A Delphi study exploring stakeholder perceptions of the role of the biomedical scientist in patient outcomes

A Delphi study exploring stakeholder perceptions of the role of the Biomedical Scientist in patient outcomes.

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ABSTRACT

Biomedical Scientists (BMSs) work in healthcare laboratories providing diagnostic testing and monitoring therapeutic effects on patients. The standards that govern the profession refer to working in the best interests of the patient and service user, yet BMSs have little or no patient contact. This raises the question of how BMSs relate their role to patient outcomes and how they evidence that they meet these requirements. This study explored stakeholder perceptions of the BMS role to determine whether there was a shared understanding of how the BMS role contributes to patient outcomes and how BMSs demonstrate that they work in the best interests of the patient and service user.

Round 1 of the Delphi study involved qualitative interviews and focus groups with staff and students on the BSc Biomedical Science programmes, practising BMSs within the National Health Service (NHS), and representatives from the Professional, Statutory and Regulatory Bodies (PSRB). Thematic analysis of the 1st round responses generated statements which participants scored using a Likert scale in round 2. The degree of divergence or consensus amongst stakeholders was assessed using a 70% consensus level.

In the 2nd round, there was evidence of divergence of opinion across the stakeholder groups. This demonstrated a gap between education and laboratory-based practice in both the student and academic groups which was described as a theory-practice gap. This was most evident in topics such as the BMS role in

patient care, professional registration and multi-disciplinary team (MDT) working. This is the first time a theory-practice gap has been identified with respect to the BMS workforce. This demonstrates a contribution to knowledge and practice of this study as students may not be adequately prepared for their role.

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ABBREVIATIONS

AHP: Allied Health Professionals

AP: Associate Practitioner

ASCP: American Society for Clinical Pathology

BMS: Biomedical Scientist

BMSs: Biomedical Scientists

CPSM: Council of Professions Supplementary to Medicine

DoH: Department of Health

ED: Emergency Department

EI: Emotional Intelligence

FEHW: Faculty of Education, Health and Wellbeing

FSE: Faculty of Science and Engineering

GDPR: General Data Protection Regulation

HCPC: Health and Care Professions Council

HPC: Health Professions Council (now the HCPC)

HRA: Health Research Authority

IBMS: Institute of Biomedical Science

ICS: Integrated Care Systems

IOM: Institute of Medicine

IR: Integrative Review

IRAS: Integrated Research Application System

KPI: Key Performance Indicator

MDT: Multi-disciplinary team

MLA: Medical Laboratory Assistant

MLS: Medical Laboratory Scientist

MLT: Medical Laboratory Technologist

MMAT: Mixed-Methods Appraisal Tool

MMR: Mixed-Methods Research

NGT: Nominal Group Technique

NHS: National Health Service

NICE: National Institute for Health and Care Excellence

PCC: Person-centred care

POCT: Point of Care Testing

PSRB: Professional, Statutory and Regulatory Bodies

QAA: Quality Assurance Agency

QC: Quality Control

RCP: Royal College of Pathologists

REC: Research Ethics Committee

SOP: Standard Operating Procedure

TAT: Turn-around time

TTP: Total testing process

UK: United Kingdom

UKAS: United Kingdom Accreditation Services

US: United States

WBIT: Wrong Blood in Tube

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CHAPTER 1. INTRODUCTION, CONTEXT AND AIM

1.1 Introduction

Biomedical Scientists (BMSs) form part of the scientific healthcare workforce within the United Kingdom (UK). However, the BMS role in patient outcomes, and the way in which BMSs evidence the impact of their practice on patient outcomes has not been previously described. This research aimed to consider stakeholder opinions of how the BMS role contributes to patient outcomes and to understand whether a lack of understanding of this aspect of the role impacts upon performance. As outlined in chapter 5, this study represents both a contribution to practice and to knowledge. The introductory chapter provides background and context of the BMS role before exploring the importance of the pathology service in patient care. The introductory chapter concludes with the exploratory aim and research focus.

1.2 Background and Context: The Biomedical Scientist role

BMSs are responsible for the preparation, analysis and reporting of pathological specimens, escalating abnormal results to clinical staff in a timely manner (Becich *et al.,* 2004; Royal College of Pathologists, 2011; Beastall, 2013; Croal, 2017). The BMS role involves little or no patient contact, but laboratory data reported by BMSs is essential for patient management and care. The regulatory body for BMSs is the Health and Care Professions Council (HCPC) who award the protected title of 'Biomedical Scientist' following the successful completion of an Institute of Biomedical Science (IBMS) accredited degree (or equivalent), a

period of laboratory-based training and an end-point assessment called the Certificate of Competence (see figure 1.1).

The professional body is the IBMS which have developed a portfolio, against which trainee BMSs can evidence that they meet the threshold HCPC standards to practice as a Biomedical Scientist (IBMS, 2018b). The IBMS also provide guidelines for professional practice in biomedical science (IBMS, 2018a), supporting registrants to meet the HCPC standards (HCPC, 2014). The IBMS offers professional qualifications, accredits training laboratories, accredits degree courses and co-ordinates statutory registration on behalf of the HCPC. The Biomedical Scientist title is protected by law, and it is a criminal offence for an individual to use this title when not entitled to (HCPC, 2018b). Increasingly, HCPC registration is achieved through the completion of a placement year in an accredited laboratory as part of an integrated BSc Applied Biomedical Science programme, therefore education providers are pivotal in supporting student understanding of the BMS role.

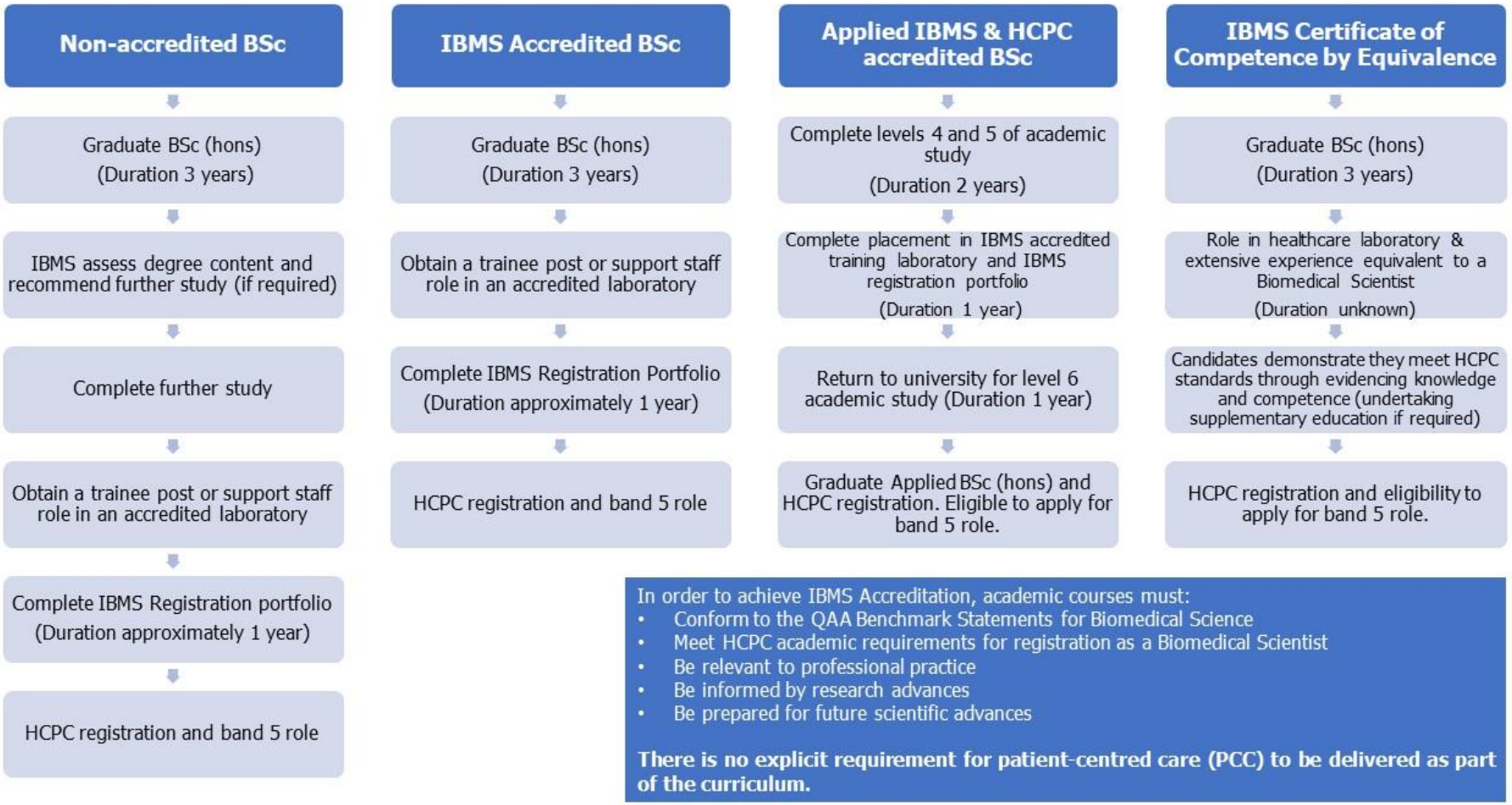


Figure 1.1. Available pathways to achieving HCPC registration as a Biomedical Scientist (IBMS, 2018b; 2020b; 2021b).

1.3 The Professional and Regulatory bodies

The Health Professions Council (HPC) (now the HCPC) was established as the regulatory body for professions allied to medicine in 2001, replacing the Council of Professions Supplementary to Medicine (CPSM) (HCPC, 2015). The HCPC was set up to protect the public, ensuring healthcare professionals meet the threshold standards of education, training, conduct and professional competence. The HCPC regulates 15 healthcare professions, determining standards of conduct, performance and ethics which apply across all registered allied health professions (HCPC, 2016). Each profession must also comply with role specific standards of proficiency, which include some standards common across multiple professions (HCPC, 2014).

The HCPC standards recognise that some regulated professions work with patients, some with clients and some with service users. The term '*service user*' is favoured in the BMS specific standards (HCPC, 2014) and is defined as "anyone who uses, or is affected by the service of registrants, for example patients or clients" (HCPC, 2016 p. 13). For BMSs, service users include both patients and clinicians using the laboratory service. Describing the patient as a *'service user'* could be considered as dehumanising or distancing the patient from the BMS role and making it more challenging for BMSs to identify their role in patient outcomes. Language used in healthcare is important because dehumanising healthcare language allows patients to no longer be seen as individuals (Dawson, 2021).

Most HCPC regulated professions require patient contact meaning that the generic standards do not explicitly state how registrants evidence that they meet these requirements. Not all graduates of the BSc Biomedical Science award aspire to a BMS career and the diverse range of career aspirations for Biomedical Science graduates is challenging for ensuring appropriate curriculum content. Academics on the BSc Biomedical Science award are from diverse backgrounds, including practitioners and researchers which contrasts with other healthcare professions, such as nursing, where most academics are experienced practitioners (Drennan, 2008).

Application of the professional standards frameworks can be challenging to apply to the BMS role. For example, HCPC standard of proficiency 2.4 states that registrants must "understand the need to respect and uphold the rights, dignity, values and autonomy of service users, including their role in the diagnostic and therapeutic process and in maintaining health and wellbeing" (HCPC, 2014 p. 7). BMSs may struggle to identify the patient's values due to a lack of patient contact and are likely to understand the patient's role in the diagnostic process as an abstract concept. The IBMS guidelines are more explicit about the importance of the patient, stating that "patient safety and delivery of a high-quality care is the expectation of all biomedical science professionals" (IBMS, 2018a p. 2). The way in which BMSs relate to these requirements required further exploration.

1.4 The Role of the Laboratory in Patient Care

Significant abnormal results are communicated to the requesting clinician urgently to accelerate appropriate action. The BMS role involves analysing a wide

range of different specimen types and BMSs specialise within a specific discipline once professionally registered. The BMS role is essential to the function of many hospital departments, including emergency department (ED), maternity and theatres, in addition to primary care services. Despite this, pathology services are considered by many to be a backroom function (Department of Health (DoH) 2006; DoH, 2008). This may impact upon ways in which the BMS role is linked to the patient's care pathway and patient outcomes.

