Title:

Examining the impact of ISO 15189: 2012 accreditation in an NHS specialist pathology laboratory: A single centre longitudinal study.

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A thesis submitted as partial fulfilment as required for the degree of a Professional Doctorate

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List of abbreviations

List of Abbreviations	Meanings
ACB	Association of Clinical Biochemists
ACP	Association of Clinical Pathologists
AfC	Agenda for Change
CE	Conformitè Europëenne
CPA	Clinical Pathology Accreditation
CQI	Continuous quality improvement
CSS	Clinical support services
CSTT FG	Clinical scientists and technician Team Focus Group
DH	Department of Health
EA	European Cooperation for Accreditation
EFCC	European Federation of Clinical Chemistry
EQA	External Quality Assessment
EFLM	European Federation of Clinical Chemistry and Laboratory Medicine
ETS	Extension to Scope
FGD	Focus Group Discussion
GIRFT	Getting it right first time
H&I	Histocompatibility and Immunogenetics
HC	Healthcare
IHA	Independent Healthcare Association
IBMS	Institute of Biomedical Scientists
IHSM	Institute of Health Service Managers
ILAC	International Laboratory Accreditation Cooperation
ISO	International Standards Organisation
KQI	Key Quality Indicator
MT FG	Management Team Focus Group
NHS	National Health Service
NC	Non-conformances
POCT	Point of Care Testing

PQAR	Pathology Quality Assurance Review
QI	Quality indicators
QM	Quality Manager
QMS	Quality Management System
RCPath	Royal College of Pathologists
RR	Repeat Rate
SUR	Surveillance visits (UKAS)
TA	Thematic Analysis
TAT	Turnaround times
TQM	Total Quality Management
TTP	Total testing process
UKAS	United Kingdom Accreditation Service
UKNEQAS	United Kingdom National External Quality Assurance Scheme
UoS	University of Salford
WHO	World Health Organisation

List of abbreviations for Laboratory Techniques

List of Abbreviations	Meanings
CDC XM	Complement Dependant Cytotoxicity Crossmatching
FCXM	Flow cytometry Crossmatching
HLA	Human Leukocyte Antigens
IgG and IgM	Immunoglobulin G and Immunoglobulin M
NGS	Next Generation Sequencing
PCR SSP	Polymerase Chain Reaction – Sequence-Specific Primer
PCR SSO	Polymerase Chain Reaction - Sequence-Specific Oligonucleotide
RT-PCR	Real Time Polymerase Chain Reaction
SBT	Sequence Based Typing
STR	Short Tandem Repeat analysis

List of keywords and terms

List of Key Terms	Meanings
Accreditation	The independent, third-party evaluation of a conformity assessment body (such as certification body, inspection body or laboratory) against recognised standards, conveying formal demonstration of its impartiality and competence to carry out specific conformity assessment tasks (such as certification, inspection and testing)
Accreditation Bodies	These are established in many economies with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body. Accreditation bodies, that have been peer-evaluated as competent, sign regional and international arrangements to demonstrate their competence. These accreditation bodies then assess and accredit conformity assessment bodies to the relevant standards.
Agenda for Change	Is the current National Health Service grading and pay system for NHS staff, except for doctors, dentists, apprentices, and some senior managers
Antibody Screening	This technique determines the level of sensitisation and / or the specificity of the antibodies present in a patient's circulation. These are detected and defined by micro bead array techniques, which are highly sensitive and specific. These semi quantitative assays are known as Luminex assays of which there are a number marketed. (LABScreen / LifeCodes)
CDC Crossmatching	The complement dependant cytotoxic crossmatch (CDC XM) is a technique introduced over 50 years ago to detect donor specific antibodies in potential transplant recipients via activation of the classical complement pathway prior to transplantation.
CE Mark	Is defined as the European Union's (EU) mandatory conformity marking for regulating the goods sold within the European Economic Area (EEA) since 1985. The CE marking represents a manufacturer's declaration that products comply with the EU's New Approach Directives.
Chimaerism monitoring	Is a well-established method for continually monitoring the state of haematopoietic stem cell transplants over time. It is performed using short tandem repeat (STR) analysis to evaluate the engraft status of the transplanted cells or the reoccurrence of the disease. This is fundamental for effective early therapeutic intervention.
Clinical outcome	These are the results of treatment and could be positive eg improved quality of life or negative such as increased morbidity or mortality.

Cost-effectiveness	Is the ability to get the best possible profit or benefits in comparison with the money that is spent.
Cost of Quality (COQ)	Is a measure of all costs related to the quality or the lack of? It is an integrated concept of the costs to achieve quality and the costs that occur due to quality issues. Thereby, COQ refers to the entire lifecycle of the product (or outcome) created by a project.
Crossmatching	Is the procedure to exclude incompatibility between donor and recipient in a transplantation scenario.
Effect	Is related to the consequences or outcomes of an action. Something that inevitably follows an antecedent (such as a cause or agent); to produce as an effect; bring about; make happen; accomplish.
Effectiveness	Is the degree to which something is successful in producing a desired result; the fact of producing the result that is wanted or intended; the fact of producing a successful result (doing the right thing).
Efficiency	Is related to value and is a measure of the cost of care associated with a specified level of quality (doing more with less) and includes avoiding waste of equipment, supplies ideas, and energy (doing things right).
Error Rate	The percentage of processing error that a department generates, measuring reliability and performance (efficiency). It is calculated by dividing the number of failures (errors) by total number of tests.
Extension to scope	This process allows additions or changes to the range of accredited activities. It covers several changes to an existing scope, including the addition of new conformity assessment activities (tests, inspections, calibrations, areas of certification,) addition of new locations and expansion into a new area of accreditation.
Fixed Scope	Clearly defined description of the specific activities for which the laboratory holds accreditation.
Flexible Scope	The scope of accreditation is expressed to allow an accredited laboratory to make changes in methodology and other parameters which fall within their currently accredited competence.
Flow Cytometry Crossmatching	Is the standard technique for evaluating the compatibility of potential kidney transplant recipients and donors using a laser-based technique. This technique allows for increased sensitivity over the CDC XM technique
Getting It Right First Time	Is a national programme designed to improve the treatment and care of patients through in-depth review of services, benchmarking, and presenting a data-driven evidence base to support change. GIRFT is part of an aligned set of programmes

	within NHS England. The programme has the backing of the Royal Colleges and professional associations.
HLA Typing	Human Leukocyte Antigen (HLA) typing is a genetic test used to match patient and donors for bone marrow, cord, or organ transplants. It is also used to confirm diagnosis of certain autoimmune disorder or predict likelihood of certain adverse drug reactions. HLA typing uses DNA based molecular techniques of which there are several offering a range of typing resolution levels from low (antigen-level) to high (allelic-level) – PCR-SSP / PCR-SSO / SBT / NGS / RT-PCR
Impact	Refers to the influence of an action on something or the change or difference made as a result of an action or intervention.;
ISO 15189: 2012	This international standard specifies requirements for quality and competence in all medical laboratories regardless of the discipline. The standard is used to assess conformance of a laboratory and its QMS, providing users and patients confidence in the quality and competence of medical laboratories.
Key Performance Indicators	Are measurable variables that demonstrate either an improvement or a deterioration in the performance of the laboratory
Medical Laboratory / Medical Laboratory Science	Provides a diagnostic service to detect and treat diseases, assisting clinicians to successfully implement treatments to improve clinical outcome.
Pathology	Refers to the speciality of medical science. It is the study of disease and injury and the bridge between science and medicine, incorporating a wide range of disciplines of medical laboratories
Quality Assurance	QA in a medical laboratory is the overall process which guarantees the final result reported is as accurate as possible. It involves a range of activities and stringent measures to ensure this is achieved and maintained, such measures include compliance against a standard.
Quality Improvement	Is a continuous systematic improvement process that focuses on systems and process. The analysis of which assists in improving performance.
Quality Indicator / measure	Provide information about effectiveness using quantitative measures. They should provide a goal, a measurement concept, and an appraisal concept to indicate good or bad quality
Quality Management Systems	Defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency continuously.

Repeat Rates	In terms of laboratory medicine these are measures of repeated laboratory testing. These percentage values are calculated using the total number of test repeats by total number of samples tested per critical process.
Scope of practice or Schedule of accreditation	The official and detailed statement of activities for which the laboratory is accredited. It is an official list of tests and/or calibrations that your laboratory is accredited to perform.
Speciality Pathology Laboratory or services	Because of the rarity of the underlying clinical conditions, infrequent need for measurement, or the technical difficulty of the procedure, are best performed in a small number of laboratories serving the country. Including services that would be provided on a national basis or serve a population greater than that of a single trust pathology service. The test provided may be straightforward but require specialist interpretation.
Standard	Provides requirements, specifications, guidelines, or characteristics that can be used consistently to ensure that materials, products, processes, and services are fit for purpose
Total Quality Management	A management philosophy concerned with process and people which focuses on user satisfaction and performance improvement using scientific principles
Turnaround Times	The period required for completing a particular process or task from the moment it is formally requested to the time the report is released
UKAS	Is the UKs national accreditation body. It assesses and accredits organisations that provide certification, testing, inspection & calibration services.
UKNEQAS	Is a charitable consortium of international external quality assessment providers. Its aim is to improve patient care via monitoring independently the quality of tests and their reporting
UKNEQAS In H&I	Is part of the UKNEQAS consortium and provides a comprehensive range of EQA schemes for laboratories operating clinical H&I services.
Value	Can mean a quantity or number, but in finance, it's often used to determine the worth of an asset, a company, and its financial performance; assigning a value to or evaluate or estimate the nature, quality, ability, extent, or significance of; relates to worth, or our ideals,
Value in healthcare	Defined as patient experience and outcome over cost

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Abstract

Introduction:

Quality and particularly the assurance of quality for service users has become a significant part of healthcare over the years. In an attempt to drive quality, quality improvement strategies such as accreditation have been introduced. Accreditation is a procedure by which an authoritative body gives formal recognition that a laboratory is competent to carry out specific procedures according to specified standards. NHS medical laboratories have been encouraged to implement ISO 15189:2012 accreditation as a tool with which to demonstrate an acceptable level of service quality. However, there is little evidence to substantiate the impact of ISO accreditation on laboratory quality, efficiency, or whether it is cost effective. Current evidence highlights a paucity of quality empirical data examining the effect of the implementation of ISO accreditation, especially in the field of Laboratory Medicine in the UK.

Method:

This is a single-centre study of the impact of laboratory accreditation employing performance measures to generate an evidence base for ISO 15189:2012 accreditation in an NHS speciality pathology Histocompatibility and Immunogenetics (H&I) Laboratory. Utilizing a convergent mixed method approach longitudinal data was collected measuring quality (repeat and error rates), efficiency (TATs), and cost effectiveness to evaluate the impact of ISO accreditation. The experiences and perceptions of laboratory personnel were captured using a questionnaire and focus group discussions. Data was integrated to establish the overall effects of ISO 15189:2012 accreditation.

Results:

- There is increasing financial impact of ISO accreditation, especially when changes to the scope of practice are required with the average percentage of laboratory budget spent at **0.56%** over the last seven years.
- There is no significant correlation between ISO Accreditation and laboratory quality (**P=0.95**), but a significant correlation was observed for efficiency where the TATs were monitored –
    - Deceased Donor HLA typing (**P=0.0001**).
    - Deceased Donor Crossmatching (**P=0.05**)
- Accreditation was not considered value for money (**86%**), viewed as expensive (**93%)** by the study group, whilst seen as a useful management tool it had a significant impact on staff workload.

Conclusion:

The findings of this study enhance the evidence-base surrounding the impact of accreditation in healthcare, generating new knowledge from the perspective of a specialist NHS laboratory. It provides valuable understanding on the impact of accreditation on both laboratory process and personnel, establishing a framework of measurements for other laboratories to employ. Evidence is generated for policy makers and managers to understand the impact of UK accreditation and recommendations of potential change, to enhance laboratory accreditation.

1. Overview

"Quality is not an act; it is a habit".

Aristotle – Greek Philosopher (384BC – 322BC)

1.1 Introduction

This first chapter introduces the Professional Doctorate (DProf) research study topic, highlighting the content and layout of the draft thesis. A brief overview of the research problem is provided, and the rationale for choosing this subject area. This being a DProf its focus is on a practice-based issue which needs an original evidence base to influence change and make a significant and original contribution to furthering professional practice.

The DProf research study examines laboratory accreditation, within a specialist Histocompatibility and Immunogenetics (H&I) laboratory, specifically against the International Standards Organisation (ISO) 15189:2012 standard and the impact it may have on practice. The aim was to better understand if the accreditation system and process influences the quality and efficiency of the laboratory services, is cost effective and value for money. The original intention of the DProf was to explore the introduction of the Flexible Scope accreditation model adopted across Europe and as part of the DProf measure the impact of this change pre and post implementation on service quality, efficiency, and cost. Unfortunately, due to the Covid-19 pandemic, the application for the Flexible Scope had to be delayed.

Laboratory accreditation has progressed in the NHS with limited evaluation as to the impact it has on quality and clinical outcomes (Zima, 2017; Adane et al, 2019; Tashayoei et al, 2020). Some evidence from Europe suggests it to be a valuable resource for medical laboratories as a management tool to improve quality with the implementation and maintenance of quality laboratory systems (Peter et al, 2010; Hamza et al, 2013; Rizk et al, 2014; Boursier et al, 2015; Zima, 2017; Plebani et al, 2017; Abdel-Wareth et al, 2018; Ramya et al, 2018). Identifying improvements in quality performance indicators and proficiency testing participation (Kibet et al, 2014; Masau et al, 2015; O'Connor et al, 2016; Adane et al, 2018; Buchta et al, 2018; Desalegn et al, 2019).

The majority of healthcare accreditation evidence has been contradictory over the years with varied and inconsistent findings (Greenfield and Braithwaite, 2008;

Alkhenizan et al, 2011; Greenfield et al, 2011; Hinchcliff et al, 2012; Mumford et al, 2013; Brubakk et al, 2015; Melo, 2016; Devkaran and O'Farrell, 2015; Hovlid et al, 2020; Tashayoei et al, 2020; Hussein et al, 2021; Van Vliet, et al., 2024). Although Alkhenizan et al. (2011) concluded that there was a good body of evidence to show clinical outcomes are improved by accreditation and that such programmes should be supported as a quality improvement tool. Others identified the development of a collaborative quality and safety culture (Greenfield et al, 2011; Hussain et al, 2021), with improvements in patient care (Bogh et al, 2015) and clinical outcome (Hussein et al, 2021). Whilst others found no evidence to support accreditation of hospitals being linked to any measurable change in quality (Greenfield and Braithwaite, 2008; Brubakk et al, 2015).

There are gaps in the evidence that examines the impact in laboratory accreditation or a framework with which to measure this impact over time, that this research seeks to address. By measuring the impact of laboratory accreditation in a single centre since the implementation of ISO 15189:2012, the thesis generates an evidence base to better understand the potential benefits and challenges of medical laboratory accreditation, particularly for an NHS specialist pathology laboratory. In addition, the impact on the cost of accreditation, service quality, efficiency, and cost effectiveness are examined, as well as exploring the experiences and perspectives of laboratory staff involved in the accreditation processes.

The findings from this in-depth single centre study provides a platform from which to measure the impact of any future changes in accreditation. It raises significant questions of the current accreditation system and its significance to the wider debate within the NHS on managing and sustaining quality services and the possibilities of any process changes.

1.2 Thesis Structure

The study is presented over seven chapters.

This chapter (1) introduces the thesis topic, the study aims and provides an overview of the researcher's rationale for choosing this research area, embedding the researcher and their practice within the study.

Chapter 2 provides a full narrative of the historical and current positioning of quality and quality improvement programmes namely accreditation in healthcare, providing the background context with a predominant focus on the medical laboratory in a specialist pathology discipline.

Chapter 3 critically analyses existing literature around the area of accreditation, specifically focusing on laboratory ISO accreditation. The summary analysis draws together the available evidence and research to highlight significant evidence gaps within the current body of empirical knowledge and develop the theoretical framework for the study.

Chapter 4 describes the methodological approach created for the study, informed by the extrapolation of key concepts of quality drawn from the literature surrounding accreditation. The themes from the evidence base and theoretical framework guided the study methodological approach. It considers the position of the researcher within the study, and the specific research methods employed. The study sample is identified, and the sampling frame discussed. Data collection methods to gather the perspective of the laboratory staff and key indicators in laboratory practice that measure quality and efficiency are presented. Ethical considerations examined and the analytical framework proposed.

Chapter 5 critically explores the data analysis process applied to interpret both the primary and longitudinal corporate secondary data collected, to understand the impact of ISO 15189:2012 accreditation in an NHS specialist pathology laboratory. Primary data was collected using survey methodology combining a questionnaire with Focus Group Discussions (FGD). It will be used to corroborate perceptions of laboratory accreditation, with data described or omitted from the literature adding to the theoretical understanding of laboratory accreditation. Longitudinal secondary data obtained using clinical laboratory performance outcome data, audit data and budget information will be crucial in establishing context. Both quantitative and qualitative methodologies are used to establish how the implementation of ISO 15189:2012 accreditation (Independent variable) over several years has impacted the identified key concepts (dependant variables); Cost, Quality, Efficiency and Cost effectiveness.

Generating a baseline for the overall study from where to measure and monitor any changes and the impact of laboratory accreditation over the years. Initially, the

secondary quality data was analysed to identify the annual mean results from the implementation of ISO 15189:2012 in 2014. The data was then extrapolated to observe any further trends and to identify more detailed changes in the measures. Pearson's Correlation Co-efficient and the coefficient of determination was also used to establish any linear relationships between each year of ISO accreditation and the established key concepts for the critical processes identified for the study. Outcomes of both are triangulated and used to fully understand the impact of accreditation in an NHS specialist pathology laboratory described in the next chapter.

Chapter 6 summarises and deliberates the key themes that have emerged from the analysis process aligned with the study objectives. Aiming to integrate the research findings and identify these within the current position of knowledge and understanding about laboratory accreditation, and how the outcomes from this study can be expanded to develop this understanding further.

Chapter 7 will present the conclusions drawn from the data collected examining the impact of ISO 15189:2012 accreditation in an H&I laboratory, the challenges, the improvements, and any recommendations for change to the assessment process for ISO accreditation. It also considers the impact of this research on professional practice including the rationale for future work and policy implications from the study findings.

1.3 Overview of Research Problem

Quality and particularly the assurance of quality for service users has become a significant part of healthcare over the years (Greenfield, and Braithwaite, 2008). Current evidence interrogated in the doctorate (Chapter 3) highlighted a paucity of quality data examining the impact of the implementation of laboratory accreditation, using the ISO 15189:2012 standard in the field of Laboratory Medicine in the UK. Empirical research available in the field of health evaluates the impact of accreditation particularly in the hospital setting (Brubakk et al, 2015; Mumford et al, 2013; Devkaran and O'Farrell, 2015; Tashayoei et al, 2020). There are legitimate concerns about healthcare accreditation and its impact and causality due to the paucity of high-quality studies that have produced contradictory findings (Hussein et al, 2021). This conflicts in part, with the outcomes identified for ISO 9000 accreditation in industry, where reducing costs, increasing quality and productivity, and building customer confidence are identified as the positives but which also resonate negatives, such has high costs

of implementation and maintenance, excessive paperwork, interpretation of standards (Romano, 2000).

Theoretical and empirical data to determine the benefits of laboratory accreditation in healthcare, especially in the medical laboratory is lacking. Yet it is being implemented and used as a tool to assure a level of quality in laboratory services (Boursier et al, 2015; Zima, 2017; Plebani and Sciacovelli, 2017). The current process for laboratory accreditation has been described by some as time consuming, bureaucratic, and costly, putting demands on the laboratory which may subsequently lead to delays and improvements to the patient centred service. (Verstraete et al, 1998; Plebani et al; 2017; Buchta et al, 2018; Campbell et al, 2020; Lapic et al, 2021, Hussein et al, 2021). There is very little quantitative data available to measure the impact of laboratory ISO accreditation to identify what difference it makes to service quality and delivery with which to substantiate or refute the findings.

The original study idea proposed using a pre- and post-implementation study design, to measure the impact of employing an alternative flexible approach to laboratory ISO accreditation currently used throughout Europe. Unfortunately, the impact of the Covid-19 pandemic and the delays to the extension to scope (ETS) application made it unrealistic that this Flexile Scope could be introduced in time for a post measure to be taken. Based on this and the paucity of evidence available during the literature search the decision was made to shift the focus of the study to increasing the evidence base around the current UK system of ISO 15189:2012 accreditation. Including capturing staff experiences to understand what accreditation looks like specifically for an H&I laboratory, including the benefits, and challenges. This doctorate research provides the first robust evidence base considering ISO 15189:2012 accreditation in the UK that delivers a platform with which to measure the impact of accreditation.

1.4 Study Aims and Objectives

The aim of the DProf study was to assess the impact of ISO 15189:2012 accreditation on cost, quality, efficiency, and cost effectiveness in an NHS specialist pathology laboratory. A secondary aim was to examine laboratory staff experiences and opinions of the current ISO accreditation approach. Outcomes of both were used to develop a robust framework to measure the impact of ISO 15189:2012 accreditation over time. Objectives include:

1. To measure the annual costs of laboratory ISO 15189:2012 accreditation for an NHS specialist pathology laboratory, to establish if accreditation as a quality improvement initiative is value for money and cost effective.
2. To measure the impact of ISO 15189:2012 accreditation on the quality and efficiency of an NHS laboratory by monitoring national key performance indicators (KPIs) and internal quality indicators (QI) for recognised critical laboratory processes.
3. To explore the impact of ISO 15189:2012 accreditation on staff and their work, to gain a deeper understanding of their perceptions of laboratory accreditation.
4. To generate an evidence-base to inform and further examine the impact of ISO 15189:2012 accreditation in a well-established NHS specialist pathology laboratory.
5. To add to the theoretical understanding of laboratory accreditation and quality in the NHS, through the lens of an NHS specialist pathology laboratory.

1.5 Summary

This chapter provided a brief overview of the study context, research topic and structure of the Thesis. The thesis will focus on evaluating the impact of laboratory ISO 15189:2012 accreditation on cost, quality, efficiency, and cost effectiveness in an NHS specialist pathology laboratory and capture staff experiences. Maintaining high quality standards is the focus of my professional role as QM and adapting, assessing, and extending service accreditation an integral activity. However, there is currently a paucity of evidence base to highlight best accreditation practice across the UK. The current system of ISO accreditation has been described as time consuming and costly (Verstraete et al, 1998; Plebani et al; 2017; Buchta et al, 2018; Campbell et al, 2020; Lapic et al, 2021), and evidence of this and its real value is lacking from the academic literature.

This research captures an evidence base over many years of laboratory accreditation considering specifically its impact on service quality, efficiency, and laboratory costs. Also including laboratory staff perceptions of ISO 15189:2012 accreditation to provide a comprehensive evaluation of the true impact of accreditation in an NHS specialist pathology laboratory. The study findings have wider implications than just the H&I service, identifying possible key indicators to measure quality and the impact of ISO accreditation that are relevant to other laboratory disciplines in the UK. Identifying that

there is possibly an alternative assessment approach that could be adopted by UKAS to assess laboratories at different stages of their accreditation journey.

Chapter two expands on the context for the study and examines the concept of quality, including quality assurance (QA) and quality improvement and accreditation in healthcare underpinning the research topic.

2. Quality and Accreditation in healthcare

2.1 Introduction

Since 1997, when the New Labour Government came into power, the subject of quality in the healthcare systems has become prominent (Department of Health [DH] 1997, 1998). This has led to a long list of legislative and regulatory initiatives, improvement programmes, new organisations and evaluation capabilities designed and implemented to improve quality and performance, termed the Quality Agenda (Leatherman and Sutherland, 2003).

Such publications imposed that service quality was now no longer discretionary and it had to become the responsibility of everyone in the NHS to ensure quality was inbuilt into systems (DH, 1997, 1998). The new quality principal of doing things right first time for the patient aligned with the teachings of an eminent American quality expert, Philip B. Crosby (Crosby, 1979) who along with others in the field of Quality developed the concepts of total quality management (TQM). This included W. Edwards Deming and his 14 points of management with the importance of continual improvement (Deming, 2000), Joseph Juran with his contributions to quality control and performance excellence (Juran and De Foe, 2010) and Walter Shewhart who introduced the use of statistical quality control (Shewhart, 2012).

Donabedian (2005) conceptualised a quality model for healthcare that refers to the manner in which care is delivered as a combination of structure, process, and outcomes. It identified that good structure within an organisation increases the likelihood of good processes, and good processes increases the likelihood of good outcomes for the patients. The three pillars of this model (structure, process, and outcomes) are vital to manage quality in healthcare and led to the development of classification measures used to monitor, to assess and compare the quality of healthcare organizations worldwide (Raleigh and Foot, 2010). At the same time, the Institute of Medicine (IoM) conceptualised in their report six core components for improvement and that quality of care should be effective, efficient, safe, patient-centred/responsive, timely and equitable (IoM, 2001).

The history of health policy has been littered with examples of plans, setting out how services need to change to be fit for the future creating what has been described as

the quality agenda (DH 1997,1998, 2003). One of the single most important aspects of the quality agenda is quality improvement. Quality improvement can be described as an internal continuous improvement process focused on changes to systems and processes. The aim of which is to bring measurable improvements by applying specific organisational or industrial methods within a healthcare setting (Health Foundation, 2013). Accreditation is one such example of a quality improvement concept (Alkhenizan and Shaw, 2011). This cyclical programme can be used to measure compliance against standards to provide quality assurance (QA) promoting acceptability and providing external accountability (Plebani, 2023). This has been applied to healthcare in both hospital and laboratory settings to improve quality of care and clinical outcomes (Brubakk et al, 2015; Bogh et al, 2015; Delaney and Shorten, 2019).

This background chapter presents the context for the study, exploring the concept of quality within the healthcare setting and its significance to the laboratory setting. Accreditation and its use within the NHS are critically examined and the advantages, disadvantages and the function of accreditation discussed in the context of health. The current position of laboratory ISO accreditation, from the perspective of an experienced specialist pathology discipline of H&I laboratory, is examined.

2.2 Quality in the NHS

2.2.1 Quality Definition

Generally, quality can be defined as the degree to which a set of inherent characteristics fulfils a requirement, which in complex systems such as healthcare is difficult to objectify (Tzankov and Tornillo, 2017). It can be best measured by how well an organisation meets the needs and requirements of its users (Tzankov and Tornillo, 2017). It is not a quantity where there are different amounts it is either present or not (AuBuchon, 1999; Aggarwal et al, 2019) and can be inherent to something or ascribed by an individual (Wilson et al, 2016). These different definitions highlight that the concept of quality is complex and is subjective to different situations and different people.

Quality is also the ability to achieve objectives that can maximise healthcare outcomes and is often considered as a multidimensional concept that incorporates many aspects

(IoM, 2001). The World Health Organisation (WHO) defined six dimensions of quality; safe, effective, patient centric, efficient, timely and equitable (WHO, 2006; p.9) aligned with the IoM concepts, which illustrated what healthcare should aim to be. There was a growing understanding that health service quality should provide evidence-based healthcare, avoid harm, and provide care responding to peoples' values and needs (WHO, 2006). To achieve this health services should aim to reduce wait times, provide a full range of service for an individual throughout their lifetime that doesn't vary in quality and is equitable. Also, services should focus on avoiding waste and making efficient use of available resources to ensure healthcare quality (WHO, 2006).

When evaluating quality in healthcare it has been identified that the following three elements: structure, process, and outcomes, should be the main focus to underpin measurements for improvement. (Donabedian, 1997). In addition, there is a need to consider areas defined by WHO (2006) and IoM (2001) which include an emphasis on patient safety, professional knowledge and evidence of competence which all align with accreditation requirements (Table 1). Process measures reflect how both the systems and processes work to deliver the service and structure measures reflect the attributes of the service such as personnel that directly impact (Campbell et al, 2000). The ultimate measure of quality and effectiveness is the clinical outcome measure which mirrors the impact on the patient. The end result of any healthcare improvement is to minimise errors and improve clinical outcomes.

TABLE 1 QUALITY IN HEALTHCARE CONCEPTS AND FRAMEWORK

IoM, (2001; p354)	Donabedian, (2005; p713)	WHO, (2006; p9)
Effective	Structure	Effective
Efficient	Process	Efficient
Safe	Outcomes	Safe
Patient-centred / responsive		Patient centric
Timely		Integrated
Equitable		Timely
		Equitable

Within healthcare, quality is based upon the Hippocratic notion that dominates patient safety, in that a practitioner in healthcare should not intentionally put a patient in any

harm (Lillrank, 2015). Patient safety and clinical outcome is tacit to all health care providers with a main aim to minimise medical errors (Plebani, 2023). The main reason preventable errors occur is due to the complex nature of systems and processes within a healthcare setting. One of the main types of medical error in healthcare are laboratory based diagnostic errors. Alongside, the use of outdated tests or the failure to administer the correct test leading to both diagnostic errors and treatment type errors (Serteser et al, 2000). Medical errors exceed any other common concern in healthcare (Plebani, 2009; Plebani, 2023; Marang-van de Mheen et al, 2024) and are considered the most difficult to prevent (Plebani, 2009) leading to patient harm or delayed diagnosis and treatment (Plebani, 2023).

Medical laboratory services contribute to various aspects of healthcare and are an integral part of clinical diagnostic and therapeutic decision making for patients, disease monitoring and prevention (Serteser et al, 2000; Plebani, 2009; Beastall, 2013; Lippi and Plebani, 2017; Plebani, 2023). They play a significant role within the complex healthcare setting, where incorrect, inappropriate, or delayed testing can significantly impact on medical errors (Serteser et al, 2000). Quality in the laboratory setting therefore is integral to clinical outcome and can be defined through accuracy, reliability, and timeliness of the reported test results, including the delivery of the right report to the right recipient at the right time (AuBuchon, 1999). This concept aligns with the quality principals of TQM of getting things right first time (Lillrank, 2015). This principal has been adopted by the NHS to Getting it Right First Time (GIRFT). This national programme within NHS England has been designed to improve patient treatment and care by identifying and tackling superfluous variation throughout the NHS (NHS, No date).

2.2.2 Quality Management System (QMS)

The principles of quality management along with QA originate from manufacturing more specifically the automotive industry. These concepts were introduced to streamline processes, increase productivity whilst maintaining the quality, with significant reduction in costs. The concept of quality and especially QA, which is integral to QM, are not new to the medical clinical laboratory. QA was first introduced in the late 1940's to reduce the high numbers of observed diagnostic errors which impact on patient care (Wallace and McCulloch, 2021).

The implementation of the QMS in healthcare have been developed with the introduction of accreditation programmes to monitor its effectiveness (Carr et al, 1997; Romano, 2020). The QMS can ensure the whole laboratory diagnostic process from the pre-analytical phase to the production of patient results (post-analytical), facilitating continual improvement through internal auditing and innovation in patient care through the verification and validation of new diagnostic assays and instrumentation (Kibet et al, 2014; Desalegn et al, 2019; Wallace and McCulloch, 2021; Mubarak, 2023). The application of assessment systems to monitor quality as part of the QMS and QA programmes, such as accreditation, has led to the introduction of QI to measure and manage quality in the medical laboratory, to drive internal quality improvement (Plebani and Sciacovelli, 2017). To operationalise the theoretical concept of quality the use of QI or quality measures need to be applied, that have a clear purpose and context providing an objective, a measurement concept, and an appraisal concept. The use of these subjective measures supports accountability and provides comparative data over time, to evaluate the effectiveness and improvements of the service (Plebani et al, 2013).

To ensure quality and continual improvement by measuring and monitoring the impact of a QMS in a medical laboratory the implementation of accreditation against the ISO 15189 standard has become a mandatory requirement (Plebani et al, 2015; Buchta et al, 2018; O'Connor et al, 2020; Mubarak, 2023). To control the QMS and ensure the efficacy are aligned with the objectives of the laboratory an external assessment by auditing is carried out to review the laboratories compliance against this standard. This assessment forming the basis of accreditation was introduced to guarantee good laboratory practice which serves as a quality measure to assure quality and ensure quality improvement (Kibet et al, 2014; Desalegn et al, 2019).

2.2.3 Cost of quality

In early management science quality was measured by inspection using a standard against manufacturing guidance and as such became something to be managed (Dale, 1999). The use of quality improvements strategies, such as accreditation, have been introduced globally in an attempt to drive quality, but have also been seen to result in significant costs to an organisation (Øvretveit, 2000; Peter et al, 2010; Hamza et al, 2013; Wilson et al, 2016; Buchta et al, 2018; Adane et al, 2019). The financial

costs to a business of the implementation of quality improvement programmes like accreditation are usually passed down to the customer. This isn't possible in non-profit making organisations such as healthcare laboratories, and the expenditure needed has never been fully explored in the laboratory setting but has been described by some has being redirected away from services or resources (Øvretveit, 2000).

The total cost of quality (CoQ) refers to the total spending incurred to maintain overall quality. It is dependent on the impact of good quality, poor quality or no quality. Where the cost of good quality is the money spent proactively to achieve a quality service incorporating the introduction of preventative costs that include quality planning, designing, implementing (a QMS) and, training. Also, appraisal costs which include the cost of inspecting, testing, auditing, and measuring to identify any problems. The cost of poor quality which includes both internal and external failures and, the money spent when failure occurs (Wilson et al, 2016) cause the most concern in healthcare where any failure can lead to significant consequences to the patient. Whilst special attention needs to be made to the costs involved in obtaining and maintaining a level of quality in healthcare due to budgetary demands its is also worth considering the risk to the patient of not having any quality improvement programmes. Quality improvement programmes have been described as complex social interventions (Walshe and Freeman, 2002; Walshe, 2007, Hussein et al, 2021) that require massive effort and personnel resources to implement and maintain. This may also have a negative impact on staff which needs to be considered that may lead to further additional hidden costs of quality (Wilson et al, 2016).

Øvretveit (2000) has explained how the time investment model for quality activities shows that initial big investment leads to overall savings for an organisation. Given rising costs around the world, value and efficiency are becoming a main focus for governments, policymakers, and healthcare organisations (Ovretveit, 2000). Value being defined as patient experience and outcomes over cost, whilst efficiency is related to value and measures the cost of care associated with a specific level of quality (Ovretveit, 2000). The objective being to improve the quality of care and patient experience by reducing waste, controlling costs, and leveraging the innovative ideas and energy of the workforce to accomplish these goals (Sorra et al, 2021). The cost of quality improvement programmes such as accreditation particularly in the medical

laboratory has never been fully estimated or evaluated to determine its impact on quality and resources.

2.3 Accreditation in the NHS

2.3.1 Accreditation Definition

To fully research the concept of accreditation and its impact on healthcare, a general definition of accreditation needs to be established. Accreditation according to the Cambridge Dictionary is 'the fact of being officially recognized, accepted, or approved of, or the act of officially recognising, accepting, or approving of something, especially to maintain satisfactory standards' (Dictionary, 2020). Accreditation is considered as an independent assessment which can ensure conformity with validated standards and requirements, evaluating an organisation's competence, structures, processes, quality, and overall outputs to provide an assurance of quality to service users (Greenfield, and Braithwaite, 2008).

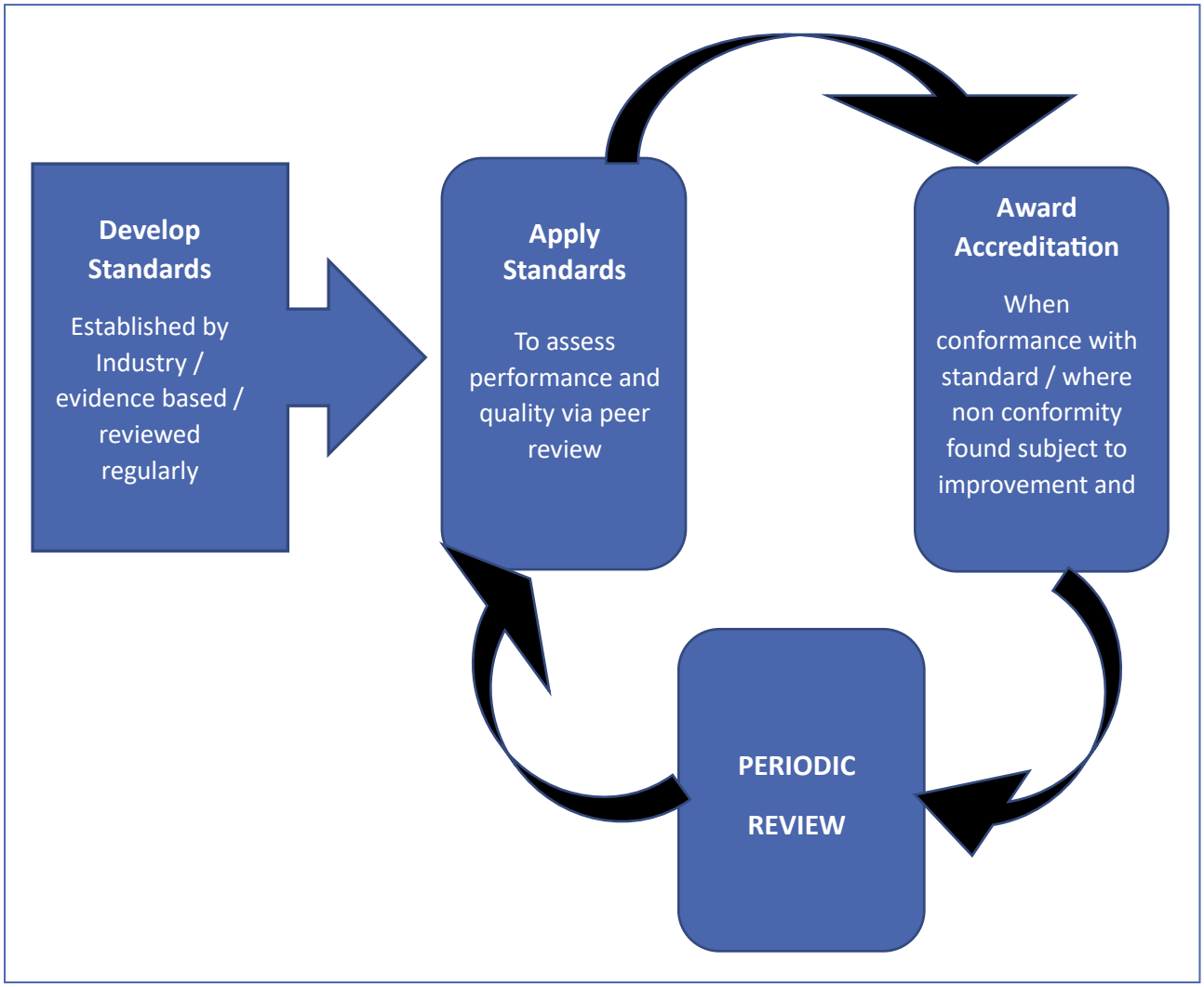
According to United Kingdom Accreditation Service (UKAS) the National accreditation body, accreditation is a means of assessing, in the public's interest, the technical competence and integrity of organisations offering evaluation services (UKAS, 2020). Stating that accreditation, has many potential benefits for the quality of goods and the provision of services, underpins practical applications of an increasingly wide range of activities across all sectors of economy, including Medical Laboratories (UKAS, 2020). Its overall core purpose with reference to healthcare involves peer review using defined standards to ensure the quality of care provided, to guarantee patient safety and provide high quality results (Shaw et al, 2010). There are over 70 national healthcare accreditation agencies worldwide that develop or apply standards for healthcare organisations (Greenfield et al, 2012). The ISO is the largest developer of standards, bringing together national standard institutes from 162 countries forming a network (Greenfield et al, 2012). Healthcare standards are ubiquitous and are promoted as an important means to improve clinical practice and organisational performance, with no real evidence of their success (Greenfield and Braithwaite, 2008; Hinchcliff et al, 2012, Brubakk et al, 2015; Melo, 2016). Each of the standards are developed by groups of international experts with technical knowledge that join to establish a technical committee. This group negotiate all aspects of the standard from

the proposal stage through to publication. A working group is established to develop a draft, this draft is circulated until a final draft is accepted and published. All member bodies interested in the subject have the right to be represented on the committee. The standards created are developed using methodologies that are effective and efficient for the healthcare industry (Greenfield et al, 2012). The International Society for Quality in healthcare (ISQua) main aim is to guide and standardise the accreditation agencies by ensuring the standards themselves meet specified standards for developing, writing and application (Greenfield et al, 2012).

The process of accreditation is perceived mainly as a QA procedure, that often feeds into quality improvement activities. This assessment of quality systems and processes is considered as one of the driving forces to verify organisational performance improvements. (Greenfield and Braithwaite, 2008; Alkhenizan et al, 2011; Hinchcliff et al, 2012, Brubakk et al, 2015). The accreditation process (Figure 1) therefore, is an external and independent peer review evidence-based assessment against a specified standard. The aim is to establish the maturity and reliability of the organizations QMS and technical abilities using trained individuals in the role of peer assessors (Alkhenizan and Shaw, 2011; Greenfield et al, 2012; Brubakk et al 2015). The standards and trained competent peer assessors are vital to a successful assessment and as such are also subject to regulation, ensuring the competence and commitment of all qualified assessors (Hinchcliff, et al, 2012; Adane, et al, 2015; Boyd et al, 2017; Tashayoei et al, 2020).

Once the assessment against the standard is complete, accreditation is either awarded due to conformance with the standards or where nonconformity is found, improvement actions are defined. Once improvement actions have been implemented and evidence confirmed accreditation can be awarded and the cycle of periodic review can continue (Appendix 1). Most accreditation assessments run over periods of three or four years depending on the standards and accreditation bodies. The ISO 15189:2012 accreditation runs over a four-year assessment cycle. These ongoing cyclical assessments provide annual snap shots in time that aim to review the whole system over the four yearly cycles to maintain the established accreditation status (Delaney and Shorten, 2019).

FIGURE 1 THE MODEL OF ACCREDITATION



2.3.2 Accreditation and its impact on healthcare

The use of evidence-based practice in healthcare decision making has resulted in several systematic reviews over the last two decades that have identified and analysed the impact of accreditation on quality, focusing specifically on the health sector (Greenfield and Braithwaite, 2008; Alkhenizan et al, 2011; Greenfield et al, 2011; Brubakk et al, 2015, Hovlid et al, 2020, Hussein et al, 2021). Overall, their findings have proven inconclusive, but all have shown that there was a paucity of suitable available empirical research data from which to form any valid conclusions (Greenfield and Braithwaite, 2008; Alkhenizan et al, 2011; Greenfield et al, 2011; Hinchcliff et all, 2012; Bogh et al, 2015; Brubakk et al, 2015, Hovlid et al, 2020; Hussein et al, 2021; Van Vliet, et al, 2024)

Greenfield and Braithwaite (2008) revealed mixed views and inconsistent findings surrounding general accreditation, where quality measures, program assessments, professionals' attitudes to accreditation, the organisation and financial impact were examined. The information to draw any conclusions with regards to the impact or effectiveness of accreditation was lacking, but robust empirical data was beginning to be collected (Greenfield and Braithwaite, 2008). This same group repeated the systematic review 14 years later focusing on healthcare standards, only to find that there was still a significant lack of empirical evidence from where to conclude the effectiveness and the impact of applying accreditation standards to healthcare settings (Greenfield et al, 2011). These two systematic reviews together covered literature spanning almost six decades from 1950 to 2009. Criticisms of the work suggested key accreditation contextual papers were omitted from the 2008 and that it had included many different types of accreditations in different fields, which limited the ability to draw any meaningful conclusions (Alkhenizan and Shaw, 2011).

A second group, Alkhenizan and Shaw (2011), carried out a review focusing on evaluating the impact of accreditation programmes on quality in healthcare services that contradicted previous findings, highlighting the limitations of the previous study. They concluded by focusing specifically on the health service, that there was indeed a good body of evidence to show clinical outcomes are improved by accreditation and that such programmes should be supported as a quality improvement tool. The previous review did not identify studies evaluating cost and the attitude of healthcare professionals, important factors that needed to be considered, to evaluate the real and complex impact of accreditation (Alkhenizan and Shaw, 2011).

In 2015 a further review examined the challenges of measuring hospital accreditation (Brubakk et al, 2015). It highlighted that only four studies out of 915 (0.4%) abstracts available were assessing the effectiveness of accreditation on hospital outcomes. Again, like others they found no evidence to support accreditation of hospitals being linked to any measurable change in quality (Greenfield and Braithwaite, 2008; Brubakk et al, 2015). There had been an increase in the number of studies in this area over the years but the number that were useful for evaluating accreditation effectiveness was limited (Brubakk et al, 2015). This review of hospital accreditation not only again highlighted the scarcity of empirical data but that the evidence available from the

studies in this area were weak, with only one of these studies employing a randomised control trial. It highlighted the lack of methodological rigour in the studies due to the use of ambiguous outcome measures and the lack of robust controls. Brubakk and colleagues also compounded that the drive for wider implementation of accreditation in the hospital setting continued without any real evidence of its effectiveness or efficiency. Stating that future studies to address these issues were essential and emphasised the need for the use of analytic approaches rather than just the qualitative approaches currently being taken (Brubakk et al, 2015). Going forward a robust methodology for any study was essential including clearly constructed outcome measures and a sound scientific approach was required (Mumford et al, 2013; Brubakk et al, 2015).

In contrast a number of positive correlations have been identified between the implementation of hospital accreditation and the development of a collaborative quality and safety culture (Greenfield et al, 2011; Hussain et al, 2021), and with improvements in patient care (Bogh et al, 2015) and clinical outcome (Hussein et al, 2021). The establishment of organisational structures and processes (Shaw et al, 2010) and professional development (Greenfield and Braithwaite, 2008) have also been identified amongst other benefits such as enhancing whole system improvements leading to the reliability of laboratory testing (Abdel-Wareth et al, 2018). Staff motivation and professional attitudes have also been identified as a key to the successful implementation of accreditation (Greenfield et al, 2011; Hinchcliff et al, 2012; Desveaux, et al, 2017; Sciacovelli et al, 2017; Van Vliet, et al, 2024).

Some studies did also identify that staff scepticism may be a major barrier to the successful implementation of accreditation (Greenfield and Braithwaite, 2008; Van Vliet, et al, 2024). Alongside these a number of facets were identified as having an unfavourable effect on staff that included, any increase in the amount of documentation and an impact on workload (Brubakk et al, 2015; Tashayoei et al, 2020; Van Vliet, et al, 2024) which also have been observed has having an adverse effect on professional stress levels (Hussein et al, 2021). The procedure of accreditation was considered without any evidence to substantiate this, as bureaucratic, and that it constrains resources (Greenfield et al, 2011; Saut et al, 2017; Hoomans and Severens, 2014). When compared with the manufacturing industry where the accreditation process has been in place longer, with the differences being that it is

voluntary and driven by competitive advantage and global competition (Carr et al, 1997; Romano, 2000; Gough and Reynolds, 2000; Brubakk et al, 2015; Tashayoei et al, 2020; Van Vliet, et al, 2024). Again both examples of negative and a positive advantages have been described similar to those seen in healthcare. (Carr et al, 1997, Romano, 2000).

Concerns have also been raised over the accreditation assessors' capabilities along with the complexity of the standards and the cost of accreditation again without any empirical evidence (Mate et al, 2014; Nicklin et al, 2017; Tashayoei et al, 2020; Van Vliet, et al, 2024). All these aspects have been identified as concerns in the manufacturing industry where the ISO standards are also implemented as a way to manage quality (Carr et al, 1997; Romano, 2000). This could open up the debate of the value of this process of continued auditing to assess quality and its benefits (Green ert al, 2020).

Healthcare accreditation is commonplace and considered as a punitive driver of quality without any conclusive evidence of its impact (Greenfield and Braithwaite, 2008; Hinchcliff et al, 2012, Brubakk et al, 2015; Melo, 2016; Hussein et al, 2021; Van Vliet, et al, 2024). It is considered a complex phenomenon and difficult to measure its effects on the organisational or clinical processes (Walshe, 2007; Hinchcliff et al 2012; Mumford, et al, 2013, Hovlid et al, 2020). Quantitative comparison of outcomes between studies have been described as problematic leaving any impact difficult to determine (Brubakk et al, 2015, Hovlid et al, 2020). There is evidence of increased compliance with hospitals especially prior to assessment, but less evidence to indicate any continual improvement to patient care (Greenfield and Braithwaite, 2008; Braithwaite et al, 2010; Bogh et al, 2015; Hussein et al, 2021; Van Vliet, et al, 2024).

2.3.3 Accreditation and its value in healthcare

Accreditation and its value to a healthcare organisation has also never been fully verified. There has been reference made to significant financial constraints and pressures on resources for healthcare provisions that require further investigation (Greenfield et al, 2011; Saut et al, 2017; Hoomans and Severens, 2014; Ovretveit, 2000; Hussein et al, 2021; Van Vliet, et al, 2024). The financial impact of hospital accreditation has been identified in both a positive way as being an investment in clinical quality (Greenfield et al, 2011) and improved efficiency (Van Vliet, et al, 2024);

and negative that participation in such accreditation programmes requires considerable human and financial resources (Greenfield et al, 2011; Saut et al, 2017; Hoomans and Severens, 2014; Hussein et al, 2021; Van Vliet, et al, 2024) with the return on investment being described as questionable (Hinchcliff et al, 2012).

Current evidence suggests that there has been a significant investment within the NHS in accreditation without any real understanding of its actual impact and whether the investment is effective (Greenfield and Braithwaite, 2008; Mumford et al, 2013; Hussein et al, 2021; Van Vliet, et al, 2024). The decision to use accreditation as a tool to manage quality in healthcare may not have been based on any economic evaluation (Mumford et al, 2013; Hoomans and Severens, 2014; Eisman et al, 2020). Others have claimed that it is difficult to determine any economic benefits due to the lack of evidence, lack of formal appraisals, weak methodological designs which need to be more robust to be able to draw any significant conclusions (Ovretveit, 2000. Ovretveit and Gustafson, 2002; Mumford et al, 2013). Cost effectiveness analysis may therefore be necessary to justify the implementation of any new approach as all improvement programmes require considerable resources and finances (Hoomans and Severens, 2014; Ovretveit, 2000).

The biggest gap in the evidence base would appear to be research located from within the UK, this seems to be specifically true around laboratory accreditation. Where there seems to be an ongoing failure to validate and share learning from quality improvements efforts, especially within the NHS with this potential knowledge being lost (Dixon-Woods and Martin, 2016). In all four of the systematic reviews none of the researchers involved in the reviews were from the UK, and only two of the reviews had found and included UK based studies (Greenfield and Braithwaite, 2008; Greenfield et al, 2011). Only two of these systematic reviews included studies involving laboratory research that dated back to 1998, only one of which was UK based (Greenfield and Braithwaite, 2008) reinforcing the lack of evidence in the current body of knowledge. Indicating approximately half the research was situated in the USA and that less than 5% of the publications assessed accreditation across several European countries. Hospitals (65%) again represented the main research setting in these studies with only nine studies involving the laboratory setting (Hinchcliff et al, 2012). The literature review in the next chapter corroborated these findings.

There was a suggestion that the choice of study design and methodological approach may bias findings, referring to some studies that included senior management and quality improvement managers in their sample, who may all be seen to have a vested interest (Desalegn et al, 2019; Tashayoei et al, 2020). When any quality interventions (such as accreditation) are implemented, there seems to be an automatic presumption by those leading the interventions that the change will be positive, this bias could skew any potential evaluation (Dixon-Woods and Martin, 2016). These issues are discussed further in the methods chapter 4.

2.3.4 NHS Laboratory accreditation

The NHS is now in its 7th decade and continues to provide free healthcare at the point of delivery to everyone in the UK. Over the years, there has been considerable investment in major aims such as reducing waiting times, improving health outcomes, and providing much more patient-focused services (NHS England, 2014).

The initial phase of change and improvements driven by the DH in England that had impact within Pathology and laboratory medicine was the Pathology Modernisation Programme (NHS Plan, 2000). In the first three years there was large investment in quality improvement projects to help improve patient outcomes and the restructuring the existing format of pathology services with the introduction of managed pathology networks and the introduction of specialised pathology services (Table 2). The DH then commissioned a further independent review of pathology services Lord Carter Review (2008). Followed by the Five-Year Forward View (NHS, 2014) which emphasised how the health service needed to change going forward by improving quality and patient experience through restructuring, refocusing and prevention. These two reviews (NHS Plan, 2000; Carter, 2008) had the biggest impact on quality and improving pathology services that I had seen in my years in the laboratory and reinforced the importance of quality in my expanding role from scientist to QM.

TABLE 2 THE HISTORY OF PATHOLOGY QUALITY IMPROVEMENT STRATEGIES IN THE NHS

Year	Improvement Strategies	Aim
1999	Pathology Modernisation Programme (DH, 1999)	To improve quality and efficient and encourage introduction of new technologies and practices
2002	Pathology – The essential service. Draft guidance on modernising pathology services; (DH, 2002)	Consultation paper to introduce Managed pathology networks as a model of service delivery within Strategic health authorities. Using a single integrated management structure and budget to address workforce and technology challenges faced by NHS
2004	Modernising pathology services; (DH, 2004)	Mainly focusing on redesigning services to build pathology capacity This document sets out steps that can be taken locally to develop pathology modernisation strategies.
2005	Modernising pathology: building a service responsive to patients; (DH, 2005)	The aim of this was to re-energise the modernisation program and promoting a service shaped around the patient using new technology and new ways of working. This announced the independent review of pathology services by Lord Carter of Coles
2005	Modernising pathology services toolkit – a practical guide to service improvement. (DH, 2005)	A toolkit for use by individual laboratories and workshops were convened to encourage the local use of Lean and Six Sigma methodology. Hospital trusts were formed introducing rationalisation of laboratory services across several sites.
2006	Report of the review of NHS Pathology services in England; (DH, 2006)	To carry out a thorough and systematic evaluation of pathology and laboratory medicine in England, using examples of best practice from around the world and a comprehensive set of recommendations were established which would be used to drive the most significant change programme within pathology yet seen.
2008	Report of the second phase of the review of NHS Pathology services in England; (DH, 2008)	To oversee a programme of pilot projects with the aim of identifying a new model of commissioning and organising NHS pathology services with a vision for integrated, clinically excellent, cost effective, pathology services responsive to users.
2013	Key Performance indicators – Proposal for implementation (RCPath, 2013)	These indicators were developed by a collaboration of groups within Pathology and accreditation body CPA/UKAS. The aim is to help laboratories demonstrate conformity with the new ISO 15189 standards and to provide a framework through which laboratories can demonstrate clinical effectiveness of their service.

2014	Pathology Quality Assurance Review (PQAR); Dr Ian Barnes (DH; 2014)	The review highlighted a need for quality assurance systems to be updated, as gaps exist. The current system was fit for the purpose for which it was designed, but less so for the future. It didn't meet the emerging need for transparency and well-evidenced quality assurance which led to the development of the Pathology Quality Assurance Dashboard (PQAD).
2016	Report of the review of NHS Pathology services in England; (DH, 2016)	Highlights the importance of Pathology in the NHS and the significant role and cost to the NHS (4% of NHS expenditure) and the importance of its reform. There is a lack of nationally collected activity, cost and performance data and addressed using pilot projects.
2019	Key assurance indicators for pathology services. (RCPath, 2019)	A revision through consultation and collaboration of the 2013 document due to changes and demands in pathology services. It now focuses on indicators that assure service quality not performance efficiency; each KPI was reframed as a key assurance indicator (KAI).

Clinical support services (CSS), a terminology used by NHS England for pathology and laboratory medicine, costs around an estimated £2.2 billion per year (NHS, 2020). In the years following The Lord Carter Review (2008) the CSS experienced immense pressure to improve and advance the quality of services within their limited budgets, or face closure or merger into pathology networks. Lord Carter recommended the need to make investments in pathology services to potentially improve the quality and lower the total cost in this area alongside the mergers. There also came significant change to the accreditation system for CSS during this period. Since 1992, Clinical Pathology Accreditation (CPA UK) Ltd had been the main assessment body for laboratory accreditation in the UK. In 1996, the first draft of a new international standard, ISO 15189 Quality Management in the Medical Laboratory was released. The uptake of the new ISO standards by European assessment bodies and the European laboratory community was almost immediate (Boursier et al, 2015), whilst in the UK; CPA (UK) continued to draft its own standards. These standards were drawn from best evidence, material from their reference sources, and international ISO standards such as ISO 9001 series of QMS standards and ISO 17025 for testing and calibration laboratories (Burnett et al, 2002). This consensus document was developed as the ISO 17025 standard alone could not address the operational and structural requirements of a medical laboratory and so an amalgamation of these two established sets of ISO

standards was developed. It was first released in 2003, with a second edition in 2007, a third edition in 2012 which was later replaced, in 2022 by the current version. The ISO 15189 standard was designed to be applied generically to all medical laboratory disciplines, including specialist pathology disciplines such as H&I (Harmer et al, 2018). The standard requires that each accredited medical laboratory demonstrates a successfully functioning and well-managed QMS. Alongside technical competence of laboratory personnel to generate valid test results (Sciacovelli et al, 2017), that are timely, accurate and dependable (ILAC-B9, 2011). Providing confidence of continual service quality, efficiency and closer interaction with the service users and patients (Theodorsson, 2016; Plebani and Lippi 2017).

Laboratory accreditation in the UK, once described as the anchor for the implementation of accreditation (Boursier et al, 2015) had advanced considerably since the 1960s, and the concept was continually evolving. The process of accreditation provided a degree of confidence to regulators, commissioners, and patients for laboratories that have obtained and attained accreditation. The uptake however was seen to be slow in the early days possibly because it was considered by some as costly and time consuming and more specifically because it remained voluntary with very little incentive to participate (Gough and Reynolds, 2000; Plebani and Lippi, 2017). Only laboratories who already had a keen motivation to improve quality within the department undertook accreditation at this time. It was perceived that a move to mandatory accreditation for all laboratories could potentially help to reduce the rising costs of accreditation (Gough and Reynolds, 2000). CPA (UK) Ltd was co-owned by the Royal College of Pathologists (RCPath), the Institute of Health Service Managers (IHSM), the Institute of Biomedical Scientists (IBMS), the Association of Clinical Pathologists (ACP), the Association of Clinical Biochemists (ACB), and the Independent Healthcare Association (IHA). All these organisations shared a vested interest raising questions of its legitimacy to independence and quality of the accreditation was put under scrutiny.

In 2000, a survey of CPA accredited laboratories in the UK highlighted several issues with the voluntary accreditation process confirming the finding in the Carter Review. Although, CPA had encouraged laboratories to focus on quality and improve their service, the standards introduced were considered to be ambiguous and the

inspection process variable and suggested also that assessors needed to be standardised. Many laboratories who participated in the study commented on the costs associated with accreditation and the hidden costs such as the increase in documentation and staff time required to obtain and attain accreditation (Gough and Reynolds, 2000) but they had not considered the impact of not implementing accreditation and any costs that could arise from this and impacts on patient safety or clinical outcome. In addition, laboratories surveyed supported CPA accreditation and were either full or partially accredited. The concept that accreditation is costly and bureaucratic has been reiterated in the literature surrounding accreditation in healthcare (Mate et al, 2014; Wilson et al, 2016; Plebani and Lippi, 2017; Gough and Reynolds, 2000). But the study results had limitations and reflect only the responses of those who had endeavoured to obtain accreditation. Seeking the views of those who had not obtained accreditation and understanding why they chose not to do so, would have been useful, to confirm whether there was indeed any financial implication. The Carter Review (2008) stressed these very points, criticising the low number of fully accredited laboratories in England, which led to two key recommendations. First quality standards should be developed that are objective and measurable, perhaps suggesting that the CPA standards were not fit for purpose. The second key recommendation of the Carter review was that pathology service providers should become subject to mandatory accreditation by an independent organisation.

The Pathology Quality Assurance Review (PQAR) which took place in 2014 emphasised the importance of pathology QA and the use of laboratory accreditation (Table 2). It declared accreditation to be a useful tool to assure the quality of the laboratory service being provided and to demonstrate the competence of medical laboratories. By ensuring the delivery of timely, accurate and reliable test results (Barnes, 2014). An underpinning hypothesis throughout all these reviews was that by annually assessing laboratory services against internationally recognised standards alongside a robust QA framework using key QI; a laboratory could demonstrate competence and quality performance. Whilst these established key performance indicators did not test systems and provision, they led to the development of the key assurance indicators over time (NHS, 2019). In practice, however, there was very little evidence generated that demonstrated accreditation against standards has any real value or impact on the quality of laboratory services (Wilson et al, 2016), or whether it

indeed provides any level of confidence of the quality. Accreditation assessments are a sampling exercise and considered only as a snapshot in time focusing on a limited area of the scope of practice (Wilson et al, 2016; Devkaran and O'Farrell, 2015). Accreditation underpins confidence that a laboratory can operate with defined procedures against specified standards ensuring competence and compliance. But it is also worth considering that accreditation status can be maintained whilst still having a number of NC identified (Carr et al, 1997) possibly indicating that there is no guarantee of continued service quality (Green et al, 2020).

Following the release of the Barnes report (2014), CPA (UK) Ltd, who had provided pathology accreditation to over 1,250 laboratories since its formation in 1992; merged with the UKs single EU recognised accreditation body, United Kingdom Accreditation Service (UKAS). UKAS is an independent, not-for-profit organisation, that is formally recognised by the UK government to assess and accredit organisations against agreed international standards, in the case of medical laboratories the standard is ISO 15189:2012. The merger supported by the DH would provide the necessary independence and transparency required to adhere to European accreditation laws. As a result, CPA (UK) ltd became a subsidiary of UKAS, becoming the main body for all accreditation in the UK including medical laboratories (Wilson et al, 2016).

2.3.5 Laboratory ISO 15189:2012 Accreditation

Medical pathology laboratories have a critical supportive role in healthcare. Test results are seen as an integral part of all clinical decisions made by consultants to diagnose and manage disease as part of the patient pathway, ensuring patient safety (Plebani and Lippi, 2017; Green et al, 2020; Plebani, 2023). NHS laboratories are also under continued pressure to improve clinical outcomes or reduce costs by conducting cost effective laboratory operations to ensure the use of the most appropriate tests (Schmidt and Ashwood, 2015).

Medical laboratory accreditation has progressed significantly over the last 30 years, providing service users with confidence in the capability of a laboratory to provide an accurate, reliable, and safe service. The move to compulsory accreditation for UK medical laboratories against the new ISO 15189 standards began in 2013 with a five-year plan and by 2018 all laboratories should have transitioned across to ISO 15189:2012 (UKAS, 2018). The new accreditation programme involved a more

rigorous assessment of data and evaluation of systems than seen with the previous CPA style standards. New standards, introduced from 2012, increased emphasis around TQM and continuous quality improvement. New requirements aligned with a QMS led to focus on documentation and internal monitoring with the introduction of QI (ISO 15189:2012). The new ISO 15189 standards look at the whole process of the specimen through the laboratory pre–, examination and post-examination phases through the whole total testing process (TTP) including managerial and technical aspects. These phases are all assessed via an external quality assessment carried out on-site by a trained UKAS assessment team, looking at both managerial and technical aspects, to determine conformity with the standards to provide greater confidence in the outcome. Laboratory quality data and documentation are required to provide evidence of conformance against the standard. Whilst the amount of documentation is not determined by UKAS or the ISO standard it is a significant aspect of the accreditation process and relies upon the subjective interpretation of the standard. Whilst adding rigour certain limitations were exposed such as it being considered time-consuming, and financially demanding (Mate et al, 2014; Wilson et al, 2016; Plebani and Lippi, 2017; Adane et al; 2019; Gough and Reynolds, 2000),

Annual on-site evidence-based assessments are performed where laboratories are periodically audited for conformance against the ISO 15189 standard over a four-year cycle (Appendix 2). Failure to meet the standard are reported as non-conformances (NC) by the assessment team to the laboratory who must remedy the NC within a time frame before accreditation is granted (Green, et al, 2020) using these NC could be a good way of monitoring laboratory quality over time. Accreditation may be seen as an appropriate way to demonstrate the effectiveness and competence of a laboratory, but is not without its challenges (Zima, 2017; Tashayoei et al, 2020). Establishing and maintaining a QMS using the standard is considered fundamental to improving services and patient care (Zima, 2017; Adane et al, 2019).

The laboratory accreditation system managed by UKAS assesses and monitors laboratories against a clearly defined repertoire of laboratory tests known as the schedule of accreditation or scope of practice (UKAS, no date). This makes clear to all parties which laboratory techniques are accredited. During an annual assessment visit a number of the prescribed list of tests and methodologies on the scope of

practice, are evaluated against the set of standards (ISO 15189:2012). To make any changes to the scope of practice in the UK, medical laboratories need to request an ETS from UKAS. This involves an application followed by a formal assessment of the new or modified procedure and associated QMS by the UKAS assessment team. These additional costs to providing a quality service have been described as significant (Buchta et al, 2018), and may not be accounted for within the laboratory's annual financial budgets. With others describing accreditation as a valuable asset to the laboratory and a necessary expense and to return to a time without accreditaion was deemed inconceivable (O'Connor et al, 2016).

2.4 Summary

This chapter has set the context of the research by identifying the background area significant for the study. Indicating that the concept of quality in the healthcare situation is complex and subjective to different situations and different individuals (Walshe, 2007). Acknowledging that laboratory accreditation has been compulsory now for many years without any empirical evidence to indicate its impact and benefit on laboratory practice. There has been a long history of pathology quality improvement strategies, the most significant may be the introduction of ISO accreditation. This has been seen to impact financially and has added additional workload pressures alongside the traditional accreditation requirements.

There has been a significant investment within the NHS in accreditation despite any understanding of its economic benefits or its effectiveness to manage quality. Any empirical evidence to substantiate any clear relationship or causality between laboratory accreditation and any improvement outcomes is absent throughout the current literature especially in the UK, indicating a clear gap in the literature.

The next chapter explores the current research surrounding accreditation, interrogating, and presenting the findings from a critical literature review. The review was performed to establish the current position of empirical evidence available to substantiate or verify the developing theory that has informed the theoretical framework for the study.

3. Literature Review

3.1 Introduction

The previous chapter examined the evidence base for accreditation in healthcare services highlighting that current data is limited, based on systematic reviews focused primarily on hospital accreditation. (Greenfield and Braithwaite, 2008; Alkhenizan et al, 2011; Greenfield et al, 2011; Brubakk et al, 2015, Hovlid et al, 2020, Hussein et al, 2021). This chapter takes forward the search for available literature to examine the current evidence explicitly surrounding medical laboratory accreditation against the ISO 15189:2012 standard. The purpose of the focused review was to provide a critical summary of the existing body of knowledge on the research topic examining the implementation and impact of ISO 15189:2012 accreditation and the present use of a flexible scope of accreditation in an NHS laboratory.

The focused literature review had four key objectives:

1. To examine the implementation and use of ISO 15189:2012 accreditation, and the impact if any, it has had on (medical) laboratories services with respect to quality, cost, and efficiency.
2. To identify gaps and limitations in the current peer reviewed literature to clearly position the research project.
3. To identify the key concepts surrounding accreditation to inform the theoretical framework and the choice of methodology for the study.
4. To assess the current use of the flexible scope approach for managing the schedule of accreditation against ISO 15189 standards in both Europe and the UK.

A review approach adopted a transparent, reproducible, methodical process that included:

- Developing a research strategy with clear questions and objectives
- Defining inclusion and exclusion criteria for the study
- A complete search of available literature
- Screening the identified studies
- Extraction of relevant data in line with research questions
- Analysis and interpretation of available data to answer the questions.

This approach was developed to avoid discrimination in evidence selection and evaluation and select the best articles available whilst allowing the analysis of a range of publication types (Young and Solomon, 2009; Crowe and Sheppard, 2011).

The methodology and search strategy of the review are presented, the findings synthesised in line with the aims of the chapter and the gaps in the literature are identified to position the study.

3.2 Search Strategy

3.2.1 Scoping Exercise

A narrative review approach was taken to generate a conceptual consideration of all available literature around accreditation in healthcare including any grey literature to provide a deeper understanding of the topic rather than empirical knowledge (Bryman and Bell, 2007). The review comprised initially of a general scoping exercise of the internet using the search engines Google, Google scholar and Research Gate around accreditation. This approach has less methodological rigidity assigned to the search method and is a less focused reproducible method (Bryman and Bell, 2007). It does not provide a transparent representation of the numbers and patterns of findings offered in the systematic review but still provides a body of information to direct the narrative of literature available in the area of research.

The objective of this exercise was not only to obtain a general overview of the study area but to develop specific search terms by scoping the literature in a methodological manner (Arksey and O'Malley, 2005; Levac et al, 2010). The scoping review was also used to highlight any significant experts in the field whose research could be identified and followed, to indicate any specific journals of significance and to locate anything available in the grey literature to direct the narrative of the study. Following the initial scoping review to map the literature available, alerts were established with Google Scholar, Research Gate, Science Direct and Oxford University Press to continually monitor the study topic. The other alerting services available such a Pubcrawler were not employed at this time due to lack of familiarity. Alerts were also established for key persons identified in the field of medical laboratory accreditation from different pathology disciplines such as Plebani, Lippi, Thelen, Sciacovelli and Huisman for any future primary articles and citations around laboratory ISO accreditation. It became apparent from published research articles obtained during the preliminary scoping

exercise that there was a paucity of reliable academic publications in the area around the implementation and impact of medical laboratory accreditation against the ISO 15189 standard.

3.2.2 Systematic Approach

The review was completed using a systematic approach to ensure transparency and full disclosure using electronic databases to search all available academic literature. The approach used an adapted PICO (Problem, Intervention, Comparison and Outcome) concept tool to systematically guide the search (Aslam and Emmanuel, 2010). The PICO concept tool was selected, because it is considered a good framework to draw out the key components of the study topic and is appropriate for evidence-based decisions and problem solving (Richardson et al, 1995). The PICO tool was adapted for the study to only include only Problem, Intervention and Outcome (PIO) search terms as it was difficult to include a comparison element to the search due to the complex nature of the research subject (Table 3).

TABLE 3 AMENDED PIO CONCEPT TOOL

Acronym	Definition	Description	Keyword(s) / Search terms
P	**Problem or Patient**	Can only be one patient / group of patients or health problem	**ISO 15189** **Laboratory Accreditation** **Laboratory Standards**
I	**Intervention**	Represents an intervention of interest	**Scope of Practice** **Flexible scope**
O	**Outcome**	Expected Results	**Quality Improvement** **Quality Assurance** **Cost** **Cost Effectiveness** **Value** **Efficiency**

3.2.3 Search terms and Key words

The search terms and key words described in table 3 were selected and combined with the Boolean operator '**AND**' and '**OR**'. Additional outcome search terms were also used, to search for publications that would help develop and ground the theoretical framework and methodological approach. The additional search terms used were '**Implementation**'; '**impact**' and '**evaluation**' to establish what was currently available in the academic literature to attempt to determine originality of the study (Table 4). The generic terms 'histopathology' and 'pathology' were considered but not chosen as search terms because the medical laboratory standard ISO 15189 is specific to all pathology laboratories including histopathology. Using the terms 'ISO 15189' and 'laboratory accreditation' alongside 'scope of practice' captured all appropriate studies and was verified during the scoping review.

TABLE 4 KEYWORDS AND BOOLEAN OPERATORS – PIO SEARCH PLAN

Concept 1 **Problem**		Concept 2 **Intervention**		Concept 3 **Outcome**
"ISO 15189" OR "Lab* Accredit*" OR Lab* adj3 standard* **(SET 1)**	AND	"Flexible scope" OR "Scope of practice" **(SET 2)**	AND	Quality adj3 Improv* OR "Quality assurance" **(SET 3)**
"ISO 15189" OR "Lab* Accredit*" OR Lab* adj3 standard* **(SET 1)**	AND	"Flexible scope" OR "Scope of practice" **(SET 2)**	AND	Cost OR Cost effective* OR Value **(SET 3)**
"ISO 15189" OR "Lab* Accredit*" OR Lab* adj3 standard* **(SET 1)**	AND	"Flexible scope" OR "Scope of practice" **(SET 2)**	AND	Efficien* **(SET 3)**
"ISO 15189" OR "Lab* Accredit*" OR Lab* adj3 standard* **(SET 1)**	AND	"Flexible scope" OR "Scope of practice" **(SET 2)**	AND	Implement* OR Impact OR Evaluat* **(SET 3)**

3.2.4 Data Source

The National Institute for Health and Care Excellence evidence service's Healthcare Database Advanced Search (NICE HDAS) was initially completed on 20th October 2020, repeated on 21st October 2021 with a final search on the 19th of April 2023 including individual searches of Medline, EMBASE, HMIC, CINAHL, PubMed including Google Scholar. Each search employed the same established search-terms and procedures ensuring that no bias was introduced and was assisted by the MFT librarian.

3.2.5 Inclusion and Exclusion Criteria

TABLE 5 INCLUSION AND EXCLUSION CRITERIA FOR LITERATURE REVIEW

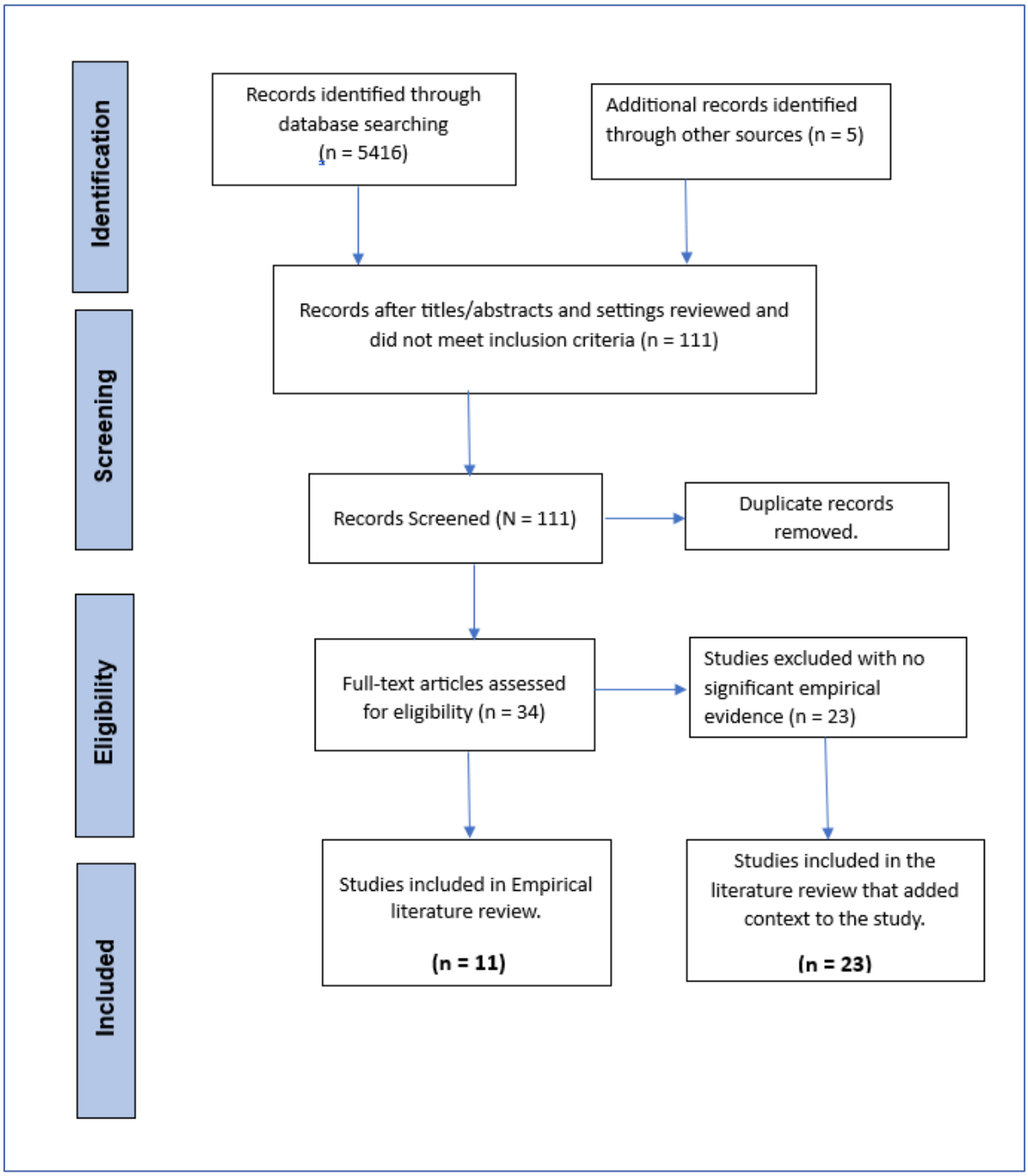
Inclusion Criteria	Exclusion Criteria
• Any theoretical and empirical publications from the peer-reviewed scientific literature with relevance to the study objectives • Laboratory accreditation and flexible scope studies with reference to ISO15189 only • No specific timeframe • Any type of study design / methodology • No restriction to country of origin • Medical laboratory / hospital laboratory only	• Studies not directly relevant to medical laboratories (Hospital / Education / Training) • Studies with no in-depth viewpoints of flexible scope of accreditation or ISO 15189 accreditation • Validation of equipment studies in line with ISO 15189 standard • Publications written in languages other than English to avoid interpretation issues. • Studies where full papers could not be retrieved (Conference abstracts) as there was insufficient detail to assess and confirm the quality of the study.

3.2.6 Outcomes of the literature search

The combined searches using the established search criteria identified a total of 5416 articles (Figure 2). The titles, abstracts and setting were firstly screened for eligibility of which 5305 were discounted. 111 were further assessed, 25 were duplicated a number of times, 14 were conference abstracts including the researchers own with several from Japan, two were not relevant to the study and another two were not in English and not appropriate to the study which left a total of **33** plus a further article identified in the grey literature (O'Connor et al, 2016).

The reference lists of all the articles identified were also hand searched for any additional suitable references or possible key materials that may have been missed that were appropriate to the study, there were no additional references identified.

