergo extensive pre-testing due to the time constraints related to the nature of a professional doctorate. In place of the pre-testing was discussion of the questions with colleagues within NHSBT with senior management level experience of transfusion laboratory practice. This felt a justifiable and pragmatic solution when combined with the survey participants' level of understanding of the topic areas in relation to: Their own senior position in a hospital trust; The position of the hospital within their pathology network; The awareness of the challenges facing pathology at the time of

participation (Section 4.1.1.1). It could be argued that the survey should have been distributed to the full RCI customer base to gain a wider range of opinion, enriching the survey from all perspectives of transfusion laboratory staff. This unfortunately was hindered by constraints related to the progression of the professional doctorate, which did not allow time to pursue NHSBT's process of approval for customer engagement (Wilkes., 2022).

From the perspective of those surveyed, there was mixed opinion relating to the impact pathology modernisation would have on RCI service provision (Section 4.1.1.3). This was potentially the result of most survey participants lacking knowledge of the exclusion of reference services, such as RCI, from the planning of the new pathology networks (Figure 4.3A). RCI perceived a threat of pathology modernisation to the continued uptake of reference services by hospital trusts, but there was no published literature found in the public domain to support this perception (Cavanagh., 2021). Pathology modernisation in general has progressed well across NHS England, and to date, there has been an upward trend in the use of the service provided by RCI (NHS Improvement and NHS England., 2019) (Figure 5-1). The only exception to this is the impact of the COVID19 pandemic, where workload in the RCI laboratory has echoed the decrease in workload across healthcare during periods of lockdown or has seen an increase at a stage of catchup (England, NHS and Improvement, NHS., 2022).

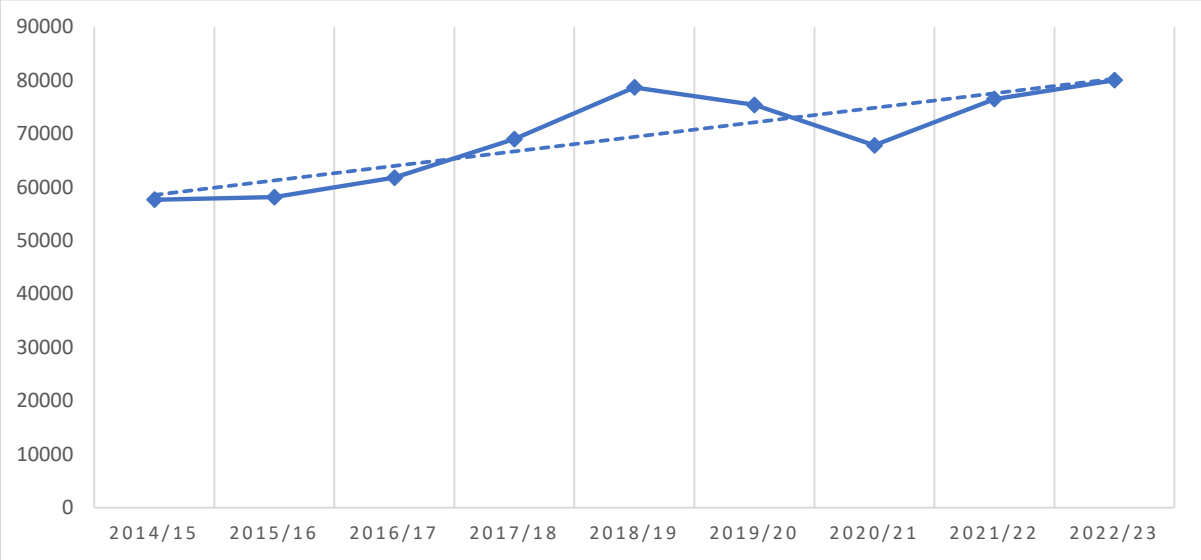


Figure 5-1: RCI end of financial year sample referral figures 2014/15 to 2022/23.
The graph highlights the number of samples referred from HTLs to RCI per financial year from the end of 2014/15 to 2022/23(blue solid line) (2022/23 data not complete). The impact of the COVID19 pandemic is observed with a decrease in sample referrals for years 2019/20 and 2020/21. An overall upward trend in sample referrals to RCI is observed (blue dotted line).

Even though the demand for the service RCI provides has not been negatively impacted by the new pathology networks and forced a change in service direction, the survey outcomes highlight HTL support for the provision of a greater variety of service themes (Section 4.1.3; Figure 4-3C and 4-3D). This could be linked to the general difficulties highlighted in the survey in relation to recruitment and retention of laboratory staff (Section 4.1.1.2). In the transfusion laboratory, falling staff numbers, decreasing skillset, and the related negative impact such as increased error rate are well known (Chaffe *et al*., 2014; UKTLC., 2019). From personal experience, suboptimal levels of staffing in the laboratory setting focuses output on higher priority workloads, such as urgent patient

investigation and RBC crossmatching. This creates a backlog of other activities, many of which were highlighted by the survey participants and attendees of the hospital partnership as something that could be addressed by new service provision from RCI e.g. Training; Service improvement; Quality; Compliance. Transfusion 2024 is a summary of key priorities for clinical and laboratory transfusion practice for safe patient care, identified in a multi-professional symposium that took place in 2019 (Allard *et al*., 2021). It highlights a need for closer integrated partnership working between NHSBT and HTLs, something that can be facilitated by using LEAN Startup for service development (Allard *et al*., 2021; Section 1.8.2). The recommendations of Transfusion 2024 aligned with the areas identified by the HTL survey results for new service themes that could be provided by RCI e.g. Transfusion laboratory safety – Scientific and technical education and training; Regulatory and compliance alignment – MHRA and ISO15189 accreditation support.

When identifying service themes and their components, it is important to have maximal understanding of what the customer requires to ensure optimal uptake of the products that are developed (Section 1.8.3). The VPC is advertised as a tool to accelerate idea formation in line with the customer's needs (Osterwalder *et al*., 2014). Highlighted mistakes that can be made in the use of the VPC include:

- Not seeing the customer profile and value proposition halves as separate tools.
- Mixing several customer segments on a canvas.
- Creating the customer profile through the lens of the value proposition.
- Only focusing on functional jobs and ignoring those that are more social or emotional in nature.
- Trying to address all customer gains and pains.

(Garner., 2015).

It was felt that this project was able to overcome most of these mistakes by:

- Completing the customer profile with the hospital partners before and separate from the value proposition
- Ensuring that the hospital partners were all the same type of customer and the event created to focus on the HTL
- The emotions and social nature of the identified jobs were openly displayed and discussed in the event
- All pains and gains were captured in the event, but the use of the Kano model allowed stratification of those identified that related to must-have service attributes.

Consideration of the potential mistakes would be required in future use of the VPC. For instance, although all hospital partners were associated with the HTL, they weren't considered in the event as separate customers from each other, who have different wants and needs. This could have been better captured by pre-event completion of separate customer segments by each attendee, potentially with their laboratory team. Another

consideration for future use related to the emotions and social nature of jobs. Although these came across well in the event, it wasn't clear if they were captured post event, or considered in the final output of the VPC. Future events would look to capture information related to participants emotions and social nature relating to the identified jobs. This broader scope of data collection could be supported using the Empathy Map, a canvas tool developed by XPLANE (Figure 5-2) (Osterwalder and Pigneur., 2010). Its use improves understanding of the customers' environment, behaviour, concerns, and aspirations (Osterwalder and Pigneur., 2010). It was unfortunate that the author of the thesis was not aware of the Empathy Map Canvas at the time of practical implementation of the VPC, consequently it was not used.

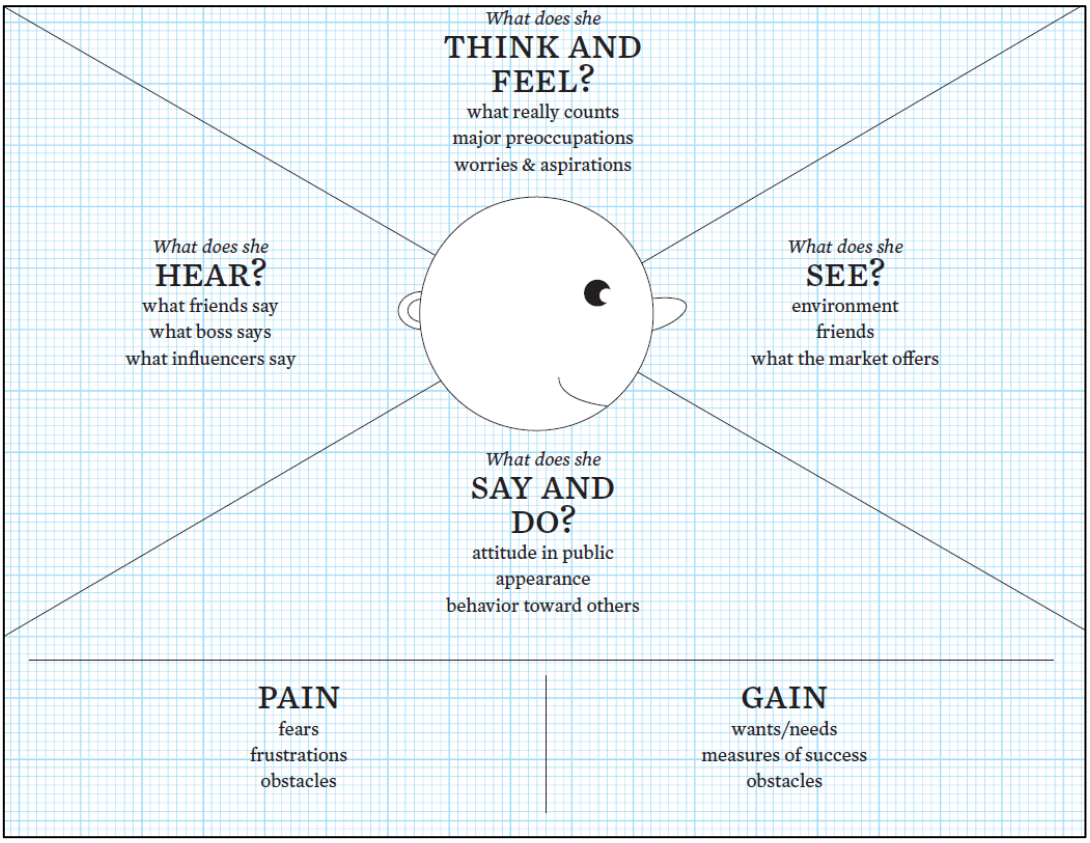


Figure 5-2: The Empathy Map
Constructed from six building blocks to map out the customers emotions and social nature related to their pains and gains. See - describe what the customer sees in her environment; Hear – Describe how the environment influences the customer; Think and feel – Try to sketch out what goes on in the customer's mind; Imagine what the customer might say or behave in public; Pain – What is the customers pain; Gain – What does the customer wish to gain (Taken from Osterwalder and Pigneur., 2010).

Critical review of the VPC, mostly in grey literature such as blogs and opinion pieces instead of peer reviewed articles, have highlighted aspects of its use (Thomsen., 2013; Ayvari and Jyrama., 2017; Payne *et al*., 2020; Belleflamme *et* al., 2021; Korolov., 2022; De Ternay., 2022). In summary, the VPC is suggested to be too simplistic and open to overloading with higher level ideas, that do not allow deeper understanding of their context, or the emotions that surround their identification when mapping onto the VPC segments (Thomsen., 2013; Ayvari and Jyrama., 2017; Belleflamme *et* al., 2021; Korolov., 2022; De Ternay., 2022).

Attendance at the hospital partnership meeting was met with a favourable outlook on the day and an overall opinion that the goal of the VPC was achieved (Sections 4.1.6.1 and 4.1.6.3a). Interaction with the canvas allowed the attendees to clearly lay out what pains the suggested themes were causing and what it meant to their service if there was support for their completion (Section 4.1.6.3a). Aligning with average opinions of the VPC identified in the literature, completion of the canvas was met with mid-level review score from the meeting attendees in relation to their understanding of the tool and ease of its use (Section 4.1.6.3a). Even though the VPC wasn't well understood, there was positive opinion in relation to the engagement with the canvas (Section 4.1.6.3a). Successful completion of the VPC was thought to have been achieved through facilitated support of attendees by the RCI representatives. In hindsight, it may have been useful to have created a learning and training pre-event pack that detailed information about the tools, how they were going to be used in the event and distributable version of the canvases (perhaps online electronic) that could have been populated allowing information to be collated before the event. There is the potential that once developed, the hospital partners may not have been able to, or wanted to engage with the package due to other pressures in their roles.

It is the opinion of the author of this thesis that support of each of the themes by a new service could ultimately have a positive impact on patient care. Even so, this was scarcely identified by attendees, or noted in the VPC. The only mentions were in customer gains that related to the quality assurance or training themes. For the quality assurance it was stated that: A service targeting this theme would increase the safety for the patient, laboratory staff members and the organisation. Relating to the training theme: Safety would be increased related to activities being undertaken in the lab and for products being issued to patients (Section 4.1.3.2). Instead of focusing on the patient, there was a lot of focus on:

(i) Improving the environment for the Scientists in the laboratory e.g. Laboratory capacity planning or Staff mentoring.
(ii) Gaining material from an external partner e.g. documents for training or validation, as well as materials to perform testing that weren't already available in the laboratory.
(iii) Creating cost savings.

Perhaps the infrequent mention of the patient impact was an oversight by the attendees, or lack of acknowledgement and direction influenced by the facilitation of the event organisers. It may have been accepted that the ultimate output of laboratory workload is to provide evidence-based practice to guide those treating the patient. Influence on the participants opinions could have been a result of the event being marketed as service provision for the HTL to allow positive impact for the patient. These opinions seemed to be supported in the post event data collection (Section 4.1.6.2). The majority agreed that service support from RCI would positively impact patient care through greater BMS empowerment, gained through improved training, communication and ultimately a reduction in delays (Section 4.1.6.2).

There are a range of different versions of the Kano model described in the literature which pose questions to allow construction of answers into graphical and table format for the identification of dissatisfaction, as well as

satisfaction of product features (Mikulic and Prebezac., 2011; Materla *et al*., 2019). The Kano model is not a canvas that is related to LEAN Startup and the version used in this project can be considered a basic form of the original, being employed to facilitate the stratification of potential service attributes into levels of desirability (must have, satisfiers, delighters). Employing the Kano model in this manner is common in NHSBT continuous improvement events. It was felt the tool would give a greater depth of understanding in relation to the attributes required to meet the service themes for the customer, tying in more closely with their emotional and social needs. The use of the tool was well received and was thought to have achieved its goal by offering greater depth of understanding of the level of desire for attributes related to service themes (Section 4.1.4.1; 4.1.4.2; 4.1.4.3; 4.1.6.3c and Figure 4-7). In hindsight it could have been useful to treat each participant as a separate customer, attaching suggestions to the Kano model separately from partners and allowing duplicates to appear across the different categories of desirability. This would have given a greater level of understanding of the emotional attachment of service users to aspects of a final service offering. The Kano model used in the event was constructed with scales that offered negative and positive attachment to an attribute (X-axis = Absent to fulfilled; Y-axis = Dissatisfied to Satisfied). Even so, it was felt that the partners in the meeting only identified positive attributes to include in service ideas, rather than those to be avoided (Section 4.1.4.1; 4.1.4.2; 4.1.4.3 and Figure 4-7). This could have resulted from facilitation of the event by RCI representatives and its theme, which was to look at what hospital partners would want in new services, rather than identifying what a service should not be. To avoid this lack of identification of negative attributes, future events should include a session dedicated to their identification.

Not all participants of the pre-hospital partnership meeting survey identified the same areas where they felt RCI could provide support through the creation of new services (Figure 4-3D). This also came out in the hospital partnership meeting open discussion of service ideas (Section 4.1.2), as well as during population of the VPC and Kano models. In the discussions that took place relating to the population of the models no active log was taken, except for the sticky notes added to each canvas. This unfortunately does not define any extended discussion relating to positioning of the final ideas, or any disagreement between partners related to the final outcomes. The summary of the open discussion does suggest that if a specific service theme was targeted, this would impact uptake by HTLs (Sections 4.1.2.2 and 4.1.2.5). It was felt that the HTLs would benefit from a service that marketed a platform for the development of a solution to their current requirement, which could draw upon the service themes identified and discussed in the hospital partnership meeting.

5.2 The Development of Novel Services for RCI Using LEAN Startup Principles and Methodology

The majority of those surveyed as part of the hospital partnership meeting acknowledged experience of developing new services, as well as experiencing difficulties during implementation (Section 4.1.1.4 and Figure 4-4A and B). Many of those answering the pre-event survey identified an awareness of LEAN Startup, but none were fully conversant in its use (Section 4.1.1.5 and Figure 4-5). This could highlight that hospital partners

answering the survey have not used LEAN Startup for service development. It could also identify that the related tools and theory were used, but not understood, leading to failure in service development. Unfortunately, the survey did not directly ask the hospital partners if they had used LEAN Startup to develop new services in the past. Consequently, the relationship of LEAN Startup with the failure of the hospital partners' historic service development is unknown. Even so, it is important to note that the use of LEAN Startup was not highlighted by the hospital partners as a related difficulty for the release of their new or amended services; perhaps suggesting it was not involved in the failure (Section 4.1.1.4 and Figure 4-4B).