Historically within the UK, and in some international settings such as the United States (US) and Canada, the laboratory scientist role involved specimen collection and analysis, providing a degree of patient contact. Within the UK, this patient contact has been largely removed as increasing laboratory workloads necessitated healthcare assistant roles, such as phlebotomists and medical laboratory assistants (MLAs) (Hand, 2007). This inevitably changed the BMS role, but professional guidelines remain focused upon the importance of the patient. This change poses the question of whether the professional guidelines and educational delivery reflect the requirements of practice to adequately prepare BMSs for a role in healthcare. Internationally, the education and training for the laboratory scientist role differs to the UK BMS role. In the US and Canada, the Medical Laboratory Technologist (MLT) or Medical Laboratory Scientist (MLS) role includes specimen collection and analysis. Registration as an MLT or MLS requires the candidate to complete a Board of Certification examination by the American Society for Clinical Pathology (ASCP).

Patient outcomes and clinical outcomes have no agreed international definition, but are generally considered to be the change in health of an individual or group attributable to an intervention (Healthcare Costing for Value Institute, 2016). Most clinical outcomes are measured using a disease model, where a pathological assessment of disease is determined by clinical presentation and symptoms (Bowling, 2005). Traditionally, clinical outcomes include mortality rate, morbidity or physical symptoms. However, this disease-centred approach does not consider meaningful measures of health status and quality of life from a patient's perspective and further removes the focus from the patient for the BMS workforce. Furthermore, the BMS role in contributing to patient outcomes and how BMSs strive to achieve these has not been defined in professional guidelines.

1.5 Laboratory Medicine and the Pathology service

Pathology services impact upon the lives of almost all patients, costing the NHS between £2.5 and £3 billion per annum and representing 1.5-3% of NHS expenditure (DoH, 2016). Estimates suggest that in excess of 70% of diagnosis and treatment decisions within the NHS are dependent upon pathology results (DoH, 2006; Hallworth, 2011; Ferraro, Braga and Panteghini, 2016). There are 26,136 BMSs working within the UK NHS (NHS Digital, 2022), suggesting this large scientific workforce is responsible for diagnostic testing of significant sample numbers and impact numerous patient care pathways. Incorrect laboratory results or inappropriate reporting can impact upon patient care leading to unnecessary diagnostic procedures, patient anxiety or even fatality (Plebani, 2014). In England, per annum, there are approximately 500 million

biochemistry tests, 130 million haematology tests and 800 million overall pathology tests performed, equating to fourteen tests per person in England and Wales (DoH, 2006; NHS England, 2014).

In the UK, pathology services are broadly divided into blood sciences (haematology, transfusion, biochemistry and immunology), microbiology, cellular pathology and cytology. Pathology services are provided by BMSs, support staff in MLA or associate practitioner (AP) roles, clinical scientists and consultants who specialise in a pathological discipline. The pathology service aids patient diagnosis and management, but there is little published evidence of the Biomedical Scientist's role in the healthcare process. In this thesis, laboratory medicine was defined as all stages of laboratory testing as carried out by a laboratory scientist.

The role of the BMS workforce in patient care is difficult to quantify due to the integrated nature of the healthcare system. Beneficial laboratory testing requires processes to be initiated at the right time, on the right patient and actioned in a timely fashion (Plebani, Laposata and Lundberg, 2011; Epner, Gans and Graber, 2013; Plebani, 2014; 2016). Rapid and accurate laboratory reports ensure referral of the patient to an appropriate clinical team for further investigation or treatment (Beastall, 2013). The BMS role is important to ensure other healthcare professionals can carry out their role effectively, but the extent to which the BMS role impacts upon patient outcomes has not been defined.

1.6 Drivers for Change in the Configuration and Deliver of Pathology Services

DoH (2006) published a report into pathology services which concluded pathology was a significant cost for healthcare services and staffing constituted a significant proportion of the NHS budget. The report made recommendations for changes to the pathology service, recognising a key role in the end-to-end patient journey as part of an integrated healthcare system (DoH, 2008). Driven by difficulties in staff recruitment and retention and the need to run pathology services as an end-to-end function within healthcare, managed pathology networks to meet the needs of patients and carers within a geographical area were proposed (DoH, 2006; 2008). These proposed networks had a single management structure, integrating pathology services over several sites. This would eliminate unnecessary testing and reduce the cost per test with a high-throughput laboratory, allowing greater buying power across the network (Alderwick *et al.,* 2016). These recent changes in the profession have focused primarily upon cost savings, whilst further distancing the importance of patient outcomes in the BMS role. McCreanor (2017) argues there is a risk that reducing pathology expenditure may have adverse consequences for patients and delay diagnosis and treatment.

In 2017, NHS Improvement proposed that the 122 NHS laboratory sites in England should integrate to become 29 pathology networks, saving the NHS a proposed £200 million by 2021 (NHS England and NHS Improvement, 2019). However, these proposed savings have been heavily criticised due to the

difficulty in identifying costs directly attributable to pathology services and due to inaccurate data included in the report (McCreanor, 2017). It was proposed that integration of pathology services across a geographical area would result in co-ordination of assay provision, staffing and analytical platforms, but the logistics of delivering this have proved challenging. These changes further distanced the BMS from the patient and others within the MDT.

All 29 pathology networks were working towards consolidation, with 97% engagement across pathology networks and 76% of networks on target to meet the 2021 target timescale (NHS England and NHS Improvement, 2019). However, there has been no further update on this target and current savings of only £33.6 million have been achieved (NHS England, 2018). This suggests that the proposed target and associated savings are unlikely to be achieved within the timescale. The challenge of aligning analytical platforms, reference ranges and staff recruitment and training across multiple sites has impacted upon this. This has had a major impact upon the profession and potentially perceptions of the BMS role in patient outcomes.

The impact of establishing pathology networks in England on the BMS role is unknown, but as delivery of pathology services has changed and continues to change, this will inevitably impact the role. In some cases, BMSs are reporting results over a wide geographical area and liaising with clinicians in other organisations or NHS Trusts. Although, beyond the scope of this thesis, a BMS working on a different hospital site may feel further distanced from the patient, which may influence their ability to focus upon patient outcomes. Hence, the

changing scope of the BMS role is important to provide context of relevant major changes in the profession, particularly as these changes have further distanced the patient from the BMS role.

1.7 Rationale for the Study

This thesis arose because of my background as a BMS within the NHS. I began working as a trainee BMS in 2007 and progressed to a Senior BMS role and then took on additional responsibility for training. Through my BMS role and training responsibilities, I became interested in why some BMSs are more focused on the impact of their actions upon patient care. In particular, I was intrigued whether this could be taught, developed through training or was an innate quality. In 2016, I began the role of Lecturer in Biomedical Science within a University setting, specialising in haematology and transfusion.

The study aimed to identify stakeholder perceptions of the BMS role in supporting diagnosis and treatment decisions. In this thesis, stakeholders were defined as persons or organisations with a vested interest in the topic being considered (Schmeer, 1999), in this case the BMS role. The motivation for this research arose from my experiences as a BMS, where some colleagues were highly motivated by the desire to 'help the patient', and yet other colleagues likened their role to factory work, considered repetitive and boring, suggesting a focus upon achieving patient outcomes may influence job satisfaction. As an academic supporting students completing a 12 month NHS laboratory placement, I discuss the importance of meeting the HCPC standards (HCPC, 2014; 2016), but recognise, from professional practice, that evidencing ways to meet these

standards can be challenging. By identifying how BMSs can evidence that they put the patient first as part of their role, these concepts can be included in the undergraduate curriculum and professional training, with a view to improving patient care.

1.8 The Importance of Person-Centred Care (PCC)

In the UK, the NHS constitution highlights seven key principles considered important NHS values (DoH, 2015). According to the NHS constitution 'The patient will be at the heart of everything the NHS does' (DoH, 2015 p. 3), which includes involving patients, families and carers in decisions about care and treatment. There are six key NHS values, including compassion, which is central to NHS care and requires staff to respond to patients with humanity and kindness (DoH, 2015). Despite these being key concepts for all staff working in the NHS, the lack of patient contact associated with the BMS role makes evidencing these characteristics challenging.

Person-centred care (PCC) is explicit within legislation in the 2008 Health and Social Care Act, stating that care and treatment of service users must be appropriate and meet their needs and preferences (The Health and Social Care Act, 2008). Several of the elements of PCC described in the Health and Social Care Act (2008), would be difficult to achieve for healthcare professionals without direct patient contact. For example, 'designing care or treatment with a view to achieving service users' preferences and ensuring their needs are met' (The Health and Social Care Act, 2008 p. 8) may be interpreted differently if the Biomedical Scientist's service user is considered as the patient, the clinical team

caring for the patient, or both. If the patient is the service user, the BMS would not be able to recognise service users' preferences as they would be largely unaware of these. However, if the clinical team are regarded as the service user, then the service user's preferences and needs may not reflect those of the patient.

The National Institute for Health and Care Excellence (NICE) guidelines for improving patient experiences of NHS services provide a series of recommendations for how PCC can be achieved in practice, including recommendations such as knowing the patient as an individual and respecting their wishes (NICE, 2016). These guidelines are applicable to all staff within NHS organisations. However, there is little scope within the BMS role to 'know the patient as an individual'. Respecting the patient's wishes is challenging because this relies upon communication with the patient. These qualities are desirable in the US healthcare system, where the Institute of Medicine (IOM) made recommendations for improving healthcare by addressing several quality issues, including patient-centredness (Institute of Medicine, 2001). Internationally, there is literature applying the IOM recommendations to laboratory medicine and improving the quality of the laboratory service to meet the IOM aims (Golemboski, Otto and Morris, 2013; Plebani, 2016). This study sought to address whether a similar approach is required with respect to the UK BMS workforce.

PCC is a key but contested concept which is widely discussed in healthcare literature as an important aspect of high-quality care. PCC allows for shared

decision making and for patients to have an input into their care. However, an accepted definition of PCC has proved challenging, with some authors arguing the term has been used to describe high-quality healthcare, whilst others suggest it has been used as a token gesture and for political gains (McCance, McCormack and Dewing, 2011; Scholl *et al.,* 2014; McCormack *et al.,* 2015). Discussions of PCC often focus upon clinicians rather than other healthcare professionals, with literature suggesting clinicians must demonstrate empathy, be respectful, honest and compassionate (Scholl *et al.,* 2014). However, there seems no reason why these qualities can only be evidenced by clinicians, suggesting other healthcare professionals need wider acknowledgement in patient care.

According to McCormack and McCance (2017) there are four key aspects of person-centredness which are: being in relation, being in a social world, being in place and being with self. This framework was originally designed for nurses but has been developed to apply to all healthcare professionals. Being in relation highlights the importance of relationships between healthcare professionals and the patient for therapeutic benefit. Being in social context recognises the need for healthcare professionals to listen to and respect the patient's story to identify the impact of care decisions. Being in place recognises the emotional connections that a patient has with their surroundings. Being with self highlights the right of every patient to be identified as a person and respecting the person's values is at the core of PCC (McCormack and McCance, 2017). However, these qualities rely upon a healthcare professional having a degree of patient contact, which is challenging for BMSs, suggesting an alternative framework is required to allow those without direct patient contact to evidence their role in PCC.

PCC is often described as what it is not, for example, it is not disease-centred or clinician-centred (Epstein *et al.,* 2010). However, achieving a common appreciation of the attributes which comprise PCC has been more elusive. PCC is established through forming and developing therapeutic relationships between care providers, patients and their carers (McCormack and McCance, 2017). The key aspects of the person-centred practice framework are presented in figure 1.2. Communication is a key aspect of PCC and facilitates shared understanding and decision making (Starfield, 2011). Although establishing therapeutic relationships and communication channels are challenging for BMSs due to a lack of patient contact, providing high-quality care with the patient at the centre is a key aspect of the BMS role. PCC can be interpreted differently by individuals, making it challenging to define and implement (Health Innovation Network, 2017). Therefore, the central concept of PCC and how it can be applied to the BMS role will be discussed throughout this thesis. There are some aspects of PCC which are common across multiple definitions, including being respectful to the patient's preferences, demonstrating compassion, empathy and supporting shared decision making. However, what it means to put the 'patient at the centre' or 'work in the best interests of the patient', terms which are often used with respect to the BMS role, do not feature within the PCC literature.