FIGURE 2 FLOW CHART OF SEARCH STRATEGY



3.2.7 Data Extraction

The full text from the **34** articles were reviewed using a data extraction sheet designed to identify the relevant data required to answer the questions of the review as shown in appendix 4 and 5. The data capture sheet was developed as described by Popay et al. (2006) around the review questions. To encapsulate all relevant aspects of identified theoretical and empirical quantitative and qualitative studies to clearly

account for the method used to appraise, abstract, and synthesise information collected from the studies (Young and Solomon, 2009). The data sheet was used to extract data that included the sample population, the study design, the location, intervention, and outcome. Once the data was extracted from each study a review of the evidence was undertaken to determine the methodological quality to answer the specific objectives of the review, minimising any potential bias (Devkaran and O'Farrell, 2015). Collecting data in this structured analytical way contributed to identifying gaps in the literature and the acknowledgment of any new knowledge observed.

Of the 34 examined only 11 provided an academic perspective and were deemed suitable for inclusion in the review (Appendix 4) including the article identified in the grey literature (O'Connor et al, 2016). Although interesting and provided some background the remaining 23 articles had no significant empirical evidence but there was information relevant for this study and used where appropriate to position ideas and theories and to provide a clearer perspective of the study (See Appendix 4).

3.3 Critical review of the selected studies

3.3.1 Outcomes from the review

There were a number of academic publications around evaluating the impact of ISO 15189 accreditation in a medical hospital laboratory setting (N=11), but none involved rigorous research strategies such as random control trials (RCT). Many of the studies were single centre studies (Kibet et al, 2014; Rizk et al, 2014; Masau et al, 2015; Ramya et al, 2018; Desalegn et al, 2019; Green et al, 2020), using mainly quantitative designs (Hamza et al, 2013; Boursier et al, 2015; Masau et al, 2015; Rizk et al, 2014; Buchta et al, 2018; Green et al, 2020; Lapic et al, 2021) again indicating a qualitative research gap in the area. As a result, wider grey literature was also included where available (O'Connor et al 2016). This suggests that there is a significant gap in this field of academic research focusing on the implementation of ISO 15189 accreditation in a medical laboratory.

The publications identified during the search for the flexible scope (N=10) were mainly theoretical opinion pieces, perspectives, and conference papers that came out of Europe (Steffen, 2002; Jelic, 2007; Balla, 2012; Huisman, 2012; Plebani and Sciacovelli, 2015; Thelen et al, 2015; Plebani and Sciacovelli, 2017; Sciacovelli et al,

2017; Thelen, 2017, Thelen and Huisman, 2018). This also suggests that there is a significant gap in this field of academic research focusing on the implementation and use of a flexible scope in a medical laboratory. These studies also provided some valuable background data for the current study.

3.3.2 Empirical Evidence Gaps

Accreditation is considered as a valuable resource for medical laboratories as a management tool to improve quality with the implementation and maintenance of quality laboratory systems (Peter et al, 2010; Hamza et al, 2013; Rizk et al, 2014; Boursier et al, 2015; Zima, 2017; Plebani et al, 2017; Abdel-Wareth et al, 2018; Ramya et al, 2018). Across Europe and the UK, laboratory accreditation is currently accepted and implemented using ISO 15189 as the primary standard for the accreditation (Huisman, 2012; Hamza et al, 2013; Boursier et al 2015). However, there is a lack of empirical evidence to substantiate any claims of improvement to system quality from the implementation laboratory accreditation. In fact, there appears to be significantly less empirical study design for laboratory accreditation when compared with the implementation of hospital accreditation discussed in other chapters. This small number of studies (N=11) reflects a clear significant knowledge gap in this field especially in the UK.

The review identified only one systematic review (Adane et al, 2019). The systematic review is seen as the gold standard providing the best evidence due to their rigorous strategies (Hawker et al, 2002). Review evidence often guides improvement research to ensure any current relevant research has been considered with minimal bias (Adane et al, 2019). Adane and colleagues used a qualitative review design, conceptualizing ideas to identify keywords to search the electronic databases around quality, quality assessment and laboratory accreditation (Adane, et al, 2019). The search covered a period of seven years (2010-2017) and found 883 published items but only 29 met their inclusion criteria, although these were not transparent in the article. The review used the defined keywords (Quality laboratory; laboratory accreditation; quality assessment, and quality) but the outcomes included a larger scope of accreditation than would be expected to be identified. There were two articles involving hospital accreditation and education included in the review, questioning the legitimacy of the inclusion criteria. This was difficult to substantiate due to the omission of any inclusion and exclusion criteria in the article. It is also worth considering that a poor study design,

search strategy and data source selection could also lead to issues with the number of identified articles.

Despite being termed a systematic review the design Adane et al (2019) used was weak, there was no clear structure or explanation of the approach adopted. There were no clearly defined aim or research question, and no explicit inclusion/exclusion criteria even though a flow diagram of the article selection was included. There was also no explanation of the methods used to appraise, abstract, and synthesise information from the studies included or reference to a table of outcomes to minimise bias. Compared with hospital systematic reviews examined in the previous chapter (Greenfield et al 2008; Brubakk et al, 2015) or the systematic review identified in Adane's search (Scott et al, 2016) the review quality was poor. It may be the context with which the research is set or possibly the lack of researcher expertise. The review by Adane and his colleagues (2019) failed to offer a unique insight or significant new knowledge, often anticipated from a systematic review. It was also difficult to reproduce the search due to the lack of a study design and selection criteria and the spelling errors in the referencing. Only 14 of the 29 identified studies were indeed academic research in nature, the rest (N=15) were theoretical comprising of narrative reviews, perspectives, and commentaries but this was not explicit in the narrative of Adane's article. The one systematic review identified in Adane's search (Scott et al, 2016), was a textbook example of a well-designed study, but Adane failed to adopt the approach of performing the search in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) guidelines (Moher et al, 2009).

The search and critical analysis of existing literature highlights that evidence of the impact and effect of implementing accreditation in the medical laboratory was lacking, articles surrounding ISO accreditation in laboratories were generally at the lowest level of evidence and to confirm other findings (Peter et al, 2010) high-quality studies do seem to be infrequent.

3.3.3 Location of study

Of all the articles that focused on the implementation and use of ISO accreditation (N=11) some had a more robust scientific empirical design, 5 of which originated from Europe (Boursier et al, 2015; O'Connor et al, 2016; Buchta et al, 2018; Green et al, 2020; Lapic et al, 2021). 5 originated from Sub-Saharan regions (Kibet et al, 2014;

Rizk et al, 2014; Masau et al, 2015; Adane et al, 2019; Desalegn et al, 2019, with one from Iran (Hamza et al, 2013), one from India (Ramya et al, 2018). There were also 13 articles included which were of a more narrative nature. These originated from the USA (AuBuchon, 1999; Peter et al, 2010), United Arab Emirates (Abdel-Wareth et al, 2018), Europe (Huisman, 2007; Gunzel and Guner, 2009; Theodorsson, 2016; Plebani and Lippi, 2017; Tzankov and Tornillo, 2017; Zima, 2017); Asia (Mate et al, 2014) and only two from the UK (Wilson et al, 2016; Gough and Reynolds, 2000). The academic study by Wilson et al assessed laboratory compliance against a different set of ISO standards (ISO 17025), although interesting fell outside of the acceptance criteria for the study (Wilson et al, 2016).

3.3.4 Methodological approach and design

In conjunction with the lack of suitable empirical evidence available around the implementation and impact of accreditation in medical laboratories there are also significant gaps in methodological approaches used when researching the subject area. A number of the articles (N=6) identified were discussion papers describing what was needed or how to implement ISO accreditation rather than attempting to fully evaluate any outcomes (Guzel and Guner, 2009; Sciacovelli et al 2017; Zima 2017; Tzankov and Tornillo, 2017; Ramya et al, 2018; Abdel-Wareth et al, 2018). Opinion pieces described the need for laboratory disciplines to harmonise or standardise practice to comply with accreditation standard ISO 15189 and harmonisation of assessments and training of assessors to help improve the objectivity of the assessments (Plebani and Sciacovelli, 2017; Thelen et al 2018). Editorials (Plebani et al, 2015) and perspectives (Sciacovelli et al, 2017) all provided anecdotal rhetoric without providing any empirical data to substantiate their commentary.

Of the articles included a small number (N=11) provided a more robust methodological approach to generate empirical evidence to substantiate any claims (Hamza et al, 2013; Kibet et al, 2014; Rizk et al, 2014; Boursier et al, 2015; Masau et al, 2015; O'Connor et al, 2016; Buchta et al, 2018; Adane et al, 2019; Desalegn et al, 2019; Green et al, 2020; Lapic et al, 2021). Many used a single centre case study approach (Kibet et al, 2014; Rizk et al, 2014; Masau et al, 2015; O'Connor et al, 2016; Tzankov and Tornillo, 2017; Desalegn et al, 2019), a number used multiple case approach (Huisman et al, 2007; Boursier et al, 2015; Buchta et al, 2018; Green et al, 2020; Lapic

et al, 2021) to add rigour to findings. One of the studies was of specific interest involving a quasi-experimental approach (Hamza et al, 2013) to evaluate the impact of ISO 15189 accreditation by looking at the cost effectiveness of the implementation, none of the other papers took this approach. Its empirical study design was novel in the literature search as it used a quasi-experimental approach to estimate the causal impact of the implementation of ISO 15189 on a study group compared to the control groups over three implementation phases (pre-implementation, and post-implementation). The impact of the implementation on the annual average cost per test was assessed using three different biochemical laboratory tests, but it was not made clear why these tests were chosen except that they represented 55% of the total tests requested. The study employed a cost effectiveness tool which provided a useful quantifiable way to measure cost effectiveness. The tool utilized the use of compliance assessment of the ISO 15189 standard and NC arising from internal audits and external accreditation assessments which have also been used in various formats in other studies to understand the impact of accreditation (Kibet et al, 2014; Buchta et al, 2018; Desalegn et al, 2019; Green et al, 2020).

Many studies adopted a quantitative retrospective meta-analysis of secondary data approach to look at the effects of implementing ISO accreditation or a QMS, which is a requirement for ISO accreditation, to verify their claims (Rizk et al, 2014; Buchta et al, 2018; Desalegn et al, 2019; Green et al, 2020). A number adopted a pre- and post-implementation design to justify any changes following the implementation strategy (Rizk et al, 2014; Masau et al, 2015; Desalegn et al, 2019), another adopted a longitudinal design (Kibet et al, 2014). All were published in peer-reviewed journals, the article by O'Connor et al. (2016) was found in grey literature, a professional publication in The Biomedical Scientist.

The use of qualitative methodological approaches that attempted to establish or discuss the opinions of accreditation on laboratory personnel was limited and only two studies were identified utilising a mixed methods approach. Mixed methods are a relatively new approach to research, only being considered as a methodology from around the late 1980's and early 1990's (Bryman and Bell, 2007; Robson and McCartan, 2016; Creswell and Creswell, 2018). In the studies found, focus groups were used to establish staff opinion (O'Connor et al, 2016) and ethnography to

determine the efficacy of the QMS alongside the appraisal of secondary quality data such as QI (Desalegn et al, 2019). In contrast, a quantitative study by Lapic et al. (2021) attempted to assess the staff's attitude to the implementation of accreditation utilising a survey. The multi-centre study included staff from three of a possible eight Croatian biochemistry laboratories, the reason for the purposive sample was not transparent. Differences between these laboratories were not explicit and the rationale for the choice was absent (Lapic et al, 2021). Their sample size could have been expanded and become more significant if they had included the other five hospitals.

The limited empirical evidence in this area along with the lack of rigour in the design of some of the studies (Adane et al, 2019; Desalegn et al, 2019; Lapic et al, 2021) demonstrates a significant gap in applied methodological approaches to attempt to evaluate any impact of laboratory accreditation, especially around the ISO 15189 standard.

3.3.5 Researcher Bias

The use of independent persons to assist with the data capture and analysis was an important feature in the research design of Green et al. (2020). Their study adopted a blinded approach to the data analysis to minimise auditor bias. This attempt to minimise bias was not described or declared in the published article indicating potential weakness in the methodological approach adopted.

Although there was less bias within the narrative of Adane et al. (2019) and Hamza et al. (2013) there was again no clear positioning of any of the authors within the research, only declarations in the articles that there was no conflict of interest. All the articles from the low resource areas (Rizk et al, 2014; Kibet et al, 2014; Masau et al, 2015; Desalegn et al, 2019) all declared there was no competing interest. This was also evident in the narrative of the study for Desalegn's group where some results included observations and experiences from some of the authors who were also experts and managers in the laboratory and may have a vested interest (Desalegn et al, 2019). The outcomes could infer some researcher bias if benefits were concluded without supporting empirical evidence.

In order to minimise bias and add rigour several of the studies used retrospective reviews of existing secondary data to establish outcomes such as QI collected as part of the laboratory's established QMS. (Kibet et al 2014; Rizk et al, 2014; O'Connor et al, 2016). To add rigour to their studies, EQA results assessed by a third party as part of a proficiency programme (Buchta al, 2018) and external and internal audit findings captured by independent, trained individuals were also adopted (Masau et al, 2015; Desalegn et al, 2019; Green et al, 2020). Only one of the studies did not use this approach and the findings may therefore be more susceptible to bias (Kibet et al, 2019).

3.3.6 Data Collection and Analysis

Laboratory accreditation is now well established and widely used in developed countries to ensure quality and reliability of laboratory test results (Kibet et al, 2014; Desalegn et al, 2019). In contrast resource limited countries have been seen to have a minimal response in applications for accreditation with claims this was due to the significant financial cost (Peter et al, 2010; Rizk et al, 2014; Kibet et al, 2014; Masau et al, 2015). Such examples of effort to implement accreditation or QMS in the first steps toward accreditation have been seen in a number of resource limited countries (Rizk et al, 2014; Kibet et al, 2014; Masau et al, 2015; Desalegn et al, 2019), with only one that attempted to measure the imposed cost (Kibet et al, 2014). They discussed briefly the approximate initial cost of the accreditation process and the additional annual maintenance fee, but this went no further. The study by Hamza et al (2013) was the only study that considered the financial implication of accreditation. They addressed this by attempting to verify the cost effectiveness of accreditation by looking at the average cost per test; this directed the development of the cost-effective tool used in this study. Whilst others have only commented anecdotally on the financial impacts in their studies it was never explored any further (Buchta et al, 2018; Adane et al, 2019; Green et al, 2020). They also commented on the massive effort required and the use of personnel resources essential to implement accreditation programmes, and suggested accreditation could be counterproductive in that it can misuse essential laboratory resources. This was also commented on in a number of the other studies (Buchta et al, 2018; Adane et al, 2019; Green et al, 2020; Lapic et al, 2021), and the need for there to be sufficient finance available was also raised (Buchta et al, 2018; Adane et al, 2019).

Many of the studies identified used a secondary data collection pre- and post-implementation strategy and were quantitative in nature. Seven studies that utilized secondary quality data to measure outcomes in their studies used outcomes from external quality assurance (EQA) schemes (Hamza et al, 2013; Kibet et al, 2014; Rizk et al, 2014; Masau et al, 2015; Buchta et al, 2018; Adane et al, 2019; O'Connor et al, 2016). Some also included the use of error rates (Hamza et al, 2013; Rizk et al, 2014; Adane et al, 2019) and Turn Around Times (Adane et al, 2019). The use of such quality assessment tools was highlighted by Adane et al (2019) as an effective way to assess performance. These measures can only identify difficulties in laboratory's quality systems but are not a gauge of laboratory performance alone.

The retrospective meta-analysis approach had a much more robust quantitative design using statistical analysis to investigate their data (Kibet et al, 2014; Rizk et al, 2014; Buchta et al, 2018; Desalegn et al, 2019). The Six Sigma analytical approach was chosen by two groups (Kibet et al, 2014; Rizk et al, 2014). This methodology once a manufacturing principal has been developed and readopted in the clinical laboratory setting over the years (Kibet et al, 2014). These robust statistical methodologies used in contrast to the descriptive statistical design adopted by other studies (Masau et al, 2015; Desalegn et al, 2019; Green et al, 2020) make the findings more robust and less open to bias.

The outcome from this demonstrates that a holistic approach is required to understand the full impact of accreditation. Adopting different quantatitve and qualitative measures and research methodologies may be more appropriate to establish the whole picture and to fully realise the impact of any accreditation programme. Adopting a mixed methodology approach with appropriate measures will provide the rich data that is currently missing. The use of specific generic laboratory quality metrics may allow the approach to be generalised across medical laboratories and more specifically those within the H&I discipline across the UK.

3.3.7 Thematic Critical Review

3.3.7.1 Implementation and use of ISO 15189 accreditation

In Europe, Boursier et al (2016), examined the uptake of laboratory accreditation (which included the UK), and suggested that ISO 15189 accreditation was a valuable

resource for medical laboratories, but failed to provide any evidence to substantiate this claim. The study simply highlighted that the ISO accreditation programme over the last decade had matured and advanced in Europe. The evidence was only generalizable to the scientific discipline of Clinical Chemistry and Laboratory medicine not any other existing pathology disciplines. The study identified that a number of European laboratories in this discipline have implemented ISO accreditation without any clear understanding of the impact or outcomes, or its value and whether it is a valuable resource (Boursier et al, 2015; Zima, 2017; Plebani et al, 2017).

There is a lack of objective evidence of the successful implementation of medical laboratory accreditation, specifically against ISO 15189:2012. What is available has been derived from countries outside of the UK, with sometimes weak methodological designs. From low resource countries who have very immature quality systems and where any baseline will surely improve due to any operational focus on quality. The significant number of research articles from low resource areas over the past few years is indicative of the pace of laboratory accreditation spreading across the world. The number and design of these studies can provide justifiable data to the funding bodies that accreditation does indeed improve quality. But this is only to be expected for those laboratories who are in the first phases of any quality improvement with a focus on quality. For those laboratories that are not well established the effort might outweigh the cost and to fully understand this accreditation needs to be explored. Therefore, it is important to realise the actual amount of funds required to maintain accreditation annually and to finance any changes in innovation through amending the scope of practice. This clearly exposes another significant gap in the current research.

3.3.7.2 Development of Key Concepts - Cost, Quality, Efficiency and Cost-effectiveness

Many of the published articles have used various laboratory performance measures such as QI to assess quality and the effectiveness and efficiency of the implementation of ISO accreditation and the QMS. These were based in resource limited laboratories in North and Sub-Saharan Africa (Rizk et al, 2014; Kibet et al, 2014; Masau et al, 2015; Desalegn et al, 2019) and also the USA and Europe (O'Connor et al, 2016; Buchta et al, 2018; Adane et al, 2019;). The main QI used during these studies have been TATs, test repeat rates, error rates including EQA failure rates, some studies included all

three approaches plus several other additional QIs (Rizk et al, 2014; Kibet et al, 2014; Desalegn et al, 2019).

Other studies have used NC arising from internal audits and external accreditation assessments (Kibet et al, 2014; Desalegn et al, 2019, Green et al, 2020) to measure the impact on quality. In the Green study, a panel of three scientists re-evaluated the NC only one of which was independent (blinded) to determine the value of continued auditing of the QMS for compliance with the ISO standards (Green et al, 2020). In the Kenyan study by Kibet et al (2014) NC gathered during internal laboratory audits by section heads was used, these unlike the previous two studies were not verified by an independent third person so therefore may be susceptible to bias. Laboratory audits are only one small part of ongoing assessments for laboratory accreditation (Green et al, 2020) so conclusions should not be based on these findings alone additional variables to measure the impact need to be included (Kibet et al, 2019). The Desalegn study (2019) also from a resource limited country again used existing data to assess the sustainability of the QMS implementation using external audit findings plus routinely measured QI (Desalegn et al, 2019). The study saw steady improvements in the QI post implementation.

There was a clear lack of data in the literature around the actual costs of accreditation to a laboratory. Just anecdotal rhetoric of the financial impacts (Buchta et al, 2018) and the challenges of the costs (Masau et al, 2015; Desalegn et al, 2019) and it being considered as a wasteful activity (Green et al, 2020) who all firmly believe that the value of accreditation must be evaluated to determine its effectiveness (Huisman et al, 2007). Green et al. (2020) highlight the significance of the potential misuse of resources in a laboratory that have already well-established quality systems and implies that external audit activities can be deemed as a significant waste of resources as these add onto already pressured staff without any significant positive outcome. The finding was only anecdotal as there was no evidence in the paper of any input from laboratory staff about their feelings towards accreditation.

Several of the articles identified the need to determine the value of laboratory accreditation by examining quality, efficiency, and cost effectiveness (Peter et al, 2010; Hamza et al, 2013; Rizk et al, 2014; Masau et al, Kibet et al, 2014; Abdel-Wareth et al, 2018; Ramya et al, 2018, Desalegn et al, 2019). Using available secondary data

obtained from participation in proficiency schemes (EQA), key laboratory QI used readily in the laboratory and NC, before and after (pre and post implementation) studies seemed to be the design most frequently adopted (Hamza et al, 2013; Rizk et al, 2014; Masau et al, Kibet et al, 2014; Buchta et al, 2018; Adane et al,2019; Desalegn et al, 2019; Green et al, 2020). The cost effectiveness tool employed in the study by Hamza et al. (2013) provided a useful quantifiable way to measure cost effectiveness and was the only one found in the literature. The tool utilized the use of compliance assessment of the ISO 15189 standard and NC arising from internal audits and external accreditation assessments which have been used in various formats in many of the other studies identified as a way to recognise the impact of ISO 15189 studies (Kibet et al, 2014; Desalegn et al, 2019; Green et al, 2020).

During Hamza's study reference material was also used monthly to test and compare the results, much in the way that External Quality Assessment (EQA) samples are sent for laboratory proficiency testing. A separate European study used EQA results to provide evidence of a positive impact of the implementation of accreditation by monitoring the error rate of participation (Buchta et al, 2018). Both studies and a third (Rizk et al, 2014) clearly indicated the value of using laboratory EQA results as a valid QI for the study as it provided a sound measure during the observation period and allowed for direct comparison over time quantifying performance (Rizk et al, 2018). The use of EQA schemes has been seen to add value to highlight service quality and performance improvement and therefore could be a suitable indicator to use in the study to measure quality over a period of accreditation.

Buchta et al. (2018) described how laboratories that already have a robust quality system with well managed and documented systems and processes are those that are generally accredited; the quality infrastructure and culture already exist making it easier for them to attain accreditation with minimal effort. They also identified 17.6% of laboratories in their study (N=16) achieved 100% performance in the EQA schemes but did not have a developed QMS. This needed further investigating as it potentially identified that a lack of a well-established QMS, is no indication of being a poorly performing laboratory. Suggesting perhaps that accreditation and a QMS is by no means a prerequisite to laboratory quality. It may also indicate that quality may be managed and measured in some other way outside of the formal accreditation process

using the principles laid out for quality management. This could include defining an appropriate and useful set of QIs with specific criteria and desirable characteristics to track quality over time, using them to benchmark against other laboratories (Marang-van de Mheen and Vincent, 2023). Monitoring these on a weekly and / or monthly basis, creating dashboards of quality reflect areas of concern that need addressing immediately rather than waiting for the annual 'snapshot' of non-conformance provided by the accreditation assessment (Wilson et al, 2016). Self-managing quality, using annual self-assessments alongside quality dashboards and the provision of audit data and IQC and EQA results for some of the years of the accreditation programme for laboratories with well-established QMS may be beneficial to both the laboratories and the accreditation bodies.

3.3.7.3 The inclusion of staff perceptions

There were limited articles identified in the search which included any empirical findings of laboratory staff opinions (O'Connor et al, 2016; Desalegn et al, 2019; Lapic et al, 2021). In some of the reviews identified specifically from the resource challenged areas of the world, the impact of accreditation on staff was identified without any reference to evidence (Kibet et al, 2014; Ramya et al, 2018). In the article by Desalegn et al. (2019) the study was described as being supplemented with observations and experiences from the authors who worked as experts or managers during the implementation, but the results of this was not clear in the findings or qualified in the discussion. The O'Connor study included surveys that comprised of both a quantitative and qualitative approaches allowing for participants to submit comments but again no findings were discussed, or conclusions drawn (O'Connor et al, 2016). The third article found comprised of laboratory personnel sample only. This multi- centre study from Croatia sought to determine the perceptions among staff regarding their professional attitudes towards accreditation. The article looked at laboratory staff from three laboratories accredited for varying lengths of time and their opinions towards ISO 15189 accreditation (Lapic et al, 2021). The methodological approach taken used a survey design, and quantitative methodology for analysis. The outcome identified that the laboratory staff recognised the value of accreditation with 56% having a positive attitude, with 70% expressing they would prefer to work in an accredited laboratory. They identified better documentation of processes (45%) as a main advantage but

40% also had a neutral attitude towards this. It wasn't without its disadvantages, identified by 62% of respondents as having excessive paperwork, impacting on staff time which introduced additional stress. They also acknowledged that additional quality monitoring such as for TAT evaluations impacted on staff workload without any significant improvements being observed (44%). When asked their opinion on the reliability of results it was clear that a number of staff considered accreditation to have increased reliability (35%) but a number considered there to be no change and described the results of laboratory analysis to be equally reliable (47%), questioning the possible validity of the quality improvement programme from the perspectives of the staff.

In the theoretical reviews caveats of accreditation were emphasised without any evidence just anecdotal rhetoric that accreditation programmes are time consuming but involvement of staff in this endeavour increases staff communication and motivation by granting inclusive responsibility (Tzankov and Tornillo, 2017). Increased staff motivation was also described as a positive accreditation effect, this claim was made without any clear evidence but by intuition. Also expressing concerns stating accreditation involves huge efforts (Tzankov and Tornillo, 2017) and has a significant impact on workload (Guzel and Guner, 2009; Plebani and Lippi, 2017; Sciacovelli et al, 2017), impacting on staff morale and motivation (Abdel-Wareth et al, 2018; Adane et al 2019). Clearly evidence to substantiate these areas are lacking as seen from the low numbers of empirical articles found in the review.

Guzel and Guner (2009) in their review discussed the importance of obtaining the opinions of laboratory staff without any clear empirical evidence. In the review they referenced data from a Belgian paper (Verstraete et al, 1998) who surveyed medical technologists in three laboratories at varying times after obtaining accreditation. Quoting information on whether they believed accreditation improved quality, its impact on work pressures, advantages, and disadvantages of the implementation. The responses over two decades ago were much the same as seen today throughout healthcare with many issues such as increased workload and increased documentation (Verstraete et al, 1998) were corroborated (Lapic et al, 2021). The main advantages were better documentation and traceability and only a small number of the staff questioned in 1998 thought that the quality of the tests had improved

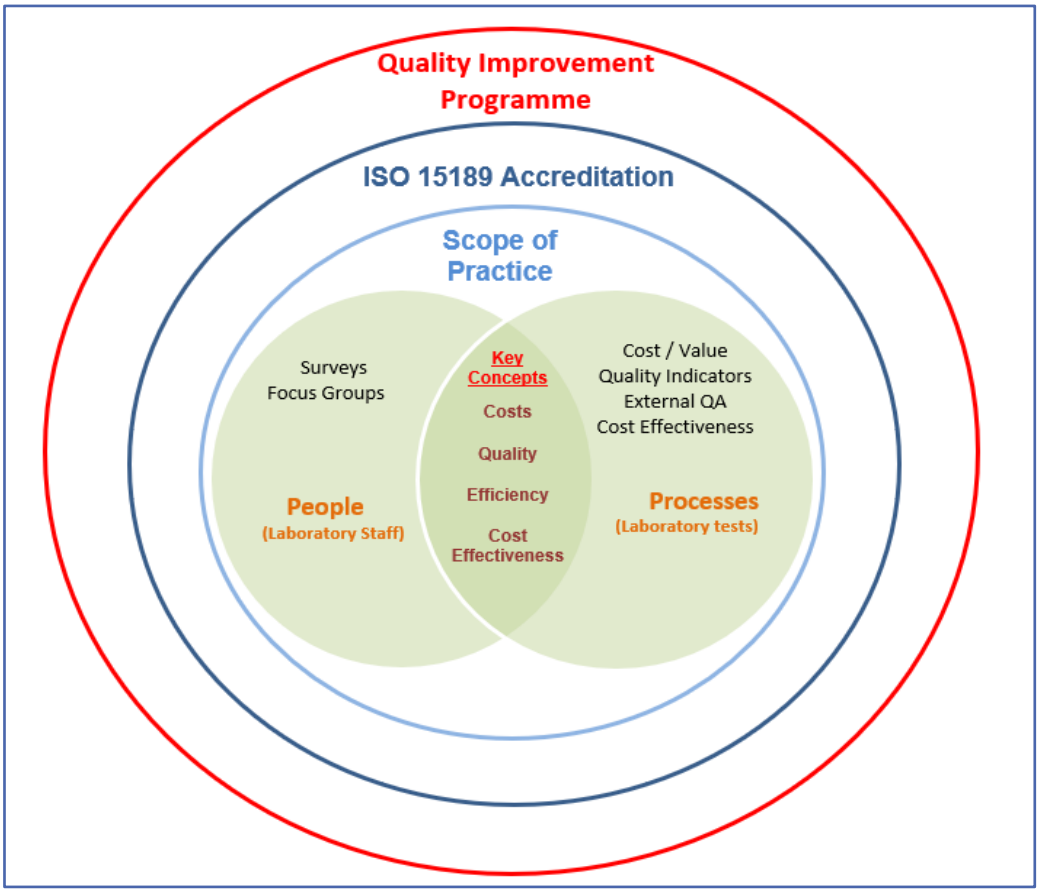
(Verstraete et al, 1998). Lapic et al. (2021) described the main advantages were again better documentation and greater reliability on results.

Whilst the potential impact on staff morale and motivation due to accreditation was muted, no study attempted to evaluate the full impact of the implementation of accreditation on the workforce. This highlighted another significant gap in the evidence and knowledge base around implementing laboratory accreditation in either UK or Europe. In-order to ensure a full review of the implementation of accreditation perceptions of the laboratory staff towards accreditation needs to be explored. This would provide a rich picture of the impact following the implementation of ISO accreditation in 2014, adding breadth and depth to the study.

3.4 Theoretical framework structure

There is modest data in the academic literature that assesses and evaluates the implementation of laboratory accreditation schemes and its impact for laboratories within the NHS. However, there is a plethora of articles that have looked at accreditation and improvements to services in the wider hospital setting which have encompassed the impact of such quality improvement programmes (Brubakk et al, 2015; Mumford et al, 2013; Devkaran and O'Farrell, 2015; Tashayoei et al, 2020). Key concepts were drawn from both laboratory and the current wider healthcare (hospital) accreditation evidence to inform a theoretical framework for the developing study (Figure 3).

Figure 3 theoretical framework



3.4.1 Identifying Key Concepts

The aim of quality improvement programmes such as laboratory accreditation is to demonstrate compliance against internationally recognised standards such as ISO 15189:2012 and to assure patient safety through the quality of the service being provided (Barnes et al, 2014). An internationally recognised evaluation process used to assess and improve the quality, efficiency, and effectiveness of a healthcare organisation (Ramya et al, 2018). There is a substantial volume of literature that highlight the necessity for accreditation within the NHS as a means of providing a standard way of monitoring and regulating healthcare services in England. Conversely there is little to signify the actual value or any assurances of improved service quality or efficiency (Melo, 2016). Particularly in the field of hospital quality improvement research where accreditation having been described as an investment rather than an expense (Greenfield et al, 2011; Ovretveit, 2020). This has led to mass implementation and the introduction of quality management as an ongoing capacity building tool (Nicklin et al, 2017) with limited quantifiable evidence of improved service quality or enhanced clinical outcomes.

Theoretical concepts (Figure 3) were informed from robust healthcare quality frameworks (Donabedian,1997; IoM, 2001; WHO, 2006) and concepts considered to influence quality (Table 1, chapter 2). These concepts have been widely used and cited within healthcare accreditation specifically hospital accreditation and quality of care (Raleigh and Foot, 2010; De Jonge et al, 2011; Lighter, 2014; Reeve et al, 2015). The six domains of the IoM framework, suggests that any aspect of healthcare should be effective, efficient, safe, patient-centred/responsive, timely, and equitable (IoM, 2001) to ensure healthcare quality (WHO, 2006). Three key domains of focus to be measured in healthcare services comprised of structural measures such as staffing, facilities and equipment, process measures and outcome measures monitoring the effects and impact of the system in question (Donabedian, 1997; Aggarwal et al, 2019). Throughout these frameworks measurement is considered an important tool to monitor and assess quality and to implement improvement actions throughout the healthcare setting. Combining these two well established frameworks and theoretical data critiqued in the review the key concepts relevant to this study were identified (Figure 3).

Accreditation has been the preferred method to promote healthcare quality, described as a key driver for healthcare quality (Braithwaite et al, 2010; Shaw et al, 2010). More recently, Tashayoei et al. (2020) have questioned the implementation of hospital accreditation, in particular expressing concerns over increasing costs, clinical relevance of the standards and the instability of assessors. The study outcomes highlighted significant challenges to implementing accreditation in a hospital setting that could potentially be transferable to the laboratory setting. These include the impact on staff due to the lack of time available to complete the documentation required for accreditation (which in the study led to fake documentation), the number of standards, and the psychological impact on staff (stress, physical and mental fatigue), highlighted in previous studies (Melo, 2016; Desveaux, et al, 2017; Delaney and Shorten, 2019). These challenges are transferable to the medical laboratory setting (Lapic et al, 2021). A limitation of the Tashayoei study was that it did not involve junior staff, sampling only senior managers responsible for quality improvement in the organisation. Junior staff experiences could have exposed additional challenges from those dealing directly with the

patients. Gaining only a managerial perspective is a common limitation of hospital accreditation (Ellis et al, 2020).

Along a similar theme in a Brazilian quantitative evaluation study (Saut, et al, 2017) specific outcome measures such as professional involvement was used to show correlations with the status of healthcare accreditation by looking at how specific concepts impact on the organisation and finances. One of the quality management outcome measures used was established QI. These were shown to have a significant correlation with accreditation which was then seen to support the vision of accreditation as being an important quality management model (Saut, et al, 2017). The study identified that the measurement of cost of accreditation was an underexplored area in the implementation of accreditation as its focused outcome measure on the financial impact of accreditation. The implementation of accreditation decision is never based on economic evaluations and such implementation strategies always have a cost which add to budgetary pressures (Hoomans and Severens, 2014; Eisman et al, 2020). These papers along with two others (Hamza et al, 2013; O'Connor et al, 2016) that focused on hospital laboratories reaffirmed the importance of economic evaluations such as cost effectiveness and the cost of accreditation as specific focus for the key concepts in the theoretical framework (Figure 3).

The Hamza study (2013) utilized a cost effectiveness tool which provided a valuable quantifiable way to measure cost effectiveness. The cost effectiveness tool was not appropriate for this study but provided an excellent example from where to adopt a suitable tool, which will be described in full in the following chapter. Without cost effectiveness data the quality implementation decisions regarding changes in practice cannot be fully appreciated or quantified to see whether it has indeed improved the diagnostic value of test results (Theodorsson 2016). Examining the cost of accreditation to the laboratory, the effects on key critical laboratory processes and the impact and perceptions of the laboratory workforce, were considered the key study concepts to evaluate the impact of laboratory accreditation and thus embedded within the theoretical framework.

In laboratory medicine the introduction of accreditation is considered a valuable way to improve quality and cost effectiveness by making laboratories accountable, positively influencing performance, and yielding long term benefits (Peter et al, 2010).

However, others perceive accreditation to have detrimental effects (Delaney et al, 2019) which needs to be explored further.

3.4.2 Defining Critical Processes and Performance Measures

The review evidence informed the study design (Hamza et al 2013; Kibet et al, 2014; Rizk et al, 2014; Desalegn et al, 2019) reinforcing the decision to include multiple laboratory tests (critical process) to examine if critical processes are influenced by ISO accreditation (Hamza et al, 2013). The laboratory tests or critical processes chosen for the study are all specific laboratory tests accredited by UKAS and listed on the laboratory's UKAS Scope of Practice (Appendix 2). These processes are also generic to the H&I scientific discipline making the study transferable to other laboratories in the H&I community, globally. All accredited laboratories have their own established scope of accreditation which indicates the laboratory techniques (critical processes) used routinely in their clinical service provision. (Appendix 2).

QI are indirect quality measures that can be established to measure performance in healthcare, accompanied by an evaluation component to measure quality. These different types of indicators have both strengths and weakness when assessing healthcare quality. These are a requirement of ISO accreditation to ensure continual improvement (Rizk et al, 2014). These are routinely used to monitor the level of quality and performance in any healthcare organisation, using standardised internal QI and national Key Quality Indicators (KQI). Using these indicators an assessment across healthcare organisations is possible including laboratories. Using the established process indicators, error and repeat rates, the study will identify changes in quality and efficiency over the years of ISO accreditation.

Efficiency is related to value and is a measure of the cost of care associated with a specified level of quality and includes avoiding waste of equipment, supplies, ideas, and energy (Sorra et al, 2021). In the empirical studies outlined in the literature review analytical QI used were TATs, error rates such as incorrect EQA submissions (Kibet et al, 2014; Rizk et al, 2014; Buchta et al, 2018). To measure quality and efficiency the study used available established secondary quality data as a way to measure the impact of ISO accreditation. This included TATs and RR of laboratory processes, along with national KQI for the key critical processes (deceased donor HLA typing and crossmatching TATs), error rates such as external audit NC, and errors in participation

in EQA schemes (Table 6). Even though there may be variation within each laboratory on how the EQA schemes are performed it is seen as a measure of laboratory performance, an assessment of the QMS providing objective feedback to aid improvement (Buchta, et al, 2018). Thus ensuring high quality pathology services by detecting both analytical and post- analytical errors, and allowing the comparison of assay performance across time and methods to safeguard best practice.

TABLE 6 PERFORMANCE MEASURES USED TO MONITOR THE KEY CONCEPTS

Critical Processes	Key Concepts		
	Quality	**Efficiency**	**Cost Effectiveness ***
HLA Typing **Antibody Screening** **Chimaerism monitoring** **Crossmatching**	**Repeat Rates** (RR of critical processes) **Error Rates** (EQA error rates & ISO 15189 NC)	**Turnaround times** (KQI TAT & TAT of critical processes)	**Cost per test** **ISO 15189 Non-conformances (NC) per assessment cycle**

Note. Adapted from a tool designed by Hamza et al (2013: p554)

The use of defined H&I critical processes and the National KQIs used alongside the laboratory quality performance indices makes this framework for measuring the impact of accreditation transferable to other H&I laboratories not just in the UK but potentially globally. The thesis has developed a model that many medical laboratories from other pathology disciplines could adopt if wishing to consider and justify the implementation of ISO accreditation and its impact.

3.4.3 The importance of Staff Involvement

One of the most detrimental effects of accreditation commented on in the healthcare literature has been the increase in staff workload (Guzel and Guner, 2009; Lapic et al, 2021) leading to inefficiencies and staff anxiety (Brubakk et al, 2015; Delaney and Shorten, 2019; Tashayoei et al, 2020). Understanding staff perceptions of accreditation, whether they feel it to be an advantage or disadvantage is considered important (Guzel and Guner, 2009; Saut et al, 2010; Ellis et al, 2020; Tashayoei et al, 2020). It has also been discussed in the literature that having staff on-

board during the implementation of accreditation is vital to its success (Greenfield et al, 2011). Staff can value accreditation if they see it has a way to enhance quality by standardising work processes (Ellis et al, 2020) alternatively, staff can be a barrier to the accreditation process due to scepticism around the potential benefits of accreditation (Alkhenizan and Shaw, 2011). Increased workload on staff leads to inefficiency, staff anxiety and stress levels, some detrimental effects of accreditation in the workplace (Guzel and Guner, 2009; Delaney and Shorten, 2019; Lapic et al, 2021). Therefore, evidence suggests understanding staff perspectives and attitudes towards accreditation is an essential component of the theoretical framework. The key concepts that capture staff perspectives include perceived quality and efficiency of accreditation, perceived cost effectiveness, impact on workload. Surveys were the most frequently used methodology adopted to review the perceptions or involvement of personnel in accreditation (Lapic et al, 2021). Quantitative data was often analysed using a statistical approach with limited exposure to qualitative approaches in the literature (Hamza et al, 2013; Kibet et al, 2014; Rizk et al, 2014; Musau et al, 2015; Buchta et al, 2018; Desalegn et al, 2019; Green et al, 2020. There was a lack of qualitative approaches used to explore staff perceptions within the current evidence base, which may reflect the scientific positivist-based paradigms of the laboratory research staff (O'Connor et al, 2016).

Therefore, the practical aspect of the impact of accreditation and its context are important issues. These needed to be included in the study to ensure a complete holistic review of the effect of accreditation can be truly assessed. Using survey methods which include both a quantitative and qualitative questionnaire alongside qualitative focus group discussions a deeper understanding of the impact of accreditation will be obtained. Triangulating (Morgan, 2007; Mertens and Hesse-Biber, 2012; Creswell and Creswell, 2018) the views of the participants against the quantitative longitudinal data collected also enabled the development of any context within the study (Øvretveit, 2010).

3.5 Summary

This focused literature review had four key objectives, the key evidence synthesised and key gaps in evidence are summarised for each objective.

Objective 1 - To examine the implementation and use of ISO 15189 accreditation, and the impact if any, it has had on (medical) laboratories services with respect to quality, cost, and efficiency.

The evidence suggests that there is support for accreditation as a valuable way to improve quality, efficiency, and cost effectiveness in laboratories (Peter et al, 2010; Hamza et al, 2013; Rizk et al, 2014; Abdel-Wareth et al, 2018; Ramya et al, 2018). However, what is available is inconclusive, with very little robust quantifiable data to determine any quality value of implementing ISO accreditation or if quality improvements are sustainable. Even when such implementations are presented, they can sometimes be of a poor design and difficult to generalise, so it is difficult to conceptualize what was done and the significance of any outcomes (Øvretveit, 2002; Walshe, 2007). There is a need for thorough and rigorous methodologies to be developed especially in the field of laboratory medicine in the UK, to examine the impact of accreditation and the introduction of new interventions and to share learnings even if interventions fail (Shaw et al, 2010).

Objective 2 - To identify any gaps and limitations in the current available peer reviewed literature to clearly position the research project.
Gaps in research include:

- Lack of existing evaluations on the implementation of laboratory accreditation and its impact on quality and efficiency in a UK based laboratory.
- Lack of economic evaluations of the implementation of accreditation or whether some accreditation methods are more costs effective than others (e.g., from the perspective of staff time or introducing new tests).
- Lack of underpinning theory that informs the need for accreditation.

Objective 3 - To identify key the concepts surrounding accreditation to inform the theoretical framework and the choice of methodology for the study.
The review identified and brought together key concepts from previous theorists (Donabedian 1997) and healthcare governance organisations (IoM, 2001 WHO 2006) to inform a theoretical framework (Figure 4) which included:

- performance measures and improvement in healthcare structure (Staff), critical laboratory process, and outcome measures to monitor the effects and impact of ISO accreditation.

- core components measuring quality of care, ensuring that healthcare should be effective, efficient, safe, patient-centred/responsive, timely, and equitable (Table 3).

To examine the key concepts identified in the theoretical framework literature review findings indicated a lack of robust data in this area to demonstrate the benefits of laboratory accreditation on both the laboratory service and also its workforce. How to explore these key theoretical concepts influenced the choice of measurement tools and best approach for the study. The evidence gap reinforces the need for a study that examines all the key concepts simultaneously using robust methods to generate new evidence and knowledge to guide and inform wider NHS laboratory services.

Objective 4 - To examine the current use of the flexible scope approach for managing the schedule of accreditation against ISO 15189 standards in both Europe and the UK.

The flexible scope of accreditation whilst being successfully adopted across Europe (Balla, 2012; Thelen et al, 2015; Thelen, 2017) there is minimal empirical evidence of its implementation, especially in the UK. The evidence is provided through theoretical papers, which deliver minimal empirical evidence of its success (Balla, 2012; Plebani et al, 2015; Thelen et al, 2015; Thelen, 2017). Nor has there been any study in Europe attempting to justify the rationale for adopting the flexible scope approach. In the UK there have been a small number of hospital-based laboratories that have implemented a flexible scope for small parts of their scope of practice but no evidence of its impact has been established or published.

The next chapter presents the research design for one of the first mixed methods studies to generate a comprehensive evaluation of laboratory accreditation. Informed by the current evidence a robust framework was generated to evaluate the cost of laboratory accreditation and its impact on laboratory Quality, Efficiency and Cost effectiveness.

4. Research Methodology

4.1 Introduction

The review of current evidence highlighted a paucity of data to substantiate the impact of ISO 15189:2012 accreditation in medical laboratories. Historically, objectives to measure laboratory quality improvement programmes were conducted mainly through a quantitative lens (Hamza et al, 2013; Kibet et al, 2014; Rizk et al, 2014; Masau et al, 2015; Buchta et al, 2018; Green et al, 2020; Lapic et al, 2021) with minimal use of qualitative approaches (O'Connor et al, 2016; Desalegn et al, 2019). Few articles in the review attempted to establish or discuss the opinions of accreditation from the experience of laboratory personnel (Lapic et al, 2021). Emerging from the review surrounding laboratory and healthcare accreditation a theoretical framework was developed bringing together key concepts, to underpin and guide the study (Chapter 3, Figure 3). Within this chapter key concepts were expanded, identifying critical processes used to measure quality, efficiency and, cost-effective measures and embraced qualitative methods to capture the impact of accreditation on people spanning several years (Chapter 3, Figure 3).

The researcher's rationale, justification, and position within the study, including both the ontological and epistemological position of the researcher within the field of QM research are provided. The methodological approach used is examined to study the effect of accreditation on an H&I medical laboratory in the NHS. The retrospective longitudinal study design combined secondary quality outcome data with a survey research design alongside qualitative focus group discussion. The convergent mixed methodology was considered the most practical approach to examine the key concepts and best answer the research aims and objectives. Triangulation of theoretical knowledge and study data generated a unique evidence base to capture the impact of accreditation in an H&I laboratory, the challenges, the improvements, and recommendations for change.

4.2 Aims and objectives.

The aim of the DProf study was to assess the impact of laboratory accreditation using the ISO 15189:2012 standard on cost, quality, efficiency, and cost effectiveness in an NHS specialist pathology laboratory. A secondary aim was to examine laboratory staff experiences and opinions of the current ISO accreditation approach. Outcomes of both

were used to develop a robust framework with which to measure the impact of ISO 15189:2012 accreditation over time.

Objectives include:

1. To measure the annual costs of laboratory ISO 15189:2012 accreditation for an NHS specialist pathology laboratory, to establish if accreditation as a quality assurance initiative is value for money and cost effective.
2. To measure the impact of ISO 15189:2012 accreditation on the quality and efficiency of an NHS specialist pathology laboratory by monitoring national key performance indicators (KPIs) and internal QI for recognised critical laboratory processes.
3. To explore the impact of laboratory accreditation on staff and their work, to gain a deeper understanding of their perceptions of laboratory ISO accreditation.
4. To generate an evidence-base to inform and further examine the impact of ISO 15189:2012 accreditation in a well-established NHS specialist pathology laboratory.
5. To add to the theoretical understanding of laboratory accreditation and quality in the NHS, through the lens of an NHS specialist pathology laboratory.

4.3 Researcher's rationale

Establishing a clear definition of quality in healthcare from the literature proved to be problematic (Chapter 2). Dual definitions of quality, identifying that both conformance quality and subjective quality exist (Dale, 1999; Lillrank and Liukko, 2004). Other explanations described quality as conformance to requirements or standards (Guzel and Guner, 2008; Gough and Reynolds, 2000; Tzankov and Tornillo, 2017) deviations from which can be measured and cost impact and value calculated (Harvey, 2007; Lillrank and Liukko, 2004; Beastall, 2013). Often quality was described as subjective and attributed by an individual (Beastall, 2013; Wilson et al, 2016; Adane, 2019). The various definitions demonstrated that the concept of quality in healthcare was complex, can be biased to different situations and different people and centred around different ontological and epistemological views of the world. The basic assumption underlying conformance quality aligns with the objectivist's epistemology and the positivists methodology (Lillrank, 2015; Barouch and Ponsignon, 2016). Identifying that quality is knowable and explicable and that conformance improves quality, consisting of repetitive processes in closed or semi closed systems capable of progress and continual improvement (Lillrank and Liukko, 2004; Perla and Parry, 2010;

Adane, 2019). Whilst the basic hypothesis of subjective quality aligns at the opposite end of the spectrum with subjectivists epistemology and the phenomenological methodology focusing on perceptions, perspectives and sensemaking (Lillrank and Liukko, 2004). Healthcare quality can be seen as a combination of paradigms, where quality or the perception of quality emerges from the interaction of the service provider and the users and standardised procedures to sustain patient safety (AuBuchon, 1999; Lillrank, 2015; Theodorsson, 2016, Plebani and Lippi 2017).

The aim of healthcare is to treat patients using evidence-based procedures (Greenfield and Braithwaite, 2008; Alkhenizan and Shaw, 2011; Greenfield et al, 2011; Beastall, 2013; Brubakk et al, 2015). Compliance with established best practice is recognised via auditing against standards to obtain accreditation or certification status (Guzel and Guner, 2008; Gough and Reynolds, 2000; Tzankov and Tornillo, 2017). The literature review exposed a paucity of evidence to confirm whether this improves quality or clinical outcomes (Greenfield and Braithwaite, 2008; Alkhenizan and Shaw, 2011; Hinchcliff et al, 2012).

4.4 Researcher's worldview

A researcher's philosophical ideals should be transparent to the reader to clarify why the approach used in the research was chosen (Morgan, 2007; Creswell and Creswell, 2018). This information should clearly explain the methodology and methods preferred for the study, positioning the researcher distinctly within the study, explaining the philosophical orientation about their world and their research (Giddings, 2006; Creswell and Creswell, 2018).

As a scientist for 35 years, knowledge created has been developed based on careful observations and measurements mostly presented in a numeric format to verify theory. It has therefore long been positioned in the positivists or post-positivists paradigm (Giddings, 2006; Bryman and Bell, 2007; Robson and McCartan, 2016; Creswell and Creswell, 2018). Often for scientists the choice of research method is predetermined by ontological considerations swayed by this paradigm. (Giddings, 2006; Neale, 2009). The positivist view considers that good quality research comes from this positivist paradigm, where experiments are the most appropriate source of quality data measured through objective methods (Onwuegbuzie and Leech, 2005; Easterby-Smith et al, 2015). This narrow quantitative approach allows the view of truth being

objective without a thought of an alternative perspective. Whilst the researcher sits firmly within the positivist paradigm, in this study a positivist approach alone would not provide answers to the research questions and aims. A wider view and more pragmatic understanding of accreditation experiences was necessary than just metrics to measure quality, efficiency, and costs alone. A mixed approach combining both quantitative and qualitative methods was considered to add depth of understanding of cost and non-conformities within the laboratory environment and to understand the experiences of staff (Giddings, 2006; Morgan, 2007; Bryman et al, 2007; Morgan, 2010; Easterby-Smith et al, 2015; Creswell et al, 2018). The lack of current evidence regarding laboratory accreditation and its wider impact on an NHS medical laboratory, could potentially be the result of the narrow ontological and epistemological positioning of research and scientists in this field. Alternative qualitative and mixed methods approaches are often not seen as scientific because any data is considered complex and difficult to quantify outside of an experimental approach (Bryman and Bell, 2007). The pragmatic worldview (Table 7) in contrast with the other paradigms allows the researcher a choice of approach to answer the research objectives. It fits with Creswell's ideas of not committing to one philosophy nor reality, just relying on the appropriate approach at that time (Creswell and Creswell, 2018). More significantly, combining approaches supports the assumption of the importance of experiences, that any reality is known through human experience (Morgan et al 2007; Neale, 2009; Roller and Lavrakas, 2015; Robson and McCartan, 2016). It also aligns with the epistemological basis for what scientists are seen to do, which is to solve a problem identified through their own experience (Gidding, 2006; Neale, 2009).

A mixed methods approach was considered the most appropriate methodology to answer the research aims for the DProf, adding validity and rigour to the study, which had been lacking in existing literature (Bryman et al, 2007; Robson et al, 2016; Panke, 2018). However, using mixed methods approach for this study was not a choice taken lightly because it is notoriously highly time and labour intensive (Johnson and Onwuegbuzie, 2004; Giddings, 2006; Bryman and Bell, 2007; Robson and McCartan, 2016; Panke, 2018) and involved adopting qualitative methods an approach from an unfamiliar paradigm for the researcher (Bryman and Bell, 2007; Robson and McCartan, 2016).

TABLE 7 ALTERNATIVE PARADIGMS

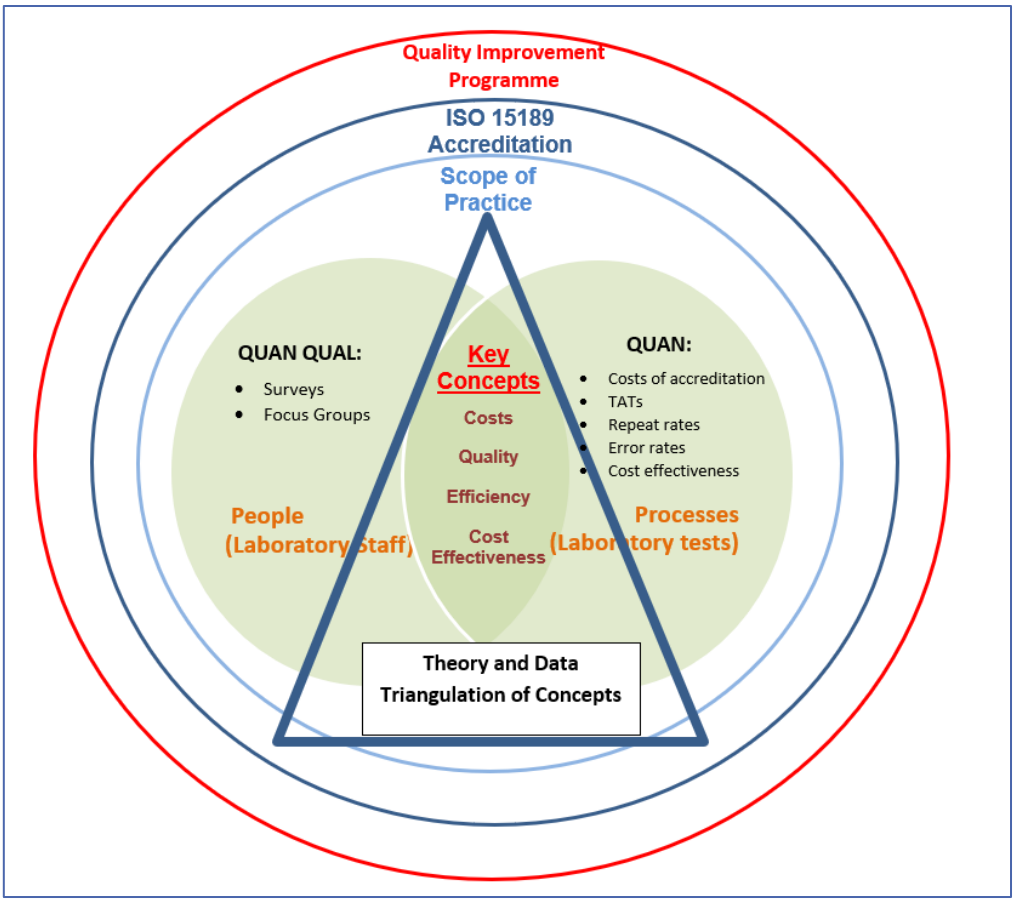
	Qualitative	Quantitative	Pragmatism (Mixed Methods)
Ontology	Reality is individualistic and relative	An absolute / real existence	No assumption about reality
Epistemology	Subjectivity	Objectivity	Intersubjectivity
Connection of theory and data	Induction	Deduction	Abduction
Inference from data	Context	Generality	Transferability

Note. Adapted from Morgan (2007) cited in Neale 2009 p270.

Generally, the choice of study design is based on both procedural and practical aims to answer the research question (Bryman et al, 2007; Creswell, 2013; Robson et al, 2016; Panke, 2018). Quantitative and qualitative evidence was to be collected with no particular method being dominant and triangulated to identify patterns in the data (Morse and Niehaus, 2016). The quantitative approach of the study framework positioned in the philosophical realms of positivism used fixed and rigid procedures to measure the relationships between theory and research in a deductive manner (Johnson and Onwuegbuzie, 2004; Bryman and Bell, 2007). Examining what was happening to the defined key concepts (cost, quality, efficiency, and cost effectiveness) over time and quantifying the findings to communicate results in a statistical manner (Robson and McCartan, 2016; Creswell and Creswell, 2018). The qualitative approach seeking attitudes, descriptions, and perceptions from the laboratory personnel aims to understand what is important (Neale, 2009; Robson and McCartan, 2016) adding depth to the studies outcomes (Denscombe, 2008; Roller and Lavrakas, 2015). The mixed approach would explore the results to gain a deeper understanding of not just what is occurring but what influences the accreditation process and impacts on laboratory test quality (Neale, 2009). This method would expose any contradictions between the longitudinal quantitative data and using qualitative data gather a more

accurate reflection of the staff perspectives of the process, in a single centre NHS medical laboratory service (Figure 4).

FIGURE 4 METHODOLOGY.



4.5 Researcher's positionality and reflexivity (Appendix 27)

As Quality Manager (QM) in a speciality pathology discipline for over 30 years the researcher has extensive experience of the changes in laboratory accreditation across NHS laboratories in the UK. The need for this research arose from a perception by myself and other laboratory managers that laboratory accreditation against the ISO 15189:2012 standard compared to CPA UK Ltd was becoming more and more costly without necessarily offering increased quality or efficiency. This perception needed to be objectively verified or refuted.

Øvretveit (2000) has explained how the time investment model for quality activities shows that initial big investment leads to overall savings for an organisation, however, this has not been my experience in practice. The laboratory has seen year-on-year increases in ISO accreditation costs, increasing prevention and appraisal costs

required to manage and maintain the QMS, participation in proficiency testing, and annual maintenance and calibration of equipment as well as hidden costs required for training and competence of staff, all necessary for compliance with UKAS. These costs are hard to justify if there is no clear evidence of improvements. Evidence of the true impact of ISO 15189 accreditation was therefore required to justify the costs and to verify its legitimacy as a quality improvement tool.

The paucity of empirical evidence was suprising as laboratory accreditation was being implemented as a tool to improve quality without any real evidence of its success. As laboratory QM, accreditation is crucial and plays an important role to monitor and maintain standards of the laboratory service. It provides an accreditation status to justify to service users, laboratory quality and efficiency. As a scientist the need for facts is a necessity to justify any rationale for change and it was clear there was a significant gap in the evidence around ISO 15189:2012 accreditation that needed addressing. It is not without doubt that there is a significant need to ensure service quality in healthcare. Accreditation has been seen as an appropriate way of achieving this in the past but the rise in laboratory accreditation costs from the fixed fees of CPA UK Ltd was alarming. There was clearly a need to justify these costs by identifying if the implementation of accreditation, using the ISO 15189:2012 standard, was having an impact on continually improving the service provision over the years.

4.6 Mixed Method Research (MMR)

4.6.1 Mixed Methods Concept

The paucity of evidence identified (chapter 3) to substantiate the impact of accreditation in healthcare reinforced the need for a robust and novel research study design. There was only one study that focused on the attitudes of laboratory personnel to accreditation, but it was of a quantitative design (Lapic et al, 2021) which failed to get the full depth of staff feeling. There were also no studies identified that used qualitative approaches and those that did used them as part of a MM approach, their outcomes were not robust (O'Connor et al, 2016; Desalegn et al, 2019). The study by O'Connor used only a staff survey to obtain feedback on the implementation process (O'Connor et al, 2016). Whilst an ethnography approach was used in the Desalegn study where the authors supplemented their retrospective analysis of data with their observations of the experience (Desalegn et al, 2019), neither obtained evidence to

provide valid and robust data of the impact of accreditation on laboratory personnel. The rest of the studies employed quantitative approaches using retrospective analysis of data including statistical analysis (Kibet et al, 2014; Rizk et al, 2014; Masau et al, 2015) whilst others just identified basic strategies to implement quality improvement systems (Ramya et al, 2018). Only one study considered the financial position imposed by accreditation and investigated the cost effectiveness. They assessed the adoption of essential clauses of the standard ISO 15189 in an hospital laboratory by evaluating compliance (Hamza et al, 2013). There was no clear theoretical framework established from any of the studies identified, and unfortunately, all of these studies fell short of measuring and defining the impact of quality improvement programmes in medical laboratories. This led to the development of a complex study, using a robust mixed methods framework. A number of measurable concepts were drawn from both the quantitative and qualitative paradigms to create a meaningful and robust reflection of the effects of accreditation in an NHS laboratory.

The study aims were set out in two distinct areas:

1. To assess the impact of laboratory ISO 15189:2012 accreditation on identified key concepts - quality, efficiency, and cost effectiveness alongside the costs of accreditation (QUAN).
2. To examine laboratory staff experiences and opinions of ISO accreditation to corroborate the findings (QUAN QUAL).

4.7 Study Framework

The study framework progressed in two phases and comprised of different components for development and design, and data collection and analysis to answer the study's overall aims and objectives (Table 8) focusing on the problem, which is synonymous the with mixed methodology approach (Creswell and Creswell, 2018).

TABLE 8 MIXED METHODS STUDY FRAMEWORK

Phase 1 Study Development	**Phase 2 Study Data Collection**		
QUAL	**QUAN QUAL**	**QUAL**	**QUAN**
Study Design Quality Metrics **(14/10/2020)**	**Primary Data Collection**		**Longitudinal secondary Data Collection (2014 – 2022)**
	(10/05/2021 – 31/05/2021)	03/12/2021 (10am and 1pm)	
Expert Panel	**A: Questionnaire**	**B: Focus Groups**	**C: Secondary Data**
Key concepts Themes from literature (Key concepts) Critical processes Pilot Questionnaire (29/04/2021)	Themes for focus group discussion Topic guide produced	Theory corroborating findings from the survey data	Theory using outcomes from the key concepts.
	Study Data Analysis - Interpretation and interrogation of data around key concepts to establish the aims and objectives		
	Descriptive statistics / Thematic analysis	Thematic analysis	Statistics
		New theory	**New theory**

4.8 Study site and population

The study focused on the impact of the implementation of ISO 15189:2012 accreditation within the specialist pathology discipline of Histocompatibility and Immunogenetics (H&I). The Laboratory is one of a small number of H&I specialists pathology laboratories in the UK (N=21). It is situated in an NHS Trust which provides a dedicated service for patients across the Northwest of England. The H&I service provision of the laboratory supports regional kidney, pancreas, heart, lung, and haemopoietic progenitor stem cell transplant programs and HLA typing for disease diagnosis and management. The laboratory processes approximately 40,000 samples a year and manages long term, patients who have both received and who are waiting for transplants in the region. This long-term monitoring includes HLA molecular typing, HLA antibody detection and definition (pre and post transplantation) and for patients who have received bone marrow transplants, chimaerism monitoring.

In 2020 / 2021 the laboratory performed:

- 14,416 HLA types, both intermediate and high resolution
- 1,556 Disease association HLA typing
- 17,837 HLA antibody investigations
- Over 174 kidney, pancreas, and islet transplants, 32 cardiothoracic transplants and 126 bone marrow transplants.
- 1013 crossmatches were completed for the 220 deceased donor transplants.

The laboratory at the time of the study comprised of a team of 45 highly skilled Clinical scientists, technical and administrative staff with many years of experience within the field of H&I and accreditation which are managed by a laboratory director and three consultant clinical scientists (see appendix 6). The laboratory is currently in its ninth year of UKAS / ISO 15189 accreditation, having just completed its second full four-year cycle in March 2023.

The target population for the study included all employees of the Transplantation laboratory (N=45) as a convenience sample, all of whom could speak and understand English (Table 9). The diversity of the staff population within the setting facilitated staff engagement of varying seniority, with different levels of experience and knowledge, generating a variety of perspectives with many years' experiences of participating in accreditation. Thus, collection of sample demographics and characteristics whilst

allowing for anonymity in the questionnaire was essential and necessary for analysis and potential interpretation of findings.

TABLE 9 SAMPLE POPULATION

Role	AfC Grade Banding	Total No.	Male	Female
Consultant Clinical Scientists	Laboratory Management Team (MT) (Bands 8a and above)	4	5	10
Principal Clinical Scientists		4		
Senior Clinical Scientists		7		
Clinical Scientists	Clinical Scientist's and Technical team (CSTT) Bands 3-7	11	5	24
Senior Technicians		5		
Technicians		4		
Medical laboratory scientists		2		
Trainees		3		
Administrative staff		4		
	Total	**45**	10	35

4.9 Staff Recruitment and Participation

Permission to contact the laboratory staff as potential participants was obtained from the Laboratory Director and Ethical approval obtained from the University of Salford (UoS) Research Ethics committee (See appendix 7 and 8), NHS REC approval was not required (Appendix 9). Access and recruitment of the study group was not difficult because everyone in the department has been involved in some way by the accreditation process and so were keen to participate. Over 82% of the study group have been employed in the department over 5 years with 64% over 10 years and so have experience of ISO accreditation. Developing trust and rapport with the participants was not difficult as the cohort have been colleagues for many years, and many understood and appreciated the research. To reduce the potential influence of the management on individual responses, and improve the chance of obtaining unbiased responses, junior colleagues were grouped together in one focus group, managers in another to ensure people were free to provide their experience of ISO accreditation.

An online presentation using Microsoft Teams was provided to all participants to explain the aims and objectives of the study, rationale for the study, the study design

and provide information regarding staff participation. This also allowed staff time to ask questions and ensure they were fully informed before deciding to take part. An email invitation sent to all departmental personnel contained an Information letter and consent form (See Appendix 10 and 11) to be completed by those wishing to participate, as agreed in the academic ethics application (See Appendix 8).

All consenting participants were asked to contribute to:

1. The Study questionnaire: each member of the department was emailed a participation invitation which included a link with the British Online Survey (Jisc) survey to complete.
2. The Focus group discussions: All the individuals who had completed the questionnaire and had consented to the study were invited to participate in the focus group via Microsoft Teams. Each Team consisted of no more than 12 employees, to allow for 'talking space' any more is considered difficult to manage (Robson and McCartan, 2016). The rationale for only inviting those who had participated in the survey was to expand and contextualise the survey findings by exploring topic areas perceived to impact on the laboratory.

During the consent process, it was explained that participation was voluntary, their decision to participate or not would have no impact on their relationship with the laboratory and they could withdraw at any time. Any information provided and used in the study would be fully anonymised for its analysis and dissemination. Consent was attributed on return of completed signed consent form.

4.10 Phase One – Development and design

4.10.1 Expert Panel

To generate consensus for the critical process measures of patient care that were identified from the available theory, an expert panel was established as a purposive sample bringing together the laboratory management team with senior managerial positions in the laboratory. Each had extensive theoretical knowledge of H&I and critical laboratory processes involved in patient care, and years of experience. This helped to develop the study design and reduce researcher bias. The management team were all provided with an information sheet for the study (See Appendix 10) and a consent form for them to agree to be involved as an expert panel, and to allow the

recording of the discussion (See Appendix 11). Using a semi structured approach utilising concepts derived from the literature a discussion schedule was developed (See Appendix 12). All fifteen senior members of the Transplant laboratory, (N=15; Table 9) were invited to join the expert panel following a scheduled management meeting on the 14th of October 2020, all 15 attended. It lasted no more than 90 mins, was digitally recorded via Microsoft Teams, and manually transcribed, themed, and coded by the researcher the following day so that the narrative and focus was still clear.

The laboratory's critical processes described within the current UKAS Scope of Practice (See Appendix 1) were examined and key critical processes relevant to the study identified using the following criteria:

- deemed to have the most significant clinical impact.
- have a direct effect on patient outcome.
- measure all laboratory process performance points in line with UKAS scope of practice.
- there may have been problems with quality and efficiency in the past.
- there was pre-existing quality performance data available for longitudinal analysis.

These critical processes selected, formed the main generic technical procedures used within H&I laboratories in the UK and Europe, which would enable the study findings to be relevant and adopted by other H&I laboratories globally.

The key concepts identified from the literature and forming the theoretical framework (Figure 4) underpinning the study were established as cost, quality, efficiency, and cost effectiveness. The performance measures used to monitor the key concepts were identified (Table 10) -

To measure and monitor the cost of accreditation -

- Annual fees paid for maintaining ISO accreditation including any ETS, assessment fees, and close out fees.

To measure and monitor quality -

- Sample testing repeat rates for each of the critical processes listed on the UKAS schedule of accreditation, where secondary data is currently being collected,

- EQA error rates for each of the critical processes (as above), and
- annual NC from each annual UKAS surveillance visit included in the study time frame.

To measure and monitor efficiency -

- Turnaround times for each of the critical processes

These generic performance measures were chosen as key QI for the study as they were relevant to all patients, readily available and collected by a third party. They all had an appraisal concept, a performance indicator with which to judge the outcome, apart from annual NC.

To measure cost effectiveness, the number of NC identified by UKAS per year and cost per test were used (see 4.2.10b Equation 1).

TABLE 10 CRITICAL LABORATORY PROCESSES AND KEY CONCEPTS

Critical Processes	Key Concepts			Methodology
	Quality	Efficiency	Cost Effectiveness *	
	Performance Measures			Quantitative
HLA Typing Antibody Screening Chimaerism monitoring Crossmatching	Repeat Rates (RR of critical processes) Error Rates (EQA error rates & ISO 15189 NC)	Turnaround times (KQI TAT & TAT of critical processes)	Cost per test* ISO 15189 Non-conformances (NC) per assessment cycle*	

Note. Adapted from a tool designed by Hamza et al, (2013 p554).

The expert panel had multiple roles in the development and implementation of the research design:

1. Agree the selection of the key critical laboratory processes and key concepts to be used in the study and verify its suitability to ensure internal validity and minimise researcher selection bias.

2. Validate key study concepts and themes drawn from the literature used to guide questionnaire development (Phase 2).
3. Pilot the data capture tool (staff questionnaire) (via email see later section)

4.10.2 Research Tools

a) Questionnaire Development -

The expert panel were consulted regarding key concepts and themes for the study and a list of key areas summarised then used to ground questions for a phase 2 wider staff service questionnaire (See Interview transcript, appendix 13). The discussion was transcribed by the researcher immediately following the session and thematically analysed to compare and contrast emerging themes with current evidence (Table 11).

The use of a questionnaire, validated by the expert panel was a convenient and inexpensive way of gathering quantitative data (Bryman et al, 2007; Robson et al, 2016) especially during a pandemic with restrictions on contact. The questions were developed from a combination of researcher experience, available evidence in the literature and using the panel of experts as a supplementary source of data (Dilshad and Latif, 2013). Draft themes and questions were developed (Table 11 and 12).

TABLE 11 TRANSCRIPT ANALYSIS THEMES AND OUTCOMES FROM EXPERT PANEL

Themes	Areas of Discussion by Expert Panel
Accreditation	the standards and translating these into practice. Competent assessors, UKAS, and comparisons to other accreditation bodies
Service quality	Repeat rates and error rates.
Staff involvement	The impact on staff workload / documentation / audits - excessive workload
Efficiency	TAT
Cost and value	Expense, not value for money
Patient Focus	value to patients, quality impact on patients
Innovation	being a service user, patient focus and changes to the laboratory scope of practice.

TABLE 12 THEMES AND QUESTION DEVELOPMENT

Themes for Questionnaire and Focus Group	Question
Accreditation and Quality	How do you think that it has affected laboratory quality?
Accreditation and staff involvement	How do you think it has impacted on the laboratory personnel / themselves?
Accreditation and efficiency	How do you think it has impacted on laboratory systems?
Accreditation and cost	Do you consider that currently laboratory accreditation is value for money?

The questions derived were closed, grounded in current evidence and expert group feedback. The statements were generated under common categories questions 1-3 (Table 13) to elicit staff opinions of accreditation, improvements to quality and efficiency, cost, and perceived value. The questionnaire incorporated a 4-point Likert scale to answer the 19 statements within the six question themes and facilitate statistical analysis (See Appendix 14). Respondents used the Likert scale (1–4) to indicate their level of agreement to several statements defined within each of the question themes (with 1 being Completely agree, 2 agree, 3 disagree and 4 Completely disagreed). The 4-point scale was chosen in place of the more commonly used 5-point scale so to minimise the risk of not getting a definitive answer from the questions (Chyung et al, 2017).

TABLE 13 QUESTIONNAIRE FORMAT

Question	Subject area
Question 1	General opinions of the respondents to accreditation.
Question 2	General opinions about accreditation and had it improved specific areas of the laboratory with focus on quality and efficiency.
Question 3	Replicate questions to confirm any answers given from the previous two questions including questions on their opinions with regards to accreditation costs and value
Question 4	Demographic information including the respondents current Agenda for Change banding
Question 5	Length of employment in the laboratory
Question 6	If the respondent had been involved in the accreditation process, this was an open question with scope for the respondent to provide input regarding their involvement.

A final open question (question 6) allowed respondents the opportunity to add comments to expand or explain their answer on an earlier question or describe their experience. Demographics details were also captured (questions 4 and 5), such as length of experience working in the lab, and qualification level, to allow the

interrogation of different staff groups. Members of the expert panel were asked to pilot a version of the questionnaire prior to administration. Seven replied, and no changes requested to the content, order, or design of the questions, they all agreed the questions were easy to understand.

The questionnaire was designed using British online surveys. The advantages of using a web-based surveys were cost reduction, speed in developing and data collection, and reduction in errors when data processing (Bryman and Bell, 2007). With the sample being a single site within the NHS, it was a simple method to administer through staff email. It was anticipated that a >50% response rate would be achieved because of the interest and importance in the topic and staff involvement in the accreditation process. Using email reminders to prompt a response the researcher attempted to achieve 100%, although this is known to be difficult (Neale, 2009). Despite reassurances that answers would be anonymised, it could have reduced staff participation if they were worried their responses may be exposed, alternatively their trust in the researcher could have encouraged increased participation (Robson and McCartan, 2016).

b) Cost Effectiveness Tool -

Cost-effectiveness analysis (CEA) is a primary tool in healthcare for comparing the cost of a health intervention and their value or expected outcome (Hamza et al, 2013). It is a method of assessing if an intervention is efficient. Without cost-effectiveness data, the diagnostic value of any implementation cannot be quantified (Theodorsson 2016). Hamza et al. (2013) utilised cost-effectiveness analysis as a way of comparing the cost of a health intervention such as accreditation to measure expected health gains and provide a quantifiable way to measure cost-effectiveness. This quasi-experimental study, comprised of control and study group data to estimate the causal impact of the implementation (Hamza et al, 2013). It consisted of pre-intervention, intervention and post-intervention phases using a self-assessment checklist against the ISO 15189 standards to indicate compliance of the study and control group. It was the only study identified in the literature that employed a cost effectiveness model in their research to evaluate laboratory compliance with ISO 15189 accreditation.

In Hamza's study (2013) the calculation of Cost effectiveness was completed in two phases by measuring in phase one annual average cost per test and in phase two the cost effectiveness ratio (CER).

Phase 1. Annual average cost per test was used as a managerial indicator for the QMS effectiveness **=**

$$\text{Cost per test} = \frac{\text{Annual total of All costs}}{\text{Annual total of tests}}$$

(The total of all costs involves all costs including reagents, maintenance, personnel, administration etc)

Phase 2. Cost-effectiveness ratio =

$$\text{Average of Cost effectiveness (CE)} = \frac{\text{Average cost per tests for group}}{\text{Average QMS compliance (\%) for group}}$$

$$\text{The cost-efficiency ratio (CER)} = \frac{\text{Study group cost effective}}{\text{Control group cost effective.}}$$

To develop the cost effectiveness tool for the study (Equation 1) phase one was implemented as described in Hamza's study. Initially, the cost per test per year was determined by calculating the annual total of all quality costs during the study period (See Appendix 21). These intervention costs (accreditation) incorporates the costs of good quality only not poor and includes all the resources consumed in implementing, operating, and delivering ISO accreditation annually (Mumford et al, 2015). In order to obtain as accurate and precise costing as possible a micro-costing approach was used to estimate economic costs by scrutinising laboratory spend, accounting for each input unit used including labour (Chapel and Wang, 2019). Including –

- Annual fees paid for maintaining ISO accreditation including any ETS, assessment fees, and close out fees
- Costs of annual participation in external proficiency testing schemes (UKNEQAS); a requirement of ISO accreditation
- Costs of annual preventative maintenance programmes; a requirement of ISO accreditation
- Annual staffing cost

N.B. The hidden costs of quality and costs of poor quality are sometimes difficult to quantify and are not necessarily accounted for within the laboratory's annual financial budgets used. The use of qualitative FGD and the quantitative questionnaire will provide data that will draw upon previous empirical findings to confirm or refute the perceived impact of accreditation on increased documentation on staff workload leading to increased stress and anxiety.

The annual total of all tests was established for each technique identified for the study (Table 15). Including the annual number of –

- HLA Typing tests.
- Antibody screening tests
- Crossmatches by CDC and by Flow cytometry
- Chimaerism monitoring

This secondary data was collected from routine budget records and available audit databases and saved into a separate Microsoft Excel spreadsheet as part of the data capture set.

Phase two of Hamza's study was adapted to measure annual cost effectiveness, not the cost effectiveness ratio because -

- The average cost per test per group was not required as the study was a single centre study.
- The cost efficiency ratio (CER) was not required as there was no control group in the study.

In phase two of the Hamza equation the calculation for the average cost effectiveness (CE) focused on the use of non-compliance to the ISO 15189 standard measured through internal audit approach using self-inspection (Hamza et al, 2013). A self-assessment checklist was employed to establish an assessment mean between the study groups that have implemented a QMS and the control groups that have not. This approach is not free from bias as it is a self-assessment tool completed by ~~each of~~ the participating groups. In contrast, during annual surveillance visit UKAS assessors use a similar assessment approach to determine laboratory compliance. This external audit approach uses the well-established ISO standards to determine conformance and where this isn't met a non-conformance (NC) is awarded. The ISO 15189:2012 standard comprises of two main clauses consisting of 25 primary sub-clauses, 15 in main clause four and 10 in main clause five (See Appendix 2). Each of these primary sub-clauses are also sub-divided into secondary and tertiary sub-clauses with lists of explicit requirements needed to comply with the standard. This totals 386 sperate clauses which each laboratory is assessed against in an annual surveillance visit. (25 primary sub-clauses; 62 secondary sub-clauses; 41 tertiary sub-clauses).