The aim of LEAN Startup is to provide the customer with a product that they need, by developing its features with real time customer input, reducing the potential for product failure (Section 1.8.2). Its use draws on the characteristics of LEAN, Design Thinking and Agile Design to facilitate product development for the entrepreneur (Reis., 2011). This opens the possibility that LEAN Startup can suffer the same difficulties and points of failure as the afore mentioned development tools. Points of failure for development tools such as LEAN Startup, LEAN, Design Thinking and Agile Design are accepted to be: A lack of organisation or management support; A general absence of understanding of the tools; A failure in project teamwork; A poor relationship with the customer; Poor project selection (Albiwi., 2014; Edison *et al*., 2015; Nirwan and Dhwanto., 2015; Kolko., 2015; Kolko., 2018; Yordanova., 2018; Euchner., 2019; Ghezzi., 2019). Of these, only inadequate project selection aligns with the identified difficulty experienced by the hospital partners when releasing a new or amended service. The hospital partners identified that difficulty was experienced because the service: Did not meet the requirements of the customer (Figure 4-4B). It could be speculated that a lack of trained individuals to provide a new or amended service highlights a lack of organisational or management support, but the answer is not detailed enough to confirm this assumption. Greater alignment of the hospital partner answers might not have been identified as the question addresses service implementation, whereas the failure points are associated with service development. A rephrasing of the question targeted to identify difficulties experienced in service development would have given greater insight relative to this project's themes. To understand potential failure points for this project a PESTLE analysis was undertaken, identifying any threats, as well as opportunities related to potential factors of risk (Section 4.2.3). Risk factors were identified that aligned with the failure points presented in the literature, such as: A lack of buy-in from the RCI Senior Management Team or reduced support due to their own workload pressures; The expectation from the hospital partner isn't met, or the customer already has a negative view of NHSBT; The project is too big and is impacted by time constraints of the professional doctorate; There is little understanding of the methodology. It's interesting to note that each of these risks were associated with the societal section of the PESTLE analysis, where in fact there was a much wider range of risk factors identified for the project across all PESTLE sections. Not all the risk factors identified related to the use of the development tools, but potentially more so to the implementation of a new product or service. The fact that the risk factors that align with the points of failure in the literature are identified as societal related risk factors, could mean that the current literature describing failure points for LEAN Startup has not considered all areas of potential failure. PESTLE analysis does have limitations, which include: Becoming outdated as new threats emerge that were not captured in the original model; Being time-consuming due to the nature of the process of capturing

and assessing all the potential risk factors (Perera., 2017). For this project the PESTLE analysis was undertaken late in the development process, following the selection of the final hospital partner. The PESTLE analysis was found to take some time to complete, but it was useful for the identification of risk factors and the associated threats and opportunities, including known points of failure when using LEAN Startup. It was felt that the PESTLE analysis was unaffected by the limitation of becoming outdated. The final development of the service took place over a short period of time and factors that did impact development were already addressed. Even so, it is agreed that the PESTLE analysis results have the potential to become dated if the development took place over a longer period. Especially when taking into consideration the world events that have taken place recently and their impact on staffing, service costs and consumable supply e.g. The COVID19 global pandemic, BREXIT, and the Russian campaign in Ukraine. This must be considered in future development opportunities that use LEAN Startup. It would be recommended that a review of the PESTLE analysis takes place at set intervals e.g. two-month intervals, capturing the emergence of new risk factors.

Threats that were identified to align with known failure points of LEAN Startup were felt to have been overcome in the project. The RCI Senior Management Team were in full support of the aims of the professional doctorate. This results from NHSBT having seen success in its daily activities to drive improvement in effectiveness and efficiency by embedding LEAN principles in its service provision (Browne., 2018; NHSBT., 2022). Furthermore, the RCI department has a drive to meet the requirements of Transfusion 2024, which has been highlighted to be supported by this project (Allard., 2021; Williams[3]., 2022) (Section 5.1). The risk of the high workload of Senior Managers impacting the project progression was mitigated by the project being driven by the author of this thesis, who is a senior member of the RCI department, and was supported during the project through supervision from Dr Mark Williams – Head of RCI. The identification of the hospital partner was fortuitous in nature because of location but also because the HTL Manager was previously employed at NHSBT as a member of the Continuous Improvement Team, leaving on good terms (Section 3.5). This resulted with an understanding by the hospital partner that the project was linked to a professional doctorate, which was innovative for RCI. Although there was the expectation of positive outcomes, the potential that these might not be achieved was understood and accepted. The link to the professional doctorate also gave understanding for the scale of the project, ensuring that all members involved (hospital partner and RCI) allowed the project output to remain achievable. The methodology used in the project was understood by the project lead through its use in a separate project that formed a module on a level 8 leadership and management course through the University of Manchester (PGDip – Leadership and Management in Healthcare Sciences) (Hazell., 2017). There is also strong supporting literature that was used throughout the professional doctorate to guide canvas interaction and completion (Osterwalder., 2010).

Aspects to consider when using the VPC have already been presented (Section 5.1). Unlike the customer segment of the VPC, the value map segment was completed by the project lead and Head of RCI without hospital partner involvement. In hindsight, this could be considered to go against the principles of LEAN Startup, where the customer is embedded in the product development, posing a risk that the service idea would not meet the

requirement of the hospital partner (Section 1.8.2). It is the opinion of the author of this thesis that due to the involvement of the hospital partners in completion of the VPC customer segment (Section 4.1.6.3a) and Kano models (Section 4.1.6.3c), population of the value proposition was influenced by the needs of the hospital partners, taking their opinions into consideration. As described in Chapter 4 and Section 5.1, it was identified that each of the hospital partners did not all require a service that targeted the same theme, or if there were multiple partners that needed service provision relating to one theme e.g. Training, then a single format of a service would be unlikely to meet all hospital partner requirements. Consequently, to meet the needs of individual hospital partners a service would need to be provided that:

- Identified the customer jobs and the pains they caused in their HTL
- Defined the gains they would achieve in addressing the jobs
- Explored what attributes are required to achieve job completion
- Provided the hospital partner access to the identified attributes to facilitate job completion and delivery of gains.

With an aim to meet these requirements, the segments of the VPC value map were populated with a MVP titled – The Laboratory Solution Development Platform. From discussion with the hospital partners and from previous experience in the RCI Senior Management Team of service development, the platform should provide a bespoke service that was hospital partner led (Section 4.1.2 and Figure 4-14). This was considered important as there had previously been a negative view of RCI, where customers had suggested the department were attempting to take control of HTL service provision (NHSBT., 2014; Williams[3]., 2022). It was envisaged that as part of the service the hospital partner would use the customer segment of the VPC canvas to identify areas where support was required. RCI would then offer guidance and support to the HTL team to decide which jobs to target and how to tackle them. The service would see RCI supporting the HTL team in data gathering and interrogation, facilitation of hospital partner led team events, assessment of success, and the provision of output reports (Figure 4-14).

To understand the wider business model of the Laboratory Solution Development Platform, the BMC was populated (Section 4.2.2 and Figure 4-15). The BMC is a visual tool that creates a shared language that allows strategic development of business ideas by mapping the dynamics related to a product or service and the market they supply (Section 1.8.4). Many positive points related to its application have been identified, including: Its ease of use, customisation, and adaptability; Short time it takes to complete; Interaction created between those utilising the canvas; The overview and understanding it gives of the business; Assistance in supporting business development (Osterwalder and Pigneur., 2010; Ching and Fauvel., 2013; Gibson and Jetter., 2014; Becker and Brocker., 2021; First Round Review., 2022). The disadvantages highlighted in the literature relate to oversimplification of information captured by the BMC and a need for expansion of the canvas (Osterwalder and Pigneur., 2012; Ching and Fauvel., 2013; Gibson and Jetter., 2014; Apt and Davis 2019). This results in the tool being static in nature and not considering important factors related to a business, such as: Competition; Environment; Complex business networks; Social interaction related to canvas segments (Osterwalder and Pigneur., 2012; Ching and Fauvel., 2013; Gibson and Jetter., 2014; Becker and Brocker., 2021). For this project,

the BMC was used as per its original design and not customised or adapted through the removal or addition of segments. The reason for not altering the BMC was linked to the limited practical experience of the project lead in use of the BMC, but ultimately that any adaptation of the BMC could impact on the overall address of the research question of the project – Can RCI provide services beyond its traditional role and related aims (using LEAN Startup)? (Chapter 2). The canvas in concept appears easy to use, but in practice this opinion was not shared. A BMC was completed at two points in the project. The first was with the hospital partners at the hospital partnership meeting (Section 4.1.5 and Figure 4-8). Most of the canvas was completed apart from key activities and key resources segments. The meeting participants felt that these segments had been covered through open discussion and by the Kano models. It is the author's opinion that the use of the BMC canvas in the hospital partnership meeting was not an easy task, where engagement felt cumbersome and forced. It must be noted that the day ran for six hours, and the BMC was the last section of the day, perhaps at a point where participants were generally fatigued from travel and a full day's engagement. This aspect was also stated by a meeting participant (Section 4.1.6.3b). Feedback from the attendees revealed that they struggled in the application of the BMC, scoring low to mid-level results in the post-event survey for all questions (Section 4.1.6.3b and Figure 4-12). Opinions shared identified that there was a general lack of understanding of how to use the tool and how the segments linked together, as well as its population feeling mechanical (Section 4.1.6.3b). This again highlights that a learning and training pre-event pack would have been useful. It could detail information about the tools, how they were going to be used in the event and provide a distributable version of the canvases (perhaps online electronic) that could have been populated allowing information to be collated before the event. The second BMC was completed by the project lead and Head of RCI. Again, the lack of inclusion of the hospital partner in population of the BMC could conflict with the principles of LEAN Startup – to include the customer in all aspects of service development. This was not thought to be true, as the second BMC was influenced by the BMC populated by the hospital partners, incorporating many of the aspects that were identified. Completion of the second BMC was a much more enjoyable experience, leading to the development of ideas through shared reflections. Many of the positive opinions identified in the literature were recognised i.e. Its ease of use; Short time it takes to complete; Interaction created between those utilising the canvas; The overview and understanding it gives of the business; Assistance in supporting business development. This was thought to relate to the experiential learning gained from previous use, but also by reading related sections in the "Business model generation: a handbook for visionaries, game changers, and challengers" (Osterwalder and Pigneur., 2010) before population of each section. This adds weight to the suggestion that future endeavours should include adequate training material for participants invited to develop services using the business development canvases. Overall, both BMCs when completed were felt to give a clear overview of the business model, allowing service development, even so, the author shares the opinion identified in the literature that this is over simplified. Much like the VPC allows for greater depth of information related to the value propositions and customer segments of the BMC, as identified in the literature, other segments need greater expansion e.g. the role key partners will play; how the key resources and distribution channels will be utilised. Further adaption of the Laboratory Service Development Platform was required. Upon implementation it was identified that operational difficulties experienced by the hospital partner related to the COVID19 pandemic meant solution

development could not be supported. The option to pivot in service design is fundamental to the principles of LEAN Startup, which is geared towards creating a product design feedback loop through the BUILD-MEASURE-LEARN Cycle (Section 1.8.2 and Figure 1-6). A decision was made to pivot and create alternative versions of the MVP. Two additional versions were created: The HTL and RCI full partnership bespoke service; The RCI led generic service template (Figure 5-3). Both versions of the Laboratory Solution Development Platform targeted the level of involvement from NHSBT, because this was the point of failure of the original service. The HTL and RCI full partnership service maintained the same pain relievers and gain creators as the original HTL led bespoke service, except there would be greater numbers of NHSBT representatives involved in the implementation of the service. These representatives would no longer only provide a supportive role, instead, they would provide greater involvement in decision making and solution development. There were only minor changes in relation to the provision of the RCI led generic service template. This related to No Access to: NHSBT development tools, as there would be no adaption of the service provision to the customer; NHSBT meeting space, as this would not be required in the service provision. If the generic level of the Laboratory Solution Development Platform was taken up by a hospital partner, NHSBT would have to make it clear and gain signed agreement from the outset that the hospital partner was procuring a service that does not allow any change to its provision to mitigate the accusation that NHSBT would be attempting to take over HTL service provision. With all three options available, as a relationship develops with a customer, or the service options become more widely known across pathology, as trust and reputation evolve, customer uptake might move from green to blue to red.

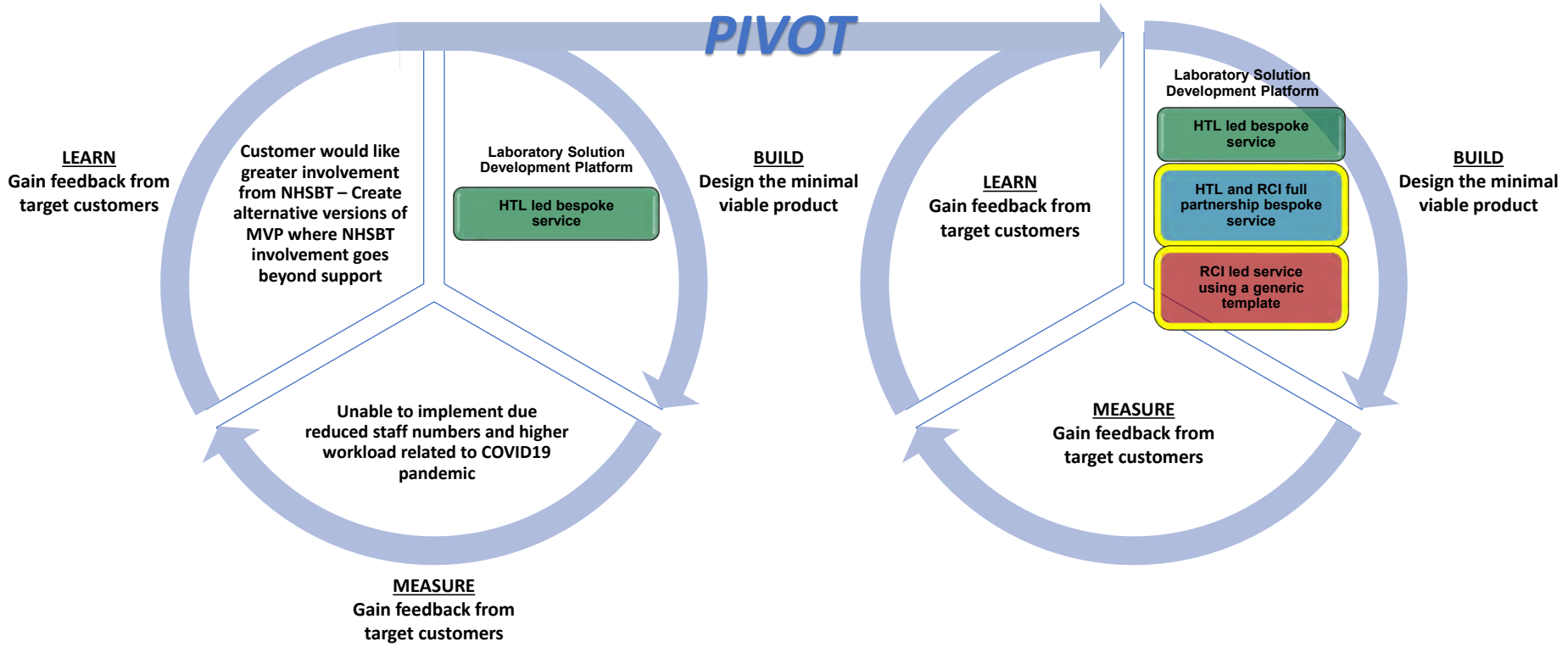


Figure 5-3: Representation of the BUILD – MEASURE – LEARN cycle related to the development of the Laboratory Solution Development Platform.
The cycle on the left presents the original HTL led bespoke service that was developed (BUILD), the identification that it could not be implemented due to operational difficulties caused by the COVID19 pandemic (MEASURE), the feedback from the customer that they would like NHSBT to have a greater involvement beyond just a supportive role (LEARN). The continuation of the left cycle into the BUILD section on the right cycle represents the decision to pivot and create two addition versions of the Laboratory Solution Development Platform.

5.3 Pilot of Novel Services and the Identification of Criteria Relevant to Expansion Beyond the Pilot

For the HTL and RCI full partnership version of the Laboratory Solution Development Platform, engagement began with completion of a VPC customer profile by the BRI HTL members of staff. In common with other occasions in this project where the canvas had been used, its simplistic nature of completion meant it was well received and easily populated. The canvas was displayed in the HTL for two week, allowing for engagement from all staff members across a range of days and shift patterns (starts of early morning, late morning, afternoon, evening and overnight). Items added to the canvas were later discussed between the HTL manager and the project lead, who then grouped them into themes. A theme was identified that related to the Laboratory Solution Development Platform supporting the merger of the BRI and Weston General HTL laboratories to meet their commitment to the pathology modernisation programme. This theme tied in well with the association of the project with pathology modernisation. If RCI successfully facilitated the merger using LEAN Startup tools, it would demonstrate the usefulness of the RCI department beyond its normal service provision and exclusion from pathology network planning. Unfortunately, the scale of such a project meant that it would not meet the related time commitment of a professional doctorate and instead the focus turned to the other themes identified in the BRI VPC customer profile[‡]. The vertical audit and process flow themes that were identified in the hospital partner's VPC customer segment (Section 4.2.4.1) echoed some aspects, but not all of those identified as part of the quality assurance and LEAN Laboratory themes previously identified in the hospital partner meeting (Section 4.1.3). As suggested in Section 4.2 and 5.2, it was expected that the identified jobs, pains, and gains would be similar between hospital partners, but one service idea would not meet the needs of all hospital partners e.g. Quality Assurance Service. The differences between the themes identified in the earlier meeting and pilot of the service supports the Laboratory Solution Development Platform's flexible service provision, which aims to identify and address the exact needs of the customer. Even though the platform is envisaged to be flexible and address the problems the customer is currently experiencing, these needs can vary in scale and scope even within a theme, reflecting the diverse factors affecting the state and resilience of each laboratory. This responsiveness is a key benefit of the LEAN Startup model. It is important to understand what the market competition is and how the attributes of their services could meet the hospital partner's needs. This helps to ensure that the service provided by RCI meets the hospital partners requirements and that RCI can meet the market standard (Hatzijordanou *et al*., 2019). Such an analysis also allows the identification of niche aspects of service provision that only RCI can offer, increasing the value of the service to the hospital partner and allowing it to compete with the market competitors (Hatzijordanou *et al*., 2019). A competitor analysis identified companies that provided services related to laboratory vertical audit and LEAN manufacturing (Table 4-1 and Table 4-2).

[‡] RCI Senior Management agreed to support the project where possible and a material transfer agreement was signed to facilitate transfer of protected information.