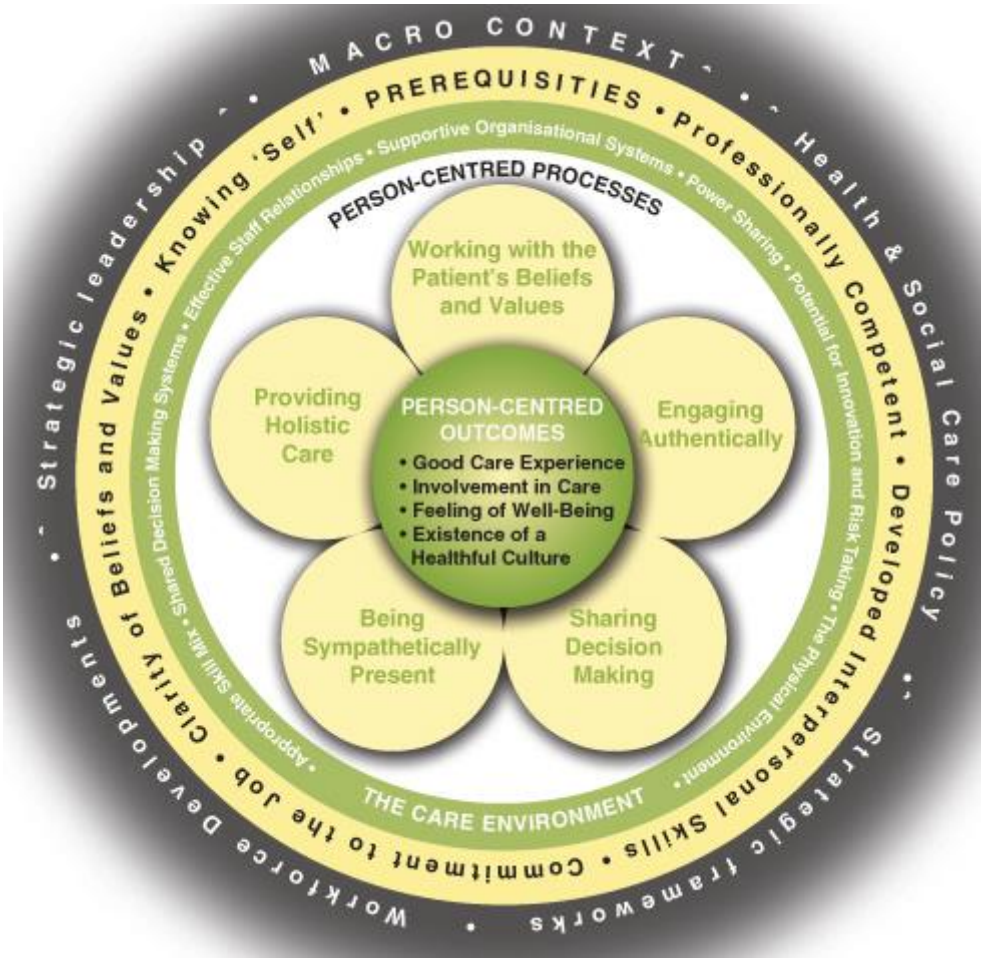


Figure 1.2. The Person-Centred Practice Framework re-presented (McCormack and McCance, 2017). Copyright holder permission in Appendix 19.

1.9 Purpose and Scope

The BMS role in healthcare is poorly understood by those external to the profession, with many patients and healthcare professionals unaware of the role and what it involves (DoH, 2006; Ferraro, Braga and Panteghini, 2016). This thesis aimed to explore stakeholder perceptions of the BMS role in patient outcomes. Stakeholders included practising BMSs, academics delivering the pre-registration Biomedical Science programmes and final year students on both the BSc Biomedical Science programme (without an integrated placement) and the BSc Applied Biomedical Science programme (including an integrated placement). Representatives from the IBMS, HCPC and DoH were invited to participate, as

these individuals have input into the professional guidelines and standards which govern the profession. These stakeholders considered how the BMS role contributes to patient outcomes to determine whether this is important within the role. In addition, this thesis determined stakeholder views on the factors which influence how BMSs contribute to patient outcomes and PCC.

This area was worthy of research because BMSs make up a significant proportion of registered healthcare staff employed within the NHS. The impact of laboratory testing upon patient care is recognised, with at least 70% of all diagnosis and treatment decisions being based upon pathology results (DoH, 2006; Hallworth, 2011). The professional guidelines provided by the IBMS and HCPC contain references to the importance of the patient and service user within the BMS role (HCPC, 2014; 2016; IBMS, 2018a). However, how this is manifested within the BMS role has not been elucidated and has the potential to influence policy, education, training and job satisfaction. This thesis aimed to determine whether the policies provided by the professional and regulatory bodies align with professional practice and are supported by education and training. It was essential to determine how BMSs gain understanding of the patient-orientated aspects of the role and whether education providers are adequately preparing students for practice through their undergraduate studies and professional training.

1.10 Research Focus

The aim of this study was to explore if there is a shared understanding within the biomedical science community and key stakeholder groups of how the BMS

role contributes to patient outcomes. The study also aimed to determine whether stakeholders expected BMSs to contribute directly to patient outcomes so that these key concepts can be delivered through the education of the future BMS workforce. This necessitated investigation of stakeholders' views on those factors which may impact upon the Biomedical Scientist's contribution to PCC and patient outcomes. To address the aims of the study, the following research questions were developed:

- Is there consensus between stakeholders regarding the role of Biomedical Scientists in contributing to patient outcomes?
- Is there a shared understanding amongst stakeholders of recognising how Biomedical Scientists work to achieve patient outcomes?
- What are the opinions of stakeholders regarding the importance of achieving patient outcomes in the Biomedical Scientist role?
- Can stakeholders identify how it can be recognised that Biomedical Scientists are working to achieve patient outcomes?

1.11 Structure of the Thesis

Chapter 2 will consider the importance of the BMS role within patient outcomes through an integrative review (IR) of the published literature (Whittemore and Knafl, 2005). Details of the literature search strategy and the inclusion and exclusion criteria used to identify the articles for analysis are included. The research aims and objectives are presented following a review of the literature.

Chapter 3 will present the methodology of the Delphi study. Delphi methodology utilises a panel of experts to determine whether there is consensus on an issue and is routinely employed in nursing and healthcare research (Keeney, Hasson and McKenna, 2011). This Delphi study consisted of two rounds; the first round consisted of two focus groups with stakeholders (one with academics and one with students on the BSc Biomedical Science awards) as well as interviews with BMSs and representatives from the Professional, Statutory and Regulatory bodies (PSRB). The 2nd round consisted of a questionnaire where stakeholders scored agreement using a Likert scale. Within this chapter, the epistemological and ontological implications of the Delphi methodology will be explored and justified. The development of the research focus and interview schedule will also be considered before outlining the process of thematic analysis (Braun and Clarke, 2013). The subsequent development of the 2nd round item pool and attitude statements will be presented.

Chapter four will present the findings and discussion of the study, beginning with the results of the 1st round thematic analysis and illustrative quotes from the participants. The findings of the 2nd round questionnaire which scored participants' agreement with a series of statements using a Likert scale will be presented. The degree of consensus or divergence of opinion for the statements will be outlined. The findings will then be contextualised within the published literature.

Chapter five will include discussion of the strengths and limitations of this study, recommendations for practice and for further research. The contribution of this

study to the field will be discussed along with the potential implications for practice.

CHAPTER 2. A REVIEW OF THE LITERATURE

2.1 Introduction

This chapter presents an IR of selected literature which has provided the foundation for this thesis. The chapter discusses the methodological approach to the literature search, selection of suitable sources and justification for inclusion. The selected literature was summarised, and a critique of the strengths and weaknesses was performed. This was followed by a constant comparison analysis of the literature and identification of common themes. Finally, discussion of the areas considered lacking within the literature and the rationale for the research aim and questions are provided.

2.2 Integrative Review Methodology

An IR following the model proposed by Whittemore and Knafl (2005) was performed. IR is a systematic and rigorous methodology, whilst allowing the utilisation of empirical and non-empirical sources to enhance understanding of a topic (Whittemore and Knafl, 2005; Souza, Silva and Carvalho, 2010). Whittemore and Knafl's IR framework was followed as it demonstrates a robust literature search and data analysis procedure and ensures quality outcomes for the IR through the five stages outlined below. Alternative frameworks for IR exist, such as the six-stage IR framework described by Souza, Silva and Carvalho (2010). However, the methodology of Whittemore and Knafl (2005) was followed as the five-stage process was designed to enhance rigour in the IR based upon the methodology traditionally associated with a systematic review.

2.2.1 Searching the Literature

Following an initial scoping search, it was evident the field of literature was limited and there were few relevant studies which considered the BMS role. Several approaches to the literature review were considered, including a systematic review, but as there were very few quantitative studies in this area, a systematic review was not suitable, whereas an IR utilises a range of literature types. An IR allows the inclusion of experimental, non-experimental and theoretical literature, providing a broad review of the literature (Whittemore and Knafl, 2005; Aveyard, Payne and Preston, 2016; Toronto and Remington, 2020).

2.2.2 Stage One: Problem Identification

The problem identification stage identifies the research problem and purpose of the review (Whittemore and Knafl, 2005). The role of the laboratory scientist within healthcare is poorly understood by patients and other healthcare professionals (Grant, 2009; Fraser *et al.,* 2013). Anecdotal evidence exists from laboratory professionals of the perceived importance of their role within patient outcomes (Hallworth, 2011; 2015). However, this has been poorly explored in the literature and terms such as 'working in the best interests of the patient' have not been defined, which allows individual interpretation of the guidelines and a variation in expectations.

2.2.3 Stage Two: Literature Search

The literature search question was developed using an adapted version of the Sample, Phenomenon of Interest, Design, Evaluation, Research type (SPIDER) tool developed by Cooke, Smith and Booth (2012). The SPIDER tool was

developed because the Population, Intervention, Comparison, Outcome (PICO) tool was not considered appropriate for qualitative or mixed-methods research (Cooke, Smith and Booth, 2012). The SPIDER synonyms used as part of this literature search can be seen in table 2.1.

Table 2.1. SPIDER synonyms used to expand the key terms when conducting the literature search.

Sample	Phenomenon of Interest	Design	Evaluation	Research type
"Biomedical Scientist"	Patient centred care	Not included	Not included	Qualitative
"Medical Laboratory Scientific Officer"	Patient centered care			Quantitative
"Medical Laboratory Scientist"	Patient focused			Mixed-methods
"Medical Laboratory Technician"	Patient oriented			
"Healthcare Scientist"	Patient orientated			
"Clinical Laboratory Scientist"	Person centred care			
"Medical Laboratory Science"	Person centered care			
	Patient outcomes			
	Health outcomes			
	Clinical outcomes			

The literature search terms were identified following an initial scoping search to identify key words regarding the pathology laboratory workforce. These were developed using synonyms and terminology relevant to both the UK and US healthcare systems. All known current terminology for 'Biomedical Scientist' in

the UK was included (Healthcare Scientist is an alternative current title, whilst Medical Laboratory Scientific Officer (MLSO) is a historical term), whereas in the US, the programme of education and training leads to registration as an MLS or MLT.

The literature review question which this chapter aimed to address was 'what is the role of the Biomedical Scientist within patient outcomes?'. The literature search was conducted in January 2020 and followed an extensive and systematic approach (table 2.2) across eight relevant databases which included CINAHL Plus, Medline, Cochrane, PubMed, Nursing and Allied Health, Embase, EThOs and Web of Science, as well as BASE grey literature. Alert updates were established across all databases and monitored throughout the study up until submission. No relevant additional articles were identified during this time. Boolean operators were utilised to combine individual searches.

Table 2.2. The literature search strategy employed across all databases. Search 1 and search 2 were conducted separately and the results of the two searches combined within the database.

Search 1		**Search 2**
"Biomedical Scientist" OR	AND	Patient centred care OR
"Medical Laboratory Scientific Officer" OR		Patient centered care OR
"Medical Laboratory Scientist" OR		Patient focused OR
"Medical Laboratory Technician" OR		Patient oriented OR
"Healthcare Scientist" OR		Patient orientated OR
"Clinical Laboratory Scientist" OR		Person centred care OR
"Medical Laboratory Science"		Person centered care OR
		Patient outcomes

Search 1		Search 2
		OR
		Health outcomes OR
		Clinical outcomes

The criteria selected for inclusion in the review are shown in table 2.3. The date limitation was applied to identify articles published since January 2002, as the HPC did not become fully operational until April 2002 (HCPC, 2015).

Table 2.3. The inclusion and exclusion criteria applied.