The equation design was adapted to include the number of NC identified against the ISO 15189:2012 standard (N=386) by the UKAS assessment team instead of by self-

assessment establish the ISO percentage compliance per year. The choice to use this approach instead of using the approach by Hamza is first that the QMS and ISO accreditation have been well established by the laboratory in this study. It is therefore not a recent implementation and so there are years of retrospective data available. Second, any NC have been determined by a third party and so unlike the approach taken in Hamza's study are free from bias and add validity to the study.

EQUATION 1 COST EFFECTIVENESS TOOL

Adapted equation developed for the study:

Cost Effectiveness Tool

$$\textit{Annual Cost effectiveness (CE)} = \frac{\textit{Cost per test per year}}{\textit{ISO Compliance (\%) per year}}$$

(NC non-conformances per accreditation year against the ISO 15189 standard)

$$\textit{Cost per test} = \frac{\textit{Annual total of All costs}}{\textit{Annual total of tests}}$$

(The total of all costs involves all direct costs including reagents, maintenance, personnel, administration etc for each critical process used in the study and includes the annual cost of accreditation)

c) Data Capture Tool -

Quantitative longitudinal corporate secondary data was collected to evaluate the implementation of ISO 15189 accreditation from 2014 (Øvretveit, 2002). The longitudinal data collection design enables changes to accreditation to be mapped within the organisation (Bryman and Bell, 2007). Retrospective data was, identified to evaluate the impact of accreditation on the proposed critical laboratory processes over the study period, and the annual cost and the cost effectiveness of laboratory accreditation.

The initial collection and analysis of the pre-existing quality performance data including the TATs and RRs available for longitudinal analysis was performed routinely by the laboratory's audit data manager. This data had been collected monthly independent of the study providing objectivity and potentially minimise any information and research bias (Bryman and Bell, 2007; Robson and McCartan, 2016). It was stored on a Microsoft Excel database on the laboratory's shared drive which is password protected. It was backed up to the NHS Trust server daily, with recovery available in

the event of an incident, via the IT manager. Access to this data was granted by the Laboratory Director. A separate secure folder on the same platform, was developed to create the quality dataset for the study from the transition from CPA accreditation to ISO 15189 accreditation in 2014.

The data set included Microsoft Excel spreadsheets for both quantitative and qualitative data, including:

- Cost of accreditation
- Cost effectiveness
- Quality
- Efficiency
- Questionnaire results
- Focus Group analysis.

A secure folder containing questionnaire responses and transcripts for each focus group, recordings, plus data summary and display tables created from the thematic analysis and any observer note was also created as part of the data set. Any computer folders and files created within the data set was given appropriate names to identify the type of data collected.

Cost of accreditation

Annual laboratory budget statements were scrutinized over the study period to evaluate the cost of accreditation. The actual costs of each accreditation cycle were established from before the transition of UKAS accreditation in 2014 to the present day. These figures include:

- the actual costs of CPA UK Ltd accreditation
- the actual cost of each annual UKAS accreditation surveillance visit
- fees for applications for any ETS
- fees for reassessments of improvement actions

These costs were calculated and transcribed into an Excel spreadsheet as part of the study quality dataset and graphically presented to depict the annual cost to the laboratory for accreditation. These findings were demonstrated as a timeline from 2014 to the present day identifying the costs per year and per accreditation cycle, the overall total annual costs and the annual surveillance costs including any ETS applications.

Cost effectiveness

The total quality budget costs per year was also established which included the annual costs of:

- Each cycle of accreditation
- The EQA schemes
- The preventative maintenance costs per year
- Personnel costs

To establish cost effectiveness the adapted equation 1 was used involving data collected from the annual budgets (total costs) divided by the number of tests per year to establish the cost per test for each year. The number of NC identified against the ISO 15189 standards during each annual ISO assessment since the transition in 2015 was collected and recorded as the number of NC per assessment year. The annual cost effectiveness was established using the cost per test divided by the percentage ISO compliance per year.

Quality

To establish laboratory quality, data included (Table 15) -

- Repeat rates (%) for each of the critical laboratory processes identified for the study in-line with the laboratory scope of accreditation. The monitoring of repeat rates (RR) was introduced by the laboratory as a quality monitoring tool in 2015 as a requirement of ISO 15189:2012. The annual average acceptance level of 5% was defined as a laboratory indicator to measure quality. Repeat rates monitor all repeat testing in the laboratory, this repeat testing may occur because of technical failures due to equipment faults, staffing and training problems or reagents and kit failures all of which can impact on service quality. These faults and failings along with increase in RRs can also impact on laboratory efficiency by affecting the TATs by delaying the reporting of testing results. These percentage figures were presented in a Microsoft Excel initially a yearly average of all the critical processes. This was later expanded for each of the critical laboratory process to increase the data set, allowing for trend monitoring and enhance rigour to the longitudinal study.
- Error rates (%) which included both an assessment of the number of NC per year and the average annual overall percentage score from the UKNEQAS EQA proficiency schemes participated in during each assessment year. These

EQA schemes are reflective of each laboratory's scope of accreditation and are a requirement of ISO 15189:2012. The percentage figures were imported into a Microsoft Excel spreadsheet in the study data set for analysis. Initially providing graphical representation of both the annual number of NC per year and the percentage compliance plus the percentage participation rate for the EQA schemes per year with an acceptance level of 100% as the laboratory QI, over the study period. The percentage compliance was also used in the adapted equation (Equation 1) to indicate the annual cost effectiveness over the years to assess if ISO accreditation had been cost-effective.

Efficiency

To establish the laboratory efficiency over the study period further performance measure were also used (TAT).

- National KQI have been established in the UK for the deceased donor programme which includes the laboratory's participation in Donor HLA typing and deceased donor crossmatching. The KQI monitor the TATs of the laboratory critical processes in an acute on call situation with an overall KPI of 8 hours that includes:
    - Donor HLA typing and
    - Deceased Donor Crossmatching
- National KQI have also been established for HPCT chimaerism monitoring with an overall KPI of five days since 2019 prior to which it was seven days.
- Laboratory defined internal QI were used for laboratory processes where there are none nationally defined. These internal TATs are routinely calculated monthly by the laboratory audit manager as part of the internal quality improvement programme. These have their own in-house performance indicators established dependant on the laboratory process, user requirements and its impact on clinical outcome.
    - HLA Tying
    - HLA Antibody screening

The TAT has several definitions but, in this instance, it is the total time taken from receipt by the laboratory of the patient sample to reporting results to the clinician. Appropriate and timely clinical decisions are required to ensure a successful outcome

and both the transplant surgeons and consultants rely on a rapid TAT of these test results.

The national KQI for the deceased donor programme because of its acute nature are recorded in hours whilst all the other TATs are measured and monitored in days. These percentage figures were imported into a Microsoft Excel spreadsheet in the study data set for analysis providing graphical representations created as part of the data set. These monthly TATs were initially represented for each of the critical processes on times series plots over the study time frame.

d) Focus Group guide -

The rationale for the use of the focus group discussions alongside the questionnaire was because it was considered a more cost-effective and efficient research tool to use for qualitative data as it generates far more than other face to face methods such as one-to-one interviews (Parker and Tritter, 2006; Roller and Lavrakas, 2015). It was also chosen due to time constraints for both the participants and researcher, especially during the pandemic completing focus group discussions using Microsoft Teams seemed an appropriately safe and efficient way to proceed (Bryman and Bell, 2007; Neale, 2009). The aim was to establish the opinions and perceptions of the groups to develop an understanding of the factors that impact the hidden costs of accreditation previously exposed in the literature.

The topic guide (See Interview schedule, Appendix 15) provided a framework to explore specific areas and key findings in more depth within the focus group discussions and to gain a deeper understanding of how accreditation impacts on staff and clarify any possible ambiguity from the quantitative questionnaire findings (Neale, 2009; Wong, 2008; Robson and McCartan, 2016). The topic guide was developed for the semi-structured focus groups using data obtained from:

- the review of the literature.
- data that had been thematic analysis from the survey findings.
- answers obtained from the open questions.

The guide was design to flow logically from one topic area to another, but with enough flexibility to adapt to unexpected but relevant issues during the discussion (Wong, 2008).

4.11 Phase Two – Data Collection and Analysis Phase

4.11.1 Primary Data Collection and analysis

Survey Methods (Table 8)

In order to understand staff opinions and perceptions of accreditation primary data was collected from the study population using a survey approach. This included both a questionnaire and follow up focus group discussions (Table 14).

TABLE 14 PEOPLE - STAFF INVOLVEMENT

<table>
<tr><td rowspan="3">Staff Involvement</td><td colspan="4">Key Concepts</td><td>Methodology</td></tr>
<tr><td>Cost / Value</td><td>Quality</td><td>Efficiency</td><td>Cost Effectiveness</td><td rowspan="2">Quantitative / Qualitative</td></tr>
<tr><td colspan="4">A. Questionnaire</td></tr>
<tr><td colspan="4">B. Semi structured Focus Group Discussion</td><td>Qualitative</td></tr>
</table>

A: Online Questionnaire (QUAN QUAL)

The questionnaire developed in phase 1 was administered to obtain a body of factual, quantifiable, and subjective information on laboratory accreditation examining the key concepts to detect patterns of association. The questionnaire captured staff opinions and perceptions of accreditation and the accreditation system quantitatively (Likert questions) and qualitatively (Open question).

This definitive version of the staff questionnaire was electronically distributed to all the participants (N=45) on the 10th of May 2021 for 21 days, two reminder emails were sent, one each week and the survey was closed for analysis on the 31st of May 2021. The quantitative and qualitative findings from the questionnaire were analyzed and results were integrated to inform and direct the focus group discussions and emerging theory. (Creswell and Creswell, 2018). Descriptive statistical analysis of the online survey where a four-point Likert scale ranging from 1 (Strongly disagree) to 4 (Strongly agree) was used to answer the 10 questions developed (See Appendix 18). The questionnaire responses were analyzed using descriptive statistics and integrated to

inform the interview guide for focus group discussions and contribute to an original study theoretical framework (Panke, 2018; Creswell and Creswell, 2018).

B: Laboratory staff focus group discussions (QUAL)

The nature of Focus group discussions is that they are generally conducted with groups of individuals who have something in common with the shared experiences and so was deemed appropriate for this study (Kitzinger, 1994; Parker and Tritter, 2006; Wong, 2008). The familiarity of the sample confirmed the requirement to divide the sample into the two distinct groups and by dividing the groups, ensured the participants were not inhibited and were free to express their views without fear or intimidation (Neale, 2009; Roller and Lavrakas, 2015). Two separate focus group discussions were adopted to collect qualitative data in order to capture the personal perceptions, opinions, and experiences of laboratory staff to gain a deeper contextual understanding of the impact of accreditation (Bryman and Bell, 2007; Wong, 2008; Roller and Lavrakas, 2015; Robson and McCartan, 2016). There were no more than 12 participants per group to allow room for useful discussion and adequate participation (Bryman and Bell, 2007; Wong, 2008; Neale, 2009; Robson and McCartan, 2016).

The two Focus groups took place on 3rd December 2021, via Microsoft Teams at 10am (CSTT) and 1pm (MT). All staff who answered the questionnaire and had completed and returned the consent form were invited to attend the focus group discussion, a Teams invite was sent. The number of attendees for the CSTT Focus group at 10 am was N=9 and the MT focus group at 1pm was N=11. During the sessions verbal consent to record was obtained and staff were reminded that all discussions would remain confidential and should not be discussed outside of the group. The researcher began the dialogue using the themes determined in the Topic Guide (See Appendix 15) to initiate the discussion. Where the topic deviated the researcher guided the narrative back in focus, but notes were made of these. Each of the Focus group discussions took no longer than 60 minutes and were digitally recorded via Microsoft Teams. During the group discussions it was difficult to prevent the participants going off topic and the more powerful persons in the group taking control of the narrative, but this was remedied by gently refocusing the discussion back which was sometimes difficult (Bryman and Bell, 2007; Neale, 2009; Robson and McCartan, 2016; Panke,

2018). It was also extremely challenging as the moderator to just moderate the groups and not to fill in the gaps when the discussion slowed or stopped (Bryman and Bell, 2007).

The video and audio data produced by Microsoft Teams were electronically downloaded to the research database and subsequently transcribed by the researcher. The Microsoft Teams recording was watched and compared to the transcript created from Microsoft Teams several times to ensure validity and to embed the researcher in the narrative (Braun and Clark, 2022). The transcript was amended as appropriate and what developed was a representation of the audio and visual data (Appendix 22 and 23).

This was achieved by following a systematic approach to ensure transcript quality:

1. The conversation was transcribed verbatim (using Microsoft Teams).
2. Inclusion of verbal and non-verbal interactions
3. The necessary levels of confidentiality were maintained throughout the discussion using codes developed for the study to identify the speakers.
4. Timestamps were used in the transcript as these were automatically generated by Microsoft Teams
5. Member-checking using one of the focus group participants from each group to confirm the transcription as a true representation of the event.

Analysis of the data obtained from the FGD included a combination of content and thematic analysis techniques constructing thematic networks where appropriate and making comparisons using data tables to organise, analyse and demonstrate the findings to ensure reliability of the data and its outcomes (Braun et al, 2006; Morgan, 2010; Castleberry, 2018; Cloutier and Ravasi, 2021). The qualitative findings from the focus group discussions were scrutinized deductively using a thematical analysis approach through several phases (Creswell, 2013; Braun and Clark, 2022). Familiarisation of the data was made by immersion with and questioning the dataset to get a deeper understanding of the findings (Rabiee, 2004; Wong, 2008; Neale, 2009). Coding using a deductive orientation (Robson and McCartan, 2016; Creswell and Creswell, 2018; Braun and Clark, 2022) was adopted, the aim was to use the data to develop existing theory and concepts uncovered from the literature constructed into the theoretical framework and contextualise the outcomes from the questionnaire (Braun and Clark, 2022). Pre-determined themes were used developed form and

reinforced by the literature review and substantiated the findings from the questionnaire whilst new themes emerged to generate new knowledge (Chapter 5, figure 6). The analysis was drafted in data summary and display tables, for each theme a table linking the sub themes and data excerpts was created (See Appendix 22 and 23) to support both data analysis and visualisation of findings (Creswell and Creswell, 2018; Cloutier and Ravasi, 2021).

C: Secondary Data (QUAN)

Secondary data was used to measure and monitor the key concepts:

- the cost of accreditation using UKAS invoices.
- Cost effectiveness using Budget statements.
- Quality and efficiency using performance data against the defined clinical processes for the corresponding laboratory techniques (Table 15).

The impact of laboratory accreditation on the key concepts (Cost, quality, efficiency, and cost effectiveness) was monitored longitudinally from 2014, where available, to 2022. The effects on the performance measures for the critical processes (see lists of abbreviation and list of key terms) were monitored retrospectively, to quantify association between effects of accreditation on the relevant key concepts over the study time frame.

Initially annual overall average performance measures were calculated and graphically presented against the laboratory QI (5%) to present a visual indication of the laboratory outcome per year. These performance measures were extrapolated further and represented for each of the critical processes on linear plots over the study time frame from year one of ISO accreditation (SUR 1) in 2015 to present day.

The overall percentage performance for each year was collected into an Excel spreadsheet as part of the Quality Dataset from where graphical representations of the findings were created. These were also represented on both annual graphs and monthly times series plots (Fretheim and Tomic, 2015) the patterns of which were scrutinised by comparative analysis and visual inspection (Devkaran and O'Farrell, 2015). Measuring of monthly multiple time points allows the underlying trends and any cyclical effects to be estimated.

TABLE 15 QUALITY DATA COLLECTED FOR DATASET

Clinical Process	Laboratory Technique	Performance Measures Included
HLA Typing	PCR SSP PCR SSO SBT RT-PCR NGS	UKNEQAS Scheme 4 National KQI TATs RR Cost
Crossmatching	CDC Flow cytometry	UKNEQAS Scheme 2A and 2B National KQI TATs RR Cost
Antibody Screening	IgG & M LifeCodes LABScreen	UKNEQAS Scheme 3 and 6 Internal QI TATs RR Cost
Chimaerism monitoring	STR analysis	UKNEQAS Scheme Internal QI TATs RR Cost

Time series linear plots were utilised to provide monthly graphical reports with which to develop into a Laboratory Quality Dashboard for the routine quality data captured during the study:

- Quality Indicators (QI) namely repeat rates and error rates were used to measure and monitor **quality.**
- Turnaround times (TATs) were used to measure the **efficiency** focusing on processes critical to the patient pathway.

These linear times series plots were also useful in demonstrating visually the correlation and relationships that exist between the variables.

To determine if the implementation of accreditation (Independent variable) over the years has impacted on the key concepts (dependant variables) the linear regression plots for these were examined using Pearson's Correlation Coefficient (r) and the Coefficient of determination (R^2). Pearson Correlation Coefficient was adopted to measure the strength of the linear association of each of the key concepts over the

study time frame to identify if accreditation influences quality, efficiency, and cost effectiveness (Bryman and Bell, 2007; Robson and McCartan, 2016).

Initially the Pearson correlation coefficient was used to examine the strength and direction of the linear relationship between the two continuous variables (years of accreditation and each of the key concepts). The larger the absolute value of the coefficient, the stronger the relationship between the variables indicating that accreditation may have impacted on the key concept. For the Pearson correlation, an absolute value of 1.0 indicates a perfect linear relationship (Bryman and Bell, 2007). If a correlation close to 0 was observed, then this would indicate there is no linear relationship between the variables. To interpret the correlation coefficient a labelling system was used (Taylor, 1990) to roughly categorise r values as either weak, moderate, or strong correlations (Table 16).

The coefficient of determination (R^2) was calculated for each linear plot using Microsoft Excel data analysis package in order to determine the proportion of variability of each of the key concepts that can be attributed to its linear relationship with the years of accreditation (Taylor, 1990; Field, 2005). The outcome indicates a percentage variability that can be explained by the relationships of the dependant variables (key concepts) and the independent variable (accreditation). This can be used to fully interpret the correlation co-efficiency more precisely than the correlation coefficient as it provides a percent value (Taylor, 1990). To establish and quantify the impact of accreditation on the laboratory over the study time frame from the transition to ISO accreditation in 2014 to present the Pearson's Correlation Coefficient (r), the coefficient of determination (R^2) and percentage total variation (%) was establish and tabulated for each accreditation assessment (SUR) year. The statistical significance for each of the key concepts was also determined to establish if ISO accreditation had had any significant impact on laboratory quality, efficiency, and cost effectiveness over the study time frame. To determine if the correlation coefficient observed were statistically significant, the corresponding P values were also calculated using the regression analysis tool in Microsoft Excel (See Appendix 24-26). Using a P value of 0.05 or lower signifies that the data observed was statistically significant and assumes that the null hypothesis is to be rejected.

TABLE 16 INTERPRETING CORRELATION COEFFICIENT

r Value	Correlation
≤ 0.35	Low or Weak
0.36 – 0.67	Modest or Moderate
0.68 – 1.0	Strong or High
≥ 0.90	Very High

It was never appropriate to conclude that changes in one variable cause changes in another based-on correlation alone (Robson and McCartan, 2016). Only controlled experiments can determine whether a relationship is causal. Also, a low Pearson correlation coefficient does not mean that no relationship exists between the variables. The variables may have a nonlinear relationship (Taylor, 1990; Bryman and Bell, 2007; Robson and McCartan, 2016). It was also not meaningful just to describe the correlation coefficient as weak or moderate as this provided only an abstract measure (Taylor, 1990) using the coefficient of determination (R2) was more appropriate.

To test the hypothesis:

Null hypothesis (H_0): *There is no linear relationship between the two variables (Dependant (y) Key concepts and the Independent (x) years of accreditation), to indicate that the length of time accredited doesn't affect the key concepts and that there is no improvement in laboratory quality, efficiency, and cost effectiveness.*

Alternative hypothesis (H_1): *There is a linear relationship between the two variables meaning with each year of accreditation there is an impact on the key concepts.*

The purpose of this mixed methods approach was to fully maximise the small single centre study population to ensure that both validity and reliability are established in the results obtained. Quantitative results from the laboratory staff using the questionnaire were corroborated against the qualitative data obtained from the focus group discussions to minimise bias and allow for validity in results providing much needed new evidence in this field. Establishing the impact of accreditation on the staff opinions and perceptions when analysed in conjunction with the quantitative results obtained

from the key concepts helped to determine an overall perspective of the actual effect of accreditation and its sustainability in an NHS specialist pathology laboratory.

4.11.3 Converging / triangulation

A convergent mixed methods design was adopted to satisfy the overall study aim (Chapter 4, Figure 4) which used the best methods available disregarding divides of the different paradigms (Neale, 2009; Bryman and Bell, 2007; Creswell and Creswell, 2018). The methods employed in the study captured measurable performance outcomes alongside contextual data from staff to provide a more robust strategy to substantiate the findings (Panke, 2018). This generated rich data to develop a stronger understanding of the research aims and objectives, enhance the reliability of the findings and minimise potential bias, and improving the generalisability of the study (Creswell and Creswell, 2018). Three integrated methods were used to extrapolate and analyse relevant study data, laboratory critical clinical outcome data (QUAN), staff survey (QUAN / QUAL) and focus group discussions (QUAL).

The study used different methods of data analysis in order to complement the different data collected, building on strengths and weaknesses of the alternative methods, which can potentially lead to stronger inferences (Robson and McCartan, 2016; Panke, 2018). It consisted of merging both the qualitative and quantitative data findings known as integration using side by side comparison (Morse and Niehaus, 2016; Creswell and Creswell, 2018) to establish the outcomes and establish the aims and objectives of the study. There are many benefits for combining qualitative and quantitative data in research not only does it enhance the validity of any results but provides a more holistic picture of the study topic, especially for complex situations such as accreditation (Robson and McCartan, 2016).

4.12 Validity and Reliability

The longitudinal study design was employed for clarity, transparency, and repeatability, adding validity to the qualitative elements of the study, enabling access to many years of data for analysis to observe patterns of change. This design is not very common in management research due to the time and costs (Bryman and Bell, 2007; Robson and McCartan, 2016). It provided the possibility to compare the influences on the key concepts over time to ascertain the impact of accreditation and its sustainability (Bryman and Bell, 2007). Often limitations can include the lack of familiarity and

complexity and quality of the data (Bryman and Bell, 2007), but not in this study given that the researcher has been the laboratory QM for many years and the expert panel used to develop the study design also had years of expert knowledge in the subject area.

The longitudinal data collection over the study period included data pre- the introduction of ISO accreditation in 2014, so therefore there was the possibility to verify in the discussion whether ISO 15189 accreditation had any significant impact on laboratory costs, quality, efficiency, and cost effectiveness. The data has already been collected by a third party as part of the laboratory' quality improvement programme, so enhances validity in the data (Dawson, 2019; Bryman and Bell, 2007; Robson and McCartan, 2016 Creswell and Creswell, 2018).

To reduce the threat to internal validity due to the lack of a control group in the study design, consideration was given to other things which may have happened during the study time frame. These may have affected the variables and thus the study outcome, so history needs to be considered when drawing any conclusion (Robson and McCartan, 2016). Consideration was given to confounding factors such as any changes to technical procedures, staffing and the Covid-19 pandemic that could have had an impact on the performance outcomes over the study period.

The participants perceptions might change due to experiences or education over the period of the study, so Maturation of the sample also needs to be considered (Robson and McCartan, 2016). A significant number of the research sample (64%) have been employed within the Transplantation laboratory for over 10 years, including the researcher. All the management team except for one have worked within the Transplantation laboratory over 10 years and have had direct association with accreditation. This one individual has been employed within another NHS laboratory within the discipline of H&I so has had exposure to ISO accreditation, all be it in a different setting. The longevity of employment within the study group also needs to be considered as a confounding factor. The culture of the study group needs to be exposed including any personal bias or preconceived ideas around accreditation that may exist leading to shared values and assumptions for both the QM and the expert panel.

The use of the Expert Panel to confirm the key study concepts and inform the questions for the staff questionnaire and focus group topic guide minimised potential

researcher bias and helped focus data collection. (Wong. 2008; Robson and McCartan, 2016). Gaining only a managerial perspective has been expressed as a common limitation of hospital accreditation (Ellis et al, 2020) therefore all members of the department were included in the study group. A further limitation is the fact that it is a single centre study with the lack of scientific rigour or external validity. A convenience sample of internal stakeholders only was employed due to the change of the study design and time limitations. The approach was used to test the research hypothesis which would lead to a larger study post doctorate to include UKAS and other H&I laboratories to extrapolate and validate any findings.

The hidden costs of quality were difficult to quantify but the significance of them described in the FGDs corroborated the views seen in the available evidence around accreditation in both healthcare and industry. The cost effectiveness of accreditation could be impacted by the continual increase in costs over the study period which may include staff salaries, cost of reagents and consumables, the introduction of new laboratory techniques which may involve revenue for equipment and also the employment of additional laboratory personnel.

4.13 Trustworthy and Credibility

When using qualitative methods alternative terms are used such as trustworthiness and credibility (Creswell, 2013; Robson and McCartan, 2016). The researcher is considered the key instrument and the primary mode of collecting and analysing the data (Roller and Lavrakas, 2015; Creswell and Creswell, 2018). Therefore, there is value in understanding and exposing the researchers position within the study, establishing credibility in the study design, analysis, and interpretation (Roller and Lavrakas, 2015; Creswell and Creswell, 2018). The researcher has been explicit throughout in placing themselves clearly within the study context and the sample population. Using reflexivity to clarify any bias, discussing how the background has shaped the design and direction of study (Creswell, 2013). Concerns could be raised around bias due to the position of the researcher in the study group as both their peer as well as the researcher / moderator (Neale, 2009; Robson and McCartan, 2016). Coercion from the researcher was considered as the sample group were aware of the vested interest of the researcher in the study. This may sway the sample to provide information of what they think the research wants to hear. To overcome this the topic guide was developed to manage the focus groups, ensuring the researcher was just a

facilitator and stimulated the discussion using the predefined open-ended questions adding credibility to the study design (Bryman and Bell, 2007; Roller and Lavrakas, 2015) and minimised any inconsistency between groups (Roller and Lavrakas, 2015). The choice of the focus group discussions was employed to ensure that the data obtained from the survey was verifiable and not due to any misinterpretation of questions by participant or assumption by the researcher (Neale, 2009; Robson and McCartan, 2016).

A key weakness of focus groups can be the potential limited ability to draw robust outcomes as a result of lack of a representative sample (Parker and Tritter, 2006; Robson and McCartan, 2016). The inclusion of all available laboratory personnel as participants allowing homogeneity as these were all from the population of interest (Wong, 2008; Roller and Lavrakas, 2015; Robson and McCartan, 2016). The focus groups were consciously divided between grades of staff, removing the managerial team to a separate FG. To also facilitate free and deep discussion and adequate participation two groups of no more than 12 participants were formed divided into managerial and non-managerial grades (Bryman and Bell, 2007; Wong' 2008; Neale, 2009; Robson and McCartan, 2016). All participants contributed and spoke freely within their respective peer groups. Anonymisation of data meant that all those who chose to participate in the study could feel free to speak openly about their opinions around accreditation without being identified later.

In order to focus only on the participants opinions, the transcripts were analysed in a deductive approach using predetermined themes that had been identified from the available literature around accreditation in healthcare and verified by the expert panel (Robson and McCartan, 2016; Creswell and Creswell, 2018). This approach pursued positive and negative experiences to capture differences and similarities in opinions presenting contrary information adding validity to accounts (Braun and Clark, 2006; Creswell and Creswell, 2018). To minimize the risk of researcher bias, any themes that emerged inductively from the data were also included to enable a deeper understanding of the data (Robson and McCartan, 2016, Castleberry, 2018). Also, notes were taken by the academic supervisor who supported and guided the focus groups. Observer's notes were also collected for each of the discussion groups. These notes provided valuable insight into individual and group interactions to identify any power dynamics within the groups during the analysis (Wong, 20080. Once the

transcript was complete it was shared with a participant of each group to conduct member checking (Roller and Lavrakas, 2015; Creswell and Creswell, 2018)

4.14 Ethics

This research project was conducted with consideration to a number of ethical principles and ethical norms (Resnik, 2020). The first concerns of any researcher are values such as objectivity, openness, transparency, and integrity so, adhering with legal and professional requirements the research project (REF: 236) obtained Ethical approval from the University of Salford Research Ethics Committee on 9th November 2020 (Appendix 8). An online application using the NHS Health Research Authority decision tool indicated that NHS REC approval was not required (Appendix 9). A discussion with a representative from the NHS Trusts R&D committee indicated that there was currently no policy in place with regards to using laboratory employees in research and is currently being investigated. Implementing a systematic, robust study design including a review of the available literature and appropriate methodological approach was imperative to ensure the quality of the researcher and to guarantee objective, verifiable, and reproducible outcomes (Aita, 2005). By ensuring training was obtained to reenforce any new skills especially with regards to qualitative research methodology and analysis, and including reflexivity throughout, would add to the integrity of the study and the researcher. The importance of reflexivity has been discussed as a principal element within MMR (Cain et al, 2019) to guide moral behaviours and attitudes that lead to ethical expertise (Hedberg, 2017; Creswell, 2013).

Another of the main ethical concerns was accountability and responsibility to the participants of the study, especially during the pandemic. A School of Health and Society risk assessment form was completed in line with University of Salford regulations (Appendix 16). A Covid-19 risk assessment was also carried out in line with the NHS hospital trust guidance (Appendix 17). The project posed no risk to the participants; all participation was voluntary, consent was essential (Jonsen, 1996; Robson and McCartan, 2016) and each participant was coded on receipt of consent form (Table 17). All participants responses remained confidential and anonymised using group demographic characteristics to facilitate sub-analysis interrogation. All findings were presented as groups not individual level to prevent participant identification; all participants FG responses were coded to maintain anonymity and to

remove any risk of embarrassment or conflict (Bryman and Bell, 2007; Creswell, 2013; Robson and McCartan, 2016). To allow for transparency and openness an Information Presentation was given to all potential participants via Teams to explain the aims, objectives, rationale, and their role within the study to ensure informed consent (Jonsen, 1996; Robson and McCartan, 2016). Participants were given an opportunity to ask questions at the session. This allowed the researcher to demonstrate research competence, honesty and integrity talking freely and answering questions posed. Consent was obtained both in writing and orally prior to the recording of each focus group meeting.

TABLE 17 STUDY UNIQUE IDENTIFIER

	Group Code	Participants Code	Focus Group Participants Code	Focus Group Session Code
Management Team	MT	MT1	*FGMT1*	*FGMT1_date*
Staff Team (CS/Tech/Admin)	CSTT	CSTT1	*FGCSTT1*	*FGCSTT1_date*

4.14.1 Data Storage

All electronic data stored in the local site files were password protected and stored on the lead investigators P:\ drive also backed up to the NHS Trust server daily. These anonymised files were also copied and stored, as a backup on the Salford University student private network again with researcher password protected restricted access. All consent forms were saved locally in a uniquely identifiable file and on receipt each candidate was given a unique identifier to allow for confidentiality throughout the project.

A Microsoft Excel study database was established to collect electronic data obtained from the questionnaires and focus groups. The questionnaire responses were captured anonymously on the British Online Survey (JISC) tool and transcribed into Excel for analysis. Each survey was given a clearly identifiable code, version number. The data was anonymised and coded for each focus group type, participant, and session by date, and data transcriptions (recordings) and analysis saved to the local site files (P:\drive) (Table 17).

Any researcher field notes from the focus group discussions were transcribed electronically and stored on a secure drive. Any hard copies of paperwork were stored in a lockable filing cabinet in the Transplantation laboratory, access given to authorised persons only.

All data will be stored for a period of five – ten years after the study has been submitted to enable verification of data if challenged. After this the data will be shredded and disposed of appropriately. Recordings from the focus groups will be destroyed once the study is complete and the data is available transcribed as both hard and electronic copies.

4.15 Summary

The convergent mixed methods approach described has maximised the data obtained from a single centre study population to establish content validity and reliability with the current evidence and the quantitative findings, alongside trustworthiness and credibility in the qualitative findings. To establish the true impact of introducing ISO 15189:2012 accreditation in the Transplantation laboratory the longitudinal data was triangulated and integrated focusing on the key concepts and overall impact on the laboratory process and personnel. Establishing staff opinions and perceptions of laboratory accreditation and to interrogate the findings alongside quantitative results provided a comprehensive overview of the service experience of 'real life' accreditation and the impact in an NHS laboratory.

Quantitative and qualitative evidence were triangulated to identify patterns in the data using the key concepts (Morgan, 2007; Mertens and Hesse-Biber, 2012; Creswell, 2013; Roller and Lavrakas, 2015; Robson and McCartan, 2016; Creswell and Creswell, 2018). To validate and verify the overall impact of ISO 15189:2012 accreditation on the NHS medical laboratory specialist pathology service (Bryman and Bell, 2007; Neale, 2009; Morse and Niehaus, 2016; Robson and McCartan, 2016). The outcomes will be acknowledged in the following chapters.

5. Impact of Accreditation

5.1 Introduction

The longitudinal mixed methods study was implemented (Chapter 4) to realise the study research aims and objectives. This chapter focuses on presenting the study findings to examine the impact of laboratory accreditation in an NHS specialist pathology laboratory. The theoretical framework developed (Figure 3, Chapter 3) identified the key study concepts which guided the qualitative and the quantitative data analysis. This included primary data collected from the staff questionnaire and focus groups to gain a deeper understanding of staff opinions, perceptions, and experiences of accreditation in the laboratory exposing new knowledge in this area.

The longitudinal secondary data obtained using the Clinical laboratory performance outcomes established context, framed using the theoretical concepts (quality, cost effectiveness, value, and efficiency). This generated a comprehensive baseline from where to measure and monitor changes and impact of ISO 15189:2012 accreditation over time.

The research study objectives were achieved, evidenced by the findings throughout this chapter:

1. To measure the annual costs of laboratory ISO 15189:2012 accreditation for an NHS specialist pathology laboratory, to establish if accreditation as a quality improvement initiative is value for money and cost effective.

2. To measure the impact of ISO 15189:2012 accreditation on the quality and efficiency of an NHS laboratory by monitoring national key performance indicators and internal quality indicators (QI) for recognised critical laboratory processes.

3. To explore the impact of laboratory accreditation on staff and their work, to gain a deeper understanding of their perceptions of laboratory accreditation.

4. To generate an evidence-base to inform and further examine the impact of ISO 15189:2012 accreditation in a well-established NHS specialist pathology laboratory.

5. To add to the theoretical understanding of laboratory accreditation and quality in the NHS, through the lens of an NHS specialist pathology laboratory.

TABLE 18 OVERVIEW OF KEY FINDINGS

Key Concepts and Findings
Cost (Value)
• There has been a rise in the annual cost of accreditation since the implementation of UKAS and ISO 15189: 2012. (5.5) • The staff opinion of ISO accreditation is that it is not considered as value for money describing it as expensive (5.5.4) • They perceived accreditation as both important and a valuable management tool but recognized significant possible hidden costs with the potential for increased psychosocial risk. (5.5.4) • Exposed perceived issues around accreditation with regards to the assessment team, the clarity of standards and UKAS as an organisation which impact on their perceived value of accreditation. (5.5.6 / 5.5.7 / 5.5.8)
Cost-effectiveness
• There is no clear correlation between accreditation and cost effectiveness seen in the data. (5.6) • It was perceived as an impact on resources specifically staff. (5.5.4)
Quality
• There is no clear correlation between accreditation and laboratory Quality. There was change over the years in error and repeat rates, but these were not statistically significant. (5.7.1) • Nearly all staff perceived that accreditation improved quality providing continual monitoring to assure this. (5.5.4) • Only around half perceived that it improved patient safety. 75% perceived that accreditation has improved RR. (5.5.4)
Efficiency
• There is no clear correlation between accreditation and laboratory efficiency. There was significant change seen in TATs for deceased donor crossmatching and HLA typing, which was statistically significant, this was not observed for chimaerism monitoring. (5.8) • Accreditation was perceived to have a significant impact on workload and described as labour intensive, impacting on innovation. (5.5.4) • In the opinion of 75% of staff accreditation does not improve TATs. (5.8.1)
Methodology
• Use of identified internal laboratory performance measures and national KPIs to assess the impact of accreditation (6.4.1) • Cost effectiveness tool designed (6.4.3) • Framework for measuring laboratory accreditation developed and tested (6.4) • Established a Model for other NHS laboratories (6.4)

An overview of the key findings and original knowledge regarding laboratory accreditation, as well as the new application of research methods to capture accreditation in the H&I laboratory, is provided signposting sections within the chapter (Summary Table 18). The study sample and staff responses are first presented and discussed.

5.2 Sample characteristics and staff response rates

5.2.1 Staff Questionnaire

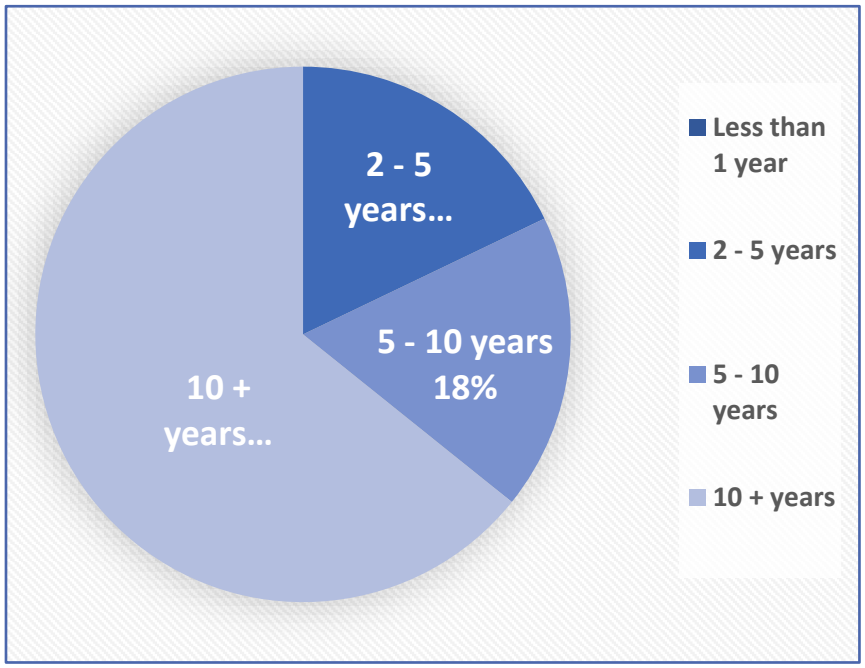
The study cohort consisted of 45 members of laboratory personnel at various AfC grades which included the researcher. The questionnaire (Appendix 14) was targeted at all members of the laboratory all of whom have had some previous experience of accreditation (N=44). From the targeted sample of 44, 28 responses were received with a response rate of **63.6%** (Table 19).

TABLE 19 DEMOGRAPHICS OF STAFF SURVEY SAMPLE

Role	AfC Banding	Total No.	Responses	Questionnaire Response Rate %	Male	Female
Consultant Clinical Scientists (8c +)	Laboratory Management Team (MT) (Bands 8a and above)	4	3	93.3%	4	10
Principal Clinical Scientists (8b)		4	4			
Senior Clinical Scientists (8a)		7	7			
Clinical Scientists (6 +7)	Clinical Scientist's and Technical team (CSTT) Bands 3-7	11	7	48.3 %	2	12
Senior Technicians (5)		5	2			
Technicians (4)		4	2			
Medical laboratory scientists (3)		2	1			
Trainees		3	1			
Administrative Staff		4	1			
Total		**44**	**28**	**63.6%**	6	22

Over 18 **(64%)** of the respondents had been employed 10+ years of which 13 **(72%)** were from the management group. This would be expected in all H&I laboratory's as it takes several years of study to train to become a Clinical Scientist in a senior position (Band 8 Clinical Scientist and above). This may impact the study findings due to the culture established around the concept of accreditation and imposed by perceptions of senior members of the laboratory. The remaining ten respondents were equally split between 5 – 10 years and 2 – 5 years so will all have had some prior experience of the accreditation process (Figure 5).

FIGURE 5 LENGTH OF EMPLOYMENT



The total number of management level staff employed in the laboratory numbered sixteen, including the researcher. The management target group was fifteen and from this there were 14 responses giving a response rate of **93.3%** (Table 19).

The total number of lower level scientific, technical, and administrative staff employed and targeted for the survey was 29 with 14 responses giving a response rate for these grades of laboratory personnel of **48.3%.** This group also included the administration team which include 4 AfC bands from grades 2 to 6 and because they are all not directly involved in accreditation but are embedded in a department where accreditation is fundamental, they were included in the survey. Of the four staff targeted there was only one response. The overall response rate for the questionnaire

was **63.6%.** Significantly less of the lower grade CS technical and admin grades responded to the survey **(48.3%)** than the management level personnel. This may reflect that they feel less engaged with accreditation or that to them it isn't important or relevant, and therefore they don't have an opinion. They may also consider that accreditation doesn't significantly impact on them in their day-to-day routine work or simply they do not feel engaged enough with accreditation or particularly the study to have any considered opinion.

The majority of respondents (**82.1%**) had been directly involved with the accreditation process (Table 20), this alongside the length of employment in the laboratory, indicating an experienced and appropriate study sample. Of the 23 staff who said they have been involved with accreditation; there was an equivalent number of responses from lower grade scientific and admin staff (CSTT) as there was from managers (MT). 11 were from the laboratory management group (n=14) and 12 were from the CSTT group (n=29). The five responses that had no direct involvements were all from the CSTT group and at a junior level where the impact of accreditation may not be so clearly understood.

TABLE 20 STAFF INVOLVEMENT IN THE ACCREDITATION PROCESS

Question 6: Have you ever been directly involved in the accreditation process?	No.	%
Yes	23	**82.1%**
No	5	**17.9%**

5.2.2 Focus Group Demographics

All the 28 respondents that completed the questionnaire were invited to participate in the FGDs, 20 participated (Table 21). Two FGs were arranged that consisted of:

- 11 participants in the MT group, a 66% representation of the laboratory management personnel and
- 9 in the CSTT group a 31% representation of all the junior personnel.

TABLE 21 FOCUS GROUP DEMOGRAPHICS

	Total No. laboratory staff (46)	Possible No. Participants (28)	Actual No. of Participants (19)
Laboratory Management Team (MT)	15	14	11
Clinical scientist /Technical / Admin Team (CSTT)	29	14	9

The development of the MMR study, which included both the collection and analysing of data was a challenge (Bryman and Bell, 2007; Neale, 2009; Robson and McCartan, 2016; Creswell and Creswell, 2018). One of the biggest challenges was in executing the focus groups because of not only the lack of familiarity, experience, and knowledge of this technique (Bryman and Bell, 2007; Neale, 2009; Robson and McCartan, 2016) but also the pandemic. The method was adopted because it was considered to be valuable in gaining an insight into a topic where little is known of the experiences to understand how the situation is perceived by those closely involved (Neale, 2009; Robson and McCartan, 2016). The approach had been previously used within health and social care in areas of service development and evaluation to capture views and opinions (Kitzinger, 1994) but are few in studies examining accreditation in hospital laboratories.

One of the most significant challenges of focus groups was how to conduct and manage them (Bryman and Bell, 2007) especially during the Covid-19 pandemic. Due to social distancing restrictions Microsoft Teams was used to manage these groups remotely which was less of a problem. Some of the failings of focus group discussions are that they are difficult to organise and are too much time and effort (Bryman and Bell, 2007; Neale, 2009; Robson and McCartan, 2016). The use of remote access to facilitate the FGDs ensured minimal effort just the knowledge of the software which had become the norm during the pandemic. This remote approach also worked well to maximise attendance by allowing flexibility as anyone could participate that had admission, but also meant that full participation may not be achieved as distractions are easy (Falter et al, 2022). To ensure active participation the topic guide was developed and used to provide pointers for the discussions, minimising researcher

influence. Everyone was provided with the opportunity to speak, and consideration was given to everyone by raising their hands if they needed to speak.

The aim of creating the two Team groups was to engage the participants and encourage everyone to contribute. The groups were split dependant on workplace seniority to account for social interaction (Neale, 2009; Robson and McCartan, 2016). This lack of proximity may have helped with the dialogue and allowed the participants to be more open in their discussions because by using Microsoft Teams they were not directly exposed to the researcher and other participants. Conversely, this may have also allowed people to be able to focus on other things whilst participating in the group.

During the discussion, it was noted that it was difficult for the participants to shift their conversations from the question to each other especially in the CSTT group where they were more junior members of the department with less experience. In both groups there were some participants who spoke more frequently throughout the discussion whilst others were initially reluctant to participate. More junior participants definitely needed significantly more encouragement to participate, this was achieved by gently asking them to comment whether the discussion reflected their experience. It was important to encourage their voice because they had joined the group so most likely had something to say. When topics were addressed that directly involved them such has the impact on their workload, they joined in the discussion freely.

5.3 Secondary Performance Data

The longitudinal secondary laboratory performance data was collected and analysed retrospectively from 2014 to 2022 (Appendix 19 & 20). Using the themes that have been identified from the literature and developed to form the theoretical framework as key concepts for the study using defined laboratory critical processes (Table 22).

- Quality
- Efficiency
- Cost effectiveness

The secondary data was originally analysed to identify the annual mean results from the implementation of ISO 15189:2012 in 2014 to 2022 for all of the key concepts and critical processes. The data was subsequently extrapolated into both annual graphs and then monthly graphs to observe any further trends and to identify more detailed changes in the measures.

TABLE 22 ESTABLISHED CLINICAL PROCESSES AND KEY CONCEPTS FOR THE STUDY

Critical Processes	Key Concepts
HLA Typing HLA Antibody Screening Crossmatching Chimaerism Monitoring	**Quality** (Repeat rates and Error Rates) **Efficiency** (TAT's) **Cost Effectiveness**

Both the collection and analysing of secondary data was a straightforward undertaking as it was readily available (Robson and McCartan, 2016). The quality and efficiency data had already been collected monthly by a third party as part of the laboratory' quality improvement programme. Anything extraneous that may have caused any monthly fluctuations in had been investigated as part of the laboratory quality monitoring programme to find the root cause. Developing the theoretical framework and key concepts (Chapter 3; Figure 3) for the study helped to frame the data but identifying the data sufficient to focus on the research aims and objectives was problematic. Since some of the performance measures (QI) have only been introduced since ISO accreditation was implemented in 2014 this meant the dataset would only consist of between seven- and eight-years data for analysis not the ten years anticipated. Another significant challenge was the amount of data available and transferring it into an appropriate format for analysis (Bryman and Bell, 2007). A further challenge was the use of statistics and determining the appropriate approach to use to answer the research aims and objectives (Appendix 24, 25 & 26).

To establish if the implementation of ISO accreditation (Independent variable) over the study timeframe had impacted on the key concepts (dependant variables) the linear regression plots for each of the critical processes were examined using inferential statistics including:

- Pearson's Correlation Coefficient (r)
- Coefficient of determination (R^2)

- The total percentage (%) variation was also determined to establish the variation accounted for in each annual accreditation cycle (SUR).

The statistical significance for each of the key concepts was determined to establish if ISO accreditation has had any significant impact on laboratory quality, efficiency, and cost effectiveness over the study time frame using Microsoft Excel regression analysis data tool to determine P values (See Appendix 24–26).

To test the hypothesis:

Null hypothesis (H_0): *There is no linear relationship between the two variables (Dependant (y) Key concepts and the Independent (x) years of accreditation), to indicate that the length of time accredited doesn't affect the key concepts and that there is no improvement in laboratory quality, efficiency, and cost effectiveness.*

Alternative hypothesis (H_1): *There is a linear relationship between the two variables meaning with each year of accreditation there is an impact on the key concepts.*

5.4 Overview of key findings

There has been a continued uptake of laboratory accreditation against the ISO 15189:2012 standard throughout Europe and the rest of the world despite any real evidence that this quality–initiative has made any significant impact on improving laboratory service quality and efficiency.

The previous chapters have described the problem in detail which has led to the development of the study that includes:

- The apparent lack of empirical evidence in this area which has driven the study.
- The formulation of a novel theoretical framework to direct the study.
- The identification and use of appropriate key concepts and critical laboratory procedures and their selection process.
- The application of adopting a mixed methods approach to ensure a robust study design to fully evaluate the impact of ISO accreditation.

This longitudinal study enhances the paucity of empirical evidence around this topic and provides a suitable framework and a substantial evidence base on which any NHS based laboratory can draw inference regarding ISO 15189:2012 accreditation and the potential impact on laboratory process performance.

This section will focus on the outcomes from the analysis of both quantitative longitudinal secondary data and primary data analysis of staff involvement. The outcome of which includes both the financial impact of accreditation and its impact on the laboratory critical processes. The findings are collated under four key themes identified in the theoretical framework as the key concepts for the study of accreditation plus emerging sub themes identified during the FGDs (Figure 6):

- Cost (Value)
- Cost effectiveness
- Quality
- Efficiency

The data describes the cost of implementing and maintaining accreditation annually and also the impact of ISO 15189:2012 accreditation on process quality, efficiency and cost effectiveness whilst unravelling alongside staff opinions and perceptions of accreditation. Using both quantitative and qualitative data to examine how the implementation of ISO 15189:2012 accreditation (Independent variable) over several years has affected the identified key concepts (dependant variables). To corroborate any findings and to get a deeper understanding of the impact of accreditation, the outcomes of the survey methodologies were triangulated with the quantitative data collected.

FIGURE 6 THEMES, SUB THEMES AND RELEVANT ISSUES IDENTIFIED FROM THE FGDS

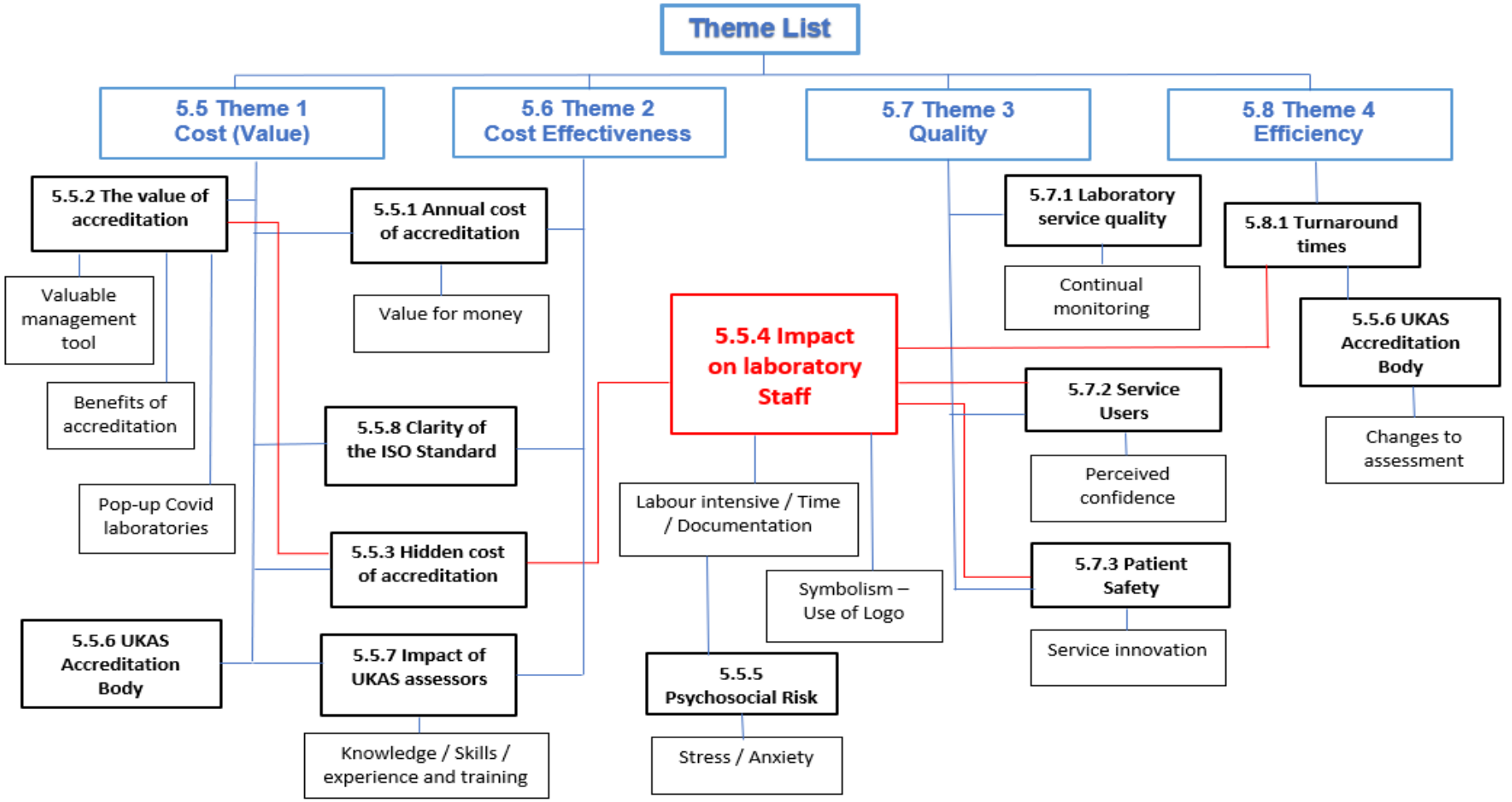
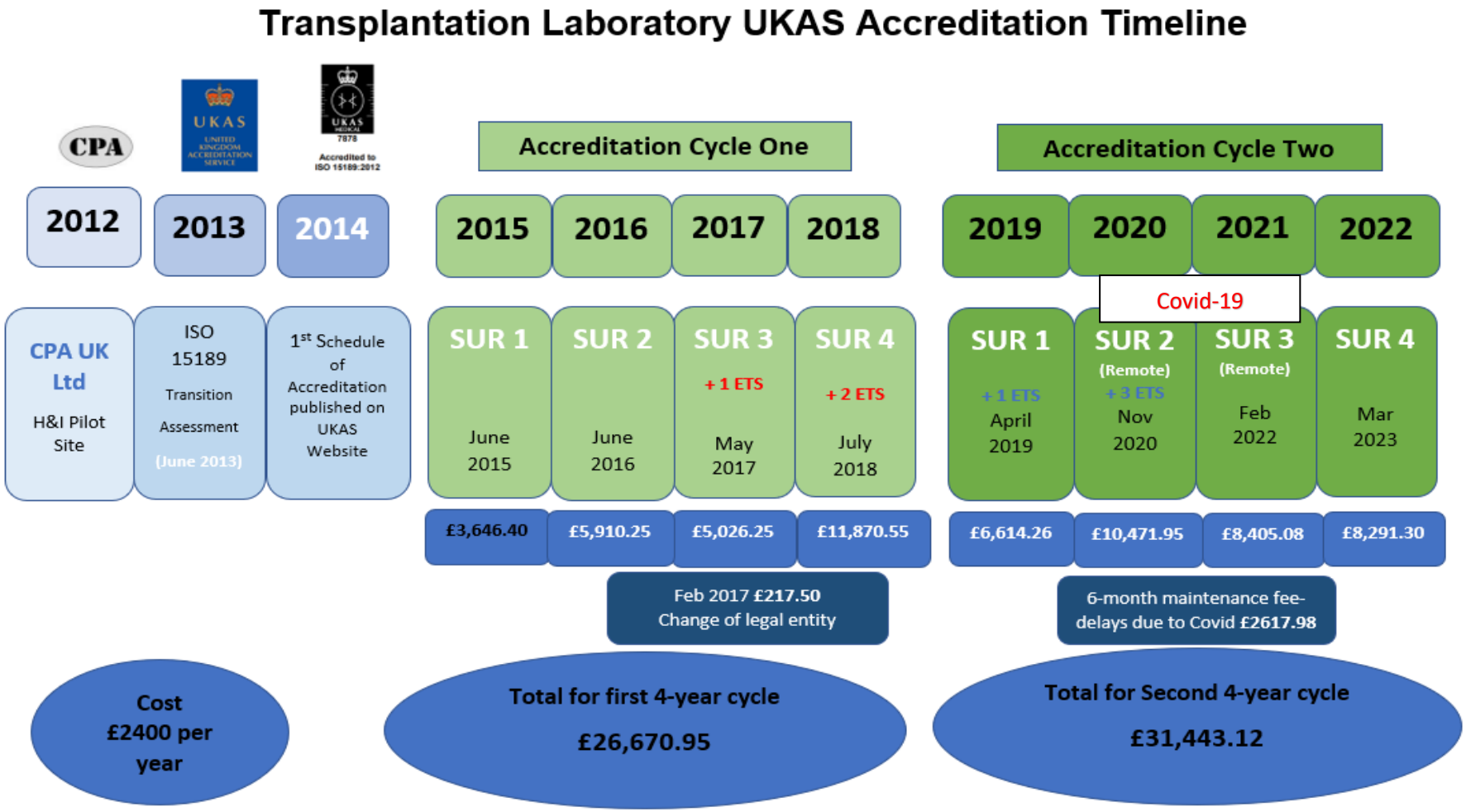


FIGURE 7 TRANSPLANTATION LABORATORY ACCREDITIATION TIMELINE



5.5 Theme 1 - Cost (Value)

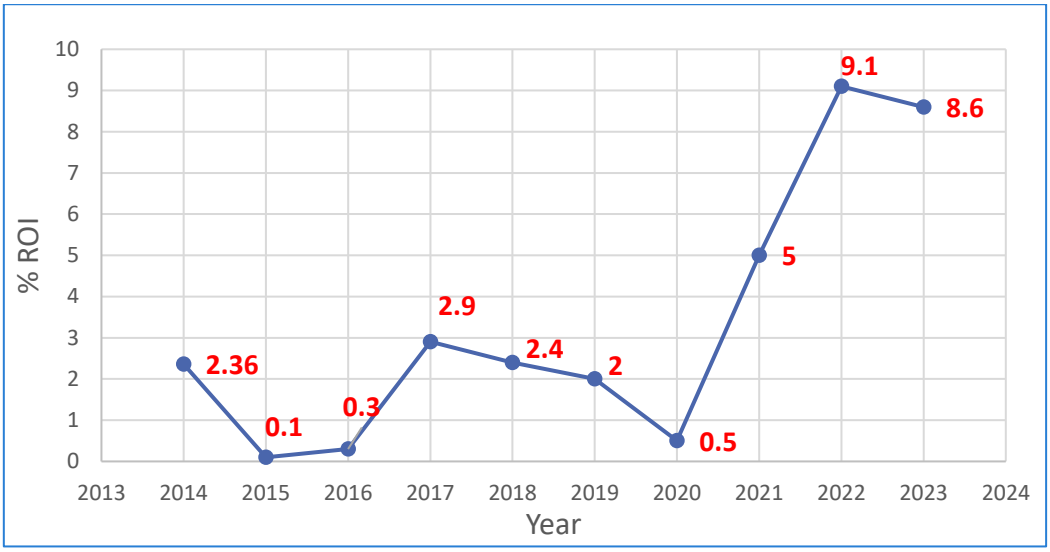
5.5.1 Sub Theme - Annual Costs of ISO Accreditation

The annual laboratory budget statements and UKAS invoices were scrutinized over the study period to evaluate the cost of ISO 15189 accreditation and any financial impact. These figures included -

- the VAT free cost of the annual UKAS accreditation surveillance visits, including site / office time and travel expenses for each of the assessment team (Figure 9)
- assessments of improvement actions and 'close outs' (Figure 9)
- charges for applications for ETS as displayed in the laboratory accreditation timeline (Figure 9).
- UKAS fees as a percentage of the laboratory budget (Figure 10)

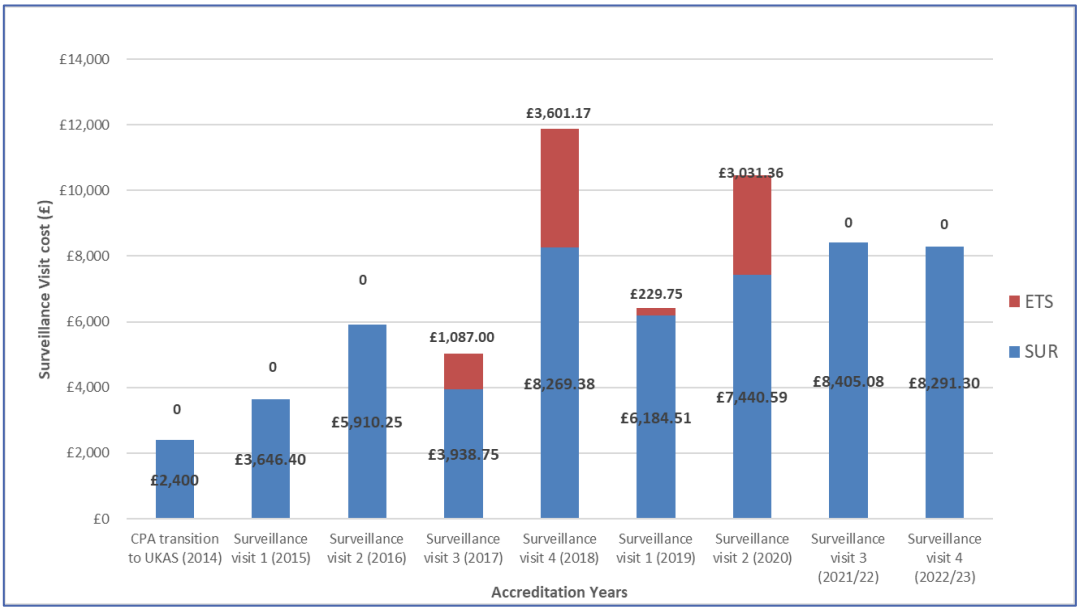
Originally, the total costs of accreditation with CPA UK Ltd was fixed at £2400 per annual on-site assessment, comprising of one surveillance visit per year and assessments of new clinical services. In the years leading up to the implementation of the ISO 15189 standard the annual cost for CPA accreditation was approximately £2400 per year with the ROI at 2.36% in pre- transition (Figure 8). Any changes to laboratory critical processes could be implemented immediately and assessed at the subsequent surveillance visit without any additional requirement for applications. The costs of the annual ISO accreditation assessments include an on-site assessment by a team of trained peer-assessors with experience and competence in a scientific discipline and an assessment manager employed by UKAS. These charges also include the office time for analysis of ETS applications, preparing reports and travel expenses for the assessment team. The financial cost for ISO 15189:2012 accreditation has fluctuated annually dependant on such factors as the number of assessors, the number of changes to the laboratory testing repertoire requiring assessment (ETS), the number of NC that arise and subsequent improvement actions (IA) and the assessors time required to approve and close these. Alongside unstable inflation rates of between 0.1% in 2015 to above 5% during the past 3 years, with 2022 being the highest at 9.1% (Figure 8).

FIGURE 8 RATE OF INFLATION (ROI) OVER THE STUDY TIME FRAME



In years 1 (2015) and 2 (2016) following the transition to UKAS and the ISO 15189:2012 standard there was an almost doubling of the annual cost compared to the previous fixed costs for CPA UK Ltd and significantly lower ROI at 0.1% and 0.3% respectively (Figure 8 and 9). An increase of 50% in year 1 (2015) and an 146% increase in 2016. With the continued demand for the laboratory to expand the service testing repertoire from both the service users and due to scientific advancement, there were additional charges observed. Each change required an ETS application, and this was observed almost annually from 2017 with some years having multiple ETS applications (Figure 7 and 9).

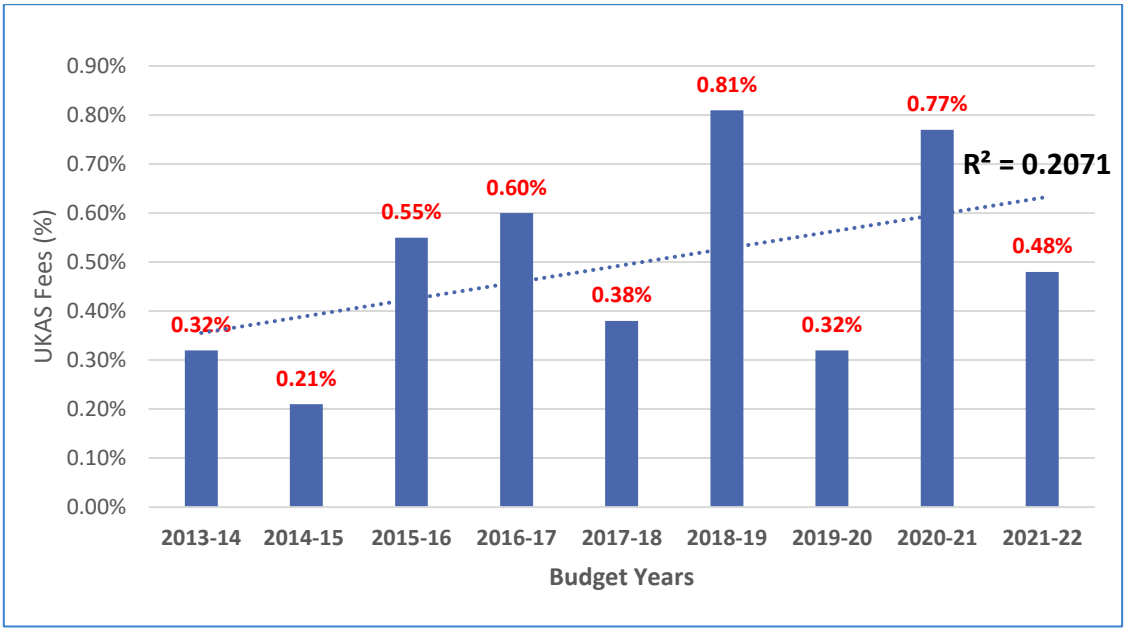
FIGURE 9 COST OF ACCREDITATION (VAT FREE)



During 2020 due to Covid-19 restrictions all annual assessment were delayed 6 months and SUR2 was carried out in November 2020 instead of May, via remote assessment using Microsoft Teams. The costs included a 50% reduction in the assessment fees due to the delay, the costs were comparable to 2019 when the assessment team were onsite. In 2018 the costs were by far the greatest due to the fact it was the fourth assessment visit of the cycle, which is intended to re-assess the laboratory's QMS in far greater detail and so is expected to take a longer at both the site and office-based time. It also included the most significant number of NC of any of the surveillance visits so far, even including the transition assessment in 2014 when the standards were novel, and the laboratory was new to the ISO standard (Figure 11). The 2 assessments (2020 and 2021/22) during the pandemic have seen a continued rise in UKAS fees even though the assessment visits had been conducted remotely. The latest surveillance visit in March 2023 (SUR 4) was again another re-assessment of the whole QMS and the surveillance costs observed was similar to the charges in 2021/2022 and also the previous full assessment in SUR4 in 2018 (Figure 9).

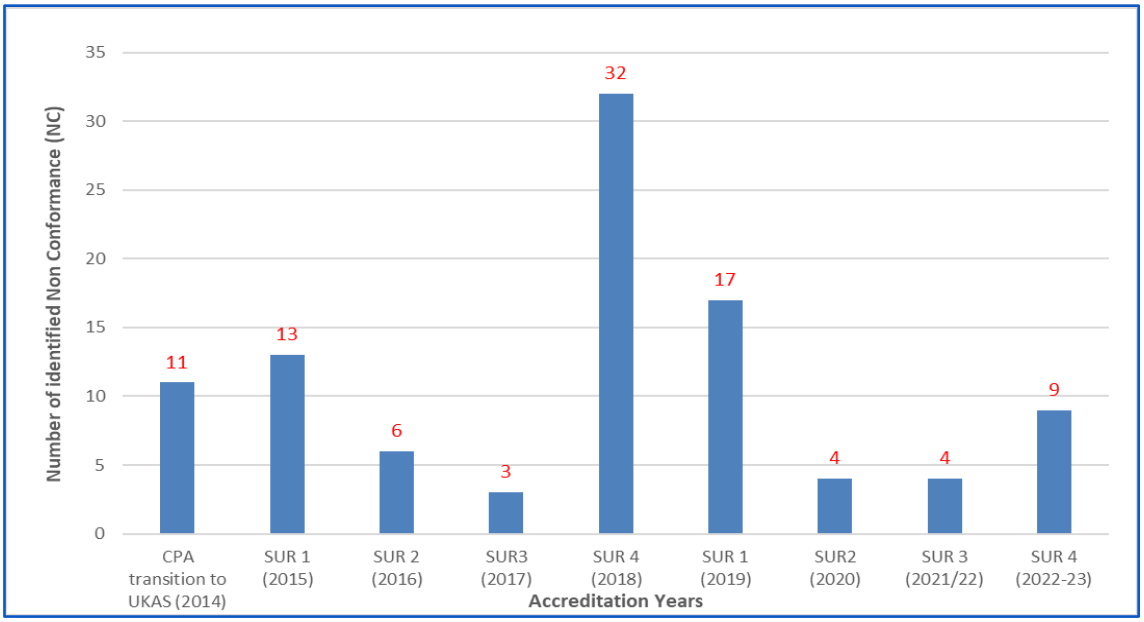
The global pandemic may have added a strain on the availability of UKAS assessors which led to the delays in the scheduled surveillance visits. The assessment visit for 2020 and 2021/22 have both been delayed by several months with the 2021 assessment finally being completed in February 2022. New Covid testing facilities in the private sector and also applications for ETS to laboratories already UKAS accredited in the private and public sectors have increased and impacted on UKAS assessors. The most recent UKAS assessment (March 2023) was also delayed by a number of months due to the availability of the assessment team. Introduced a new UKAS assessment manager, the third in as many years, who was not a medical laboratory scientist but from industry. Providing new eyes and a new perspective which may be beneficial to the accreditation process supplying another subjective approach to understanding and implementing the standard. Perhaps also identifying the possible difficulty of recruitment or retention of assessment managers and peer assessors in such specialist pathology disciplines as H&I.

FIGURE 10 UKAS FEES AS A PERCENTAGE OF THE LABORATORY BUDGET



The cost of accreditation (fees paid to UKAS) come from the laboratory budget and as a percentage have fluctuated over the period of the study (Figure 10). There is no specific allocation of the budget for accreditation fees, but it was observed that during the study period the charge for UKAS was always less than 1% of the budget spend. The biggest percentage being in 2018–19 which correlated with the largest assessment (SUR4) and the largest UKAS fee.

FIGURE 11 THE NUMBER OF NON-CONFORMANCES IDENTIFIED DURING EACH SURVEILLANCE (SUR) VISIT



As figure 11 demonstrates NC against the ISO 15189:2012 standard have fluctuated year on year. Surveillance year 4 in 2018 had the most significant number of NC identified at 32. The changes in the number of NC may reflect the subjectivity of both the standards and the assessment team. This narrative was explored during the MT FGD where further sub themes emerged around the impact of UKAS assessors (See Sub Theme 5.5.7) and the clarity of the standards (See Sub Theme 5.5.8) identifying opinions and perceptions of the participants that haven't been explored before in the literature in this context.

To obtain an understanding of the staff perception of the financial impact of laboratory accreditation the questionnaire asked if ISO accreditation was considered to be *value for money (Q3.8) where 24 (**86%**)* of the respondents disagreed, not all of which were from the management team. They were also asked in their opinion if they considered accreditation to be *expensive* (Q3.4) of which 24 of the participants (**93%)** agreed that they perceived accreditation to be expensive, including lower grade staff (Table 23). Of the four respondents that agreed that accreditation was value for money, two were band 3 – 5 and may be unaware of the actual costs. The other respondents, one was a band 6-7 and one from the MT both considered it value for money but expensive. To get a deeper understanding this would be considered further during the FGDs.

TABLE 23THE COST OF ACCREDITATION

Cost of Accreditation		MT (N=14)		CSST (N=14)			
		Band 8+		Bands 6 – 7 (N=9)		Bands 3 - 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q3.4	Expensive	14	0	9	0	3	2
Q3.8	Value for money	1	13	1	8	2	3

The analysis of the Focus group discussions confirmed the questionnaire outcomes regarding the financial impact of accreditation. The greatest voice came from the MT who clearly stated their belief that they did not consider accreditation to be value for money or cost effective (See 5.6, Theme 2). This outcome could be explained due to their senior positions within the laboratory and the close proximity of their roles to the

accreditation process. The perceptions in the CSTT group towards the costs could have been grounded in hearsay over their employment period or from the information data sheets provided for the study. The focus of the discussion in the CSTT group was the hidden costs of accreditation and its impact on laboratory staff time which is discussed in detail later (See Sub themes 5.5.3 Hidden Costs of accreditation and 5.5.4 Impact on staff).

5.5.2 Sub Theme – The Value of accreditation in the laboratory

In the questionnaire the participants perceptions of ISO accreditation were explored and if they thought ISO accreditation was of value to the laboratory by asking if they perceived it as a valuable management tool (Q1.1) from which 27 of the 28 participants **(96.4%)** agreed (Table 24).

TABLE 24 THE VALUE OF ACCREDITATION

Valuable Management Tool		MT (N=14)		CSST (N=14)			
		Band 8+		Bands 6 - 7 (N=9)		Bands 3 - 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q1.1	Accreditation is a valuable management tool	14	0	8	1	5	0
Q3.1	Important	14	0	8	1	5	0
Q3.2	Informative	10	4	4	5	4	1
Q3.3	Essential	11	3	8	1	5	0

All the management team **(100%)** and the AFC 3 - 5 **(100%)** agreed it was a valuable tool whilst one of the AFC band 6-7 had the polar opinion and completely disagreed that accreditation was a valuable management tool. To ensure that the survey respondents understood the question and were being transparent about their opinions they were also asked if they thought the current system of accreditation was *important* (3.1). A similar response was observed **(96.5%)** with the same individual completely disagreeing, which verified that the respondents did in fact consider accreditation to be important and a valuable management tool to be used by an organisation.

Again, to add validity to the responses obtained regarding the value of accreditation question 3 asked if the current system of accreditation was considered to be

informative (Q3.2) and *essential* (Q3.3). Eighteen respondents considered the current system of accreditation to be informative **(64%)** and 24 respondents, an even larger proportion considered it essential **(85%).** Overall, the management team consisting of AFC Band 8+ Clinical scientists and the lower-level Bands 3 – 5 considered it more informative than the Bands 6–7. With regards how essential they considered the current accreditation system **79%** of the MT (11 participants), **89%** of the Bands 6–7 (8 participants) and **100%** of the Bands 3-5 all considered accreditation as essential. The four respondents who didn't consider accreditation to be at all essential, three were from the MT and one band 7+. All but one of the 28 participants in the questionnaire agreed that accreditation was important and a valuable management tool.

To get a deeper understanding of these perceptions the findings were investigated and corroborated in the FGDs. The different groups conveyed the value of accreditation differently. The MT saw it quite positively as an approach to provide confidence and build trust with the clinical users (see sub theme 5.7.1). Whereas the junior CSTT group interpreted this question slightly differently and considered the importance and value of accreditation to be more directed towards the laboratory, providing the existence of a '*framework*' with which to work and to drive laboratory improvement, delivering a set of *'standards'* to be used leading to improvements in quality.

> *'I'm sure we would stick to doing things properly but It's kind of arbitrary what that properly is, isn't it? And at least this gives us that framework, like CSTT03 says, to know all lab stick roughly to the same standards in the same kind of ways of doing things. It gives you confidence if you are getting things from other laboratories as well. You know we get results from other places, don't we for patients, for example, who are transferring or things like that and it makes you trust what they've done. Because if you see that they are accredited like us you kind of assume that they're working to the same standard.' (CSTT06)*

> *'Well, like CSTT06 said, it just gives us a framework to work too. So, in the lab we know we have certain standards that we need to meet and that falls into the accreditation process. And we usually don't see the other side of it. We don't see all the paper trail and all the other work that goes on behind closed doors, so it doesn't always affect us in the same way. But we still know that we have the same standards to work too, and that works up from whether you were technologist or an MLA right up to being management level.' (CSTT09)*

The CSTT group when asked, considered accreditation to be essential and it was considered to be *'necessary'* by several participants, corroborating the outcomes of the questionnaire where 13 **(86%)** of the respondents viewed accreditation as 'essential', but not necessarily value for money.

> *'So, like the fact we need to be accredited to be used by labs for bone marrow for example, like that sort of stuff. I suppose that would be why you could say it's necessary, but I think it's useful to have a set of standards that we work up to and to inform the patient that had considering how disjointed the services generally or the different. I mean, you see that selecting of bone marrow donors on this as an example of it, the different processes and practices performed by every lab. So, I think it's more from that side that I'd say it was useful. Obviously, whether or not you get value for e, is a different question.' (CSTT03)*

> *'It's obviously necessary, so as much as some people seem to, you know, love it or hate it more than others. It's just it's needed, isn't it? And I think even if it wasn't, it would be right to regulate yourself in some way, as a department wouldn't. Even if we didn't have to do all the things that we do. I mean, it can feel a bit repetitive at times. You know, the way that you have to audit? Like every single process, even though some processes might be similar to each other and maybe you know if we could think about sort of streamlining things in some way and you know when we're trying to improve the processes by having, say, Q pulse rather than other systems that we've had in the past and we are trying to make it so that it takes up less staff time, but you know, everyone just needs to have a, uh, attitude of well It does need to be done and there's a reason why it's done, and it does impact positively on patient care. Erm but it does, it does just feel like quite a lot sometimes, doesn't it, but it is. It is necessary, so I think we all just do the best that we can, don't we?' (CSTT04)*

Although one of the CSTT participants did refer to accreditation as a *'necessary evil'*.

> *'And I think it's one of those things, isn't it? We all know how important it (accreditation) is. We all know we have to do it. We all know it's essential but sometimes it can feel like a lot of work for something that we don't necessarily all personally see the benefit of.' (CSTT06)*

The MT FGD emphasised continual improvement as an important and positive role of accreditation leading to it being considered as a valuable management tool. Whilst

the CSTT just considered it to be a ‘necessary’ process providing a framework with which to achieve and maintain accreditation. Whilst reflecting on the value of accreditation the majority of responses took a positive note emphasising within the MT new developments that accreditation had brought to the laboratory leading to consistence and continual monitoring.