For companies providing audit, because of the small number of results in the search it was decided to include accreditation bodies and regulators in the competitor analysis. This was also useful as laboratory audits are conducted to support the standards against which these organisations would be assessing the HTL. Completion of the competitor analysis identified what was accepted as the current market standard, which included: No accreditation of the service provider required; Audit provided against ISO15189; A bespoke service offering that includes the option for training and support from HCPC registered scientists (or equivalent); Post-contract support; Provision of a formative output meeting and summary report. No competitor identified in the analysis met all these requirements, meaning that if RCI built a service provision that delivered all these attributes for vertical audit, it would challenge competitors. Provision of such a service was considered possible for RCI, as these attributes aligned with those required to provide its own internal ISO15189 vertical audit process (Figure 4-15). Since RCI provides a service that is in the same discipline as the BRI hospital partner, this was considered an attribute that RCI can offer to a hospital partner. When assessed against the competitors in the analysis none were identified to align with providing a related service to the hospital partners, presenting a niche for RCI's service. The attribute is considered important to the hospital partner for the management of the risk relating to acceptance of a service from an external partner. It gives a greater level of assurance for the hospital partner in the output being able to support their accreditation requirements. RCI could offer this because of the knowledge and understanding RCI have of the accreditation standard through maintaining the department's own ISO15189 accreditation for routine service provision (Section 1.7).

A range of companies was identified to provide services that undertake LEAN process improvement related activities. Completion of the competitor analysis identified the current market standard of attributes a service provision would need to include: Certification through the LEAN competency system; A bespoke hands-on service offering, over a contracted period, that includes the creation and provision of resource material and a summary report. Much like the audit service, no competitor aligned with all these attributes, identifying the potential to provide a service that challenges those already available. RCI can provide all the attributes which have been presented in the BMC for the Laboratory Solution Development Platform e.g. Continuous improvement experts that are certified through the LEAN competency system; Bespoke continuous improvement initial state assessment, problem solving and future state vision creation and implementation (Figure 4-15). Again, none of the identified competitors provided work that related to the hospital partners own service provision. This offered RCI a niche for their service provision, where they would have a greater level of understanding related to processes that were undergoing improvement in the HTL. As described before, this attribute is considered important to the hospital partner for the management of the risk relating to acceptance of a service from an external partner. They could have a greater level of assurance in the output supporting their requirements. This was strengthened by the fact that the competitors did not currently match RCI in employing HCPC registered Scientists that were trained in LEAN manufacturing techniques. This means that the competitors lack the hands-on process experience that would be gained from accepting a service provision from RCI.

The bespoke design of the Laboratory Solution Development Platform using the VPC customer profile identified that the hospital partner's current process for auditor training and for undertaking vertical audit did not meet the ISO15189 accreditation requirement. The BRI hospital partner didn't want the solution to this to be dependent on an external partner undertaking their vertical audit programme, like the services identified in the competitor analysis. Instead, it was recognised that they required interim support for audit completion that would allow time to redesign the training process, which would empower the HTL BMSs to undertake the HTL audit schedule. To understand how to solve the hospital partner's pains and deliver the gains, data gathering exercises were undertaken to capture the current audit training and completion processes, as well as, what's good, not so good and areas for improvement related to previous audit output (Section 3.9; 4.2.5.1; 4.2.5.2 and 4.2.5.3). RCI then hosted an online event where a multidisciplinary team, made up of event facilitators, subject matter experts and lay persons interrogated the pre-collected data to enable improvement in the processes. This style of event is standard practice for NHSBT and was included in the Value proposition for the Laboratory Solution Development Platform as a pain reliever and gain creator (Section 4.2.1).

It is important that HTL staff receive adequate training to perform a vertical audit. This ensures the output of the audit process results in quality improvement and positive impact on clinical outcomes, patient trust and satisfaction (Foy *et al*., 2005; Harper *et al*., 2010; Hut-Mossel *et al*., 2017; Desai *et al*., 2022). The audit training undertaken in the laboratory was self-taught through the reading of related documentation e.g., Standard operating procedures, reflecting on the material with a standard set of questions and then completing an audit. The trainee would be able to approach senior staff to ask questions related to the audit, but the hospital partner suggested this training lacked experiential learning gained from observing an audit taking place from a member of staff well versed and trusted in the process (White., 2022). The author has >5 years' experience of performing vertical audit against the ISO15189 at multiple RCI laboratories, for a range of processes across the department. From this experience of vertical audit, it is the authors opinion that the current method of training in the HTL was not robust enough to ensure the trainee auditor understood: The process; What its output means; How to identify and assign non-conformities found in the process.

In the improvement event the audit training process was redesigned (Section 4.2.5.4). The low number of steps identified was maintained in the new process, but it was ensured that each step created greater understanding of vertical audit. This incremental approach would be beneficial in empowering the BMS through greater support in training and a greater level of knowledge to identify ISO15189 non-conformities. This was achieved through classroom-based training and check, as well as shadowing a trained auditor and then in return being shadowed by a trained auditor. The involvement of a BMS that is already trained in vertical audit would allow guidance for the trainee and the opportunity for them to ask questions. Final sign off would be achieved through solo completion of an audit and review with the Hospital Transfusion Manager. It felt important to allow a fast-track route of training for BMSs who joined the laboratory with an extensive knowledge of audit. This was achieved by removing the training step of a trained auditor shadowing the BMS training to undertake vertical audit (Figure 4-19). The stages in the training process that had been created meant that even though members of the

laboratory were training to audit, they could continue to support the vertical audit schedule, addressing the hospital partner's pain/gain of having staff ready for audit (Section 4.2.4.1). As part of the redesign of the process enablers and people required to achieve success in the process were identified. Amongst the more obvious items identified e.g. a training package and knowledge check; it was identified that an assessment list would be useful to track progression of the trainee auditor, ensuring timely development, as well as completion of each stage before moving onto the next. The completed record was important to the hospital partner to demonstrate to an external auditor the level of training and understanding the staff have when trained to vertical audit.

Unlike the training process, the audit process was quite detailed, utilising the quality management system and engagement with senior laboratory and quality members of staff. Nine out of the fourteen steps that were identified to make up the vertical audit process were suggested to give top score for criticality to the process by the hospital partner. No pattern between these steps could highlight why they were critical to the process e.g. related to electronic system use or interaction with senior staff members. The three non-critical steps to the vertical audit process and one out of two semi-critical steps were related to points of engagement with a senior member of staff (transfusion of quality assurance manager) (Section 4.2.5.2). These steps were suggested by the hospital partner to be unnecessary and repetitive. Perhaps the steps were in place to cover potential knowledge gaps that remained following the auditor training process, forcing the auditor to discuss aspects with a senior staff member who would have a greater level of knowledge related to the vertical audit process (Marrs., 2014). The checking steps could have been introduced as corrective and preventative actions relating to quality incidents that resulted from human factors that have been linked to the process (Reason., 2000; Marrs., 2014; Health and Safety Executive., 2022). In this project, there was no evidence identified for the reason they were part of the process, so they were not included in the future state process design (Figure 4-20). It was interesting to note that the vertical audit process was considered by the hospital partner to align more with the process of a document audit, because the procedure saw the BMS print documentation related to the process being audited for review in a location away from the laboratory (White., 2022). This opinion may have resulted from the HTL manager being new in post, having fresh eyes on the processes for audit training and completion, not being involved in their original conception and implementation, and having a different experience or idea of vertical audit. When looking at the results of the review of historic audits it was clear to see a greater number of negative opinions related to the current process (Section 4.2.5.3). Most of the comments that identified what was good about the vertical audit process described positive interactions with the electronic QMS, where it simplified and guided the audit process. The use of the QMS was also identified critical to the audit process in the current state assessment of the process steps (Section 4.2.5.2). Both points highlighted the importance of maintaining at least the current level of use of the QMS in the design of the new vertical audit process, a point made easier for staff engagement, because of the current positive opinion of the QMS in the HTL. Maintaining the level of use in the process would also support a current expectation in transfusion practice where electronic systems have been identified to be critical in laboratory process management and improving safety (Serious Hazards of Transfusion Steering Group., 2021). The assessment of what's not so good as well as areas to improve identified where to focus in the new audit process, these were: The process flow of the Vertical Audit, Level of

detail captured (to include desktop and witness stages); Ensure assessment against all relevant elements of the ISO15189 standard; The assessment of risk of a non-conformance and identification of a required action where the standard is not met; Time for pre-audit preparation, post-audit report generation and team engagement; A standard form to populate during audit completion and submit post-audit. The redesign of the audit process maintained the use of the QMS as well as all the critical steps identified in the review of the current process (Section 4.2.5.5). It introduced aspects of pre audit (scoping meeting and pre audit planning time), as well as designated points for feedback to senior managers post audit completion that did not act as check points while the audit was taking place (audit closing meeting and final review and close of vertical audit). There was also the production of a new form to be completed by the auditor that laid out the steps in the order they were required to be completed (Scoping meeting – Document check – Training record check – Equipment check – Previous audit findings – Quality incidents – Performing the audit – Summary of findings) (Appendix 5). Although creating a new process for vertical audit of laboratory process against ISO15189 standards to identify and reduce the risk of non-conformities, the designed audit checklist allowed for the identification of good practice points. This is important as it allows a positive association in the laboratory with the vertical audit process, by giving merit to the auditee through the identification of good practice related to the process being audited. It's also important because it is shared with the laboratory team, leading to positive influence and change in the process. The author of this thesis is an experienced ISO15189 vertical auditor for the RCI laboratories, allowing agreement with the hospital partner to trial the new process for training and completion of an audit with a HTL laboratory BMS that required training. Feedback was positive in relation to the new processes, but it was impacted by ongoing staff shortages and increased sample numbers related to the COVID19 pandemic (Reyland., 2022). The training was close to being completed at the time this report was being written, with them the BMS completing classroom training (Part A), shadowing an experienced auditor (Part B), and completing an audit while being shadowed (Part C) (Appendix 6).

The success of LEAN is well known across a range of industries and is an established culture in NHSBT to reduce waste in processes, to create value for the organisation's customers (Bhamu and Sangwan., 2014; Costa and Filho., 2016; Browne., 2018; Dias., 2018). The VPC customer profile completed as part of the Laboratory Solution Development Platform identified that LEAN principles and methodology were not embedded in the HTL environment, and that there was believed to be waste in the laboratory processes. The hospital partner suggested that this was impacting sample investigation times, which would cause delay in patient diagnosis and treatment. A future goal for the hospital partner was to have HTL BMSs trained in LEAN manufacturing principles, allowing the continuous improvement of laboratory processes. For the original version of the Laboratory Solution Development Platform two members of staff at the BRI trained to an entry Practitioner level of LEAN. This allowed them to be certified through the LEAN competency system, an internationally recognised workplace-based qualification, aligning them with a universal standard (LEAN Competency System., 2022). This aimed to address the VPC customer profile by improving the understanding of LEAN principles for the HTL staff and begin embedding the methodology in the HTL. Further strengthening of the methodology was to be achieved through NHSBT RCI and Continuous Improvement department staff members supporting an

improvement event led by the certified HTL staff members, to target selected laboratory processes and improve their flow. Unfortunately, staff sickness and high workload related to the COVID19 pandemic meant that further embedding of LEAN manufacturing principles and methodology could not be achieved. As part of the HTL and RCI full partnership service level of the Laboratory Solution Development Platform, the event was led by the author of this thesis with support from NHSBT continuous improvement facilitators and invited members of the HTL and RCI service. The opportunity to gather pre-event data for the event was negatively impacted due to: low staff numbers, high HTL workload; An increase in time constraints in the project resulting from the failure to implement the original version of the LEAN Service Development Platform. These factors were identified as threats in the PESTLE analysis, but the related opportunities that were also presented were realised by service pilot (Section 4.2.3). The support given by NHSBT/RCI through the LEAN Service Development Platform allowed the HTL to undertake service improvement activity that was needed to take place, but alone could not with the current pressures facing the NHS.

Process mapping has been identified to provide the essential support for continuous improvement exercises. It is suggested to offer material that can be used to engage multidisciplinary teams and enable shared understanding of the processes being interrogated (NHS Institute for Innovation and Innovation and Improvement., 2005; Taylor and Randall., 2007; Browne., 2018; Antonacci *et al*., 2021). Success is achieved with process mapping when it is implemented in a project from start to finish (NHS Institute for Innovation and Innovation and Improvement., 2005; Antonacci., 2012). This allows effective identification and monitoring of the required change (Antonacci *et al*., 2021). Pre-event process mapping in this project was implemented from the beginning and used to gather pre-event data. As per the literature, its use from the start was more likely to result in success of the desired improvements. The shortened time frame resulting from pivot of the service design meant that the number of process mapping observations for pre-event data gathering was reduced. The sample verification and automation process were mapped once, and the manual crossmatch was mapped twice. A greater number of times for the manual crossmatch process was undertaken because the process was more complex and took place across a greater area of the laboratory (Section 4.2.6.1). Even though the opportunity to gather data in this project was impacted, the output was believed to be thorough and valuable, offering detailed insight into the processes flow (Section 3.10.1 and 4.2.6.1), waste (Section 3.10.2 and 4.2.6.2) and risks (Section 3.10.3 and 4.2.6.3). Even with a small number of observations for data collection, it was clear to see that the output would facilitate the engagement and discussion amongst event members. As suggested in the literature it would allow them to engage with each other about the current process and enable future improvements. Although positive team engagement was predicted according to the literature, this was achieved even with the fewer observations undertaken. Future iterations of a service that targets LEAN processing would likely offer greater time for data gathering and observations.

The process maps identified that designated areas were not present in the laboratory for the sample verification and manual crossmatch processes, with both sprawling out across large sections of the laboratory and creating waste with long movement steps (Section 4.2.6.1 and 4.2.6.2). This also created waste related to people. The

long distance between process steps meant the end of incubation or centrifuge runs were not identified by the BMS undertaking the process, resulting in another BMS becoming involved in completion (Section 4.2.6.2). The location of the manual serology workbench was identified as a pain in the VPC customer section by the hospital partner, creating a dead end in the laboratory. This was observed in process mapping and identified in the event discussions to result in the poor process flow. Other areas of the laboratory that were identified to be problematic was the position of the: Blood issue bench, which caused a narrow walkway for staff to pass; Storage location of consumables, racks, and sample storage as well as the position of the laboratory computers and printers that forced movement of the BMSs to edges of the laboratory (Figure 4-22B). Waste related to waiting is inevitable in the laboratory when mapping a single process, this is because sample preparation and test incubations are unavoidable. For all the processes touch time was considerably less than flow time (Sample verification >50%; Automation >75%; Manual crossmatch) (Section 4.2.6.1 and Table 4-4). It could be interpreted that the waste results with inactivity of the BMSs involved in a process, but when taking into consideration the full range of laboratory processes, the BMS would likely be performing other tasks rather than being inactive while waiting. The final risk identified in process mapping was interruptions in the process, with a common theme being related to discussion either with colleagues, the manager or on the phone with clinical teams. This is important to note as human factors such as interruptions have been associated with an increased risk of patient harm caused by related mistakes in the transfusion process (Serious Hazards of Transfusion Steering Group., 2017; Serious Hazards of Transfusion Steering Group., 2018; Serious Hazards of Transfusion Steering Group., 2019; Serious Hazards of Transfusion Steering Group., 2020). With the risks known in association to the processes being mapped, possible solutions were identified through discussion on the team event. This allowed for FMEA, with and without solutions, to be scored separately for the impact of the risk, the likelihood of it occurring, as well as the ease of its detection (Section 3.10.3). FMEA calculation has been successfully used in healthcare to identify and target the greatest risks of failure for intervention and improvement (Coles *et al*., 2005; Prabhakaran *et al*., 2015; Teixeira *et al*., 2015; Sorrentino., 2016; Schuller *et* al., 2017; Liu *et al*., 2019). The impact of potential solutions was observed through the FMEA scoring exercise, where the result was reduced by >75% (Section 4.2.6.3). Not all the solutions could be implemented as part of this project as some were considered out of scope e.g. software changes or staff job roles; but now they are identified they can be managed through future improvement exercises. Solutions that could be tested related mostly to relocation of benching, storage locations (samples, automation racks and consumables) and small equipment (printers and computers) (4-22B). When these changes were tested in the laboratory, post-event process mapping observations identified positive improvements that included: Reduction in the number of process steps; Reduction in the number of steps walked (sample verification and automation only); Touch and flow time; Interruptions (automation and manual crossmatch only). These positive improvements aligned with the gains the customer suggested they would receive through support with the improvement of laboratory process flow (Section 4.2.4.1).

Pilot of the Laboratory Solution Development Platform allowed for a financial summary to be created for service provision that assisted the hospital partner to identify job themes and resolving related pains of one theme. The

pilot identified the need to include charges that related to: Initialisation; Advertisement; Meetings between NHSBT/RCI and the hospital partner; Data gathering and analysis; Multidisciplinary events; Follow-up sustainment meetings; Summary report writing. The Laboratory Solution Development Platform has bespoke options that allow the hospital partner to decide the support they receive from NHSBT/RCI. To achieve this, chargeable items were created in blocks, allowing for accurate costing related activity. The overall price was in line, if not cheaper than services that had been identified in the competitor analysis (Section 4.2.4.2b). Various options for payment by hospital partners for the service were identified in the BMC (Section 4.2.2), however, future work is required to understand if the suggested price is affordable for NHS Trusts.

5.4 Identification of the Benefits of the Novel Services to NHSBT/RCI; User (NHS/Private) and the Patient

The principles of LEAN Startup align well with a setting like healthcare that offers high levels of uncertainty in diverse and dynamic environments. Even so, the use of the methodology is still considered novel for healthcare service development (Section 1.8.3). The software development sector is the biggest user of LEAN Startup, where the BML cycle is applied for rapid testing of code (Section 1.8.3). For this reason, it is unsurprising that healthcare projects that have trialled the methodology are related to data services (Section 1.8.3). Two successful uses were noted in the literature, with both developments focusing on the BML cycle principle of LEAN Startup methodology and related benefits gained from its use (Neyem *et al*., 2016; Risso *et al*., 2016). The main benefits resulted from the customer feedback gained through multiple rotations of the BML cycle allowing rapid testing and feedback of various versions of product ideas (Neyem *et al*., 2016; Risso *et al*., 2016). This resulted in less waste for the developers before moving forward with a MVP (Neyem *et al*., 2016; Risso *et al*., 2016). It was clear to see in the project output – the Laboratory Service Development Platform, which provided LEAN and audit related business support to the hospital partner, that as regional pathology networks develop RCI can allow access to, or new exploration of service provision for the NHS. The use of LEAN Startup and related business tools (BMC and VPC) is a novel concept for RCI, introducing a usefulness of the department beyond its normal service, which has the potential to provide benefits for NHSBT/RCI, the hospital partners and the patient. The iterative nature of the BML cycle gave RCI an offering of incremental improvement based on lessons learned. This is much better than historic service development that offers a “one and done” assessment of need and solution. This is important in the field of pathology, especially in the NHS where the inertia to introduce change can be slow, meaning implementation of new services takes time. As a result, circumstances related to service need can change, but, using the BML cycle reflection and redesign is achieved by multiple rounds of service development. Rather than releasing a single iteration, which is already out of date by the time of implementation, a service proposal can remain fresh and provide the customer with what they want.