Inclusion	Exclusion
January 2002 onwards	Pre 2002
Scientific healthcare workforce	Studies without reference to the laboratory
English language	
Any methodology	
Peer-reviewed	
Primary or secondary articles	

The search identified 149 articles from EBSCO host databases and 1,367 from other databases and sources. After duplicates were removed, 1,490 articles remained which were further selected or rejected via the abstract content. There remained 99 articles which were then further assessed for relevance via the abstract, resulting in 39 articles, of which 18 met the inclusion and exclusion criteria for the review. These articles were selected for critical appraisal utilising an appropriate Critical Appraisal Skills Programme (CASP) tool (Critical Appraisal Skills Programme, 2018) or Joanna Briggs Institute appraisal tool (McArthur *et al.,* 2015). For primary research articles, a quality appraisal score was determined (Kmet, Cook and Lee, 2004; Hong *et al.,* 2018). The remaining included articles were identified by hand-searching. The number of studies

included and excluded at each stage of the literature search process are shown in a PRISMA chart (figure 2.1) (Liberati *et al.,* 2009).

Opinion pieces were appraised by considering the expertise of the author, whether sufficient literature had been consulted and whether there was rationale for the author's argument (MacArthur *et al.,* 2015). The review articles were appraised by considering the quality of the literature review process carried out by the authors, how the quality of the reviewed articles was determined and how this information was combined into a review (Critical Appraisal Skills Programme, 2018). The inclusion of secondary literature in the review is a recognised limitation but was necessary due to the limited range of primary literature in this field.

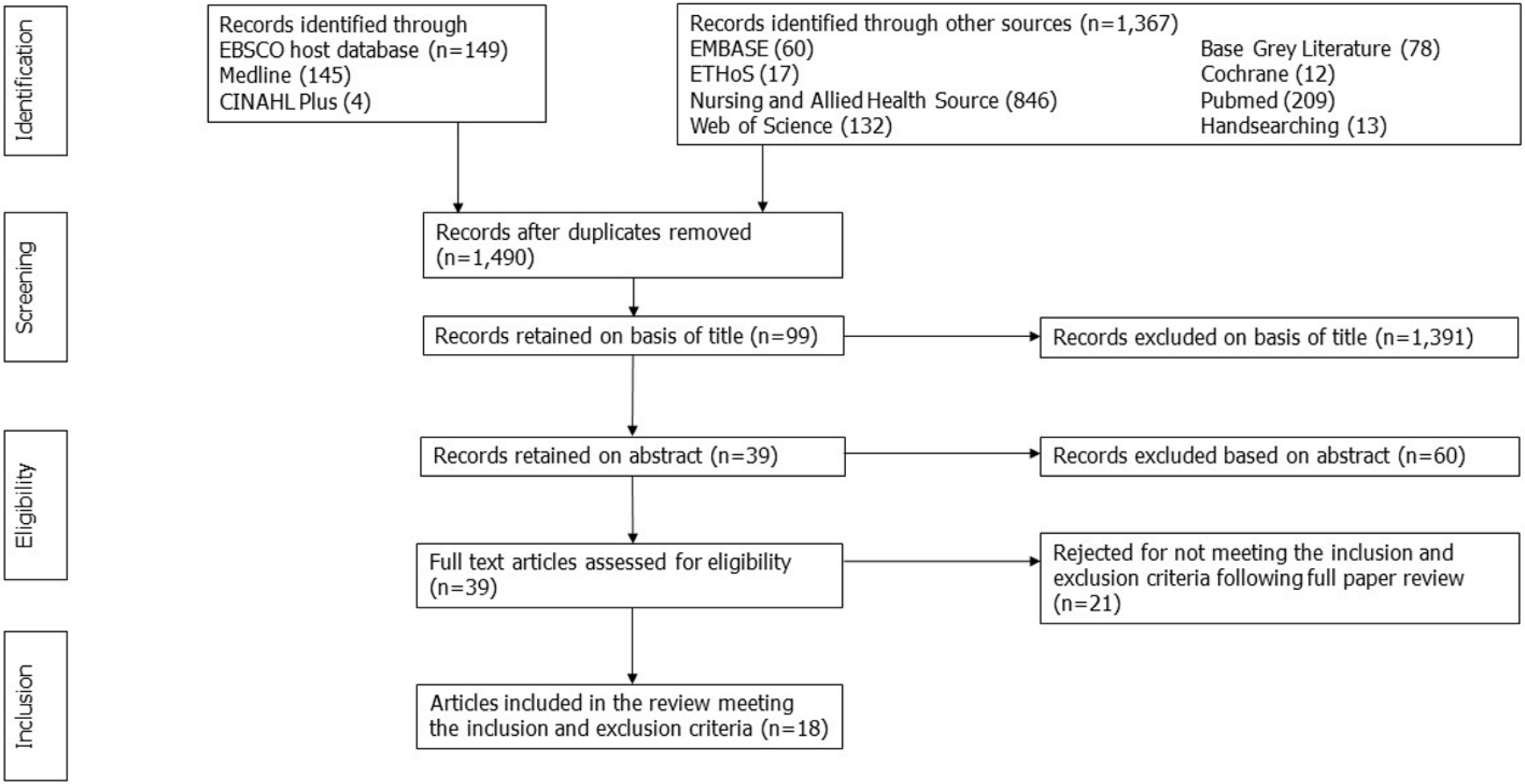


Figure 2.1. PRISMA flow chart showing selection of articles for inclusion in the review (Liberati *et al.,* 2009).

2.2.4 Stage Three: Data Evaluation

To assess quality of mixed-methods research (MMR), a mixed-methods appraisal tool (MMAT) was used (Hong *et al.,* 2018). Quality appraisal scores for qualitative and quantitative primary literature were determined using the Kmet, Cook and Lee (2004) scoring system. This system analyses qualitative and quantitative studies and scores them on a number of parameters as either fully met (2), partially met (1) or not met (0) (Kmet, Cook and Lee, 2004). This score is then divided by the total possible score to give a percentage quality score for the research. The literature selected for inclusion consisted of 18 articles, of which 4 were primary research and the remaining 14 were secondary literature. The primary articles comprised 2 quantitative, 1 qualitative and 1 mixed-methods study.

2.2.5 Stage Four: Data Analysis

The data analysis stage of an IR requires the selected sources to be ordered, coded and categorised to identify appropriate themes which are summarised to draw an integrated conclusion (Whittemore and Knafl, 2005). This involved a process of data reduction and display, as seen in table 2.4 (Whittemore and Knafl, 2005). Data analysis occurred using a constant comparison technique, which converted extracted data into systematic categories (Whittemore and Knafl, 2005). The literature was examined to identify themes and patterns following an item-by-item comparison. Four key themes were identified within the literature:

a. The importance of maintaining a high-quality laboratory service
b. The wider impact of laboratory services on healthcare

c. The role of laboratory services in achieving patient outcomes
d. The technical and analytical nature of the laboratory scientist role

Many of the papers focused upon the US or Canadian healthcare systems, with few articles referring to the UK systems. This international literature was selected for inclusion due to a lack of UK-based literature. It was considered important to draw comparisons with a closely related international healthcare profession due to the better-established research fields regarding the laboratory scientist role in the US and Canada.

2.2.5.1 The importance of maintaining a high-quality laboratory service

The importance of providing a high-quality laboratory service was identified in 12 of the 18 included articles, as detailed in table 2.4. Patient safety featured strongly as one of the key aspects of a high-quality laboratory service (Bennett *et al.,* 2014).

Birse (2010) conducted a study focused upon the patient safety climate amongst Canadian MLSs. This was a quantitative study with questionnaire responses from 1210 members of the Canadian Society for Medical Laboratory Science in which participants scored a series of patient safety questions using a Likert scale. There was no reference to whether ethical approval was obtained. The study had a low response rate of 11.2%, meaning findings have a greater risk of low validity, with minimum acceptable response rates considered as 60% and above (Fincham, 2008; Morton *et al.,* 2012). The study reported 69.4% of respondents perceived the laboratory patient safety climate as positive, with 97% believing

that laboratory professionals have a role in patient safety and 80.9% perceiving patient safety to be a priority within their laboratory (Birse, 2010). However, an explanation of how MLSs can prioritise patient safety was lacking. The author concluded that in the Canadian MLS profession, laboratory personnel are seemingly intuitive that they have a role in patient safety.

Hilborne, Lubin and Scheuner (2009) conducted a narrative literature review focused upon patient safety and the role of laboratory professionals in the US. However, the authors acknowledged patient safety and quality issues in the laboratory were not restricted by geographical location. The literature search strategy used in the article was not provided and there was no discussion of how the quality of the literature was appraised. The review concluded that no patient should be harmed because of a laboratory error, and steps must be implemented to ensure abnormal laboratory findings are acted upon (Hilborne, Lubin and Scheuner, 2009). This conclusion was supported by Hallworth *et al.* (2015). This aspect of the role is reliant upon the multi-disciplinary team (MDT) to action any abnormal findings and it is essential to recognise that laboratory medicine cannot exist in isolation. Whilst laboratory professionals have an impact upon patient safety due to the number of specimens received, correct clinical actions must be initiated based upon laboratory results to ensure appropriate patient outcomes.

Morris, Otto and Golemboski (2013) gave a narrative review focused upon the importance of patient safety in the undergraduate curriculum for MLSs by considering how graduates are prepared to meet the IOM Quality Aims (Institute of Medicine, 2001). This article focused upon the US MLS role and concluded

that the IOM Quality Aims were not integrated into the MLS curriculum, leaving graduates poorly equipped for practice. Although the IOM quality aims are not applicable to UK healthcare, PCC is considered a central aspect. The authors stated that laboratory professionals must focus upon enhancing quality and patient safety and embedding these into the curriculum (Morris, Otto and Golemboski, 2013). Whilst these recommendations apply to the US MLS curriculum, these aspects were absent from the Quality Assurance Agency (QAA) Benchmarks (QAA, 2019) suggesting that students may not receive these key aspects of their education through their degree programme, instead placing the burden on the employer.

Otto (2011) provided a review of the literature focused upon patient safety and the medical laboratory. This article provided a brief overview of the literature, written by an MLS in the US. Patient safety was defined as the avoidance and prevention of adverse outcomes or injuries that arise during care, but recognised the complexity of the healthcare system meant each interaction with a patient impacted subsequent processes (Otto, 2011). The author concluded that to provide high-quality and safe patient care, laboratories must aspire to improve patient's lives, but there was no discussion of how this can be achieved. In the UK, it would be unlikely that a BMS would be aware of how an individual test has impacted upon a patient's life and this is arguably not a realistic expectation.

Plebani (2002) conducted a literature review which considered the wider role of laboratory medicine in healthcare. The author was based in Italy and focused upon features of the Italian healthcare system, but also referred to the UK

systems. Laboratories must focus upon effectiveness and patient outcomes, rather than just efficiency in laboratory testing (Plebani, 2002). This assertion was also noted by Hallworth (2015). Plebani (2002) concluded that it was essential to support clinical areas to improve pre-analytical and post-analytical aspects of the total testing process (TTP) to improve patient outcomes and patient-centred services. Inaccurate or incorrect laboratory results may compromise patient care, leading to anxiety and unnecessary investigations. Plebani (2002) stated that the effect of laboratory services on patient outcomes should be further investigated through clinical audit, but this does not address the contribution of the BMS.

Plebani, Laposta and Lundberg (2011) conducted a narrative review of the TTP and the 'brain-to-brain loop' whereby a laboratory test is considered from requesting through to actioning results. The article considered errors in laboratory testing and the risk of patient harm, concluding that the pre-analytical and post-analytical aspects of laboratory testing are associated with the greatest risk of error. This observation was also made by Beastall (2013) and Ferraro, Braga and Panteghini (2016). The pre-analytical and post-analytical stages largely lie outside of the laboratory's control, with pre-analytical errors referring to those during specimen collection, transportation or pre-processing (including mislabelled specimens) and post-analytical errors including misinterpretation and failure to action abnormal results. The authors concluded that the goal of laboratory medicine was to improve patient care through reliable laboratory data, therefore adding value. To achieve this, laboratories must become better

integrated into the MDT to recognise the key role of diagnostic testing in patient care pathways.

Plebani (2014) provided a narrative review of laboratory and diagnostic errors and the impact of these on patient outcomes, drawing upon guidelines from professional bodies, accrediting bodies and the wider literature. For laboratories to practice PCC it is necessary to investigate any possible defect in the TTP which may negatively impact patient outcomes (Plebani, 2014). However, the author failed to acknowledge whether PCC applied directly to laboratory staff with little patient contact, or whether reducing errors in laboratory testing supported clinical teams to deliver PCC. The author suggested that by identifying quality indicators and outcome-based measures for laboratory testing, laboratories can achieve a patient-centred approach.