> *‘One thing I did like about accreditation even though the standards were ridiculously, was the measurement of uncertainty because I think it made us look at our assays in a better way and in a more scientific way that we haven't done before, and I think it makes us pay more attention to whether or not they're working properly, even if it's difficult to, Uh, achieved for all our different H&I assays. I feel that that's a really positive thing and I do feel that our systems are better for us having looked at them in that area.’ (MT01)*

> *‘In terms of the training as well, It has made us be more consistent with our training, uh, which has improved the quality of the training, and that's reflected in the results, the consistency of the results that we get.’ (MT07)*

> *We've certainly put ways of, you know ways of measuring things and I obviously, as I say, you can put, you can take these things too far, but ways of looking at how we are producing results and the quality of those and what we can do to make them better in a way that perhaps we might not do if we weren't having to look at the way that ISO we're looking at it, for example.’ (MT02)*

The suggestion that accreditation was seen as a ‘necessary evil’ was interesting and gave a possible negative slant to the participants perceptions of accreditation. This may well be explained when further analysing the data provided by participant CSTT06 who during the FG had a similar negative narrative to a number of their responses.

> *‘I think it probably makes us constantly assess what we're doing, doesn't it? And sometimes it you need to assess whether what you're changing effects other things, and by doing the audits, that kind of forces us to do that, doesn't it?’*
> *‘Well, it's for all of us, isn't it? I mean, in some respects you could say the people actually doing the tests its almost more important because they're the ones that have physically abiding by the rules set out that we have to do. It's it applies to everybody, doesn't it coz it applies to the whole process from the doing, the test to*

the report of the test to the checking of the test. So, it's it applies to everybody.' (CSTT06)

A further issue emerged during this discussion relating to the Pop-up covid laboratories that had appeared during the pandemic and laboratory accreditation. This participant's opinion of the importance of accreditation in this situation were conflicting, identifying the role of accreditation in this context to be crucial at that time.

'I think the stuff that's been in the news recently has kind of proved why you need accreditation. The whole scandal with the COVID testing done by a lab that wasn't ISO accredited and look what happened there.' (Laughing) (CSTT06)

This sentiment was also corroborated by a participant from the management team.

'I suppose we've had some really good examples within the past two years with all the pop up COVID labs that yeah, have happened and actually the fact that really most, a lot of them have not been accredited to the same level and we know because it gets reported. We obviously only know the tip of the iceberg, but we do know of a lot of the issues they've had with the training of the staff, with the processes that they've had and the results coming out that you know well, basically, you know the impact of the fact that they haven't had accurate results, and we are obviously we're not internal to a COVID lab. Actually, had they had inspectors go in would these things have been picked up?' (MT03)

Indicating potentially that the participants considered accreditation vital to laboratory services. Considering that the changes made to the UKAS assessments carried out during the pandemic due urgent need were perhaps not as robust as they might have been before the pandemic (UKAS, 2020). But the participants in both groups identified that the general public were conceivably more aware now of accreditation and its value. Where now more than ever the importance of medical laboratories had come to the fore and the failings of these laboratories where a bad reflection on all accredited laboratories. Suggesting that the participants were proud of the accreditation status of the laboratory.

'Yeah, I was just going to follow up on what (MT03) said because I saw a lot of heated arguments on Twitter and social media around this. What (MT03) raised about COVID and lab testing and certainly the public were aware of accreditation,

and they weren't necessarily scientists that we're bringing it up. And I thought that was really interesting.' (MT05)

'I was gonna make the point about what MT03 and MT05 made about the pop-up COVID Labs, and I saw all the Twitter feed on that, and it was non-scientist who were commenting on it, and it was eroding public confidence in scientific services. So, I think now more than ever we need to have that confidence there that, that laboratories are providing a service that has been reviewed by somebody else and deemed acceptable.' (MT12)

The management team were vocal with regards to the benefits of accreditation discussing the new processes that have been introduced as part of the QMS and the ISO standard. Describing the introduction of the measurement of uncertainty and the training and competency assessments into the laboratory and the significant impact these have had on improving systems and processes –

'One thing I like about accreditation and the standards were ridiculously, the measurement of uncertainty because I think it made us look at our assays in a better way and in a more scientific way that we haven't done before, and I think it makes us pay more attention to whether or not they're working properly, even if it's difficult to, Uh, achieved for all our different H&I assays. I feel that that's a really positive thing and I do feel that our systems are better for us having looked at them in that area.' (MT01)

'I agree definitely, but I also wanted to make a separate point that I think that as a result of looking at ISO, asking us to provide documentation of training and competency I think the introduction, which is as a by-product of that, but we may well have come up with it anyway. But I think that as a team introducing the key trainers has been a really good and very helpful development in how we train folk. So yes, OK and we may well have come up with that, but I do wonder if we've come up with that because we've had to answer a number of questions to inspectors about training and competency. And actually, some of that I realized this has been erm, what's the word? Not difficult? Involved maybe, but I do think it's been a major development to have to have key trainers. I don't know if anyone else would agree with that or whether they think there's actually nothing to do with accreditation, which of course it may well not be.' (MT02)

'Yeah, I would agree with MT02 in terms of the training as well. It has made us be more consistent with our training, uh, which is improved, the quality of the training,

and that's reflected in the results, the consistency of the results that we get.' (MT07)

The implementation of further processes that have all lead to the continual improvement programme used in the laboratory may be considered by the participants as the most significant benefit and desired consequence of accreditation.

'A separate example is It makes us review regularly and investigate our repeat rates and turnaround times and SSO being a prime example of Uh, when we have been monitoring repeat rates over time and investigating issues we have now seen a significant improvement in those repeat rates are being recorded, so I think that has given us a measurable improvement there and the fact that we could argue that you change the staff, you changed the kit over time as well. So, by having accreditation it keeps you checking these things over time. You don't just implement something and check it; you keep checking and also the way we have to document any incidents. So, the system review process is the way we have to think about preventative corrective actions and then follow up on those actions. Obviously helps us continually improve our processes.' (MT07)

'Obviously, that's not visible to the patient or even to their clinician, but it hopefully is to the people who are working in the lab that they can see that actually we're doing quality improvement essentially.' (MT02)

The discussion also led to the emergence of a further sub theme indicating the hidden costs of accreditation identifying the negatives of accreditation.

5.5.3 Sub Theme - Hidden Costs of Accreditation

The literature available around accreditation as an intervention for improving quality has exposed issues around hidden costs of accreditation and the possible negative effects (Wilson et al, 2016). The narrative amongst the FGD's demonstrated that documentation required for the routine management of the QMS, the preparation for; and during the accreditation assessment was seen as a consequence and, corroborates existing evidence (Gough and Reynolds, 2000; Wilson et al, 2016; Buchta et al, 2018) and is discussed further in section 5.5.4.

Both teams during the FGDs discussed these hidden costs of accreditation with differing opinions observed between the groups which is to be expected due to the diffing roles of the two groups. In the CSTT group the hidden costs were described

initially as costs to the laboratory identifying all additional expenses incurred by the laboratory since the implementation of ISO accreditation –

> (*Nodding) 'Yeah, I agree, the maintenance of equipment and then there's all the NEQAS schemes and all that kind of stuff. And then when you're either training or become a clinical scientist, even personal cost, you have to pay for your registration.' (CSTT07)*
>
> *'There are so many hidden things like every year we have to pay eh, the Q Pulse licence and there are so many hidden things people don't realise. And if you were to, add up, if you were to add up not just the um, the cost of the ISO costs, but also, like CSTT07 said, about maintenance, and I think we would be shocked just how much, how much it adds up to.' (CSTT05)*
>
> *'But overall, I think it is important that we do it but whether you know you've got the cost of like the time that it takes to do something or even down to like reagents and stuff it takes, It takes the cost of different reagents which are expensive to, you know, validate kits, and follow through audit trails and stuff, it's hard to sometimes see the point of it, but oh well. If you then step back and you look at the bigger picture, obviously there is a point to it.' (CSTT08)*

Which led the CSTT group to acknowledge the importance of accreditation but also the significant impact it places on the workforce with the amount of time designated to the accreditation process as one of the most major hidden costs.

> *'It's a really good point that if everybody worked out how much time, logged the time each week as to how much time they did spend on quality issues and accreditation and it really makes you wonder how much, what the total bill would be. I think we'd all be shocked.' (CSTT05)*
>
> *'I generally in my experience with the accreditation I don't have any great issues with it, and I understand why we carry out accreditation and understand how it can benefit myself and the patients. Uh, other labs as well. It's yeah, just mainly the cost. I just erm the cost and time that it takes it. It's a lot of a lot of work for something that you do, it never feels tangible.' (CSTT01)*
>
> *'It's just the same as CSTT06. It's just that you're using everyone from the technologist, MLAs upwards and you know all our time comes at a cost. So, by*

the time you've dealt with all this documentation, all the testing and everything, it's a lot of man hours that equal a lot of money.' (CSTT11)

Which was corroborated by the MT, again where the narrative focused on the impact on the workforce developing a further significant sub theme for the study.

'But there's also the fact that there's so many man hours there tide up with the documentation and the processes that I'm sure many people as well feel that they could spend their time better actually at the bench doing the work. Not saying that the work isn't getting done but, it's just it's competing with the work, isn't it?' (MT11)

5.5.4 Sub Theme – Staff Involvement in accreditation

The quantitative outcome from the questionnaire (See Appendix 18; Staff Questionnaire Outcome) identified that nearly everyone disagreed that accreditation had no impact on their job role (Q1). When the participants were asked about their involvement (Q1.4) in accreditation two thirds disagreed that their involvement was minimal, **(64%)** indicating their participation in accreditation activities were having a significant impact on their workload which verified responses seen in a separate question regarding whether they considered accreditation to be labour intensive (Q3.6). There was a significant impact on the involvement of laboratory staff with regards to their workload and duties (Q1.2 and Q1.3). The outcome of the survey identified that 100% of the respondents agreed or completely agreed that the current system of accreditation was labour intensive (Q3.6), with significantly more of the Management team completely agreeing **(64%)** perhaps identifying that this group are affected significantly more than any of the lower grades or are perhaps more invested (Table 25).

TABLE 25 STAFF INVOLVEMENT

Staff Involvement		MT (N=14)		CSST (N=14)			
		Band 8+		Bands 6 – 7 (N=9)		Bands 3 – 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q1.2	Accreditation has no significant effect on my day-to-day duties	0	14	6	3	0	5
Q1.3	Accreditation has no significant impact on my day-to-day workloads	1	13	2	7	1	4
Q1.4	My involvement in accreditation is minimal	0	13	5	4	4	1
Q3.6	Labour intensive	14	0	9	0	5	0

To obtain a greater understanding of laboratory staff involvement in accreditation and its impact the data captured from the open question (Q6) in the questionnaire was analysed.

TABLE 26 NUMBER OF RESPONSES TO QUESTION 6 (OPEN QUESTION)

Written Responses Provided	No. YES	%
Total (N=28)	21	**75%**
Laboratory Management Team (N=14)	13	**62%**
Clinical scientist /Technical / Admin Team (N= 14)	8	**57%**

Of the 28 participants that returned the questionnaire 21 (75%) of the participants answered question 6. 13 (62%) of the respondents from the MT group completed the question whereas only 8 of the 14 (57%) CSST group answered this question signifying that either they have no direct exposure to accreditation, or it is perceived

that way. On analysis of these response, it was clear that the MT had the most direct exposure with the assessment specifically during the assessment explaining perhaps why more of this group answered the question. (Table 26)

TABLE 27 DESCRIPTION OF INVOLVEMENT – WRITTEN RESPONSES TO QUESTION 6

Involvement with Accreditation	MT (N=13)	CSST (N=8)
Surveillance visits	9	4
Conforming to standards	2	0
Improvement actions	2	0
Creating Documentation	4	1
Following procedures	0	1
Implementation of new techniques	2	1
Admin / QMS	1	1
Training staff	0	1

The CSST group described their participation in the accreditation process from simply just following procedures day to day, to creating documents such as SOPs, validation reports, to the implementation of new techniques and participating in the assessments by speaking to assessors or being directly observed as part of the assessment visits. One band 6-7 described training of staff as a consequence of accreditation which was considered to impact on their workload. Whereas the management team defined their participation in accreditation more directly by being involved with the preparation for the assessment visits by preparing reports, and other documents and by participating in audits and ensuring compliance. By being involved in the validation process for new techniques, creating and maintaining policies and procedures and post assessments implementing any required improvement (Table 27). This demonstrated that in the opinions of the participants accreditation had directly impacted on workload and duties of laboratory staff at all levels to varying degrees. It became clear that most of the participants had been involved in accreditation in some way. (See Appendix 18, Staff Questionnaire)

When the effect of their involvement and the impact of accreditation was discussed during the FGs it was evident that accreditation could be considered by the participants as a negative experience. The focus of the discussion had a significant emphasis placed on the direct impact accreditation has on laboratory personnel in both groups developing the notion of it being labour intensive.

> *'I think it's the manpower thing, isn't it? Because we're always short staffed, and its prioritizing things, isn't it? So, it can be sometimes quite difficult to fit in that validation work, but also keep in your turn around times, right for the patients which I think we all probably feel is the most important thing. But equally you want to do the new things because you know that could improve things for the patients. So, it's finding that balancing act isn't it.'*
>
> *'Time, yeah, time because as mentioned previously, well it's the common thing isn't it. There are never enough people and it's yeah it can be quite labour intensive sometimes.' (CSTT06)*

One aspect discussed by the CSTT group was their perceived increase and use of documentation required for the accreditation process and the impact this may have on staff time and workload. This confirmed findings previously highlighted in the literature, that accreditation was perceived as labour intensive by laboratory staff (Gough and Reynolds, 2000; Wilson et al, 2016; Buchta et al, 2018). This observation was to be expected as this particular group of participants form the portion of the laboratory personnel who are most likely to be significantly impacted by this additional workload without any clear value being observed –

> *'Yeah, I think it's easier to see the direct result of having to spend time doing validations and everything and you can see the amount of time gets put into those and it takes away from working on patients' stuff, but it's harder to see potentially the impact of all that audits and validations. And whether they improve things over a longer period of time, I think it can be harder to see the results of that.' (CSTT07)*

> *'We need to make sure that you have evidence of it to be able to prove the process you've gone through to get to the decisions you've made in. Be able to verify it, and that gives you traceability for if something does go wrong at the other end, or it can also help inform further practice. By looking back at what was done previously, so I'd say a lot of documentation comes from that.' (CSTT03)*

But whilst all these comments seemed to reflect a negative feeling towards accreditation, the participants also recognised the importance of any documentation required for accreditation –

> *'It's about documenting everything, and it makes it easier when you want to go back, you know, because we've had it in the past where we've assessed a piece of equipment decided we didn't like it, and then three or four years later it comes around again and we don't have to assess it again, because we've already decided we didn't like it, or we can assess it again because it may well be that things have changed in lab. We might have a different technique that it may be valuable, but at least we've got the previous documentation to say why we didn't like it in the first place, for example.' (CSTT06)*

Justifying positive approaches to accreditation that signifies its usefulness.

> *'Yeah, I think it's good that we do audits and everything, then we can make improvements and check that, nothing that we've changed has changed other things as well and, yeah, it's important that for patients that we are accredited, and I think like day-to-day probably affects us like time wise. It's like having to do extra things like put stuff on audit databases and yeah, just cost as well has a big impact.' (CSTT08)*

> *'We need to make sure that you have evidence of it to be able to prove the process you've gone through to get to the decisions you've made in. Be able to verify it, and that gives you traceability for if something does go wrong at the other end, or it can also help inform further practice. By looking back at what was done previously, so I'd say a lot of documentation comes from that.' (CSTT03)*

A further issue emerged around symbolism where accreditation was considered by the MT as a *'logo'*. The use of the UKAS logo, an emblem of quality, on patient reports was deemed by the MT as the crucial part of signifying accreditation status. The concept of not being able to use the UKAS logo on a report until the procedure had been verified by UKAS and added to the scope of practice raised concerns. Senior managers were concerned by having to remove the logo from reports because of how it could appear to service users, that accreditation status and quality are an issue for the laboratory. Plus the impact on staff having to amend reports or add the comment to state that the laboratory may not be accredited for a certain technique posed concerns for the MT.

'I think it's really unfair that we all take the logos off of something that we've, validated within an inch of its life.' (MT05)

'I just think that why can't you use it? It's just silly that you can't have it on a report when you validated something, and they've been in before and inspected the lab for previous techniques and been happy with what we've done. It just seems pointless that you know you have to wait until, they give you the thumbs up there.' (MT12)

'It's just silly you can't have it on the report when you've validated something, and they've been in before and inspected the lab for previous techniques and been happy with what we've done. It just seems pointless' (MT05)

'I think for me it's not the logo and actually using the logo cause I don't really care. It's the thought that we are not accredited to use that technique despite having gone through the process, in order to do the validation and that our users who may rely on this and if that's the truth then they may be looking at our reports thinking Oh they're not accredited for that because we are actually meant to state on it, aren't we? That we are not accredited to do that particular task.' (MT01)

From the perspective of the CSTT, they saw this symbolism and the use of the logo slightly different to the MT. They discussed their concerns being as discussed by the MT as the impact on workload to achieve the *'logo'* and its impact on the laboratory personnel.

'It's a lot of a lot of work for something that you do, it never feels tangible. Uh, obviously I know we then get to put all the logo on all of our reports, but just for the effort you sometimes think, oh, you know you don't really see much for it on a day-to-day basis.' (CSTT01)

'It just depends on your viewpoint of it like whether you look at it as a day today or whether you look at it, say a wider picture because obviously, it is of benefit when you look at overall, if you look at the bigger picture it's not just like a logo but when you're doing stuff day today, you do think, oh, for God's sake, you know we've got do this all over again.'(CSTT08)

This added new contextualised knowledge to the paucity of evidence around accreditation and was a novel concept absent in the current literature. Although the participants perceived accreditation to be valuable and important, they also appeared to perceive it to be just *a* symbolic gesture of laboratory quality.

'So, for all that time effectively we're really not accredited if we can't put their logo on the reports and I'm not really sure about the principles surrounding that, I feel, that having inspected us they have an obligation to allow us to use their logos, even on a provisional basis, until they can ratify our new techniques, extensions to scope that we've submitted in good faith.' (MT01)

5.5.5 Sub Theme – Psychosocial risk

The accreditation surveillance visits (SUR) were considered to have a compounding psychosocial effect on the laboratory staff which was also reflected upon during the focus groups developing a further sub theme. Its impact was felt even at the management level where adding extra pressure causes workplace stress.

'My negative aspects might just be my personal opinion, but sure, everyone doesn't really enjoy that experience of being inspected. It's stressful. And it shouldn't be I suppose if everything was in place, and everything was a dream, but you can't deny it's a stressful experience to be inspected.' (MT07)

Its impact on the day-to-day workload was further acknowledged by the management team describing stress and anxiety when *'trying to fit things in alongside their daily job'.*

'Yeah, this will be probably controversial, but it's just It's obviously caused stress and anxiety to people trying to fit that in alongside their daily job. And I know it's important and I know it has to be done, but it does cause some stress particularly as we've seen over Covid, when we've had unexpected isolations, not saying it's not important at all but it has added extra pressure.' (MT05)

The CCST group also corroborated these opinions of the management team when discussing the amount of work involved with accreditation during their working day.

*'I think we can all agree that it sometimes can feel a bit overwhelming' (*Documentation*). (CSST06)*

5.5.6 Sub Theme – UKAS: Accreditation Body

The debates around the costs of accreditation and their perception of its value developed within the FGs and a further sub-theme was exposed which was novel and undocumented in the literature around accreditation. The MT began to reflect on the accreditation organisation, UKAS, and how public sector workers especially in the

NHS tend to be suspicious of the motives behind private sector organisation like UKAS.

> *'Yeah, I think, I don't want to get overly political, but I think possibly, as well, I think people who work for the public sector they do tend to be a little bit sort of suspicious about the motives of private organizations, and so I'm quite surprised actually that something as big as accreditation, especially for medical laboratories, it's not a public body which is responsible for overseeing and monitoring the accreditation of labs in the UK. I think people may have more confidence in the system if it was under public ownership, but that doesn't mean to say that I'm anti-privatisation it's just, you know, it's just something that I think most people who work in the NHS may feel.' (MT11)*

One of the other MT participants commented about UKAS's 'not-for-profit' status as an organisation which caught the attention of the group.

> *'Just to come in on that (MT11), UKAS is actually a 'not-for-profit' organization supposedly, although when you look at their annual report, they make about £1,000,000 profit surplus a year. So, it's a bit of a woolly one that's meant to be reinvested back in. Apparently, that's what 'not for profit' means, but yes, I would agree with you that it's uh, not transparent, shall we say.' (MT03)*

With another describing UKAS as *'a monopoly'* corroborating a previous finding in the literature where UKAS was described as 'becoming a cartel' (Wilson et al, 2016) as the UK's main accreditation service which isn't open to competition. This developed further emerging themes around UKAS and its function and the subjective role it has.

> *'For me, the biggest thing that I find difficult to come to terms with is the way they that UKAS, Uhm, dictate that we need to use UKAS accredited, companies just to maintain our centrifuges or to perform services for us so that they will then be happy with the level of maintenance and I do understand that it's all about standards, but it looks like it's a monopoly, it doesn't look quite so open and honest and open to competition anymore and it is driving up prices. That's for me one of the things I find most difficult to accommodate.' (MT01)*

In the CSTT group, one participant view of the whole process of accreditation identified and accepted the necessity but indicated that they considered UKAS in a suspicious way.

'I think the actual costs sometimes can feel like a lot, and it feels like someone is trying to make some money somewhere. You know the ISO inspections and the fact that they charge you when you want to introduce a technique can sometimes feel a bit. I don't know, not, right?' (CSTT06)

The service quality provided by UKAS as an organisation was brought into question, discussing the organisational TATs and its accountability and the MT had negative opinions of UKAS –

'I mean, that we've had the service from them, I'm not sure about the quality of service because we're still not been signed off for the extension to scope, because they haven't decided and you know, even to the smaller point where we've tried to get trained as inspectors, there isn't that responsiveness on their side, so I don't. I'm not entirely sure we're actually getting, you know, value for money or cost-effective for ISO specifically.' (MT03)

'Going back to the turnaround times, I always feel the quality organization should really lead by example and they should be quality really because if you're going to go and inspect a laboratory and you're going to say right? Why are these, turnaround times not meeting these targets. I think they can't really say that if you can't even meet your own targets.' (MT13)

One member of the MT group considered the efficiency of UKAS and how the speed with which they dealt with the applications to extend the scope of practice can impede service provision.

'I have, one thing that I feel is very negative is that although annually we pay, and we get inspected and we change our scope as quickly as we can. UKAS is extremely slow with that and in the time that we've submitted an application to extend our scope to allow a new typing technique to say, be processed. It can take them over a year to get back to us (referring to the Flexible Scope application) *and in that time, we might have moved on and we might be using that process routinely because that's how our service works, but we're not allowed to use their logo.' (MT01)*

This introduced the concept of the potential concerns the MT have with UKAS including issues with their perceptions of UKAS TATs and service quality. This could possibly contradict the outcomes from the questionnaire with the perceived value of accreditation being less favourable particularly from the experience and

opinions of the MT participants. This concept was not as emotive in the CSST group, with only one individual having an opinion in this area which may be perceived from interacting with the participants of the MT. This is only to be expected as the MT have more direct exposure and interaction with UKAS.

5.5.7 Sub Theme – Impact of assessment team

The UKAS annual surveillance visits (SUR) are carried out by an assessment team consisting of one or two peer assessors with the appropriate competency and an assessment manager employed by UKAS. These experienced trained assessors can vary each assessment visit. This may be beneficial to the process providing new opinions and fresh eyes, which can be invaluable for those embedded in a system. There is also the potential impact of these different opinions and perspectives when interpreting the standard. This may have an impact on the assessment outcome, bringing into question whether these standards are really genuine indicators of laboratory quality when there is no consistent interpretation and are reliant solely on subjectivity? The subjectivity and the potential inconsistences of the accessors when interpreting the standard during the assessment visits was examined during the FGDs. Where it was identified by the laboratory staff in the CSTT when discussing the assessment team.

> *'I think it's also useful sometimes the fact that you do have different people coming in with different perceptions on how, how somethings are interpreted because you may then get suggestions that you haven't seen, you haven't thought of yourself because you haven't had that experience, so I think there's something to be said for personal experience. But obviously, it's when it goes the other way and people end up judging you against their standards when you both might be right that you get the problem. So, I think it comes down to the assessors more than anything and their approach to work and quality.' (CSTT03)*

Both teams described how having the assessors onsite were sometimes seen as a potential advantage with their perceived knowledge and experience, identifying issues perhaps not obvious to those embedded in the process.

> *'Yeah, I was just going to say the same, it's probably good to have someone from the outside looking in and checking to get their opinion.'* (CSTT08).

'Considering how long we've done CDC for, and it's never occurred to us to assess that has been someone else's opinion and someone else coming in. Has been really useful and it's flagged up extra training issues that we perhaps weren't aware of and that can be actually where it's good that there's a bit of interpretation involved with the guidelines.' (MT10)

'It shouldn't just be like one person makes this decision about a whole lab, but also as well, the assessors will have a lot of experience. You're not going to have somebody who has only worked as a scientist for two years coming in doing the assessment so they will have seen a lot of different labs. They will have seen a lot of different processes, and you just have to trust their knowledge and their experience is trying to make your lab be better and it's all about improvement. It's not really about trying to like to say, somebody's worse than somebody else. It's about trying to improve everybody all the time, isn't it?' (CSTT04)

Another commented on the importance of the assessors training.

'I think, I think you'd hope that the assessors as part of their training would be trained to work in different ways and work with people and understand that everywhere works differently.' (CSTT05).

The inconsistencies between the different assessors were not necessarily viewed as a negative by the CSTT group. The findings from the MT FGD around this theme was less prescriptive and they considered peer assessors post-inspection outcomes favourably as 'valuable', with one of them expressing it from their own position as an inspector, considering themselves to be objective.

'Yeah, so I think for me what it comes down to is, I suppose, as a scientist you know it's external peer review of our service effectively and certainly as an inspector going elsewhere. That is something that you know, you know the systems, you know the standards that you're expecting, and you can look at it objectively.' (MT03)

Others too especially within the MT, valued the feedback, finding it beneficial to the laboratory in improving system and processes.

'And I think that's how it helps improve because you've got someone else coming in to look at you and say OK, you know it's valuable to get the feedback really. Generally, I might contradict myself later on when, you know, in some parts but generally I think accreditation is helpful'. (MT05)

'So just in terms of streamlining things in the lab or I am thinking about the whole process. You can actually get feedback as a result of an inspection that means that you put into place systems that make what we do better, and I don't mean necessarily, obviously, that's not visible to the patient or even to their clinician, but it hopefully is to the people who are working in the lab that they can see that actually we're doing quality improvement essentially; I suppose. I realise not always, and I realise these things can go to the NTH degree, but I think you know, overall, I've seen that definitely, you know, Yeah, I've seen, I've seen progress, I suppose.' (MT02)

Also finding it as a positive experience which helps to improve patient services by ensuring that the focus is placed on things that might very well be overlooked without these assessments.

'I just thought of another example to what MT02 was alluding to. MT02 was talking about, and it was through the ISO inspection looking at the difference in the performance of the different instruments in the department. So, for example, differences between the two are now three LABScan or the two light cycler's and looking to see if there's any variation in those. That's something that we didn't particularly look at I don't think before the ISO inspection, and I think that's beneficial because we can see that there has and is a difference between those. Then it will help us put better procedures in place. Uh, and it has done. If you know we've had issues with those particular assays.' (MT12)

5.5.8 Sub Theme – Clarity of Standards

The ISO 15189:2012 standard used in the assessments were also discussed between the participants in a negative way, where it was commented on the subjectivity and generalisability of the ISO standard.

'I think one thing we have to watch is the UKAS standards, they are quite open to interpretation.' (MT13)

'I know it's not about EFI, but I think this is maybe where we have the difference with you've got ISO UKAS that is also for Medical Labs actually are still very generic and trying to write a standard that fits every kind of lab and every kind of you know diagnostic service within those labs into the same standard. Which is maybe why to some extent EFI is a little bit more understandable because it is just H&I. So generally, the processes are the same, but when you're trying to compare us and a Biochem lab and a virology lab, and you know Histology, that's does bits

of tissue, it, it's those processes that are going to be very different. But somehow, we all have to meet the same standard. So, I think some of the, the intended, I suppose the way it's been interpreted as a) How does each field interpreting from for themselves, but b) They've left the wooliness in there almost on purpose, cause if you write it too clearly, then, it might not actually apply to some, I don't know.' (MT03)

'Absolutely you've only got to read them. You could have like 15 interpretations of any one thing at least depending on the people you ask.' (MT13)

It was also clear from the narrative that the MT thought that the standard needed to be reviewed and updated to enhance the clarity, which could make the interpretation by the assessment teams easier.

'In certain areas of the standard when you do read them the clarity could be improved, so I think I would set the campaign for plain English onto them (UKAS) because they can be quite difficult to interpret so I can see MT13 point there where you might think you've addressed something and then another point could be raised as a result of it. So, I think if you're going to have standards, they need to be really clear in what the purpose and what they're asking you? Maybe it's the way they're trying to say it, not what they're saying. It's just an improvement in the clarity of what they actually mean when they're asking for something.' (MT12)

But by having a single standard suitable for all medical laboratories will always allow for differences in interpretation dependant on the scientific discipline. Using discipline specific peer assessors would potentially minimise this but the discussions have yet to prove this. The continual changes in NC against the same standard using the same peer assessors, signifies a potential issue with the interpretation of the standard bringing into question whether this type of assessment is appropriate to establish and ensure laboratory quality.

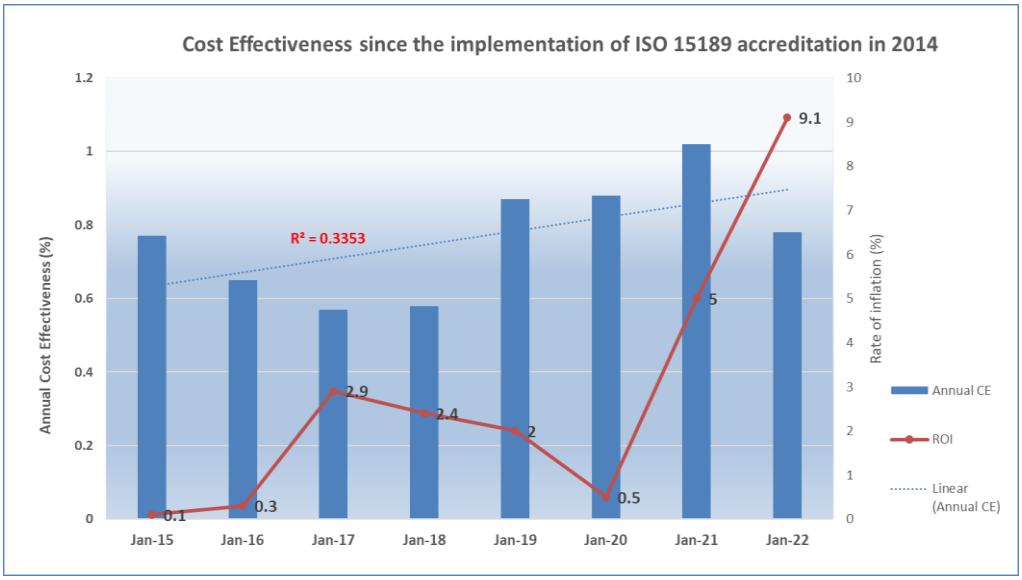
5.6 Theme 2 – Cost Effectiveness

To determine if ISO accreditation as a quality improvement intervention is appropriate for an NHS specialist pathology laboratory cost effectiveness analysis was also determined using a tool (See Equation 1, Chapter 4, page 91) developed based on the concept design by Hamza et al (2013). Using equation 1 the annual cost effectiveness was calculated for each accreditation year post implementation of ISO

15189:2012 accreditation in 2014 calculating the annual cost (cost per test) and the consequence of the intervention of ISO accreditation (number of non-conformances per year and percentage compliance) to establish if laboratory accreditation can really be described as cost effective (See Appendix 21).

In order to determine if there was any linear relationship between annual cost effectiveness and accreditation each annual CE figure was plotted (Figure 12), and the Pearson's Correlation Co-efficiency was established (See Appendix 26).

FIGURE 12 COST-EFFECTIVENESS OF ACCREDITATION SINCE THE TRANSITION TO ISO 15189:2012



The Coefficient of Determination (Figure 12) was calculated as **R^2 = 0.3353** indicating that 33.5% of the total variation in the cost effectiveness can be accounted for by the variation in each annual accreditation year.

The Pearson Correlation co-efficiency for the study period was calculated as **r = 0.579** showing that the strength of the linear relationship is moderate with a statistical significance of **P=0.13** (See Appendix 26) which is insufficient to reject the Null hypothesis.

For each of the first four years since the implementation of ISO 15189 in 2014 there was an observed reduction in the annual percentage cost effectiveness. In 2018 there was a change in the assessment team and a sizeable number of NC were identified during this surveillance visit (SUR4). SUR4 is normally a more thorough assessment of the laboratory QMS but again with a new assessment team came new challenges. The UKAS assessment manager and a trainee that managed the visit were unfamiliar

with the discipline. It proved a challenging assessment for all and was felt by several of the laboratory team that the UKAS assessment team were not as subjective as they might have been. This then brought their interpretation of the ISO standard into question, which was corroborated during the FGDs (see sub theme 5.5.7 Impact of UKAS Assessors and 5.5.8 Clarity of the ISO standard). NCs were identified in areas of the standard there had not been any concerns in previous cycles with preceding assessment teams. This then directed a number of the laboratory team to be cautious of the assessment team's objectivity and their rationale for NC, which were made apparent in the FGD where the MT deliberated on the assessment process.

> *'I think one thing we have to watch is the UKAS standards are quite open to interpretation. It's quite often you'll put something in place and then things seem to spiral a bit so an Inspector will come along and it's very good that you've put that in place, but sometimes it's almost like they're on, like a bonus scheme whereby they have to identify something for you to fix or to improve and things just seemed to kind of go on and on and on, and I think every time you have like a little bit of an add-on It kind of detracts away from the original purpose and kind of makes you process slightly less streamlined. I suppose every now and again you kind of have to rethink the whole thing. But I think maybe when they do come round perhaps, we need to start instead of just accepting things, perhaps we need to kind of almost kind of give a counterargument a bit more vigorously sometimes. Because quite often, if you would say well, where is that precise thing in the standards they can't, they wouldn't be able to show you because it's their interpretation of the standards.' (MT13)*

The analysis of the FGDs confirmed the questionnaire outcomes regarding the budgetary impact of accreditation (See Table 23, page 127), where over **86%** (24) of the respondents did not consider accreditation to be value for money and **93%** (26) considered it to be expensive in both participant groups. The strongest opinion was from the MT who clearly voiced their belief that they did not consider accreditation to be cost effective. This may have impacted on the perceptions of the CSST group. This illustration would be expected due to their senior positions within the laboratory and the close positions of their roles to the accreditation process. The perceptions in the CSTT group towards the costs could have been grounded in hearsay during their employment period or from the information data sheets provided for the study exposing limitations to the study (see 6.6.2).

'Yeah, UM cost-effective. I tried to remember when CPA became UKAS and we got told we had to. And I also remember at that time the massive hike in the cost of accreditation specifically not the internal cost to us, of doing all these extra steps, but the actual cost to UKAS of a) getting credited b) having an extension to scopes c) extra things. And I'm not entirely sure it's cost-effective, and you look at our circumstances now we pay a lot of money and I'm not entirely sure. I mean, that we've had the service from them, the quality of service because we're still not been signed off for the extension to scope, but they haven't decided and you know, even to the smaller point where we've tried to get trained as inspectors, there isn't that responsiveness on their side, so I don't. I'm not entirely sure we're actually getting, you know, value for money or cost-effective for ISO specifically.' (MT03)

'I think the word cost effectiveness is difficult when you talk about UKAS accreditation because there always seems to be an added cost to maintaining or gaining the extra accreditation status when we're trying to improve our service, so in that respect it's difficult to say it's cost effective.' (MT07)

'Yeah, I just think it would in the long run be cost effective because we're making sure that our tests are working properly basically, because if we had instruments that didn't work properly or reagents that we're storied incorrectly or you know people that weren't trained properly, then it was going to cost more money to get your result out.' (MT09)

'Just to touch on the cost thing to play devil's advocate with it, the argument for saving money, I suppose, would be in the fact that your techniques are better. You have to repeat them less. In an ideal world, if you're making these improvements and everyone is working to set a set standard. So, you're making savings from that side of it'. (CSTT03)

5.7 Theme 3 – Quality

To measure quantitatively the impact of accreditation on laboratory Quality both, repeat rates (RR) and error rates were employed. Repeat rates are laboratory performance measures which are routinely monitored monthly as part of the laboratory continual improvement programme. These are collected monthly for each of the critical laboratory processes identified from the UKAS Schedule of accreditation (Appendix 1). The error rates used for the data set included the number of non-conformances (NC) identified against the ISO 15189 standards during each annual ISO assessment

(SUR) since the transition in 2015. Alongside this, the mean annual percentage performance score for the UKNEQAS proficiency schemes participated in during each assessment year was also used to establish error rates.

5.7.1 Sub Theme- Laboratory service quality

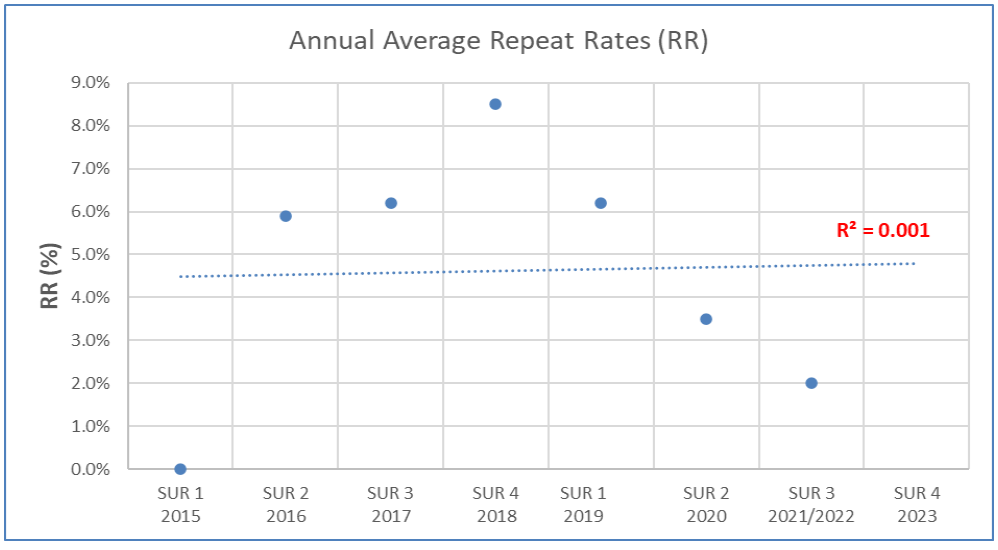
a) Repeat Rates

This data provides quantitative evidence of the laboratory overall mean yearly repeat rates per fiscal year from April to March, for all critical processes listed as the scope of practice on the schedule of accreditation under UKAS (Appendix 1) included in the study for the critical processes:

- HLA Typing.
- HLA Antibody screening.
- Chimaerism monitoring.
- Donor – Recipient Crossmatching.

The KQI for all the laboratory RRs is set at 5%, the mean results for the RRs have consistently been above the 5% threshold until 2020 when it dipped below the threshold for the first time (Figure 13). The data for RRs unlike TATs could not be expanded further to include any data pre-2015 because monitoring RR was only introduced as part of the implementation of the ISO 15189:2012 standards in 2015 (See Appendix 19).

FIGURE 13 AVERAGE COEFFICIENT OF DETERMINATION (R^2) FOR ANNUAL REPEAT RATES



The Coefficient of Determination (R^2) for annual mean repeat rates was calculated using Microsoft Excel (Figure 11) as **R^2 = 0.001** which indicates that only 0.1% of the total variation in laboratory repeat rates can be accounted for by the variation in annual accreditation.
The Pearson Correlation co-efficiency for the study period was calculated as **r = 0.031** demonstrating that the strength of the linear relationship is weak, but graphically there is a non-linear (quadratic) relationship seen between overall laboratory repeat rates and annual accreditation with a statistical significance of **P= 0.95** which is insufficient to reject the Null hypothesis. Indicating that there is **no** linear relationship between annual average repeat rates and accreditation (See Appendix 24).

Ideally because accreditation is considered to be a quality improvement programme it should be expected that with each year of accreditation an improvement should be observed. The first four-year accreditation cycle saw an increase in average annual repeat rates year on year, but improvement was only observed during the second four-year cycle where average annual RRs declined year on year. This could be perhaps indicative of continual improvement due to managing and monitoring performance following the implementation of accreditation but could also reflect changes over the years, with staffing and training of the staff, equipment aging and replacement with new models and advancing technical procedures.

A reduction in repeat rates would be an expected outcome as quality improves due to the implementation of and continuing participation with accreditation over the years. The improvements seen in the repeat rates over the years may not be reflective of just the impact of accreditation. There may be other contributory factors such as changes to techniques and technologies that may also be at play not just compliance to a standard. Issues with HLA typing using PCR-SSP over the years led to the implementation of new and innovative typing procedures to manage the problems which led to the introduction of RT-PCR as an alternative typing technique in 2019-2020. This has seen a continued reduction in RRs to the present day. HLA antibody detection and definition procedures have remained consistent over the study period with very little changes in comparison with HLA typing techniques. Chimaerism monitoring procedures have also remained consistent with a change in 2019 from in

house primers to commercial, from where a continued reduction in RRs has been observed.

To obtain more depth and breadth for the study the repeat rates were examined in more detail. Each of the laboratory techniques as defined within the UKAS scope of practice (Appendix 1) and identified as critical process for the study were analysed individually over the study timeframe (2015 to 2022) to expand the sample size and provide significantly more data points for analysis.

i. HLA Typing

The advancement of molecular techniques for HLA typing of DNA sequence polymorphisms has offered the scientific discipline of H&I flexibility of resolution, improved reproducibility, and greater accuracy over the years. The use of polymerase chain reaction (PCR) revolutionised HLA typing and has advanced over the years from using primarily PCR sequence specific primers (PCR-SSP) and PCR sequence-specific oligonucleotide probes (PCR-SSO) until PCR-SSP was phased out in 2019 / 2020. This paved the way for the introduction of Real Time PCR techniques (LinkSeq) which was introduced in 2017 / 2018 and other molecular typing techniques which allowed greater resolution. RT-PCR was introduced into the laboratory and was part of the laboratory's UKAS ETS application during 2018. This technique replaced PCR-SSP for cadaveric donor HLA typing as a more innovative robust typing methodology with a higher-level resolution typing than PCR-SSP.

Sequence based typing (SBT) which was already in place to HLA type at a high resolution was replaced in 2017 / 2018 by Next Generation Sequencing (NGS) which was considered significantly more efficient. NGS was introduced into the HLA typing strategy workflow as a replacement for SBT and was part of the ETS application to UKAS in 2018. SBT had limitations due to technological challenges leading to issues with RR's, the introduction of NGS provided a single methodology to obtain high resolution HLA typing results for the stem cell transplant patient population.

The typing techniques used for HLA typing are dependent on the patient cohort and the level of resolution required in their diagnosis. The need for such techniques has expanded with clinical need for the patient and has introduced a repertoire of techniques suitable for use which is generic within the H & I discipline and beyond. Any of these technical changes have the potential impact on quality and may be the

rationale for improvements seen to RRs and TATs for HLA typing not the impact of ISO accreditation.

Table 28 below represents an overview of the regression coefficient analysis for all the HLA typing techniques evaluated. The outcome identifies that they all have negative correlations, indicating as one variable increases the other decreases which would be expected of repeat rates over time. Out of the five techniques evaluated only two of these correlations were statistically significant for both HLA Typing by PCR-SSP (Figure 14) and RT-PCR (Figure 16).

The statistical significance expressed as the P value for each of the typing techniques (Table 28) identifies that there is sufficient evidence to reject the Null hypothesis for the alternative hypothesis indicating that there is a relationship between repeat rates for HLA typing using PCR-SSP and RT-PCR and years of laboratory accreditation.

FIGURE 14 ANNUAL AVERAGE REPEAT RATES FOR HLA TYPING BY PCR-SSP

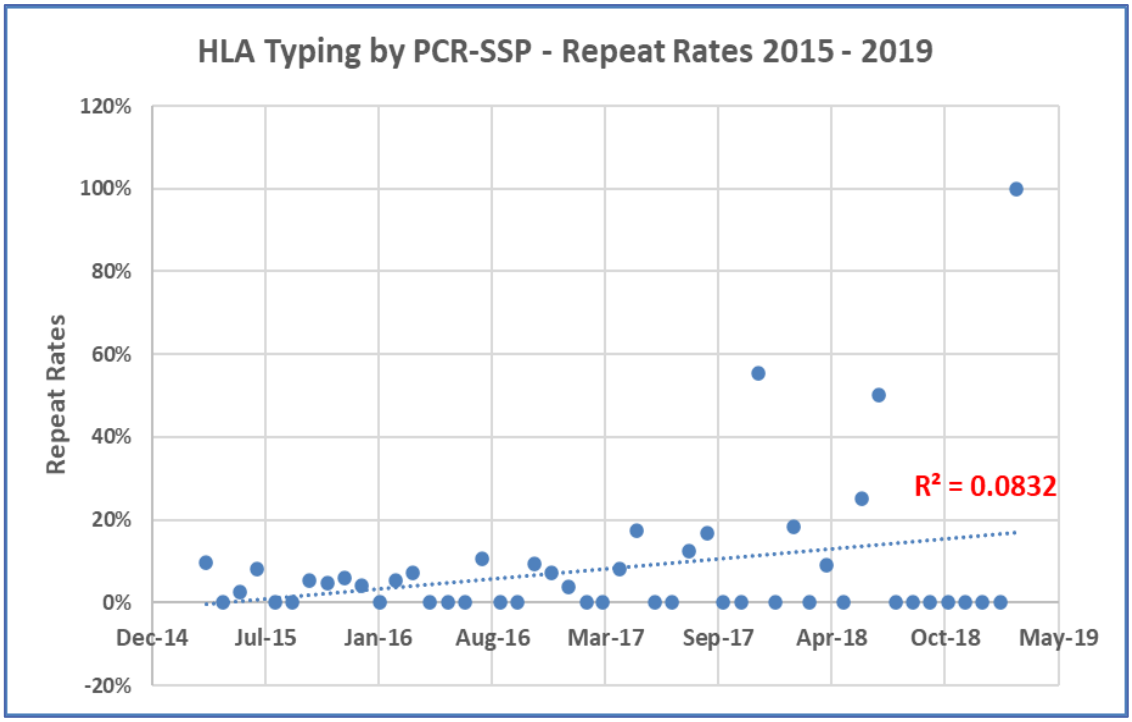


FIGURE 15 ANNUAL AVERAGE REPEAT RATES FOR HLA TYPING BY PCR-SSO

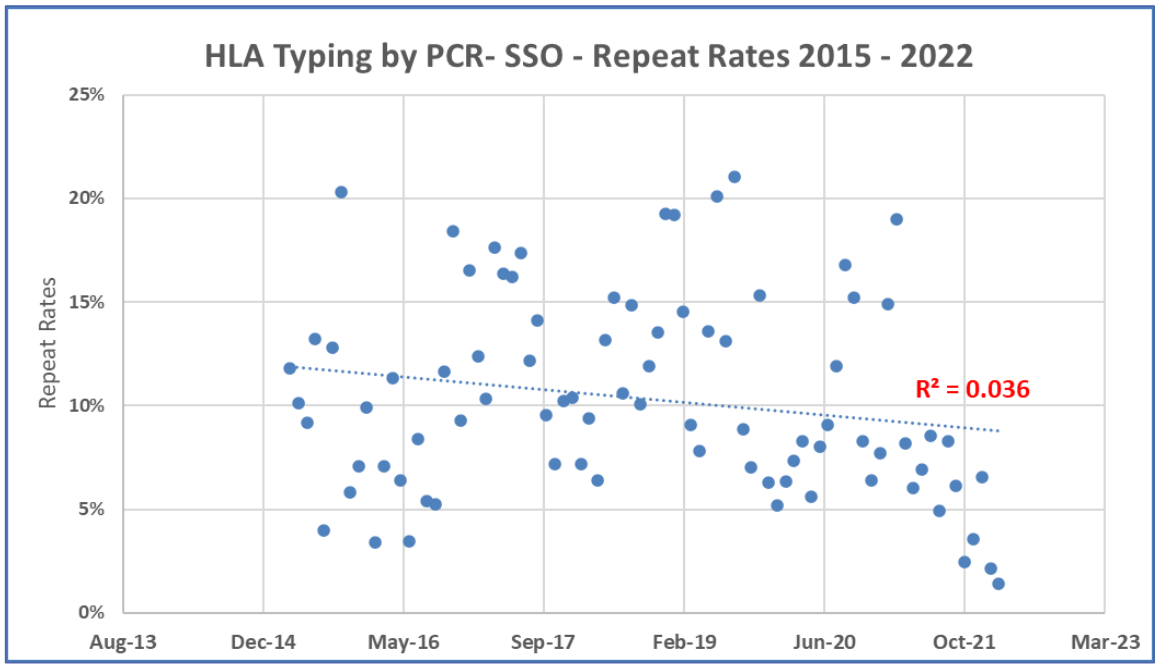


FIGURE 16 ANNUAL AVERAGE REPEAT RATES FOR RT-PCR HLA TYPING BY LINKSEQ

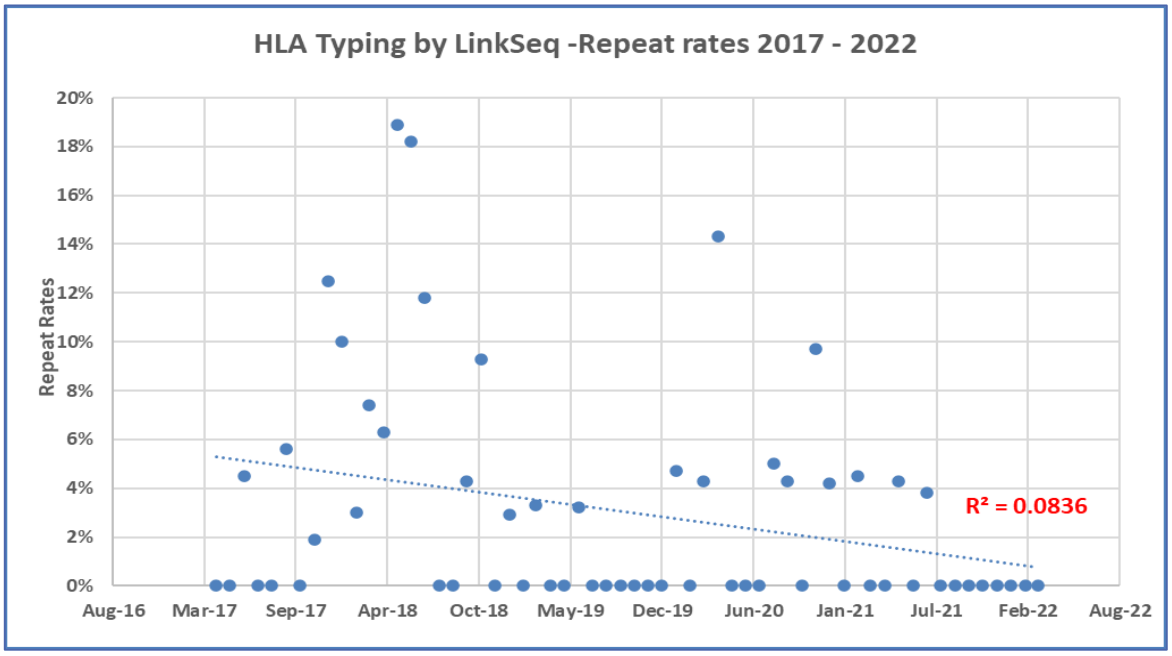


FIGURE 17 ANNUAL AVERAGE REPEAT RATES FOR HLA TYPING USING SEQUENCE BASED TYPING (SBT)

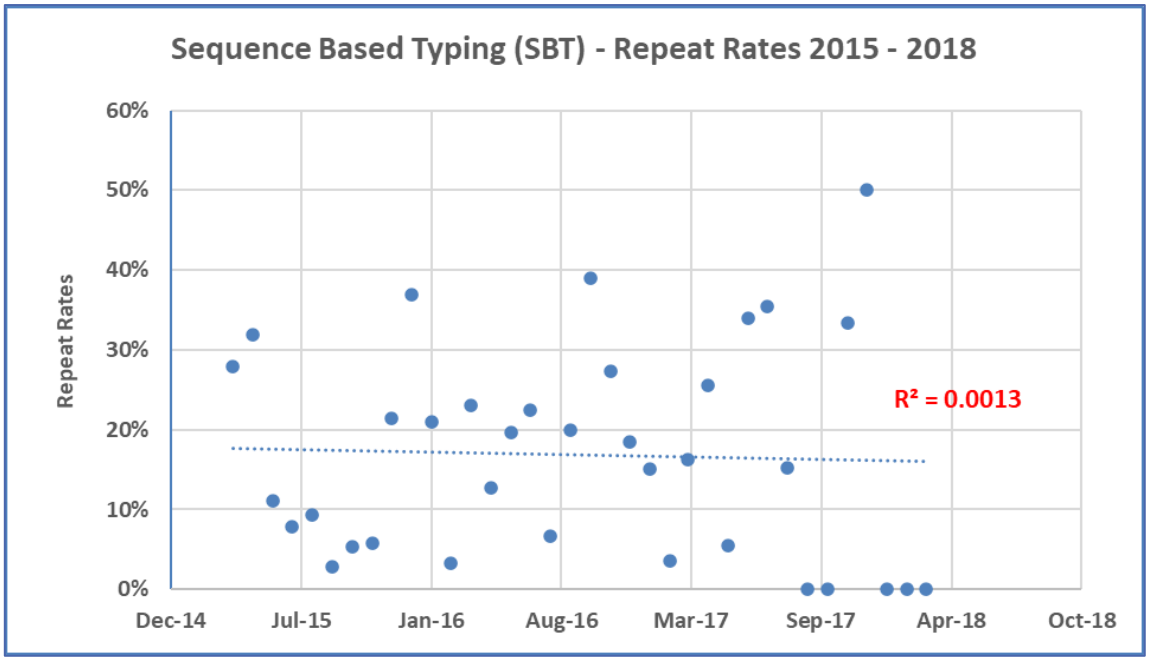


FIGURE 18 ANNUAL AVERAGE REPEAT RATES FOR HLA TYPING USING NEXT GENERATION SEQUENCING (NGS)

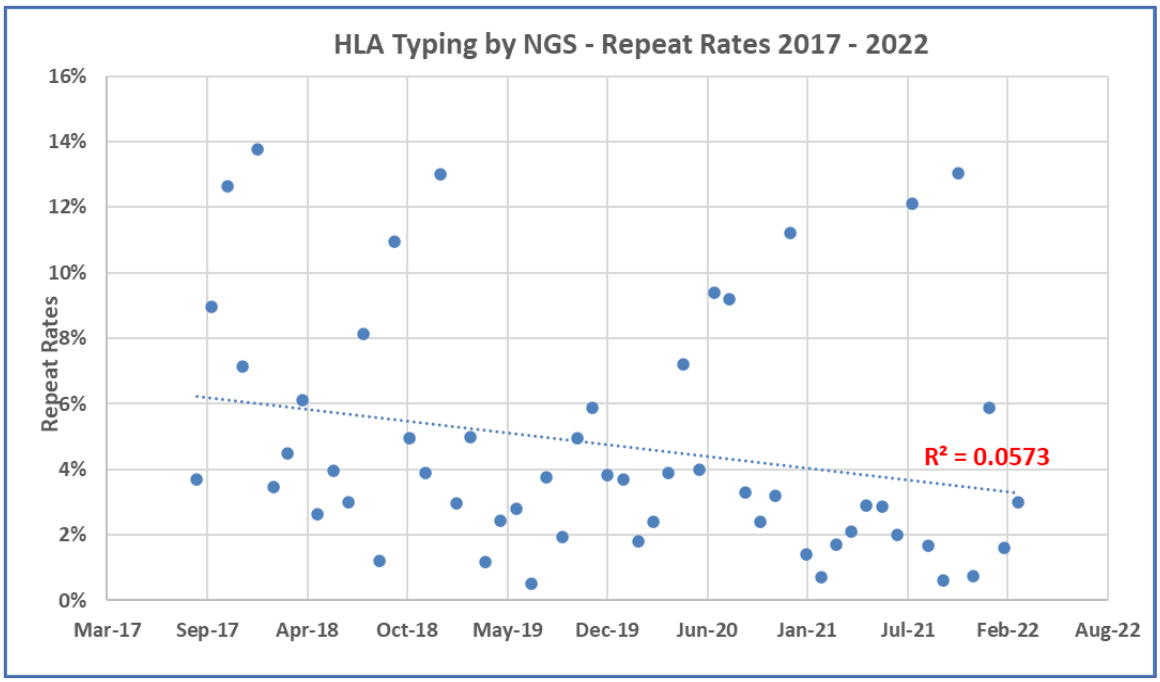


TABLE 28 OVERVIEW OF THE STATISTICAL OUTCOME FOR HLA TYPING TECHNIQUES REPEAT RATES

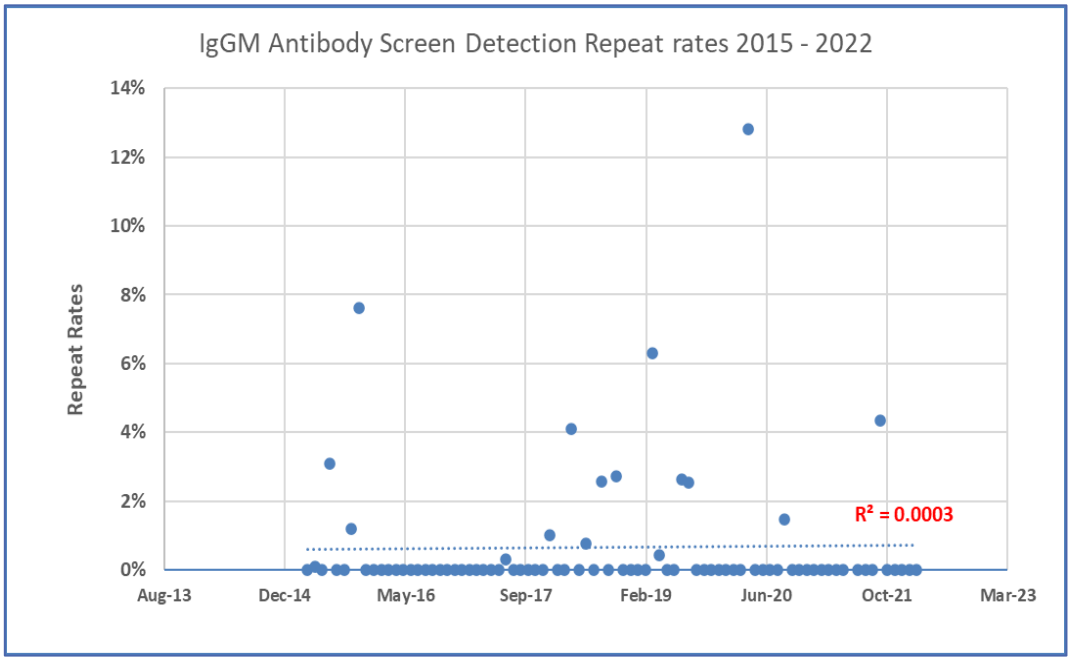
Key Concept	HLA Typing Technique	r	R^2	%	Strength of Linear Relationship	Correlation	P-value (≤0.05)
Quality	**PCR -SSP**	-0.288	0.0832	8.3	Weak	Negative	0.05
	PCR-SSO	-0.189	0.036	3.6	Weak	Negative	0.08
	RT-PCR	-0.284	0.0804	8.0	Weak	Negative	0.03
	SBT	-0.036	0.0013	0.13	Weak	Negative	0.83
	NGS	-0.239	0.0573	5.73	Weak	Negative	0.08

ii. Antibody Screening

The detection and definition of HLA antibodies in transplant recipients is essential for patient management in the transplant programme. Detecting and identifying pre-existing HLA antibodies in patients awaiting transplant can assist in avoiding graft failure and reduction of the positive crossmatch rate by determining clinical relevance of the antibody present. It can also minimise prolonged cold ischaemic times for donor organs by reducing the subsequent shipping of organs due to positive crossmatches. The main screening techniques employ Luminex technologies using screening microbead array, these techniques have been part of the laboratories screening repertoire since the implementation of ISO accreditation with minimal variation of techniques over the study period adding rigor to the findings.

Figure 19 displays the monthly average repeat rates for antibody detection over the study period. Figure 20 displays the monthly average repeat rates for antibody definition over the study period.

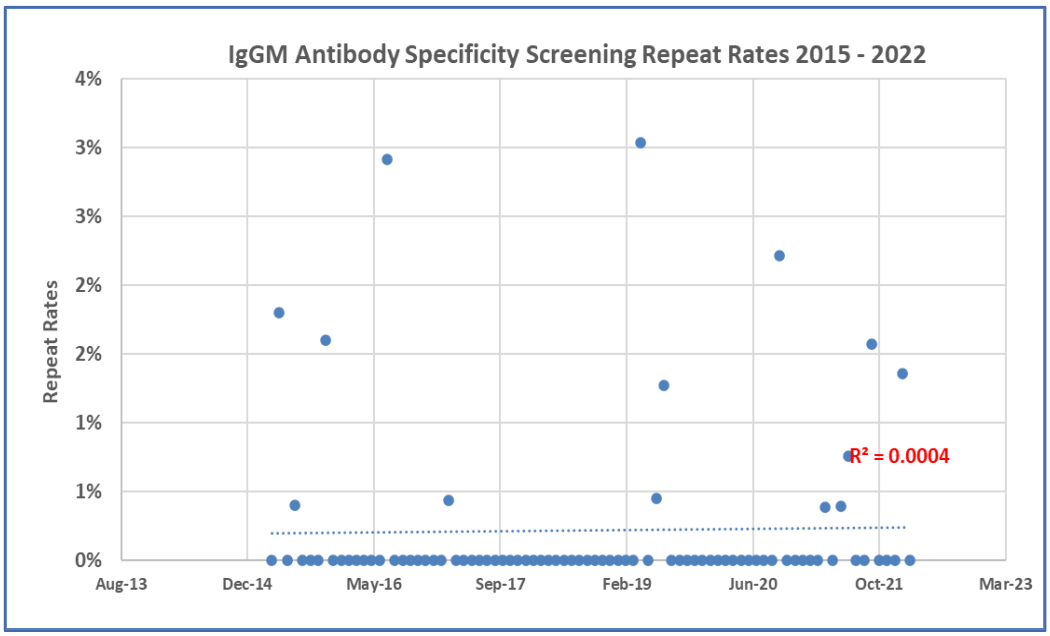
FIGURE 19 AVERAGE PERCENTAGE REPEAT RATES FOR ANTIBODY DETECTION



The Coefficient of Determination for the study period was calculated using Microsoft Excel **R^2 = 0.0004** indicating that 0.04% of the total variation in the repeat rates for antibody detection can be accounted for by the variation in annual accreditation (Figure 19).

The Pearson Correlation co-efficiency for the study period was **r = 0.02** demonstrating that the strength of the linear relationship is weak with a statistical significance of **P=0.864** (See Appendix 24).

FIGURE 20 AVERAGE REPEAT RATES FOR ANTIBODY DEFINITION



The Coefficient of Determination was calculated for the study period using Microsoft Excel and was **R^2 = 0.0004** highlighting that 0.04% of the total variation in repeat rate for antibody definition can be accounted for by the variation in annual accreditation (Figure 20).

The Pearson Correlation co-efficiency calculated for the study period was **r = 0.02** demonstrating that the strength of the linear relationship is again weak with a statistical significance of **P=0.865** (See Appendix 24).

The repeat rates observed for HLA antibody detection and definition (Table 29) over the study time frame remained below the 5% QI but appeared to be random without any correlation being observed. There appeared to be a weak linear relationship that was not statistically significant and so the null hypothesis is accepted, identifying that there is no relationship between antibody screening and continuing years of accreditation.

TABLE 29 OVERVIEW OF THE STATISTICAL OUTCOMES FOR HLA ANTIBODY SCREENING REPEAT RATES

Key Concept	HLA Antibody Screening	r	R^2	%	Strength of Linear Relationship	Correlation	P-value (≤0.05)
Quality	**Detection**	0.02	0.0004	0.04	Weak	None	0.864
	Definition	0.02	0.0004	0.04	Weak	None	0.865

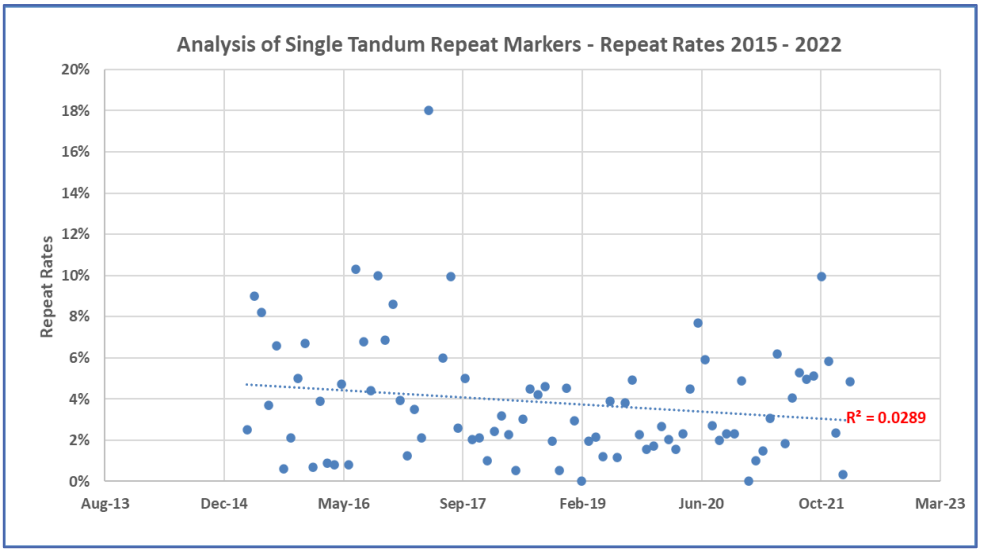
iii. Chimaerism Monitoring

Following a bone marrow engraftment "short tandem repeat" (STR) marker in the patient's peripheral blood or bone marrow aspirate are monitored. This post-transplant engraftment monitoring is referred to as Chimaerism monitoring. STR markers are variable DNA sequences, which differ in length by multiples of repeated units. The variability of these markers means that in most cases, the donor and recipient will not share the same sized STR marker. By monitoring these size differences in the post-transplant sample, the success of the engraftment can be measured by calculating the percentage of donor derived cells in the recipient's sample. In some scenarios post stem-cell transplant it is of clinical value to assess donor engraftment in more than one cell lineage in the post-transplant period. Several options exist and the assay can be tailored to a specific patient. This procedure has been well established in the laboratory for many years initially using in house primers but the move to a commercial kit to maximise efficiency and improve quality meant the procedure was an ETS application to UKAS in 2019.

The Coefficient of Determination calculated for the study period using Microsoft Excel was **$R^2 = 0.0289$** highlighting that 2.9% of the total variation in chimaerism monitoring RRs can be accounted for by the variation in annual accreditation (Figure 21).

The average Pearson Correlation co-efficiency calculated for the study period was **r = -0.17** demonstrating that the strength of the linear relationship is weak with a statistical significance of **P=0.131** (See Appendix 24).

FIGURE 21 AVERAGE REPEAT RATES FOR CHIMAERISM MONITORING USING SINGLE TANDEM REPEATS (STR)



For the analysis of the Chimaerism monitoring repeat rates (Table 30) there again appeared to be a weak linear relationship that was not statistically significant and so the null hypothesis can be accepted. Once again signifying that there is no linear relationship between chimaerism monitoring repeat rates and years of accreditation.

TABLE 30 OVERVIEW OF THE STATISTICAL OUTCOME FOR CHIMAERISM MONITORING REPEAT RATES

Key Concept		r	R^2	%	Strength of Linear Relationship	Correlation	P-value (≤0.05)
Quality	**Chimaerism monitoring**	-0.17	0.029	2.9	Weak	Negative	0.131

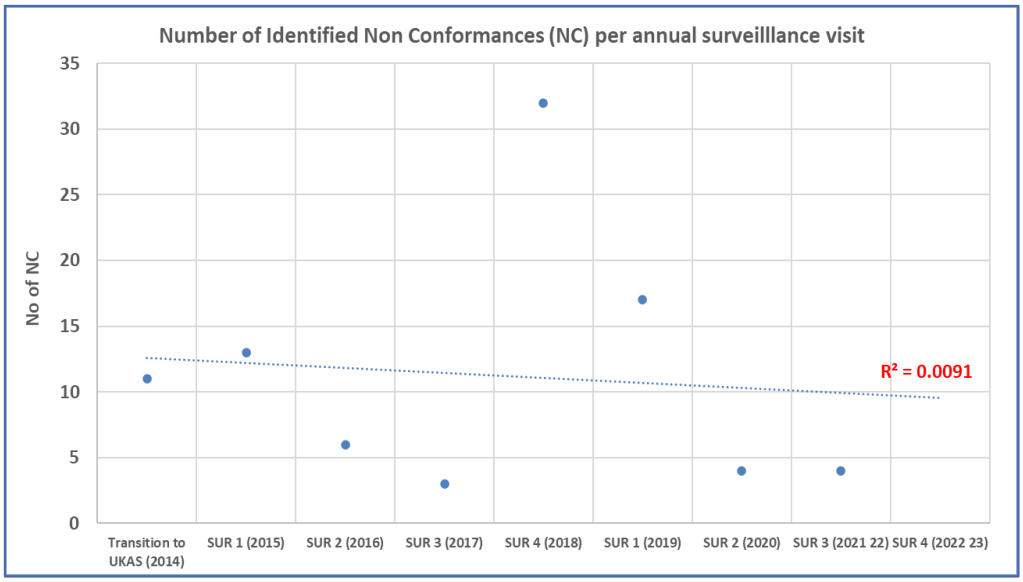
b) Error Rates

The error rate is another category of QI used within the laboratory to manage and monitor quality. The secondary data analysed included both, the number of ISO accreditation NC, which are failures to meet the ISO standard, identified by the assessor during each annual accreditation surveillance visit. Also, the annual average results for participating in the appropriate UKNEQAS proficiency scheme was also used to demonstrate error rates.

UKAS Non-conformances (NC)

The Coefficient of Determination calculated for the study period was **R2 = 0.0091** highlighting that only 0.1% of the total variation of ISO non-conformances identified that are accounted for by the variation in annual accreditation (Figure 22).

FIGURE 22 ISO DEFINED NON-CONFORMANCES (NC) PER SURVEILLANCE VISIT



The Pearson Correlation co-efficiency was **r = -0.095** demonstrating that the strength of the linear relationship between the number of NC and each assessment year is very weak with a statistical significance of **P=0.82** (See Appendix 24) which is insufficient to reject the null hypothesis and so the null hypothesis can be accepted. Once again signifying that there is no linear relationship between chimaerism monitoring repeat rates and years of accreditation.

Graphically a slight decrease in NC was observed over the study period associated with a negative correlation (Figure 22) this would be an expected outcome for laboratories who participate in accreditation due to continual maintenance of the standards.

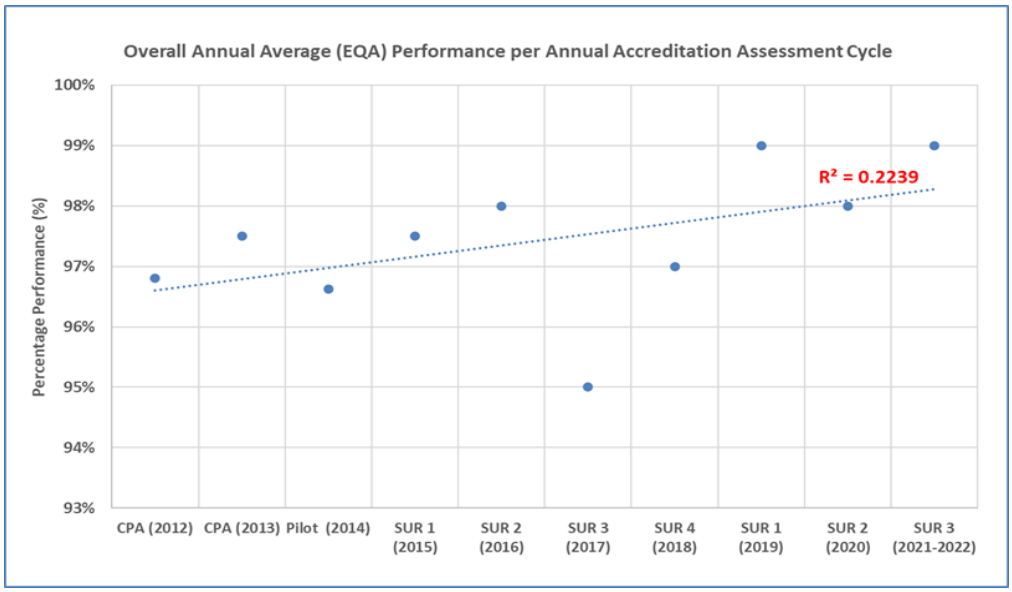
UKNEQAS Participation

Participation in and successful completion of proficiency testing schemes are a requirement for compliance with ISO 15189 accreditation. All schemes vary dependant on the pathology discipline, and all will have their own acceptance criteria for assessments but are all considered by UKAS as a useful tool to recognise quality.

The laboratory has defined target (KQI) for the participation in the UKNEQAS proficiency testing schemes of 100%.

The overall annual average performance per accreditation cycle was calculated and plotted (Figure 23).

FIGURE 23 OVERALL ANNUAL AVERAGE PROFICIENCY SCORE (EQA) PER ACCREDITATION CYCLE



The Coefficient of Determination calculated for the study period was **R^2 = 0.2239** highlighting that 22.4% of the total variation in EQA scores can be accounted for by the variation in annual accreditation (Figure 23).

The Pearson Correlation Co-efficiency calculated was **r = 0.473** showing that the strength of the linear relationship is moderate with a statistical significance of **P=0.17** (See Appendix 24) which is insufficient to reject the Null hypothesis, signifying there is no linear relationship between EQA performance and years of accreditation.

Graphically there was observed that there was an increase in the EQA schemes score over the study period (Figure 23) except for a slight dip during 2017.

Table 31 represents an overview of the regression coefficient analysis for error rates. The outcome identifies that there is a negative correlation for the UKNEQAS proficiency test participation, indicating as one variable increases the other decreases which again would be expected of error rate over time due to continual improvement. The results could also indicate that because the correlation coefficient for NC is closer to zero than to one that there is no relationship between the key concept error rates

(Dependant variable) and the years of accreditation (Independent variable), and any changes observed is completely unrelated. Neither of the outcomes are statistically significant and so the null hypothesis is not rejected for the error rates identifying that there is no linear relationship between error rates and accreditation.

TABLE 31 OVERVIEW OF THE STATISTICAL OUTCOMES FOR ERROR RATES

Key Concept	Error Rates	r	R^2	%	Strength of Linear Relationship	Correlation	P-value (≤0.05)
Quality	**NC**	0.009	0.0091	0.91	Weak	None	0.821
	UKNEQAS	0.223	0.2239	22.39	Weak	Negative	0.167

In order to appreciate staff opinions and perceptions of whether the respondents thought the current system of ISO accreditation had *improved the overall laboratory service and service quality* questions in number two were developed in the questionnaire (See Appendix 14).

It was clear when observing the data obtained from the survey methods that the participants in the study perceived that accreditation played a crucial part in improving laboratory quality (Table 32). From the outcomes of the questionnaire 26 **(93%)** participants agreed that in question two ISO accreditation had improved the overall laboratory service quality (Q2.6), with 19 **(68%)** of these agreeing that it improved the number of errors that occur in the laboratory (Q2.3). In question 3 when this question was raised again (Q3.5) there was a shift with 23 **(82%)** participants agreeing that ISO accreditation improves quality, this was discussed during the FG to confirm the findings and obtain a clearer understanding.

During the FGD both teams were asked their opinion of whether ISO accreditation had improved laboratory quality over the years to corroborate the findings obtained in the questionaries and to gain a deeper understanding. The outcome was mixed, and the MT narrative became more concentrated towards service users and patient safety with a number of sub themes being established from the narrative.

TABLE 32 QUESTIONNAIRE RESPONSES REGARDING QUALITY

Quality		MT (N=14)		CSST (N=14)			
		Band 8+		Bands–6 - 7 (N=9)		Bands–3 - 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q2.1	The overall service we provide	13	1	8	1	5	0
Q2.3	The number of errors that occur in the laboratory	9	5	6	3	1	4
Q2.4	The laboratory focus on patients' safety	9	5	3	6	4	1
Q2.5	The ability to improve laboratory services by introducing new processes	6	8	3	6	5	0
Q2.6	The overall laboratory service quality	13	1	8	1	5	0
Q3.5	Improves quality	11	3	6	3	5	0

So, when the teams were asked if they perceived accreditation improved quality the CSTT replied.

> *'I would hope so because'it's a framework to do it within, 'sn't it? it encourages that kind of behaviour I suppose.' (CSTT03)*

> *'Yeah, I think the same as CSTT02 and CSTT09. Yeah, it affects the quality. And'it's important, I think we deal with accreditation like testing and stuff, bu' I'm not sure if it improves efficiency.' (CSTT08)*

The perception of accreditation improving laboratory quality was corroborated by the MT, providing examples of introducing best practice to measure quality metrics due to accreditation assessments.