The project drove closer interaction between NHSBT/RCI and the hospital partner, allowing multidisciplinary teams representing both parties to work together to create a platform that enabled shared learning and understanding to solve identified problems. This has led to a greater level of trust between the two, having the

potential to elevate the relationship beyond the current service provider – customer interaction. For RCI, an improved partnership with hospitals deepens the department's understanding of its current market, providing early intelligence in the way the industry is behaving. A good example for this is when compulsory change occurs across the NHS e.g. recent release of a new version of ISO15189, where a bespoke partnership for the provision of an audit service would allow observation of how trusts and assessors are interacting with the new standard.

Development and sustainment of a transfusion service requires skills that can change depending on the stage currently being faced by a HTL. Each hospital partner will have different requirements that relate to the stage in their journey for service provision. This may differ relative to the stage RCI is in its own journey for service provision. This would enable RCI to maintain skill sets associated to the stage faced by the hospital partner as well as developing associated skills to its own stage of service provision e.g. Early-stage implementation of continuous improvement, which offers easier and bigger wins related to late-stage continuous improvement where there are marginal gains. As with RCI gaining new experiences or refreshing old skills, the hospital partner shares in these benefits, gaining from the shared new experience or avoiding difficulties experienced by RCI in the past. Service ideas built using LEAN Startup and related business tools would allow for increased opportunity to facilitate RCI staff learning, training (providing and attainment), competency (providing audit, facilitating CI) and leadership opportunities (project lead).

For the hospital partner it creates an interaction that is a collaborative partnership, working in a way that the hospital partner wants. The programme empowers the hospital partner to smooth tidal activity, supporting the HTL service to improve standard working and focus on routine service provision e.g. support related to audit process improvement allows the hospital partner to maintain its audit schedule from within its own team or through employ of NHSBT/RCI members of staff. There is a cost outlay for the support from NHSBT/RCI, but uptake of the LEAN Service Development Platform has been demonstrated by this project to offer rewards related to patient safety, time savings, consumables, and staffing. The latter is provided through the indirect employ of experts from NHSBT/RCI in a bespoke (HTL led bespoke service or HTL and RCI full partnership bespoke service) or fixed (RCI led generic template service) service provision, to offer guidance and advice related to the hospital partner's objective. In this project it was vertical audit service provision and LEAN continuous improvement, where the hospital partner's problems were verified, and a solution validated. This is an important benefit of the tools employed, as they ensure true identification of the problem, and a solution that is fit for purpose. The service provision from RCI is beneficial for the department, but also for the hospital partner, as it is not only bespoke, but also dynamic. This benefit has been demonstrated by the real time assessment of the Laboratory Service Development Platform using the BML cycle, identifying the need to pivot the service design and create a service with greater options for NHSBT/RCI involvement and support for the hospital partner.

A positive impact on a HTL service will lead to improvements for patients. The Laboratory Solution Development Platform has the potential to create improvements that will vary each time it is employed. This is because it will relate to the identification of the hospital partners customer jobs, which will differ between HTLs. In this project, the benefit for the patient was a safer service. This was provided by enhanced training of BMSs to vertical audit,

improving their understanding and empowering them to identify non-conformities in a process. Furthermore, there was an improvement in the design of the vertical audit process, making it more structured, thorough, and fit for purpose. This was achieved by providing pre-audit preparation time, ensuring checks of documentation, training, competency, quality, and equipment records; while making sure the audit was conducted in view of the process being audited and not as a silo document-based exercise. Importantly it ensured that there was a route for follow-up of non-conformities, identification of lessons learnt, as well as feedback from users. Safety for the patient was also increased through process mapping, where redesign of the laboratory layout created a reduction in failure mode effect analysis risk score, and interruptions related to the sample verification, automation, and manual crossmatch processes. Process mapping also created the benefit of a quicker route to patient treatment, due to a faster turnaround in laboratory results resulting from a reduction in process related waste. This was achieved through better understanding by the HTL staff of LEAN continuous improvement and the completion of process mapping. The resulting redesign of the laboratory layout created savings in time (touch and flow), reductions in the number of steps in the process and distance travelled.

Chapter 6 Conclusion

This Professional Doctorate has fulfilled its intended aims by using LEAN Startup principles and related business tools to identify, develop and pilot novel services for the RCI department. Benefits were identified that related to: A better understanding for RCI of its current market; An improved relationship between RCI and the hospital partner; Empowerment of the HTL and its staff; Improved patient safety and treatment times. The Professional Doctorate demonstrates that by using LEAN Startup RCI can provide services beyond its traditional testing role, to the wider transfusion industry.

Chapter 7 References

Albliwi, S. Antony, J. Lim, S.A.H. and van der Wiele, T. (2014). 'Critical failure factors of Lean Six Sigma: a systematic literature review'. *International Journal of Quality & Reliability Management*.

Alonso-Cerezo, M.C. Martín, J.S. Montes, M.A.G. and de la Iglesia, V.M. (2009). 'Appropriate utilization of clinical laboratory tests'. *Clinical chemistry and laboratory medicine*, 47(12), pp.1461-1465.

Allard, S. Cort, J. Howell, C. Sherliker, L. Miflin, G. and Toh, C.H. (2021). 'Transfusion 2024: A 5-year plan for clinical and laboratory transfusion in England'. *Transfusion Medicine*, 31(6), pp.400-408.

Anonymised Stakeholder Interviews. (2017). *1 to 1 Interviews with Hospital and RCI Stakeholders regarding RCI Service and Pathology Networks* [Verbal] (Personal Communication, 2017).

Antonacci, G. Lennox, L. Barlow, J. Evans, L. and Reed, J. (2021). 'Process mapping in healthcare: a systematic review'. *BMC health services research*, 21(1), pp.1-15.

Apte, U.M. and Davis, M.M. (2019). 'Sharing economy services: business model generation'. *California Management Review*, 61(2), pp.104-131.

Äyväri, A. and Jyrämä, A. (2017). 'Rethinking value proposition tools for living labs'. *Journal of Service Theory and Practice*.

Bajpai, M. Kaur, R. and Gupta, E. (2012). 'Automation in immunohematology'. *Asian journal of transfusion science*, 6(2), p.140.

Barnes, I. (2014). *Pathology Quality Assurance Review*. [Online] Accessed 17/11/2017 Available at: https://www.england.nhs.uk/wp-content/uploads/2014/01/path-qa-review.pdf.

Beastall, G.H. (2008). 'The modernisation of pathology and laboratory medicine in the UK: networking into the future'. *The Clinical Biochemist Reviews*, 29(1), p.3.

Beastall, G.H. (2013). 'Adding value to laboratory medicine: a professional responsibility'. *Clinical chemistry and laboratory medicine*, 51(1), pp.221-227.

Becker, M. and Bröcker, J.O. (2021). *Business Model Canvas-Overview of the main advantages and disadvantages*. [Online] Accessed 03/12/22 Available at: https://www.econstor.eu/bitstream/10419/234963/1/Business-Model-Canvas-Overview-of-main-advantages-and-disavantages.pdf

Belleflamme, P. and Neysen, N. (2021). 'A multisided value proposition canvas for online platforms'. *Journal of Business Ecosystems*, 2(1), pp.1-14.

Bhamu, J. and Sangwan, K.S. (2014). 'Lean manufacturing: literature review and research issues'. *International Journal of Operations & Production Management*.

Bieraugel, M. (2015). 'Managing library innovation using the lean startup method'. *Library Management*.

Blank, S. (2013). 'Why the lean start-up changes everything'. *Harvard business review*, 91(5), pp.63-72.

Bolton-Maggs, P. Mistry, H. Glencross, H. Rook, R. and UK Transfusion Laboratory Collaborative. 2019. 'Staffing in hospital transfusion laboratories: UKTLC surveys show cause for concern'. *Transfusion Medicine*, 29(2), pp.95-102.

Browne, T. (2018). *Case Study: Applying LEAN Thinking in Clinical Pathology*. [Online] Accessed 05/12/22 Available at: https://www.leancompetency.org/lcs-articles/case-study-applying-lean-thinking-in-clinical-pathology/

BSH. (2017). *British Society for Haematology*. [Online] Accessed 29/10/17 Available at: https://www.b-s-h.org.uk/

Buschle, C. Reiter, H. and Bethmann, A. (2022). 'The qualitative pretest interview for questionnaire development: Outline of programme and practice'. *Quality & Quantity*, 56(2), pp.823-842.

Carter, P. (2016). *Operational Productivity and Performance in English NHS Acute Hospitals: Unwarranted Variations*. [Online] Accessed 29/10/2017 Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf

Cavanagh, G. (2021). *Marketing plan RCI*. Unpublished internal document. NHSBT.

Chaffe, B. Glencross, H. Jones, J. Staves, J. Capps-Jenner, A. Mistry, H. Bolton-Maggs, P. McQuade, M. and Asher, D. (2014). 'UK Transfusion Laboratory Collaborative: minimum standards for staff qualifications, training, competency and the use of information technology in hospital transfusion laboratories 2014'. *Transfusion Medicine*, 24(6), pp.335-340.

Ching, H. Fauvel, C. (2013). 'Criticisms, Variations and Experiences with Business Model Canvas'. *European Journal of Agriculture and Forestry Research*. 2(1), pp.26-37.

Coles, G. Fuller, B. Nordquist, K. and Kongslie, A. (2005). 'Using failure mode effects and criticality analysis for high-risk processes at three community hospitals'. *The Joint Commission Journal on Quality and Patient Safety*, 31(3), pp.132-140.

Costa, L.B.M. and Godinho Filho, M. (2016). 'Lean healthcare: review, classification and analysis of literature'. Production Planning & Control, 27(10), pp.823-836.

Darzi, A. (2008). *High Quality Care for All*. [Online] Accessed 07/10/2018 Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228836/7432.pdf. Accessed 23/01/2017

Deakin, M. (2022). 'NHS workforce shortages and staff burnout are taking a toll'. *British Medical Journal*, 377.

Desai, K.N. Bhatt, P.S. Kumar, A. and Shaik, R.A. (2022). 'A Study of the Utility of Vertical Quality Audits in a Blood Transfusion Centre as a Quality Improvement Tool: Comparison and Differences between Vertical and Horizontal Audits'. *Maedica*, 17(2), p.387.

De Ternay. (2022). *Value Proposition Canvas: How to Use Better Alternatives to This Template*. [Online] Accessed 29/11/22 Available at: https://guerric.co.uk/value-proposition-canvas/

Dias, A.C. Reis, A.C. Oliveira, R.P. Maruyama, Ú. and Martinez, P. (2018). 'Lean manufacturing in healthcare: A systematic review of literature'. *Revista produção e desenvolvimento*, 4(2), pp.111-122.

Edison, H. Wang, X. and Abrahamsson, P. (2015), 'Lean startup: why large software companies should care'. *In Scientific Workshop Proceedings of the XP2015* (pp. 1-7).

England, N.H.S. and Improvement, N.H.S., (2022). *Delivery plan for tackling the COVID-19 backlog of elective care*. [Online] Accessed on, 11/10/22 Available at: https://www.england.nhs.uk/coronavirus/publication/delivery-plan-for-tackling-the-covid-19-backlog-of-elective-care/

Euchner, J. (2019). 'Yes… and: Making lean startup work in large organizations'. *Research-Technology Management*, 62(6), pp.36-43.

Fiorio, C.V. Gorli, M. and Verzillo, S. (2018). 'Evaluating organizational change in health care: the patient-centered hospital model'. *BMC health services research*, 18(1), pp.1-15.

First Round Review. (2022). *The One Tool Startups Need to Brainstorm, Test and Win*.[Online] Accessed 03/12/2022 Available at: https://review.firstround.com/To-Go-Lean-Master-the-Business-Model-Canvas

Fisher, E. and Scobie, S. (2022). *Was the NHS Overwhelmed Last Winter*. Nuffield Trust [Online] Accessed 13/08/22 Available at https://www.nuffieldtrust.org.uk/research/was-the-nhs-overwhelmed-last-winter?gclid=Cj0KCQjwl92XBhC7ARIsAHLl9anCS47p_0WCbq3Rrbn6i_ORtAzpYl0mb_dSSX4kvjI06j6XdYcxIWUaAh8vEALw_wcB#key-points

Foy, R. Eccles, M.P. Jamtvedt, G. Young, J. Grimshaw, J.M. and Baker, R. (2005). 'What do we know about how to do audit and feedback? Pitfalls in applying evidence from a systematic review'. *BMC health services research*, 5(1), pp.1-7.

Garner, B. (2015). *5 Common Mistakes to Avoid When Using the Value Proposition Canvas*. [Online] Accessed 28/11/2022 Available at: https://www.strategyzer.com/blog/posts/2015/2/19/5-common-mistakes-to-avoid-when-using-the-value-proposition-canvas

Ghezzi, A. (2019). 'Digital startups and the adoption and implementation of Lean Startup Approaches: Effectuation, Bricolage and Opportunity Creation in practice'. *Technological Forecasting and Social Change*, 146, pp.945-960.

Ghezzi, A. and Cavallo, A. (2020). 'Agile business model innovation in digital entrepreneurship: Lean startup approaches'. *Journal of business research*, 110, pp.519-537.

Gibson, E. and Jetter, A. (2014). 'Towards a dynamic process for business model innovation: A review of the state-of-the-art'. *In Proceedings of PICMET'14 Conference: Portland International Center for Management of Engineering and Technology; Infrastructure and Service Integration* (pp. 1230-1238). IEEE.

GOV.UK. (2022). *Direct and indirect health impacts of COVID-19 in England: emerging Omicron impacts*. [Online] Accessed 13/08/22 Available at https://www.gov.uk/government/publications/direct-and-indirect-health-impacts-of-covid-19-in-england-emerging-omicron-impacts/direct-and-indirect-health-impacts-of-covid-19-in-england-emerging-omicron-impacts

Harijith, R.G. and Naduthodi, H. (2017). 'Kano model customer satisfaction analysis of medical services'. *Int. Res. J. Eng. Technol*, 4(6), pp.1426-1429.

Hatzijordanou, N. Bohn, N. and Terzidis, O. 2019. 'A systematic literature review on competitor analysis: status quo and start-up specifics'. *Management Review Quarterly*, 69(4), pp.415-458.

Hazell, M. (2017). 'Develop a Plan for Developing and Testing an Idea for an Innovation (a New Product or Service)', *A4 – Leadership & Quality Improvement in the Clinical and Scientific Environment*. University of Manchester. Unpublished essay.

HCPC. (2019). *Why your registration matters*. [Online] Accessed 13/08/22 Available at https://www.hcpc-uk.org/registration/your-registration/why-your-registration-matters

Health and Safety Executive. (2019). *Human factors: Managing human failures*. [Online] Accessed 20/12/22 Available at https://www.hse.gov.uk/humanfactors/topics/humanfail.htm

Hunt, B.J. Allard, S. Keeling, D. Norfolk, D. Stanworth, S.J. and Pendry, K. (2015). 'A practical guideline for the haematological management of major haemorrhage'. *British journal of haematology*, 170(6), pp.788-803.

Hut-Mossel, L. Welker, G. Ahaus, K. and Gans, R. (2017). 'Understanding how and why audits work: protocol for a realist review of audit programmes to improve hospital care'. *BMJ open*, 7(6), p.e015121.

ISO. (2012). *ISO15189:2012 Medical Laboratories – Requirements for Quality and Competence*. [Online] Accessed 11/12/2017 Available at https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:v2:en

ISO. (2016). *ISO13485:2016 Medical Devices – Quality Management Systems for Regulatory Purposes*. [Online] Accessed 04/02/2018 Available at https://www.iso.org/obp/ui/#iso:std:iso:13485:ed-3:v1:en

Jones, J. Ashford, P. Asher, D. Barker, J. Lodge, L. Rowley, M. Staves, J. Coates, T. and White, J. (2014). 'Guidelines for the specification, implementation and management of information technology systems in hospital transfusion laboratories'. *Transfusion Medicine*, 24(6), pp.341-371.

JPAC. (2017). *Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee*. [Online] Accessed 29/10/2017 Available at https://www.transfusionguidelines.org/.

Kolko, J. (2015). 'Design Thinking Comes of Age'. *Harvard Business Review*. Sept, pp 66-71.

Kolko, J. (2018). 'The divisiveness of design thinking'. *Interactions*, 25(3), pp.28-34.

Korolov, S. (2022). *Value Proposition Canvas – A Tool to Understand Your Product's Value from the Customer's Perspective*. [Online] Accessed 28/11/22 Available at: https://railsware.com/blog/value-proposition-canvas-a-tool-to-understand-your-products-value-from-the-customers-perspective/#Why_the_value_proposition_canvas_usage_may_be_ineffective.

Kotzé, A. Harris, A. Baker, C. Iqbal, T. Lavies, N. Richards, T. Ryan, K. Taylor, C. and Thomas, D. (2015). 'British Committee for Standards in Haematology Guidelines on the Identification and Management of Pre-Operative Anaemia'. *British journal of haematology*, 171(3), pp.322-331.

LEAN Competency System. (2022). *About the LEAN Competency System*. [Online] Accessed 22/12/22 Available at: https://www.leancompetency.org/about/

Lean Enterprise Institute. (2018). *Principles of Lean*. [Online] Accessed 10/02/2018 https://www.lean.org/WhatsLean/Principles.cfm

Linsdell, P. (2017). *The prognosis of UK pathology services*. [Online] Accessed 05/11/2017 Available at https://www.labnews.co.uk/features/prognosis-uk-pathology-services-07-02-2017/

Lippi, G. and Simundic, A.M. (2012). 'Laboratory networking and sample quality: a still relevant issue for patient safety'. *Clinical chemistry and laboratory medicine*, 50(10), pp.1703-1705.