These articles demonstrated the importance of laboratory medicine in improving and enhancing patient safety and outcomes. Several authors referred to the importance of PCC for laboratory professionals without defining PCC in the laboratory setting (Otto, 2011; Morris, Otto and Golemboski, 2013; Plebani, 2014; Sutton, 2014; Ferraro, Braga and Panteghini, 2016). Despite frequent references to the importance of laboratory medicine in patient safety, no author provided an explanation of how laboratory professionals can explicitly contribute to patient safety and reducing patient harm. It was assumed that through the impact on patient care pathways that laboratory professionals can optimise laboratory processes and achieve accurate, timely and reliable results. This reflects the integrated nature of the UK healthcare system where numerous

professionals feed into a patient's care pathway. Through striving to act in the best interests of the patient, the laboratory aims to provide a high-quality pathology service and support effective patient care, but the role of the BMS in patient outcomes was not discussed.

2.2.5.2 The wider impact of laboratory services on healthcare

Eleven articles discussed the wider impact of laboratory medicine on healthcare as detailed in table 2.4. These articles discussed the added value of laboratory medicine through improvement in laboratory quality and patient safety. Bennett and colleagues (2014) reviewed laboratory workforce requirements on behalf of the ASCP task force. This article focused upon the US healthcare system. The review made recommendations for the future laboratory workforce, including the promotion of the laboratory scientist role and accurately assessing the needs of the future scientific workforce. Although many of the issues related to the general pathology workforce, the applicability of findings to the UK BMS profession is unknown.

Ferraro, Braga and Panteghini (2016) authored a review article focused upon laboratory medicine in healthcare. Although the authors were based in Italy, there were references to both the UK and US healthcare systems. Laboratory medicine is pivotal to the wider healthcare system, forming the basis of clinical decisions for prevention, diagnosis, monitoring and treatment. Birse (2010) suggested all healthcare professionals had a role in the patient's continuum of care, including those in the laboratory and those involved in the MDT. No single healthcare speciality provides all the answers for patient care, supporting

collaborative care with the patient's best interests in mind. As a result, it may be challenging to identify the patient's best interests from a laboratory perspective and these were not defined.

Fraser *et al.* (2013) utilised qualitative methodology to conduct round table discussions considering the attributes of previous medical laboratory science students and which skills were desirable in graduates. The study was carried out in Canada, where the programme of training and education is more closely aligned to the US system. The article did not provide details of the ethical approval for the study and there is little information provided regarding the recruitment strategy, but the authors state there were 7 groups involved, each containing 5-10 participants. The participants were MLTs attending a conference, and they identified desirable qualities for graduates as empathy, to be 'patient-centred' and to take responsibility for their mistakes (Fraser *et al.,* 2013). The authors concluded it was important for graduates to work to achieve a high-quality service for patients. However, there was no explanation of how laboratory scientists could demonstrate empathy and a patient-centred approach or how these skills could be developed, which are important issues which the study failed to address.

Hallworth (2011) wrote an editorial article focused upon the evidence base that 70% of all medical diagnoses are dependent upon pathology laboratory results. This figure is often quoted in support of the wide-reaching impact of the laboratory in healthcare (Hilborne, Lubin and Scheuner, 2009; Beastall, 2013; Hallworth, 2015; Hallworth *et al.,* 2015). Hallworth (2011) recognised that those

who work in laboratory medicine are aware of its importance in effective, safe patient care, however systematic evidence of this is lacking due to the integrated nature of healthcare. Hallworth (2011) argued that the quoted 70% figure had not been systematically proven despite laboratory medicine being an essential element of healthcare and integral to clinical decision making.

Sutton (2014) is an opinion article written by an MLS in the US with responsibility for point of care testing (POCT). The article focused upon the use of POCT (assays performed near to the patient by non-laboratory personnel) as a method to improve the laboratory service and achieve PCC. The author stated that to evidence PCC, the services provided to the patient should put their needs first. This requirement was also supported by Otto (2011) and Morris, Otto and Golemboski (2013). This definition of PCC differs to the statement that the patient-centred approach recognises the individual needs of the patient and provides them with the ability to make informed decisions (Mead and Bower, 2000). Whether this definition of PCC can be applied to the laboratory setting, where little or no patient contact occurs, has not been determined. Sutton (2014) drew upon a single reference to support this argument and therefore this is synthesised using a narrow field of literature and the author's opinion. Sutton (2014) argued that the laboratory plays a key role in the wider MDT and that POCT has the potential to improve laboratory services by providing rapid results and earlier diagnosis.

Laboratory medicine has a wide-ranging impact and is involved in a significant proportion of medical diagnoses. The laboratory has historically been regarded

as a 'back-room' function, with the public and health professionals having little understanding of the role (DoH, 2006). To provide the best standard of care, healthcare teams must work collaboratively, recognising the essential role of each team in improving patient outcomes (Bennett *et al.,* 2014; Hallworth *et al.,* 2015). The healthcare system relies upon the MDT to add value to patient outcomes, and this is true for laboratory medicine (Hilborne, Lubin and Scheuner, 2009). The authors concluded that laboratory professionals should focus upon their role in patient outcomes, rather than solely on the technical and analytical aspects of their role. Despite frequent use of the term 'patient-centred care' the only definition provided from a laboratory perspective was to put the needs of the patient first (Otto, 2011; Morris, Otto and Golemboski, 2013; Sutton, 2014). However, the literature failed to define what it means to 'put the needs of the patient first' and how this can be demonstrated by laboratory professionals.

2.2.5.3 The role of laboratory services in achieving patient outcomes

Seven articles referred to the role of laboratory medicine in achieving patient outcomes as detailed in table 2.4. Most of these articles were focused upon the importance of laboratory medicine in patient outcomes. However, it was recognised that it was challenging for laboratory medicine to highlight the impact of the service upon patient outcomes and become fully integrated into the MDT (Plebani, 2002).

Beastall (2013) is an opinion paper which discussed the value of laboratory medicine in healthcare and recognised the essential role in prevention, diagnosis

and treatment of disease. The article outlined the importance of adding value to laboratory tests by influencing patient management and clinical outcomes, providing clinicians with information to make a diagnosis or commence treatment. The importance of rapid and accurate laboratory reports which allowed patient referral was recognised to improve clinical outcomes (Beastall, 2013). This was also acknowledged by Plebani (2002). The author concluded with recommendations for the integration of laboratory medicine as part of the MDT to optimise patient outcomes. However, the article focused upon the contribution of the laboratory service in patient outcomes rather than the laboratory professional themselves.

Epner, Gans and Graber (2013) authored a viewpoint article which recognised the importance of an outcomes-based approach to laboratory medicine to reduce patient harm. The authors recognised that measures of laboratory quality, such as specimen turn-around time (TAT), were poor indicators of the quality of patient care. Epner, Gans and Graber (2013) stated that TAT failed to include the time before the specimen reached the laboratory, and the time after the result was reported. The Royal College of Pathologists (RCP) also acknowledged that laboratory TATs are often based upon inappropriate measures, but recognised that it is impossible for laboratories to audit the impact of results on patient outcomes (Royal College of Pathologists, 2013). The authors acknowledged that stronger links were required between laboratory testing and patient outcomes. Without these, laboratory testing becomes a factory environment recording input and output, a description also used by Plebani and colleagues (2011). This description has also been used by some practicing BMSs

to describe their role (see section 1.4). Whilst patient safety and avoidance of errors were considered important aspects of laboratory testing, the contribution of laboratory testing to patient outcomes was largely unknown.

Hallworth (2015) wrote an editorial which considered the impact of laboratory medicine on clinical outcomes. The author recognised those working in laboratory medicine have anecdotal evidence of the importance of laboratory results in safe and effective patient care, but that systematic evidence of this was lacking. Recommendations were made for new roles for laboratory professionals which optimise patient outcomes, adding value to the diagnostic process, however no details of these new roles or how they will add value were provided. The importance of the MDT was highlighted, as using laboratory medicine optimally to support patient care was considered essential to evidence the impact of laboratory testing. However, the way in which laboratory medicine impacted upon patient outcomes was not defined.

Hallworth and colleagues (2015) authored a narrative review which considered effective practice of patient-centred laboratory medicine. This review was written for an international audience, so did not focus upon the nuances of a specific national healthcare system and aimed to be universally applicable. The role of laboratory medicine is to support the interaction between patients and clinicians by providing relevant data for healthcare decisions to optimise patient outcomes (Hallworth *et al.,* 2015; Ferraro, Braga and Panteghini, 2016). However, the impact of the laboratory scientist role upon patient outcomes was not considered. The authors discussed the importance of patient-centred laboratory

medicine and ensuring correct and timely test selection, communication of results and appropriate action from clinicians. The authors explained that to achieve this it was essential to select the right test, on the right patient, at the right time and deliver the results to an appropriate clinician who can interpret and action the results in a suitable timeframe (Hallworth *et al.,* 2015). Despite the author's use of the phrase 'patient-centred laboratory medicine' the appropriateness of patient centredness for the BMS workforce was not considered.

It is essential that laboratory results add value to patient care and support diagnosis, monitoring or treatment of a condition. Clinicians must receive laboratory results in a timely fashion and must not be subject to under-alerting or over-alerting (Hallworth *et al.,* 2015). The articles suggested that laboratory professionals should shift focus from laboratory TAT to the TTP, focusing upon how laboratory results impact patient outcomes. To do this, the authors suggested laboratories need to become better integrated into the MDT and focus upon patient outcomes as an indicator of laboratory quality, rather than TAT.

2.2.5.4 The technical and analytical nature of the laboratory scientist role

Five articles referred to the technical and analytical nature of the laboratory scientist role in healthcare as detailed in table 2.4. Two of these articles referred to the importance of emotional intelligence (EI) for healthcare professionals (Adams *et al.,* 2011; Price, 2015). EI refers to an individual's ability to understand and manage emotions and relationships with others and recognises the

importance of empathy and understanding how another individual feels (Goleman, 1996). EI is thought to be important in career choice and future professional success (Adams *et al.,* 2011).

Adams and colleagues (2011) used a quantitative methodology, which included a Likert scale questionnaire and hypothesised that students who chose a degree course leading to a career with high patient contact (e.g. nursing) would show higher levels of EI than students aspiring to roles with less patient contact (e.g. laboratory scientists). This study recruited 401 students at a US university, including 109 who were studying Clinical Laboratory Science, which is similar to the UK BSc Biomedical Science course. The authors failed to acknowledge their position as insider researchers and the potential for coercion of students recruited to the study. There was no statistically significant difference in scores for questions related to emotional perceptions between the two groups, suggesting there was no difference in EI (Adams *et al.,* 2011). However, the study was conducted with students rather than practicing laboratory scientists, and the impact of professional experience on this finding requires further investigation. It is possible that a better understanding of patient care and the laboratory scientist's role within patient outcomes is developed in practice rather than in the academic setting.

Price (2015) utilised a mixed-methods methodology, which involved a questionnaire with a Likert-type scale and qualitative analysis of free text responses to identify the role of EI skills within the clinical laboratory. The questionnaire was distributed to 1800 members of the Clinical Laboratory

Members Association in the US and 413 responses were received. The role that EI played in successful practice as an MLS was unknown and Price (2015) aimed to identify whether this quality was desired by employers. The author failed to acknowledge their insider position within the study. The study concluded that medical laboratory administrators believed EI skills were key to succeed in the medical laboratory (Price, 2015). The responsibility for developing these skills were believed to lie with the individual and education providers. However, there were no strategies for encouraging development of these skills included in the article.

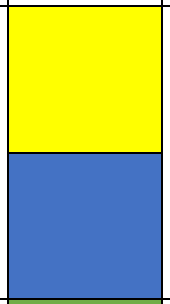
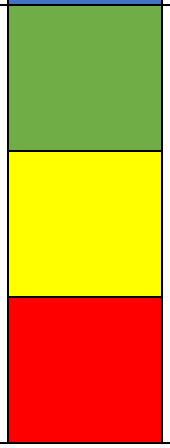
The laboratory environment is focused upon standard operating procedures (SOPs) and adherence to strict protocols resulting in the need to focus upon technical and analytical skills (Adams *et al.,* 2011; Bennett *et al.,* 2014; Sutton, 2014). SOPs provide a series of standardised instructions for a procedure or technique and consider regulatory requirements. The laboratory environment is increasingly automated and robotic in nature, suggesting that laboratory scientists may struggle to develop softer skills required for communication and emotional interaction. There was no reason to believe that technical abilities and softer skills should be mutually exclusive, however, this assumption was made by Adams *et al*. (2011). For laboratory professionals, most interactions occur over the telephone with other healthcare professionals and patient contact is minimal. The studies concluded that laboratory scientists who demonstrated EI and softer skills in addition to accuracy and precision enhanced the quality of the laboratory service. However, the needs of the patient were not defined within the literature.