> *'When there was a new technique that we were introducing into the lab, we were inspected a number of times by both EFI and ISO and I think some of the systems that we put in place as a result of that have been very helpful in terms of monitoring quality metrics and various things that we might not have done otherwise.' (MT02)*

Identifying that they consider accreditation important with regards to quality through continual improvement by continually monitoring.

'Yeah, I think it's probably mostly just quite easy to forget where improvements have come from, so when, er the reason why SOPs are good is because uh, you to do them to a standard. The reason why yeah, we make improvements to techniques, even techniques that have been here for years we still improve them all the time because we do examination audits and all kinds of stuff. And then, it's I think, it's just easy to forget where those come from.' (CSTT07)

'I guess there's ultimately, there's no endpoint. The whole point is that you continue to try and improve so they can feel like a bit of a treadmill and a slog that you are continually working along and then like CSTT07 says, this stuff that's happened before you don't think back and think over three SOPs ago we were doing this, like so yeah, what you've got to show for it at the end of the day, being a little emblem doesn't quite hit home when you're doing however many, two audits a year and ten SOP reviews or risk assessments or what have you.' (CSTT03)

'Yeah, I think, it's good that we do audits and everything, then we can make improvements and check that, nothing that we've changed has changed other things as well, and Uh, yeah, it's important that for patients that we are accredited, and I think like day-to-day probably affects us like timewise. It's like having to do extra things like put stuff on audit databases and yeah, just cost as well as a big impact.' (CSTT08)

The MT emphasised that accreditation encourages the laboratory to provide a 'quality service'. Also, that it assists the laboratory to improve systems, referring to the comprehensive QMS that has been employed in the laboratory.

'I think so because it makes people conform to processes that it might not. Well, you might want to, well it might stop you if you want to maybe cut corners (Laughing). So, I think it makes people not do that, and I think we try and provide a quality service. Not that we, you know… I think it really focuses your mind on it.' (MT05)

'We've certainly put ways of, you know ways of measuring things and I obviously, as I say, you can put, you can take these things too far, but ways of looking at how we are producing results and the quality of those and what we can do to make them better in a way that perhaps we might not do if we was n't having to look at the way that ISO are looking at it, for example.' (MT02)

'That's something that we didn't particularly look at I don't think before the ISO

inspection, and I think that it's beneficial. Then it will help us put better procedures in place. Uh, and it has done. As you know we've had issues with those particular assays.' (MT12)

This was echoed again from the CSTT discussions where the impact of accreditation on quality was described as a way of managing the processes by continuously reviewing them possibly indicating they also saw this as continual improvement in laboratory quality.

'It definitely increases the level of quality within the department. I think that the rules they set for document control and the quality management system, and it keeps us on our toes. And keeps everything up to date.' (CSTT05)

'It probably makes us constantly assess what'we're doing, do'sn't it? And sometimes you need to assess whether what 'ou're changing affects other things, and by doing the audits, that kind of forces us to do that, do'sn't it? Because 'ou're looking at everything t'at's referenced within, uh, say an SOP, for example, do'sn't necessarily just affect that test 'ou're doing. It can then have an impact further down on other things, so it makes us constantly look at how'we're doing things and whether we can make it better.' (CSTT06)

Only two participants from either of the FGs clearly stated that they thought accreditation improved quality '*I think it does improve the quality of the department*', (CSTT09) and '*definitely increases the level of quality within the department*' (CSTT05). The narrative became more focused towards service users and patients identifying further sub themes from the MT FGD.

5.7.2 Sub Theme- Service Users

The MT saw the value and importance of accreditation more as a sign to our clinical users and patients which increases their confidence that the laboratory is providing a certain standard of service.

'It's just that it increases the confidence of the user in the service that 'ou're providing because you've passed a certain standard from when the inspectors have come in and sent your documentation off and so on…'

I'd say that if you can prove that 'ou've reached a certain standard in a particular area or across the board, then I would say that as a user, you would feel more

confident in using the services from that laboratory. So, it would increase patient and clinical confidence in the service it would provide.' (MT12)

'I think it is important to be accredited because then you can show the quality of service that your laboratory is providing to your clinical users and also to the patients as well. And then in terms of managing what you do on a day-to-day basis if you can show that 'ou're accredited and for techniques or the quality management system etc then I think t'at's what people would want to see, to have trust in a in a lab.' (MT05)

This sentiment was corroborated by further participants who also reasoned that the users would have 'confidence' in the laboratory because accreditation could be seen as a recognised certification.

'It's just that we obviously have our own, like internal reasons as to why we should be accredited as a as a lab, but I think as well, if you look at like the external side of it, I would imagine or would hope that for example, a patient if he knows that, or if they know that the our lab is ISO accredited that it would give them confidence that we actually knew what we were doing. I think if you were to make comparisons and find out that there were other labs that we'en't quite you know, strict about things that, that might you know it might not equate to the same thing, so I'm hoping anyway that to external people that it will at least you know, make us look as if we know what we're doing.' (MT11)

But there was concern has to whether patients actually understood accreditation and its values and benefits - *'I'm not entirely sure that patients understand necessarily what accreditation means. I d'on't know, mayb' I'm being a bit sort of patronising. But unless you are well informed of what accreditation actually stands for, I would question whether they actually understand that our service is better than you know, the lab that 'sn't accredited. But t'at's just a comment.' (MT03)*

5.7.3 Sub Theme: Accreditation and Patient Safety

The questionnaire findings identified that there was a slightly even split with regards to whether the participants considered that ISO accreditation had *improved the laboratory focus on patient safety*. With overall **57%** (16) of the respondents agreeing, the biggest majority being from the management group where 9 participants (**62%)** and 4 participants in Bands 3 – 5 **(80%)** agreed, whilst in contrast most of the Bands

6 – 7 participants (6) disagreed with this statement **(67%).** This was in slight contradiction to another similar question when the group were asked if they considered the current system of ISO accreditation as *patient focused* (Q3.7) where 16 participants (**57%)** disagreed (Table 33).

TABLE 33 QUESTIONNAIRE RESPONSES REGARDING PATIENT SAFETY

Patient Safety		MT (N=14)		CSST (N=14)			
		Band 8+		Band–6 - 7 (N=9)		Band–3 - 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q2.4	The laboratory focus on patients' safety	9	5	3	6	4	1
Q2.5	The ability to improve laboratory services by introducing new processes	6	8	3	6	5	0
Q3.7	Patient focused	4	10	4	5	4	1

To obtain some depth the FGs were introduced the sub theme about accreditation and their perceived impact on patient safety and if they believed it made the laboratory more patient focused.

> *'But it is what it is, 'sn't it? And we have to do it.'It's yeah,'it's just finding that balance between the actual day-to-day patient work that we all know is important and fitting this in around it.' (CSTT06)*

Again, emphasising the impact ISO accreditation has on the day-to-day workload and the competing strains imposed on the laboratory describing the workload required for validating any new innovations impacting on laboratory efficiency (Theme 4).

> *'So, it can be sometimes quite difficult to fit in the validation work, but also keeping your turn around times right for the patients, which I think we all probably feel is the most important thing. But equally you want to do the new things because you know that could improve things for the patients. So,'it's finding that balancing act 'sn't it.' (CSTT06)*

The CSTT discussed the positives of accreditation by ensuring that appropriate processes are adopted to ensure patient safety.

'Yeah, and I would just want to add about the patient safety aspects as well because obviously'we're in the healthcare field and obviously I see it is quite important especially when'we're bringing in new techniques. It's the safety-first aspects of it because'we're all human and we might break something along the way of introducing something new and I just think that's one important aspect and I think why it (accreditation) exists is that we don't have any near misses or incidents involving patient care.' (CSTT02)

'I think it does improve patient safety in that it ensures that we're following the correct procedures. It makes us look at the test to see whether they're the right ones for the right patient, but equally. It's often logistically and paperwork difficult to introduce new tests because things have to be agreed by ISO etc. And things like that, so'it's almost it becomes quite difficult to start introducing new things sometimes.' (CSTT06)

The theme of standardisation and accreditation emerged to ensure patient safety and was identified as a positive of accreditation:

'I mean it goes beyond us to improve patient safety really because obviously the point of the accreditation being to ensure everyone is working the same standard and everyone got the access to the same health care. So, it goes sort of outside of us as a lab that approach to it. But yeah, the amount of work, particularly obviously with this whole flexible scope thing you've been trying to go through shows the effort to put in, to actually get new tests validated.' (CSTT03)

But the participants also raised concerns that perhaps there wasn't the understanding of accreditation by patients either:

'*'I'm not entirely sure that patients understand necessarily what accreditation means. I 'on't know, maybe I'm being a bit sort of patronising. But unless you are well informed of what accreditation actually stands for, I would question whether they actually understand that our service is better than you know, the lab that 'sn't accredited. But t'at's just a comment …' (MT03)*

But for those that did it would provide, like the clinical users, confidence in the quality of the laboratory and its service provision.

'I would imagine or would hope that for example, a patient if he knows that, or if they know that our lab is ISO accredited that it would give them confidence that we actually knew what we were doing. I think if you were to make comparisons and find out that there were other labs that we'en't quite so, you know strict about

things that, that might you know it might not equate to the same thing, s' I'm hoping anyway that to external people that it will at least you know, make us look as if we know what'we're doing.' (MT11)

In the questionnaire (Q2.5) when the laboratory staff were asked their opinions of whether they thought ISO accreditation has improved the ability for laboratory to advance innovation by introducing new processes and advanced the laboratory services for its users to improve efficiency and patient safety, the results were split almost 50:50. The management group with almost a similar 50:50 spilt seemed undivided, only 8 participants **(57%)** of this group disagreed that the current system of accreditation improved the laboratory's ability for innovation and introduce new processes. In the Band 6 – 7 group 6 participants **(67%)** disagreed that the current system hadn't improved the ability to introduce new processes and in the Bands 3-5 group the outcome was conflicting with all of the participants **(100%)** agreeing that the current system had improved the laboratory's ability to introduce new processes. This might reflect the lack of understanding of the accreditation process and the strategy for new implementation of processes or just their lack of exposure to this aspect of accreditation.

During the MT FG, the impact of accreditation was perceived as problematic for innovation, developing an emerging theme and corroborating findings previously identified in the literature (Balla, 2012; Thelen et al, 2015). In the questionnaire there was a 50: 50 spilt of staff that considered the current system of ISO accreditation improved the laboratory's ability for innovation and introduction of new processes. The MT group discussed this, and accreditation was perceived to '*stifle innovation'* by, in their opinion, delaying the implementation of new laboratory procedures due to the need for the ETS applications. Where any changes to accredited process could only be implemented following the internal validation procedure to ensure the effectiveness of the new process was evaluated by UKAS. The MT were more exposed to this side of accreditation and therefore had a deeper appreciation and opinion of this issue.

'I think I haven't got any examples of where this has happened in our lab, but I would imagine that the time to process could serve to stifle innovation because I think in the past where'we've done things'we've just gone ahead and done things, you know, new things, whereas now if you're having to think of everything in terms of the implications and the amount of documentation that has got to be produced

and all the rest of it that goes with it, it could be a bit of a disincentive. So that's probably one possible long-term negative aspect.' (MT11)

'I agree with MT11. Uhm, it might stifle it, but it would also delay, sort of implementing something if you wanted to change something very quickly. You could follow all the necessary steps, but it still might be a significant delay, as'we've found, before you can get things added to your scope of practice.' (MT07)

Where as the CSTT FG discussed their perceptions of the impact of accreditation on innovation as more of an effect directly on laboratory personnel describing the workload required for validating any new innovations which may also impact on laboratory efficiency (Theme 4).

'So, it can be sometimes quite difficult to fit in the validation work, but also keeping your turn around times right for the patients, which I think we all probably feel is the most important thing. But equally you want to do the new things because you know that could improve things for the patients. So, it's finding that balancing act isn't it.' (CSTT06)

The narrative around UKAS being described as *'extremely slow'* (MT01) at responding to ETS applications was also powerful in the MT FGD. This group are far more aware of the ETS applications and their time frames than the CSTT. The delays in the ETS applications means any improvements and changes to the patient testing repertoire could be delayed. This perception has occurred from the length of time the flexible scope ETS has taken. They theorised around the possibility of delays in the service provision and periods where the laboratory may not be accredited for a new procedure and how it could all impact on the service provision and patient safety.

5.8 Theme 4 - Efficiency

To measure the laboratory efficiency established performance measures were used to measure the impact of accreditation over the study period. TATs of the laboratory critical processes (HLA typing and Crossmatching in an acute on call situation) have been established which monitors the TATs of both Donor HLA typing and deceased donor crossmatching using both flow cytometry and complement dependant cytotoxic crossmatch (CDC-XM) and are generic across the H&I community (See Appendix 20).

Crossmatching is a pre-transplant test in which donor lymphocytes are tested against serum samples from the potential recipient(s) to determine there is a possibility of transplant rejection due to presence of donor–reactive HLA antibodies. These donor reactive HLA antibodies are a contraindication to transplantation and cause a positive crossmatch result. These are detected in the on-call situation by using either or both a cytotoxic cell killing test which uses donor cells and recipient sera alongside the flow cytometry crossmatch which is a more sensitive test that again uses fluorescence to detect antibody binding to donor cells.

5.8.1 Turnaround times

In this scenario national KQI are used that have been established which are generic for all NHS based H & I laboratories in the UK that provide a transplant programme. The KQI for HLA typing a deceased cadaveric donor is four-hours from receipt of sample to reporting (Figure 24) and the KQI for deceased donor crossmatching is four-hours from receipt of sample to reporting (Figure 25) with an overall eight-hour window for both techniques. The KQI for chimaerism monitoring (Figure 26) was originally established at <7days until 2019 when it was reviewed and reduced to <5 days (Appendix 20).

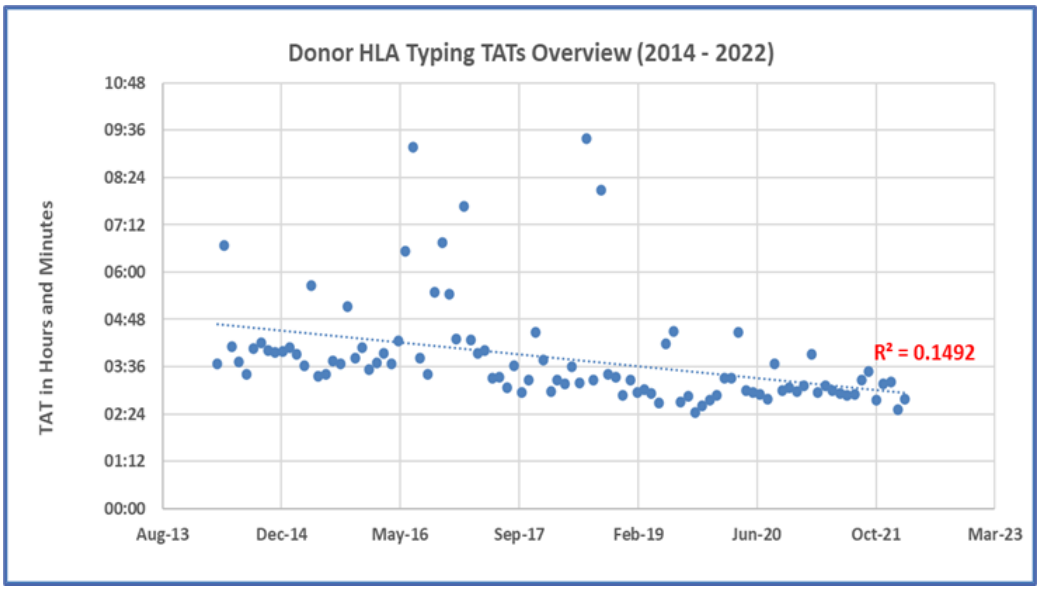
a) Deceased Donor HLA Typing

The Coefficient of Determination or the study period was **R^2 = 0.1492** indicating that 14.9% of the total variation in HLA tying TAT can be accounted for by the variation annual accreditation (Figure 24).

The Pearson Correlation co-efficiency for the study period was calculated as **r = -0.386** showing that the strength of the linear relationship is once again weak with a statistical significance of **P=0.0001** (See Appendix 25) which is sufficient to reject the Null hypothesis. This signifies there may be a potential relationship between Donor HLA typing TATs and accreditation.

Graphically it can be observed that there is an ongoing downward trend for HLA typing TATs which would be an expected outcome of continual improvement (Figure 24), but this may not necessarily be a response to annual participation in accreditation it may be due to changes in technical approaches to HLA typing over the study time frame.

FIGURE 24 HLA CADAVERIC DONOR TYPING - ANNUAL MONTHLY AVERAGE TAT (KPI <4 HOURS)



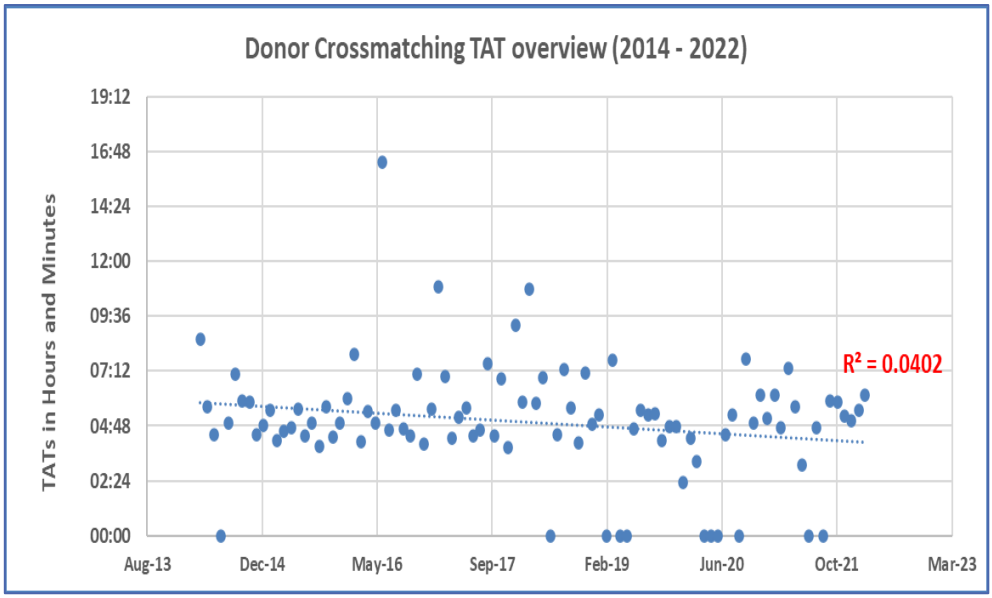
b) Deceased Donor Crossmatching

The Coefficient of Determination for the study period was **R^2 = 0.0402** highlighting that 5.9% of the total variation in the crossmatching TAT can be accounted for by the variation in annual accreditation (Figure 25).

The Pearson Correlation co-efficiency calculated for the study period was **r = -0.20** showing that the strength of the linear relationship is weak with a statistical significance of **P=0.05** (See Appendix 25) which also is sufficient to reject the Null hypothesis. This again signifies there may be a potential relationship between Donor crossmatching TATs and accreditation.

Graphically it was observed that there was an annual decrease in the crossmatch TAT which is reflective of what should be being achieved if accreditation is indeed improving efficiency as TATs improve. Over the last 5 years the laboratory has achieved and maintained the national KQI for HLA typing with the annual TAT being consistently on or below 4 hours (Figure 24). It was also observed that there was an annual downward trend in the crossmatch TAT which is reflective of what should be achieved if accreditation is improving laboratory efficiency as TATs improve (Figure 25).

FIGURE 25 CADAVERIC DONOR CROSSMATCHING - ANNUAL MONTHLY AVERAGE TAT (KPI<4 HOURS)



c) Chimaerism Monitoring

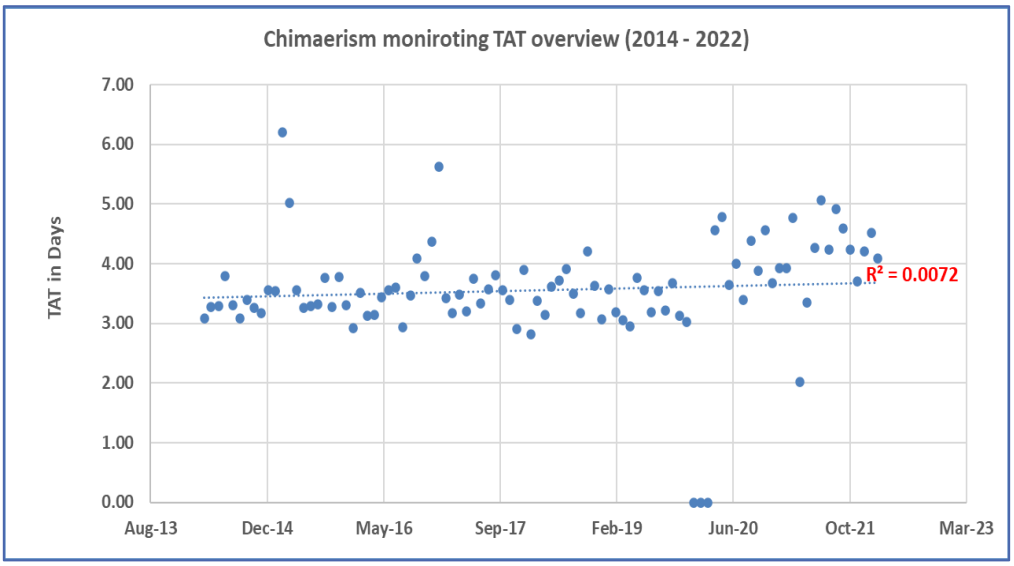
The Coefficient of Determination for the study period was calculated as **R^2 = 0.0072** indicating that 0.72% of the total variation in the TAT can be accounted for by the variation in annual accreditation (Figure 26).

The Pearson Correlation co-efficiency calculated for the study period was **r = 0.085** showing that the strength of the linear relationship is weak with a statistical significance of **P=0.41** (See Appendix 25) which is insufficient to reject the Null hypothesis.

Graphically it could be observed there appears to be a linear relationship between chimaerism monitoring TATs and annual accreditation (Figure 26) showing an ongoing trend in increasing TATs for this procedure over the period of accreditation which is contradictory to what should be expected if quality and efficiency were improving.

Since 2019 when the TAT was reduced from 7 days to 5 days it has been observed that the TATs have steadily increased even though they have remained within the acceptable range. This could be reflective of an increase in laboratory workload which will be explored in the next chapter.

FIGURE 26 CHIMAERISM MONITORING TAT (KPI <5 DAYS PRE-2019 & <7 DAYS)



Between 2017 and 2020 several ETS applications were made to UKAS to amend the scope of practice and introduce new technical advances to the HLA typing regime (Figure 7). There has been observed a continual improvement in HLA typing TATs (Figure 24). The process of CDC crossmatching and Chimaerism monitoring have remained relatively static for many years, and this is reflected in the consistency of the TATs observed (Figure 25 & 26). This indicates service quality is remaining static, although there appears to be an increasing trend in TATs for chimaerism monitoring which needs mentioning and further monitoring.

In Table 34 below an overview of the regression coefficient analysis for all the metrics involved in measuring efficiency for the study are evaluated. All three of the metrics have negative correlations, indicating as one variable increases the other decreases which would again be expected of TATs over time. The results could also indicate that because the correlation coefficient for crossmatching and chimaerism monitoring are closer to zero than to one there is no relationship between the key concepts efficiency (Dependant variable) and the years of accreditation (Independent variable), and any changes observed is completely unrelated. Both HLA typing and crossmatching are statistically significant thus rejecting the null hypothesis.

TABLE 34 OVERVIEW OF THE PEARSON CORRELATION CO-EFFICIENCY, THE COEFFICIENT OF DETERMINATION AND TOTAL VARIATION FOR LABORATORY TURNAROUND TIMES

Key Concept	Metric (TATs)	r	R^2	%	Strength of Linear Relationship	Correlation	P value (≤0.05)
Efficiency	**HLA Typing**	-0.386	0.149	15%	Weak	Negative	0.0001
	Crossmatching	-0.20	0.04	4%	Weak	Negative	0.05
	Chimaerism Monitoring	0.085	0.007	0.7%	Weak	Negative	0.41

In order to determine staff opinions and perceptions of whether the respondents thought the current system of ISO accreditation had improved efficiency they were asked in the questionnaire whether in their opinion ISO accreditation improved TATs (Q2.2). Interrogating the findings from the staff questionnaire it was observed that over **85%** of the responses (24) believed that the current system of ISO accreditation has had no impact on *improving the turnaround times in* the department. The 4 (14%) that did consider that accreditation improved the laboratory TATs were from the MT, one was a band 6-7 and one was a band 3-5 (Table 35).

TABLE 35 QUESTIONNAIRE RESPONSES REGARDING EFFICIENCY

Efficiency		MT (N=14)		CSST (N=14)			
		Band 8+		Band–6 - 7 (N=9)		Band–3 - 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q2.2	The laboratory Turn around Times	2	12	2	7	0	5

During the FGD's both groups discussed the impact of accreditation on improving TATs and what transpired was contradictory. During the CSTT discussions it was commented that the documentation required for accreditation always seems to impact on the laboratory personnel causing conflict and prioritisation of any accreditation documentation over patient testing which could potentially have an impact on laboratory TATs and RRs.

> *'I think it's the manpower thing', isn't it? becau'se we're always short staffed, and its prioritising thing', isn't it? So, it can be sometimes quite difficult to fit in that validation work, but also keeping your turn around times right for the patients, which I think we all probably feel is the most important thing. But equally you want to do the new things because you know that could improve things for the patients. So, it's finding that balancing act isn't it.' (CSTT06)*

The staff perception of the impact of quality documentation was quite significant for the CSTT who need to complete this alongside their routine technical roles. Quality is inbuilt into the laboratory culture with everyone playing a role in maintaining laboratory accreditation, from validations and verifications, documentation review and quality auditing.

During the FGD a member of the CSTT commented on accreditation and its impact on laboratory efficiency.

> *Yeah, it affects the quality. 'nd it's important, I think we deal with accreditation like testing and stuff,'but I'm not sure if it improves efficiency.' (CSTT08)*

Along with quality improvement, accreditation can provide the opportunity for a laboratory to improve efficiency by highlight gaps and weakness to minimise waste of time, resources, and effort. It is considered as an approach to enhancing not just quality but effectiveness, and efficiency. Therefore, suggesting accreditation can also be described as a tool to improve efficiency.

TABLE 36 OVERVIEW OF THE PEARSON CORRELATION CO-EFFICIENCY, THE COEFFICIENT OF DETERMINATION AND TOTAL VARIATION

Key Concept	Metric	r	R^2	%	Strength of Linear Relationship	Correlation	P value (≤0.05)
Quality	Repeat Rates (Average)	0.031	0.001	0.1%	Weak	Nonlinear	0.95
	Error Rates (EQA Results)	0.473	0.224	22%	Moderate	Positive	0.17
	Error Rates (ISO NC)	-0.095	0.0091	0.1%	Weak	Negative	0.82
Efficiency	HLA Typing (TAT)	-0.386	0.149	15%	Weak	Negative	0.0001
	Crossmatching (TAT)	-0.20	0.04	4%	Weak	Negative	0.05
	Chimaerism Monitoring (STR TAT)	0.085	0.007	0.7%	Weak	Positive	0.41
Cost Effectiveness		0.579	0.007	0.7%	Weak	Positive	0.13

5.9 Summary of Data Analysis

The analysis of the secondary quantitative performance data identifies (Table 36) that there appears to be no clear linear association with annual accreditation and laboratory quality observed in this single centre study. With both repeat rates and ISO NC having a weak linear relationship but an increase in the strength of the relationship between accreditation and EQA performance was observed. There was also no clear linear association with accreditation and laboratory efficiency. But there was observed an increase in the relationship between accreditation and TATs, but this may be a consequence of the changes in typing technologies rather than in continual participation in accreditation as illustrated with the repeat rates. The statistical significance of the data observed for the relationship between quality and cost effectiveness and accreditation was insufficient to reject the null hypothesis. Whereas the statistical significance of the data observed for the relationship between efficiency including the TATs for both cadaveric donor crossmatching and cadaveric donor HLA typing was sufficient enough to assume that the null hypothesis can be rejected and potentially accreditation as an improvement program can influence the laboratory TATs which corroborates the perceptions of the laboratory staff involved in accreditation. Unfortunately, this was not observed for all the data where it was detected that the outcome for the chimaerism monitoring TATs was insufficient to reject the null hypothesis. It is worth considering also in light of these findings that it is never appropriate to conclude that changes in one variable will cause changes in another based-on correlation alone (Robson et al, 2016). Only with the use of properly controlled experiments can it be determined whether a relationship is causal. A second consideration is that a low Pearson correlation coefficient does not necessarily mean that no relationship exists between the variables. The variables may just have a nonlinear relationship (Bryman et al, 2007; Robson et al, 2016) as seen with the data observed for average repeat rates over the study period (Figure 15). It is also important to consider if the data observed results in the failure to reject the null hypothesis it doesn't mean that the null hypothesis is true only the data in this study did not prove it to be false.

The overall findings from the quantitative data in this single centre study identified there were no significant improvements observed. The concept of accreditation being

a tool for quality improvement can be challenged, as the outcomes remained consistent over the years. This consistency of the findings could possibly signify that maintaining accreditation may not necessarily lead to improvements but quality and efficiency remaining constant could signify that there may not be any problems with the current systems and process in place.

The chapter presented the quantitative longitudinal secondary data obtained for each of the Clinical laboratory performance outcomes providing a baseline for the overall study where any changes and the impact of accreditation over the years can be clearly observed. It also presented primary data collected from the staff survey methods that have been examined to provide an overview of the current perceptions of accreditation in the laboratory. This included both the qualitative primary data collected from the FGDs and the quantitative data obtained from the survey. The qualitative data collected and analysed to examine the impact of laboratory ISO 15189:2012 accreditation in an NHS specialist pathology laboratory was presented in themes, sub themes and emerging themes to obtain a true reflection of the impact of accreditation.

Interrogating mixed methods data collected around key concepts was useful, guided by a unique accreditation evidence-based theoretical framework (Figure 4, Chapter 3). The data confirmed the findings established from the questionnaire highlighting subjective meaning and contextualised description to better understand outcomes. Perceptions of accreditation reinforced and challenged current literature to identify new knowledge of staff experiences and perceptions within a laboratory setting. As a QM the recognition that the accreditation system needed to change was clear but there was no evidence base to confirm this concept. This single centre study provides the new and original evidence base. Framed by useful key concepts replicable by other laboratories to examine quality, cost effectiveness and the value of accreditation moving forward (discussed in the next chapter). Key findings included:

- The participants did not consider the ISO accreditation value for money, describing it as expensive. Confirming the views found in the literature from Øvretveit, 2000; Peter et al, 2010; Hamza et al, 2013; Masau et al, 2015; Wilson et al, 2016; Buchta et al, 2018; Adane et al, 2019; Desalegn et al, 2019; Green et al, 2020.

- The participants perceived ISO accreditation to be a valuable management tool that improved laboratory quality confirming previous studies in the literature (Peter et al, 2010; Hamza et al, 2013; Rizk et al, 2014; Boursier et al, 2015; Zima, 2017; Plebani and Sciacovelli, 2017; Abdel-Wareth et al, 2018; Ramya et al, 2018).
- Three-quarters of the participants perceived that ISO accreditation had enhanced efficiency by advancing TATs. This concept was also seen in many other studies around accreditation (Kibet et al, 2014; Rizk et al, 2014; Buchta et al, 2018; Van Vliet, et al, 2024).
- Only half of the participants perceived accreditation to improve patient safety (Boursier et al 2015; Zima, 2017; Plebani and Lippi, 2017; O'Connor et al, 2020).
- The participants perceived there to be significant hidden costs involved with ISO accreditation impacting on workload. (Guzel and Guner, 2009; Brubakk et al, 2015; Wilson et al, 2016; Tzankov and Tornillo, 2017; Plebani and Sciacovelli, 2017; Plebani and Lippi, 2017; Zima, 2017; Buchta et al, 2018; Gough and Reynolds, 2000), corroborating the idea of it being a bureaucratic process (Mate et al, 2014; Wilson et al, 2016; Plebani and Lippi, 2017; Gough and Reynolds, 2000; Tashayoei et al, 2020; Van Vliet, et al, 2024).
- Three-quarters of the participants perceived ISO accreditation had enhanced efficiency by advancing TATs. (Kibet et al, 2014; Rizk et al, 2014; Buchta et al, 2018; Van Vliet, et al, 2024).
- The perception of the participants was that ISO accreditation may be increasing the psychosocial risk of laboratory personnel potentially adversely affecting professional stress levels (Guzel and Guner, 2009; Delaney and Shorten, 2019; Lapic et al, 2021; Hussein et al, 2021).
- The standards and assessment team were subjective and open to variation. (Huisman, W, 2012; Mate et al, 2014; Nicklin et al, 2017; Tashayoei et al, 2020; Van Vliet, et al, 2024)
- The participants described accreditation as a symbolic gesture of quality relying on a logo. (*New Knowledge)*
- The overall perception of UKAS as an organisation was negative. (*New Knowledge*)

The principal of using a collection of key critical processes to measure and monitor the impact of accreditation is novel to the field of study especially within the UK. The use of national KQI specific to a specialist pathology discipline to monitor and measure efficiency is also a novel concept which makes it generalisable and transferable to other laboratories in the H&I community. Overall, the findings provided a much needed:

- Evidence-based data to understand the impact of laboratory accreditation.
- Framework for measuring laboratory accreditation.
- Quality Map for laboratory services.
- Laboratory staff opinions on accreditation including expressions exposing UKAS as an organisation.
- Empirical data to inform policy makers.

Chapter 6 will examine in more detail the analysis of the outcomes for the key concepts. Discussion and conclusions will be drawn from the data collected examining the impact of accreditation in a H&I laboratory, the challenges, the improvements, and recommendations for change.

6.Discussion

6.1 Introduction

This longitudinal mixed methods study adds new knowledge to the paucity of empirical evidence, generating a substantial evidence base and deeper understanding surrounding the topic of laboratory accreditation. Providing other NHS laboratories, policy makers and healthcare organisations data with which they can draw inferences regarding the impact of laboratory accreditation using the ISO 15189:2012 standard.

The data established and presented in chapter five has led to several unique findings and demonstrates a contribution to new knowledge and theory. This chapter integrates the research findings and positions this within the current knowledge and theory about laboratory accreditation exposing how the outcomes from this study will be expanded to develop understanding.

6.2 Themes for discussion

The overall aim of the DProf study was to understand the impact of laboratory accreditation in an NHS specialist pathology laboratory. Assessing established performance measures and key concepts identified from the literature and used to develop the theoretical framework. A parallel aim was also to investigate laboratory staff experiences and their perceptions and opinions of ISO 15189:2012 accreditation.

Objectives included:

- To measure the annual costs of laboratory accreditation for an NHS specialist pathology laboratory, to establish if accreditation as a quality assurance initiative is value for money and cost-effective.
- To measure the impact of accreditation on the quality and efficiency of an NHS laboratory by monitoring National Key performance indicators and internal QI for recognised critical laboratory processes.
- To explore the impact of laboratory accreditation on staff and their work, to gain a deeper understanding of their perceptions of laboratory accreditation.
- To generate an evidence-base to inform and further examine the impact of ISO 15189:2012 accreditation in a well-established NHS specialist pathology laboratory.

- To add to the theoretical understanding of laboratory accreditation and quality in the NHS, through the lens of an NHS specialist pathology laboratory.

These objectives in line with the aims have been employed to develop the themes for discussion and identifying new knowledge as follows:

1. Understanding the impact of laboratory accreditation in an NHS specialist pathology laboratory the 'real value of accreditation' was established which included:
    - Understanding the financial costs
    - Understanding the outcomes of laboratory performance
    - Understanding the perceived value of accreditation (through the lens of the staff directly involved).
2. A robust systematic framework to be utilised by medical laboratories.
3. Accreditation for the future

6.3 Understanding the impact and value of laboratory accreditation.

The data collated in this study to develop an understanding of the real value of laboratory accreditation is novel and has not been collected and presented before in the academic literature. The review of current evidence identified a significant need for empirical evidence in the area around accreditation in healthcare (Greenfield and Braithwaite, 2008; Alkhenizan et al, 2011; Greenfield et al, 2011; Brubakk et al, 2015, Hovlid et al, 2020). In the literature the current process for accreditation has been described as time consuming, bureaucratic, and costly, with demands on the laboratory, without any empirical evidence to verify (Verstraete et al, 1998; Plebani et al; 2017; Buchta et al, 2018; Green et al, 2020; Lapic et al, 2021). The outcome from this study will fill this data void providing new knowledge and theory around the impact of accreditation and whether this type of inspection of laboratory service quality is effective (Hovlid et al, 2020).

6.3.1 Financial costs

This study has demonstrated that over the period observed (2014 – 2023) the financial costs of accreditation to a single centre NHS specialist laboratory can be significant and that no correlation between cost effectiveness and accreditation was observed. As previously described these annual costs include assessment fees for the UKAS assessment teams' onsite visit, it also includes expenses for the team of assessors,

office time to review documentation and complete assessment reports and assess improvement actions for identified NC. The costs exhibited here were from one laboratory within a single NHS hospital trust. When you consider there are approximately 215 NHS trusts (The Kings Fund, 2023), with around 105 hospitals in England alone providing pathology services at a cost of over £2 billion (NHS England, no date). All of which require UKAS accreditation, identifies an area of expenditure that could substantially contributes to the rising NHS costs (NHS, 2019). The data from this study therefore provides a much need evidence base for other NHS pathology laboratories and NHS decision makers to establish a theoretical understanding of the financial impact of accreditation. Identifying specifically the financial costs to an organisation and the NHS, exploring also, the question of value for money which has not previously been addressed in this area.

The research problem highlighted (chapter 1 and 2) that the main purpose of implementing quality improvement programmes such as accreditation was to assure the quality, efficiency and effectiveness of the service being provided (Greenfield and Braithwaite, 2008; Hinchcliff et al, 2012, Brubakk et al, 2015; Melo, 2016; Ramya et al, 2018) by compliance with standards. Such programmes have been described has having significant cost implications (Øvretveit, 2000; Peter et al, 2010; Gough and Reynolds, 2000; Balla, 2012; Hamza et al, 2013; Wilson et al, 2016; Buchta et al, 2018; Adane et al, 2019). As a QM with many years of experience, it was important to assess the financial impact of accreditation and its significance, as the expenditure on such improvement programmes has never been explored before from a laboratory perspective (Figure 9 & 10). There has been a plethora of articles in the literature that have looked at accreditation and improvements to services in healthcare which encompassed the financial impact of such quality improvement programmes (Brubakk et al, 2015; Mumford et al, 2013; Devkaran and O'Farrell, 2015; Mumford et al, 2015). With many of them describing significant costs to an organisation (Øvretveit, 2000; Peter et al, 2010; Hamza et al, 2013; Mumford et al, 2013; Mumford et al, 2015; Buchta et al, 2018; Adane et al, 2019; Green et al, 2020). These were mainly hospital focused, (Greenfield and Braithwaite, 2008; Greenfield et al, 2011; Hinchcliff et al, 2012; Mumford et al, 2013; Mumford et al, 2015) very few were found within the specific field

of laboratory accreditation and those that did provided little or no empirical evidence just anecdotal evidence (Buchta et al, 2018; Adane et al, 2019; Green et al, 2020).

There was also a dearth of evidence-based research that addressed laboratory accreditation as an intervention and specifically its cost effectiveness for medical laboratories (Hamza et al, 2013). To defend the implementation of any new approach cost effectiveness analysis (CEA) is crucial because such interventions may require considerable resources and finances (Ovretveit, 2000; Hoomans and Severens, 2014; Mumford et al, 2015). Without exploring the cost of accreditation there was the potential for there to be a waste of resources (Greenfield et al, 2011; Saut et al, 2017; Hoomans and Severens, 2014). Resources which included staff, time, and financial aspects, were all equally important in the success of implementing any improvement programme (Øvretveit, 2000; Hoomans and Severens, 2014; Wilson et al, 2016; Alshamsi et al, 2020; Sorra et al, 2021). These issues emerged throughout the literature review, where lack of financial resources, staff shortages, and time constraints were identified as a barrier in the process of accreditation implementation and corroborated in a number of healthcare based studies (Hinchcliff et al, 2012, Greenfield et al, 2012; Hoomans and Severens, 2014, Saut et al, 2017; Buchta et al, 2018; Adane et al, 2019; Green et al, 2020; Tashayoei et al, 2020; Lapic et al, 2021). The financial and cost effectiveness evidence produce from this study and the lack of correlation between accreditation and cost effectiveness could be used to initiate a dialogue for NHS finance executives and policy makers with regards to value for money.

In the literature a number of single centre studies from resource limited countries considered implementing laboratory quality and service improvement working towards accreditation (Kibet et al, 2014; Risk et al,2014; Masau et al, 2015; Desalegn et al, 2019). The main consideration was that any costs would be offset by improved laboratory efficiencies, without any real empirical evidence (Kibet et al, 2014; Masau et al, 2015). Not one study included the measurement of associated costs or investigated any potential long-term expense of achieving and maintaining accreditation status. One group considered that the costs involved were ‘high enough to be a major deterrent’ but this was not investigated further and would be significant for such laboratories in resource-limited countries (Kibet et al, 2014). This cost saving

component could be regarded as a principal factor to resisting accreditation, particularly for such restricted laboratories, and definitely warrants further investigation as a barrier to accreditation not a defence for implementation.

The implementation and maintenance of accreditation as been described as requiring both immense effort and personnel resources identifying significant hidden costs of quality (Wilson et al, 2016; Øvretveit, 2000; Sorra et al, 2021). This was corroborated in part by the outcomes of this study which identified both a significant annual increase in budgetary spend over the nine years of UKAS accreditation (from 2014 to 2023) along with the perceived impact of accreditation described by laboratory personnel providing further new empirical evidence (See 6.3.3). In 2014 accreditation under CPA UK Ltd cost a flat fee of £2,400 per year, which was also at the time considered costly (Gough and Reynolds, 2000). The cost of accreditation assessments have increased considerably since 2014 ranging from anywhere between £6,000 and £8,000 per year depending on the surveillance visit and UKAS interaction, without any significant improvements observed in performance. Additional costs for any laboratory wishing to enhance the testing repertoire in line with service and technological demand were also introduced. These applications for ETS to UKAS can add an additional £2-£3,000 to the annual fees for assessments to amend the scope of practice (Figure 9).

No studies in the UK or Europe have compared costs and cost effectiveness of ISO accreditation, alongside key outcome measures to identify the true value of accreditation (Hoomans and Severens, 2014; Ovretveit, 2000). This study therefore provides substantial data for healthcare policy makers, and economic evaluations to proceed, asking the question of the true value of accreditation and its impact on performance (Hoomans and Severens, 2014; Mumford et al, 2015; Eisman et al, 2020). The costs identified in the study highlight the charges for maintaining ISO accreditation in an NHS laboratory, identifying that there is a continual increase in the annual cost of accreditation that impacts on every medical laboratory budget. These costs will not deter the continued implementation and maintenance of accreditation in medical laboratories especially now with accreditation being a mandatory requirement of all NHS laboratories. Understanding the expenditure overtime may be important for NHS decision makers to ensure budget allocation.

6.3.2 Outcomes of laboratory performance.

There was no definitive correlation between laboratory quality and efficiency and the implementation of laboratory accreditation seen in this study. There was a significant change over the years in error and repeat rates, but these were not statistically significant (See Section 5.7). TATs of the laboratory critical processes saw an improvement over the study period in two out of the three national performance indicators, which was statistically significant (See Section 5.8). Improvement year on year should be observed for laboratories that have implemented and maintained accreditation due to it being considered as a continual improvement tool (Alkhenizan and Shaw, 2011; Hoomans and Severens, 2014; Ovretveit, 2000) rather than consistency in performance as observed in this study. In light of the findings this concept could therefore be disputed, and accreditation only be considered as a continuing monitoring tool to facilitate and identify possible improvement.

Literature surrounding hospital accreditation identified a number of positive correlations between the implementation of accreditation and the development of a collaborative quality and safety culture (Greenfield et al, 2011), and with improvements in patient care (Bogh et al, 2015) presumably due to the outcome measures used for the study. Conversely, the results of this study indicated that there have not been consistent efficiency changes year on year in most of the performance measures to justify continued or sustainable improvements, except TATs for the national QI (See 5.8.1). This may reflect the fact that these national indicators have direct patient outcome implications that are monitored externally to the laboratory and not as a consequence of continual maintenance of accreditation. This outcome reinforces other observations that could not draw any definitive conclusion that the implementation of accreditation had had an effect on quality or improved patient outcomes (Greenfield and Braithwaite, 2008; Alkhenizan et al, 2011; Greenfield et al, 2011; Brubakk et al, 2015, Hovlid et al, 2020; Green et al, 2020).

Participation in and successful completion of proficiency testing (EQA) schemes are a requirement for compliance with ISO 15189 accreditation (UKAS, 2012). All schemes vary dependant on the pathology discipline, and all have their own acceptance criteria for assessments but are considered a useful tool to recognise quality (Hamza et al, 2013; Buchta et al, 2018). The outcomes of which could provide insight into the long-

term impact of accreditation (Wilson et al, 2016) by identifying persistent poor performance. The outcome from this study reflected other studies where assays remained satisfactory (90-100%) (Masau et al, 2015; Desalegn et al, 2019). Where trends towards improvements were observed (Rizk et al, 2014; Desalegn et al, 2019) but were not statistically significant (Kibet et al, 2014). In contrast there were studies where no changes at all were observed (Masau et al, 2015; O'Connor et al, 2016) and where both accredited and non-accredited laboratories had comparable performance (Buchta et al, 2018). The outcome from the study identifies new knowledge that brings into question the legitimacy of EQA schemes and whether these proficiency results are an appropriate tool with which a laboratory or its users should employ to recognise quality (Walshe et al, 2016) or whether it really does give insight into the long-term effects of accreditation (Wilson et al, 2016). Identifying that perhaps these schemes may be more appropriate for laboratories to measure internal staff proficiency and competence alone.

The study identified that the number of ISO NC and observations made by the UKAS assessment teams on each surveillance visit fluctuated over the years. The number of NC was high in the transition year (2014) which is to be expected as the laboratory moved over from one set of standards and assessment body to another (Table 37).

TABLE 37 NUMBER OF NON-CONFORMANCES AND POTENTIAL RATIONALE

Surveillance Visit		Year	Number of NC	Potential Rationale
Transition		2014	**11**	New standards / New UKAS assessment team
Cycle 1	1	2015	**13**	Embedding of new assessment team / standards
	2	2016	**6**	QMS maturing / Improvement / assessment team
	3	2017	**3**	QMS maturing / Improvement / assessment team
	4	2018	**32**	Full assessment / New assessment manager
Cycle 2	1	2019	**17**	New assessment manager
	2	2020	**4**	**Remote assessment**
	3	2021 - 22	**4**	**Remote assessment**
	4	2022 - 23	**9**	On site / New assessment manager

The fluctuation in the amount of reported NC identified could reflect that, initially the introduction of the new ISO 15189: 2012 standard in 2014 and the interpretation of

these against the laboratories systems by the new UKAS assessment team. Although training is provided by UKAS to all members of the assessment teams, its efficiency and effectiveness is difficult to determine but is essential for its success (Alkhenizan and Shaw, 2011; Greenfield et al, 2012; Hinchcliff, et al, 2012; Mate et al, 2014; Adane, et al, 2015; Brubakk et al 2015; Nicklin et al, 2017; Tashayoei et al, 2020). The fluctuation in the number of NC may also suggest the subjectivity of the standard and interpretation of them by the assessment team's , which was raised during the FGDs. It could also identify issues with the interpretation of the standards internally by the laboratory team which may have led to the misinterpretation and the introduction of systems and processes that may not have necessarily been required. This may lead to the introduction of unnecessary documentation impacting on already busy laboratory staff.

The theme which developed around the UKAS assessment team is novel and has never been illustrated in the literature, in comparison to literature available around the importance of training and competence of peer assessors (Hinchcliff, et al, 2012; Adane, et al, 2015; Plebani et al, 2015; Plebani and Sciacovelli. 2017; Tashayoei et al, 2020). This was corroborated by the fluctuating numbers of NC identified in an assessment where there were new assessment managers (Table 37). The reductions observed in the number NC could be indicative of an improvement in laboratory quality but has these assessments are only snap shots in time it is difficult to conclude (Wilson et al, 2016; Devkaran and O'Farrell, 2015). It may also be a consequence of the laboratory QMS maturing and so indicating that continued auditing from the same standard generates declining gains (Wilson et al, 2016; Green et al. 2020).

The continued number of ISO NC achieved annually is potentially either a clear indication that accreditation fails to ensure quality and continual improvement or that there is a possible flaw in the design of the accreditation system. Perhaps also identifying that the NC detected are unlikely to have any significant consequence to quality and patient outcome (Wilson et al, 2016; Green et al. 2020). It could be considered that any improvements observed may be just a result of strong leadership, or a culture change, as people become more focused on quality and continual improvement (Walshe and Freeman, 2002; Kibet et al, 2014; Nicklin et al, 2020; Hovlid et al, 2020). Indeed, training laboratory staff to be more efficient and standardising

laboratory processes could be counterfactual reasons for any improvements seen. These are easily achieved and maintained without the need for accreditation by simply continually working towards quality creating an internal culture of quality (Bracewell and Winchester, 2021). This proposition was not a consideration for the resources-limited laboratories, who citied accreditation to be the only rationale for any improvement.

6.3.3 Understanding the perceived value of accreditation by Staff.

The use of staff questionnaires is minimal in this field of research with only one study being identified which was of a quantitative design (Lapic et al, 2021). Using quantitative findings in collaboration with the qualitative data analysed from the FGDs to explore the objectives was novel in this field of research. Gathering structured laboratory staff opinions and perceptions on accreditation to identify the impact and effects on the staff at various grades was novel. Understanding how staff feel and the true impact day to day was indeed unique. The laboratory team's opinions and perception of accreditation, the analysis of the questionnaires alongside the FGD data, produced novel themes around the concept of ISO 15189:2012 accreditation in an NHS laboratory.

The information collected from the questionnaire created a narrative that confirmed previous studies which was explored further in the FG. In this study the FG reflected on cost effectiveness, where it was described as time consuming, redirecting resources away from patient care as found by others in the literature (Gough and Reynolds, 2000; Greenfield et al, 2011; Plebani and Lippi, 2017; Saut et al, 2017; Hoomans and Severens, 2014; Tashayoei et al, 2020). This was expanded on further when it was recognised by the teams that increased workloads can impact on efficiency and the service (Guzel and Guner, 2009; Tzankov and Tornillo, 2017; Plebani and Sciacovelli, 2017; Plebani and Lippi, 2017; Zima, 2017) the increase in workload being a perceived consequence of ISO accreditation. This emotive area developed a further new theme around the psychosocial risks to staff. Staff declared there was a significant impact on their day-to-day duties describing accreditation has 'labour intensive' causing 'stress and anxiety', that 'added extra pressure' which corroborated the quantitative outcomes of the only study found of laboratory professionals' attitudes to accreditation (Lapic et al, 2021), also providing further anecdotal rhetoric around the impact on the workforce (Guzel and Guner, 2009;

Plebani and Lippi, 2017; Sciacovelli et al, 2017; Tzankov and Tornillo, 2017; Abdel-Wareth et al, 2018; Adane et al 2019).

This critical aspect of accreditation has never been fully addressed and comes with a heightened awareness of mental health in the workplace and the death of a Berkshire Headteacher succeeding a critical Ofsted report (Ng and Kingsley, 2023). There have been calls for a halt to such inspections and reform amid claims by the family that her death was a direct result of the process and outcomes (Singh, 2023). This has led to concerns amongst the teaching profession claiming there is a need for accountability and that the current system is flawed, with variability quoting that 'It is unacceptable that the pressure of an impending inspection (or the outcome of one) should make committed professionals ill or worse' (Keeling, 2023). They talked of reform to the system which are less bound to fixed principles, and more attuned to the differences and contexts within each establishment. This type of restructuring may also be consideration for UKAS with healthcare laboratories which have significant differences and specialisations. Specialisation in pathology disciplines have seen a positive impact on quality when comparing the analytical performance due to a higher level of competence because of other official inspections required in such specialisations (Buchta et al, 2018). However, the opposite has also been observed with the impact of accreditation being seen has having no significant impact on quality (O'Connor et al, 2016). This highlighted the complexity of this field of study, it could be argued that the more a laboratory is under scrutiny and assessment the more well managed their systems and process may be (Buchta et al, 2018). This new data has never been collected and collated to illustrate the impact of laboratory accreditation specifically through the lens of an NHS specialist pathology laboratory. With the outcomes corroborating Buchta's theory on specialisation in pathology disciplines.

A further issue highlighted in the FG was staff opinions and perceptions of the cost of accreditation, these perceptions were corroborated by the quantitative findings from the study around the concept of accreditation. This was an extremely emotive area where the management team especially, whom are more directly involved, voiced genuine concerns regarding the significant costs of accreditation. When compared with other accreditation authorities such as the European Federation of Immunogenetics (EFI) who's fees are fixed at €1050 per year and in comparison, were

considered minimal. This led to the emergence of a new theme regarding the national accreditation body and their perception of UKAS as a ‘not-for-profit’ organisation, which has been discussed previously with focus on hospital accreditation (Braithwaite et al, 2010; Hinchcliffe et al, 2012; Brubakk et al, 2015). Describing UKAS as possibly dominating accreditation due to the lack of competition. This aspect has never been considered in the literature and provides new knowledge concerning accreditation services which needs further investigation. The lack of competition is not a reflection of UKAS itself but the system created following the Lord Carter report and it is now common place through out Europe with most European countries havinga single accreditation body.

Accreditation was also perceived by the laboratory staff as being problematic for innovation, corroborating anecdotal evidence in the literature around healthcare that had described it as ‘stifling innovation’ (Balla, 2012; Thelen et al, 2015), without any empirical evidence (Verstraete et al, 1998; Plebani et al; 2017; Buchta et al, 2018; Lapic et al, 2021). In line with this, during the FGDs the staff opinions of accreditation was that it was nothing more than a symbolic gesture of quality in their rhetoric. The use of the UKAS logo seemed the most significant part of the accreditation status and a key influencer for people, identifying a symbol of quality (Tashayoei et al, 2020). The logo can only be displayed on reports for accredited procedures that have been assessed by UKAS. This symbol was considered by the MT as a vital component of the accreditation process as it validates the laboratory competence in the eyes of the service users and the general public but the rhetoric was not as important to them. This needs to be expanded on further post doctorate, to establish whether or not the users consider the accreditation process as important as the MT.

This ideology around symbolism was novel and had not been observed in any of the articles around laboratory accreditation. This developed into a further theme where it appeared unclear whether the staff believed that the patients or clinicians fully understood or appreciated the accreditation status or whether it was indeed important to them. Questioning whether the process of accreditation and the time and effort spent in expediting the assessments were worthwhile leading back to efficiency. It also posed the question whether this aspect of understanding the value of accreditation should be opened up to other stakeholders in future research.

The role of the surveillance team (assessors) was deemed 'important' and their feedback invaluable but there were questions raised over their subjectivity and differences of opinions. Surprisingly the staff also expressed concerns that they sensed that assessors had to find NC as part of a '*bonus scheme*' during the assessment visit. During the Covid-19 pandemic when the assessments were carried out remotely there was a reduction in NC observed. This could reflect either an issue with remote assessments as a new approach may not be as robust a system or an issue with the inconsistency of the assessment teams and their subjectivity or training and competence corroborating previous published studies (Hinchcliff et al, 2012; Adane et al, 2015; Boyd et al, 2017; Tashayoei et al, 2020). It could also be an issue with the clarity of the standard and the interpretations made by both the assessment team and the laboratory team. This narrative around the peer assessors is novel and not been fully explored in the literature. If assessments are considered unreliable this could undermine the credibility of accreditation in the eyes of the staff and any stakeholders (Boyd et al, 2017).

At the end of 2022, the standards (ISO 15189:2022) were revised and published which addresses the topics and generating clarity to various concepts of the old 2012 version, enhancing and consolidating term definitions (Ilinca et al, 2023). This now introduces a new period of change while everyone including the UKAS assessment team becomes familiar (ISO, 2022). This new standard offers increased flexibility in developing the QMS although the technical requirements have not substantially changed. Documents that were once mandatory, such as the quality manual, are no longer a requirement, but this doesn't mean the information contained in it isn't required. There is also an increased focus on risk management which may lead to further documents such as risk analysis, but it doesn't specify how this should be performed, with the potential for ambiguity amongst laboratories and assessment teams.

A positive of accreditation identified was that it was considered as a valuable management tool for medical laboratories to improve quality with the implementation and maintenance of quality laboratory systems to maintain patient safety (Boursier et al 2015; Zima, 2017; Plebani and Lippi, 2017; O'Connor et al, 2020). From the analysis of data, there were different perceptions identified and described dependent on the staff grade. Uncovering and exposing perceptions of laboratory accreditation

that are novel. The management team placed a greater emphasis on improvement as an important part of accreditation which made it a valuable management tool. Seeing it as an essential means to improve clinical practice and performance (Greenfield and Braithwaite, 2008; Hinchcliff et al, 2012; Brubakk et al, 2015; Melo, 2016) but evidence in the study indicated mixed feelings towards any on-going improvement to patient care (Greenfield and Braithwaite, 2008; Braithwaite et al, 2010; Bogh et al, 2015). Whereas the Clinical scientists and technical team considered it to be a necessary process providing a framework with which to achieve and maintain accreditation. One of the main concerns of the staff was the perceptions of patients of accreditation and whether they or the service users understood the concept or if they really cared if the laboratory had an accreditation status. This aspect of accreditation is novel and would be an interesting development to explore post-doctorate. To progress this concept and to build a data source around this theme to establish the true value of laboratory accreditation from the perspective of the service users and patients may further examine the requirement of the accreditation process.

6.4 A robust systematic framework to be utilised by medical laboratories.

Methodological research challenges have been identified as a reason for the lack of consistent evidence on the impact of quality improvement programmes such as accreditation (Ovretveit, 2002; Ovretveit and Gustafson, 2002). The development of this systematic framework for the study which includes both a theoretical and a methodological framework is novel. The notion of using a number of defined key concepts and critical laboratory processes alongside a survey style approach of FGDs and a questionnaire in one single centre study to evaluate the implementation is innovative and bold. ~~and~~ It has provided a robust approach to answer the research aims and objectives. This framework can be adopted by other NHS laboratories as a model to measure the impact of ISO accreditation and to validate any requirement for change, providing further data to inform policy and decision makers in NHS trusts.

6.4.1 Theoretical Framework

The theoretical framework was developed following a systematic review of the academic literature which focused primarily on healthcare accreditation considering hospital and medical laboratory settings (Chapter 3, Figure 3). This was unique to the study and developed to contextualise and direct the research. The model framework

established the key concepts to be examined alongside staff opinions, to evaluate and understand the impact of accreditation over the study timeframe. The review of the literature identified a finite amount of research material in this area in-order to corroborate the use of these defined concepts. There were studies that used KQI such as TATs error rates and RRs as a way to measure any impact (Hamza et al, 2013; Kibet et al, 2014; Rizk et al, 2014; Masau et al, 2015; Buchta et al, 2018; Green et al, 2020) but there was a significant lack of use of robust qualitative data to formulate outcomes (O'Connor et al, 2018; Desalegn et al, 2019). The inclusion of the different approaches of quantitative analysis using numerous KQIs and the staff surveys combined with the use of qualitative data obtained from the FGDs is unique and contributes to the development of significant new knowledge in using a variety of methods in this area.

There was support in the literature for the implementation of accreditation as a valued way to improve quality, and efficiency in laboratories (Hamza et al, 2013; Rizk et al, 2014; Masau et al, 2015; Ramya et al, 2018; Green et al, 2020) using quality metrics (Kibet et al, 2014; O'Connor et al, 2016; Desalegn et al, 2019). Including the implementation of a QMS to manage laboratory quality (Masau et al, 2015), using QI to measure laboratory performance (Rizk et al, 2014; Ramya et al, 2018), outcomes of proficiency testing (Buchta et al, 2018), and error rates which involved conformity to standards (Green et al, 2020). These quality indicators and key concepts need to be embedded and measured to illustrate the impact of accreditation over time. To demonstrate if quality improvements in H&I laboratories are sustainable and identify reduced quality upon which to act. The use of National established KQIs (OTDT, 2022), specific internal medical laboratory KQIs and UK recognised proficiency test data (UKNEQAS) makes the study more significant and generalisable to other medical laboratories especially those within the field of H&I in the UK and globally. This research generated a framework for an accreditation evaluation model that can be used by other laboratories to assess their current position with respect to accreditation without adding study bias.

6.4.2 Methodological Approach

Evidence surrounding the implementation of projects are often subjective, discussion or descriptive pieces (Guzel and Guner, 2009; Mate et al, 2014; Sciacovelli et al, 2017;

Tzankov and Tornillo, 2017; Zima 2017; Abdul-Wareth et al, 2018) whereas this study is bold, moving away from the anecdotal rhetoric. It provides a sound body of evidence to understand the impact of accreditation that is so desperately required (Peter et al, 2010). The longitudinal mixed methodological approach provided data at a higher level of evidence than previously seen in the literature (Wilson et al, 2016), providing robust evidence rather than assumptions.

The use of a single centre case study seems to be a common methodological approach when investigating the implementation of laboratory accreditation in developed and resource limited countries and was seen in several of the publications (Guzel and Guner, 2009; Kibet et al, 2014; Rizk et al, 2014; Masau et al, 2015; O'Connor et al, 2016; Tzankov and Tornillo, 2017; Abdel-Wareth et al, 2018; Ramya et al, 2018; Desalegn et al, 2019; Green et al, 2020). Indeed, the methodological approach using mixed methods is ambitious and unique to the evaluation of the implementation of accreditation and its impact. This approach was scarce in the literature and where it was observed it was not peer reviewed (O'Connor et al, 2016) or was of poor quality as it failed to include data to inform improvements in laboratory quality (Desalegn et al, 2019). These characteristics lead to the rationale and development of the methodology, reinforcing the use of mixed methods to capture the data. To ensure the design was robust QI and national KPI to measure and monitor quality and efficiency were defined.

In order to rigorously test the impact of accreditation, it is necessary to investigate change over time, which cannot be captured by a cross-sectional study. For medical laboratories what is required is a longitudinal analysis, as there needs to be consideration of how long it takes a laboratory to implement accreditation standards and show improvements. Longitudinal designs are necessary as cross-sectional designs cannot alone establish causality (Devkaran and O'Farrell, 2015). To negate any methodological weaknesses a time series analysis of quality indicators was established during the periods post implementation of ISO 15189: 2012 accreditation (through a month-by-month comparison). This time series methodological approach permits a rigorous test of whether ISO accreditation impacts upon the quality and efficiency of the service provided. Although causality cannot be inferred based only on a single case study due to the complexity of the study variables, the outcomes

suggest important relationships between some of the key concepts and accreditation which merit further investigation.

One of the most detrimental effects of laboratory accreditation described in the literature has been the impact on the workforce and understanding the impact, challenges and effects is crucial (Guzel and Guner, 2009; Tzankov and Tornillo, 2017; Lapic et al, 2021). These studies all used a quantitative methodology alone to address their study aims and were exposed to potential design weakness and research bias. The use of qualitative methodological approaches has been minimally employed in the field of medical laboratory research into laboratory accreditation (Desalegn et al 2019; O'Connor et al, 2016). To corroborate the findings from the questionnaire FGDs were introduced to the design. The FGs were used to expand the knowledge developed from the questionnaire through discussion to include the experiences of the participants and their shared perceptions (Alshamsi et al, 2020). The thematic analysis from the FGDs was triangulated with the quantitative findings to fully understand and support in drawing conclusions around the laboratory team's opinions and perceptions of accreditation (Braun and Clarke, 2022). This methodological approach in the study design is once again novel for assessing the impact of ISO 15189 accreditation in an NHS laboratory, identifying for the first time the true impact of accreditation on the laboratory workforce.

6.4.3 Research Tools

The laboratory senior management team was used to establish an expert panel for the study. This was a novel approach within the available methodological designs presented as a way to develop the research tools and to control potential researcher bias. The need to declare and control research bias is important and especially so when the researcher is embedded in the research. In this study in an attempt to add rigour and validity and control researcher bias several approaches were taken. The longitudinal outcome quality data that represented the key concepts for the study was collated by third parties independent of the study (Green et al, 2020; Wilson et al, 2020). RRs and TATs used were routinely captured by the Audit data manager and taken from that database to the study dataset for analysis. The error rates were also defined by an independent third party, the NC were obtained from each assessment cycle that had been identified independently by the UKAS assessment teams. The

error rates for the EQA schemes were established by the team at UKNEQAS for H&I from laboratory participation the proficiency tests. All these key concepts along with the selection of the critical laboratory processes were agreed by the expert panel, who played a significant role in validating the key themes for the questionnaire development.

Cost effectiveness analysis was required to support the implementation of any new approach as these can require considerable resources and finances (Hoomans and Severens, 2014; Ovretveit, 2000). There seemed to be a lack of empirical evidence in this area considering if there has been a significant investment in laboratory accreditation within the NHS over the last several years. The development of the cost effectiveness tool specific to the study was an adaption from a design by Hamza (2013), the only available tool tested in the current literature. This study revised the cost effectiveness ratio to develop an assessment tool (Equation 1) that can be used widely by NHS laboratories to collaborate and expand the data set to determine the actual cost effectiveness of ISO accreditation in the NHS.

6.5 Accreditation in practice - the future

In my role as laboratory QM my interest with accreditation has been ongoing for over three and a half decades. It initially started through my practical role as clinical scientist and then as QM in a specialist pathology discipline with hands on everyday experience of developing and managing the QMS.

Thelen et al (2015) suggested a way that laboratories could adopt a new flexible approach that was less restrictive and allowed changes to methods to be amended to a laboratory's scope, where competence had previously been verified (UKAS, 2004). This was the initial driver for this doctorate but as discussed previously with delays in ETS applications during covid the study had to be redirected. The study developed into an assessment of the impact of the current ISO 15189:2012 accreditation programme using the analysis of longitudinal data of performance measures and staff perceptions.

Across Europe and the UK, accreditation was being implemented using ISO 15189:2012 as the primary standard for medical laboratories (Huisman et al, 2007; Huisman, 2012; Hamza et al, 2013; Boursier et al, 2015) without any empirical

evidence to substantiate any claims of quality improvement. This study takes a pragmatic step back and has generated a valuable evidence base which has evaluated the impact of accreditation on a single centre NHS specialist laboratory. It has also developed a theoretical framework that can be adopted and adapted by other laboratories to establish their own current position. Collating and analysing the data could produce a more significant body of knowledge with which to understand the impact of ISO 15189:2012 accreditation.

As the study transitioned still one question continued to underpin the study, which was could the process of laboratory accreditation be modified to become more efficient and cost effective. Could laboratories better use their autonomy, their trained and skilled HCPC and RCPath registered professionals and mature well managed QMS to maximise efficiency and develop service provision and innovation in line with clinical demand (Balla, 2012). With adjustments to the current UKAS accreditation assessment programme or has previously thought the implementation of the flexible scope for the whole scope of practice (Thelen et al, 2015).

The data created from this study provided a context to the rationale for the requirement for change, generating a deeper understanding of the impact of laboratory accreditation. The motivation for evaluating cost effectiveness in this study was to justify if the resources employed to establish and maintain accreditation were effectively being used to improve quality and clinical outcome (Hinchcliff et al, 2012; Hoomans and Severens, 2014; Øvretveit, 2000; Sorra et al, 2021). The rationale for assessing performance measures was to identify any significant changes in quality and efficiency longitudinally over the study period to verify the impact of accreditation.

During the pandemic there was evidence of a new 3-staged approach which was being used by UKAS to assess the new covid laboratories, plus the use of remote assessments indicated that adjustment to the current accreditation assessment programme by UKAS are possible (UKAS, 2020). Just like in the early years of the CQC where criticisms of their performance lead to changes in the inspection procedures (Allen et al, 2020). Potentially simple changes to the accreditation assessments could be made (Nicklin et al, 2020). Introducing the use of bi-annual self-assessments, submission of evidence of continual quality improvement alongside intelligent monitoring (IM) routine monitoring of monthly defined performance

measures (Allen et al, 2020). All of which may be less time consuming than an on-site surveillance visit, potentially less costly, and possibly having significantly less psychosocial impact (Alshamsi et al, 2020; Allen et al, 2020). This change in procedure may potentially free up resources for UKAS themselves who may struggle to recruit peer assessors. Moving to less frequent onsite assessments could also necessitate a possible reduction in the yearly charges for an onsite visit, with a smaller office or admin fee for reviewing the provided self-assessments and supporting documents. More significant changes could mean a complete transformation to the current process of laboratory accreditation to a tiered approach. Where dependant on the pathology discipline, specialisation, and length of accreditation different approaches to assessments could exist.

This tiered approach could include the following:

Tier 1 – New laboratories (Years 1–4) would have the current level of assessments until a full 4-year cycle is complete and UKAS is confident of the strength of the QMS and laboratory management team. The laboratory scope of practice will be fixed.

Tier 2 – Intermediate laboratories (Years 5+) would include the current system with biannual onsite visits and self-auditing, the submission of QI annually and evidence of continual improvement, evidence of further inspections. The laboratory scope of practice will remain fixed with the possibility of some flexibility.

Tier 3 – Specialist and well managed laboratories; including remote assessments, self-auditing including the submission of QI annually and evidence of continual improvement, evidence of further inspections. With one on-site assessment at the end of the 4-year cycle with potential spot checks. The flexible scope approach will be adopted.

6.6 Strengths and Limitations

6.6.1 Strengths of the study

- The study examines an accreditation programme that is utilised worldwide in hospital pathology laboratories, so results could be transferable but may require additional interpretation.
- The creation of a robust theoretical framework to ensure cohesion across the study, which can be adopted as a model for others.

- Use of a retrospective mixed methodology to establish the impact of accreditation in an NHS based hospital laboratory.
- The comprehensive approach to the study involving measurement of quality, efficiency, and cost effectiveness along with staff perceptions.
- Use of linear control charts to clearly visualise data trends.
- Use of objective measures to evaluate critical healthcare domains as defined by IOM (IoM, 2001).
- Use of an Expert panel in the study design to minimise bias and increase validity of the study design.
- Creation of a model of analysis for those laboratories wanting to implement and monitor the impact of ISO 15189 accreditation in the future.
- Use of a mixed methodology to obtain the findings and triangulation of these outcomes to add rigour, strengthening validity, reliability, and trustworthiness of the data, reducing potential bias.
- The monitoring of the research population during the study period to confirm no major changes in organisational structure or management that may impact on the findings.

6.6.2 Limitations of the study

- The outcomes from this single centre study due to its small sample may not be generalisable to all NHS laboratories. It may be more appropriate to laboratories within the specialist pathology discipline of H&I or those of similar size and structure.
- Challenges of the data source: Completeness (correct data), Comprehensive (contains relevant variables) , validity (free from bias / reflecting reality) and timeliness / availability.
- Unavailable retrospective data as far back as 10 years to provide a decade of laboratory performance data pre-implementation of ISO 15189:2012, but sufficient to demonstrate and capture change and impact of accreditation.
- Any causal conclusions could not be drawn due to the lack of control over any exogenous confounders, but these were all considered.
- The choice performance measures and QIs, and whether these were appropriate to measure the study outcomes.

- A large amount of data was generated from using mixed methods, this was time consuming to manipulate and analyse, which needs to be considered when using this approach.
- It is important to note that the data cleaning and error checking conducted to ensure all data was available and correct was laborious and time consuming, again a consideration of having adequate time and resources to achieve this if adopting this comprehensive approach.
- The hidden costs of accreditation described in other studies (increased documentation and impact on staff time) was difficult to quantify over time as there was no secondary data available. This primary data using survey methodology, including a questionnaire and FGD, was captured to corroborate or dispute previous empirical evidence.
- Perceptions of laboratory accreditation was only gathered from laboratory personnel and not service users or external stakeholders (UKAS), understanding their opinions would expand the research boundaries and provide additional new knowledge.
- Laboratory culture and potential bias towards accreditation may have been driven by the opinions of the MT or the QM who have had direct exposure to the accreditation process for many years.

6.7 Contribution to knowledge and originality of the research

The specific aim of the study was to fully understand the impact of laboratory ISO accreditation in an NHS specialist pathology laboratory by assessing established performance indicators and key concepts alongside staff experiences and opinions of accreditation.

Gaps in research identified in the literature review included:

- Lack of existing evaluations on the implementation of laboratory accreditation and its impact on quality and efficiency in a UK based laboratory.
- Lack of economic evaluations of the implementation of accreditation or whether some accreditation methods are more costs effective than others (e.g., from the perspective of staff time or introducing new tests).

- Lack of evidence base as to why ISO accreditation would impact on quality and efficiency of an NHS Laboratory.
- Lack of underpinning theory that informs the requirement for accreditation.

In order to address the gaps, the research makes the following contributions:

- The study responds to the call by researchers to expand the available evidence around accreditation in the literature (Shaw et al, 2010, Greenfield et al, 2012, Mumford et al, 2013). It also identifies and fills a significantly large gap in evidence around laboratory accreditation.
- It is the first study to be conducted to look at the comprehensive impact of ISO 15189:2012 accreditation in an NHS specialist laboratory and therefore contributes to the current body of knowledge of accreditation in healthcare.
- There was a paucity of data around the perspectives of the individuals directly involved in accreditation (Braithwaite et al, 2010; Hinchcliff et al, 2013), specifically laboratory accreditation (O'Connor et al, 2016; Lapic et al, 2021). This study incorporated the perceptions of laboratory personnel when evaluating the impact of accreditation, providing valuable new knowledge of their experiences of accreditation in practice.
- This research developed a theoretical framework adopting a mixed methods approach to measure the impact of accreditation on both processes and people, using evidence-based key concepts. This is the first time this approach has been adopted within the field of laboratory accreditation, providing a novel and unique design which can be adopted as a model for other laboratories.
- The study proposed a new 3-tiered approach for the assessment of laboratory accreditation which could be adopted by UKAS, allowing medical laboratories to grow and develop their autonomy and credibility with UKAS to manage their own scope of practice with the use of their proven well-managed QMS and skilled management team.

6.8 Summary

This chapter presented the data from the study as themes for discussion, critically evaluating the strengths and weaknesses of the research, and exposing the contributions to knowledge of the study findings. Initially the findings from the study

were triangulated and discussed using themes to develop an understanding of the impact of accreditation considering its value, its impact on laboratory processes and the effect on laboratory personnel. The outcomes identified that there was not a clear correlation between accreditation and improvement of laboratory quality and efficiency but there was an impact on both the financial costs and hidden costs to a laboratory that were exposed by the FGDs. Significant gaps in the literature around laboratory accreditation exist, evidence to confirm any impact accreditation has as a quality improvement programme were missing, and the outcomes of this study help to bridge this gap.

The development of the theoretical framework used for the study was visited and the concept exposed that this can be adapted as a model for other laboratory wishing to justify their own position. The unique mixed methods approach developed to evaluate the study's aims and objectives was discussed, and its rationale described to create a novel approach.

Potential changes to the UKAS assessment were developed and discussed as a possible benefit to both UKAS and a medical laboratory. This needs further development post-doctorate to include the thoughts and perceptions of UKAS to both the thesis outcomes and possible change implications. Also including the service users to review their opinions of accreditation as a way to measure quality.

Chapter 7 draws a conclusion to the research journey and the thesis, offering study recommendations, and consideration for future work, alongside policy implications from the outcomes.

7. Conclusions, Recommendations and Future Work

7.1 Conclusion

There has been a significant investment in accreditation within the NHS without any real understanding of whether the investment is effective (Greenfield and Braithwaite, 2008; Mumford et al, 2013; Melo, 2016; Ovretveit, 2000). This decision to use accreditation as a tool to manage quality in healthcare has not been based on any economic evaluation (Hoomans and Severens, 2014; Eisman et al, 2020). Any studies examining hospital accreditation have demonstrated mixed results with inconsistent findings with regards to its implementation (Greenfield and Braithwaite, 2008; Hinchcliff et all, 2012; Bogh et al, 2015). Overall, there is a paucity of suitable available empirical research data from which to form any valid conclusions (Greenfield and Braithwaite, 2008; Alkhenizan et al, 2011; Greenfield et al, 2011; Brubakk et al, 2015, Hovlid et al, 2020). There seems to be an ongoing failure to validate and share learning from quality improvements efforts, especially within the NHS where this potential knowledge is being lost (Dixon-Woods and Martin, 2016) especially in the field of laboratory medicine which this study has exposed.

NHS medical laboratories are under continued pressure to implement value-based healthcare whilst having to remain focused on patient safety, improving outcomes and reducing costs by conducting cost effective laboratory operations to ensure the use of the most appropriate tests (Schmidt and Ashwood, 2015). In the literature there was a number of studies that identified accreditation as a valuable management tool to improve quality with the implementation and maintenance of quality laboratory systems (Peter et al, 2010; Hamza et al, 2013; Rizk et al, 2014; Boursier et al, 2015; Zima, 2017; Plebani et al, 2017; Abdel-Wareth et al, 2018; Ramya et al, 2018). This perception was corroborated by the outcomes of the study where 94% of the study group agreed. Accreditation has also been described as an effective way to demonstrate the effectiveness and competence of a laboratory, but is not without its challenges (Zima, 2017; Tashayoei et al, 2020). Adding extra pressures which have been perceived to impact on time and cost constraints, redirecting resources from within the laboratory budget (Buchta et al, 2018; Tashayoei et al, 2020) and with the potential to impact on innovation (Balla, 2012; Thelen et al, 2015).