Lishman, S. (2017). *Pathology Networks – College Response*. [Online] Accessed 12/11/17 Available at https://www.rcpath.org/discover-pathology/news/pathology-networks-college-response.html

Liu, H.C. Zhang, L.J. Ping, Y.J. and Wang, L. (2020). 'Failure mode and effects analysis for proactive healthcare risk evaluation: a systematic literature review'. *Journal of evaluation in clinical practice*, 26(4), pp.1320-1337.

Lizarelli, F.L. Torres, A.F. Antony, J. Ribeiro, R. Salentijn, W. Fernandes, M.M. and Campos, A.T. (2021). 'Critical success factors and challenges for Lean Startup: a systematic literature review'. *The TQM Journal*.

Long-Mira, E. Washetine, K. and Hofman, P. (2016). 'Sense and nonsense in the process of accreditation of a pathology laboratory'. *Virchows Archiv*, 468(1), pp.43-49.

Marrs, S. (2014). *Want to reduce process mistakes? Reduce the steps!* [Online] Accessed 20/12/22 Available at https://www.processexcellencenetwork.com/lean-six-sigma-business-performance/articles/want-to-reduce-process-mistakes-reduce-the-steps

Martin, G.P. Sutton, E. Willars, J. and Dixon-Woods, M. (2013). 'Frameworks for change in healthcare organisations: a formative evaluation of the NHS Change Model'. *Health services management research*, 26(2-3), pp.65-75.

Materla, T. Cudney, E.A. and Antony, J. (2019). 'The application of Kano model in the healthcare industry: a systematic literature review'. *Total Quality Management & Business Excellence*, 30(5-6), pp.660-681.

MHRA. (2017). *Medicines & Healthcare products Regulatory Agency*. [Online] Accessed 29/10/2017 Available at: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency.

Mikulić, J. and Prebežac, D. (2011). 'A critical review of techniques for classifying quality attributes in the Kano model'. *Managing Service Quality: An International Journal*.

Milkins, C. Berryman, J. Cantwell, C. Elliott, C. Haggas, R. Jones, J. Rowley, M. Williams, M. and Win, N. (2013). 'Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories'. *Transfusion Medicine*, 23(1), pp.3-35.

Miro. (2021). *Miro online whiteboard (no version provided)*. RealTimeBoard [Online] Accessed 23/06/21 Inc. https://www.miro.com

Mistry, H. Bolton-Maggs, P. Rook, R. (2017) *UK Transfusion Laboratory Collaborative Survey 2017*. [Online] Accessed 05/11/2017 Available at: https://www.shotuk.org/wp-content/uploads/2017-UK-Transfusion-Laboratory-Collaborative-Survey.pdf

Model Health System. (2022). *Model Health System*. [Online] Accessed 13/08/22 Available at: https://model.nhs.uk/.

National Audit Office. (2017). *A Short Guide to the Department of Health and NHS England*. [Online] Accessed 29/10/17 Available at: https://www.nao.org.uk/wp-content/uploads/2017/09/2017-Short-Guide-to-the-Department-of-Health-and-NHS-England.pdf

Neyem, A. Carrillo, M.J. Jerez, C. Valenzuela, G. Risso, N. Benedetto, J.I. and Rojas-Riethmuller, J.S. (2016). 'Improving Healthcare Team Collaboration in Hospital Transfers through Cloud-Based Mobile Systems'. *Mobile Information Systems*, 2016.

NHSBT. (2014). *NHSBT Customer Satisfaction Survey Results 2013 – 2014*. Unpublished internal document. NHSBT.

NHSBT. (2017). *Blood Transfusion – Make the Right Choice for You*. [Online] Accessed 06/11/2017 Available at: https://www.nhsbt.nhs.uk/what-we-do/blood-services/blood-transfusion/.

NHSBT. (2018). *Reagents*. [Online] Accessed 04/02/2018. Available at: http://hospital.blood.co.uk/diagnostic-services/reagents/.

NHSBT[1]. (2018). 'What is Lean'. Unpublished internal document. NHSBT.

NHSBT. (2022). *Continuous improvement.* NHSBT intranet site [Online] Accessed 08/10/22 Available at https://nhsbloodandtransplant.sharepoint.com/sites/ContinuousImprovement2.

NHS Choices. (2015). *Blood Transfusion – Why is it Done*. [Online] Accessed 05/11/2017 Available at: https://www.nhs.uk/conditions/blood-transfusion/why-its-done/

NHS Choices. (2016). *Pathology Services*. [Online] Accessed 05/11/17 Available at: https://www.nhs.uk/NHSEngland/AboutNHSservices/pathology/Pages/pathology-services-explained.aspx..

NHS England. (2017). *Funding and Efficiency*. [Online] Accessed 19/11/17 Available at: https://www.england.nhs.uk/five-year-forward-view/next-steps-on-the-nhs-five-year-forward-view/funding-and-efficiency/

NHS Improvement[1]. (2017). *NHS Improvement Operation Productivity – Proposed Pathology Consolidation Networks*. [Online] Accessed 29/10/2017. Available at: https://improvement.nhs.uk/uploads/documents/Consolidation_Networks_CEO_Letter_RE11.pdf,

NHS Improvement[2]. (2017). *Pathology Networks*. [Online] Accessed 29/10/17 Available at: https://improvement.nhs.uk/resources/pathology-networks/

NHS Improvement[3]. (2018). *Pathology Networking in England: The State of the Nation*. [Online] Accessed 10 August 2021 Available at: https://www.england.nhs.uk/wp-content/uploads/2021/05/pathology-networking-state-of-the-nation-2018.pdf

NHS Improvement and NHS England. (2019). *Pathology Networking in England: The State of the Nation*. [Online] Accessed 10 August 2021 Available at: https://www.england.nhs.uk/wp-content/uploads/2021/05/pathology-networking-state-of-the-nation-2019.pdf.

NHS Institute for Innovation and Innovation and Improvement. (2005). *Improvement Leaders' Guide Process Mapping, Analysis and Redesign General Improvement Skills*. [Online] Accessed 24/12/22 Available at: https://www.england.nhs.uk/improvement-hub/wp-content/uploads/sites/44/2017/11/ILG-1.2-Process-Mapping-Analysis-and-Redesign.pdf

Nilsen, P. Seing, I. Ericsson, C. Birken, S.A. and Schildmeijer, K. (2020). 'Characteristics of successful changes in health care organizations: an interview study with physicians, registered nurses and assistant nurses'. *BMC health services research*, 20(1), pp.1-8.

Nirwan, M.D. and Dhewanto, W. (2015). 'Barriers in Implementing the Lean Startup Methodology in Indonesia–Case Study of B2B Startup'. *Procedia-Social and Behavioral Sciences*, 169, pp.23-30.

Osaro, E. and Chima, N. (2014). 'Challenges of a negative work load and implications on morale, productivity and quality of service delivered in NHS laboratories in England'. *Asian Pacific journal of tropical biomedicine*, 4(6), pp.421-429.

Osterwalder, A. and Pigneur, Y. (2010). *Business model generation: a handbook for visionaries, game changers, and challengers*. John Wiley & Sons.

Osterwalder, A. and Pigneur, Y. (2012). 'Designing business models and similar strategic objects: the contribution of IS'. *Journal of the Association for information systems*, 14(5), p.3.

Osterwalder, A. Pigneur, Y. Bernarda, G. and Smith, A. (2014). *Value proposition design: How to create products and services customers want*. John Wiley & Sons.

Payne, A. Frow, P. Steinhoff, L. and Eggert, A. (2020). 'Toward a comprehensive framework of value proposition development: From strategy to implementation'. *Industrial Marketing Management*, 87, pp.244-255.

Perera, R. (2017). *The PESTLE analysis*. Nerdynaut.

Plebani, M. and Lippi, G. (2010). 'Is laboratory medicine a dying profession? Blessed are those who have not seen and yet have believed'. *Clinical Biochemistry*, 43(12), pp.939-941.

Pourabdollahian, G. and Copani, G. (2014). 'Proposal of an innovative business model for customized production in healthcare'. *Modern Economy*, 5(13), p.1147.

Prabhakaran, S. Khorzad, R. Brown, A. Nannicelli, A.P. Khare, R. and Holl, J.L. (2015). 'Academic-community hospital comparison of vulnerabilities in door-to-needle process for acute ischemic stroke'. *Circulation: Cardiovascular Quality and Outcomes*, 8(6_suppl_3), pp.S148-S154.

Public Health England. (2017). *Atlas of Variation*. [Online] Accessed 23/11/2017 Available at http://fingertips.phe.org.uk/profile/atlas-of-variation

Reason, J. (2000). 'Human error: models and management'. *BMJ*, 320(7237), pp.768-770.

Reis, E. (2012). *The Lean Startup*. *New York: Crown Business*.

Retter, A. Wyncoll, D. Pearse, R. Carson, D. McKechnie, S. Stanworth, S. Allard, S. Thomas, D. and Walsh, T. (2013). 'Guidelines on the management of anaemia and red cell transfusion in adult critically ill patients'. *British journal of haematology*, 160(4), pp.445-464.

Reyland, L. (2022). *Discussion related to progress in relation to becoming a trained vertical auditor* [Verbal] (Personal communication, 08/11/22).

Risso, N.A. Neyem, A. Benedetto, J.I. Carrillo, M.J. Farías, A. Gajardo, M.J. and Loyola, O. (2016). 'A cloud-based mobile system to improve respiratory therapy services at home'. *Journal of Biomedical Informatics*, 63, pp.45-53.

Schneider, E. Sarnak, D. Squires, D. Shah, A. Doty, M. (2017). 'Mirror, Mirror – International Comparison Reflects Flaws and Opportunities for Better U.S'. *Health Care*.

Schuller, B.W. Burns, A. Ceilley, E.A. King, A. LeTourneau, J. Markovic, A. Sterkel, L. Taplin, B. Wanner, J. and Albert, J.M. (2017). 'Failure mode and effects analysis: A community practice perspective'. *Journal of applied clinical medical physics*, 18(6), pp.258-267.

Serious Hazards of Transfusion Steering Group. (2017). *Annual SHOT Report 2017*. [Online] Accessed 24/12/22 Available at: https://www.shotuk.org/wp-content/uploads/myimages/SHOT-Report-2017-WEB-Final-v4-25-9-18.pdf.

Serious Hazards of Transfusion Steering Group. (2018). *Annual SHOT Report 2018*. [Online] Accessed 24/12/22 Available at: https://www.shotuk.org/wp-content/uploads/myimages/SHOT-Report-2018_Web_Version-1.pdf

Serious Hazards of Transfusion Steering Group. (2019). *Annual SHOT Report 2019*. [Online] Accessed 24/12/22 Available at: https://www.shotuk.org/wp-content/uploads/myimages/SHOT-REPORT-2019-Final-Bookmarked-v2.pdf

Serious Hazards of Transfusion Steering Group. (2020). *Annual SHOT Report 2020*. [Online] Accessed 24/12/22 Available at: https://www.shotuk.org/wp-content/uploads/myimages/SHOT-REPORT-2020.pdf

Serious Hazards of Transfusion Steering Group. (2021). *Annual SHOT Report 2021*. [Online] Accessed 13/08/21 Available at: https://www.shotuk.org/wp-content/uploads/myimages/SHOT-REPORT-2021-FINAL-bookmarked.pdf

Shepherd, D.A. and Gruber, M. (2021). 'The lean startup framework: Closing the academic–practitioner divide'. *Entrepreneurship Theory and Practice*, 45(5), pp.967-998.

SHOT[1]. (2017). *Welcome to SHOT – The UK Independent, Professionally-Led Haemovigilance Scheme*. [Online] Accessed 12/11/2017 Available at: https://www.shotuk.org/

SHOT[2]. (2019). *United Kingdom Transfusion Laboratory Collaborative Survey 2019*. [Online] Accessed 13 August 2022 Available at: https://www.shotuk.org/wp-content/uploads/myimages/UKTLC-2019-summary-final.pdf.

Silva, S.E. Calado, R.D. Silva, M.B. and Nascimento, M.A. (2013). 'Lean Startup applied in Healthcare: A viable methodology for continuous improvement in the development of new products and services'. *IFAC Proceedings Volumes*, 46(24), pp.295-299.

Sorrentino, P. (2016). 'Use of failure mode and effects analysis to improve emergency department handoff processes'. *Clinical Nurse Specialist*, 30(1), pp.28-37.

Stearn, M. (2017). 'Assessing the Impact of the Merging and Reconfiguring of Service on their Accreditation' [PowerPoint presentation]. Pathology Sustainability and Transformation Plans, Attended: 28/11/17.

Stennett, P. (2017). *The Path(ology) to Quality Improvement*. [Online] Accessed 19/11/2017 Available at: https://thepathologist.com/issues/0216/the-pathology-to-quality-improvement/.

Still, K. (2017). 'Accelerating research innovation by adopting the lean startup paradigm'. *Technology Innovation Management Review*, 7(5).

Sull, A. Harland, N. and Moore, A. (2015). 'Resilience of health-care workers in the UK; a cross-sectional survey'. *Journal of Occupational Medicine and Toxicology*, 10(1), p.20.

Taylor, A.J. and Randall, C. (2007). 'Process mapping: enhancing the implementation of the Liverpool Care Pathway'. *International Journal of Palliative Nursing*, 13(4), pp.163-167.

Teixeira, F.C. de Almeida, C.E. and Saiful Huq, M. (2016). 'Failure mode and effects analysis based risk profile assessment for stereotactic radiosurgery programs at three cancer centers in Brazil'. *Medical physics*, 43(1), pp.171-178.

The Royal College of Pathologists[1]. (2017). *Consolidation of Pathology Services Lessons Learnt*. [Online] Accessed 04/11/2017 Available at: https://www.rcpath.org/asset/7023C6E2-A94F-4C67-A3B9A3FB743D7E99/

The Royal College of Pathologists[2]. (2017). *About the College*. [Online] Accessed 04/11/2017 https://www.rcpath.org/about-the-college.html

Thomson, P. (2013). *Value Proposition Canvas Template*. [Online] Accessed 29/11/2022 Available at: https://www.peterjthomson.com/2013/11/value-proposition-canvas/

Tufail, M.M.B. Shakeel, M. Sheikh, F. and Anjum, N. (2021). 'Implementation of lean Six-Sigma project in enhancing health care service quality during COVID-19 pandemic'. *AIMS Public Health*, 8(4), p.704.

Tzankov, A. and Tornillo, L. (2017). 'Hands-On Experience: Accreditation of Pathology Laboratories according to ISO15189'. *Pathobiology*, 84(3), pp.121-129.

UKAS. (2017). *Welcome to UKAS*. [Online] Accessed 29/10/2017 Available at: https://www.ukas.com/

UKAS[1]. (2017). *Medical Laboratory Accreditation (ISO15189)*. [Online] Accessed 17/11/2017 Available at: https://www.ukas.com/services/accreditation-services/medical-laboratory-accreditation-iso-15189/

UKAS[2]. (2017). *Clinical Pathology Accreditation.* [Online] Accessed 17/11/2017. Available at: https://www.ukas.com/services/accreditation-services/clinical-pathology-accreditation/

UKTLC. (2019). *UKTLC Survey 2019 – Key Findings*, [Online] Accessed 16/10/22 Available at: https://www.shotuk.org/wp-content/uploads/myimages/UKTLC-2019-summary-final.pdf

Verduyn, D. (2014) *About the Kano Model*, [Online] Accessed 02/06/22 https://kanomodel.com/about-the-kano-model

White, S. (2022) *Discussion with the BRI and Weston Trust Hospital Transfusion Laboratory Manager regarding their audit training and completion process* [Verbal] (Personal Communication (Personal communication, 23/06/22).

Wilkes, C. (2022). *Surveying and auditing of NHSBT Customers*. Unpublished internal document. NHSBT.

Winfield, V. (2019). *Discussion with NHSBT RCI National Improvement Manager, regarding the Kano Model* [Verbal] (Personal communication, 05/03/19).

Winfield, V., (2022). *Red Cell Immunohaematology User Guide*, [Online] Accessed 13/08/2022 Available at: https://hospital.blood.co.uk/diagnostic-services/user-guides/..

Williams[1], M. (2017). *Discussion with NHSBT Head of RCI, regarding pathology networks* [Verbal] (Personal communication, 01/11/17).

Williams[2], M. (2022). *Discussion with NHSBT Head of RCI, regarding accreditation and compliance of the RCI service* [Verbal] (Personal communication, 27/07/22).