Table 2.4. Brief overview of the studies included in the IR, colour coded according to themes identified in the literature review.

Key:

a. The importance of maintaining a high-quality laboratory service	
b. The wider impact of laboratory services on healthcare	
c. The role of laboratory services in achieving patient outcomes	
d. The technical and analytical nature of the laboratory scientist role	

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
Adams *et al.*, (2011), US	Primary, quantitative.	Questionnaire distribution on perceptions of emotions amongst 401 healthcare students from 7 disciplines.	Nursing and respiratory students ranked themselves lowest in all areas of emotional aptitude. Laboratory Science students were at or above average in all areas except interpersonal communication. ANOVA revealed no statistically significant difference by degree programme studied.		Relied upon self-perception which is highly subjective. Used students studying healthcare courses rather than registered healthcare professionals. Based at only one US university.	77% (Kmet, Lee and Cook, 2004)

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
Beastall (2013), UK	Secondary, opinion paper	Narrative commentary of adding value to laboratory medicine.	Laboratory medicine makes a major contribution to improving clinical effectiveness, by providing accurate, timely results. Focused upon patient outcomes and working as part of the MDT.		Opinion of one individual, supported with the use of limited literature.	
Bennett *et al.*, (2014), US	Secondary, review	Narrative review on behalf of American Society for Clinical Pathology Task Force.	Decreased overall vacancy rates for the US Medical Laboratory workforce, despite several challenges to recruitment. Impact of laboratory staffing on patient outcomes is lacking. Recognised benefit of laboratory scientists to care delivery.		Based upon US healthcare system. Staffing levels may not reflect UK.	

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
Birse (2010), Canada	Primary, quantitative.	Likert questionnaire distribution to 1210 members of Canadian Society for Medical Laboratory Science regarding patient safety.	69.4% of respondents perceived a positive safety environment in laboratory. 97.3% of medical laboratory professionals believed they have a role in patient safety. 80.9% believed patient safety is a priority within laboratory.		Canadian healthcare system Sampling based upon membership to a professional body. Low response rate (11.2%) may mean results are not representative.	60% (Kmet, Lee and Cook, 2004)
Epner, Gans and Graber (2013), US	Secondary, viewpoint	Narrative commentary of diagnostic errors and patient harm and requirement	Laboratory key-performance indicator (KPI) TAT did not consider the impact of testing on patient and the clinical situation.		Based upon the US healthcare system.	

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
		for outcomes-based approach to laboratory medicine.	Need to develop stronger links between diagnostic tests and patient outcomes.			
Ferraro, Braga and Panteghini (2016), Italy	Secondary, review	Narrative review of role of laboratory medicine in healthcare.	Essential to reduce errors in TTP by focusing upon the laboratory-clinical interface. Laboratory played a central role in improving clinical effectiveness and optimising operational efficiency		Based upon the Italian healthcare system.	
Fraser *et al.,* (2013), Canada	Primary, qualitative	Round-table discussion workshop to identify desirable attributes in laboratory professionals	Desirable skills included being a team player, enthusiastic, compassionate and professional. Requirement for patient-centred values in graduates. Soft skills considered harder to teach.		Participants recruited at a conference workshop. Potential for coercion or peer-pressure to participate.	40% (Kmet, Lee and Cook, 2004)

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
Hallworth (2011), UK	Secondary, editorial	Commentary of evidence base for claim laboratory medicine underpins 70% of healthcare decisions.	Anecdotal evidence of role of laboratories in patient outcomes. Evidence base for 70% claim is lacking. Objective evidence of contribution was required.		Opinion of one individual. Drew upon limited literature within the field.	
Hallworth (2015), UK/ international	Secondary, editorial	Commentary of impact of laboratory medicine on patient outcomes.	To improve patient outcomes laboratories must improve test utilisation, define new roles for laboratory professionals, develop patient-centred protocols and consider impact of TTP on patient outcomes.		Opinion of one individual. Definition of patient-centred protocols for laboratory professionals not provided.	
Hallworth *et al.*, (2015), UK/ international	Secondary, review	Narrative review of future perspectives of patient-centred laboratory medicine.	Perform right rest, right patient, right time. Guidance for interpretation and follow up required. Clinical collaboration needed.		Definition of patient-centred laboratory medicine and suitability of this term is not discussed.	

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
			Suggested use of patient outcome as measure of laboratory effectiveness.			
Hilborne, Lubin and Scheuner (2009), US	Secondary, review	Narrative review of patient safety and implications for laboratory	Following evidence-based practices improves clinical outcome. Improvements to TTP required at pre and post analytical stages. Change required in laboratory culture to prevent errors and patient harm. Work as part of MDT.		Focused upon US healthcare system.	
Morris, Otto and Golemboski (2013), US	Secondary, focus article	Narrative review of improving patient safety and quality for MLS	Need to focus laboratory education on the IOM guidelines. Improve the TTP from patient's perspective. Need for interprofessional working as part of the MDT		US healthcare system. Focused upon students rather than registered healthcare professionals.	
Otto (2011), US	Secondary, focus article	Narrative review of patient safety	Need to adopt the IOM aims for quality healthcare into laboratory		Focused upon US healthcare system.	

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
		and medical laboratory.	environment to gain skills and improve healthcare delivery			
Plebani (2002), Italy	Secondary, review	Narrative review of role of the medical laboratory in the changing healthcare setting	Change in priority from treating disease to preserving health. Laboratory role to identify markers of susceptibility. Now focused upon patient outcomes and improving TTP.		The article is quite old in relation to the fast-paced field of laboratory medicine.	
Plebani (2014), Italy	Secondary, review	Narrative review of laboratory associated errors	Focused upon TTP and sources of error in laboratory testing. Need to investigate these errors to improve PCC.		No evidence of systematic selection of literature. Italian healthcare system.	
Plebani, Laposata and Lundberg (2011), Italy/ international	Secondary, review	Narrative review of brain-to-brain loop in laboratory medicine 40 years on	Brain-to-brain loop allows better connections between physician and laboratory by focusing upon clinical outcomes.		Focused upon Italian and US healthcare systems.	

Author(s), year, country	Type of literature	Methodology	Results and key findings	Themes	Limitations	Quality Score
Price (2015), US	Primary, mixed methods	1800 practicing MLSs invited to participate in a survey about EI. 413 responses were received. Likert scales and thematic analysis were utilised.	Technical skills scored highly for MLSs, as did integrity, dependability and respect for others. There is greater disparity for importance and satisfaction of EI skills. Academic institutions should be responsible for developing EI skills.		US healthcare system. Relatively low response rate (30%).	60% (Hong *et al.*, 2018)
Sutton (2014), US	Secondary, opinion	Narrative commentary of the role of POCT in PCC	POCT allowed the provision of PCC by providing access to safe, fast, accurate results.		Focused exclusively on POCT rather than traditional laboratory testing. US healthcare system.	

2.2.6 Stage Five: Presentation

The final stage of the IR process is data presentation, where the findings are represented in a table or diagram, along with synthesis to draw a conclusion (Whittemore and Knafl, 2005). Table 2.4 provides a summary of each of the articles, the themes identified within and any limitations of the study design. The strongest recurring theme was the provision of a high-quality service which prioritised patient safety (Hilborne, Lubin and Scheuner, 2009; Birse, 2010; Otto, 2011; Plebani, Laposata and Lundberg, 2011; Morris, Otto and Golemboski, 2013; Bennett *et al.,* 2014; Hallworth *et al.,* 2015). Prioritising patient safety requires a reduction in potential harm due to errors in laboratory testing. Numerous strategies were discussed for reducing errors in the TTP, but these were focused upon the laboratory service rather than the professionals who deliver laboratory testing. The way in which BMSs can evidence a focus upon patient safety was not elucidated.

There were frequent references to the importance of laboratory medicine in patient outcomes, and to achieving high quality patient care as part of the MDT (Hilborne, Lubin and Scheuner, 2009; Beastall, 2013; Epner, Gans and Graber, 2013; Plebani, 2014; Hallworth, 2015; Hallworth *et al.,* 2015). Laboratory medicine underpins many diagnoses, and therefore impacts upon numerous patient care pathways. Despite use of the term PCC, there was no discussion of this concept with respect to the laboratory environment where little or no patient contact occurs. Excellent standards of laboratory testing can only be achieved by fully integrating laboratory medicine into patient outcomes and all healthcare professionals must strive to optimise these (Hilborne, Lubin and Scheuner, 2009;

Beastall, 2013; Hallworth, 2015; Hallworth *et al.,* 2015). However, none of the authors explained how this can be achieved or how to determine whether laboratories are optimising patient outcomes, with Hallworth *et al.* (2015) concluding that it is not possible to collect this data due to a lack of control over the TTP.

The personality traits of individuals working in healthcare but opting for technical or analytical roles rather than patient facing roles were considered. Several studies acknowledged that softer skills, such as empathy and compassion, were of high importance for MLSs (Adams *et al.,* 2011; Fraser *et al.,* 2013; Price, 2015). There was no significant difference between the measurement of EI amongst MLS students and those students on patient facing degree programmes such as nursing (Adams *et al.,* 2011). This suggests that development of softer skills, as well as technical and analytical skills are required for those destined to enter laboratory roles, however the author implied that these qualities were mutually exclusive. It was unclear why having technical and analytical skills would prevent an individual also demonstrating empathy.

2.3 Discussion and Implications for Practice

This IR aimed to define the BMS role in patient outcomes. Historically, IRs have been criticised for a lack of rigour and inconsistent review methodology, which led to the development of more robust methodology by Whittemore and Knafl (2005). Due to the limited primary literature available for this review, a systematic review was not considered appropriate.

Despite the low visibility of the laboratory scientist role, several authors agreed that laboratories contributed to patient care by enhancing care quality and improving patient outcomes and safety (Plebani *et al.,* 2006; Hilborne, Lubin and Scheuner, 2009; Birse, 2010; Golemboski, 2011; Epner, Gans and Graber, 2013; Golemboski, Otto and Morris, 2013; Plebani, 2013; Bennett *et al.,* 2014; Plebani, 2016). The value of laboratory medicine lies outside the laboratory in the impact of laboratory results on patient outcomes (Greaves *et al.,* 2019). The laboratory workforce are described as patient advocates, suggesting laboratories do not just generate data but manage information and create knowledge for patient diagnoses (Kroft, 2018). Laboratory scientists must take responsibility for the TTP, improving patient safety at all stages to reduce harm and provide accurate, high-quality results in a clinically relevant timeframe. This is one way in which BMSs and other laboratory professionals can evidence their contribution to patient outcomes.

The role of laboratory medicine in healthcare is demonstrated by impact upon diagnosis, monitoring, treatment and disease prevention. The number of clinical decisions impacted by pathology results is estimated as 70%, despite the unknown evidence base for this figure (Grant, 2009; Hallworth, 2011; Plebani, 2014; Hallworth, 2015; Hallworth *et al.,* 2015; Ferraro, Braga and Panteghini, 2016). Numerous clinical decisions depend upon pathology results and patient outcomes are impacted by the laboratory professionals performing sample analysis. However, the number of interventions involved in actioning laboratory results makes determining impact of these results in isolation difficult (Grant, 2009). Therefore, it is difficult to determine the BMS role in patient outcomes

and whether desire to achieve these is developed through education, training or is an innate quality.

Several authors commented upon the importance of the laboratory in achieving patient outcomes (Plebani, 2002; Morris, Otto and Golemboski, 2013; Hallworth *et al.,* 2015; Ferraro, Braga and Panteghini, 2016). The patient should be at the heart of the laboratory service to provide safe, effective care. However, the literature fails to define essential terms, such as 'working in the best interests of the service user' or 'putting the patient first' in the context of laboratory medicine. Failure to define these terms may make striving to achieve these is more challenging for BMSs. Despite frequent references to the laboratory's role in achieving patient outcomes, it was not elucidated in the literature how BMSs contributed to patient outcomes and whether laboratory scientists are expected to work in this way. The role of laboratory medicine in the TTP is assumed to contribute positively to patient outcomes, without evidencing the skills and attributes BMSs require to demonstrate these values.