The most significant findings from this single centre study indicates that:

1. The annual cost of ISO 15189:2012 has risen significantly year on year compared to the historic static fixed payment for CPA UK Ltd.
2. Laboratory accreditation was not considered by the study group as ‘value for money’ with 94% considering it ‘expensive’. Although 96.4% did considered it to be a ‘valuable management tool’, agreeing it was ‘informative’ (64%) and ‘essential’ (85%) and describing the ISO 15189 standard as a ‘framework’ to drive laboratory improvements.
3. There was no clear correlation between ISO 15189:2012 and cost effectiveness with respect to fostering quality improvement. The opinion of the study group was that accreditation had a direct impact on resources, specifically staff. It was also perceived that accreditation was a significant ‘burden’ to staff due to the increased workload it presents, with 100% of the study group describing laboratory accreditation as ‘labour intensive’. It was also the opinion of 50% of the study group that ISO accreditation has a negative impact on innovation. Their perception being that it delayed service improvements due to recent delays seen in ETS applications. It was also the opinion of the study group that the annual ISO assessments (SUR) exposed staff to unnecessary psychosocial risk.
4. There was no clear linear association between quality and laboratory accreditation, to signify continual improvement which would be expected by a laboratory participating in improvement programmes such as accreditation. Both repeat rates and ISO NC had a weak linear relationship and there was an increase in the strength of the relationship between accreditation and EQA performance seen. This contradicts the study group who considered that ISO accreditation improves both quality (82%) and overall service quality (93%) and improves the number of errors (68%).
5. There was again no clear linear association between laboratory accreditation and efficiency observed when analysing TATs for routine patient testing. There was however a significant change seen for two out of the three national KQI which was statistically significant (Deceased donor crossmatching and HLA-typing). This provided conflicting evidence when compared with the study group

opinions where 85% of the study group perceived that laboratory accreditation had no impact on improving TATs.

6. The statistical significance of the data observed for the relationship between quality and cost effectiveness and laboratory accreditation was insufficient to reject the null hypothesis.
7. Whereas the statistical significance of the data observed for the relationship between efficiency measured by the TATs of the national KQIs was sufficient enough to assume that the null hypothesis could be rejected. Identifying that ISO accreditation as an improvement program can influence the laboratory TATs. Unfortunately, this was not observed for all TATs monitored in the study.
8. Laboratory accreditation could be considered as a useful tool to monitor current systems; providing observable consistency over the years in outcome measures with very little decline in quality or efficiency observed.

The overall findings highlight a significant question about accreditation and possibly whether assessments like these really work in practice from the perceptions of those directly involved. Reiterating suggestions many years earlier that inspections are not appropriate to improve or indeed guarantee quality (Dale, 1999; Kemp, 2006; Nicklin et al, 2020). Perhaps indicating accreditation to be a monitoring tool rather than an improvement tool with the outcomes for the RRs (error rates) being consistent over the study period being observed. Indeed, an aspect of the study findings that requires further investigation, is to determine the opinions of the peer assessors to the current process of laboratory accreditation. The outcomes of which could also be used to develop and drive policy and process changes for accreditation, providing much needed empirical evidence for UKAS and other accreditation authorities globally. The use of external auditing itself is not an efficient or effective way to highlight issues with quality and can lead to audit fatigue (Green et al, 2020). Perhaps identifying the need for reform of the current system of laboratory accreditation away from the annual onsite assessment process to one that has a more efficient and effective use of time and resources, as described in section 6.5.

7.2 Policy Recommendations

Establishing a new laboratory accreditation agenda that aims to estimate the resources needed for accreditation implementation and maintenance and develop a plan to reinforce the programme with resources to help the laboratories.

The theoretical framework could be used as a model by other medical laboratories to establish their current position, consider the costs and justify the actual impact of laboratory ISO 15189:2012 accreditation. Enabling NHS Trusts to have available data that can be used for Hospital management to measure all pathology disciplines within the trusts to determine the cost of accreditation and its overall impact.

The Department of Health and Social Care could use any data captured to assess if UKAS and ISO 15189:2012 accreditation are cost effective as a quality improvement programme and also use the data as a monitoring system for UKAS to consider its value and effectiveness.

7.3 Future Research

This study has been limited to a single site so the opportunity to investigate if the findings from this study are reproduced elsewhere would be advantageous by creating an initially a quality improvement collaborative (Ovretveit, 2002) within the H&I discipline. Using the theoretical framework as a model, data could be collected and analysed from each of the 21 collaborative sites to establish if the same phenomena was observed by all the laboratories involved. This could also be expanded to include pathology laboratories within an individual trust to provide NHS managers a clearer understanding of the impact of laboratory accreditation and its financial impact on the organisation.

In this study, only the perceptions of laboratory personnel were sought as they are central to the laboratory accreditation process. A new and novel theme was exposed around psychosocial risk of staff and with the new Mental Health Matters agenda within the NHS. This could be an additional focus for future work to expand on this knowledge by developing a larger study involving laboratory personnel from the 21 collaborative sites and other medical laboratories who are also involved with ISO 15189 accreditation.

Service users were not included but findings from the study have signposted to the possibility that to get a greater understanding of the impact of accreditation and its relevance to our service users, this should be considered. These questions could lead to evidence-based data that may clearly expose the position of laboratory accreditation.

The data collected for this study can be used going forward as part of a quasi-experimental methodology to represent the pre-implementation phase of the implementation of the Flexible Scope. Once the ETS for the flexible scope has been agreed by UKAS the theoretical framework could again be adopted to capture the data 12 months post implementation. To assess if there have been any significant changes to the pre-implementation data to show if the move to a Flexible Scope has had any impact on laboratory quality, efficiency, and cost effectiveness.

The data collected identifying the significant cost of accreditation could be expanded to all the pathology laboratories in the NHS. Using the methodology as a model for other laboratories to measure the costs of accreditation in each centre (pathology network) to understand the full cost to the NHS to work with NHS Finance services.

Finally, to work alongside UKAS to:

> Provide sufficient empirical data for UKAS to consider policy and process changes for accreditation including the frequency of assessment using self-assessment years that includes monitoring KPIs that will have long term benefits for medical laboratories of all disciplines, UKAS and their peer assessment teams and NHS trusts.

7.4 Summary

This study has provided an evidence-based approach to understanding the true impact of laboratory accreditation in the UK from the perspective of an NHS specialist pathology discipline. It may not completely bridge the research void that exists currently in this area but hopefully it will encourage others to reflect on their current positions and inspire further consideration for any future changes to the UKAS surveillance assessments. Furthermore, it has provided baseline data for policy makers and other managers in healthcare to use when considering the justification of implementing ISO 15189:2012 accreditation.

In summary, the strength of this thesis is that it has not only succeeded in developing and administering a valid and reliable theoretical framework to be used by medical laboratories, but it has also produced findings that make important contributions to the knowledge base around laboratory accreditation in the UK. It has provided valid and reliable structure and information to allow decision makers to make informed judgments about the impact of laboratory accreditation (Ovretveit et al, 2002). Furthermore, it has provided baseline data for policy makers and other managers in healthcare to use when considering the impact of ISO 15189:2012 accreditation. It also has policy implications, that could lead to possible rationale for changes in the utilisation of the ISO 15189:2012 accreditation program going forward, which could potentially lead to long-term savings to the NHS.

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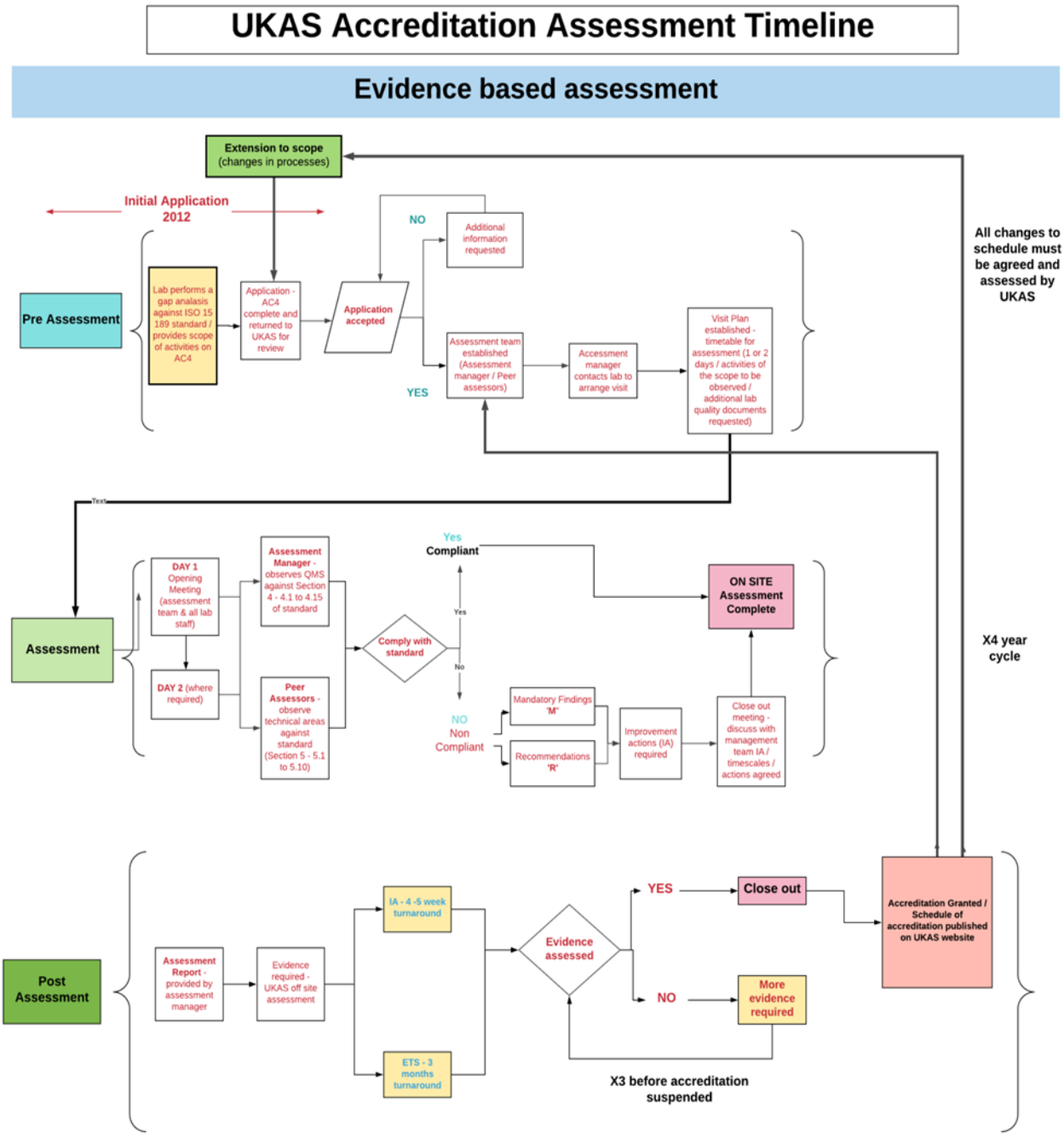
Appendix 1 UKAS Accreditation Assessment Timeline



Appendix 2 Scope of Practice

Schedule of Accreditation

issued by

United Kingdom Accreditation Service

2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

UKAS MEDICAL
7878

Accredited to
ISO 15189:2012

Manchester University NHS Foundation Trust

Issue No: 008 **Issue date:** 10 November 2020

Testing performed at the above address only

DETAIL OF ACCREDITATION

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
Human fluids and tissues as identified below: Blood Buccal swabs Spleen Lymph node Serum	Histocompatibility and Immunogenetic examinations for the purpose of clinical diagnosis for transplantation, disease association and drug hypersensitivity	DNA extraction using the DNA EZI system and quantitation of DNA using the Nanodrop instrument by in-house documented procedures based on manufactures guidelines and equipment manuals as relevant
	Immunogenetics Examinations	In-house documented procedures based on manufactures guidelines and equipment manuals as relevant
Genomic DNA extracted in house from the above sample type or received as a primary sample from external source	**Human Leucocyte Antigen (HLA) Typing –** (HLA-A, B, C, DRB1, 3, 4 & 5, DQA, DQB, DPA & DPB, KIR)	SOP-IT001 / IT028/ IT035 / IT038 using PCR SSO typing and Luminex Labscan 3D technology SOP IT058 HLA typing using Real Time PCR technology on Roche 480 II Light Cyclers, LinkSeq kits and Sure Typer analysis software SOP - IT063 / IT064 Disease association and Drug Hypersensitivity testing SOP - IT001/ IT028/ IT035 /IT038 using PCR SSO typing and Luminex Labscan 3D technology SOP - IT058 High Resolution HLA typing using NGS on Illumina Miseq Sequencer Using SOP IT065 and IT066

UKAS MEDICAL
7878

Accredited to
ISO 15189:2012

Schedule of Accreditation
issued by
United Kingdom Accreditation Service
2 Pine Trees, Chertsey Lane, Staines-upon-Thames, TW18 3HR, UK

Manchester University NHS Foundation Trust

Issue No: 008 **Issue date:** 10 November 2020

Testing performed at main address only

Materials/Products tested	Type of test/Properties measured/Range of measurement	Standard specifications/ Equipment/Techniques used
	Immunogenetics Examinations (cont'd)	In-house documented procedures based on manufactures guidelines and equipment manuals as relevant
Blood Bone Marrow	Haemopoetic Progenitor Stem cell Transplantation Engraftment Monitoring - reported as % donor engraftment	SOP-IB007, IB0017, IB008, ID010, ID021, IB026 by fragment analysis using GenePrint 24short tandem repeat markers and an ABI 3500XL genetic analyser
Human fluids and tissues as identified below: Blood Spleen Lymph node Serum	**Histocompatibility Examinations**	In-house documented procedures based on manufactures guidelines and equipment manuals as relevant
Blood	The detection and definition of HLA Specific Antibodies for the purpose of clinical diagnosis for Transplantation (HLA-A, -B, Cw, -DR, -DQ, DP) Pre Transplant HLA specific allo antibody screening Post Transplant HLA specific allo antibody monitoring	SOP - S063 / S065 and using Microbead array assays and Luminex technology SOP – S066 SOP - S064 and using Microbead array assays and Luminex Labscan 3D technology SOP – S066 SOP- S057 using Microbead array assays and Luminex Labscan 3D technology SOP - S035
Blood (cells & serum) Spleen Lymph node	Crossmatch testing for solid organ transplantation Detection of IgG HLA antibodies to donor T and B lymphocytes	Using Imunofluorescence flow cytometry on a Beckman Coulter Navios Flow Cytometer according to SOPs: XM030, XM033, XM034 and XM035
	Complement dependent cytotoxicity (CDC) testing for solid organ transplantation through detection of IgG and IgM HLA antibodies to donor lymphocytes	CDC test using cell viability staining SOP-XM002, XM004 and inverted fluorescent microscopy-
	END	

Appendix 3 ISO 15189:2012 Medical Laboratories – Requirements for quality and competence

ISO 15189:2012 Medical Laboratories – Requirements for quality and competence	
4. Management requirements	**5. Technical requirement**
4.1 Organisation and management responsibility	5.1 Personnel
4.2 Quality management system	5.2 Accommodation and environmental conditions
4.3 Document control	5.3 Laboratory equipment, reagents, and consumables
4.4 Service agreements	5.4 Pre-examination processes
4.5 Examination by referral laboratories	5.5 Examination processes
4.6 External services and supplies	5.6 Ensuring quality of examination results.
4.7 Advisory services	5.7 post-examination processes
4.8 Resolution of complaints	5.8 Reporting of results
4.9 Identification and control of non-conformities	5.9 Release of results
4.10 Corrective actions	5.10 Laboratory information management
4.11 Preventative actions	
4.12 Continual improvement	
4.13 Control of records	
4.14 Evaluation and audit	
4.15 Management review	
15 primary sub-clauses	10 primary sub-clauses
20 Secondary sub-clauses	42 Secondary sub-clauses
13 tertiary sub-clauses	28 tertiary sub-clauses
145 points in the lists	162 points in the lists

Appendix 4 Empirical Articles Identified from literature review.

	Author / Citation	Title & Aims of the study	Material Type / Method	Location / Sample Size	Outcome measures and Key findings	Relevance to study
1.	Adane, et al (2019) Ethiopian Journal of Health Science	**How does ISO 15189 laboratory accreditation support the daily healthcare in Ethiopia? A systematic review.** **Aim:** To assess the value of accreditation on the performance of healthcare institutions in ensuring quality improvement intervention.	Systematic review (qualitative) 2010 - 2017	Ethiopia	29 out of 883 – eligible Results – all statements no real critical analysis / anecdotal **1. Success factors** Leadership / competency. Accreditation driver of Q improvement. Important to ensure efficient use of resources and increase value. Successful implementation = guarantees Q of results, supports Cont. QI and boosts moral. **2. Contributing factors for ISO 15189** **3. Accreditation process** Principal aim accreditation – improve Q and improve patient safety. Clearly specific tests performed under accreditation for users. Cost effective accreditation. Should be sufficiently financed. Should continue to monitor Q post implementation of accreditation – Q Improvement **4. Accreditation experience in healthcare setting (African Lab)** Errors occurs all area of lab – Pre -, analytical and Post. African labs – developing world offered interim accreditation with flexible standards (? Difficult to determine if ref to scope)	Methodology – weak No clear aims, inclusion / exclusion criteria not included in paper. PRISMA include but no CASP tool. Included paper on hospital accreditation?? Not relevant to search criteria. No critical analysis of findings **QI** to evaluate entire process and performance. **EQA / QA** tools important to assess performance. **Errors and TAT's** Staff morale / motivation **Use of Pre – Post accreditation** – QI as markers

2.	Boursier, et al (2015) Clinical Chemistry and Laboratory Medicine	**Accreditation process in European countries – an EFLM survey.** **Aim:** To review the current state of the accreditation process in European countries – Focus – 1. Mandatory status 2. Est No of accredited labs 3. Possibility of Flexible scope 4. Concerned medical fields. 5. POCT	Quantitative study – survey Declared shortcomings of survey – inability to express real number of medical labs per country (only focused on societies include in Clinical Chemistry)	Europe 39 EFLM scientific societies	29 responses including UK (74% Response rate – Good) All societies declared there was an accreditation process in their country. (UK using CPA UK Ltd – 80% of lab certified in this society) 5/29 – mandatory accreditation (not UK) All 29 working towards ISO15189 12 also using ISO17025 & in UK CPA (UK) Ltd Flexible scope offered in 19 /29 (UK included but no lab has taken it up??) Medical Laboratories concerned -Clinical Chemistry, Haematology, Microbiology, Genetics, molecular biology, Blood transfusion, Immunohematology and Clinical toxicology covered (No H&I -? maybe if including some NBTS) POCT is the responsibility of Med labs in 20 of the labs responding – 7 of which have it in accreditation (UK included)	Up to 2015 - the last 10 years seen accreditation become more widely implemented. (Without proof it improves quality) CPA UK ltd – 2015 has been amalgamated with UKAS as NAB and move to ISO15189 standards. Flexible scope has been available in 2/3rds of countries but never used in UK labs – mainly used in France, Netherlands Sweden. Move to Flexible scope for labs who have demonstrated competence with Fixed scope. Focus mainly on lab med disciplines – may have include some H&I labs in the Blood Transfusion service – not clear where survey went. Future work – direct and indirect costs and benefits of accreditation
3.	Buchta, et al (2018). Clinical Chemistry and Laboratory Medicine (2018)	**Evidence for the positive impact of ISO 9001 and ISO 15189 quality systems on laboratory performance – evaluation of immune haematology external quality assessment results during 19 years in Austria.**	Retrospective meta-analysis of data (quantitative)	Austria 179 labs out of 182 responded. (Independent, Hospital and	The effectiveness of the use of Q systems measured by – 1. Rate of incorrect results 2. Rate of incorrect results of those labs who underwent accreditation during the study period to look at before and after period.	Increasing No of labs being accreditation to ISO15189 Implementations involves huge effort and financial and personnel resources – lack of robust and high-quality data on impact on QI – no real evidence base.

		Aim: To compare the analytical performance of labs with or without ISO 9001 and ISO 15189 and to investigate if analytical performance changed after laboratory attained these. Incorrect EQA results were used as a measure of analytical performance. Cell immunohematology EQA results (1999 – 2017)		Transfusion labs)	Overall, Error rate low – 1.1% Reduction of error rate of accreditation labs (is it accreditation alone??) 17.6% labs reported **NO** incorrect results and were not accreditation. Type of lab impacted on performance – lowest error rate in Transfusion labs	**Key QI** to assess performance is error rate - Use **EQA** results to measure quality over period of accreditation (**Pre and Post implementation**) Quality not due to accreditation? – long history of Q embedded / specialist lab for testing / increased competence EQA schemes monitor analytical performance not procedural performance – need to analyse this to fully understand effect.
4.	Desalegn et al, (2019) African Journal of Laboratory Medicine	**Medical laboratory accreditation in a resourced-limited district health centre laboratory, Addis Ababa, Ethiopia** **Aim:** Share the experiences, benefits, and challenges of implementing ISO accreditation in a primary health care laboratory in Ethiopia	Journal Article Mixed Methods - Retrospective analysis of data supplemented with observations from the authors?? Pre and post – longitudinal Descriptive stats	Sub Saharan Africa **(Ethiopia)** Single centre – case study	QMS enables lab to provide reliable service / strengthens overall quality of patient care. Challenges to implementation = poor infrastructure / low HR capacity / inappropriate tech. KQI / external audit findings (WHO-AFRO) - checklist scoring system (stars) Pre (2012) – WHO-AFRO assessment result 0 stars – not enough staff to handle additional workload from intro QMS. – extensive paperwork. Created a plan moving forward (Staff / training of standards / EQA) – Year on year saw improvement in WHO AFRO – in 2015 could apply for ISO (limited scope due to staffing / limited resources and inadequate experience. Challenges – workload / lack of IQC and reagents / PPMs costs and availability of engineers / infrastructure / building issues due to lack of funding. Staff and Management accepting the standards. Benefits – steady Improvements seen, no service interruptions, improved EQA.	WHO-AFRO Est a step wise process for developing countries (SLIPTA), those with outstand performance accelerated towards ISO 15189 accreditation. V low number of accredited labs in Ethiopia – limited scope QI = objective measures – evaluate performance improvements (TATs / Error rates = equipment failure, service interruptions, specimen rejection, stock levels) – covers all Pre – analytical and post – routinely monitors. Challenges – workload / lack of IQC and reagents / PPMs costs and availability of engineers / infrastructure / building issues due to lack of funding. Staff and

					Use of QI = indicators of system weakness. Over 3 years saw - TAT improved, equipment downtime declined, rejection rate declined, stock issues declined. Ethnography used for determining efficacy of QMS carried out by researcher. ?? Bias	Management accepting the standards.
5.	Green, et al (2020) Practical Laboratory Medicine	**Investigation of the long-term yield of auditing for conformity with ISO 15189:2012 quality standard in a hospital pathology laboratory** **Aim:** To investigate the value of continued auditing for compliance with ISO 15189:2012 standard as a means of assuring long term QoS and mitigation patient harm in the clinical laboratory whose QMS has become established over a 6-year period of accreditation to ISO 15189: 2012	Retrospective meta-analysis of data (quantitative)	Republic of Ireland 483 NC from audits carried out between 2012 – 2018. Single centre	Covers period since ISO accreditation granted. Include internal and external audit NC's – audits reassessed against set of criteria Est from Wilson et al 2016 study to look at likely impact on QoS rather than deviation from standard. Reassessed by 3 CS with experience and training in QMS / ISO and auditing (only 1 was independent)- blinded. Real Time NC – came from error detection systems / staff / complaints (incidents) – gathered and used to provide data on effects of accreditation on QoS. Of the 483 – 395 (81.8%) classified unlikely to affect QoS; 88 (18.2%) Possible and None considered Probable. Most related to Doc control issues. Significant increase in NC at beginning of accreditation journey – (2013) – No. reduces over time – indicating Q improvement – could be consequence of many factors (diff people taking audit / training and competency / QM or staff / audit fatigue) = artificial decrease. RTNC = also downward shift, but increased as time went on? (? increase in Q ethos of staff) Maturity of QMS leads to reduction in NC. Audit process needs improving – promote efficient and effective use of time and resources. Define better QI of QoS ISO more useful for poor performing labs / or without QMS.	The use of **NC** The value of include Pre accreditation data, it was missing in this paper would have been helpful. Use of **incident** reporting as a data source for evidence of impact of accreditation. Investigator bias discussed. Re use of Wilson et al approach. Importance of discussing other cause of any changes seen Are audits worth the effort? Audits and ISO are a point in time exercise - small area and may miss any real problems. Need to use QI to see if there are indeed improvements. Use of QI pre and post accreditation to show improvement.

					Audit fatigue – complacency in auditing	Cited 2016 Study – O'Connor et al – found Biomed journal – typical example of reluctance to publish?
6.	Hamza et al (2013) Iranian Journal of Public Health	**Cost effectiveness of adopted quality requirements in hospital laboratories.** **Aim:** To present strategies designed to aid medical laboratories with the ISO 15189 and to determine the impact on annual average cost per test	Quasi experimental study (quantitative)	Iran Study and Control group. (12 labs – 6 in each group)	Lab errors arise due to problems in QMS. Pre -, Intervention and post – intervention phases used to measure implementation of ISO 15189	Used to develop tool to measure **cost effectiveness** in study. Use of Pre -, Intervention and post – intervention phases Use of Biochemical tests = lab **critical processes** and **EQA** scheme results
7.	Kibet et al, (2014) Am J Clin Pathol	**Measurement of improvement achieved by participation in International Laboratory in Sub-Saharan Africa.** **Aim:** To measure the impact of the accreditation process using quality measures – 7 Pre, 10 Analytic, 8 Post, 5 admin between 2009 – 2012 – 4 years – using Six Sigma metrics. 3 phase model -design and implement of accreditation. Yates corrected 2-tail for stat significance.	Journal article. Retrospective analysis of data comparison Longitudinal pre and post accreditation (2009 and 2012) QUAN – using Yates corrected two-tail X2 analyses	Sub Saharan Africa **(Kenya)** Single centre – case study	Of the 25 Pre – Analytical and Post- measures used all showed significant improvement except 2 – equipment malfunction and failed EQA – but this showed a trend towards improving over the years but not significant. Management perf indicators – all 4 significant improvements esp. complaints reduction by 15% Cost savings of $40k US per year due to reduction in reagent waste due to expiry and repeat testing – off set accreditation cost? Initial cost of accreditation $90K + $30K annually to maintain costs offset by improved efficiency. EQA – trend to improvement but not Sat Sig TAT - improvements	Resource limited country – financially difficult Pre accred may not have had the funding – Resource limited country – many have had quality systems many years. Is improvement due to accreditation or focus on improvement. – will this be maintained or improved as year continue Mentions staff but no results on effects
8.	Lapic et al, 2021 Biochem Med (Zagreb)	**Laboratory professionals' attitude towards ISO 15189:2012 accreditation: an anonymous survey of three**	Journal article. Survey QUAN	Croatia Multi-centre	RR = 76% Preferences of working in Accred lab Main advantages = better process docs 68% = increased workload – excessive paperwork main contributor	Impact of ISO on staff and workload Accred is well accepted among lab staff, with satisfaction increasing over time (Ref Zima et al 2017)???

		Croatian accredited medical laboratories **Aim:** To assess the attitudes of lab staff regarding implementation of various requirements of ISO to identify any weak points for future improvements to ensure better adherence for the future. Evaluating differences in practical implementations between labs and duration of accreditation		Staff from 3 labs (297)	ISO comprehensive guidance for Est QMS – practical requirements vary between labs. 68%increase usual workload Advantages = better docs and reliability of results Disadvantages = XS paperwork only 8% said XS workload. Evidence keeping for lab activities considered useful only 13% said demands by increased workload?? 42% = up to 50% of work obligated to Accred. Increase stress- no impact on Q.	Staff competence and understanding of Accred crucial for effective compliance – include in survey / focus group. QUAL to get a deeper understanding of the survey outcomes. Staff recognise value of Accred – but increase work = document = time consuming
9.	Masau et al, 2015 INT J TUBERC LUNG DIS	**Experience in implementing a quality management system in a tuberculosis laboratory, Kisumu, Kenya** **Aim:** Share experiences of implementing QMS based on QI prior to accreditation.	Journal article. Before and after study QUAN Odds ratio OR & 95% Confidence interval CI	Sub Saharan Africa **(Kenya)** Single centre – case study	Improvement seen in all areas = culture contamination rates; Waste due to expiry; Client satisfaction – expect EQA assessments – no change. Cost savings seen US$10K due to reduction in regent expiry (no mention of offset of cost of Accred or cost of accreditation) Implementing a QMS and working towards Accred can benefit a lab. Cost saving = Decreases Error / RR and waste due to better stock control (is this really cost saving = hidden costs) EQA no change Uses user satisfaction survey.	Implementing a QMS improve efficiency – QMS requirement for accreditation so is it the QMS and its impact or Accred that improve quality and efficiency. Ongoing requirement to maintain Accred ongoing focus on Q. In developed countries – focus on QMS for a long time
10	O'Connor et al (2016)	**Evaluating the impact of ISO 15189 on an Irish histopathology laboratory** **Aim:**	Journal article. Mixed methods	Republic of Ireland	Adapted ISO methodology. 6 Perf indicators used – TATS / EQA / User Survey / Staff survey QMS / ISO implementation	ISO methodology for assessing the impact of the standard.

	The Biomedical Scientist **Grey Literature**	To develop a new model / method applicable to hospital laboratory settings to evaluate the impact of ISO 15189 on hospital laboratories using non-economic markers based on ISO methodology		Single centre – case study	Mixed methods – QUAN QUAL Quality data, surveys, focus groups and No impact on TATs or EQA seen but changes to the procedures seen. **QMS = benefits** seen Org effectiveness / User satisfaction / Compliance with ISO / Improvement in lab culture (standardised SOP) / improved doc. **Disadvantages =** Cost (set up and maintenance = includes PPM / calibrations EQA inspection fees) – beyond scope of paper. Training (pressure on staff time, TATs) Employee resistance – communication important to manage change and maintain Pos's work ethos. Disruption of work processes – during implementation and before assessment. QMS as KPI = overall Pos's effect as resulted in standardised procedures (value driver)	Use of Pre and Post implementation quality data (one year pre- 3 years post) KPIs / TATs / EQA / Satisfaction surveys / Communication – staff survey = 100% staff = implementation as Pos 90% ISO improved service 90% improved resources and conditions 40% staff needed more training & more involvement in ISO process. Focus group used to assess ISO implementation = Staff opinions. Implementation seen as Pos. Neg = doc moved to electronic Choice of internal audits need monitoring to ensure informative and relevant. ISO 15189 a continued necessary expense but should be considered as a valuable asset that delivers real results. No improvements seen in TATs or EQA Staff impressed with method standardisation, transparency of NC.

11	Ramya, et al 2018 Indian Journal of Pathology: Research and Practice	**Impact of Haematology laboratory accreditation on patient care and Health systems: Our experience.** **Aim:** To provide accurate, reliable, and universally acceptable results to patients in cost effective way and improve TATs. To improve operational efficiency & safety of lab personnel by periodic training & strictly implementing health precautions To encourage / guide labs to o for accreditation & improve their standards of patient care	Original research article Quantitative	India Single centre case -study Haematology dept	No empirical evidence to substantiate findings - basic strategy to show implementation. Right tests right time for patients Gained confidence of clinicians & patients by universal standard of results. Clinician feedback form – to see if service met needs. Mentions staff – no feedback on effect on them. The efficiency & performance of staff improved / staff more confident and focused. Productivity increased due to decreased errors / waste of resources. Cost effectiveness improved by proper utilization of chemicals. Decrease in TATs and STAT via automated results – TATs from 8 hours to 4 hours	**Quality** **Efficiency** **Cost effectiveness** Report quality poor – no evidence to substantiate findings. No real empirical data collected -
12	Rizk et al, 2014 Journal of Egyptian Public Health	**Evaluating laboratory key performance using quality indicators in Alexandria University Hospital Clinical Chemistry laboratories** **Aim:** To promote accuracy in the analytical phase of a university hospital laboratory and assurances of reliability in the pre and post analytical phases in accordance with ISO 15189	Journal article. Meta analysis of data QUAN Pre and post intervention (quality improvement) Cat variables = Freq & % Two sided X2 test for associations	Sub Saharan Africa (Egypt) Single centre – case study	Pre – Analytical and Post QI - different to Kibet who was a longer study 3 years – better outcome data / more QI to measure. Use six sigma to analysis. Statistical significance Four pillars of lab service = Accuracy Precision Timeliness Authenticity Benchmark used = TAT	QIs = Specimen reception TATs RRs EQA Useful to measure improvement post intervention Used critical results. Already Accred ISO 15189 – interventions used for improvement not reflective of accreditation. (Training – workshops and lectures)

Appendix 5 Articles Identified from literature review - Opinion Pieces / Perspectives

	Author / Citation	Title / Aims of the Study	Material Type / Method	Location / Sample Size	Outcome measures / Key Findings	Relevance to study
1.	Abdel-Wareth, et al 2018 Archives of Pathology and Laboratory Medicine Arch Pathol Lab Med Vol 142, Sept 2018 pp. 1047 - 53	Fast Track to Accreditation. An implementation review of College of American Pathologists and Internal Organization for Standardisation 15189 Accreditation. Aim: To share experience of implementation of ISO 15189 accred – challenges and opportunities	Opinion paper	United Arab Emirates	Quality, Efficiency and Cost effectiveness – Ref Peter et al, 2010 ISO 15189 – originates from ISO 9001 and ISO 17025 – addresses requirement of competence and quality in Med lab. ISO 15189 intro to UAE 2005 – now mandatory Jan 2017. Challenges and Opportunities to the start-up – - Manpower (shortage) / training and comp assessment - Q Management and Q Culture – role of QM crucial / lab leadership involvement - Doc control / Q Manual / AMR - Method validation / MoU - Safety, Facility maintenance and Enviro conditions - LIMS (Validation) - KPIs / Id and control of NC / adverse incident reporting (Risk Management) - Audits / continual Improvement - Proficiency testing (EQA) - Staff morale	Quality, Efficiency and Cost effectiveness is paramount. Important to have staff on board (Survey staff understanding and morale) ISO important for Est a QMS Operational rigor and Cont. Imp obtained from the use of audits. Accred helps reduce incidents / motivate staff and imp competence. ISO standards provide a good structure to Q for newly develop labs
2.	Aslan, D (2018)	**Which skills are needed and how they should be gained by**	Perspective / Opinion piece	Turkey	Need for QMS – QC / EQA Management of TTP – controls	Challenges to Accred – training assessors

	eJIFCC	**lab professionals for successful ISO 15189 accreditation?** **Aim:** Paper presents main areas and basic tools for gaining ISO 15189:2012 accred. Share experience as tech expert and trainer.		NA	Cont. Imp – methods required. QI – for each test process in Accred scope Training – core competencies / KSF needed for disciplines. Accred adds value to HC quality – provides data for collection and use (QI)	Role of lab to provide test results timely and cost effectively – value-based HC
3.	AuBuchon, J, P (1999) Archives of Pathology & Laboratory Medicine	**Optimising the Cost-effectiveness of Quality Assurance in Transfusion Medicine.** **Aim:** Presents his own perception of QA systems – claims he is not trying to justify QA in terms of financial benefit – he claims justify themselves in improved service to patients	Perspective	USA NA	Def of quality in context of QA = meeting requirements (Est all req for process to ensure Q) Outputs to measure = functional/temporal or financial Quality categorical not continuous variable QC important but can't measure entire performance (process control) QA – Cont. Impro = measure trends over time Doc – no written proof then it didn't occur – increased need for doc with QA systems. Cost of QA = price of NC and is 10x more expensive to correct than prevent a problem?? Does this apply to labs – in manufacturing / industry yes? Ref ISO and benefits of implementation lab1997	QA schemes – resource investment required. Use of outcome measures to measure q over time
4.	Balla, J (2012) Chem. Listy 106, s147-s148 Chemicke Listy	**Flexible scope of accreditation in Clinical Biochemistry and Immunochemistry** **Aim:** Review states the objective to focus attention of labs seeking accreditation on guiding and regulating requirements.	Lectures	Slovakia Lab Med	Lab accreditation based on fixed scope – changes made via ETS anytime – rigid and restrictive – can't react quickly. Flex scope requirements – competent staff and validation system.	ETS (cost & time) Flexible scope - Makes it possible to react faster with specific desires, more responsibility transferred to med lab. Lab needs defined system of validation / tech competence to intro / modify new methods without accreditation assessment.

						Flexible scope v rarely used in Europe especially in clin Chen and immunochemistry. Accreditation bodies adopt concept of Flexible scope warily. Trained assessors essential
5.	Gough, L, A and Reynolds T, M (2000) British Journal of Clinical Governance	**Is Clinical Pathology Accreditation worth it? A survey of CPA accredited laboratories** **Aim:** Independent review of CPA – View of the service delivered by CPA. All grades from consultants to MLSOs	Original paper	UK Survey 14d hospital UK = Accred (partial / Full) Path areas (4) -Clin Chem; Haem; microbiol; histology/cytology	Made lab focus on Q. Training – improved. Customer viewpoint Inspection & report – Pos's response to inspections but concerns re how appropriate they were. Polices and SOPs – excessive doc. Value for money – expensive Accred lab's opinion of CPA	4 years = annual registration + fee; form stating cont. compliance and info of any substantial changes CPA non-profit making – excess funds used for QA in pathology. Costly (reg fee £350 + assessment fee £1000). Full Accred – if any deficiencies Full Accred withheld = partial Bureaucratic Inefficient – standards inconsistent Excessive doc required
6.	Guzel and Guner (2009) Clinical Biochemistry Clinical Biochemisrty 42 (2009) 274 - 278	**ISO 15189 accreditation: Requirements for quality and competence of medical laboratories, experience of a laboratory I.** **Aim:** Not clear – appears to be personnel experience of implementing ISO 15189	Discussion	Turkey Case study (Single centre)	Preparation and implementation for accred – Documentation Determining scope of accred Role of EQA Application Assessment visit – NC / actions (re assessment at 2 years) -scope can be changes as assessments – 4 assessors attended. Accredited Lab Personnel – practical impact assessed with survey (multiple	Impact on lab staff important – Do they feel Q improved? Advantages and Disadvantages for them? Does it cause more work pressure? Do they prefer to work in accred or non accred lab? Qualitative data would have been useful to get full picture

					choice) – 2 private labs in Belgium =? unsure of the Number of people involved. 85-95% = increase workload 15 – 28% though it improved Q test results – this almost double after a year (46%) Advantages = • Better Doc • Traceability of causes of errors • Better understanding of analysis performed. Disadvantages= • Increased paperwork • Discrepancies between SOPs and reality. (Reduced by 50% after a year) • Greater emphasis on formalities. • Majority of staff preferred to work in an accred lab.	
7.	Huisman et al, (2007) Clinical Chemistry and Laboratory Medicine	**Accreditation of medical laboratories in the European Union** **Aim:** **To explore current state of accreditation prior to producing essential criteria for assessors and assessments (training)**	Questionnaire	Europe Representatives 25 societies (Clinical Biochem and Lab Med) (UK rep)	19 returns (76%) Accreditation bodies – EA / independent / unknown Selection, Training and Evaluation of assessors – differed – Mainly lab specialists / Q specialists Selection –accred body – criteria differed. Training – length varies; by EA linked bodies using guidelines. NC grading taught - subjectivity.	Specific to clinical chem and lab med 15189:2003 primary standard Experience and objectivity are essential. Harmonisation required. Scope of accred – needs consideration to reflect lab. Freq of assessments – consider the impact on staff / expense / finding assessment team

					Appraisal – during training and monitoring Assessment times differ in Europe. Diff approaches to scope of accreditation – service vs test approach	
8.	Huisman, W (2012) Clinical Chemistry and Laboratory Medicine	**European Medical Laboratory Accreditation. Present situation and steps to harmonization** **Aim:** To identify in their own experience from participating in the EFCC (now EFLM) Working Group the present situation of lab accreditation and the steps to harmonisation across Europe	Review Author – Netherlands and Chair of Working Group on Accred and Standards	Europe Not Applicable	2012 still small percent of lab accreditation in Europe (UK 51-75%) – Survey by Spanish Accreditation Body 2011) Harmonising of accreditation process across Europe needs attention Flexible scope is important for accreditation to ensure all tests are covered – important for users. Variations in assessments (freq, Hours spent, numbers in team) – economic consequence (cost of accreditation) Survey 2009 / validated in 2011 - 1 lead + 1 Tech to 1 lead + 4 tech = mostly 2 + 2 = costs Assessment time = 48hrs to >90hrs – majority 80+ hours Assessors – open minded Random sample of lab but still a good indicator of overall practice	2012- UK still under CPAUK Ltd Training of assessors important and needs constant assessing of their competence and practice. A badly performed assessment can jeopardise the whole value of accreditation – need for competent assessors in field. Author ref to 'The added value of accreditation' – no clear reference of how this is justified. Point in time sample assessment of people and process. Lab professional's involvement at all levels important Quality Flexible scope
9.	Jelic, M (2007) International journal of quality research	**Flexible Scope of Accreditation – Introducing vagueness or better expression of scope.** **Aim:**	Conference article	Serbia Single centre – testing lab	Described from perspective of a person on Accreditation board. Practical advice. Requires tech competent staff / key responsibilities defined / validation is key.	Fixed scope – restrictive Flexibility allows for changes to same testing technique already accredited for -

	Vol.1, No.3, 2007 pp227 – 232. International Quality Conference Kragujevac, Serbia	Experience of Flexible scope / application - definitions. Experience for EA / practicality for assessors. Important that scope is clear, not vague, or open ended.			Record of scope required. Describes full process required for flexible scope - validation to report of results - EQA use of AMR to confirm QMS can control flexible scope. Perspective of an assessor included - discuss difficulty. Concluded need for accreditation to adapt to new developments to remain in final level of control in implementation of new approach. Answering to need of marketplace (p232) - adapt their scope of accreditation to meet needs of labs who must adapt to the needs of their users. Assessors too must have abilities to assess / broad knowledge of sector concerned.	1. Materials 2. Parameters 3. Performance of methods. Flexible scope not generally given to labs in first 4-year cycle back in 2007. Important lab managed properly to maintain flexible scope. Change control / validation.
10.	Mate et al, (2014) Globalization and Health	**Accreditation as a path to achieving universal quality health coverage.** **Aim:** Describes major considerations of health system leaders in developing and implementing a successful and sustainable national accred prog – use Thai accred prog as model	Commentary	Thailand NA	Low/middle income countries – even though resource limiting still believe improves Q impact on efficiency. Questions – Can accred create culture of Q imp. What the International evidence and experience recommend	Standards must be achievable and not overly prescriptive. SOP / policies – on site assessment / improve strategies – all costly esp. in low middle-income countries – can lead to poor info mgt / fixing doc. Assessors need to be well trained / knowledgeable & Obj. If seen as bias goal of accred in stim a culture of improv would fail. Financing See accred as an investment
11.	Peter, et al (2010) American Society for Clinical Pathology	**Impact of Laboratory accreditation on patient care and the health system** **Aim:**	Conference paper	USA Lab Med	Significant investment seen in accreditation – difficult for labs in developing countries. In developing countries 60-80% patient management decisions based on lab tests	Cost Efficiency Quality

	Am J Clin Pathol 2010:134;550-555	Review impact of accreditation on quality of healthcare for patients – developing country setting (Africa)			Lab errors – automation and manual procedures subject to inaccuracies – may be significantly higher in developing labs. Lab accreditation (ISO 15189) can reduce frequency of errors – by providing verification lab is adhering to standards. Minimum uptake of accreditation in resource limited countries. Q Standards - improves operational efficiency, customer service & reduces errors – limited published data but direct links with participation in EQA schemes. Efforts to implement accred – focus lab on improvements.	All discussed but no evidence of how they have assessed these. Evidence minimal only EQA Studies on the impact of accreditation on lab errors, testing Q and patient outcomes limited.
12.	Plebani and Lippi (2017) Journal of laboratory and precision medicine	**Uncertainty, quality, safety, and accreditation in laboratory medicine** **Aim:** Discuss pro and cons of accred from perspective of the only 2 labs in Italy currently accred with ISO 15189 (2017)	Editorial	Italy NA	Reason accred not popular – Lab director not on board – not seen as reason for Q imp. Excess doc and reorg of current systems Doubts around process of accred esp. for specialist labs (Mol Biol) Requirements unnecessary e.g., MoU Accred is voluntary	Ref used. Boursier et al 2016 (10) Plebani et al 2015 (14)
13.	Plebani, et al (2015) Clinical Chemistry and Laboratory Medicine	**Once upon a time: A tale of ISO 15189 accreditation** **Aim**	Editorial	Italy NA	Flexible scope allows labs to address their efforts more effectively to assure total quality and patient safety. Quality of total service – needs evaluating	Fixed vs Flexible scope Quality not the only measure but also that of the total service including TATs and

	Clinical Chem & lab Med 2015; 53(8): 1127-9				Harmonisation of QI Competence assessors essential Dutch experience of Flexible scope = pragmatic approach that should be adopted by other countries. Quote – The journey towards a reliable accreditation system started 2 decades ago but the time has come to provide an effective translation of the right principles to effective practice. ISO 15189 main goals – 1. Improve lab service Q and adopting philosophy of Cont. Improvement 2. Eval of quality systems and tech competence 3. Q should be evaluated and improved at every point of TTP 4. Flexible scope allows lab to address efforts effectively to assure total Q and pat safety. 5. Harmonisation req involvement of all EAs 6. EAs should coop with scientific societies to assure comp of assessors. 7. Harmonisation of QI	Cost efficiency EA and ILAC position papers used. Effective and efficient lab services to patients Thelen et al, 2015 paper clarification of risks and benefits of Flexible scope and Dutch experience. Accreditation = Improve Q and Pat safety. (Donabedian) Once voluntary and educational now the emphasis on inspection and compliance. – now mandatory (France / Belgium)- (considered proof of its value??) – standardises labs standards originally used to cause confusion led to intro of ISO 15189 (ISO 9001 & ISO 17025) – introduced TAT & cost effectiveness not just the quality of the measurements. Harmonisation across med labs important. Small No labs accred across Europe – ref Huisman 2012 EA uses Fixed or Flexible scopes – Flexible scope preferred (scope consists of coherent groups of services not fixed list of methods / procedures) – controlled by lab not accreditation body ref Thelen et al, 2015

14.	Plebani and Sciacovelli (2017) Journal of Medical Biochemistry Biochem 2017; 36 pp225 - 230	**ISO 15189 Accreditation: Navigation between quality management and patient safety.** **Aim:** Italian perspective of ISO 15189 accreditation and Flexible scope in Laboratory Medicine	Original Paper	Italy Not Applicable	Accreditation according to ISO15189 guarantees the implementation of process / procedures that comply with standard = express labs best practice / assures staff competency Accred valuable resources Competent assessors Harmonised procedures of assessment Fixed vs Flexible scopes of accreditation Harmonisation needed in Flexible scopes in scientific disciplines for lists of tests for scope – scopes for complete service. To ensure reliability of results – MoU, Verification of procedures, QI	2008 EA approved accreditation with Flexible scope in Europe. Harmonisation required to Est definition of scope criteria to clarify and assure clear understanding for scientific community diff countries and users / patients. Quality in TTP Accuracy of results Efficiency – cost containment Costs and impact on workload of accreditation implementation EQA and QI & assurance of effectiveness of QMS = reduce errors – show lab quality (Use QI / EQA to indicate effects of accreditation) = QMS maintained during transition (pre and post implementation) Use QI and EQA results in own study to indicate effective QMS is being maintained
15.	Sciacovelli et al (2017) Journal of Laboratory and Precision Medicine	**ISO 15189 accreditation and competence: a new opportunity for laboratory medicine.**	Perspective	Italy Lab Med	Implementing ISO 15189 – gold standard – tech and management requirements for lab quality - includes choice of scope. Strong staff involvement required to understand standards and implementation – time and cost constraints.	First released of ISO - fixed scope, all med labs required ability to provide largest possible number of tests, so this not well received by labs in Europe. Flexible scope deemed more appropriate based on accreditation of tests with same characteristics. Lab given trust from EA, so lab professionals have responsibilities - competence /compliance guaranteed for all tests,

					Staff training – knowledge of accreditation / standards Importance of competence, training, validation, and audit to ensure QMS is functioning. Long journey towards ISO important all contribute to achieving full success, solutions to problems = research to implementation of ISO has been undertaken in Europe not U.K. but no evidence of success. Competence of assessors (audit team) and management of accreditation bodies – compliance with standards (NC) Other standards lead to development of ISO15189 – specific for lab med. Discussed the sharing of accreditation experience – lacking in UK	verified by auditor at next assessment visit. Use ISO NC and IA pre and post implementation. Staff involvement – on the job training re accreditation – understanding of and implementation (survey)
16.	Steffen, B (2002) Accreditation and Quality Assurance Accred Qual Assur (2002) 7:25 - 28	**The Flexible scope of accreditation** **Aim:** Experience of accreditation - flexible scope.	Policies and concepts	Germany Single centre case -study Testing lab	Description of Flexible scope / examples of flexible scopes / need to keep list of accredited methods. If deviate from this there are consequences from EA Difficult to react to customers' demands – new task and get formal acceptance from accreditation body – esp. for labs in non-routine fields (H&I). Labs only apply for it if it saves time and money. Since 2002 when written – no actual research into Flexible scope of impact (NEW KNOWLEDGE)	In 2002 only few EAS allow Flexible scope / few labs apply for it because most labs routine labs / clear prescribed methods. Flexible scope requires highly qualified staff / assessors. Only part of scope is Flexible. Accreditation doesn't provide any ranking / status for lab - no PR effect, then labs only apply for it if it saves time and money in daily work. Flexible scope differs between sectors and accreditation bodies.

17.	Thelen, et al (2015) Clinical Chemistry and Laboratory Medicine Clin Chem lab med (2015); 53(8): 1173-1180	**Flexible scope for ISO 15189 accreditation: a guidance prepared by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group Accreditation and ISO/CEN standards (WG-A/ISO)** **Aim:** Presents the guidance developed by the EFLM working group for accreditation and ISO standards regarding Flexible scope of ISO 15189 accreditation	EFLM Position Paper	Europe (No UK representative) Not Applicable	Choosing between fixed and flexible scope -purpose and risk Clear scope needed for users of service. The Dutch approach to implementing a flexible scope – Include the whole scope of practice – needs to be specific to ensure users and assessors are clear what's included. Continued requirements for validations and verifications Harmonise across disciplines	Clarity of scope for users – too nonspecific Fixed scope stifles (is a burden) to innovation – need to continuously change scope leads to ETS which have impact on service provision and financial impact. Generic Scope required for H&I community??
18.	Thelen, M. H.M (2017) J Lab Precis Med; 2:84 Journal of Laboratory and Precision Medicine	**Flexible scope for ISO 15189 accreditation requires harmonization of scope specificity.** **Aim:** To discuss guidance, provided by EFLM to stimulate the use of flexible scopes. Harmonised approach of different disciplines to find optimal balance between specificity and flexibility – increasing specificity is leading to flexible scope becoming fixed?	Perspective	Netherlands Lab Med	Clinical labs build QMS round standards – different ones used. Appreciation of accreditation (ISO15 189) = national governments > Mandatory Scope required for users to list tested accredited. Flexible enough to facilitate innovation but specific enough to define limitations to customers and assessors. (Scope limitation) Less defined scope of practice - lab can perform additional services under current scope following validation - without assessing body evaluation. Use of a risk-based approach to Est scope definition EFLM 2015 guidelines promoting use of Flexible scope - consensus paper for scientific societies and National	Fixed vs Flexible scope of practice EA promotes use of Flexible scope but in 2017 not many labs moved from Fixed scopes. Facilities innovation Source scope (For each discipline) needs defining for H&I Source scope may be required for H&I discipline – (Future) Granularity – too much may move back to fixed scope.

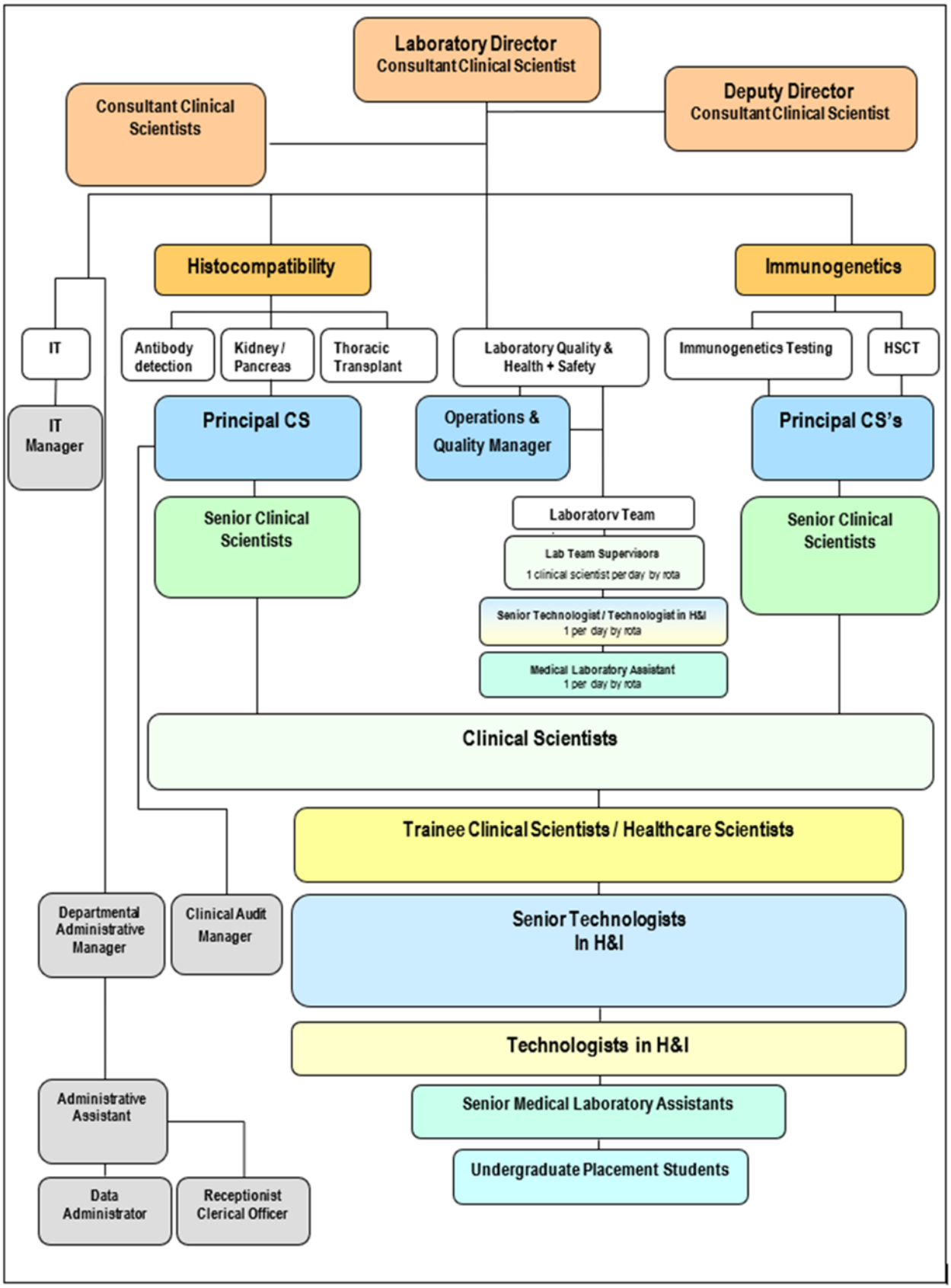
					Accreditation bodies (NAB) to define degree of specificity based on Netherland's experience - specific to Clin chem and harm. Transition from national accreditation CCKL to ISO - already using a flexible approach - need to be flexible for ISO - provided what was known as a scope source.	
19.	Thelen, et al (2018) Clin Chem Lab Med (2018); 56(10): 1637 – 1643 Clinical Chemistry and Laboratory Medicine	**Harmonisation of accreditation to ISO 15189** **Aim:** Challenges and opportunities in the further development of the standards with regards to it leading principles (Limitations of paper are explicit the articles don't include whether accreditation, the standard or its application, improves quality)	Opinion paper	Netherlands LAB med	Historical background of quality – QUALITY- most errors pre – analytical outside of lab control. Need to monitor Q inside lab to improve Q led to vol accred and CPA. Harmonisation – Discipline specific guidance to run parallel with standards to harmonise assessments. Scientific community (EFLM) – questionnaire to feedback re standards Standards – Future of ISO15189 –	use of EQA schemes = evidence of analytical performance / improvement. Development in different countries of use of QMS = different assessment process – UK = CPA program. In Europe EFLM working group to harmonise accreditation across Europe = use of ISO 9001 and ISO17025 > ISO15189. Harmonisation of technical and QMS with the standards across disciplines / within and across countries to ensure objectivity, preserve intention of standards to promote transparency and comparability of accred status. Standards are generic and allows autonomy – need for knowledgeable trained peer assessors – importance of training and objectivity. Harmonisation of scope used – flexible scope promoted in Europe = consists of coherent group of related procedures within same medical field, technical field and material.

20.	Theodorsson, E (2016) Journal of Medical Biochemistry J Med Biochem 35: 103-112, 2016	**Quality Assurance in Clinical Chemistry: A touch of statistics and a lot of common sense**	Review article	Sweden Lab Med Clinical Chem setting QA / QC / TQM	Accreditation risk of becoming an obstacle to innovation – automation etc. – intense monitoring when major restructuring occurs. Not yet Est if accred improved diagnostic value of results (Plebani et al, 2015) Bureaucratic systems Errors – move to automation = reduced repeats. Analytical phase – focus of measures in lab – quality of TTP. EQA Staff motivation – measures to increase motivation of staff leads to overall service quality	Flexible scope - partial solution to problem but accreditation body are afraid of change in lab processes leads to decrease in quality. (Ref Plebani et al, 2015 / Thelen et al, 2015) Use Error rates to measure. Innovation – research projects / QI projects important for staff motivation – designed to improve service Q for patients. Involvement of staff in research and innovation projects – motivational External inspections (ISO 15189) renew important commitment and focus on purpose (patient focus)
21.	Tzankov, et al (2017) Pathobiology Pathobiology 2017; 84:121 - 129	**Hands on experience: Accreditation of Pathology laboratories according to ISO 15189** **Aim:** Describes practical experience of ISO 15189 accreditation within pathology laboratory outlining advantages, addressing critical points and discussing caveats of process	Discussion	Switzerland Lab Med	Advantages of accred – analyse, describing and critically question a lab (by accred) – intuitively sub to improvement (showed 10% of trad processes – waste of resources and eliminate – 20% considerably improved) = reduced TATs / No of tech errors (doc of errors used for learning – improve systems Showed changes is #nprocess lead to financial savings Accred effort = teamwork, engages staff (doc prep / audit / involvement in cont. improv) = increases staff motivation and inclusive responsibility – intuitive not measured	Advantages of Accreditation- The process of accreditation intuitively subjects the lab to improvement – EQA & TATs / RR's critical errors monitoring lead to process changes (by measuring you can see problems). Participation in EQA schemes Staff involvement – motivation - Staff engagement essential – increases staff motivation – what evidence?

					Disadvantages –Time consuming to Est (staff need to set up and run) Quality difficult to objectify – EQA schemes / successful runs. Meeting needs or users Lab Def QI – verify Q. TATs / RRs Caveats -Documentation important but only of things that improve end results for patients anything else do minimal to reduce bureaucracy. Accreditation time consuming. human resource planning should be considered.	Bureaucratic Staff motivated by involvement in accred – no evidence of how he came to this – (use of staff survey in study) Does not include financial costs. Time consuming
22.	Wilson et al (2016) Microbiology Open	**Meta-audit of laboratory ISO accreditation inspection: measuring the old emperor's clothes.** **Aim:** **To reassess past audits and non-conformances by evaluating the potential effects of each NC on the validity of results and quality of service**	Retrospective meta-analysis of data (quantitative)	N Ireland	333 audits conducted between 2000 – 2013 = 188 NC; when reassessed by 2 independent Clinical scientists showed only 17 may have impacted on results and quality of service. NC related to clauses of ISO standards not likely to affect results or quality of service. True Pos and True neg rates - indicates that accreditation leads to substantial misdirected effort and waste. Source of some NC were third party issues outside of lab / documentation / recording of training etc.	Not using ISO15189 standards to assess NC used ISO 17025 but process the same. Importance of minimizing and controlling bias (very bias tone throughout paper – author QM) Value of accreditation needs determining, implementation of accreditation may be counterproductive – misdirect effort. NC and audits only one aspect of accreditation – to fully understand impact of accreditation need to include other aspects in study. Scope and strength of evidence is weak.

					Compliance audits poor use of resources their effects on quality of results and service are minimal. Declared limitations to study = subjectivity EQA schemes add value – Quality of service (outside of accreditation) More objective evidence needed	Use EQA results to measure quality over period of accreditation (Pre and Post implementation)
23.	Zima, T (2017) Journal of Medical Biochemistry J Med Biochem 36: 1-6, 2017	**Accreditation of medical laboratories – System, Process, benefits for labs.** **Aim:** **Describe implementation of accreditation Czech Republic** **Increased No med lab accreditation 2006 to 2013 in Cz Rep**	Professional paper	Czech Republic NA	Key priority to improve Q – QMS (therefore accred important) Reducing errors & TATs Edu and training Accreditation body – impartial & independent Ref – Zima 2010 Boursier et al 2016 Guzel et al 2009 Theodorsson 2016 Huisman et al 2007	Quality Clinical effectiveness Cost effectiveness Pros and cons of accreditation – Expense of accreditation

Appendix 6 Transplantation Laboratory Staff Structure



Appendix 7 Laboratory Director Consent to contact

NHS
Manchester University
NHS Foundation Trust

18 June 2020

To Whom it May Concern

JULIE JOHNSON: RESEARCH PROJECT

As the Director of the Transplantation Laboratory, I fully support the proposed research which will be carried out by Julie A Johnson. The research is innovative and will provide a robust evidence base on which to develop practice essential for our service.

As the Director, I agree to provide access to hospital data to measure the quality clinical processes that influence the quality accreditation for the laboratory. The Senior Management team will oversee that the research follows good ethical practice principles when undertaken and approaching staff in the clinical area. Julie Johnson will be responsible for providing a quarterly report on the progress of her research to the Training Management Team within the department so that progress is supported.

Yours sincerely,

Consultant Clinical Scientist
Transplantation Laboratory

Appendix 8 University of Salford Ethics Application Ref: 236 Approval

University of Salford MANCHESTER

Research, Enterprise and Engagement
Ethical Approval Panel

Doctoral & Research Support
Research and Knowledge Exchange,
Room 827, Maxwell Building,
University of Salford,
Manchester
M5 4WT

T +44(0)161 295 2280

www.salford.ac.uk

9 November 2020

Dear Julie,

RE: ETHICS APPLICATION – Ref. 236 – Evaluating the Implementation of a Flexible Scope of Accreditation in an NHS Laboratory: A single centre longitudinal study.

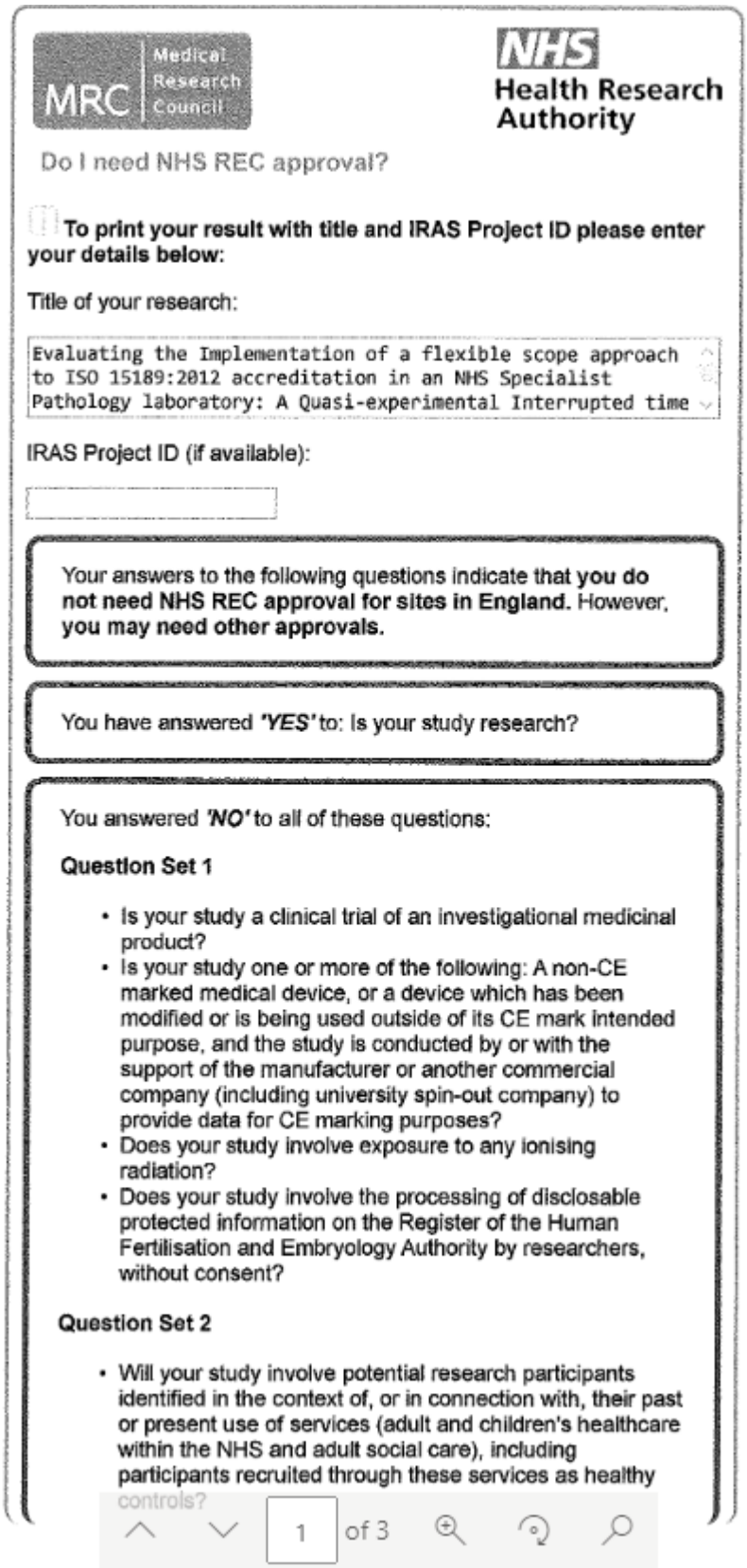
Based on the information that you have provided I am pleased to inform you that application Ref. 236 has been approved.

If there are any changes to the project and/or its methodology, then please inform the Panel as soon as possible by contacting Ethics@salford.ac.uk

Yours sincerely,

Professor Andrew Clark
Chair of the Research Ethics Panel

Appendix 9 NHS REC Approval



MRC Medical Research Council

NHS Health Research Authority

Do I need NHS REC approval?

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

Title of your research:

Evaluating the Implementation of a flexible scope approach to ISO 15189:2012 accreditation in an NHS Specialist Pathology laboratory: A Quasi-experimental Interrupted time

IRAS Project ID (if available):

Your answers to the following questions indicate that **you do not need NHS REC approval for sites in England.** However, **you may need other approvals.**

You have answered ***'YES'*** to: Is your study research?

You answered ***'NO'*** to all of these questions:

Question Set 1

- Is your study a clinical trial of an investigational medicinal product?
- Is your study one or more of the following: A non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose, and the study is conducted by or with the support of the manufacturer or another commercial company (including university spin-out company) to provide data for CE marking purposes?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?

Question Set 2

- Will your study involve potential research participants identified in the context of, or in connection with, their past or present use of services (adult and children's healthcare within the NHS and adult social care), including participants recruited through these services as healthy controls?

1 of 3

- Will your research involve collection of tissue or information from any users of these services (adult and children's healthcare within the NHS and adult social care)? This may include users who have died within the last 100 years.
- Will your research involve the use of previously collected tissue or information from which the research team could identify individual past or present users of these services (adult and children's healthcare within the NHS and adult social care), either directly from that tissue or information, or from its combination with other tissue or information likely to come into their possession?
- Will your research involve potential research participants identified because of their status as relatives or carers of past or present users of these services (adult and children's healthcare within the NHS and adult social care)?

Question Set 3

- Will your research involve the storage of relevant material from the living or deceased on premises in the UK, but not Scotland, without an appropriate licence from the Human Tissue Authority (HTA)? This includes storage of imported material.
- Will your research involve storage or use of relevant material from the living, collected on or after 1st September 2006, and the research is not within the terms of consent from the donors, and the research does not come under another NHS REC approval?
- Will your research involve the analysis of DNA from bodily material, collected on or after 1st September 2006, and this analysis is not within the terms of consent for research from the donor? And/or: Will your research involve the analysis of DNA from materials that do not contain cells (for example: serum or processed bodily fluids such as plasma and semen) and this analysis is not within the terms of consent for research from the donor?

Question Set 4

- Will your research involve at any stage intrusive procedures with adults who lack capacity to consent for themselves, including participants retained in study following the loss of capacity?
- Is your research health-related and involving prisoners?
- Does your research involve xenotransplantation?
- Is your research a social care project funded by the Department of Health and Social Care (England)?

If your research extends beyond **England** find out if you need NHS REC approval by selecting the *'OTHER UK COUNTRIES'* button below.

OTHER UK COUNTRIES

If, after visiting all relevant UK countries, this decision tool suggests that you do not require NHS REC approval follow this link for final confirmation and further information.

Appendix 10 Participant Information Sheet

Title of study: Evaluating the Implementation of a Flexible Scope of accreditation in an NHS Laboratory: A single center longitudinal study.

Name of Researcher: Julie Johnson

1. Invitation paragraph

You are being invited to take part in a Professional Doctorate research project to investigate the impact of implementing a flexible scope of accreditation into an NHS laboratory. Before you decide on whether to take part, it is important for you to understand why the research is being undertaken and what it will involve. You will be invited to attend a presentation to provide full details but please take time to read the following information carefully before you decide if you wish to take part. You are welcome to discuss this project with others before you make your decision. Please email (j.a.johnson3@edu.salford.ac.uk) or personally ask me if there is anything that is not clear or if you would like more information. (tel.0161 276 6424)

2. What is the purpose of the study?

The current laboratory accreditation system managed by UKAS accesses and monitors laboratories against a clearly defined repertoire of tests known as the 'scope of practice' or a 'Fixed Scope'. During each annual "on site" inspection this list of tests and methodologies along with the quality management system are evaluated for compliance against a set of standards. A drawback of this approach is that within a clinical demand-led NHS pathology service there are constantly new tests being developed, but this fixed accreditation approach does not allow services to respond and change practice in a timely fashion. Indeed, many UK laboratories under the current fixed scope approach may well be reducing the quality of their service because they cannot expedite the implementation of new methods and tests effectively to meet clinical demand. To change the scope of practice, laboratories need to request an 'Extension to Scope' (ETS) from UKAS. This may involve additional formal on-site assessment of the new or modified procedure and quality management system, which bring with it a financial charge to cover associated on-site and administrative costs. Currently, there is a lead-time of at least three months for this process to be reviewed and assessed by UKAS, before a new or modified technology can be classified as accredited by a laboratory.

In Europe, many medical laboratory disciplines have implemented 'Flexible Scopes' with support and guidance from European Assessment bodies (EA). This progressive way of working potentially allows for an independent and more flexible management of the scope of practice by the laboratory but we don't know if such an approach will have an impact on the quality or cost of service delivery, or staff workload. We don't know if the approach will allow the laboratory to work more effectively and be more responsive to research and development. This study plans to develop an innovative evidence base to inform practice nationally for clinical laboratories.

Within this study we plan to investigate the implementation of the 'Flexible scope' approach to accreditation within the clinical laboratory in which you work. The study will include examining the impact of 'Flexible Scope' on service delivery quality, efficiency and cost effectiveness alongside gathering the perceptions and experiences of staff members. It will start with an initial research phase where the impact of accreditation will be examined over the study period to develop a rationale for the implementation of the Flexible scope.

3. Why have I been invited to take part?

As part of the Transplantation laboratory team the effects of accreditation in the laboratory directly impact on you and therefore so too will any changes to the current accreditation approach. The information you provide will be fundamental in exploring the effects of accreditation, the rationale for implementing a Flexible scope and finally the impact of introducing the flexible scope.

4. Do I have to take part?

It is up to you to decide whether to take part. If you do decide to take part, you should keep this information sheet for reference. In addition, you will be asked to sign a consent form prior to actively participating in the study. However, you can still withdraw at any time without giving a reason. If you do withdraw you should, however, note that any data you have already provided will continue to be part of the study data and processed. It will only be used for research study purposes and in an anonymised way, so that you cannot be identified.

5. What will happen to me if I take part?

Part 1 – Expert Panel

Initially staff members who form the Laboratory Management team (Band 8a and above Clinical Scientists) will be involved in an Expert Panel discussion confirming by group consensus the appropriate critical processes to monitor during the project. These processes were chosen by the researcher based on -

- the laboratory's current UKAS accredited scope of practice
- those processes that have a direct effect on patients care
- those considered to have the most significant clinical impact.

The appropriate laboratory quality indices appropriate to each process was also determined to be used to monitor the critical processes longitudinally during the project to obtain quantitative data. This will be done following a scheduled routine management meeting and will be voice recorded. Any member of the Team that has not completed the consent form and/or does not wish to participate will be required to leave the meeting. Any member of the team who is shielding, socially isolating, or working from home and is therefore unable to physically attend the Laboratory management meeting will be invited to join via Microsoft Teams as routine. Again, anyone who hasn't completed the consent form and / or doesn't wish to participate in the study can leave the Teams meeting. Continued attendance in the Teams meeting will signify that you have given consent for the discussion meeting to be recorded via Teams and used in the study.

The Laboratory Management team's perceptions on accreditation and its impact on quality, efficiency and cost effectiveness will also be captured at this meeting and used to develop the questions for the staff survey and semi structured focus group discussions.

Part 2 - All Transplantation laboratory Staff (at all levels)

Your input to the study will involve –

- Completing a short survey of no more than 10 questions, annually (Pre and Post the implementation of the Flexible scope)
- Voluntary participation in a focus group (Pre and Post the implementation of the Flexible scope)

You will be asked to do these twice over the study, initially pre- the implementation of the Flexible scope and then post implementation.

As part of the study all members of the Transplantation laboratory team at all grades including the laboratory management team (n=38) will be invited to participate in the on-line survey via British Online Surveys (Jisc). Following the survey there will be 2 different focus groups sessions held via Microsoft Teams, one consisting of Senior Clinical scientists (bands 8A and above) and a second consisting of the MLAs / Technologists and band 6 and 7 scientists. Volunteers of staff groups will be required to participate in each of the focus groups and the only prerequisite will be that you must have completed the survey.

The aim of these groups will be to provide the opportunity to discuss and expand on the findings developed from the survey pursuing topics identified by the staff as crucial to accreditation or impacting on the service. The focus groups will be confidential each being approximately 60 minutes in length and will be digitally recorded on Microsoft Teams, anonymised, transcribed and the data then analysed. As a participant in this study, it is important that you are able to attend all relevant Focus groups over the study period. If you are unable to attend, please let the research lead know immediately via email j.a.johnson3@edu.salford.ac.uk or telephone 0161 276 6424. Your consent will be requested before recording, continued attendance in the Teams meeting will signify that you have given consent for the meeting to be recorded via Teams.

Contact details of Face-to-face participants will be kept securely for 21 days to enable contact tracing in the event an immediate member of the group tests positive for Covid-19 or develops symptoms to enable contract tracing. This will be established in addition to the MFT Test and Trace protocol currently in place for MFT staff working on site.

6. Expenses and payments?

No expenses will be available to participants.

7. What are the possible disadvantages and risks of taking part?

There are no disadvantages to participation in this study except perhaps the inconvenience of completing the survey and attending the focus group. There may be slight discomfort for those who do not like participating in discussion groups, but as this is a voluntary process these people need not volunteer.

8. What are the possible benefits of taking part?

The study will not directly benefit you but the information we get from the study will increase the understanding of the impact of implementing the flexible scope in an NHS laboratory. It will help to provide new knowledge around the subject area of accreditation and advance knowledge through research.

9. What if there is a problem?

Concerns or Complaints:
If you have a concern about any aspect of this study, you should ask to speak to the researcher by email (j.a.johnson3@edu.salford.ac.uk) or by telephone (0161 276 6424) who will do their best to answer your questions.

Following this, if you have any issues or complaints, you may contact the research supervisor, Professor Paula Ormandy by email (P.Ormandy@salford.ac.uk) or by telephone (0161 295 0453)

If you remain unsatisfied you can direct your concerns to Prof Andrew Clark, Chair of the School of Health & Society Research Ethics Panel, University of Salford. Email a.clark@Salford.ac.uk

10. Will my taking part in the study be kept confidential?

All personal details will be kept confidential and anonymised and will not be revealed to people outside the research team. If you take part in a focus group then your participation will be known to the other group members, but everyone involved will be asked to keep any focus groups discussion and participant names confidential as part of their consent to take part. If during the course of the research, poor practice is revealed, or it is suspected that harm may come to an individual it will be reported to a relevant authority.

11. What will happen if I don't carry on with the study?

Nothing you are free to withdraw from the study at any time but any information that you have contributed to the study up to that point will still be used and remains part of the study.

12. What will happen to the results of the research study?

The results will form the basis of the researchers Professional Doctorate thesis, other publications, conference posters and presentations, and further research. When reporting the study results any responses or quotes used will not be attributed to an individual or a role if this will be identifiable, data will be anonymised throughout.

13. Who is organising or sponsoring the research?

Transplantation Laboratory, Manchester University Foundation Trust (MFT) and VHBio ltd are providing the funding and support for the Professional Doctorate.