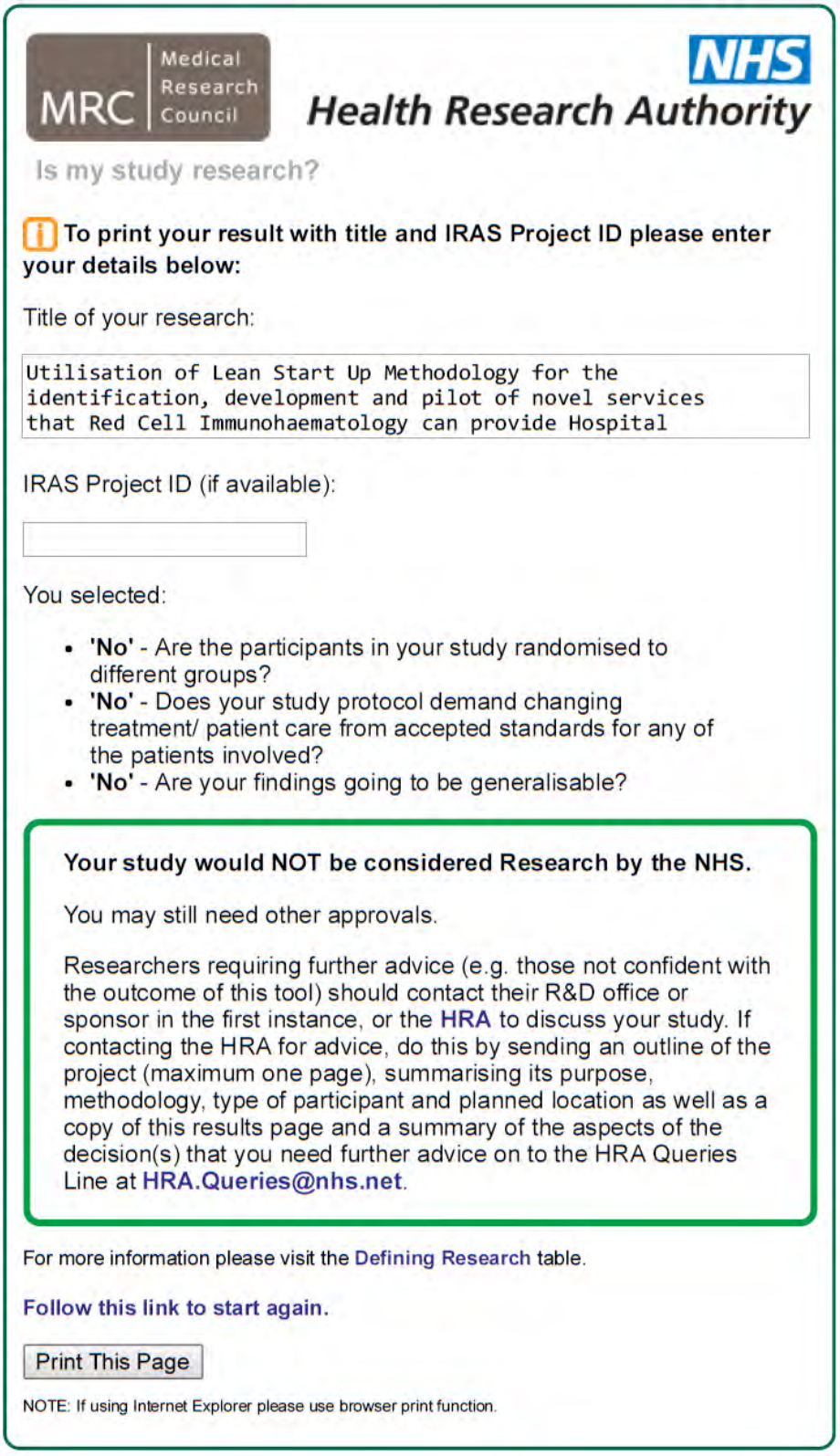
Williams[3], M. (2022). *Discussion with NHSBT Head of RCI, regarding the RCI service past present and future* [Verbal] (Personal communication, 23/11/22).

Wolf, C. Joye, D. Smith, T.E. Smith, T.W. and Fu, Y.C. (2016). *The SAGE handbook of survey methodology*. Sage.

Yordanova, Z.B. (2018). 'Lean startup method hampers breakthrough innovations and company's innovativeness'. *International Journal of Innovation and Technology Management*, 15(02), p.1850012.

York, J.L. and Danes, J.E. (2014). 'Customer development, innovation, and decision-making biases in the Lean Startup'. *Journal of Small Business Strategy*, 24(2), pp.21-39.

Appendix 1 Health Research Authority Ethics Decision Tool Result



MRC Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

Utilisation of Lean Start Up Methodology for the identification, development and pilot of novel services that Red Cell Immunohaematology can provide Hospital

IRAS Project ID (if available):

You selected:

- **'No'** - Are the participants in your study randomised to different groups?
- **'No'** - Does your study protocol demand changing treatment/ patient care from accepted standards for any of the patients involved?
- **'No'** - Are your findings going to be generalisable?

Your study would NOT be considered Research by the NHS.

You may still need other approvals.

Researchers requiring further advice (e.g. those not confident with the outcome of this tool) should contact their R&D office or sponsor in the first instance, or the HRA to discuss your study. If contacting the HRA for advice, do this by sending an outline of the project (maximum one page), summarising its purpose, methodology, type of participant and planned location as well as a copy of this results page and a summary of the aspects of the decision(s) that you need further advice on to the HRA Queries Line at HRA.Queries@nhs.net.

For more information please visit the Defining Research table.

Follow this link to start again.

Print This Page

NOTE: If using Internet Explorer please use browser print function.

Appendix 2 Post Hospital Partnership Meeting Survey Questions

Service development day questionnaire

1. How beneficial did you find the RCI Service Development Day?
   1-10
2. How much did you enjoy the RCI service development Day?
   1 didn't enjoy any part of the day - 10 Enjoyed all aspects of the day
3. How relevant was the Lean Service Development event to your Hospital Transfusion laboratory? Irrelevant
   1 (not relevant) – 10 relevant
4. Do you think RCI should use events of this nature to develop services in the future
   Yes / No
   If Yes – Why
   If No – Why not
5. Could you suggest 3 areas of patient care that can be improved by the services discussed in the RCI service development day.
   1
   2
   3
6. How well do you think patient care will be improved if the services planned in the event are developed by RCI?
   1-10
7. The RCI Service Development Day saw the use of the VPC, Kano model and BMC; please rank these from most to least useful for the development of new services.
   Most useful –
   –
   Least useful –
8. The goal of the VPC was to understand the jobs undertaken in the transfusion laboratory (Benchwork out of scope), the pains they cause, as well as, the gains achieved if a service were created to undertake the jobs.
   6A To what level would you state you enjoyed the VPC session?
   1-10
   6B What level would you state you understood the goal of the VPC?
   1-10
   6C How well do you think the goal of the VPC was met?
   1-10
   6D How easy did you find the VPC to use?
   1 – 10
   6E How well do you think new service ideas and the components required for their development were identified using the VPC

1-10

6F Do you feel you were able to engage with the VPC session?

1-10

6G What was a barrier to your engagement in the VPC?

…….

6H How likely are you to use the VPC in the future?

1 – 10

6I What did you like about the VPC?

……..

6J What didn't you like about the VPC?

…….

9. The goal of the Kano Model was to identify aspects (must haves, satisfiers, delighters) that were important to creating a service

7A To what level would you state you enjoyed the Kano Models session?

1-10

7B To what level would you state you understood the goal of the Kano Models?

1-10

7C How well do you think this goal of the Kano model session was met?

1-10

7D How easy did you find the Kano model to use

1 – 10

7E How well do you think new service ideas and the components required for their development were identified using the Kano Model

1 – 10

7F Do you feel you were able to engage with the Kano model session?

1-10

7G What was a barrier to your engagement in the Kano Model?

…….

7H How likely are you to use the Kano Model in the future?

1 - 10

7I What did you like about the Kano models?

……..

7J What didn't you like about the Kano models?

…….

10. The goal of the Business Model Canvas was to give an overview of the total Business so that aspects required for the release of a viable service could be identified – e.g. Key partners, activities, resources, revenue streams.

8A To what level would you state you enjoyed the Business Model Canvas session?

1-10

8B To what level would you state you understood the goal of the Business Model Canvas?

1-10

8C How well do you think the goal of the Business Model Canvas session was met?
1-10

8D How easy did you find the Business Model Canvas to use
1 – 10

8E How well do you think new service ideas and the components required for their development were identified using the Business Model Canvas
1 – 10

8F Do you feel you were able to engage with the Business Model Canvas session?
1-10

8G What was a barrier to your engagement with the Business Model Canvas?
…….

8H How likely are you to use the Business Model Canvas in the future?
1 - 10

8I What did you like about the Business Model Canvas?

……..

8J What didn't you like about the Business Model Canvas?

……..

11. Would you be likely to attend another event of this nature?

Yes/No

If Yes why?

If No, Why not?

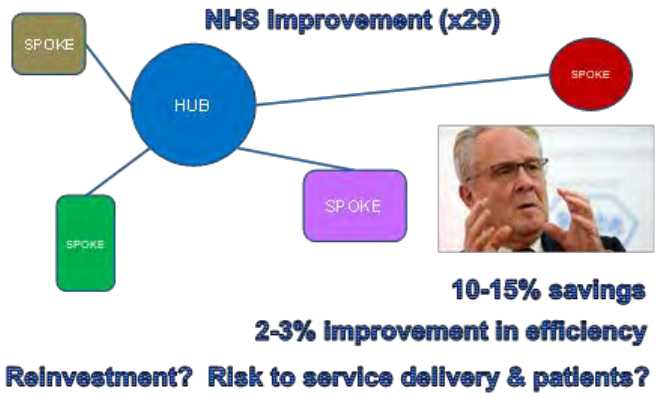
Appendix 3 Presentation Used to Pitch Project to Hospital Partner and primary meeting notes

Matthew Hazell

RCI Lean Service Development

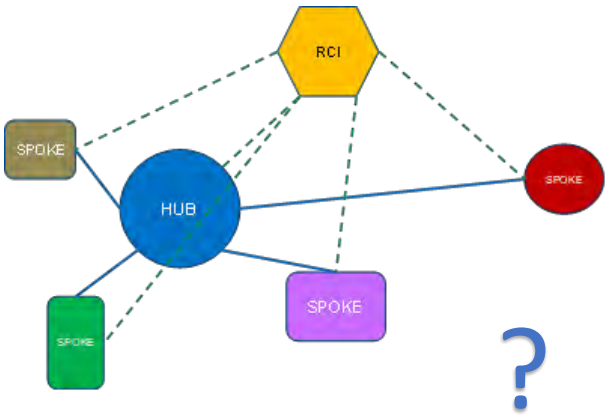
Pathology Networks

What we know

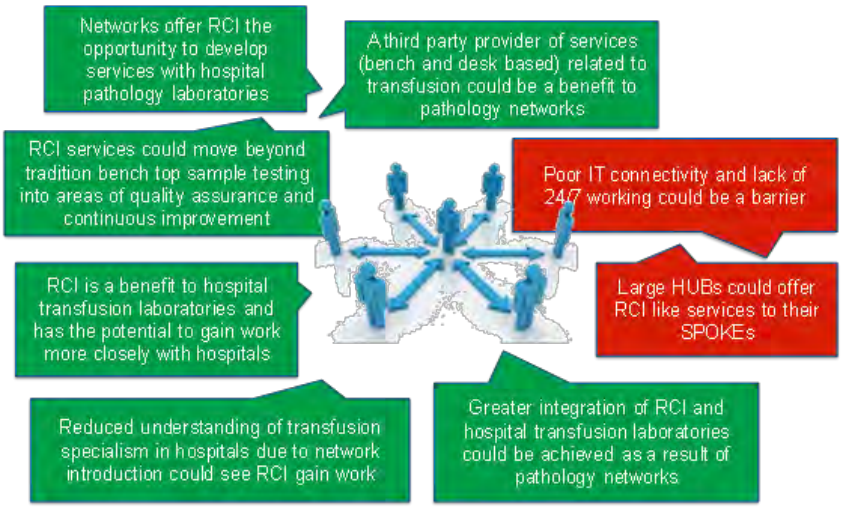


Impact of pathology networks on RCI

Unknown



Stakeholder engagement



Lean Startup

Lean Startup - The Identification, Development and Pilot of Novel Services

educe pitfalls it ean tartup

o e e dea	re o w a s wa ed a d w e sed y e s o er ro er s o de e op e	o a o rea ed a d adop ed k y

Entrepreneurs are everywhere	A human institution designed to create new products a services under conditions of extreme uncertainty
Entrepreneurship is management	A new kind of management specifically geared to its con extreme uncertainty
Validated learning	Frequent experiments that allow entrepreneurs to test e element of their vision
Build-measure-learn	All successful startup processes should be geared to acc that feedback loop
Innovative learning	How to measure progress, how to set up milestones and h prioritize work

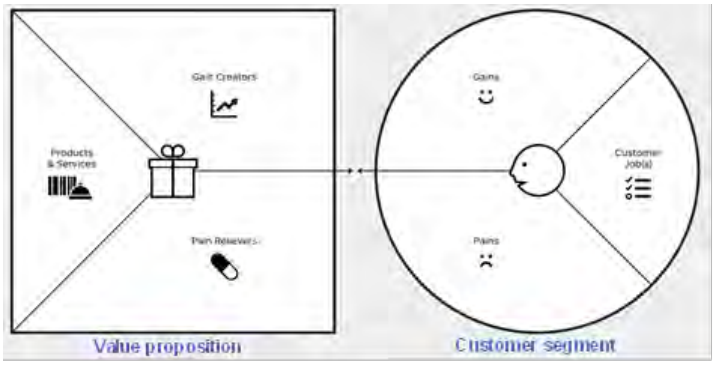
Lean Startup

Validated learning | Build-measure-learn | Innovative learning

Service development

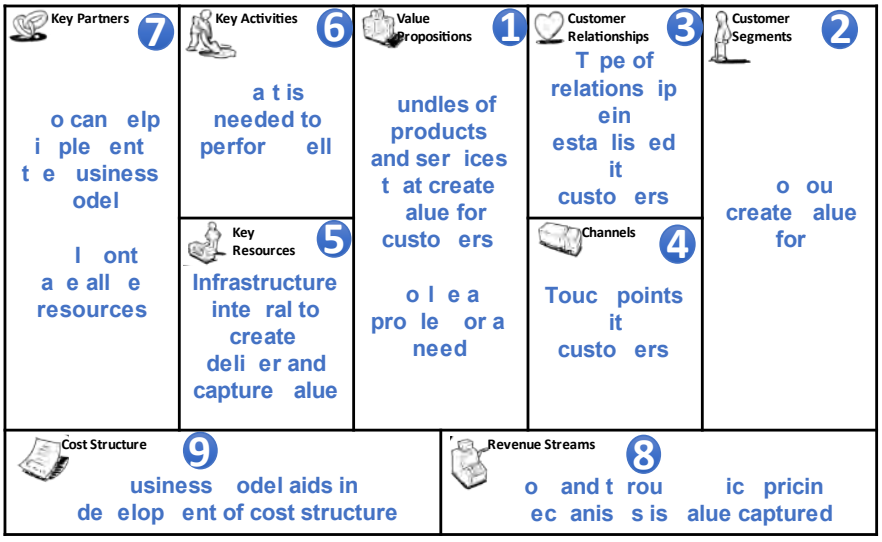
Build

Value proposition canvas



Service identification

Service Development canvas



Measure

Service development

Learn

Service development

BRI Visit for Lean startup pitch

Laboratory is currently going through a merger – becoming the University Hospital Bristol and Weston NHS Trust.

BRI is the Hub and Weston is a spoke – 2 transfusion laboratories

Need to align the process – docs and processes, this needs to be the best for both sites, not just the Weston adopting BRI process or vice versa.

Would like help with how to do this – identify the differences and choose the best route

This has recently taken place in RCI with the merger of the Leeds and Sheffield laboratories into Barnsley. Contact Head of RCI MW to discuss support.

Need to have an opening meeting – would like to have included in it:

- Lessons learnt
- How it was successful
- What was easy/hard

HTL Manager would like support to develop a project plan to target specific areas of importance to the merger, most importantly defining an order that things should take place.

Potential to hold a number of events which will include representatives from both sites to work together in merger process. HTL Manager is open to developing and using the best processes/practice from either laboratory – or even new ones that take the best elements from each laboratory. Would like to empower individuals from both labs

2 main areas of interest for the professional doctorate

Lean laboratory and Audit – the project needs to have a positive impact on patient care

The project is service development with the Lean startup tools – need to complete business model canvas and value proposition canvas for these two types of products

Potential positive impacts

- Consultancy for Lean laboratory – Reduced TRT, better staff focus, reduced waste in system
  Product - assessment of current state, lead an event to guide and define target state and assist with what metrics – also do some training to embed principles/tools of lean with staff.
  Customer will implement changes, product will continue to support progress with meetings/events and summary report. READING

- Audit – Safer systems in place, better understanding of process from staff, maintain accreditation with MHRA and UKAS

Lean laboratory service focus

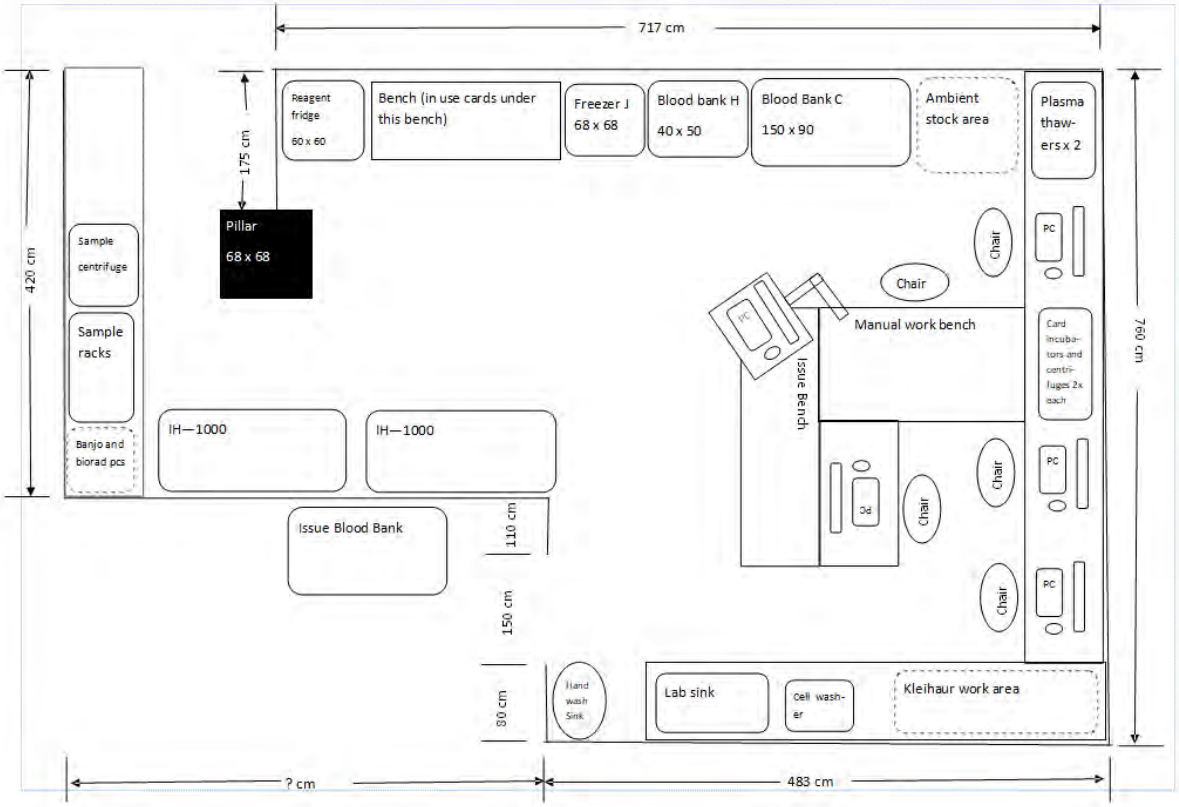
Sample movement/testing and general laboratory flow; need to improve the layout of the laboratory – Work flow optimisation

The development needs to have involvement with the laboratory staff to make it a success, need to make them feel empowered, they need to feel like they have made the change, that it is their choice to allow them to buy in to it.