The literature demonstrated preconceptions that those in scientific roles were regarded as analytical and technical rather than compassionate and caring (Adams *et al.,* 2011; Fraser *et al.,* 2013; Price, 2015). However, focusing upon the technical aspects of the role detracts from the value of the clinical information provided by laboratory testing (Scott *et al.,* 2015). Another study considered EI in Allied Health Professionals (AHPs) and concluded similar personality traits were found in AHPs, nurses and clinicians (Campbell, Eley and McAllister, 2014). Employers of MLSs suggest that one of the most desirable characteristics is being

'patient-centred' or displaying empathy (Adams *et al.,* 2011; Otto, 2011; Fraser *et al.,* 2013; Morris, Otto and Golemboski, 2013; Hallworth *et al.,* 2015). Much of this literature originated in the US or Canada, and caution should be exercised when applying the same assumptions to the UK BMS role. However, the lack of UK literature meant that the international literature was worthy of exploration.

The concept of PCC for laboratory scientists was mentioned frequently in the literature (Bennett *et al.,* 2014; Plebani, 2014; Sutton, 2014; Hallworth *et al.,* 2015; Ferraro, Braga and Panteghini, 2016). However, the accepted definition of PCC recognises the individual needs of the patient and provides them with the ability to make informed decisions about their own health (Mead and Bower, 2000). Recognising the individual needs of a patient within the BMS role is challenging, but accurate and timely result reporting can support patients to make decisions about their own health.

According to the IOM (2001), PCC encompasses compassion, empathy and responsiveness to patient needs. How laboratory scientists with little or no patient contact practice PCC is worthy of exploration, because the generally accepted definition is challenging to apply. Figure 2.2 provides an overview of the literature relating to PCC with respect to the BMS workforce and other healthcare professions. Exploring stakeholder's views of the importance of PCC for BMSs and how this can be demonstrated required further investigation. The literature focused upon the laboratory's role in patient outcomes and discussion of the BMS role in patient outcomes was lacking. Investigating the BMS role in achieving patient outcomes will allow identification of potential misalignment

between documentation issued by the professional and regulatory bodies, the content delivered by educational institutions and practice.

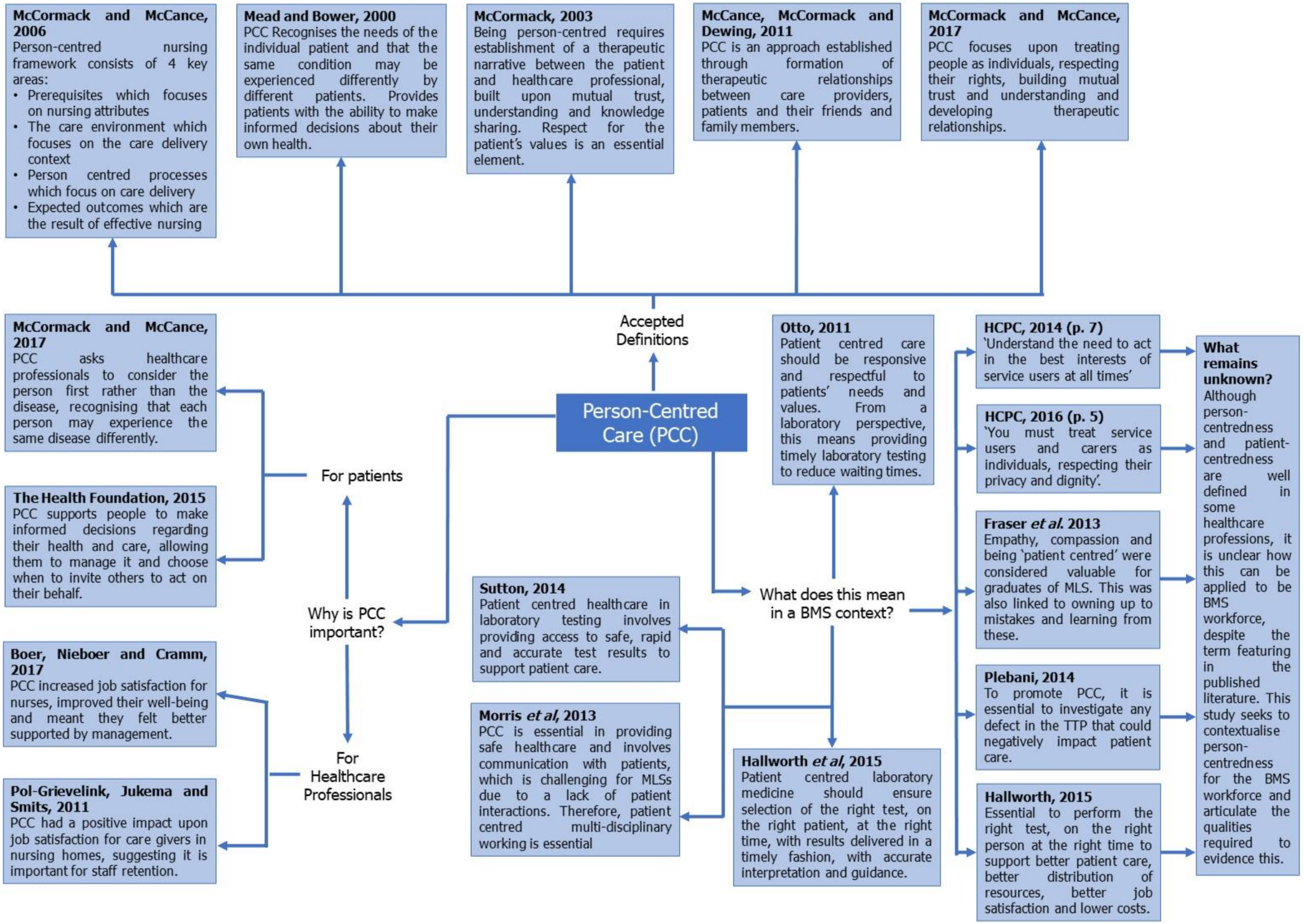


Figure 2.2. A schematic overview of the literature related to PCC in connection to the BMS role and wider healthcare professions.

2.4 Research Focus

The literature review identified that a clear definition of how the BMS role supports PCC is not defined, with discussions suggesting it was important, but not articulating how BMSs can evidence this. Due to the large number of BMSs employed within healthcare laboratories and the significant impact of diagnostic testing upon patient care, this was worthy of further exploration. Therefore, this study was undertaken to address this gap and provide a better understanding of the BMS role in patient outcomes. As a result, the following research aim and research questions were developed. Further details of the development of these are provided in chapter 3.

Exploratory aim:

To explore if there is a shared understanding within the biomedical science community and key stakeholder groups of how the Biomedical Scientist role contributes to patient outcomes.

Objectives:

To determine whether key stakeholders expect Biomedical Scientists to contribute directly to patient outcomes.

To elicit stakeholders' views on those factors which may impact upon the Biomedical Scientist's contribution to PCC and patient outcomes.

Research Questions:

- Is there consensus between stakeholders regarding the role of Biomedical Scientists in contributing to patient outcomes?

- Is there a shared understanding amongst stakeholders of recognising how Biomedical Scientists work to achieve patient outcomes?
- What are the opinions of stakeholders regarding the importance of achieving patient outcomes in the Biomedical Scientist role?
- Can stakeholders identify how it can be recognised that Biomedical Scientists are working to achieve patient outcomes?

The approach taken to address these research questions is described in chapter 3, with the findings presented in chapter 4.

CHAPTER 3. METHODOLOGY ROUNDS ONE AND TWO

3.1 Introduction

The study aimed to contextualise the BMS role in patient outcomes and determine how stakeholders perceived this was evidenced. This chapter presents an overview of the Delphi methodology used in this study. The merits of Delphi are presented, including epistemological and ontological considerations and methodological alternatives. Strategies for recruitment, data collection and transcription are presented, followed by thematic analysis utilising the Braun and Clarke (2013) framework. The development of attitude statements from the 1st round responses and the item pool reduction will also be described. Ethical approval will be outlined, along with the impact of the COVID-19 pandemic upon data collection and recruitment. The methodology chapter will conclude with distribution and analysis of the 2nd round questionnaire.

3.2 Research Methods

This section presents the methods for the study, reviewing the philosophical basis and suitability of Delphi.

3.2.1 Research Aims

Development of research aims and questions for qualitative or mixed-methods research are key as poorly conceived questions are likely to cause problems in later stages (Agee, 2009). The exploratory aim, objectives and research questions outlined in chapter 2 were developed following a review of the literature and identification of a gap. The aim of the study was addressed by

development of four sub-questions, designed to address specific aspects of the research topic (Agee, 2009). The research questions were refined by the researcher during development, resulting in the statements presented in chapter 2. Within the literature there was a lack of discussion of these concepts, particularly around commonly used phrases such as 'working in the best interests of the patient'. These concepts may also impact upon the understanding of the BMS role within the MDT and BMS job satisfaction, demonstrating a rationale for the study. The approach taken to address these questions will be outlined later in this chapter.

3.2.2 The Delphi Methodology

This is a consensus methodology which uses a group of informed individuals or 'experts' to explore the level of consensus on a topic (Campbell and Cantrill, 2001; Barrett and Heale, 2020). The methodology is based upon the assumption that the opinion of a group of informed individuals is more valuable than the opinion of one (Keeney, Hasson and McKenna, 2011). There are no published studies which have considered the BMS role (or international equivalent) in achieving patient outcomes and how BMSs evidence they meet these requirements. Delphi is used to generate ideas, understand problems and complex issues and is useful when there is a lack of empirical data in a field (McKenna, 1994), meaning it was suitable for this study. Classic Delphi methodology involves a multi-stage survey designed to achieve consensus on an issue (McKenna, 1994).

Consensus methodology was considered appropriate for addressing the exploratory aim and research questions. Although Delphi studies are often designed to achieve consensus on a topic, the methodology can be used to determine whether consensus exists (Keeney, Hasson and McKenna, 2011). In this study, the Delphi methodology was used to determine whether consensus or divergence existed amongst stakeholders. In a classical Delphi study, a group of experts or informed individuals participate in multiple rounds. In the qualitative 1st round, participants are presented with open-ended questions in the form of a questionnaire, and the researcher uses the responses to develop the 2nd round questionnaire (Barrett and Heale, 2020). There are usually 2 to 4 subsequent rounds in which participants score their agreement with a series of statements using a Likert scale (Hsu and Sandford, 2007).

Participants' responses from the 1st round should be re-presented in subsequent rounds with minimal editing, using the words and phrases of the participants to minimise researcher bias (Hasson, Keeney and McKenna, 2000). As this study aimed to identify whether consensus existed amongst stakeholders and in which areas of the BMS role, data collection involved two rounds; a qualitative first round consisting of semi-structured interviews and focus groups and a quantitative second round consisting of a questionnaire where participants scored their agreement with a series of statements. This differs to the classical Delphi approach, which aims to achieve consensus amongst participants. This approach is arguably more closely aligned to a policy Delphi, which is discussed further in section 3.2.7.

3.2.3 Philosophical Underpinnings

Epistemology and ontology are essential research elements to ensure methodology is aligned with researcher positionality. Researchers must ensure their own ontological and epistemological views are aligned with methods utilised for data collection and interpretation (Sutrisna, 2009; Bracken, 2010). Epistemology is the study of knowledge and demonstrates the knowledge assumptions underpinning the researcher's methodology (Williams, 2016). Ontology is concerned with being, the subject of existence and the nature of reality (Scotland, 2012; Williams, 2016).

As a scientist by background, positivism, with assumptions of an objective reality knowable through methods of empirical verification was familiar throughout my education and training (Guba and Lincoln, 1994; Angen, 2000; Ryan, 2006). These assumptions contrast with the underpinnings of social constructionism, which suggests that reality is created through human interactions (Williams, 2016). This suggests that social constructionism was not an appropriate philosophical position for someone of a traditionally scientific background. Positivism transformed to post-positivism whereby the notion of verification was replaced by falsification (Guba and Lincoln, 1994). However, approaching social science research in this way is regarded as outdated (Guba and Lincoln, 1994; Ryan, 2006; Haughton, 2011; Al-Saadi, 2014). Therefore, an alternative research paradigm was required which combined my scientific background, and an interpretative research field and pragmatism was adopted as an alternative approach.