14. Further information and contact details:

Researcher team:

Julie Johnson (Laboratory Operations and Quality Manager) Lead Researcher
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MFT Supervisor –
Professor Kay Poulton
Kay.poulton@mft.nhs.uk

Appendix 11 Consent Form

University of Salford MANCHESTER

Research Code:

Appendix 6 - CONSENT FORM

Title of study: Evaluating the Implementation of a Flexible Scope of accreditation in an NHS Laboratory: A single center longitudinal study.

Name of Researcher: Julie Johnson

Please initial the boxes to show you agree and sign this form **after** you have read and understood the study information sheet provided.

	Initial in each Box
1. I confirm that I have seen the Patient information presentation Version [2], [dated 15.09.2020], read and understand the study information sheet Version ***[2]***, dated ***[14/09/2020]***, for the above study. I have also had the opportunity to consider the information and to ask questions which have been answered satisfactorily.	☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my rights being affected.	☐
3. If I decide to withdraw, I understand that the information I have given, up to the point of withdrawal, will continue to be used in the research.	☐
4. I understand that by participating in this study I am required to complete the 2 annual surveys and actively participate in the 2 focus group associated with the survey when required.	☐
5. I understand that my personal details will be kept confidential and will not be revealed to people outside the research team, and in turn	☐
6. I agree not to reveal any other individuals identity participating in the focus group and that all discussions are confidentially kept within the group.	☐
7. I understand that if during the course of the research if any poor practice is revealed or it is suspected that any harm may come to an individual that it will be reported to the relevant authorities.	☐
8. I understand that my anonymised data will be used in the researcher's Professional Doctorate thesis, other academic publications, conferences/presentations, and further Research. This data will be kept confidential except in circumstances where poor practice may be revealed, or where harm may come to an individual.	☐
9. I agree to all the focus / discussion groups being electronically recorded.	☐

I agree to take part in the study:

_____	_____	_____
Name of participant	**Signature**	**Date**
_____	_____	_____
Name of researcher taking consent	**Signature**	**Date**

Version [3] Date [03/10/2020]

1

Appendix 12 Expert Panel Discussion Schedule – 10/10/2020

Introduction - housekeeping (microphones off, hands up to speak, don't talk over people, please don't talk for too long give others a chance to say something so few of us and I will stop and move on to others) to prompt you.
Obtain permission to record.

The main aim of this consensus meeting is to -

1. validate the selection of the key critical processes to be monitored during the PDoc.
2. develop the framework of the questions for the survey looking at perceptions of laboratory accreditation.

The meeting will take place in 2 parts and last no longer than 90 mins.

Part 1 -
Display the Key critical process table for consensus –

Critical Processes	**Technique used**	**Code**
HLA Typing	Polymerase Chain Reaction– Sequence specific oligonucleotides	PCR-SSO
	Real Time Polymerase Chain Reaction	RT-PCR
	Next Generation Sequencing	NGS
HLA antibody screening - detection and definition	LABScreen Single antigen or mixed antigen screening	LABScreen
	LifeCodes single antigen screening	LifeCodes
Chimaerism monitoring	Short tandem repeat markers	STR's

1. The aim will be to establish which, or the laboratory's critical processes as described within the UKAS Scope of Practice should be included in the project evaluation to ensure that the quality, efficiency and cost-effective elements of the laboratory service are captured.
2. There is pre-existing quality performance data available for longitudinal analysis that will provide a robust retrospective baseline to the study. These

critical processes are the main generic technical procedures used within a Histocompatibility & Immunogenetic (H&I) laboratory in the UK. This consensus approach will aim to minimise any researcher bias introduced through independent selection.

The rationale for selection will include:

- they are deemed to have the most significant clinical impact
- have a direct effect on patients
- measure all laboratory process performance points in line with UKAS scope of practice
- where there may have been problems with quality and efficiency in the past

Part 2 –

You will be asked your perceptions of accreditation around the following 4 topics -

- Accreditation and Quality (How do you think that it has affected laboratory quality?)
- Accreditation and staff involvement (How do they think it has impacted on the laboratory personnel / themselves?)
- Accreditation and efficiency (How do they think it has impacted on laboratory systems?)
- Accreditation and cost (Do they consider that currently laboratory accreditation is value for money?)

The outcome will frame the questions for the staff survey along with data obtained from the literature review.

Use pauses and probes.
Can you explain further?
Can you give examples?
I don't understand.

Summary and close
Thank you so much, interesting feedback.

Thanks for contributing as well as assisting in the development in the research tools for the study you are assisting in validation and minimising bias to ensure a robust study design.

EFI seems really logical - best practice and peer regulated. ISO, I think I have my doubts about ISO I think we are just drowning in paperwork, as you should know (ref to QM) coz you cop for it all. Part of the problem with ISO is coz it's for all medical laboratories lot of stuff that probably doesn't really affect us but still have to comply.	Accreditation - Generic standards
Yes	
Too generic	
Yeah exactly	
My main bug bear with ISO is its conflict with HCPC coz we're all state registered clinical scientists, that are kind of qualified to do the job all give this stamp by the government which we pay for but it doesn't count for anything with ISO so spend all time proving that you can do what you're supposed to do when you already have a stamp that says we can do that. I think we need one or the other, having 2 is a waste of time.	Accreditation conflicts with Training and competence
Yes, I think the Flexible scope thing you are trying to go for will be a really good thing, I think ISO stifles innovation as well.	Innovation
Yes, I think that Innovation	Innovation
Nods in agreement	
Continues with - the pace at which our discipline has changed over the past 10 years has been massive and I think....	Innovation
Can't keep up.	
So flexible scope would be great in that respect.	
Conversation stopped.	
Interview started the conversation - So we all agree with this from a Managerial side. A positive side of accreditation is that the generic standard is to make it fair across the board. Medical Lab	

accreditation for all medical laboratories. Issues may be with the peer assessors not looking at standards. They need to establish if quality inbuilt into system.	Peer assessors / training
I mean were on the inside aren't we looking at all the paperwork and drowning under it but if you were to pretend and we are sometimes patients of other lab tests and we take it outside and the public if you have standards and are doing this test you must comply with this level of quality standards to show that you can do the test well, that you are assured that the result is accurate that means everything to me as a patient if I am to have my full blood count I want to know that there are no problems coz actually the machines drifted out and no one's picked it up so you have to look at it from that side potentially its gone a bit too far (meaning accreditation) but actually from a patients care point of view you know it's no different to having some invasive thing, you want to know it's all been looked after been calibrated correctly and whatever there doing to you be it an MRI scan or anything else is detecting what it should be, it goes for all interventions for patients and that's what we are about. My issue here is, not sure if accreditation if just for public labs or private labs to maintain, there is a requirement for the public sector what about the private? I personally believe all should and if they can't be.	Staff involvement - Paperwork Patient Focused
Conversation stopped.	
Moderator began the discussion - Do patients know or care, would they check if we are accredited?	
I think they would do, it's like school inspections but it's just a snapshot in time, isn't it?	**Snapshot in time.**
Nods in agreement	
Depends on what they have looked at on the day so to the public they may look at that and think that's great they have accreditation and so the public fells safer but we know, we know our practices are good because we strive for that in this laboratory but we also know it's just a snap shot in time and just depends on what they look at, what processes they choose to look at on that day.	**Snapshot in time.**
No, I would agree with you, but at the same time the patients don't necessarily get the choice of who's doing the testing, so you know you go to your GP or hospital, and you know...so in a way can we expect people to lay people to understand the importance of it all.	Patient focus - do they need us to be accredited. Ofsted - accreditation

No, I think it's like when you're looking at schools you are looking for the one with a good Ofsted don't you so you'd want to know the lab is accredited coz that would make you feel more secure, but we know internally that it's just a snapshot in time isn't it that their assessing. Yep yeah and that if you do maintain there is still variation between just scraping over...did they actually look at something that particular inspection as it not enough time to fully inspect everything down check you really do comply so we all know that that you know when they come in you hold your breath a bit going, please don't let them look at this or that too closely as we know that there are bits that may not be how we would like them to be. But **Conversation stopped.** **Moderator comments** that this issue with 'papering the cracks' just before the visit is it always an issue? And to some extent there is a bit of just form filling, lip service here .....told a story from previous experience in lab where back filling of report done just prior to accreditation - to demonstrate what was the point of that form anyway. Cleanings not serious but this type of thing could lead to a Staffordshire with the Francis report where that's exactly what they did, they said there's a report somewhere they'd done it but just not documented the report, and it turned out they hadn't done it...and its one of those things where do you draw the line. It's a bit of a spiral, decline if you're not careful. (Ref to TV programme Chernobyl) if anyone has been watching Chernobyl can see where quality system as started, can see why required and started no SOP, no management structure...accreditation needed to ensure all processes in place and I think probably most of it is good stuff and that's what it puts in place, it's just the minutiae of it kind of makes thing difficult and a lot of it comes down to the inspectors interpretation of the standards, not that I have seen the ISO standards coz we are only allowed one copy but when you look at them the standards are not very specific in what they mean so can apply those in lots of different ways and it just depends if the inspector thinks you are applying it in the correct way or not. **Nods Nonverbal**	Lip service. Importance of records / documentation Inspectors – subjectivity

Nods Nonverbal Yeah Continues...quite a lot of the time when they do come and inspect our processes there is kind of, quite a lot of overlap between what they're inspecting and what EFI overlap and when you actually look at the standards, I am not even sure why they are actually looking at those things because they are not actually covered by ISO standards. There is a level of subjectivity still... Yes Yes Continued... you have any, to some extent with EFI, if you are doing this test, you must put this control in? Yes Continues .... that's pretty obvious, I mean there is some level of, you know, variation but generally it's understandable, it's clear. They are easier to follow, you know what they want from you. You do hear between centres that some other centre got pulled up for something that a lot of people do or don't do and then other labs don't get pulled up on it? But there definitely seems to be inconsistencies in how standards are applied. Asked other members of group if they remembered the good example from ISO inspection how the lady from genetics didn't know anything about wipe test? To show no contamination in tests. When inspected by ISO she didn't have a clue what wipe teste were. Explained that because wipe tests are specific to H&I and the EFI standards. Example of how different standards can be and different ways of doing things. At least you can look up the EFI standards online.	Overlap with other accreditation bodies. Subjectivity Difficult standards to understand. Inconsistent applied (assessors) Assessors - knowledge Availability of standards (free of charge) Cost of accreditation Difficult to interpret.

Laugh Nonverbal **Laugh Nonverbal** Continued....ISO seems shrouded in..... and you have to pay for this and that…… Mystery..... **laughs** continues.... not very...I don't like that about it at least then you know with EFI that you can cross check things you need to be looking at and its sensible but that doesn't seem to make sense to me at all. **Smiles Nonverbal** I mean to some extent it also highlights there are issues .... so, you talk about the wipe tests - you will all be cursing me (smile) when I first joined (the lab) and I talked about the Quality Time we had, and it didn't seem to work. It came from incident in last place when I was writing the incident report for contamination and spoke to team couldn't find out when last wipe test was...hadn't been done for 6 months. Therefore, not complying with EFI standard. Asked why and it was due to them not having time to do it, testing came first, had to get patients results out. I said that's all very well, but your tests are compromised if the quality checks that you need to do aren't done. Standards highlighted a system need to be changed to give them the time to make sure the quality tasks were done, the thermal cycles check, cleaning etc. So, could argue if we didn't have that standard, it would have just drifted and none of us would have done the wipe test because it was never a priority, but results are then compromised, churning results out are they right or did you just type someone's contamination? We would all agree about the wipe tests being important, but we just found it strange that genetics don't do wipe tests. (Referring to the assessor not knowing what wipe tests were) Yeah, Yeah Yeah no no sorry.... The amount of work they do in their department. we found out something interesting from the inspection.	Time to do quality / **positive** of standards. Inconsistency of assessments Expensive?? Cost

That also highlights again the difference in the 2 different sets of standards that exist. But with regards to the ISO standards, they are very generic for the simple fact they have to cover every single discipline there not just specific, that's why we have the EFI for our peer assessing techniques.	(Personal experience re EFI - Learning - PEER ASSESSORS)
Moderator redirected to Costs of accreditation due to time.	
Who profits out of it? Does someone profit out of it?	
UKAS is meant to be a not-for-profit organisation, but their annual report last year reported a profit of something like £1.5M, they say that goes back into improving their systems? But **Positive** of accreditation we can learn from each other, different labs learn from each other particularly by EFI, but I guess if we adopt the flexible scope then it paves the way for other labs to do the same so if its beneficial to us then its beneficial to others. But particularly I guess EFI you can go, I mean inspectors can go between labs ask different questions but also I guess we have conversations between us as labs as well don't we and compare what we might do for various things and I think in that respect I suppose we help one another certainly with the NGS stuff when a colleague came from Denmark and she was asking about all sorts of things with our NGS and we were chatting backwards and forwards about different ideas was really helpful.	Personal experience re EFI - Learning - PEER ASSESSORS UKAS Not responsive to users Shared learning
The other nice thing about EFI with **that sharing** in mind that do respond to users so one of thing that a lot of the UK labs do now is not prospective cross match and you know we do a virtual one particular lab started by saying we have done an audit and showed we have not an unexpected retrospective positive cross match so we stopped doing it, technically non-compliant but that goes back to EFI.	
Moderator requested to move back to discussions regarding ISO.	ISO ref but mean UKAS. Inspectors
Was just wanting to point out ISO isn't as responsive to users.	
Moderator comment - we could use the ISO standards to our benefit and use to educate inform others by publications of audits / validations.	Training and competence
MoU for chimaerism's wasn't defined, part paper written with L&I UKNEQAS all labs not just H&I all have to have ISO.	
Conversation stopped.	Assessing the assessor

Moderator introduced the concept of harmonising with ref to Europe and Clinical chem - perhaps consider for H&I to help with a fair system for inspections. Harmonisation of system seems a good idea but may be difficult coz still all do things different. ISO do seem to be kind of resistant to that type of thing though because when the RCPath introduced the MoU document quite often the inspectors would come and says well ISO doesn't agree with that we have our own way of doing things and the annoying thing about an ISO inspector is when you say well what do you recommend, they say they aren't allowed to make any recommendations so it's difficult to kind of educate and move on. Problem maybe with assessor and not necessarily the standards. Standards are standards it's how they're interpreted, problem with **training and poor assessment of the training.** I was going to say is that not a problem with their training, actually you know they haven't been validated.... you know. Reminder of trainee assessor we had that was being audited, I think half the problem is ISO is Europe wide and it's trying to be all things to all labs and clearly can't whereas with EFI we can give a bit of feedback very specifically. Answer would be to get some assessors on the board for standards review?? (Chair of EFI standards committee) **Bringing it back to flexible scope** - If we need to speed up the TATs for our quality data is this feasible how will it impact on staff? It's the sort of thing you can concentrate on when WFH (concept introduced due to covid-19) because in the day you tend to get interrupted with phone calls, people coming to ask questions, people needing set up observations and I know MT02 /MT14 / MT12 plan that heavily into the time plan so when people are at home it's much easier for them to concentrate on things like that Asks if they then consider the new system of WFH will help with the validation etc write up? I hope so.	Quality data required for accreditation = time to do it difficult Ways to get quality work done - Time for staff to do Quality documents. the Quality time was mentioned.

Nodded Nonverbal I think being devil's advocate for a second, I do think sometimes we are such a slave to this constant roll over of testing that sometimes just have to get the quality out of the way and then everything will catch up with itself later and where if you keep concentrating on the next test that's coming through it just never gets done. that's before you have key performance indicators to meet, that's why we insist on things going out on time and meeting the turnaround times, we have got to learn to fit the quality in around that! Yes that's what I mean for the STR TATs it's much more difficult, there are sometime we can afford, if we are getting things out in 3 days instead of 5 days you've got 2 days to play around with although you really don't want to be flying too close to the sun, but yeah, I think it's difficult to organise that, it's the micromanagement and how that fits around everything else but yeah **Conversation stopped.** **Moderator asked** - Does anyone else have an opinion any ideas how we can inbuild this? We know they need to be done but sometimes from my perspective they seem to be taking a long time to get to me. Sometimes it feels like pulling teeth, are people uncomfortable about doing them? As managers we are going to have to deal with when we move to the flexible scope, in order to move our systems, forward we need to find a way do this, I know testing takes priority, but we need to find a way to build quality into the system as well. - but I genuinely think it works well for me and I know other people have said it's easier to do from home so if you have a day **dedicated to WFH** you tend to take validations to do unless they've been asked to do analysis from home, I mean the 3 PCS's will be able to comment more on that about the specifics but... I think logistically you are right definitely, to even just fitting it around the analysis coz it's not like the would perhaps take all day so therefore there is time around it where when you're in work you know you are doing other stuff because you know there are always things to be done, phones to answer etc emails to answer whereas your more uninterrupted. Yes like today I said it to someone WFH, there is other reporting that you can do but concentrate on the validations you have got to write up first get those out of the way first and if you have any time left then get back in touch, should there be any	WFH to get Quality work done for accreditation = staff member out of lab? Pressure on rest of team. During covid made lab more quality focused – but more documents.

time left so it's quite useful in that respect being able to go backwards and forwards with what's most important, yeah we do when its time at home we are able to say yes actually the quality is really important At the risk of being shot and creating more work here could we do a reactive audit to show our TAT on quality documents since we started WFH / Covid we are getting them through quicker? Would that be helpful just to show that the change really benefitted. Would you need to look at it over the period of time when the transplant programme was started again though? For the solid organ? Workload still there but decreasing, to do a fair comparison would have to look at it over time. **Moderator - Let's go back now to focus group discussion. Does anyone think accreditation has improved our systems?** Our systems in general? Or our TATs **Any part or no part?** I think so, very specific thing one random thing that springs to mind. I think we were doing what we were doing in terms of monitoring quality of the NGS already but certainly weren't doing it in quite such a focused way and I think since doing in a focused way following recommendations we had from the inspection we do it in a much more efficient way and it is recorded and we can look at it and we can go back over the last however much data we've looked at and I think I don't know whether SJJ or PW who've worked in the team whether you were there when they were recommending these and they we knew and we adopted practices at that time that have then helped us now and it's just quite efficient and I would argue that that has been a bonus, erm yeah. Yeah, completely agree, it's just part and parcel of it now, like you say capturing that quality of the data bit that we needed to do at the time, it's no hardship I can't see how it's not improved. **So, what about TATs and RRs and the monitoring within your teams more regularly has helped?**	Part of normal work now Positive - Importance of monitoring NC / recommendations = improves systems

Yes, I think so! Yes, and it's like MT02 says it's about putting in tangible evidence in an organised manner because not that we would, but it stops you from slipping into bad habits, doesn't it? I mean even if we're not improving our TATs or having mass improvement it is stopping us from declining, but we are all very professional and that wouldn't happen but has a principal CS it's quite important to acknowledge that. I think now while we are all working as well, we tend to be been doing a lot more team work and cross cover things like the quality metrics for the NGS as a result of the recommendations we were given are all clearly laid out if you are working in that way it is very easy to come to it and see what you need to complete and double check, that's been really helpful as well. The same with the other techniques as well. I would say also what I have seen is it is easier to incorporate the quality standards for something like NGS, a new technique that the standards are already existing when we brought it in to make sure it complies as part of the whole flow rather than to try to retrofit some of the existing techniques that have been around for ages like SSO, we still don't comply with some of the things like batch testing every delivery. We do, there is a process in place for that now. We thought we would get pulled about it at the next thing. So basically, as a result of what Anna and the team did with NGS, MT012 has modelled the SSO batch delivery on that, so we have learnt from that system that's gone on learning from recommendations - expand to other lab processes. Yeah, but what I'm saying I think it's easier to design a flow from scratch for a new technique than to retrofit updated standards into existing processes. I think sometimes because a process already exists its quite hard to go okay...how can we, short of changing, sometimes you have to change an entire process to fit it in and comply in an easy efficient way and I think that is easier with something like NGS and probably you know when we bring in Histospot or whatever else it will be designed to comply from the beginning and I think sometimes every time they update the standard and we are trying to do something to something that is already there it's maybe more, clunky is maybe the way I want to put it. I think that's the good thing the standards seem to stay stagnant for a good while, this have been around since 2012 so not much change, they are in the process of reviewing these not knowing what	Importance of validation of new processes before implementation - required in-depth doc for ETS. Standards Lab Improvement

the changes will be. This is the problem, people in EUROPE have been working within these standards for a while and know where they need improvement, in UK still catching up not everyone yet ISO accredited.	Standards
Can I just say one of the things I like about ISO is the one that causes everyone the biggest grief, they have asked to do things we probably wouldn't have done otherwise so I quite like the uncertainty measurement in all our testing. I think it's good to know the parameters of the assays and limits of detection and all the rest of it. Another thing they asked us to do one time that we'd just never done in all these years was to check the same results on the Luminex LABScan 3Ds. They asked us to put the same test through didn't they and did we get the same result out of each machine (laughing) that we had in department and of course we didn't, and we never had thought to look but those things really are quite important aren't they?	Accreditation - positives
Conversation stopped.	
Yes, I think we are made to think, like you say it's an obvious thing now you think about it but at the time it wasn't something we thought to do, on hindsight for the future it will be one of the first things you will do as part of the introduction and development!	Learning / Education
I think the audits are good that we do, because people who aren't necessarily involved in something can audit something can end up coming up with really good suggestions. I think it's useful for that as well.	Education and training - understand standards.
I agree coz you know your own processes really well and you can often not see what's missing coz you know it so well.	
Yes	
Your kind of almost gloss over the process because it's very clear to you don't see almost the obvious that's in front of you.	
I think the way we've done the quality audits have been really useful as well because working your way through the process and checking what is the evidence and where things are it really does help I	

still it in your head a lot better than just reading the standards and say yeah, we need that, so I think it is really useful for that work to be split up between the team.	Peer assessor - benefits
Well that actually goes back to the benefit of not having an **assessor** who is not H&I based as well to bring in their ideas.	
Yep,	
It kind of works both ways.	
Everyone nods in agreement. Non-verbal	Peer assessor - benefits
You have to take the rough with the smooth with an **assessor** they might not know the ins and outs of an H&I technique, but they might bring your ideas like that so.	
Yes,	
Nods of agreement Non-verbal	
Conversation stopped.	
Moderator -Try to bring conversation to financial impact. What is everyone's thoughts of cost of accreditation?	Cost
Costs too much, it's shocking...you know my opinion on it, so I won't say anything else (laughing)	
It's a bit of a money-making racket, for instance when Barts merged trust to change of name of organisation every lab had to pay fee. Why not charge one fee for MFT not all labs. Barts put all pathology labs through on one scope which meant all labs got inspected in same week coz on same scope of practice thing...it was absolute hell utter hell but that's the way they did it to try to save cut cost coz they could afford to pay that much money for all of these different labs. So cost is prohibitive and detrimental to what's good for the labs and these services so one lab who worked hard to comply could get accredited until the lowest denominator complied which was years later. Yeah, so too much.	UKAS money making
As someone not directly involved with the costs from it just seems like there should be one all-inclusive cost that covers the basic, I mean I don't understand why they are charging you for	Costs

accreditation and then charging you for looking at the rules of accreditation surely by paying for your accreditation you should be allowed to you know be given the handbook about what you should be following it seems common sense these general things should be built within the base price and they shouldn't charging extra for these small amendments.	
We have to pay for every ETS so that's why because we will be implementing a number of new techniques the flexible scope seems a good idea and I will be comparing costs.	Expense
Who can you complain to about that and so is there anybody who you can complain to about UKAS to say it's **too expensive**?	**compulsory accreditation**
It is something we are required to do.	
Surely there is an organisation you can write to say you know to say everyone here as a complaint about the **cost** and so on is there anybody out there who you can write to its **extortionate**. Can we have a breakdown of the costs?	Expensive
A media investigation is what we need.	
Laughter nonverbal	
It needs a Panorama programme about it.	
Nods and smiles in agreement nonverbal	
There is **absolutely no accountability**, there is no breakdown of where the money goes, it's just scandalous.	UKAS accountability
It's just an extra cost to the public sector **at a time when the money is not coming in anyway.**	financial constraints on lab
Could we not get Dominic Woods, he's your man (**laughing**)?	
Ripe off Britain	
Laughter nonverbal	

Moderator - Bring to an end one last question. I have explained about FS, does anyone have any questions that they want to ask me about it. Think about what the impact and pressures might be, we may need to speed up the timeframes for writing up audit and validations. May need to be shortened timeframes we have at the minute and as managers we have to manage that. What are your expectations? I want to try and measure and manage these and meet them if possible. Do you think the FS will benefit us? Will it impact on the junior members of the team? Use the survey to try to understand expectations so we can manage them. Understand the managers to help develop survey. With the changes in H&I particularly with the typing techniques in NGS and platforms we can use, this will mean that we can implement things more quickly if we want to change something? Yes And also What we do our current approach with regards to ETS we implement before it has been signed off and so we can't use the UKAS logo - not accredited to use so need to change our reports to reflect this. Flexible scope will help with this. So, if we got this flexible scope, it would save us money as we won't need to keep applying for ETS? Theoretical yes and that's what I will be trying to measure as part of the project, looking at how much we have paid out in previous years and look at the costs of our ETS over the year longitudinal Would just be of benefit to this lab coz all other labs in hospital have to be UKAS accredited and if we achieve that will benefit the hospital coz it would fit in with the **money saving money exercise,** if flexible scope could be rolled out it would save the trust a lot of money, wouldn't it? Nodded **nonverbal** Nodded **nonverbal**	Symbol / Logo **Flexible scope** Money saving Money saving to NHS if all labs FS

Nodded **nonverbal** **Conversation stopped.** **Moderator explained - in Europe labs all Flexible scope and was encouraged by EA, UKAS seem to be resistant but may since COVID people have had to change systems and processes quickly, more and more people may want to move to flexible scope, but whether again it will improve or it will change anything is another thing, no body to say whether, people just implement accreditation where is the evidence?** Probably the improvement will be not able to quantify it will be improvement in responsiveness and innovation and be able to improve a patient's services and provide the best service we can without going you know what we got to wait six months until they come in or check the paperwork before we can do this. How do you quantify this I don't know that's your job Ha. but that's where the improvement will be? **Moderator** – I want to quantify this by looking at the impact on the staff? So, (addressing the interviewer), my comment there would be that the senior technologists are really good at looking at new techniques, well certainly what we've seen of them and suggesting change and they may feel very valued with the flexible scope because whatever they do suggest we may be able to implement without saying to them that we can't do that, or we can't do this. So that might improve the relationship as well. Don't forget to measure, capture the impact on the QM, no I am being serious as you take the brunt of getting the extension to scope and whatever else so somehow without being biased you somehow need to quantify how much work you were having to do before and actually will that change improve for you, you're not having to worry about what's change. it's alright coz we still have to record all that stuff and still have to have the momentum changes and what have you but will actually will that lessen your burden to some extent as well and you will have to capture that in there., we can do it for you if you need someone on the external. **Moderator** - That's right and something I hadn't considered and is probably an important thing to consider, the impact on me...but it's not all about me but yeah, your right it does have an impact and	Innovation / patient service - focus / service quality Staff impact Staff involvement Positive impact on change. Can be implemented and seen quicker with Flexible scope. Reflexivity of researcher - Look at impact on QM.

does take its toll the day after the inspection...the week after the inspection or rather for 6 weeks when we have to submit our improvement actions. You could use your smart watch to measure your heart rate??? Laughing I don't wear it for the inspection as it would flat line - **Laughing.** I think millilitres of gin would be a good measure **laughing** consumed before and after **Laughing and nodding** **Coming to an end.... any final comments?** Yes just to say I think by being more responsive as a department it will allow us to provide more responsibility to individual members of staff and involve them more and be more responsive to feedback from our staff so in that way **I think morale would increase**, there might be workload but by being able to implement suggestions faster for example if a cheaper kit came along or something like that I think generally it would be difficult coz sometimes things aren't necessarily constant metrics that can be measured maybe it's just like peaks and troughs but I think there will be a time when that's really useful and that will be a great asset to the department. **Anybody else would like to comment, ask a question about anything we've discussed today?** I would like to comment from another point of view the thing that annoys me about UKAS accreditation is that while when we do need to change and when we are in the process of changing things we can submit all our data to UKAS and then they tell us we are no longer accredited to do that technique until they have reviewed everything and it can take them over a year and in all that time we are not allowed to use the UKAS logo on our reports or to say that we are accredited for that technique and **I feel that the amount of money that we pay they should be quicker and they should be more responsive and they should not be the one holding us to account there we should be accredited and they should have to hurry up with our evaluation of our ETS.** I think that's the thing that makes me cross, in all the time that we be been accredited I honestly think there has been half the time particularly for NGS where we haven't been able to use the logo for the technically coz, they	increase morale. UKAS - Impact on innovation – delays

have been busy evaluating everything. Yeah, I think quality organisation.... So, I don't know how we can measure that? Do they produce their own TATs? **Laughing** Yes, they do because BSHI submitted a **complaint** because of this and they audited as a result and upheld our complaint and found they were not achieving their expected TATs for getting the documents for processing the documents after an inspection, so not sure if I sent you that, but I can send the letter on to you if that's helpful? **Moderator -**This could be looked at from the time it's taken from when we applied for ETS to when we get it back. I can check online for the TAT; It's meant to be 3 months? Yeah, it's a big fib **laughing.** Hopefully when we move to Flexible scope, we won't have to worry about it. **Nods in agreement** **That's if they let us (UKAS), they've been looking at it for the last 12 months (laughing) Will UKAS allow us to have a flexible scope if it saves us money?? Only allows those in 2nd cycle therefore perhaps all new changes are done in first cycle and so won't be an impact on money spent with UKAS??** I just feel if I am paying thousands of pounds to say that my departments good and its accredited, I feel I should be allowed to use their logo. I understand there is going to be this change over period but all that time I am still paying it out it's not like we get a discount for not being accredited all that time and yet I am not allowed to use the logo. I think that that's one of my bug-bares with it.	Monitoring UKAS?? BSHI complaint Costs

Your right that once your accredited and they've assessed and proven your systems and process are fine you should then be able to use that. I think it's because, being devil's advocate when you introduce something new they've not seen how its fitted into our infrastructure but with a flexible scope they should understand our infrastructure and how we do things and therefore we have to take some responsibility and we've followed our own guidelines sufficiently enough to implement something correctly and fairly, we still have to send them the documents to review but we won't have that time lag where we can't send our reports out with the logo on I think I wouldn't mind if we got a discount for the days, we weren't accredited and weren't able to use the logo, might make them move a bit quicker (laughs) I don't think they will give us a discount (**laughing)** No, I don't... They should get penalties. **END** **Moderator asked – if group would pilot the questionnaire once developed**	Costs / delays by UKAS Symbol

Appendix 14 Staff Questionnaire Questions

Question 1. In your opinion how much do you agree or disagree with the following statements?

- Accreditation is a valuable management tool
- Accreditation has no significant effect on my day-to-day duties
- Accreditation has no significant impact on my day-to-day workloads
- My involvement in accreditation is minimal
- I understand the principles of accreditation

Question 2. In your opinion do you agree or disagree with the statement that the current system of ISO accreditation has improved the following -

- The overall service we provide
- The laboratory Turn around Times
- The number of errors that occur in the laboratory
- The laboratory's focus on patients' safety
- The ability to improve laboratory services by introducing new processes.

Question 3. Do you agree or disagree that the current system of ISO accreditation is?

- Important
- Informative
- Essential
- Expensive
- Improves quality
- Labour intensive
- Patient focused
- Value for money

A 4-point Likert scale (completely agree; agree, disagree; completely disagree) was used to collect the responses. Using the summating rating scale allows for a systematic approach to ensure internal consistency. This 4-point approach was chosen instead of the traditional 5 point to remove the option for a respondent to be undecided to a question and to get a true reflection of the respondents' opinions.

Question 4 and 5 was designed to obtain demographics of the population responding -

Question 4: What is your current Agenda for Change (AfC) grade?

- Band8+
- Band 6& 7
- Band 3 - 5

Question 5: How long have you worked in the Transplantation Laboratory?

- Less than 1 year
- 2 - 5 years
- 5 - 10 years
- + 10 years

Question 6: Have you ever been directly involved in the accreditation process?

- Yes
- No

With question 6 details of the respondents' involvement were requested using a free text box.

Appendix 15 Focus Group Interview Schedule and Topic Guide – 03/12/2021

Introduction - housekeeping (microphones off, hands up to speak, don't talk over people, please don't talk for too long give others a chance to say something so few of us and I will stop and move on to others) to prompt you. (Only 1 hour)
You have been asked to join the focus group as you completed the survey a few months ago Should last no more than 60 mins, recorded, notes taken (by Paula – University supervisor)

Aim is not to repeat the survey to gather some further details to the survey results to understand why and what people's experience of accreditation is.
I would like to understand everyone's perspective of the **'old accreditation system'** there is no right or wrong answer, just your experiences and perceptions. Both neg and Pos comments are important to the study.
I would appreciate you really being descriptive in your answers, I'm particularly interested in exploring whether accreditation makes a difference to service quality, lab efficiency and cost, and in turn patient care so this will primarily be the focus.

Questions

1. 96.4% of lab staff thought accreditation was a valuable management tool? why do you think accreditation is valuable?
    - Does it increase quality?
    - Does it make a lab more effective and reliable?
    - Does it save money?
    - Does it make you more careful and safer practice?
    - Does it make it easier to introduce new processes?
    - is it just for management?
2. A majority (57%) of staff felt the ISO accreditation had improved the laboratory focus on patient safety - in what way has this improved, what difference has it made? Others felt the current process stifled the ability to introduce new processes - can anyone expand on this perspective?
3. Many lab staff felt the current accreditation system (which is XXX explain what this is) improved the overall laboratory service - in what way can you give me any examples? (Quality, effectiveness, cost)
4. How does accreditation impact on your workload? Can you give me examples of what extra tasks you do, paperwork, time needed to complete them etc?
5. Some responses to the survey suggested it was labour intensive - can you give me examples of what this means?
6. The accreditation was considered expensive and value for money by most staff - why is it expensive, what is the biggest cost and why?
7. There was consensus in the survey that the accreditation process was essential (85%) informative (64%) why is it essential? What information has it provided?
8. Is there anything you feel you need to add re accreditation.?

Use pauses and probes.
Can you explain further?
Can you give examples?
I don't understand.

Summary and close
Thank you so much, interesting feedback.

I will be gathering your opinions on the Flexible scope when agreed by UKAS as the second part of my study and I hope you will continue to be involved as this is novel as it is the first study of its type to measure the impact of accreditation in laboratories in the UK and the implementation of a flexible scope.

Thanks for contributing.

Appendix 16 Risk Assessment Form

ALL projects MUST include a risk assessment. If this summary assessment of the risk proves insignificant, i.e. you answer 'no' to all of the questions, then no further action is necessary. However, if you identify any risks then you must identify the precautions you will put in place to control these.

1. What is the title of the project?

Evaluating the Implementation of a Flexible Scope of accreditation in an NHS Laboratory: A single centre longitudinal study

2. Is the project purely literature based? **NO**

If YES, please go to the bottom of the assessment and sign where indicated. If NO, then please complete section 3 and list your proposed controls.

3. Please highlight the risk(s) which applies to your study:

Hazards	**Risks**	**If yes, consider what precautions will be taken to minimise risk and discuss with your supervisor**
Use of ionising or non-ionising radiation	Exposure to radiation **NO**	Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.
Use of hazardous substances	Exposure to harmful substances **NO**	Obtain copy of existing risk assessment from place of research and attach a copy to this risk assessment summary.
Use of face-to-face interviews Interviewees could be upset by interview and become aggressive or violent toward researcher	Interviewing … Own classmates= Low risk **NO** Other University students=Medium risk **NO** Non-University personnel=High risk **YES** **Work Colleagues**	**NB:** Greater precautions are required for medium & high-risk activities. **Consider:** • How contact with participants will be made - i.e. do not give out personal mobile number, home number or home email, etc. • Location of interviews – to be held in a safe environment, e.g. University building, workplace. • What support will be available, i.e. will anyone else be available to assist if you call for help, etc. e.g. a colleague knows where the interview is to take place and will be contacted when completed and safe – and what action to take after a certain time if not contacted?

		• How to deal with aggressive/violent behaviour, what precautions will be taken to prevent this from happening?
Use of face-to-face interviews Participants or interviewees could become upset by interview and suffer psychological effects.	**YES**	**Consider:** • What initial and subsequent support will be made available for participants or interviewees? • What to do if researcher uncovers information regarding an illegal act? • What/who will be used to counsel distressed participants/interviewees, and what precautions will be taken to prevent this from happening?
Sensitive data	Exposure to data or information which may cause. upset or distress to the researcher. **NO**	**Consider:** • What initial and subsequent support will be available to the researcher
Physical activity	Exposure to levels of exertion unsuitable for an individual's level of fitness **NO**	**Consider:** • Health Questionnaire/ Medical declaration form / GP clearance. • Trained First Aid personnel/ Equipment.
Equipment	Exposure to faulty or unfamiliar equipment. **NO**	**Consider**: • Equipment is regularly checked and maintained as per manufacturer's instructions. • Operators receive adequate training in the use of. • Participants receive induction training prior to use.
Sensitive issues i.e. Gender/Cultural e.g. when observing or dealing with undressed members of the opposite sex	Exposure to vulnerable situations/ sensitive issues that may cause distress to interviewer or interviewee. **NO**	**Consider:** • Use of chaperones/translators. • What initial and subsequent support will be made available for participants or interviewees?
Children	**NO**	• Adhere to local guidelines and take advice from research supervisor.

Manual handling activities	Exposure to an activity that could result in injury. **NO**	• Adapt the task to reduce or eliminate risk from manual handling activities. Ensure that participants understand and are capable of the manual handling task beforehand. • Perform health questionnaire to determine participant fitness prior to recruitment.

If you have answered 'YES' to any of the hazards in section 3, then please list the proposed precautions below:

Low Risk - Focus group using work colleagues.

Focus groups split into different teams to encourage free speech (senior laboratory management will attend different groups)
All participants in each group will be asked to keep the information shared and attendees in the focus group confidential.
All participants will be coded.
Meeting scheduled to accommodate 6 – 8 staff (social distancing rules apply – see MFT Risk assessment).
Conducted in a seminar room on site in MFT within the department that has been risk assessed and classified as COVID secure to accommodate 14 people safely (see MFT Risk assessment)
Contact made to participants via email or through routine internal meetings.
Not anticipating uncovering illegal acts or distressed participants; may have emotive responses to topic, no personal information needed.
Conflict resolution in house training for researcher
UoS supervisor to act as assistant moderator.
Groups meetings are still currently held in the laboratory following COVID guidelines and the focus groups will mirror these guidelines or take place through Microsoft TEAMS if preferred by participants or they are shielding / under lock down or working from home. (See MFT Risk Assessment).
COVID symptom assessment prior to group; MFT Test and Trace will be followed as required.
Impact of researcher's role – anticipated that those who volunteer for the Focus groups will be those who will provide direct observations and not feel intimidated by researcher's role / survey will be anonymous. The research project is of an external body / process and affects the whole department – is independent of my role.

Signature of student Julie Johnson Date 03/10/2020

Signature of Supervisor Prof Paula Ormandy Date 03/10/2020

Appendix 17 MFT Covid-19 Risk Assessment

MCS / Hospital:	[redacted]	***Risk Assessor:***	*Julie Johnson*
Directorate:	[redacted]	***Assessment Date:***	*14/09/2020*
Department:	[redacted]	***Review Date:***	*14/09/2020*
Description of service activities:	*Face to Face Focus Groups for PDoc study*	***Accepted by (Risk Owner):***	*Professor Kay Poulton*

Risk Ref.	***Type of Hazard(s)***	***Risk Description*** *If (what could happen) occurred, then this would/could result in (the impact/potential impact)*	***Existing Controls and Precautions*** *If the existing controls do not reduce the risk, so far as is reasonably practicable, detail action(s) to be taken in action log on last page.*	***Current Risk Score**** *[Risk Matrix]*			***Risk adequately controlled and accepted? *****	
				S	***L***	***R***	***Yes***	***No***
	Infection Control	*Risk of transmission of Coronavirus between staff during study's face to face focus group and meetings.*	• *The various HR, Health & Wellbeing and IPC protective measures already enacted for all Trust employees – screening, attendance management, testing etc.* • *The seminar room is well ventilated for the session with sufficient space to allow social distancing for participants. Limit numbers of participants according to space available. (6 – 8 the room will facilitate 14 according to MFT COVID Secure risk assessment)* • *Focus groups are set in bubbles of onsite staff that already work closely together (Laboratory Managers / Technical and scientific teams).* • *X has introduced Test and Trace protocol which will be followed as required.* • *Assess for COVID-19 symptoms – temperature, new continuous cough, loss of taste/smell – prior to each session, exclude any participants with symptoms (Set up attendance via Microsoft Teams).* • *Do not provide refreshments.*	***4***	*1*	*4*	*Y*	

			• *Provide hand washing facilities and/or hand gel for all sessions.* • *Use disinfectant to wipe down any surfaces etc. before each session, before and after each use.* • *Arrange room layout to achieve social distancing (6 to 8 per group)* • *All participants have MFT face masks and may wear these or visors during the focus group if they wish (not necessarily due to COVID secure risk measures in place).*					

Risk Assessment Action Log

– to be completed where additional controls are required to adequately manage the risk

Ref.	***Hazard(s) and Risk Description***	***Actions - Additional Control Required***	***Responsible Person***	***Target Date (mm/yyyy)***	***Completed Date (mm/yyyy)***	***Risk Adequately controlled?***		***Residual Risk Score* [Risk Matrix]***		
						Yes	***No***	***S***	***L***	***R***

Appendix 18 Overview of Staff Questionnaire Outcome

Responses

Responses (Total 28 / 45)	Total No. lab staff (45)	No. responses (28)	% overall responses to survey	% responses to survey
Laboratory Management Team	16	14	88%	**50.0%**
Clinical scientist /Technical / Admin Team	29	14	48%	**50.0%**

Outcome

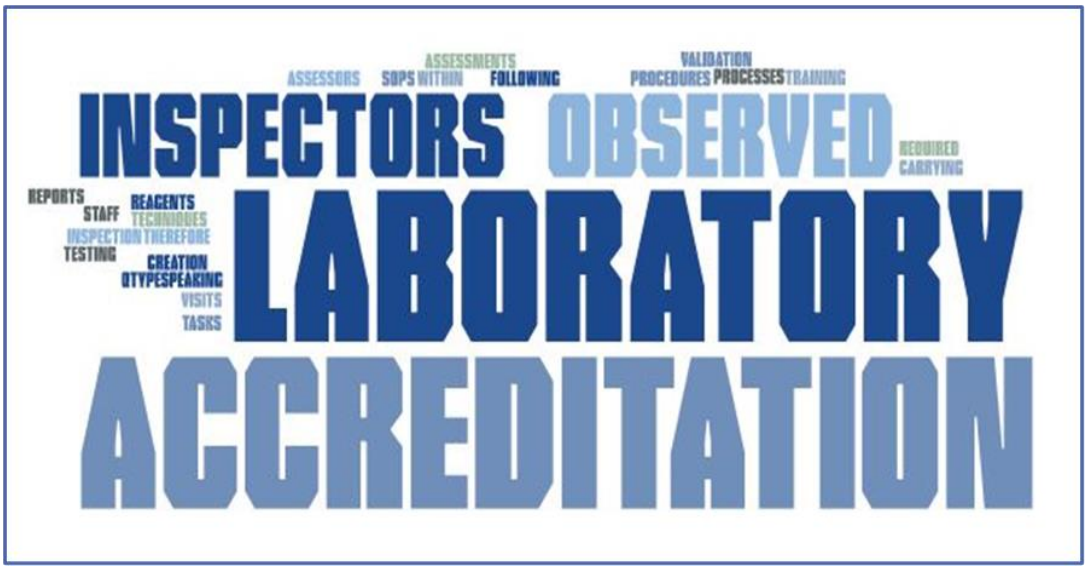
	4 point Likert scale				Summary Statistics		
Question 1. In your opinion how much do you agree or disagree with the following?	Completely agree (Rank value = 1)	agree (Rank value = 2)	Disagree (Rank value = 3)	Completely disagree (Rank value = 4)	Mean Rank	Variance	Standard Deviation
1.1 Accreditation is a valuable management tool	14	13	0	1	1.57	0.46	0.68
1.2 Accreditation has no significant effect on my day to day duties	0	2	8	18	3.21	0.31	0.56
1.3 Accreditation has no significant impact on my day to day workloads	0	4	19	5	3.04	0.32	0.57
1.4 My involvement in accreditation is minimal	0	9	16	2	2.74	0.34	0.58
1.5 I understand the principles of accreditation	11	17	0	0	1.61	0.24	0.49
Question 2: In your opinion do you agree or disagree with the statement that the current system of ISO acceditation has improved the following -							
2.1 The overall service we provide	6	20	2	0	1.86	0.27	0.52
2.2 Turn around Times	1	7	19	1	2.71	0.35	0.59
2.3 The number of errors that occur	0	19	8	1	2.36	0.3	0.55
2.4 The laboratory's focus on patients safety	3	13	10	2	2.39	0.6	0.77
2.5 The ability to introduce new processes	3	11	14	0	2.39	0.45	0.67
2.6 The overall laboratory service quality	6	20	1	1	1.89	0.38	0.62
Question 3: Do you agree or disagree that the current system of ISO accreditation is -							
3.1 Important	11	16	1	0	1.68	0.43	0.66
3.2 Informative	0	18	9	1	2.39	0.31	0.56
3.3 Essential	9	15	3	1	1.86	0.55	0.74
3.4 Expensive	20	6	2	0	1.36	0.37	0.61
3.5 Improves quality	8	15	4	1	1.93	0.57	0.75
3.6 Labour intensive	15	13	0	0	1.46	0.25	0.5
3.7 Patient focused	0	12	13	3	2.68	0.43	0.66
3.8 Value for money	1	3	16	8	3.11	0.52	0.72

Question 1. In your opinion how much do you agree or disagree with the following statements?		MT (N=14)		CSST (N=14)			
		Band 8+		Bands 6 - 7 (N=9)		Bands 3 - 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q1.1	Accreditation is a valuable management tool	14	0	8	1	5	0
Q1.2	Accreditation has no significant effect on my day to day duties	0	14	6	3	0	5
Q1.3	Accreditation has no significant impact on my day to day workloads	1	13	2	7	1	4
Q1.4	My involvement in accreditation is minimal	0	13	5	4	4	1
Q1.5	I understand the principles of accreditation	14	0	9	0	5	0

Question 2. In your opinion do you agree or disagree with the statement that the current system of ISO accreditation has improved the following -		MT (N=14)		CSST (N=14)			
		Band 8+		Bands 6 - 7 (N=9)		Bands 3 - 5 (N-5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q2.1	The overall service we provide	13	1	8	1	5	0
Q2.2	The laboratory Turn around Times	2	12	2	7	0	5
Q2.3	The number of errors that occur in the laboratory	9	5	6	3	1	4
Q2.4	The laboratory's focus on patients safety	9	5	3	6	4	1
Q2.5	The ability to improve laboratory services by introducing new processes	6	8	3	6	5	0
Q2.6	The overall laboratory service quality	13	1	8	1	5	0

Question 3. Do you agree or disagree that the current system of ISO accreditation is -		MT (N=14)		CSST (N=14)			
		Band 8+		Bands 6 - 7 (N=9)		Bands 3 - 5 (N=5)	
		Agree	Disagree	Agree	Disagree	Agree	Disagree
Q3.1	Important	14	0	8	1	5	0
Q3.2	Informative	10	4	4	5	4	1
Q3.3	Essential	11	3	8	0	5	0
Q3.4	Expensive	14	0	9	0	3	2
Q3.5	Improves quality	11	3	6	3	5	0
Q3.6	Labour intensive	14	0	9	0	5	0
Q3.7	Patient focused	4	10	4	5	4	1
Q3.8	Value for money	1	13	1	8	2	3

Q6 Responses of Clinical Scientists and Scientist Team Involvement



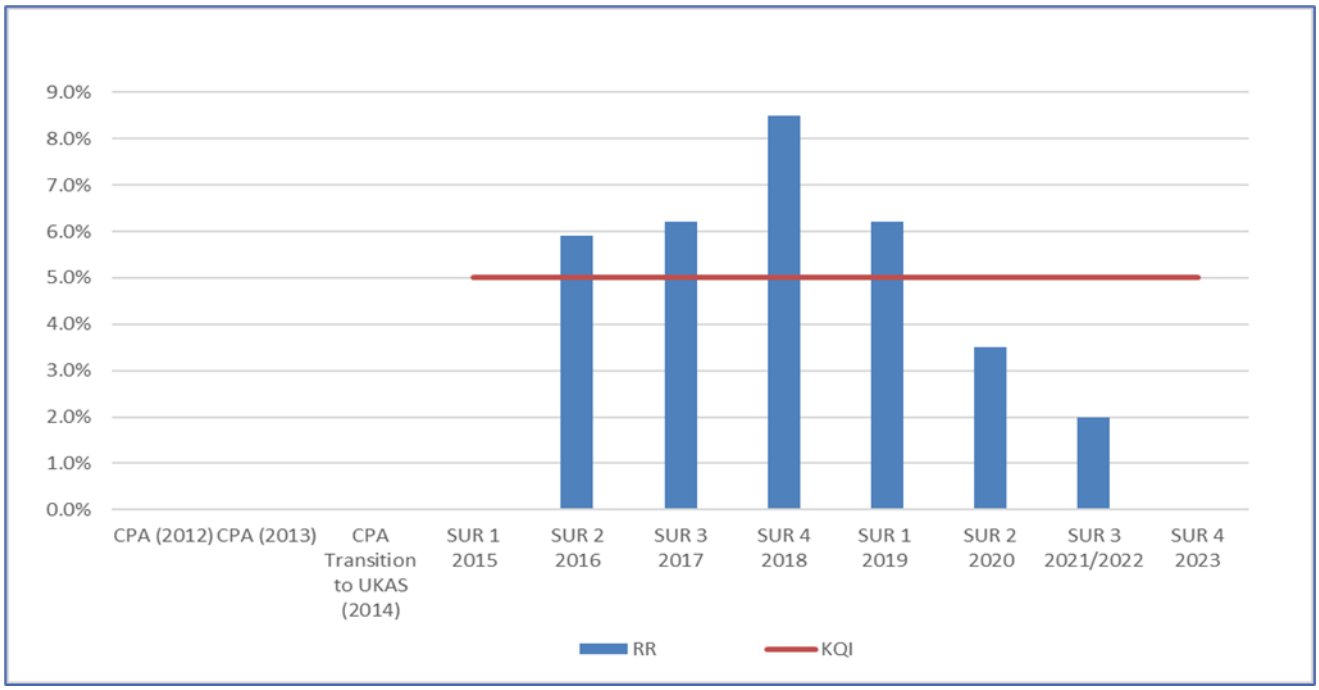
Q 6 Responses of Management Team Involvement

Appendix 19 Impact of ISO Accreditation on Key Concepts - Quality

Repeat Rates

Annual Mean Repeat Rates (RR) Following the Transition to ISO Accreditation for all critical process included in the study.

(Yearly average)	RR	KQI
CPA (2012)		
CPA (2013)		
CPA Transition to UKAS (2014)		
SUR 1 2015	0.0%	5%
SUR 2 2016	5.9%	5%
SUR 3 2017	6.2%	5%
SUR 4 2018	8.5%	5%
SUR 1 2019	6.2%	5%
SUR 2 2020	3.5%	5%
SUR 3 2021/2022	2.0%	5%
SUR 4 2023		5%



The KQI for the laboratory RRs is set at 5%, the mean results for the RRs have consistently been above the 5% threshold until 2020 when it dipped below the threshold for the first time. The data for RRs unlike TATs could not be expanded further to include any data pre-2015 because monitoring RR was only introduced as part of the implementation of the ISO 15189:2012 standards in 2015.

HLA Typing Repeat Rates

Pearson Correlation Coefficient, the coefficient of determination and total variation for HLA PCR-SSP

PCR SSP	r	r2	%
2015-2016	0.095	0.009	9
2016-2017	0.061	0.0037	0.37
2017-2018	0.111	0.0123	1.23
2018-2019	0.231	0.0534	5.34
2019-2020			
2020-2021			
2021-2022			

The coefficient of determination (R^2) was calculated from the linear charts using Microsoft Excel (Figure 9) for the study period from April 2015 to March 2019 **R^2 = 0.083** highlighting that 8.3% of the total variation in PCR-SSP repeat rates can be accounted for by the variation in annual accreditation.

The Pearson Correlation co-efficiency was calculated for the study period **r = 0.288** which demonstrates that the strength of the linear relationship is weak between PCR-SSP repeat rates and annual accreditation. Graphically a continuing increase in repeat rates over the study period can be observed (Figure 9) with a statistical significance of **P=0.05** (Appendix 24) which is sufficient to reject the Null hypothesis.

PEARSON CORRELATION COEFFICIENT, THE COEFFICIENT OF DETERMINATION AND TOTAL VARIATION FOR HLA PCR-SSO

PCR-SSO	r	r2	%
2015-2016	0.337	0.1138	11.38
2016-2017	0.512	0.2625	26.25
2017-2018	0.877	0.7685	76.85
2018-2019	0.367	0.135	13.5
2019-2020	0.521	0.2723	27.23
2020-2021	0.488	0.2383	23.83
2021-2022	0.736	0.5412	54.12

The Coefficient of Determination (R^2) for the study period (Figure 15) was calculated using Microsoft Excel as **R^2 = 0.036** highlighting again that 3.6% of the total variation in PCR-SSO repeat rates can be accounted for by the variation in annual accreditation.

The Pearson Correlation co-efficiency was calculated for the study period **r = -0.189** which demonstrates that the strength of the linear relationship is very weak between PCR-SSO repeat rates and annual accreditation. Graphically it depicts a decrease in

PCR-SSO repeat rates over the years of accreditation shown as a negative correlation (Figure 10) with a statistical significance of **P=0.08** (Appendix 21) which is insufficient to reject the Null hypothesis.

Pearson Correlation Coefficient, the coefficient of determination and total variation for RT-PCR by LinkSeq

RT-PCR	r	r2	%
2017-2018	0.6	0.3599	35.99
2018-2019	0.618	0.3814	38.14
2019-2020	0.389	0.1512	15.12
2020-2021	0.233	0.0545	5.45
2021-2022	0.462	0.2137	21.37

The Coefficient of Determination for the study period (Figure 11) was **R^2 = 0.0804** indicating that 8.0% of the total variation of RT-PCR repeat rates can be accounted for by the variation in annual accreditation.

The Pearson Correlation co-efficiency was calculated **r = -0.284** for the study period and again demonstrates that the strength of the linear relationship is very weak between RT-PCR repeat rates and annual accreditation. Graphically it depicts a decrease in RT-PCR repeat rates over the years of accreditation with a negative correlation (Figure 16) with a statistical significance of **P=0.03** (Appendix 24) which is also sufficient to reject the Null hypothesis.

Pearson Correlation Coefficient, the coefficient of determination and total variation for SBT

SBT	r	r2	%
2015-2016	0.134	0.018	1.8
2016-2017	0.174	0.0303	3.03
2017-2018	0.306	0.0938	9.38
2018-2019			
2019-2020			
2020-2021			
2021-2022			

The Coefficient of Determination for the study period (Figure 12) was calculated using Microsoft Excel **R^2 = 0.0013** highlighting that only 0.13% of the total variation in SBT repeat rates can be accounted for by the variation in annual accreditation.

The Pearson Correlation co-efficiency for the study period was calculated **r = -0.036** which demonstrates the strength of the linear relationship between SBT, and accreditation is also weak. Graphically it depicts almost a non-linear relationship between SBT typing and annual accreditation (Figure 17) with a statistical significance of **P=0.83** (Appendix 21) which is insufficient to reject the Null hypothesis.

Pearson Correlation Coefficient, the coefficient of determination and total variation for NGS

NGS	r	r2	%
2017-2018	0.137	0.0188	1.88
2018-2019	0.209	0.044	4.4
2019-2020	0.324	0.105	10.5
2020-2021	0.396	0.1574	15.74
2021-2022	0.152	0.023	2.3

The Pearson Correlation co-efficiency was calculated using Microsoft Excel for the study period **r = -0.239** which again demonstrates that the strength of the linear relationship is very weak. Graphically this depicts a decrease in NGS repeat rates over the years of accreditation (Figure 13).

The average coefficient of determination for the study period (Figure 13) was **R^2 = 0.0573** highlighting that 5.7% of the total variation in NGS repeat rates can be accounted for by the variation in annual accreditation with a statistical significance of **P=0.078** (Appendix 24) which is insufficient to reject the Null hypothesis.

Pearson Correlation Coefficient, the coefficient of determination and total variation for IgGM Antibody screening

Detection	r	r2	%
2015-2016	0.042	0.0018	0.18
2016-2017	0	0	0
2017-2018	0.744	0.0553	5.53
2018-2019	0.078	0.0061	0.61
2019-2020	0.322	0.1039	10.39
2020-2021	0.487	0.237	23.7
2021-2022	0.043	0.0003	0.19

The Coefficient of Determination for the study period was calculated using Microsoft Excel **R^2 = 0.0004** indicating that 0.04% of the total variation in the repeat rates for

antibody detection can be accounted for by the variation in annual accreditation (Figure 14).

The Pearson Correlation co-efficiency for the study period was **r = 0.02** demonstrating that the strength of the linear relationship is weak with a statistical significance of **P=0.864** (Appendix 24).

Pearson Correlation Coefficient, the coefficient of determination and total variation for IgGM Antibody specificity screening

Definition	*r*	*r2*	*%*
2015-2016	*0.257*	*0.0662*	*6.62*
2016-2017	*0.148*	*0.0219*	*2.19*
2017-2018	*0*	*0*	*0*
2018-2019	*0*	*0*	*0*
2019-2020	*0.593*	*0.3518*	*35.18*
2020-2021	*0.044*	*0.0019*	*0.19*
2021-2022	*0.066*	*0.0044*	*0.44*

The Coefficient of Determination was calculated for the study period using Microsoft Excel and was $\mathbf{R^2 = 0.0004}$ highlighting that 0.04% of the total variation in repeat rate for antibody definition can be accounted for by the variation in annual accreditation (Figure 15).

The Pearson Correlation co-efficiency calculated for the study period was **r = 0.02** demonstrating that the strength of the linear relationship is again weak with a statistical significance of **P=0.865** (Appendix 24).

Graphically both figure 14 and 15 depicted an almost non-linear relationship between HLA antibody detection and definition repeat rates and annual accreditation. The P values for both detection and definition signify insufficient evidence to reject the null hypothesis.

Annual averages of Pearson Correlation Coefficient, the coefficient of determination and total variation for chimaerism monitoring

STR	*r*	*r2*	*%*
2015-2016	*0.447*	*0.1996*	*19.96*
2016-2017	*0.065*	*0.0042*	*0.42*
2017-2018	*0.567*	*0.3218*	*32.18*
2018-2019	*0.171*	*0.0292*	*2.92*
2019-2020	*0.148*	*0.0218*	*2.18*
2020-2021	*0.571*	*0.3255*	*32.55*

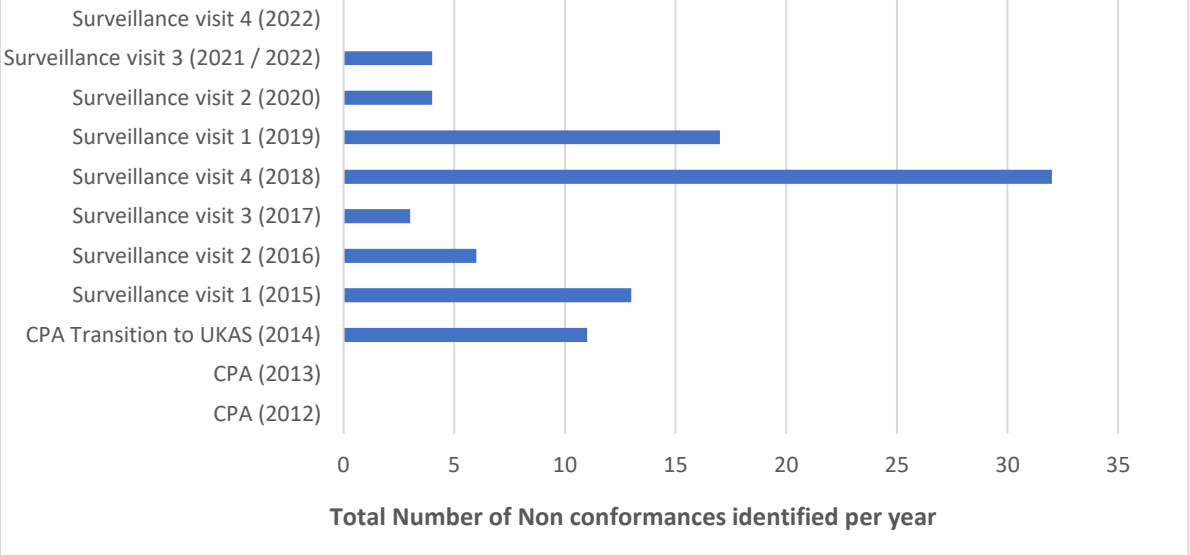
2021-2022	*0.033*	*0.0011*	*0.11*

The Coefficient of Determination calculated for the study period using Microsoft Excel was **R^2 = 0.0289** highlighting that 2.9% of the total variation in chimaerism monitoring RRs can be accounted for by the variation in annual accreditation.

The average Pearson Correlation co-efficiency calculated for the study period was **r = -0.17** demonstrating that the strength of the linear relationship is weak with a statistical significance of **P=0.131** (Appendix 24) signifies insufficient evidence to reject the null hypothesis. Graphically there was identified a decrease in STR RRs over the study period with a negative correlation (Figure 16) which is what would again be anticipated but again may not be reflective of the impact of accreditation alone.

Error rates

ISO 15189:2012 standard defined non-conformances per Surveillance Visit



The Coefficient of Determination calculated for the study period was **R^2 = 0.0091** highlighting that only 0.1% of the total variation of ISO NC identified that are accounted for by the variation in annual accreditation.

The Pearson Correlation co-efficiency was **r = -0.095** demonstrating that the strength of the linear relationship between the number of NC and each assessment year is very weak with a statistical significance of **P=0.82** (Appendix 24) which is insufficient to reject the Null hypothesis.

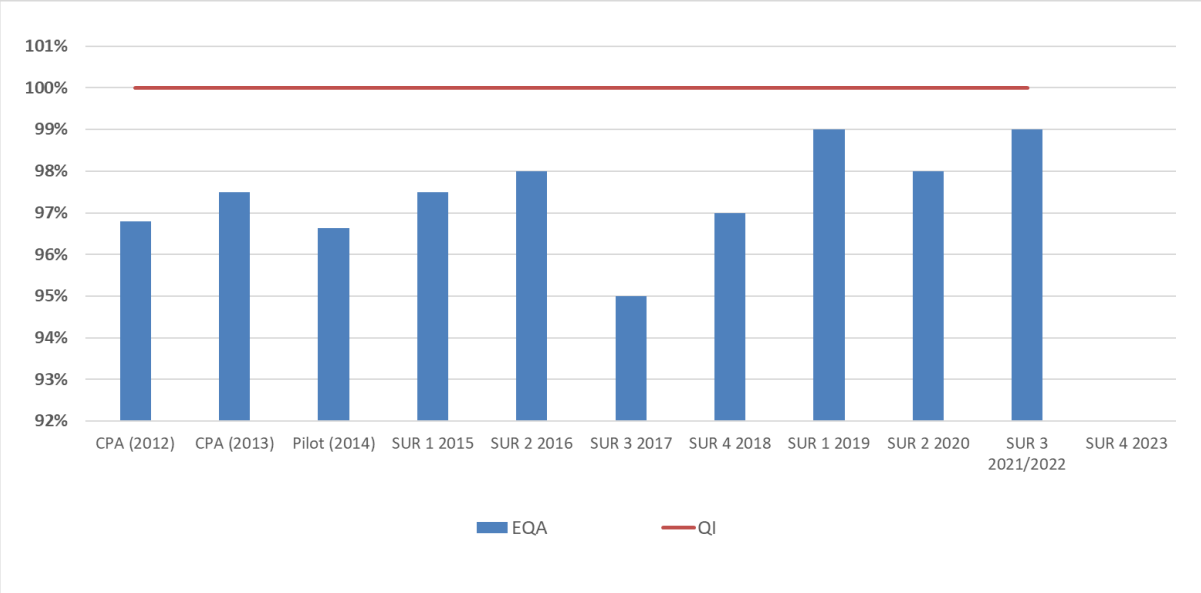
Graphically a slight decrease in NC was observed over the study period associated with a negative correlation (Figure 17) this would be an expected outcome for

laboratories who participate in accreditation due to continual maintenance of the standards.

UKNEQAS Scheme Annual Average Results

	EQA	QI
CPA (2012)	96.80%	100%
CPA (2013)	97.50%	100%
Pilot (2014)	96.63%	100%
Surveillance visit 1 (2015)	97.50%	100%
Surveillance visit 2 (2016)	98%	100%
Surveillance visit 3 (2017)	95%	100%
Surveillance visit 4 (2018)	97%	100%
Surveillance visit 1 (2019)	99%	100%
Surveillance visit 2 (2020)	98%	100%
Surveillance visit 3 (2021/2022)	99%	100%

Annual Average UKNEQAS EQA Scheme Results Following the Transition to ISO Accreditation



The Coefficient of Determination calculated for the study period was **R^2 = 0.2239** highlighting that 22.4% of the total variation in EQA scores can be accounted for by the variation in annual accreditation (Figure 18).

The Pearson Correlation Co-efficiency calculated was **r = 0.473** showing that the strength of the linear relationship is moderate with a statistical significance of **P=0.17** (Appendix 24) which is insufficient to reject the Null hypothesis.

Appendix 20 Impact of ISO Accreditation on Key Concepts - Efficiency

Turnaround times

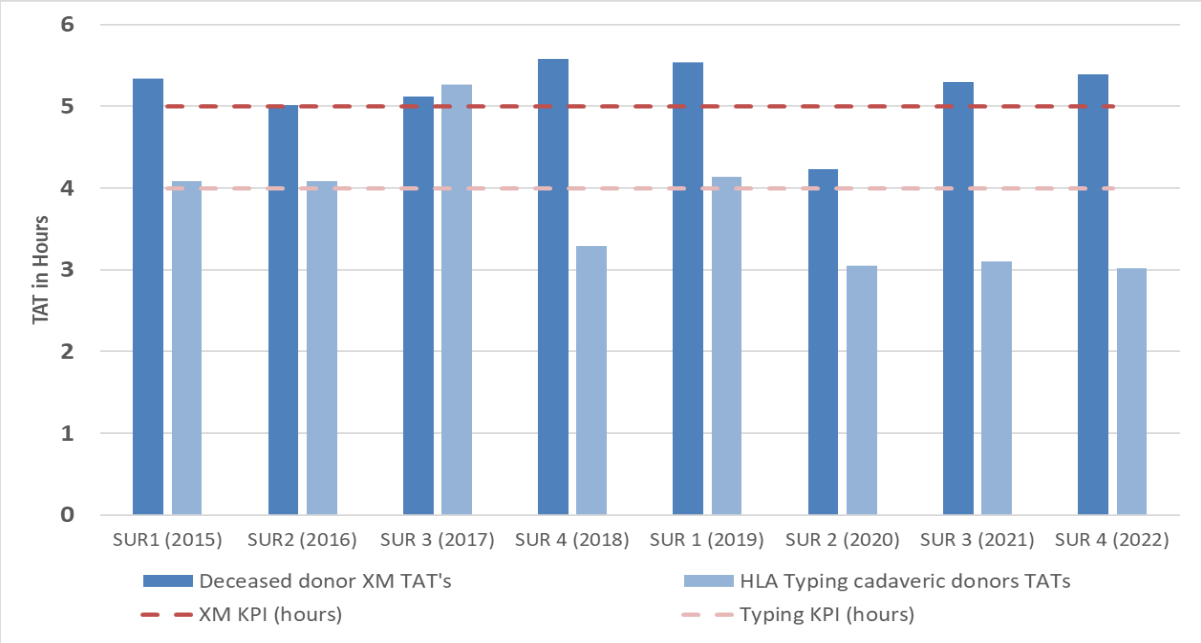
To measure the laboratory efficiency established QIs were used to measure the impact of accreditation over the study period. TATs of the laboratory critical processes (HLA typing and Crossmatching in an acute on call situation) have been established which monitors the TATs of both Donor HLA typing and deceased donor crossmatching using both flow cytometry and complement dependant cytotoxic crossmatch (CDC-XM) and are generic across the H&I community.

Crossmatching is a pre-transplant test in which donor lymphocytes are tested against serum samples from the potential recipient(s) to determine there is a possibility of transplant rejection due to presence of donor–reactive HLA antibodies. These donor reactive HLA antibodies are a contraindication to transplantation and cause a positive crossmatch result. These are detected in the on-call situation by using either or both a cytotoxic cell killing test which uses donor cells and recipient sera alongside the flow cytometry crossmatch which is a more sensitive test that again uses fluorescence to detect antibody binding to donor cells.

NATIONAL KQIS DECEASED DONOR CROSSMATCHING AND HLA TYPING

UKAS Surveillance Visit	Deceased donor XM TAT's	XM KPI (hours)	HLA Typing cadaveric donors TATs	Typing KPI (hours)
2014 2015	5.34	5	4.09	4
2015 2016	5.01	5	4.09	4
2016 2017	5.12	5	5.27	4
2017 2018	5.58	5	3.29	4
2018 2019	5.54	5	4.14	4
2019 2020	4.23	5	3.05	4
2020 2021	5.3	5	3.1	4
2021 2022	5.39	5	3.02	4

Annual TATs (Hours) for the National KPIs since the Transition to ISO Accreditation



The Coefficient of Determination or the study period was **R^2 = 0.1492** indicating that 14.9% of the total variation in HLA tying TAT can be accounted for by the variation annual accreditation.

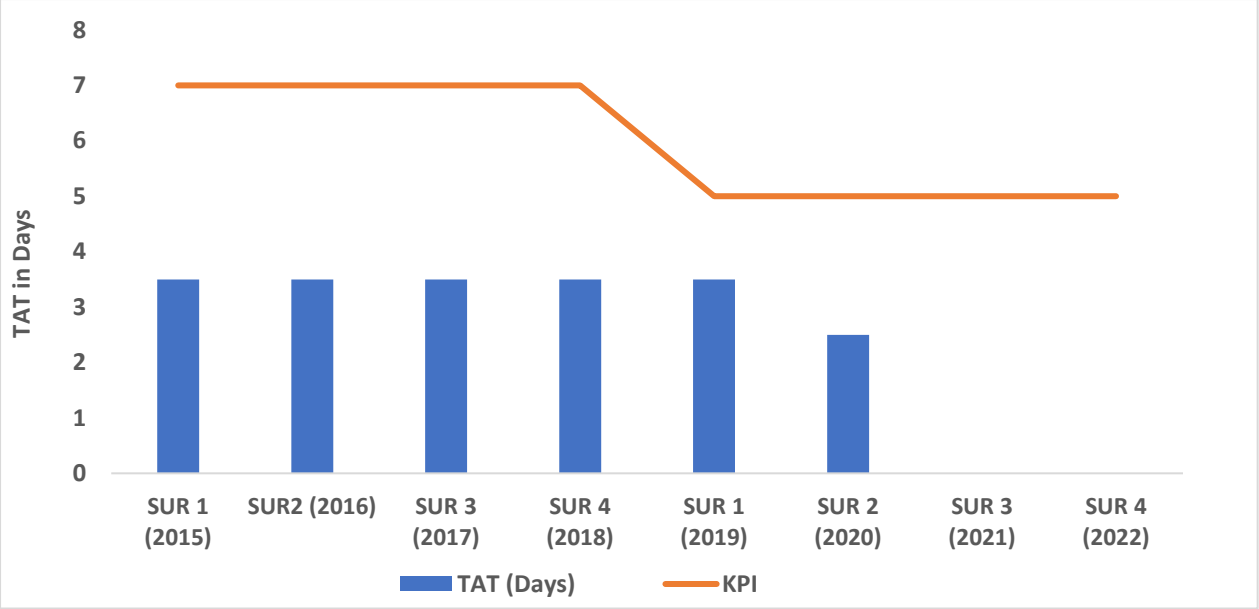
The Pearson Correlation co-efficiency for the study period was calculated as **r = -0.386** showing that the strength of the linear relationship is once again weak with a statistical significance of **P=0.0001** (Appendix 25) which is sufficient to reject the Null hypothesis. Graphically it can be observed that there is an ongoing downward trend for HLA typing TATs which would be an expected outcome of continual improvement due to participating in accreditation assessments (Figure 19), but this may not necessarily be a response to annual participation in accreditation it may be due to changes in technical approaches to HLA typing over the study time frame.

The Coefficient of Determination for the study period was **R^2 = 0.0402** highlighting that 5.9% of the total variation in the crossmatching TAT can be accounted for by the variation in annual accreditation (Figure 20).
The Pearson Correlation co-efficiency calculated for the study period was **r = -0.20** showing that the strength of the linear relationship is weak with a statistical significance of **P=0.05** (Appendix 25) which also is sufficient to reject the Null hypothesis.

Chimaerism Monitoring (STR)

UKAS Surveillance Visit	TAT (Days)	KPI
Surveillance visit 1 (2015)	3.5	<7 days
Surveillance visit 2 (2016)	3.5	<7 days
Surveillance visit 3 (2017)	3.5	<7 days
Surveillance visit 4 (2018)	3.5	<7 days
Surveillance visit 1 (2019)	3.5	<5 days
Surveillance visit 2 (2020)	2.5	<5 days
Surveillance visit 3 (2021/2022)		<5 days

TAT (Days) for Chimaerism Monitoring of Quality Indicators since the Transition to ISO Accreditation



The Coefficient of Determination for the study period was calculated as **R^2 = 0.0072** indicating that 0.72% of the total variation in the TAT can be accounted for by the variation in annual accreditation.

The Pearson Correlation co-efficiency calculated for the study period was **r = 0.085** showing that the strength of the linear relationship is weak with a statistical significance of **P=0.41** (Appendix 25) which is insufficient to reject the Null hypothesis.

Graphically it could be observed there appears to be a linear relationship between chimaerism monitoring TATs and annual accreditation (Figure 21) showing an ongoing trend in increasing TATs for this procedure over the period of accreditation which is contradictory to what should be expected if quality and efficiency were improving.