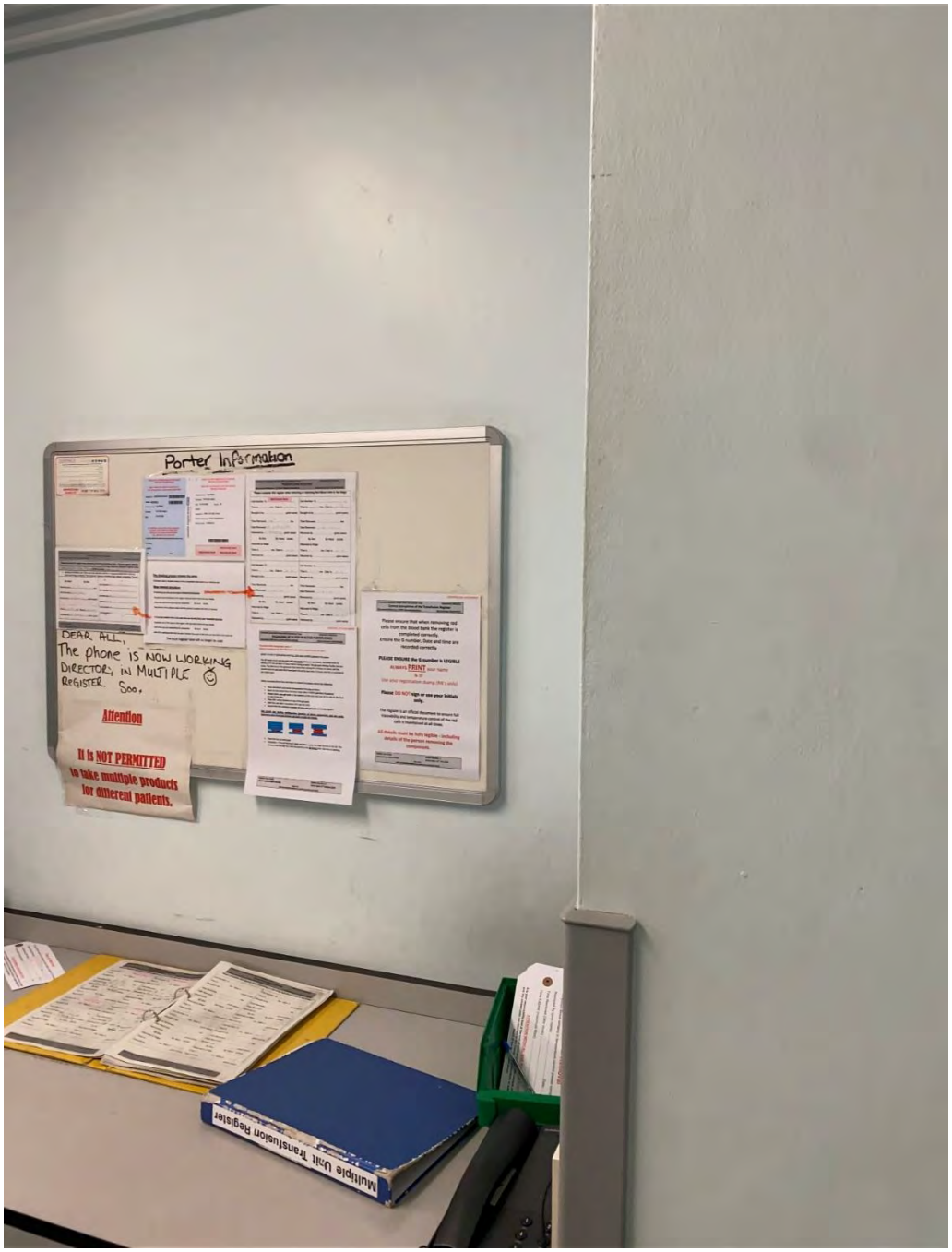
An event is required, likely to be an online event – need to introduce some form on bulletin board, or chat to allow the staff to constantly be part of the process even if they cant attend the event. For every event there needs to be an output that staff can engage with. Close out meeting, or report that they can feedback directly to HTL Manager and HSST MH about.

Needs to be a fortnightly meeting that identifies the following:

- Where we are
- Are we still on target
- Any issues or barriers
- What additional resources are required (NHSBT or RCI)



Entrance before main laboratory



Inside Entrance to laboratory

Centre of laboratory

Walkway from Tx laboratory to Haem laboratory (IH1000 position)

Entrance from laboratory into main haematology laboratory

Audit Service

Audit is regularly undertaken in the HTL, however, the process needs changing. General overview is staff member will take SOP, read and suggest changes to the SOP and then implement with agreement from senior members. Would like to see more of a live process, watching and auditing with a final report. Would, like at least 1 audit to take place per month (12 minimun for the year).

This is more of a training service with a focus to train the staff in laboratory audit.

Could see the service being built as – theory training, then shadow experienced auditor (report gets generated), then carry out own audit and produce report with experienced auditor oversight and then complete an audit alone with only the report overview from the experienced auditor. Final sign off and certification from the service provider.

Would like this to be ISO15189 audit standards; Overall aim would be to empower hospital staff.

Appendix 4 Financial Summary Spreadsheet Displaying Values and Formulas

Spreadsheet 1 = Displaying values of the costings

	A	B	C	D	E	F	G	H	I	J
1	Activity	Time (h	Band	Cost (Top of Ban	Cost (Middle of Ban	Cost (Bottom of Ban		Hourly rate (Top of Band)	Hourly Rate (Middle of Band)	Hourly Rate (Bottom of Band)
2	Intialisation/advertisement	7.50	8b	£311.22	£267.54	£266.26		41.50	35.67	35.50
3	Intialisation/advertisement	7.50	8d	£441.87	£382.85	£381.47		58.92	51.05	50.86
4	Scoping meeting Preparation	3.00	8b (1)	£124.49	£107.01	£106.50		41.50	35.67	35.50
5	Scoping meeting Preparation	3.00	8b (2)	£124.49	£107.01	£106.50		41.50	35.67	35.50
6	Scoping meeting	1.00	8b (1)	£41.50	£35.67	£35.50		41.50	35.67	35.50
7	Scoping meeting	1.00	8b (2)	£41.50	£35.67	£35.50		41.50	35.67	35.50
8	Scoping meeting output	1.00	8b (1)	£41.50	£35.67	£35.50		41.50	35.67	35.50
9	Scoping meeting output	1.00	8b (2)	£41.50	£35.67	£35.50		41.50	35.67	35.50
10	Data gathering	15.00	8b	£622.43	£535.07	£532.52		41.50	35.67	35.50
11	Data analysis	15.00	8b	£622.43	£535.07	£532.52		41.50	35.67	35.50
12	Service development	22.50	8b (1)	£933.65	£802.61	£798.78		41.50	35.67	35.50
13	Service development	22.50	8b (2)	£933.65	£802.61	£798.78		41.50	35.67	35.50
14	Proposal meeting Preparation	3.00	8b	£124.49	£107.01	£106.50		41.50	35.67	35.50
15	proposal meeting	1.00	8b	£41.50	£35.67	£35.50		41.50	35.67	35.50
16	proposal meeting output	1.00	8b	£41.50	£35.67	£35.50		41.50	35.67	35.50
17	Option redevelopment proposal Preparation	3.00	8b	£124.49	£107.01	£106.50		41.50	35.67	35.50
18	Option redevelopment proposal meeting	1.00	8b	£41.50	£35.67	£35.50		41.50	35.67	35.50
19	Option redevelopment proposal output	1.00	8b	£41.50	£35.67	£35.50		41.50	35.67	35.50
20	Event scoping preparation	3.00	8b	£124.49	£107.01	£106.50		41.50	35.67	35.50
21	Event scoping meeting	1.00	8b	£41.50	£35.67	£35.50		41.50	35.67	35.50
22	Event scoping output	1.00	8b	£41.50	£35.67	£35.50		41.50	35.67	35.50
23	Data gathering	15.00	8b	£622.43	£535.07	£532.52		41.50	35.67	35.50
24	Data analysis	15.00	8b	£622.43	£535.07	£532.52		41.50	35.67	35.50
25	Event preparation	3.00	8b (1)	£124.49	£107.01	£106.50		41.50	35.67	35.50
26	Event preparation	3.00	8b (2)	£124.49	£107.01	£106.50		41.50	35.67	35.50
27	Event Meeting	7.50	8b (1)	£311.22	£267.54	£266.26		41.50	35.67	35.50
28	Event Meeting	7.50	8b (2)	£311.22	£267.54	£266.26		41.50	35.67	35.50
29	Event Meeting	2.00	8d	£117.83	£102.09	£101.72		58.92	51.05	50.86
30	Event Meeting	3.75	4	£60.87	£60.77	£55.23		16.23	16.20	14.73
31	Event Meeting	7.50	(optiona	£224.39	£205.61	£194.95		29.92	27.42	25.99
32	Event Meeting	7.50	(optiona	£189.94	£166.41	£157.00		25.33	22.19	20.93
33	Event Output	2.00	8b	£82.99	£71.34	£71.00		41.50	35.67	35.50
34	Implementation training	4.00	8b	£165.98	£142.69	£142.01		41.50	35.67	35.50
35	Implementation idea	30.00	8b	£1,244.86	£1,070.15	£1,065.04		41.50	35.67	35.50
36	Sustainment meeting (1)	3.00	8b (1)	£124.49	£107.01	£106.50		41.50	35.67	35.50
37	Sustainment meeting (1)	1.50	8b (2)	£62.24	£53.51	£53.25		41.50	35.67	35.50
38	Sustainment meeting (2)	3.00	8b (1)	£124.49	£107.01	£106.50		41.50	35.67	35.50
39	Sustainment meeting (2)	1.50	8b (2)	£62.24	£53.51	£53.25		41.50	35.67	35.50
40	Sustainment meeting (3)	3.00	8b (1)	£124.49	£107.01	£106.50		41.50	35.67	35.50
41	Sustainment meeting (3)	1.50	8b (2)	£62.24	£53.51	£53.25		41.50	35.67	35.50
42	Sustainment Data gathering	15.00	8b	£622.43	£535.07	£532.52		41.50	35.67	35.50
43	Sustainment data analysis	15.00	8b	£622.43	£535.07	£532.52		41.50	35.67	35.50
44	Formal close preparation	3.00	8b	£124.49	£107.01	£106.50		41.50	35.67	35.50
45	Formal close	2.00	8b	£82.99	£71.34	£71.00		41.50	35.67	35.50
46	Report writing	7.50	8b	£311.22	£267.54	£266.26		41.50	35.67	35.50
47										
48	Total	278.75		£11,429.51	£9,853.46	£9,783.46				

Spreadsheet 1 = Displaying formula of the costings

	A	B	C	D	E	F	G	H	I	J
1	Activity	Time (hr)	Band	Cost (Top of Band)	Cost (Middle of Band)	Cost (Bottom of Band)		Hourly rate (Top of Band)	Hourly Rate (Middle of Band)	Hourly Rate (Bottom of Band)
2	Intialisation/advertisement	7.5	8b	=$B2*H2	=$B2*I2	=$B2*J2		='Pay Scale 2223 tbc'!AG65	='Pay Scale 2223 tbc'!AG63	='Pay Scale 2223 tbc'!AG60
3	Intialisation/advertisement	7.5	8d	=$B3*H3	=$B3*I3	=$B3*J3		='Pay Scale 2223 tbc'!AG77	='Pay Scale 2223 tbc'!AG75	='Pay Scale 2223 tbc'!AG72
4	Scoping meeting Preparation	3	8b (1)	=$B4*H4	=$B4*I4	=$B4*J4		=H$2	=I$2	=J$2
5	Scoping meeting Preparation	3	8b (2)	=$B5*H5	=$B5*I5	=$B5*J5		=H$2	=I$2	=J$2
6	Scoping meeting	1	8b (1)	=$B6*H6	=$B6*I6	=$B6*J6		=H$2	=I$2	=J$2
7	Scoping meeting	1	8b (2)	=$B7*H7	=$B7*I7	=$B7*J7		=H$2	=I$2	=J$2
8	Scoping meeting output	1	8b (1)	=$B8*H8	=$B8*I8	=$B8*J8		=H$2	=I$2	=J$2
9	Scoping meeting output	1	8b (2)	=$B9*H9	=$B9*I9	=$B9*J9		=H$2	=I$2	=J$2
10	Data gathering	15	8b	=$B10*H10	=$B10*I10	=$B10*J10		=H$2	=I$2	=J$2
11	Data analysis	15	8b	=$B11*H11	=$B11*I11	=$B11*J11		=H$2	=I$2	=J$2
12	Service development	22.5	8b (1)	=$B12*H12	=$B12*I12	=$B12*J12		=H$2	=I$2	=J$2
13	Service development	22.5	8b (2)	=$B13*H13	=$B13*I13	=$B13*J13		=H$2	=I$2	=J$2
14	Proposal meeting Preparation	3	8b	=$B14*H14	=$B14*I14	=$B14*J14		=H$2	=I$2	=J$2
15	proposal meeting	1	8b	=$B15*H15	=$B15*I15	=$B15*J15		=H$2	=I$2	=J$2
16	proposal meeting output	1	8b	=$B16*H16	=$B16*I16	=$B16*J16		=H$2	=I$2	=J$2
17	Option redevelopment proposal Preparation	3	8b	=$B17*H17	=$B17*I17	=$B17*J17		=H$2	=I$2	=J$2
18	Option redevelopment proposal meeting	1	8b	=$B18*H18	=$B18*I18	=$B18*J18		=H$2	=I$2	=J$2
19	Option redevelopment proposal output	1	8b	=$B19*H19	=$B19*I19	=$B19*J19		=H$2	=I$2	=J$2
20	Event scoping preparation	3	8b	=$B20*H20	=$B20*I20	=$B20*J20		=H$2	=I$2	=J$2
21	Event scoping meeting	1	8b	=$B21*H21	=$B21*I21	=$B21*J21		=H$2	=I$2	=J$2
22	Event scoping output	1	8b	=$B22*H22	=$B22*I22	=$B22*J22		=H$2	=I$2	=J$2
23	Data gathering	15	8b	=$B23*H23	=$B23*I23	=$B23*J23		=H$2	=I$2	=J$2
24	Data analysis	15	8b	=$B24*H24	=$B24*I24	=$B24*J24		=H$2	=I$2	=J$2
25	Event preparation	3	8b (1)	=$B25*H25	=$B25*I25	=$B25*J25		=H$2	=I$2	=J$2
26	Event preparation	3	8b (2)	=$B26*H26	=$B26*I26	=$B26*J26		=H$2	=I$2	=J$2
27	Event Meeting	7.5	8b (1)	=$B27*H27	=$B27*I27	=$B27*J27		=H$2	=I$2	=J$2
28	Event Meeting	7.5	8b (2)	=$B28*H28	=$B28*I28	=$B28*J28		=H$2	=I$2	=J$2
29	Event Meeting	2	8d	=$B29*H29	=$B29*I29	=$B29*J29		=H3	=I3	=J3
30	Event Meeting	3.75	4	=$B30*H30	=$B30*I30	=$B30*J30		='Pay Scale 2223 tbc'!AG27	='Pay Scale 2223 tbc'!AG24	='Pay Scale 2223 tbc'!AG21
31	Event Meeting	7.5	7 (optional)	=$B31*H31	=$B31*I31	=$B31*J31		='Pay Scale 2223 tbc'!AG53	='Pay Scale 2223 tbc'!AG49	='Pay Scale 2223 tbc'!AG45
32	Event Meeting	7.5	6 (optional)	=$B32*H32	=$B32*I32	=$B32*J32		='Pay Scale 2223 tbc'!AG44	='Pay Scale 2223 tbc'!AG40	='Pay Scale 2223 tbc'!AG36
33	Event Output	2	8b	=$B33*H33	=$B33*I33	=$B33*J33		=H$2	=I$2	=J$2
34	Implementation training	4	8b	=$B34*H34	=$B34*I34	=$B34*J34		=H$2	=I$2	=J$2
35	Implementation idea	30	8b	=$B35*H35	=$B35*I35	=$B35*J35		=H$2	=I$2	=J$2
36	Sustainment meeting (1)	3	8b (1)	=$B36*H36	=$B36*I36	=$B36*J36		=H$2	=I$2	=J$2
37	Sustainment meeting (1)	1.5	8b (2)	=$B37*H37	=$B37*I37	=$B37*J37		=H$2	=I$2	=J$2
38	Sustainment meeting (2)	3	8b (1)	=$B38*H38	=$B38*I38	=$B38*J38		=H$2	=I$2	=J$2
39	Sustainment meeting (2)	1.5	8b (2)	=$B39*H39	=$B39*I39	=$B39*J39		=H$2	=I$2	=J$2
40	Sustainment meeting (3)	3	8b (1)	=$B40*H40	=$B40*I40	=$B40*J40		=H$2	=I$2	=J$2
41	Sustainment meeting (3)	1.5	8b (2)	=$B41*H41	=$B41*I41	=$B41*J41		=H$2	=I$2	=J$2
42	Sustainment Data gathering	15	8b	=$B42*H42	=$B42*I42	=$B42*J42		=H$2	=I$2	=J$2
43	Sustainment data analysis	15	8b	=$B43*H43	=$B43*I43	=$B43*J43		=H$2	=I$2	=J$2
44	Formal close preparation	3	8b	=$B44*H44	=$B44*I44	=$B44*J44		=H$2	=I$2	=J$2
45	Formal close	2	8b	=$B45*H45	=$B45*I45	=$B45*J45		=H$2	=I$2	=J$2
46	Report writing	7.5	8b	=$B46*H46	=$B46*I46	=$B46*J46		=H$2	=I$2	=J$2
47										
48	Total	=SUM(B2:B47)		=SUM(D2:D47)	=SUM(E2:E47)	=SUM(F2:F47)				

Spreadsheet 2 = Pay Scales 2023 (to be confirmed at the time) – only showing band 4 – 8d.

	A	B	C	D	E	F	G	H	I	J	K	AA	AB	AC	AD	AE	AF	AG
1							REVIEW						22/23 Salary				Salajy	Total
2		Banding	Point	Code	Years	Salary	Empers	Weeks	Hours	Hours		Salary	Annual		Uplift %		Cost	Cost
3								per Annum	per Week	per Year			Cost				per Hour	per Hour
21		Band 4	11	XN0401	< 1 year	24,258.73	20.3%	52.14	37.50	1,955.36		23,949.00	28,800.63		6.2%		12.25	14.73
22		Band 4	12	XN0402	1-2 years	24,221.51	20.4%	52.14	37.50	1,955.36		23,949.00	28,844.89		6.2%		12.25	14.75
23		Band 4	13	XN0403	2-3 years	24,210.00	20.5%	52.14	37.50	1,955.36		23,949.00	28,858.60		6.2%		12.25	14.76
24		Band 4	14	XN0404	3-4 years	24,198.50	20.6%	52.14	37.50	1,955.36		26,282.00	31,684.92		5.6%		13.44	16.20
25		Band 4	15	XN0405	4-5 years	24,177.73	20.7%	52.14	37.50	1,955.36		26,282.00	31,712.13		5.6%		13.44	16.22
26		Band 4	"	XN0406	5-6 years	24,157.00	20.8%	52.14	37.50	1,955.36		26,282.00	31,739.35		5.6%		13.44	16.23
27		Band 4	"	XN0407	6+ years	24,157.00	20.8%	52.14	37.50	1,955.36		26,282.00	31,739.35		5.6%		13.44	16.23
28		Band 5	16	XN0501	< 1 year	24,907.00	20.8%	52.14	37.50	1,955.36		27,055.00	32,672.86		5.5%		13.84	16.71
29		Band 5	17	XN0502	1-2 years	26,988.51	20.9%	52.14	37.50	1,955.36		27,055.00	32,709.42		5.5%		13.84	16.73
30		Band 5	18	XN0503	2-3 years	26,970.00	21.0%	52.14	37.50	1,955.36		29,180.00	35,302.75		5.0%		14.92	18.05
31		Band 5	19	XN0504	3-4 years	27,446.34	21.3%	52.14	37.50	1,955.36		29,180.00	35,397.68		5.0%		14.92	18.10
32		Band 5	20	XN0505	4-5 years	27,456.67	21.3%	52.14	37.50	1,955.36		32,934.00	39,936.54		4.4%		16.84	20.42
33		Band 5	"	XN0506	5-6 years	27,416.00	21.4%	52.14	37.50	1,955.36		32,934.00	39,995.79		4.4%		16.84	20.45
34		Band 5	"	XN0507	6-7 years	30,615.00	21.4%	52.14	37.50	1,955.36		32,934.00	39,995.79		4.4%		16.84	20.45
35		Band 5	"	XN0508	7+ years	30,615.00	21.4%	52.14	37.50	1,955.36		32,934.00	39,995.79		4.4%		16.84	20.45
36		Band 6	21	XN0601	< 1 year	31,386.97	21.4%	52.14	37.50	1,955.36		33,706.00	40,933.32		4.3%		17.24	20.93
37		Band 6	22	XN0602	1-2 years	31,365.00	21.5%	52.14	37.50	1,955.36		33,706.00	40,962.00		4.3%		17.24	20.95
38		Band 6	23	XN0603	2-3 years	33,232.76	21.6%	52.14	37.50	1,955.36		35,572.00	43,253.23		4.1%		18.19	22.12
39		Band 6	24	XN0604	3-4 years	33,176.00	21.8%	52.14	37.50	1,955.36		35,572.00	43,327.23		4.1%		18.19	22.16
40		Band 6	25	XN0605	4-5 years	33,791.12	22.0%	52.14	37.50	1,955.36		35,572.00	43,384.80		4.1%		18.19	22.19
41		Band 6	"	XN0606	5-6 years	33,779.00	22.0%	52.14	37.50	1,955.36		40,588.00	49,520.24		4.0%		20.76	25.33
42		Band 6	"	XN0607	6-7 years	33,779.00	22.0%	52.14	37.50	1,955.36		40,588.00	49,520.24		4.0%		20.76	25.33
43		Band 6	"	XN0608	7-8 years	37,890.00	22.0%	52.14	37.50	1,955.36		40,588.00	49,520.24		4.0%		20.76	25.33
44		Band 6	"	XN0609	8+ years	37,890.00	22.0%	52.14	37.50	1,955.36		40,588.00	49,520.24		4.0%		20.76	25.33
45		Band 7	26	XN0701	< 1 year	38,895.85	22.0%	52.14	37.50	1,955.36		41,659.00	50,826.94		4.0%		21.31	25.99
46		Band 7	27	XN0702	1-2 years	38,890.00	22.0%	52.14	37.50	1,955.36		41,659.00	50,834.59		4.0%		21.31	26.00
47		Band 7	28	XN0703	2-3 years	40,883.68	22.3%	52.14	37.50	1,955.36		43,807.00	53,576.50		4.0%		22.40	27.40
48		Band 7	29	XN0704	3-4 years	40,894.00	22.3%	52.14	37.50	1,955.36		43,807.00	53,562.98		4.0%		22.40	27.39
49		Band 7	30	XN0705	4-5 years	44,662.06	22.4%	52.14	37.50	1,955.36		43,807.00	53,606.58		4.0%		22.40	27.42
50		Band 7	31	XN0706	5-6 years	44,660.39	22.4%	52.14	37.50	1,955.36		47,637.00	58,295.54		3.9%		24.36	29.81
51		Band 7	32	XN0707	6-7 years	44,660.94	22.4%	52.14	37.50	1,955.36		47,637.00	58,294.81		3.9%		24.36	29.81
52		Band 7	33	XN0708	7-8 years	44,611.86	22.5%	52.14	37.50	1,955.36		47,637.00	58,358.96		3.9%		24.36	29.85
53		Band 7	34	XN0709	8+ years	44,503.00	22.8%	52.14	37.50	1,955.36		47,637.00	58,501.70		3.9%		24.36	29.92
54		Band 8a	35	XN0801	< 1 year	45,801.86	22.9%	52.14	37.50	1,955.36		48,526.00	59,657.17		3.0%		24.82	30.51
55		Band 8a	36	XN0802	1-2 years	45,753.00	23.1%	52.14	37.50	1,955.36		48,526.00	59,720.88		3.0%		24.82	30.54
56		Band 8a	37	XN0803	2-3 years	45,900.50	23.2%	52.14	37.50	1,955.36		48,526.00	59,784.59		3.0%		24.82	30.57
57		Band 8a	38	XN0804	3-4 years	45,818.94	23.4%	52.14	37.50	1,955.36		48,526.00	59,891.01		3.0%		24.82	30.63
58		Band 8a	"	XN0805	4-5 years	45,753.00	23.6%	52.14	37.50	1,955.36		48,526.00	59,977.32		3.0%		24.82	30.67
59		Band 8a	"	XN0806	5+ years	51,668.00	23.6%	52.14	37.50	1,955.36		54,619.00	67,508.17		2.6%		27.93	34.52
60		Band 8b	39	XN0901	< 1 year	53,168.00	23.6%	52.14	37.50	1,955.36		56,164.00	69,417.76		2.6%		28.72	35.50
61		Band 8b	40	XN0902	1-2 years	53,168.00	23.8%	52.14	37.50	1,955.36		56,164.00	69,517.66		2.6%		28.72	35.55
62		Band 8b	41	XN0903	2-3 years	53,315.34	24.0%	52.14	37.50	1,955.36		56,164.00	69,634.15		2.6%		28.72	35.61
63		Band 8b	42	XN0904	3-4 years	53,226.30	24.2%	52.14	37.50	1,955.36		56,164.00	69,750.64		2.6%		28.72	35.67
64		Band 8b	"	XN0905	4-5 years	53,168.00	24.3%	52.14	37.50	1,955.36		56,164.00	69,827.12		2.6%		28.72	35.71
65		Band 8b	"	XN0906	5+ years	62,001.00	24.3%	52.14	37.50	1,955.36		65,262.00	81,138.41		2.2%		33.38	41.50
66		Band 8c	43	XN1001	< 1 year	63,751.00	24.3%	52.14	37.50	1,955.36		67,064.00	83,378.79		2.1%		34.30	42.64
67		Band 8c	44	XN1002	1-2 years	63,751.00	24.5%	52.14	37.50	1,955.36		67,064.00	83,470.12		2.1%		34.30	42.69
68		Band 8c	45	XN1003	2-3 years	63,932.37	24.6%	52.14	37.50	1,955.36		67,064.00	83,561.45		2.1%		34.30	42.73
69		Band 8c	46	XN1004	3-4 years	63,841.56	24.8%	52.14	37.50	1,955.36		67,064.00	83,680.31		2.1%		34.30	42.80
70		Band 8c	"	XN1005	4-5 years	63,751.00	25.0%	52.14	37.50	1,955.36		67,064.00	83,799.18		2.1%		34.30	42.86
71		Band 8c	"	XN1006	5+ years	73,664.00	25.0%	52.14	37.50	1,955.36		77,274.00	96,556.99		1.8%		39.52	49.38
72		Band 8d	47	XN1101	< 1 year	75,914.00	25.0%	52.14	37.50	1,955.36		79,592.00	99,453.42		1.8%		40.70	50.86
73		Band 8d	48	XN1102	1-2 years	75,914.00	25.1%	52.14	37.50	1,955.36		79,592.00	99,594.50		1.8%		40.70	50.93
74		Band 8d	49	XN1103	2-3 years	76,035.16	25.3%	52.14	37.50	1,955.36		79,592.00	99,735.57		1.8%		40.70	51.01
75		Band 8d	50	XN1104	3-4 years	75,974.53	25.4%	52.14	37.50	1,955.36		79,592.00	99,815.16		1.8%		40.70	51.05
76		Band 8d	"	XN1105	4-5 years	75,914.00	25.5%	52.14	37.50	1,955.36		79,592.00	99,894.75		1.8%		40.70	51.09
77		Band 8d	"	XN1106	5+ years	87,754.00	25.5%	52.14	37.50	1,955.36		91,787.00	115,200.52		1.5%		46.94	58.92

Appendix 5 Blank ISO15189 Vertical Audit Form

Audit:	Process:
Auditor:	Standard: ISO15189
Date:	Total time taken:

Scoping meeting

The meeting was held on the XXXX

In scope

Out of scope

Audit plan

Audit to take place on XXXX following a review of laboratory staffing levels.

Auditee =

Audit to commence at XXXX following audit brief of staff member being observed.

Audit out brief planned for XXXX; location = XXXX.

Page 1 of 2

Audit:
Auditor:
Date:

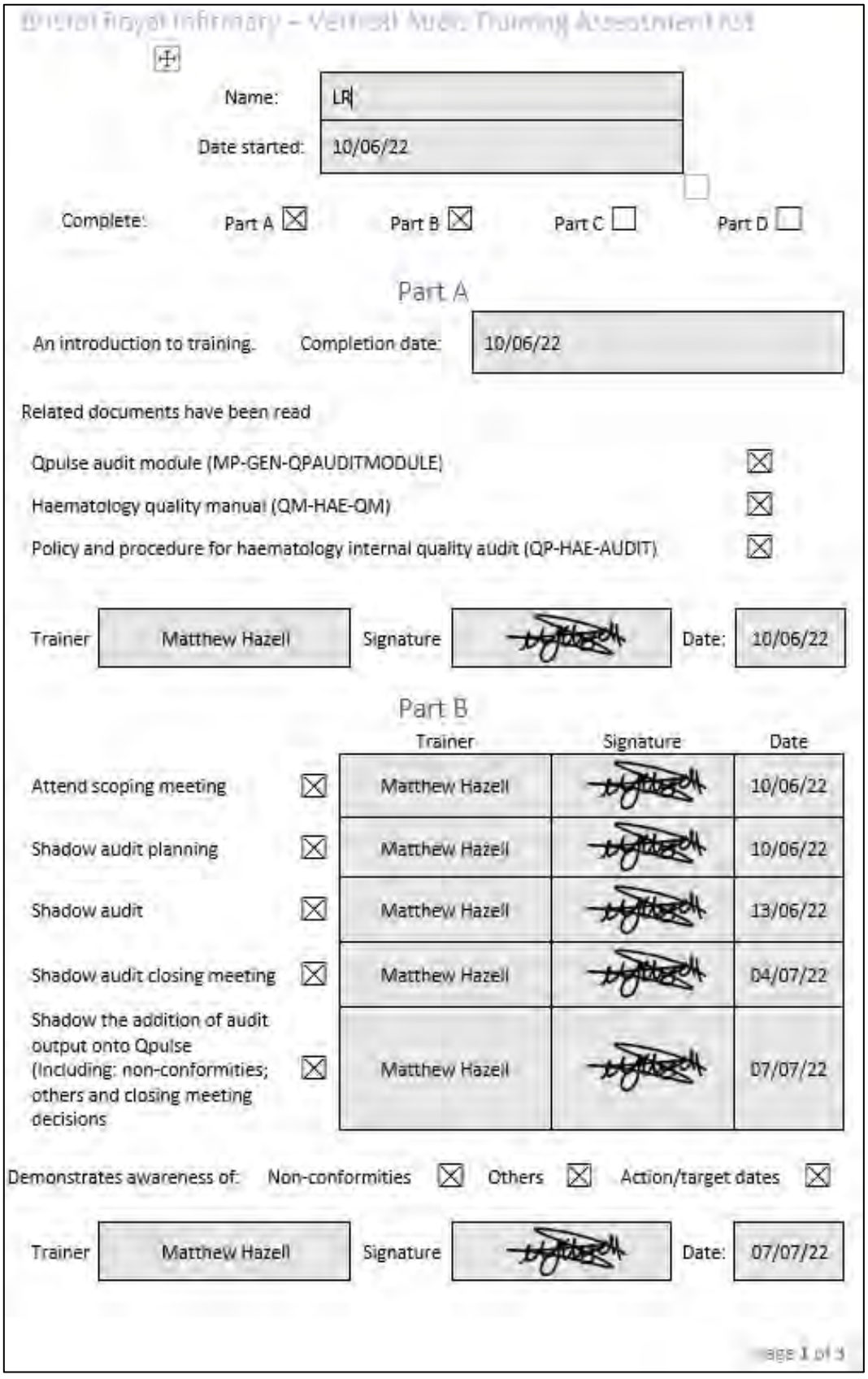
Process:
Standard: ISO15189
Total time taken:

Audit Report

Information	NC/Com number
Items identified and viewed before the audit – date = XXXX **Documents**	
Doc title XXXX (Version XX; active XXXX) •	
Doc title XXXX (Version XX; active XXXX) •	
Document Change Requests •	
Training Records •	
Equipment •	
Previous Audit Title = XXXX • Started XXXX • Finished XXXX • Closed XXXX Non-Conformances:	
Quality Incidents •	
Witness Audit of process XXXX Equipment used: XXXX Consumables used: XXXX Details: •	

Page 2 of 2

Appendix 6 Audit Trainee Assessment Form



Bristol Royal Infirmary – Ventesti Audit Training Assessment Kit

Name: LR

Date started: 10/06/22

Complete: Part A ☒ Part B ☒ Part C ☐ Part D ☐

Part A

An introduction to training. Completion date: 10/06/22

Related documents have been read

Qpulse audit module (MP-GEN-QPAUDITMODULE)	☒
Haematology quality manual (QM-HAE-QM)	☒
Policy and procedure for haematology internal quality audit (QP-HAE-AUDIT)	☒

Trainer: Matthew Hazell Signature: [signature] Date: 10/06/22

Part B

		Trainer	Signature	Date
Attend scoping meeting	☒	Matthew Hazell	[signature]	10/06/22
Shadow audit planning	☒	Matthew Hazell	[signature]	10/06/22
Shadow audit	☒	Matthew Hazell	[signature]	13/06/22
Shadow audit closing meeting	☒	Matthew Hazell	[signature]	04/07/22
Shadow the addition of audit output onto Qpulse (Including: non-conformities; others and closing meeting decisions	☒	Matthew Hazell	[signature]	07/07/22

Demonstrates awareness of: Non-conformities ☒ Others ☒ Action/target dates ☒

Trainer: Matthew Hazell Signature: [signature] Date: 07/07/22

Page 1 of 3

Bristol Royal Infirmary – Vertical Audit Training Assessment list

Part C

Perform an audit – Items completed

Audit number	AUD-HAE-366
Process being audited	Examination audit of phenotyping and DAT

Organise scoping meeting ☒ Date/time provided: (Recommend 30 mins) 08/07/22 – 12:00

Undertake scoping meeting ☒

Information gained in scoping meeting:

Date/time of Audit	08/07/22 – 13:00
In scope: • Parts of the process/related processes • Documents • Equipment	• Performing, reporting and authorisation of process • LP-BTR-Pheno; LP-BTR-RhK Pheno; LP-BTR-DCT; LF-BTR-Phenochange •
Out of scope • Parts of the process/related processes • Documents • Equipment	• Any samples referred to RCI for related process • LP-BTR-RhKPheno – Section relating to RhK tube phenotyping (3.6 – tube technique) • SN for tube washer
Date/time of audit out brief meeting	08/07/22 – 17:00

Organise pre-audit planning time ☒ Date/time provided: (recommend 3hours) 07/07/22 – 2 hours

Undertake pre-audit planning ☒

Information checked in pre-audit planning

Related Documents and outstanding CRs	☒
Previous audit record and non-conformities	☒
Qis since last audit	☒
Related Equipment numbers and service records	☒
Training records of auditee	☒

Undertake audit ☒ Date/time started 08/07/22 – 13:00 Date/time complete 08/07/22 – 17:00

Page 2 of 3

Bristol Royal Infirmary – Vertical Audit Training Assessment list

Lead closing meeting ☒

Presented/discussed items:

Non-conformities ☒ Others ☒ Actions ☒ Target dates ☒

Audit summary report created ☐

Audit output added to Qpulse
(Including non-conformities; others; closing meeting decisions) ☐

Trainer		Signature		Date:	

Part D

Completed audit presentation questionnaire form (CF-GEN-Audit) ☐

Audit summary report agreed

Head of Section		Signature		Date	
Quality Manager		Signature		Date	

Audit Output documented on Qpulse agreed

Head of Section		Signature		Date	
Quality Manager		Signature		Date	

Trainer		Signature		Date:	