Appendix 21 Calculating Cost Effectiveness

EQUATION 1 COST EFFECTIVENESS TOOL

Adapted equation used for the study:

Cost Effectiveness Tool

$$\textit{Annual Cost effectiveness (CE)} = \frac{\textit{Cost per test per year}}{\textit{ISO Compliance (\%) per year}}$$

(NC non-conformances per accreditation year against the ISO 15189 standard)

$$\textit{Cost per test} = \frac{\textit{Annual total of All costs}}{\textit{Annual total of tests}}$$

(The total of all costs involves all costs including reagents, maintenance, personnel, administration etc for each critical process used in the study and includes the annual cost of accreditation)

Calculating the Annual Total of Quality Costs

	Accreditation	EQA Schemes	PPM Costs	Personnel	Total of costs
2014-15	£2,400.00	£4,637.00	£376,588.00	£1,848,985	£2,232,610.00
2015-16	£3,646.40	£4,623.40	£74,443.00	£1,909,737	£1,992,449.80
2016-17	£5,910.25	£5,140.40	£81,861.00	£1,991,046	£2,083,957.65
2017-18	£5,025.75	£5,343.00	£129,472.00	£2,025,455	£2,165,295.75
2018-19	£11,870.55	£6,259.00	£49,487.00	£2,367,803	£2,435,419.55
2019-20	£6,414.26	£6,051.00	£158,157.00	£2,440,848	£2,611,470.26
2020-21	£10,471.95	£6,091.00	£62,904.00	£2,452,192	£2,531,658.95
2021-22	£8,405.80	£6,219.00	£99,642.00	£2,593,992	£2,708,258.80
2022 23					

Calculating the Annual Total of Tests

		HLA Typing	AB Screening	Crossmatching	Chimerism monitoring	Annual total of tests
	Total of costs	Total of tests	Total of tests	Total of tests	Total of tests	
	£1,901,552.00					
2014-15	£2,323,610.00	19,245	9,801	622	1575	31,243
2015-16	£1,992,449.80	18,193	10,966	954	1753	31,866
2016-17	£2,083,957.65	20,353	14,446	732	1666	37,197
2017-18	£2,165,295.75	17,713	16,622	1157	2027	37,519
2018-19	£2,435,419.55	11,516	15,838	1013	2174	30,541
2019-20	£2,611,470.26	12,153	15,935	727	2702	31,517
2020-21	£2,531,658.95	9,218	12,575	311	2917	25,021
2021-22	£2,708,258.80	13,879	16,605	510	3860	34,854

Calculating the Costs per Test

	Total of costs	Annual total of tests	Cost per Test
2014-15	£2,232,610.00	31,243	74.37
2015-16	£1,992,449.80	31,866	62.53
2016-17	£2,083,957.65	37,197	56.03
2017-18	£2,165,295.75	37,519	57.71
2018-19	£2,435,419.55	30,541	79.74
2019-20	£2,611,470.26	31,517	82.86
2020-21	£2,531,658.95	25,021	101.18
2021-22	£2,708,258.80	34,854	77.7

Calculating Percentage Compliance with the ISO Standards Per Year

	No of ISO NC per year	% NC	% Compliance
2013-14			
2014-15	11	2.8	**97.2**
2015-16	13	3.4	**96.6**
2016-17	6	1.6	**98.4**
2017-18	3	0.3	**99.7**
2018-19	32	8.3	**91.7**
2019-20	17	4.4	**95.6**
2020-21	4	1.0	**99**
2021-22	4	1.0	**99**

Calculating Annual cost effectiveness (CE)

	Cost per test per year (£)	% Compliance with ISO	Annual CE
2013-14			
2014-15	74.37	97.2	**0.77**
2015-16	62.53	96.6	**0.65**
2016-17	56.03	98.4	**0.57**
2017-18	57.71	99.7	**0.58**
2018-19	79.74	91.7	**0.87**
2019-20	83.86	95.6	**0.88**
2020-21	101.12	99	**1.02**
2021-22	77.64	99	**0.78**

Appendix 22 Focus Group Discussion Group 1 (CSTT Staff)

Transcript

Quality

Yeah, I think it definitely increases the level of quality within the department. I think that the rules they set for document control and the quality management system, and it keeps us on our toes. And keeps everything up to date.
(CSTT05)
Yeah, I agree with CSTT05, it kind of opens up questioning of our process, how can we be striving towards better quality services, maybe streamlining services etc.
(CSTT01)

Value of Accreditation (essential / informative)

Valuable management tool

I think because I've seen the invoices that come in and for exactly how much it costs, so I think it's really expensive for what we get. (laughing)
(CSTT05)
Well, it's **essential** because we have to do it, don't we? We all know we have to be a EFI accredited We have to be ISO accredited to function and to be able to do our report, and so it's, It's a necessary evil. (Laughing)
(CSTT06)
It was only going to be the same point CSTT06 was making there. So, like the fact we need to be JACIE accredited to be used by lab for bone marrow for example, like that sort of stuff so it's. I suppose that would be why you say it's **necessary,** but I think it's useful to have a set of standards that we work up to and to inform the lab considering how disjointed the service is generally or the different. I mean, you see that selecting of bone marrow donors as an example of it, the different processes and practices performed by every lab. So, I think it's more from that side that I'd say it was useful. Obviously, whether or not you get value for money, is a different question.
(CSTT03)
Yeah, I was going to say exactly the same thing as CSTT06 and CSTT03 because we do a lot of work for external laboratories and it's **necessary** that we're accredited with them so. Yeah, same as CSTT06 and CSTT03.
(CSTT05)
I was just going to say that if you sort of try and see it from the **patients' point of view** as well, imagine if we weren't accredited and you were just getting your samples, you know you were trusting your samples to be tested properly by this lab that you know nothing about. You do trust that all of these places have got the necessary equipment and the necessary training, and everything has been done correctly, don't you? Wouldn't you, just wouldn't really imagine that they wouldn't be (accredited). You do need to be accredited and sort of tested in some way that you're doing what you should be doing. Don't know otherwise the whole system would fall down, wouldn't it?
(CSTT04)
Well, I was just going to say I think the stuff that's been in the news recently has kind of proved why you need accreditation. The whole scandal with the COVID testing done by a lab that wasn't ISO accredited and look what happened there. (Laughing) (CSTT06)
Well, it's (accreditation) for all of us, isn't it? I mean, in some respects you could say that for the people actually doing the tests it's almost more important because they're the ones that have physically abiding by the rules set out that we have to do. It applies to everybody, doesn't it coz it applies to the whole process from the doing, the test to the report of the test to the checking of the test. So, it's it applies to everybody. (CSTT06)

Well, like CSTT06 said, it just gives us a framework to work too. So, in the lab we know we have certain standards that we need to meet and that falls into the accreditation process. And we usually don't see the other side of it, **we don't see all the paper trail** and all the other work that goes on behind closed doors, so it doesn't always affect us in the same way. But we still know that we have the same standards to work too, and that works up from whether you were technologist or an MLA right up to being management level. (CSTT09)

*What, **why is it informative for us?***

This is all the stuff you have to do based on best practice, isn't it? So, you'd hope with them being revised and reflective of new technologies coming through and variance for healthcare stuff that you end up getting better care because it provides better care to your patients by following the new and

improved Uhm, guidelines that come out through it be it for quality management system or what have you. (CSTT03)

I think it probably makes us constantly assess what we're doing, doesn't it? And sometimes you need to assess whether what you're changing affects other things, and by doing the audits, that kind of forces us to do that, doesn't it? Because you're looking at everything that's referenced within, uh, say an SOP, for example, doesn't necessarily just affect that test you're doing. It can then have an impact further down on other things, so it makes us constantly look at how we're doing things and whether we can make it better. (CSTT06)

Patient Safety

Well, I think both of those things can be true, can't they? they're not mutually exclusive because, I think it does improve patient safety in that it ensures we're following the correct procedures. It makes us look at the test to see whether they're the right ones for the right patient, but equally. It's often logistically and paperwork difficult to introduce new tests because things have to be agreed by ISO etc. And things like that, so it's almost it becomes quite difficult to start introducing new things sometimes. (CSTT06)

Yeah, it well. I mean it goes beyond us to improve patient safety really because obviously the point of the accreditation being to ensure everyone is working the same standard and everyone got the access to the same health care. So, it goes sort of outside of us as a lab that approach to it. But yeah, the amount of work, particularly obviously with this whole flexible scope thing you've been trying to go through shows the effort to put in to actually get new tests validated. (CSTT03)

Yeah, and I would just want to add about the patient safety aspects as well because obviously we're in the healthcare field and obviously I see it is quite important because especially when we're bringing in new techniques it's the safety for aspects of it 'cause we're all human and we might be something along the way of introducing something new and I just think that's one important aspect and I think why it exists is that we don't have any near misses or incidents involving patient care. (CSTT02)

Staff Impact

Workload

And I would say we recently validated the AlloSeq protocol, which is a different technique, but in some ways it's just an improvement to the previous NGS version, and there was a lot of work to do just to bring that in. The Technique behind it is a bit different, but it was for the same purpose. Yes, uh, so yeah, it something is essentially just an improvement on the previous version. There's a lot of work to go into doing it. (CSTT07)

I think it's the manpower thing, isn't it? because we're always short-staffed, and its prioritizing things, isn't it? So, it can be sometimes quite difficult to fit in the validation work, but also keeping your turn around times right for the patients, which I think we all probably feel is the most important thing. But

equally you want to do the new things because you know that could improve things for the patients. So, it's finding that balancing act isn't it. (CSTT06)
Yep, I was just going to add about even though testing in the lab doesn't feel like it as a day-to-day impact, it's all written into the SOPs in the processes, and you're trained on the SOPs. So even though it doesn't feel like it as a day-to-day impact, it really does 'cause of the processes that you're performing, so It's actually having effects every day. (CSTT02)
Why do we think it's so labour intensive?
We need to make sure that you have evidence of it to be able to prove the process you've gone through to get to the decisions you've made in. Be able to verify it, and that gives you traceability for if something does go wrong at the other end, or it can also help inform further practice. By looking back at what was done previously, so I'd say a lot of documentation comes from that. (CSTT03)

I think it's your favourite phrase,. If it isn't written down, it didn't happen. (Laughter) And it's about documenting everything, and it makes it easier when you want to go back, you know because we've had it in the past where we've assessed a piece of equipment and decided we didn't like it. And then three or four years later it comes around again and we don't have to assess it again, because we've already decided we didn't like it, or we can assess it again because it may well be that things have changed in the lab, you know, we might have a different technique that it may be valuable, but at least we've got the previous documentation to say why we didn't like it in the first place, for example. (CSTT06)

Well, yeah it can. I think we can all agree that it's sometimes can feel a bit overwhelming (Documentation). (CSST06)

Efficiency (TATs)

Impact of documentation

Well, it's hard to know, isn't it? because like every NHS place, we're short staffed aren't we all the time so it's again trying to **find that priority of what** sometimes, it's well, what do you want to do? do you want? do we do the patient work, or do we do the validation or the audits? And you know that they're all important, but it's, **which is the most important is** the burning question every day? (CSTT06)
Yeah, I think it's easier to see the direct result of having to spend time doing validations and everything and you can see the amount of time gets put into those and it takes away from working on patients' stuff, but it's harder to see potentially the impact of all that audits and validations. And whether they improve things over a longer period of time, I think it can be harder to see the results of that. (CSTT07)

Improving lab service – no answer

Is it a continual improvement tool?

Yeah, that's a Posh way of putting it, yeah. (CSTT06)

CSST04, you were nodding is there anything you want to add.

I think that's a really good point that sort of everything you do is interconnected here, isn't it? If you try and improve one process or one SOP, it's easy enough to think 'Oh well, I'll just review that SOP', or 'I'll just change that one' as a standalone, actually for so many processes you can't do that they do

have a knock-on effect to a lot of other things as well.
And it's a good point that you could then use your accreditation standard, you almost start at the beginning and go through, say, an audit process or whatever all the way through and it might have had a knock on some things you wouldn't have originally thought of, so I think it's good to remember that everything is linked together as well, by changing one thing you might then actually have to change or improve five other things, but the outcome is that everything has been made better. (CSTT04).

Does it drive our improvements, or would we do this anyway?
I would hope so because it's a framework to do it within, isn't it? it encourages that kind of behaviour I suppose. (CSTT03)

Think it's probably a mixture of the two, isn't it? I'm sure we would stick to doing things properly but It's kind of arbitrary what that properly is, isn't it? And at least this gives us that framework, like CSTT03 says, to know all labs are sticking roughly to the same standards in the same kind of ways of doing things. It gives you confidence if you are getting things from other laboratories as well. You know we get results from other places, don't we for patients, for example, who are transferring or things like that and it makes you trust what they've done. Because if you see that they are accredited like us you kind of assume that they're working to the same standards. (CSTT06)

Improve Quality / Efficiency?
Yeah. I think it does improve the quality of the department. Because you know you've got a certain standard to meet, and everyone has to meet that same standard and if you don't then you know you're not falling within It within the…. I can't think of the word that I'm trying to think of now. Yes, it does, it does. (CSTT09)

Yeah, I think the same as CSTT02 and CSTT09. Yeah, it affects the quality. And it's important, I think we deal with accreditation like testing and stuff, but I'm not sure if it improves efficiency. (CSTT08)

ISO standards / Assessment team (Subjectivity)

I think there is always going to be some difference of opinion, shall we say about how to interpret the standards. But I don't think you can ever get around that because you can't be so prescriptive that everything has to be detailed to the NTH degree because there has to be some leeway surely. And I think you just have to trust that everybody is, I mean, that probably comes down to the fact that we're all state registered clinical scientist, or state, registered whatever and that you have to kind of trust people's judgment to a certain extent because you can't possibly legislate for every possible eventuality, can you? (CSTT06)

Yeah, I'd like to say something similar to that every lab is different in terms of the number of staff, and what you're using the test for, so you might be using the same test but might be using it in different ways, so you can't quite legislate for that but yeah again, as you just touched on before, it's useful for the framework. I don't really have much to add from CSTT06, but I felt like I had to have to continue then. (Laughing)
(CSTT03)
I think it's also useful sometimes the fact that you do have different people coming in with different perceptions on how, how somethings interpreted because you may then get suggestions that you haven't been, you haven't thought of yourself because you haven't had that experience, so I think

there's something to be said for personal experience. But obviously, it's when it goes the other way and people end up judging you against their standards when you both might be right that you get the problem. So, I think it comes down to the assessors more than anything and their approach to work and quality. (CSTT03)
Yeah, I was just going to say the same and also, it's probably good to have someone from outside looking in and checking to get their opinion. (CSTT08)

I was just gonna say I mean I, don't actually know how it works once it all goes up to the higher levels, but presumably, there's also the opportunity for you to feedback or appeal any decisions that are made if you felt like you were treated differently to you know to other labs or differently to how you should have been treated, or if you didn't pass something that you felt that you should have done or something like that, there should obviously be a process for that. It shouldn't just be like one person makes this decision about a whole lab, but also as well, the assessors will have a lot of experience. You're not going to have somebody who has only worked as a scientist for two years coming in and doing the assessment so they will have seen a lot of different labs. They will have seen a lot of different processes and you do so just have to trust their knowledge and their experience is trying to make you, you know, make your lab be better and it's all about improvement. It's not really about trying to say that somebody's worse than somebody else. It's about trying to improve everybody all the time, isn't it? (CSTT04)

I think I think you'd hope that the assessors as part of their training would be trained to work in different ways and work with people and understand that everywhere works differently, I would have thought. (CSTT05)

Cost / Value for money

Time, yeah, time because as mentioned previously, well it's the common thing isn't it. There are never enough people and it's yeah it can be quite labour intensive sometimes. (CSTT06)

It's just the same as CSTT06. It's just that you're using everyone from the technologist, MLAs upwards and you know all our time comes at a cost. So, by the time you've dealt with all this documentation, all the testing and everything, it's a lot of man-hours that equal a lot of money. (CSTT01)

Yeah, I was going to say the same thing. It's a really good point that if everybody worked out how much time, they logged the time each week as to how much time they did spend on quality issues and accreditation, and it really makes you wonder how much the total bill would be. I think we'd all be shocked. (CSTT05)

Hidden costs on the department of accreditation?

(Nodding) Yeah, just like I agree, the maintenance of equipment, and then there's all the NEQAS schemes and all that kind of stuff. And then when you're either training or becoming a clinical scientist, even personal cost, you have to pay for your registration. (CSTT07)

Have we seen an improvement in EQA schemes? *– no answer / unfair question - use for MT?*

Sorry yeah, going back to cost. There are so many hidden things like every year we have to pay eh, the Q Pulse licence, and there are so many hidden things people don't realise. And if you were to, add up, if you were to add up not just the um, the cost of the ISO costs, but also, like CSTT07 said, about maintenance, and I think would be shocked just how much, how much it adds up to. (CSTT05)

I can't really think of anything else other than what I've said. Just uhm, it's obviously necessary, so as much as some people seem to, you know, love it, or hate it more than others. It's just it's needed, isn't it? And I think it's even if it wasn't, it would be right to regulate yourself in some way, as a department wouldn't. Even if we didn't have to do all the things that we do, I mean, it can feel a bit repetitive at times. You know, the way that you have to audit every single process, even though some processes might be similar to each other and maybe you know if we could think about sort of streamlining things in some way and you know when we're trying to improve the processes by having, say, Q Pulse rather than other systems that we've had in the past and we are trying to make it so that it takes up less staff time, but you know, everyone just needs to have a, uh, attitude of well It does need to be done and there's a reason why it's done, and it does impact positively on patient care. Erm but it does, It does just feel like quite a lot sometimes, doesn't it, but it is. It is necessary, so I think we all just do the best that we can, don't we? (CSTT04)

I, generally in my experience with accreditation I don't have any great issues with it, and I understand why we carry out accreditation and understand how it can benefit myself and the patients. Uh, other labs as well. It's yeah, just mainly the cost, I just erm the cost and time that it takes it. It's a lot of a lot of work for something that you do, it never feels tangible. Uh, obviously I know we then get to put all the logo on all of our reports, but they're just for the effort you sometimes think, oh, you know you don't really see much for it on a day-to-day basis. (CSTT01)

Um, yeah, I don't really know. Like I say, it's just you just you know we're paying a huge amount for, for a logo essentially, and it's it just, it just seems a lot of work to then say, hey Mr Inspector here's some documentation and that's it, really. (CSTT01)

Yeah, I think it's probably mostly just quite easy to forget where improvements have come from, so when, er the reason why SOPs are good is because uh, you to do them to a standard. The reason why yeah, we make improvements to techniques, even techniques that have been here for years we still improve them all the time because we do examination audits and all kinds of stuff. And then it's I think it's just easy to forget where those come from. (CSTT07)

I guess there's ultimately, there's no endpoint. The whole point is that you continue to try and improve so they can feel like a bit of a treadmill and a slog that you are continually working along and then like CSTT07 says, this stuff that's happened before you don't think back and think over three SOPs ago we were doing this, like so yeah, what you've got to show for it at the end of the day, being a little emblem doesn't quite hit home when you're doing however many, two audits a year and ten SOP reviews or risk assessments or what have you. (CSTT03)

Just to touch on the cost thing to play devil's advocate with it, the argument for saving money, I suppose, would be in the fact that your techniques are better. You have to repeat them less. In an ideal world, if you're making these improvements and everyone is working to set a set standard. So, you're making savings from that side of it. Uhm? Is the only thing I'd add to the whole cost conversation? (CSTT03)

Yeah, I think it's good that we do audits and everything, then we can make improvements and check that, nothing that we've changed has changed other things as well, and Uh, yeah, it's important that for patients that we are accredited, and I think like day-to-day probably affects us like timewise. It's like having to do extra things like put stuff on audit databases and yeah, just cost as well as a big impact. (CSTT08)

And I think it's just a repeat of what everybody else has said really, like looking at thing's day today. It's easy to not really understand why you're doing something or why you're having to put information in 15 different databases. And it's the same information over and over again, and but it just depends on your viewpoint of it like whether you look at it as a day today or whether you look at it, say a wider picture because obviously, it is of a benefit when you look at overall, it's if you look at the bigger picture it's not just like a logo but when you're doing stuff day today, you do think, oh, for God's sake, you know we've got do this all over again. But overall, I think it is important that we do it but whether you know, you've got the cost of like the time that it takes to do something or even down to like reagents and stuff it takes, It takes the cost of different reagents which are expensive to, you know, validate kits, and follow through audit trails and stuff, it's hard to sometimes see the point of it, but If you then step back and you look at the bigger picture, obviously there is a point to it. And it's again if you're coming into something say you are a newer member of staff, you don't necessarily know how things were however many years ago, to understand how that process has changed over time, whereas if you have been in for a long time, you can see how the constant improvement of tests and techniques has improved and then has ultimately saved money because it's improved the turnaround time, it takes for a test. I'm Yeah, but other than that, everything else has been touched on by other people here. (CSTT08)

And I think it's one of those things, isn't it? We all know how important it (accreditation) is. We all know we have to do it. We all know it's essential but sometimes it can feel like a lot of work for something that we don't necessarily all personally see the benefit of, and I think the actual costs sometimes can feel like a lot, and it feels like someone is trying to make some money somewhere. You know the ISO inspections and the fact that they charge you when you want to introduce a technique can sometimes feel a bit. I don't know, not, right? But it is what it is, isn't it? And we have to do it. It's yeah, it's just finding that balance between the actual day-to-day patient work that we all know is important and fitting this in around it. (CSTT06)

I think just, uh, it makes you look at all your processes, continuously, like CSTT03 said before, like Uhm? just reviewing things every year, every two years. There's always going to be things you can change and yeah, yeah. It definitely does help improve quality; I think. (CSTT07)

I just think it doesn't help that quality has got a bit of an image problem with that other see quality and the first thing it brings to mind to people are almost a negative. The negative connotations with it and after work, *(CSTT03)*

Why? What did, what did? What are those negative connotations?

like, well, the time, the bureaucracy, the money, other things that we sort of touched on in here that's associated with it that you don't ever *really hear the positive spin on it or positive case for it. (CSTT03)*

So, is it accreditation? Do you think that anyone cares if we didn't have accreditation?

Well. I'm not sure if it's accreditation per se because you could argue it's the implementation of the accreditation, so whether or not you're in interpreting the accreditation as it should be as it's meant or whether people who are setting it. Uhm, think about how it translates into laboratory practice. I think there's an element to be made of which side that responsibility falls on, but I don't think we review our quality systems quite enough to maybe reduce the work that we have to. So, I mean, Q

pulse is obviously the current sort of topic that you could apply that to you, and so we're trying to remove some of the hard work for people with that. But it's definitely an attitude that we come up with every time we try and say something for Q pulse, I'd say when you're giving a presentation to someone or something. There's a. There's a tacit understanding that it's quality and people feel like it's going to be a bit of a drag. (CSTT03)
Is that's honest enough for you, Julie.

Time of Focus group – 45 mins

Group No = 9

Useful Themes and Quotes

Theme 1 - Valuable Management tool
It's a framework to do it within….it encourages that kind of behaviour (continual improvement) gives us that framework'. 'it just gives us a framework to work to too and that works whether you are a technologist or an MLA right up to management level'. 'All labs stick roughly to the same standards in the same kind of ways of doing things.'

‘Provides a framework to work too’.
‘It’s useful for a framework’.
‘It gives you confidence’.
‘it makes you trust what they've done’.

Theme 2 - Importance of accreditation (Essential / Informative)

‘based on best practice’.
‘really works for document control and the quality management system, and it keeps us on our toes’.
‘It kind of opens up questioning of our process, how can we be striving towards better quality service’.
‘it's essential because we have to do it to function and to be able to do our report, and so It's a necessary evil.
‘like the fact, we need to be accredited to be used by the lab for bone marrow. I suppose that would be why you say it's necessary.
‘we do a lot of work for external laboratories and it's necessary that were accredited with them’.
‘it's obviously necessary And I think even if it wasn't, it would be right to regulate yourself in some way’.
‘You do need to be accredited and sort of tested in some way that you're doing what you should be doing’.

Pop-up Covid labs

‘The whole scandal with the COVID testing done by a lab that wasn't accredited…’.

Theme 3 - Patient Safety (Users / Clinicians)

- **Standardisation**

‘I think it does improve patient safety in that it ensures we're following the correct procedures.’
Following correct procedures… ‘to see whether they're the right ones for the right patient’.
‘.the point of the accreditation is to ensure everyone is working to the same standard and everyone got access to the same health care’.
‘All labs stick roughly to the same standards in the same kind of ways of doing things.

- **Delays in innovation**

‘It’s difficult to introduce new tests because things have to be agreed upon by ISO’
‘becomes quite difficult to start introducing new things sometimes’.
‘one important aspect and I think why it exists is that we don't have any near misses or incidents involving patient care’.

Theme 4 - Improve Laboratory service.

‘And keeps everything up to date.’
‘end up getting better care because it provides better care to your patients by following the new and improved Uhm, guidelines that come out through it’.
‘…but the outcome is that everything has been made better’.
‘Because you know you've got a certain standard to meet’.
‘definitely increases the level of quality within the department’.
‘I think it does improve the quality of the department’.
‘it makes us constantly look at how we're doing things and whether we can make it better’. **(Quality improvement)**

- **Improvements**

‘ I think it's probably mostly just quite easy to forget where improvements have come from… because we do examination audits and all kinds of stuff’.

‘The whole point is that you continue to try and improve so they can feel like a bit of a treadmill and a slog that you are continually working along’.
‘I think it probably makes us constantly assess what we're doing - by doing the audits, that kind of forces us to do that’. (**continual improvement**)
‘but I'm not sure if it improves efficiency’.

Theme 5 - Staff impact – on workload (Manpower/time)

- **Manpower –** because we're always short-staffed, and it’s prioritizing things,

‘There's never enough people and it's yeah it can be quite labour-intensive sometimes’ (Time)
‘It does just feel like quite a lot sometimes, doesn't it, but it is. It is necessary, so I think we all just do the best that we can, don't we?’
‘it's just finding that balance between the actual day-to-day patient work that we all know is important and fit in this in around it’.

- **Hidden Costs**

‘Time comes **at a cost** by the time you've dealt with all this documentation, all the testing and everything, it's a lot of man hours that equal a lot of money’.
‘if everybody worked out how much time, logged the time each week as to how much time did spend on quality issues and accreditation and it really makes you wonder how much, what’s total Bill would be. I think we'd all be shocked’.
‘I think day-to-day probably affects us IS timewise. It's like having to do extra things like put stuff on audit databases and yeah, just cost as well that has a big impact.’
‘And we usually don’t see the other side of it. We don’t see all the paper trail and all the other work that goes on behind closed doors, so doesn’t always affect us in the same way’.
‘it doesn’t feel like it has a day-to-day impact, it’s all written into the SOPs’ in the processes…. So even if it doesn’t really feel like it’s a day-to-day impact, it really does’

- **Innovation**

‘the amount of work……. the effort you need to put in to actually get new tests validated’.
‘we recently validated the AlloSeq protocol, which is a different technique, but in some ways it's just an improvement to the previous NGS version, and there was a lot of work’.
‘sometimes quite difficult to fit in that validation work, but also keep in your turn around times, right for the patients which I think we all probably feel is the most important thing’.
‘Do we do the patient work, or do we do the validation or the audits? And you know that they're all important, but it's with, **which is the most important.** Is the burning question every day?’ (validations/patients)
‘amount of time gets put into those and it takes away from working on patients’ stuff,’.
‘you can't be so prescriptive that everything has to be detailed to the NTH degree because there has to be some leeway surely’.

- **Documentation**

‘it's harder to see potentially the impact of all those audits and validations. And whether they improve things over a longer period of time, I think it can be harder to see the results of that’.
‘it can feel a bit repetitive at times. You know, the way that you have to audit? Like every single process, even though some processes might be similar to each other’
‘I think it's good that we do audits and everything, then we can make improvements and check that, nothing that we've changed has changed’.
‘We need to make sure that you have evidence of it to be able to prove the process…… so I'd say a lot of documentation comes from that’.
‘Everything is about documents…… If it isn't written down, it didn't happen’.
‘sometimes it can feel a bit overwhelming’.
‘So even though it doesn’t feel like it has a day-to-day impact, it really does…..it actually has an effect every day’.

Importance of Documentation –

'but at least we've got the previous documentation to say why we didn't like it in the 1st place',

'Be able to verify it, and that gives you traceability for if something does go wrong at the other end, or it can also help inform further practice. By looking back at what was done previously, so I'd say a lot of documentation comes from that'.

Theme 6 - Cost of accreditation (Cost-effective)

'seen the invoices that come in and for exactly how much it costs, so I think it's really expensive for what we get'.
'whether or not you get value for money, is a different question'
Time…… 'There are never enough people and it's yeah it can be quite labour intensive sometimes. all our time comes at a cost'.
'it's a lot of man-hours that equal a lot of money'.
'If everybody worked out how much time they did spend on quality issues and accreditation……I think we'd be shocked'

Emerging Themes – UKAS Assessments – Peer review

<u>Assessors / Assessment team</u>

'It's probably good to have someone from outside looking in and checking to get their opinion?'
'..there's something to be said for personal experience'.
'assessors will have a lot of experience'.
'have to trust their knowledge and their experience'.
'It's not really about trying to like to say, somebody's worse than somebody else. It's about trying to improve everybody all the time, isn't it?'
'it's all about improvement'.
'good to have someone from outside looking in and checking'.
Objectivity -
'I think I think you'd hope that the assessors as part of their training would be trained to work in different ways and work with people and understand that everywhere works differently'.
Judging against their standards when you both might be right ….it comes down to the assessors more than anything and their approach to work and quality.'
'I think it's also useful sometimes the fact that you do have different people coming in with different perceptions on how, how somethings are interpreted'.
'..going to be some difference of opinion, shall we say about how to interpret the standards'.

Emerging Theme UKAS -

Standards -

'but I think it's useful to have a set of standards that we work up to'

Symbolism (Logo) -

'We then get to put all the logo on all of our reports, but they're just for the effort you sometimes think, oh, you know you don't really see much for it on a day-to-day basis.'
'we're paying a huge amount for, for a logo essentially,'
'it is of a benefit when you look at overall, it's if you look at the bigger picture it's not just like a logo'
HIDDEN COST -

‘the maintenance of equipment and then there’s all the NEQAS schemes and all that kind of stuff.’
‘many hidden things like every year we have to pay eh, the q pulse licence’
‘the cost of the ISO costs but also, about maintenance’
‘the cost and time that it takes it. It's a lot of a lot of work for something that you do, it never feels tangible’.
‘the cost of different reagents which are expensive to, you know, validate kits, and follow through audit trails and stuff, it's hard to sometimes see the point of it’,
‘and it feels like someone is trying to make some money somewhere. You know the ISO inspections and the fact that they charge you when you want to introduce a technique can sometimes feel a bit. I don't know, not, right?’

Appendix 23 Focus Group Discussion Group 2 (MT Staff)

MT Focus Group Transcript

a valuable management tool?

I think it is important to be accredited because then you can show quality of service that your laboratory is providing to your clinical users and also to the patients as well. And then in terms of

managing what you do on a day-to-day basis if you can show that you're accredited and for techniques or the quality management system etc then I think that's what people would want to see, to have trust in a in a lab. (MT05)

improves the quality?

I think so because it makes people conform to processes that it might not. Not. Well it might want to maybe cut corners…(he hem – Laughing). So I think it makes people not do that, and I think he we try and provide a quality service. Not that we, you know… I think it really focuses your mind on it. (MT05)

Yeah, my point was very similar. It's just that increases the confidence of the user in the service that you're providing because you've passed a certain standard from when the inspectors have come in and sent your documentation off and so on. (MT12)
No, Not reliability, I'd say that if you can prove that you've reached a certain standard in a particular area or across the board, then I would say that as a user, if you, you would feel more confident in using the services that that laboratory. So, it would increase patient and clinical confidence in the service it would provide. (MT12)

Importance of accreditation in laboratory?
Yeah, so I think for me what it comes down to is, I suppose, as a scientist you know it's external peer review of our service effectively and certainly as an inspector going elsewhere. That is something that you know, you know the systems you know the standards that you're expecting, and you can look at it objectively. (MT03) And I think that's how it helps improve because you've got someone else coming in to look at you and say OK, uhm. you know it's valuable to get the feedback really. Generally, I might contradict myself later on when, you know, in some parts but generally I think accreditation is helpful. (MT03)
Er, the only thing I would question there though is when people say now you know. You know our service users know; er I suppose service users could be the clinicians. I'm not entirely sure that patients understand necessarily what accreditation means. I don't know, maybe I'm being a bit sort of patronising. But unless you are well informed of what accreditation actually stands for, I would question whether they actually understand that our service is better than you know, the lab that isn't accredited. But that's just a comment. (MT03)

Yeah, sorry I was just going to say that because of a lot of people who are in industry and lots of other areas are familiar with UKAS accreditation. I think that some people would look at that and see that as a stamp of approval. I agree maybe not so much with EFI because that wouldn't mean a lot to folks outside the H&I community, but I think UKAS certainly in other areas and in industry is a recognized body for accrediting. (MT12)

Yeah, it probably overlaps a bit with what MT03 said, but I just wonder if it helps us as well as a department too keep up to date in terms of thinking about how we can improve, so perhaps some of the things that we put in place that we, I don't know, at the time might feel like why we have to examine this to the NTH degree, actually can end up being beneficial for us in terms of improving our service that we do provide. So just in terms of streamlining things in the lab or I am thinking about the whole process. You can actually get feedback as a result of an inspection that means that you put into place systems that make what we do better, and I don't mean necessarily, obviously, that's not visible to the patient or even to their clinician, but it hopefully is to the people who are working in the lab that they can see that actually we're doing quality improvement essentially; I suppose.
I realise not always, and I realise these things can go to the NTH degree, but I think you know. Overall,

I've seen that definitely, you know, Yeah, I've seen I've seen that in progress, I suppose. (MT02)

Yeah, I think so. We've certainly put ways of, you know ways of measuring things and I obviously, as I say, you can put, you can take these things too far, but ways of looking at how we are producing results and the quality of those and what we can do to make them better in a way that perhaps we might not do if we weren't having to look at the way that ISO we're looking at it, for example. (MT02)

I think probably from my time when I was working more on the NGS side of things. When that was a new technique that we were introducing into the lab, we were inspected a number of times by both EFI and ISO and I think some of the systems that we put in place as a result of that have been very helpful in terms of monitoring quality metrics and various things that we might not have done otherwise. Also, in terms of training and Competency audits and other such things that we've put in place systems which I know that, obviously have been as a result of having to do it for accreditation which other teams potentially have been well, other teams have been able to kind of benefit from the thought processes that we had to go through wouldn't necessarily have chosen to necessarily, you know, especially, but I know that other teams that have benefited from being able to think similarly, so hopefully, hopefully that's a reasonable example. (MT02)

I just thought of another example to what MT02 was alluding, MT02 was talking about, and it was through the ISO inspection looking at the difference in the performance of the different instruments in the department. So, for example, between the two are now three LABScan or the two light cycler's and looking to see if there's any variation in those. That's something that we didn't particularly look at I don't think before the ISO inspection, and I think that's beneficial because we can see that there has and is a difference between those. Then it will help us put better procedures in place. Uh, and it has been done. As you know we've had issues with those particular assays. (MT12)

And yeah, it's just that we obviously have our own, like internal reasons as to why we should be accredited as a, as a lab, but I think as well, if you look at like the external side of it, I would imagine or would hope that for example, a patient if he knows that, or if they know that our lab is ISO accredited that it would give them confidence that we actually knew what we were doing.
I think if you were to make comparisons and find out that there were other labs that weren't quite, you know strict about things that, that might you know it might not equate to the same thing, so I'm hoping anyway that to external people that it will at least you know, make us look as if we know what we're doing. (MT11)

On the back of that, actually, I suppose we've had some really good examples within the past two years with all the pop up COVID labs that yeah, have happened and actually the fact that really most, a lot of them have not been accredited to the same level and we know because it gets reported. We obviously only know the tip of the iceberg, but we do know of a lot of the issues they've had with the training of the staff, with the processes that they've had and the results coming out that you know well basically, you know the impact of the fact that they haven't had accurate results, and we obviously we're not internal to a COVID lab but actually, had they had inspectors go in would these things have been picked up? (MT03)

Yeah, I was just going to follow up on what (MT03) said because there were a lot of them, I saw a lot of heated arguments on Twitter and social media around this what (MT03) raised about COVID and lab testing and certainly the public were aware of accreditation, and they weren't necessarily scientists that we're bringing it up. And I thought that was really interesting. (MT05)

As in as in the whole, all of the group will just our management group well…wow (MT03)

I'm just on that point. Uh, me. I suppose it's how people interpret that comment. Isn't it patient Facing? No, we're not physically patient facing. So, expose it's the interpretation of that (MT07)

Do you think accreditation as any direct impact on our laboratory services with regards to efficiency/ cost effectiveness / quality

Yeah, I'm going. I'm trying to think of an answer
I think the word cost effectiveness is difficult when you talk about UKAS accreditation because there always seems to be an added cost to maintaining or gaining the extra accreditation status when we're trying to improve our service, so in that respect it's difficult to say it's cost effective. (MT07)

Yeah, I just think it would in the long run be cost effective because we're making sure that our tests are working properly basically, because if we had instruments that didn't work properly or reagents that we're storied incorrectly or you know people that weren't trained properly, then it was going to cost more money to get your result out. (MT09)

You'd like to hope so, yes, but I mean, it (accreditation) really does focus the mind, doesn't it? And the tasks. And we make a big effort to give protected time so that all this kind of thing gets done, you know, and it seen to be done because of accreditation. (MT09)

Yeah, UM cost-effective. I tried to remember when CPA became UKAS and we got told we had to. And I also remember at that time the massive hike in the cost of accreditation specifically not the internal cost to us, of doing all these extra steps, but the actual cost to UKAS of a) getting credited b) having an extension to scopes c) extra things. And I'm not entirely sure it's cost-effective, and you look at our circumstances now we pay a lot of money and I'm not entirely sure I mean, that we've had the service from them, *I'm not sure about* the quality of service because we're still not been signed off for the extension to scope, but they haven't decided and you know, even to the smaller point where we've tried to get trained as inspectors, there isn't that responsiveness on their side, so I don't, I'm not entirely sure we're actually getting, you know, value for money or cost-effective for ISO specifically. (MT03)

Get rid of it completely? No because you know there was a massive step up, wasn't there from CPA to ISO with what we had to look at, and I think if all accreditations went Uh, I'm not entirely sure we would. NGS is a great one. When we when we came to implement in a whole new technology, a whole new technique that we hadn't done before, we had to go through the standards line by line saying, how are we going to meet this standard? And it made us think about how we were implementing and there were some things in there like oh, we hadn't thought about that bit.
And I think it was helpful if you took it away completely, I don't think we would have necessarily thought well have we addressed such and such, but you ask. (MT03)

Uh, I think based on everyone's answers from the first question in terms with you know it provides that confidence to the users and the patients. I think it would be very hard then to turn around and say, but we don't actually need it, could we opt out because you would lose that status then wouldn't you? (MT07)

Well, we don't know do we directly, but the point is, it's helping to provide a quality service which in

the end, effects the patient. But then if you remove it and you're up against labs, as people have said that have accreditation, you will always go with the one that was accredited. It's a difficult argument, isn't it? If it could be a better service that was provided to us at a more reasonable cost, of course you'd choose to have it then. (MT07)

Is there any sort of self-accreditation process that you could, you could have maybe?
So you still working to standards, but this yourself accrediting yourself. But then that's gonna have to be assessed by somebody at some point to a cost, isn't it? (MT07)
I think we've probably gone past the point that I was going to make really, but it was just it, so I'm not surprised that it's like a score of 50/50 because I'm sure that everybody feels that accreditation is worthwhile for all the reasons that were said. But there's also the fact that there's so many man hours there tide up with the documentation and the processes that I'm sure many people as well feel that they could spend their time better actually at the bench doing the work. Not saying that the work isn't getting done but, it's just it's competing with the work, isn't it? (MT11)
Sorry, I'm yeah it was just going back to that point again about, you know you said what, what? Why did the public think that we you know I would have the public see that we needed accreditation and I was going to make the point about what MT03 and MT05 made about the pop-up COVID Labs and I saw all the Twitter feed on that, and it was non-scientist who were commenting on it and it was eroding public confidence in scientific services? So, I think now more than ever we need to have that confidence there that, that laboratories are providing a service that has been reviewed by somebody else and deemed acceptable. (MT12)
Yeah, I'm just thinking about the fact that we're, we are essentially accredited twice, aren't we? And I know that both bring different things, and one obviously looks more at the quality management system in a way that I realise EFI doesn't in quite the same way.
Em, but are we accredited double in a way that we don't, Yeah, it's just that question, isn't it? It you wonder about the benefit of. I can obviously see the benefit of EFI because it's H&I specific. The benefit of ISO? I realize that some of the stuff I've talked about in terms of NGS would only have been done, because if ISO it wasn't because of EFI, although there were lots of things because of EFI, so it's hard to say that I think that one, yeah, one shouldn't happen and one should em, but I do wonder in terms of cost-effectiveness weather two is right, but then of course I'm aware also that EFI is by no means the financial impact that ISO is either. I don't know how if any of that is very helpful, but it's just a thought. Bringing in the idea of as actually being accredited twice, really. (MT02)

I wonder if it's because they hear us talking a lot about having to pay for extension to scope. Potentially when they can see that actually, fundamentally not, not a lot has changed, but or we want to add something in and they and they hear us, perhaps talking about how Yeah, and also as well of course, how that can not necessarily happen very quickly, and obviously they'll hear us talking about the fact that yeah, that's not ideal. I don't know. (MT02)

For me, the biggest thing that I find difficult to come to terms with is the way that UKAS Uhm, dictate that we need to use UKAS-accredited Uhm, companies, just to maintain our centrifuges or to perform services for us so that they will then be happy with the level of maintenance and I do understand that it's all about standards, but it looks like it's a monopoly or there's it doesn't look quite so open and honest and open to competition anymore and it is driving up prices. That's for me one of the things I find most difficult to accommodate. (MT01)

Yeah, It was just on that comment really about the junior team and it's kind of follows on what MT02 says about what they hear was potentially talking about and maybe the level of experience, or knowledge about the reasons behind accreditation and the benefits of it isn't necessarily uhm? they might not be aware of it basically, there might be a lack of awareness about the relevance and the benefits and the requirements of it, but then they do hear the cost side of things and maybe from that, that might be one of the reasons. (MT07)
Well, I think with them doing the BSHI certificate and the diploma, so obviously incorporated into their learning and understanding, so I think it should be, their understanding should be there if they've gone down that route of training at this point. MT07

I'm actually quite surprised that it's Just the junior team that's saying it's not value for money. I'd be I, you know, all of us understand the benefit of it, but personally value for money for the amount we pay for it. I'm not entirely sure, so I I'm surprised actually there were If you're saying, there weren't many of the management team that are saying it was value for money. (MT03)

I think one thing we have to watch is the UKAS standards are quite open to interpretation. It's quite often you'll put something in place and then things seem to spiral a bit so an Inspector will come along and it's very good that you've put that in place, but sometimes it's almost like they're on, like a bonus scheme whereby they have to identify something for you to fix or to improve and things just seemed to kind of go on and on and on, and I think every time you have like a little bit of an add-on It kind of detracts away from the original purpose and kind of makes you process slightly less streamlined. I suppose every now and again you kind of have to rethink the whole thing.
But I think maybe when they do come around perhaps, we need to start instead of just accepting things, perhaps we need to kind of almost kind of give a counterargument a bit more vigorously sometimes. Because quite often, if you would say well, where is that precise thing in the standards they can't, they wouldn't be able to show you because it's their interpretation of the standards. (MT13)
Absolutely you've only got to read them. You could have like 15 interpretations of any one thing at least depending on the people you ask. (MT13)

In certain areas the standards when you do read them the clarity could be improved, so I think I would set the campaign for plain English onto them because it's they can be quite difficult to interpret so I can see ??? point there where you might think you've addressed something and then another point could be raised as a result of it. So, I think if you're going to have standards, they need to be really clear in what the purpose and what they're asking you? Maybe it's the way they're trying to say it, not what they're saying. It's just an improvement in the clarity of what they actually mean when they're asking for something. (MT12)

Well, I think this is. I know it's not about EFI, but I think this is maybe where we have the difference with you've got ISO UKAS that is also for Medical Labs are actually still very generic and trying to write a standard that fits every kind of lab and every kind of you know diagnostic service within those labs into the same standard which is maybe why to some extent EFI is a little bit more understandable because it is just H&I. So generally, the processes are the same, but when you're trying to compare us and a Biochem lab and a virology lab, and you know Histology, that does bits of tissue, it, it's those processes that are going to be very different. But somehow, we all have to meet the same standard. So, I think some of the, the intended, I suppose the way it's been interpreted as a) How does each field

interpreting from for themselves, but b) They've left the wooliness in there almost on purpose, because if you write it too clearly, then, it might not actually apply to some, I don't know. (MT03)

Yeah, I think I think I don't want to get overly political, but I think possibly, as well. I think people who work for the public sector they do tend to be a little bit sort of suspicious about the motives of private organizations, and I think that's if, I'm quite surprised actually the something as big as accreditation, especially for medical laboratories, It's not a public body which is responsible for overseeing and monitoring the accreditation of labs in the UK. I think people may have more confidence in the system if it was under public ownership, but that doesn't mean to say that I'm anti privatisation is just, you know, it's just something that I think most people who work in the NHS may feel along those lines. (MT11)
Just to come in on that (MT11) UKAS is actually a not-for-profit organization supposedly, although when you look at their annual report, they make about £1,000,000 profit like 'surplus' a year. So, it's a bit of a woolly one that's meant to be reinvested back in. Apparently, that's what 'not for profit' means, but yes, I would agree with you that it's uh, not transparent, shall we say. (MT03)

Just yeah, it's just on that point that (MT03) made in coming back to one that MT01 made earlier, and (MT11) just made. How, do they provide a reason if they are a non-profit organisation as to why they recommend certain companies to do particular tasks over others? (MT12)

It's not so much they recommend certain company-named companies. They say they have to have UKAS accreditation, and you don't have to but the documentation that you then have to provide is a lot more involved if they're not UKAS accredited, cause you somehow have to assess your supplier company? (MT03)

One thing I did like about accreditation even though the standards were ridiculously, was the measurement of uncertainty because I think it made us look at our assays in a better way and in a more scientific way that we haven't done before, and I think it makes us pay more attention to whether or not they're working properly, even if it's difficult to, Uh, achieved for all our different H&I assays. I feel that that's a really positive thing and I do feel that our systems are better for us having looked at them in that area. (MT01)
I agree definitely, but I also wanted to make a separate point that I think that as a result of looking at ISO, were asking us to provide documentation of training and competency I think the introduction, which is as a by-product of that, but I and we may well have come up with it anyway. But I think that as a team introducing the key trainers has been a really good and very helpful Uhm, development in how we train folk. So yes, OK and we may well have come up with that, but I do wonder if we've come up with that because we've had to answer a number of questions to inspectors about training and competency. And actually, some of that I realized this has been erm, what's the word? Not difficult? Involved maybe, but I do think it's been a major development to have to have key trainers. I don't know if anyone else would agree with that or whether they think there's actually nothing to do with accreditation, which of course it may well not be. (MT02)

Thumbs up from MT14 / MT12
Yeah, I would agree with MT02 in terms of the training as well. It has made us be more consistent with our training, uh, which has improved the quality of the training, and that's reflected in the results, the consistency of the results that we get. (MT07)

A separate example It makes us review regularly and investigate our repeat rates and turnaround times and SSO being a prime example of Uh, when we have been monitoring repeat rates over time and investigating issues we have now seen a significant improvement in those repeat rates are being recorded, so I think that has given us a measurable improvement there and the fact that we could argue that you change the staff you changed the kit over time as well. So, by having accreditation it keeps you checking these things over time. You don't just implement something and check it, you keep checking and also the way we have to document any incidents. So, the system review process is the way we have to think about preventative corrective actions and then follow up on those actions. Obviously helps us **continually improve** our processes. (MT07)

Yeah, I think one area that accreditation has improved is our erm maintaining the continuity of the service when say there is an IT breakdown. So, I think that's so that that'll obviously convert our contingency plans for those, those circumstances. Uh, I think we would have done that anyway without accreditation, but I think because of the fact that you know we're having to produce documentation and so on and meet other types of standards that I think it's sort of made us look more closely and more thoroughly, so I think that's one area that it may well have improve over time. (MT11)

Yeah, and it's quite a specific example, but I'm coming from the fact that I do the CDC training in the recent action that was brought up with regards to reading the CDC trays and how we would assess the competency of that. Considering how long we've done CDC for, and it's never occurred to us to assess that has been someone else's opinion and someone else coming in. Has been really useful and it's flagged up extra training issues that we perhaps weren't aware of and that can be actually where it's good that there's a bit of interpretation involved with the guidelines. (MT10)

Yeah, this will be probably controversial, but it's just It's obviously caused stress and anxiety to people trying to fit that in alongside their daily job. And I know it's important and I know it has to be done, but it does cause some stress particularly as we've seen over Covid, when we've had unexpected isolations, not saying it's not important at all but it has added extra pressure. (MT05)

Yeah, and there's the hidden costs we talk about the cost of accreditation in terms of the actual paying of UKAS, but how many extra staff have we had to get to incorporate, to make sure that we can as MT05 said, you know, keep, the job going? Keep the routine results coming out but do all the quality and look at, I mean this morning is a perfect example. We sat around all of us together saying we've got a new IT system coming in a year's time, but we still have to maintain all of these audits and we cannot let it, even though we have clearly, I would argue a very valid reason to say we could do without these for a moment while we focus elsewhere. But actually, no, we've got to keep doing them, so you know, it's almost as if to say if we let it slip for one year, doing an audit on all of our processes, suddenly they're going to fall apart. So yeah, I would say that's a downside. (MT03)

Yeah, I think I haven't got any examples of where this has happened in our lab, but I would imagine that over time to process could serve to stifle innovation because I think in the past where we've done things we've just gone ahead and done things, you know, new things, whereas now if you're having to think of everything in terms of the implications and the amount of documentation that's got to be produced and all the rest of it that goes with it, it could be a bit of a disincentive. So that's probably one possible long-term negative aspect. (MT11)

Yeah, I agree with MT11. Uhm, it might stifle it, but it would also delay, sort of implementing something if you wanted to change something very quickly. You could follow all the necessary steps, but it still might be a significant delay, as we've found before you can get things added to your scope of practice. (MT07)

Uh, my negative aspects might just be my personal opinion, but sure, everyone doesn't really enjoy that experience of being inspected. It's stressful. And it shouldn't be I suppose if everything was in place, and everything was a dream, but you can't deny it's a stressful experience to be inspected. (MT07)
I have, one thing that I feel is very negative is that although annually we pay, and we get inspected and we change our scope as quickly as we can. UKAS is extremely slow with that and in the time that we've submitted an application to extend our scope to allow a new typing technique, to be processed. It can take them over a year to get back to us and in that time, we might have moved on and we might be using that process routinely because that's how our service works, but we're not allowed to use their logo. So, for all that time effectively we're really not accredited if we can't put their logo on the reports and I'm not really sure about the principles surrounding that, I'm not, feel, that, UM, having inspected us they have an obligation to allow us to use their logos until they can you know, even on a provisional basis, until they can ratify our new techniques and our extensions to scope that we've submitted in good faith. (MT01)

Oh, I did but MT01 said exactly what I was going to say, and I completely agree with MT01. I think it's really unfair that we all take the logos off or something that we've, validated within an inch of its life. (MT05)
That's exactly what I was going to say as well about the logos, and particularly because we've been inspected before for different things. So, we know the type of things that they're going to be looking out for in a validation and we will have covered that to the NTH, so I would back MT01 and MT05 point of view up completely there. That's one of my biggest bugbears with the logos. (MT12)

No, I just think that why can't you use it? It's just. It's just silly that you can't have it on a report when you validated something, and they've been in before and inspected the lab for previous techniques and been happy with what we've done. It just seems pointless that you know you have to wait until, they give you the thumbs up there. (MT12)

I think for me it's not the logo and actually using the logo 'cause I don't really care. It's the thought that we are not accredited to use that technique despite having gone through the process, In order to do the validation and that our users who may rely on this and if that's the truth then they may be looking at our reports thinking Oh they're not accredited for that because we are actually meant to state on it, aren't we? That we are not accredited to do that particular task. (MT01)

Going back to the turnaround times, I always feel the quality organization should really lead by example and they should be quality really 'cause if you're going to go and inspect a laboratory and you're going to say right? Why are these, turnaround times not meeting these targets. I think they can't really say that if you can't even meet your own targets. And while, all right, yeah accreditation isn't all about logos, but everybody really loses out of us not having that logo on our reports. Not just

us, but also ISO because if we're reporting things and people don't notice whether that logos there or not, then it kind of devalue them somewhat. (MT13)

Yeah, it's on the back of leading by example now BSHI put in a complaint on behalf of all H&I labs about how long it was taking UKAS to do the inspections and to return, and to deal with the actions. Uhm, and actually yeah, they did an investigation and upheld our complaint that their performance was not good enough as a whole. But still, given that they've upheld the complaint and that was what 18 months ago when it actually longer than that, was pre-COVID, wasn't it? We've lost two years, in the middle of here. Uhm, but nothing happened, nothing changed. I don't see any improvements in the quality of their service so they can look into themselves, do an investigation, and then well, where's the improvement? So yeah. (MT03)

I was just thinking about the fact that what MT02 said about the complaint that went in from BSHI and the response to that, it's to do, isn't it as well with the fact that yeah, a lot of the Yeah, I don't know why lot of what they're trying to ask us for in terms of us being able to show that we are accredited. Yeah, I'm not explaining myself very well, let me think about it. (MT02)

I've kind of experienced this several times where, for instance, on measurement of certainty you be talking to an inspector who will say, well, OK, you've decided to do it that way what's that based on, and you refer it back to the Royal College of Pathologists, for example? And ISO will just trample all over the royal college and just say, well, they're a totally separate organization and we don't believe in what they have to say, and I think that's, that's a huge thing. Just like I think it is good that we follow all of our competency monitoring but then it's kind of In that comes the HCPC and their role because they don't recognize that either. I think we probably do need to organize; they do need to accept the views of other organizations the moment they don't seem to. (MT13)

We're rewriting the RC path guidelines for measurement uncertainty at the moment, so I wonder if that's a pointless exercise then. No, I don't. I don't mean it, however. (MT02)
Let's see. (MT13)
Yeah, I totally agree with you. MT13 basically. Actually, if we're trying to standardize across H&I labs, what we do in terms of something like, for example, measurement uncertainty then actually all we can do, I suppose it's put those documents in place, can't we? And continue to, you know? Update them you know obviously was put in place a few years ago by and contributed to majorly by this lab, so you know, and all we're doing is reviewing them at the moment. But I think so long as we can say that we have things in place that they can refer to, I think then that means that we're doing the right thing as organizations and societies to put those things in place that people can be referred to.
I think it's important that together we do those things still so that they can be consistency across the discipline, basically. (MT02)

Hello, I'm I'd like to go back to the patients you know when you point that you made at the very start and are we making a difference. I don't, I'd like to know just from a personal point of view, does it ever get explained to the patients by the clinical teams, or just something they don't even think about? You know, it's important that you're the lab that we use is accredited to even bring it up to the need to. I don't know. I don't know the answer to it. (MT05)

Yeah, no, I think I mean from, you know, various comments. I think the lack of oversight or the lack of quality metrics on UKAS itself. I'm sure UKAS must have to hold some kind of accreditation itself, but I don't think that they are performing, and I think that you know all of our annoyance much as we see the benefit of accreditation, I don't think any of us think it should go out the window. I think the current, uh, body that's in charge itself, you know there's a big hole there that actually we are being overseen by people that are not actually competent to do that. And I don't mean competent in as much as you know, have they had their training as an inspector, but actually a competent body in terms of their ability to uphold the standards that they think we should, you know, it's that dual standard, isn't it? They? You know they do not uphold their own standards in terms of turnaround times and uh or even just communication quite frankly, on a basic level. (MT03)

My point was just about how we, you know we've been communicating during the pandemic, which has been over Zoom and teams and stuff and whether UKAS would move up to using that tool to save money for its users because presumably, it costs inspectors to go here, there, and everywhere you know to send 2-3 inspectors to a department is, could a lot of this be done uhm, over a system like Teams or Zoom permanently. (MT12)

That's a fair point, because actually do you remember pre COVID one of the last inspections we had and we had a bill for £600 for traveling expenses for three inspectors one of which came from Birmingham, one from Sheffield, I don't remember where the UKAS one came. And you're like hang on a minute, I can get to Birmingham for less than £200 and same to Sheffield. So actually, is it a bit of a raw deal we getting.? (MT03)

Yeah, it's I mean this might be pie in the sky, but it would be nice if at some point in the future, we had an increased amount of self-governance available for accreditation and thinking about. You know the number of years that we've actually been accredited and to such a high degree there maybe the accrediting body should be able to trust us a bit more that we do actually, know what we're doing. I don't know if, does the flexible scope sort of help in that respect? (MT11)

Time of focus group = 1 hour and 6 mins

11 participants

Useful Themes and Quotes

When asked their opinion of accreditation –

Theme 1 - Valuable Management tool
'it makes people conform to processes……might not cut corners' (joking) '…. accreditation is helpful'. 'can be seen as a stamp of approval' (UKAS is a recognized body for accrediting). 'To external people…….it makes us look as if we know what we're doing'. 'Helps us as a department to keep up to date in terms of thinking about how we can improve'. 'Systems we have put into place, as a result, have been very helpful in terms of monitoring quality metrics and various things we might not have done otherwise…..'.
Theme 2 - Importance of accreditation (Essential / Informative)
'it is important to be accredited because then you can show quality of service that your laboratory is providing to your clinical users and also to the patients'. 'I think that's what people would want to see to have trust in a lab'. Standards are useful when implementing new techniques – we had to go through the standards line by line saying how we were going to meet the standards. It made us think about ….. it was helpful. It provides confidence to the users……if we opted out, we would lose the status' **<u>Pop-up covid labs</u>** 'a lot are not accredited to the same level' (remote assessments) '…..hadn't had accurate results……but had the inspectors gone in would these things have been picked up?' '..was non-scientists commenting on it (Accreditation), eroding public confidence in scientific services. So, I think now more than ever we need to have that confidence there'.
Theme 3 - Patient Safety (Users / Clinicians)
'not entirely sure that patients understand necessarily what accreditation means'. 'But unless you are well informed of what accreditation actually stands for, I would question whether they actually understand that our service is better than you know, the lab that isn't accredited'. '…… it would give them confidence that we actually knew what we were doing'. **Conformance to the standard –** 'So, it increases patient and clinical confidence in the service it would provide'. **Innovation-** 'Over time the process (of accreditation) could serve to stifle innovation…..if you are having to think of everything in terms of implications and the amount of documentation that's got to be produced…….it could be a bit of a disincentive'. 'It might stifle it (innovation) but it would also delay ……if needed to change something very quickly.'

‘One thing that I feel is very negative is that although annually we pay, and we get inspected and we change our scope as quickly as we can, UKAS are extremely slow….it can take them over a year ……. but we’re not allowed to use their logo. So, for all that time we are essentially not accredited’.
Theme 4 – Improve Laboratory Service
‘Stops people cutting corners’ ‘try and provide a quality service. ……it really focuses your mind on it’. ‘that increases the confidence of the user in the service that you're providing a certain standard. feel more confident in using the services’. ‘You can actually get feedback as a result of an inspection that means that you put into place systems that make what we do better’, ‘Obviously, that's not visible to the patient or even to their clinician, but it hopefully is to the people who are working in the lab that they can see that actually we're doing quality improvement essentially’. ‘examine this to the NTH degree, actually can end up being beneficial for us in terms of improving our service that we do provide’. ‘put into place systems that make what we do better’,
Theme 5 - Staff impact – on workload (stress and anxiety)
‘you can take these things too far’, ‘examine this to the NTH degree’, ‘other such things we have put into place …..as a result of accreditation’ ‘we make a big effort to give protected time so that all this kind of thing gets done, you know, and it is seen to be done because of accreditation’. ‘There are so many man hours there tide up with the documentation and the processes ….. it's competing with the work’, ‘Obviously causes stress and anxiety to people trying to fit things in alongside their daily job’. ‘Added extra pressure…’ (during Covid) ‘the experience of being inspected, it’s stressful.’
Theme 6 - Cost of accreditation (Sub-theme - cost-effective)
‘there always seems to be an added cost’ ‘Maintaining or gaining the extra accreditation status when we're trying to improve our service, ‘think it would, in the long run, be cost-effective because we're making sure that our tests are working properly’. ‘the massive hike in the cost of accreditation not just the internal costs but the actual cost to UKAS of a) getting accredited, b) having an extension to scope c) extra things’ ‘EFI and ISO ……in terms of cost-effectiveness whether two is right…….im aware the EFI is by no means the financial impact that ISO is’. ‘like it's a monopoly, it doesn't look quite so open and honest and open to competition anymore and it is driving up prices’. ‘UKAS is a not-for-profit organisation supposedly…..when you look at their annual report, they make about £1,000,000 profit like ‘surplus’ a year’.
Emerging themes UKAS Assessments –
<u>Assessors / Assessment team</u>

‘it's an external peer review of our service’.
‘Objectively’.
‘you know it's valuable to get the feedback really’
‘think that's how it helps improve because you've got someone else coming in to look at you’
‘a bonus scheme whereby they have to identify something for you to fix or to improve’.

Continual Improvement

‘You can actually get feedback as a result of an inspection which means that you put into place systems that make what we do better’
‘Something that we didn’t particularly look at before the ISO inspection and I think that’s beneficial…..helps us put better procedures in place’

Emerging Theme UKAS (organisation) -

Service quality -

‘we've had the service from them, the quality of service because we're still not been signed off for the extension to scope’
‘we change our scope as quickly as we can, UKAS are extremely slow….it can take them over a year’.
‘I always feel a quality organisation (UKAS) should really lead by example…….you can’t really say anything if you can’t meet your own targets (TATs)’
‘I don’t see any improvement on the quality of their (UKAS) service….’
‘Uphold their own standards in terms of TATs and even just communication quite frankly, on a basic level’.

Standards -

‘standards are quite open to interpretation’. – Subjective
‘clarity could be improved….need to be really clear in what their purpose and what they are asking you’
‘You could have 15 interpretations of any one thing at least’
‘Very generic and writing a standard that fits every kind of lab……trying to compare us and a Biochem lab and a virology lab……processes all very different’
‘They’ve left the wooliness in there……’

An alternative approach to UKAS?

‘Is there any sort of self-accreditation process?’
‘working to standards…… accrediting yourself. This will at some point need assessing by someone at some point at a cost’.
‘..whether UKAS would move to use that tool (Teams/Zoom) to save money for its users because presumably, it costs inspectors to go here there and everywhere….’
‘… it would be nice that at some point in the future, we had an increased amount of self-governance available for accreditation……. the number of years we’ve been accredited maybe the accrediting body should be able to trust us a bit more than we do actually know what we’re doing’.

What’s the benefit?

‘Accredited twice essentially……EFI and ISO’
‘Introduction of MoU - …..I feel that’s a really positive thing and I do feel our systems are better for us having looked at them in that area’.
‘Made us more consistent with training……’
‘….maintaining continuity of the service…….contingency plans…….flagged extra training issues’

'….its never occurred to us to assess the competence (CDC crossmatching). It has been very useful and flagged up extra training issues we weren't aware of'
'Makes us review regularly and investigate repeat rates and TATs…. Now seen significant improvements'
'…having accreditation keeps you checking things all the time'

Negatives-
'Dictate that we need to use UKAS-accredited companies to maintain our centrifuges or perform services'
'…. which is a by-product of that, but I mean we may well have come up with it anyway'.
'Hidden costs (staffing) – extra staff to… keep routine work coming out but do all the quality'
'It's almost as if to say if we let it (the audit cycle) slip for one year……. suddenly they are going to fall apart. So yeah, I would say that's a downside'
Symbolism (Logo) –
'I think it's completely unfair that we all take the logos off……. validated within an inch of its life'.
'We know the types of things that they (UKAS) are going to be looking for…….and we cover that to the end'.
'It's just silly you can't have it on the report when you've validated something, and they've been in before and inspected the lab for previous techniques and been happy with what we've done. It just seems pointless'
'It's not the logo and using the logo because I don't really care. It's the thought we are not accredited to use the technique despite going through the process….and our users who may rely on this….'
'looking at the report think they're not accredited for this….'
'Because if we are reporting things and people don't notice whether that logos there or not, then it kind of devalues them (UKAS) somewhat.'

Appendix 24 Regression Analysis of Key Concept – Quality

Annual Average Repeat Rates -

HLA Typing

SUMMARY

Regression Statistics	
Multiple R	*0.03153556*
R Square	*0.00099449*
Adjusted R Square	*-0.19880661*
Standard Error	*863.824936*
Observations	*7*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*3714.11055*	*3714.11055*	*0.004977409*	*0.94649018*
Residual	*5*	*3730967.6*	*746193.521*		
Total	*6*	*3734681.71*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*43517.1084*	*645.9236*	*67.3719128*	*1.36422E-08*	*41856.709*	*45177.5079*	*41856.709*	*45177.5079*
X Variable 1	*852.139426*	*12078.3882*	*0.07055076*	*0.946490179*	*-30196.3458*	*31900.6247*	*-30196.3458*	*31900.6247*

Repeat Rates for Individual Critical Processes

HLA PCR-SSP

SUMMARY

Regression Statistics	
Multiple R	*0.288948419*
R Square	*0.083491189*
Adjusted R Square	*0.063567084*
Standard Error	*0.171547649*
Observations	*48*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.123319391*	*0.123319391*	*4.190461278*	*0.04638908*
Residual	*46*	*1.353715407*	*0.029428596*		
Total	*47*	*1.477034798*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*-0.003458103*	*0.048757666*	*-0.070924292*	*0.943765468*	*-0.101602195*	*0.094685989*	*-0.101602195*	*0.094685989*
Time Period	*0.0036588*	*0.001787343*	*2.04706162*	*0.04638908*	*6.10664E-05*	*0.007256534*	*6.10664E-05*	*0.007256534*

PCR-SSO

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.189760733*
R Square	*0.036009136*
Adjusted R Square	*0.02425315*
Standard Error	*0.046890909*
Observations	*84*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.006734897*	*0.0067349*	*3.063046809*	*0.083831955*
Residual	*82*	*0.180298101*	*0.00219876*		
Total	*83*	*0.187032997*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.11860077*	*0.010141747*	*11.6943135*	*3.72047E-19*	*0.098425604*	*0.138775936*	*0.098425604*	*0.138775936*
Time Period (Years)	*-0.00036929*	*0.000211004*	*-1.75015622*	*0.083831955*	*-0.000789045*	*5.04643E-05*	*-0.000789045*	*5.04643E-05*

Real Time PCR (RT-PCR)

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.283501953*
R Square	*0.080373357*
Adjusted R Square	*0.064517726*
Standard Error	*0.044597578*
Observations	*60*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.010082102*	*0.010082*	*5.069073*	*0.028159813*
Residual	*58*	*0.115358748*	*0.001989*		
Total	*59*	*0.12544085*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.052131148*	*0.011372585*	*4.583931*	*2.48E-05*	*0.029366445*	*0.074895851*	*0.029366445*	*0.074895851*
Time Period (Years)	*-0.000748513*	*0.000332457*	*-2.25146*	*0.02816*	*-0.001413998*	*-8.30287E-05*	*-0.001413998*	*-8.30287E-05*

Sequence Based Typing (SBT)

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.036010443*
R Square	*0.001296752*
Adjusted R Square	*-0.028076873*
Standard Error	*0.135175866*
Observations	*36*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.000806673*	*0.000807*	*0.044147*	*0.834834757*
Residual	*34*	*0.621265505*	*0.018273*		
Total	*35*	*0.622072178*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.176918381*	*0.044135822*	*4.008499*	*0.000316*	*0.087223599*	*0.266613163*	*0.087223599*	*0.266613163*
Time Period (Months)	*-0.000455673*	*0.002168721*	*-0.21011*	*0.834835*	*-0.004863044*	*0.003951698*	*-0.004863044*	*0.003951698*

Next Generation Sequencing (NGS)

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.23965691*
R Square	*0.057435435*
Adjusted R Square	*0.039651198*
Standard Error	*0.035758302*
Observations	*55*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.004129509*	*0.00413*	*3.22957*	*0.07801837*
Residual	*53*	*0.067768776*	*0.001279*		
Total	*54*	*0.071898286*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.062225369*	*0.009513269*	*6.540903*	*2.47E-08*	*0.043144167*	*0.08130657*	*0.043144167*	*0.08130657*
Time Period (Months)	*-0.000545843*	*0.000303735*	*-1.7971*	*0.078018*	*-0.001155059*	*6.3373E-05*	*-0.001155059*	*6.3373E-05*

Antibody Screening – Detection

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.019095053*
R Square	*0.000364621*
Adjusted R Square	*-0.011976556*
Standard Error	*0.019394497*
Observations	*83*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*1.11133E-05*	*1.11E-05*	*0.029545*	*0.863955228*
Residual	*81*	*0.030467869*	*0.000376*		
Total	*82*	*0.030478982*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.005881113*	*0.004219459*	*1.393807*	*0.167188*	*-0.002514288*	*0.014276513*	*-0.002514288*	*0.014276513*
Time Period (Months)	*1.52731E-05*	*8.88553E-05*	*0.171887*	*0.863955*	*-0.000161521*	*0.000192067*	*-0.000161521*	*0.000192067*

Antibody Screening – Definition

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.018856327*
R Square	*0.000355561*
Adjusted R Square	*-0.011835225*
Standard Error	*0.006212887*
Observations	*84*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*1.12582E-06*	*1.13E-06*	*0.029166*	*0.864816145*
Residual	*82*	*0.003165197*	*3.86E-05*		
Total	*83*	*0.003166323*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.002016479*	*0.001343747*	*1.500638*	*0.13729*	*-0.000656663*	*0.00468962*	*-0.000656663*	*0.00468962*
Time Period (Months)	*4.7746E-06*	*2.79573E-05*	*0.170782*	*0.864816*	*-5.08415E-05*	*6.03907E-05*	*-5.08415E-05*	*6.03907E-05*

Chimaerism Monitoring - Single Tandem Repeats (STR)

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.167015765*
R Square	*0.027894266*
Adjusted R Square	*0.01589296*
Standard Error	*0.029602767*
Observations	*83*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.002036813*	*0.002037*	*2.324269314*	*0.131265116*
Residual	*81*	*0.070982229*	*0.000876*		
Total	*82*	*0.073019041*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.046704597*	*0.006440367*	*7.251854*	*2.19255E-10*	*0.033890287*	*0.059518906*	*0.033890287*	*0.059518906*
Time Period (Months)	*-0.000206767*	*0.000135624*	*-1.52456*	*0.131265116*	*-0.000476616*	*6.3083E-05*	*-0.000476616*	*6.3083E-05*

Annual Average Error Rates -

Proficiency Testing (UKNEQAS EQA)

SUMMARY

Regression Statistics	
Multiple R	*0.473178936*
R Square	*0.223898305*
Adjusted R Square	*0.126885593*
Standard Error	*0.011106122*
Observations	*10*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.000284673*	*0.000284673*	*2.307927*	*0.167199804*
Residual	*8*	*0.000986768*	*0.000123346*		
Total	*9*	*0.001271441*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.966070909*	*0.006527665*	*147.9963895*	*4.86E-15*	*0.951018086*	*0.981123732*	*0.951018086*	*0.981123732*
Time Period (Years)	*0.001857576*	*0.001222744*	*1.519186458*	*0.1672*	*-0.000962076*	*0.004677228*	*-0.000962076*	*0.004677228*

UKAS ISO 15189: 2012 Non-Conformances

SUMMARY

Regression Statistics	
Multiple R	*0.095558583*
R Square	*0.009131443*
Adjusted R Square	*-0.156013317*
Standard Error	*10.49924411*
Observations	*8*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*6.095238095*	*6.095238095*	*0.055294*	*0.821915403*
Residual	*6*	*661.4047619*	*110.234127*		
Total	*7*	*667.5*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*12.58333333*	*6.777232934*	*1.856706632*	*0.112737*	*-3.999958251*	*29.16662492*	*-3.99995825*	*29.16662492*
Time period (Years)	*-0.380952381*	*1.620068539*	*-0.235145842*	*0.821915*	*-4.345117289*	*3.583212527*	*-4.34511729*	*3.583212527*

Appendix 25 Regression Analysis of Key Concept – Efficiency

Turn Around Times –

Deceased Donor Crossmatching

SUMMARY

Regression Statistics	
Multiple R	*0.200588619*
R Square	*0.040235794*
Adjusted R Square	*0.030025536*
Standard Error	*0.103516065*
Observations	*96*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.042227113*	*0.042227*	*3.940722745*	*0.050045019*
Residual	*94*	*1.007264111*	*0.010716*		
Total	*95*	*1.049491224*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.242903834*	*0.020966114*	*11.58554*	*8.32389E-20*	*0.201275123*	*0.28453255*	*0.201275123*	*0.284532546*

Time Period (Months)	*-0.000756838*	*0.000381255*	*-1.98513*	*0.050045019*	*-0.001513828*	*1.5177E-07*	*-0.00151383*	*1.51766E-07*

Deceased Donor HLA Typing

SUMMARY

Regression Statistics	
Multiple R	*0.386288935*
R Square	*0.149219141*
Adjusted R Square	*0.140168281*
Standard Error	*0.050714314*
Observations	*96*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.042402922*	*0.042403*	*16.48674*	*0.000101373*
Residual	*94*	*0.241762511*	*0.002572*		
Total	*95*	*0.284165433*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.194774886*	*0.010271663*	*18.96235*	*6.89E-34*	*0.174380259*	*0.215169513*	*0.174380259*	*0.215169513*
Time Period (Months)	*-0.000758412*	*0.000186783*	*-4.06039*	*0.000101*	*-0.001129275*	*-0.00038755*	*-0.00112927*	*-0.00038755*

Chimaerism Monitoring

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.084701034*
R Square	*0.007174265*
Adjusted R Square	*-0.003387711*
Standard Error	*0.897235228*
Observations	*96*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.546820628*	*0.546821*	*0.679254*	*0.411930042*
Residual	*94*	*75.6729191*	*0.805031*		
Total	*95*	*76.21973973*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*3.425552279*	*0.181725769*	*18.85012*	*1.07E-33*	*3.064731505*	*3.786373053*	*3.064731505*	*3.786373053*

Time Period (Months)	*0.002723515*	*0.00330456*	*0.824169*	*0.41193*	*-0.003837766*	*0.009284797*	*-0.003837766*	*0.009284797*

Appendix 26 Regression Analysis of Key Concept – Cost Effectiveness

SUMMARY OUTPUT

Regression Statistics	
Multiple R	*0.579103224*
R Square	*0.335360544*
Adjusted R Square	*0.224587302*
Standard Error	*0.139231166*
Observations	*8*

ANOVA

	df	*SS*	*MS*	*F*	*Significance F*
Regression	*1*	*0.058688095*	*0.058688095*	*3.02745082*	*0.132518236*
Residual	*6*	*0.116311905*	*0.019385317*		
Total	*7*	*0.175*			

	Coefficients	*Standard Error*	*t Stat*	*P-value*	*Lower 95%*	*Upper 95%*	*Lower 95.0%*	*Upper 95.0%*
Intercept	*0.634166667*	*0.089873331*	*7.056227473*	*0.000405481*	*0.414254548*	*0.854078785*	*0.414254548*	*0.854078785*
Time period (Years)	*0.037380952*	*0.021483835*	*1.739957132*	*0.132518236*	*-0.015188099*	*0.089950003*	*-0.015188099*	*0.089950003*

Appendix 27 My Research Journey: A Personal Reflection

My interest with accreditation has been ongoing for over three and a half decades, initially through my practical role as clinical scientist and then as QM in a specialist pathology discipline with hands on everyday experience of developing and managing the QMS. Then more specifically by being involved with UKAS as part of the roll out of the new ISO 15189:2012 standard as the pilot site for the specialist pathology discipline of H&I. Although it was the end of an era with the CPA (UK) Ltd being merged with UKAS I was fully invested and a true advocate for the new standards and UKAS. Over the years since the transition to UKAS there was observed, a significant increase in the cost of accreditation cost year on year with no apparent significant changes to our quality indicators. There was also observed significant delays with any applications to the ETS made to UKAS causing significant departmental concerns. A publication on the UKAS website titled 'Lab39 Guidance on the Implementation and Management of Flexible Scope accreditation within laboratories' published in August 2004 was discovered. This publication gave me some food for thought and it was clear that there was a way that laboratories could adopt this new approach that was less restrictive and was clearly described in the document allowed changes to methods to be amended to a laboratory's scope where competence had been verified previously. The document also acknowledged a potential issue in that ETS timescales may delay innovation and the ability to meet user timeframes. In 2018 the first application was made to UKAS for the application to move to a flexible scope, having fully digested and acknowledged all the key requirements of the document. We were currently on the fourth year of the first UKAS accreditation cycle. Having been fully assessed three previous time before we considered ourselves to be in an excellent position to prove our capability to manage our scope of practice. This was not the case; we were given a new assessment manager for this assessment who was not familiar with our discipline. The whole assessment was a significant challenge for the whole department which lead to one of the largest findings of NC we have ever known. These issues had obviously been either missed during previous assessments or not fully understood by the new team questioning the legitimacy of the whole process. After several months of providing evidence in an attempt to clear the NC and provide data to obtain the ETS for the Flexible scope it was denied with a very large assessment fee. Several months after this in October 2019 the Flexible scope

guidance was re drafted and became Gen 4 UKAS Policy and guidance for the implementation and management of flexible scopes of accreditation perhaps in preparation for a number of other laboratories to apply for this alternative scope.

In 2019 I enrolled for the DProf with the key aim of implementing the Flexible scope and evaluating how the implementation would impact on laboratory quality, efficiency, and cost effectiveness. It was clear now following the literature search that in Europe, the EA had allowed all medical laboratories to automatically move to the Flexible scope, posing the question why UKAS had not adopted this same approach. It also highlighted that accreditation was considered to be a valuable management tool with which to improve quality through the implementation and maintenance of quality laboratory systems (Boursier et al 2015; Zima 2017; Plebani and Lippi, 2017). Across Europe and the UK, it was being accepted and implemented using ISO 15189:2012 as the primary standard for the accreditation of medical laboratories (Huisman et al, 2007; Huisman, 2012; Hamza et al, 2013; Boursier et al 2015) without any empirical evidence to substantiate any claims of quality improvement.

In March 2020 the world and my doctorate encountered a significant period of uncertainty with the outbreak of the Corona virus pandemic. Unlike some of the world working from home did not become the new normal for my work life but it definitely did for the doctorate. Everything went to Zoom or Teams which came with benefits and also some negatives. It was a new skill, that needed to be embraced overnight. This was very helpful for attending training session at the university these all went virtual so were easier to attend than face to face. It also meant that we could keep in contact with supervisors and importantly the Saturday peer support group. It was also of use during the FGDs as Teams has the ability to record and transcribe the meeting to assist with the text of the sessions. It was also of benefit during the pandemic to capture any staff who may have been working from home, self-isolating or having difficulty with childcare.

This was a difficult time both personally and professionally trying to home school a teenager whist trying to work and focusing on my doctorate. Further delays due to Covid-19 in ETS applications with UKAS meant that the direction of the study had to be reassessed. It became clear that the second application made for the flexible scope was significantly behind and so a new direction was needed. Using the data already

collected for the pre-implementation section of the study which itself had created significant new knowledge. According to Greenfield and Braithwaite (2009), the fact that the empirical evidence base for accreditation, remains substantially undeveloped, creates a serious legitimacy problem for accreditation providers, policymakers, and researchers. The literature search corroborated this identifying that there were significant gaps in the empirical evidence around the implementation of laboratory accreditation (Peter et al, 2010; Wilson et al, 2016) and its effects on quality, efficiency, and cost effectiveness, if any, and the justify for adopting the flexible scope. The data collected so far could be used, and the theoretical framework could be adapted to create a model for other laboratories to use to evaluate their position was new and novel in the literature. Also, a robust methodological design was developed to collect and analyse the study data, this was again novel introducing a new cost effectiveness tool developed for the study. The mixed methodology including qualitative analysis using thematic analysis was new to the researcher and proved a challenge, but a new skill worth adopting. Where once I evaded Microsoft Excel for fear of the statistical package, I now embrace it and it is now my new best friend.

This study has involved both a significant personal and academic journey. Shifting a concept from theory into practice; obtaining results that are clear and coherent and positioning them within the reach of anyone in the field of medical laboratory science or pathology who would want to use them. Academically I feel I have a gained a number of innovative skills all of which have led to a newfound resilience with improved writing skills and a full range of research skills from literature searching to analysing data both from the quantitative and qualitative paradigms. For a while I was plague with imposter syndrome and now, having overcome these insecurities, I have confidence in my own abilities and knowledge enough to now own my own work with pride. Having to redefine and redirect the study during Covid-19 illustrates a capacity to overcome and recover quickly in order to keep within the study timeframe. This new confidence has also led me to strive to move towards harmonizing accreditation across the UK by forming collaborations with my peers in H&I and moving towards a movement to adopt the flexible scope for this specialist discipline. Also, to challenge the current position of UKAS and ask why the flexible scope has not been more widely employed by medical laboratories unlike Europe to allow more autonomy. Creating a potential dialogue with UKAS so that there is an understanding of the potential benefits

to their organisation when they are struggling to find peer assessors for the smaller specialist pathology disciplines and meet ETS timeframes.

Overall, the whole experience has proved to be challenging but also a valuable and, in most parts, enjoyable experience. It has provided me with academic tools that I never dreamed of and will remain with me for the rest of my life, positioning me now as an expert in my field!