By adopting a pragmatic approach to this study, it was possible to focus upon the problem to be investigated and solving 'real world' problems. This allows researchers to be free of constraints offered by alternative philosophical positions such as post-positivism or constructivism (Feilzer, 2010). Rather than being solely concerned with the ontological and epistemological issues of the research, pragmatism recognises the value of different approaches to enquiry (Morgan, 2014). In pragmatism, the reality of the world is determined by our practical orientation to it, recognising that we cannot claim to know anything outside of our experience (Williams, 2016). Pragmatism crosses both the interpretative and post-positivist paradigms, combining both subjective human experiences and generalisability (Brady, 2015). Utilising a pragmatic approach allowed selection of a research methodology that appropriately addressed the research aims, providing a voice for the stakeholders of the BMS profession and allowing exploration of key issues.

3.2.4 Philosophical basis of Delphi

Delphi methodology employs a mixed-methods approach involving both qualitative and quantitative data collection. The philosophical paradigm of Delphi methodology is often debated (Keeney, Hasson and McKenna, 2011). Delphi methodology offers an interpretative analysis of qualitative data, suggesting that it can be classified within the interpretative paradigm, which aligns with the principles of constructionism (Stewart, 2001). It has also been argued that Delphi methodology sits within a positivist paradigm, due to quantitative data collection methods and identification of statistical consensus (Hanafin, 2004). Pragmatism has been considered a bridge between the interpretative paradigm with a focus

upon human experience and the generalisability and objectivity considered important in the post-positivist paradigm (Brady, 2015). Therefore, adopting a pragmatic approach allowed an objective, scientific approach to an interpretative field of research.

As the Delphi method was developed for practical research, it complies with the assumptions of Pragmatism (Jason and Glenwick, 2016). Delphi methodology utilises a purposive sample of individuals with expertise on a particular topic, and the research seeks to directly influence practice and decision making (Jason and Glenwick, 2016). These characteristics align Delphi methodology with a pragmatist paradigm because the methodology is flexible, utilising both qualitative and quantitative data collection methods, lacks complexity making it suitable for practitioners and researchers and facilitates research designed to have a direct bearing on practice and policy (Brady, 2015). This supported the use of Delphi methodology as appropriate for addressing the research aim and influencing practice and policy.

3.2.5 Theoretical Framework

The theoretical framework for a research study is derived from an established existing theory which has been validated and tested by other researchers and is generally accepted (Grant and Osanloo, 2014; Kivunja, 2018). The theoretical framework provides the foundation of the research study and should underpin the research aims and research questions. It guides the researcher to provide an explanation of an event in their own field using major theories relevant to the

study (Imenda, 2014; Kivunja, 2018). The theoretical framework for this thesis draws upon the theory surrounding PCC as shown in figure 3.1.

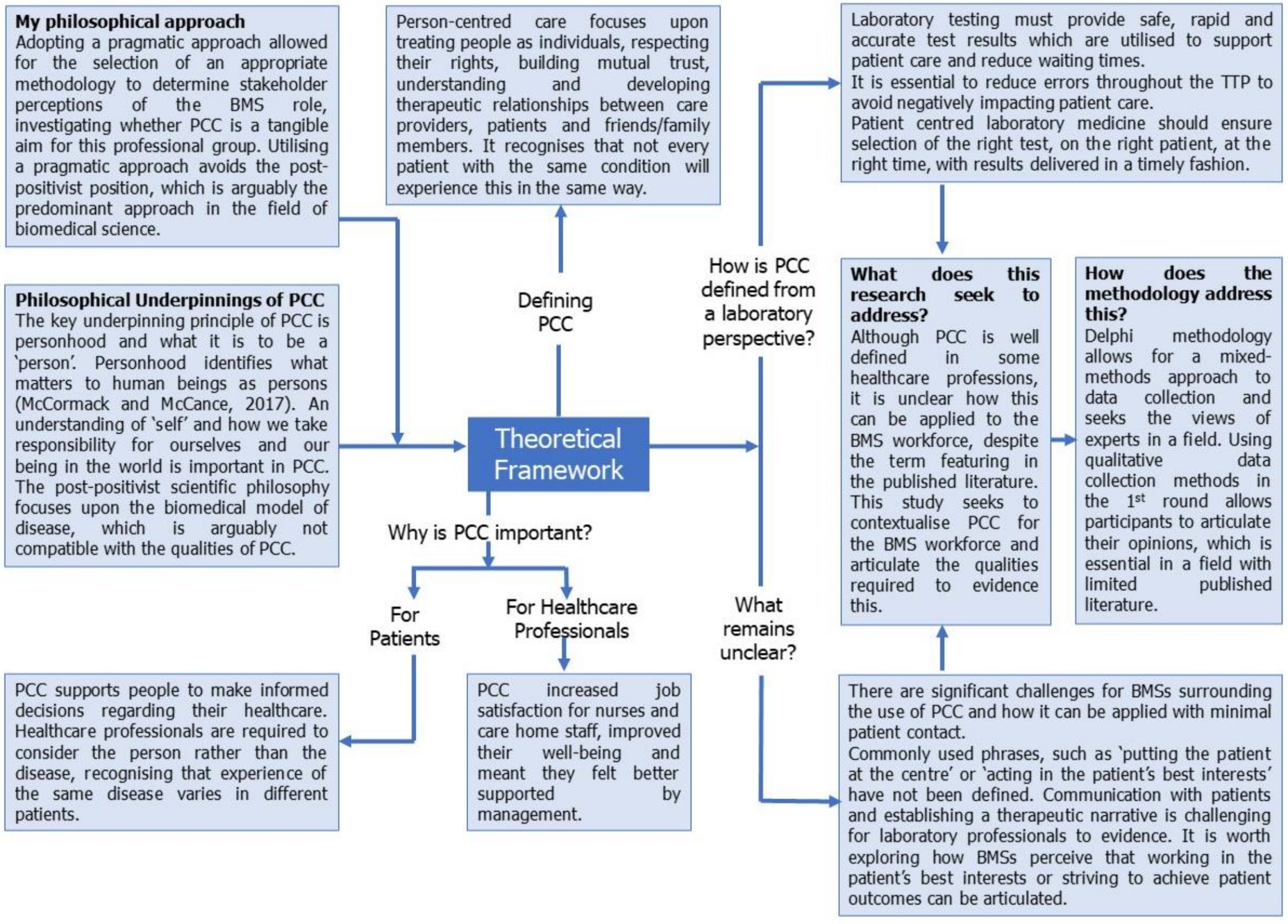


Figure 3.1. A schematic representation of the theoretical framework drawing upon the theory of person-centred care (PCC).

3.2.6 Suitability of the methodology

The strengths and weaknesses of Delphi methodology have been described extensively and are shown in appendix 17 (McKenna, 1994; Campbell and Cantrill, 2001; Hsu and Sandford, 2007; Keeney, Hasson and McKenna, 2011). One strength is the ability to generate discussion points in a field which lacks published literature, which was a key consideration for this study (McKenna, 1994). Sullivan and Brye (1983) recognised that Delphi methodology was appropriate with a heterogenous sample of participants. To assess nursing curriculum requirements, Delphi studies involving academic staff and practicing nurses were conducted, which demonstrated that Delphi was valuable for combining experiences of different stakeholder groups (Sullivan and Brye, 1983; Almalkawi, Jester and Terry, 2018). This supported the use of Delphi methodology to consider the opinions of practicing BMSs, academics, students and PSRB representatives.

One limitation of the Delphi methodology is a lack of standardisation (Keeney, Hasson and McKenna, 2011). To demonstrate rigour, it is important to define the study purpose from the outset and justify any modifications as the study evolves (Humphrey-Murto *et al.,* 2017). The steps taken to ensure methodological rigour are outlined in appendix 18 (Hill and Fowles, 1975). It was important to select an appropriate number of rounds or identify criteria for the end of data collection. In this study, the existence of consensus or divergence was required to address the research aim, therefore 2 rounds of the study were included rather than 3 or 4 rounds which are necessary to achieve consensus (Keeney, Hasson and McKenna, 2011). This 2 round approach has been adopted

by a number of studies concerned with identifying areas in which consensus was reached, rather than focusing solely upon reaching consensus (Chichetti, 2011; Chen *et al.,* 2017; Marseu *et al.,* 2022).

The existence of consensus on a topic is not definitive because consensus can be achieved if participants all have the same misconception (Keeney, Hasson and Mckenna, 2001). Delphi studies have significant variation in participant numbers, with panels varying from 4 to 3000 participants (Campbell and Cantrill, 2001). Focus groups typically include 5 to 10 participants and groups of more than 12 become difficult to manage (Krueger and Casey, 2009). As Delphi method is not prescriptive, the researcher determines the number of participants according to the study design and research aims. The number of rounds and the involved nature of the research means there is often a high degree of attrition between rounds or low response rates (Hsu and Sandford, 2007). To reduce attrition, it was essential to minimise the time between rounds and to inform participants of expectations from the outset (Keeney, Hasson and McKenna, 2011).

Delphi studies rely upon the selection of '*experts*', but there is no agreed definition of an expert in this context. An expert is defined as an individual with experiences of numerous scenarios, allowing each unresolved situation to be addressed intuitively through prior experience (Dreyfus, 1981). Students participated in the study as, although they did not have work-based experience, they provided valuable knowledge around how the BMS role is understood. Due to the heterogeneity of the stakeholder groups in this study, the definition of

McKenna (1994) was adopted which requires participants to be 'informed individuals'. Delphi methodology is associated with a pressure to conform, whereby a participant may change their response to fit with the group (Hsu and Sandford, 2007; Keeney, Hasson and McKenna, 2011). This study aimed to identify whether consensus or divergence existed between stakeholder groups and in which areas providing a rationale for including only 2 rounds. The decision to include only 2 rounds will be discussed in section 5.9 of this thesis where a proposed 3rd round of data collection is outlined.

3.2.7 Alternative methodologies

Nominal group technique (NGT) and consensus conference methodologies were also considered for this study. NGT utilises a highly structured approach where face-to-face participants are presented with an initial question and individually provide a written response (Campbell and Cantrill, 2001). These are then shared in a 'round-robin' and participants have input into the responses of others within the group (Keeney, Hasson and McKenna, 2011). Participants individually score or rank the items and consensus is determined and does not involve an initial review of the literature. NGT is more commonly utilised with the lay person rather than a panel of experts (McMillan, King and Tully, 2016). As the study required a more nuanced understanding of the BMS role in patient outcomes, NGT would not have provided the same quality data as Delphi.

Consensus conference utilises a purposive sample of individuals and delivers focused presentations on a topic and why achieving consensus is important and is usually adopted in matters of high importance, such as research priorities or

policy issues (Keeney, Hasson and McKenna, 2011). Following a series of presentations, the audience members split into groups to discuss the issue being considered and the conference ends with a vote on key matters (Keeney, Hasson and McKenna, 2011). This methodology was not considered appropriate due to a lack of literature in the field, suggesting presentation topics may be influenced by researcher perceptions.

In hindsight, a policy Delphi may have been a suitable methodology for this study. The differences between a classic Delphi and policy Delphi are as follows; classic Delphi strives to achieve consensus whereas a policy Delphi aims to generate the strongest possible opposing views on a topic (Turoff, 2002). Consensus in a policy Delphi occurs by chance, which conflicts with the aim of this study to identify whether consensus or divergence existed for stakeholders of the BMS role. The policy Delphi utilises a heterogenous set of participants which also reduces the likelihood of achieving consensus (Manley, 2013). Whilst it may have been appropriate to adopt a policy Delphi, this study aimed to determine whether consensus existed amongst stakeholders and where areas of divergence existed which meant a classic Delphi approach was adopted.

3.3 Study Design

This section outlines the study design and includes details of the interviews, thematic analysis and questionnaire that were performed.

3.3.1 Overview of the Study

The study utilised a modified Delphi methodology consisting of two rounds. In the 1st round, participants included academics, final year students and BMSs

invited to attend virtual focus groups or interviews to gauge stakeholder opinion on pertinent issues to the BMS role. Focus groups are a recognised method of data collection in the 1st round of a modified Delphi and were used to gain rich, high-quality data (Hasson, Keeney and McKenna, 2000). Policy influencing representatives from PSRB organisations, including the IBMS, HCPC and DoH, were invited to attend telephone or online individual interviews. Individual interviews were chosen with the PSRB representatives to allow for more nuanced data collection from this smaller group of stakeholders with a diverse range of backgrounds.

In round 2, participants were presented with a series of statements to score using a 5-point Likert scale. Illustrative quotes and themes identified following analysis of the 1st round data are presented in chapter 4. Figure 3.2 provides a schematic representation of the methodology employed in this Delphi.

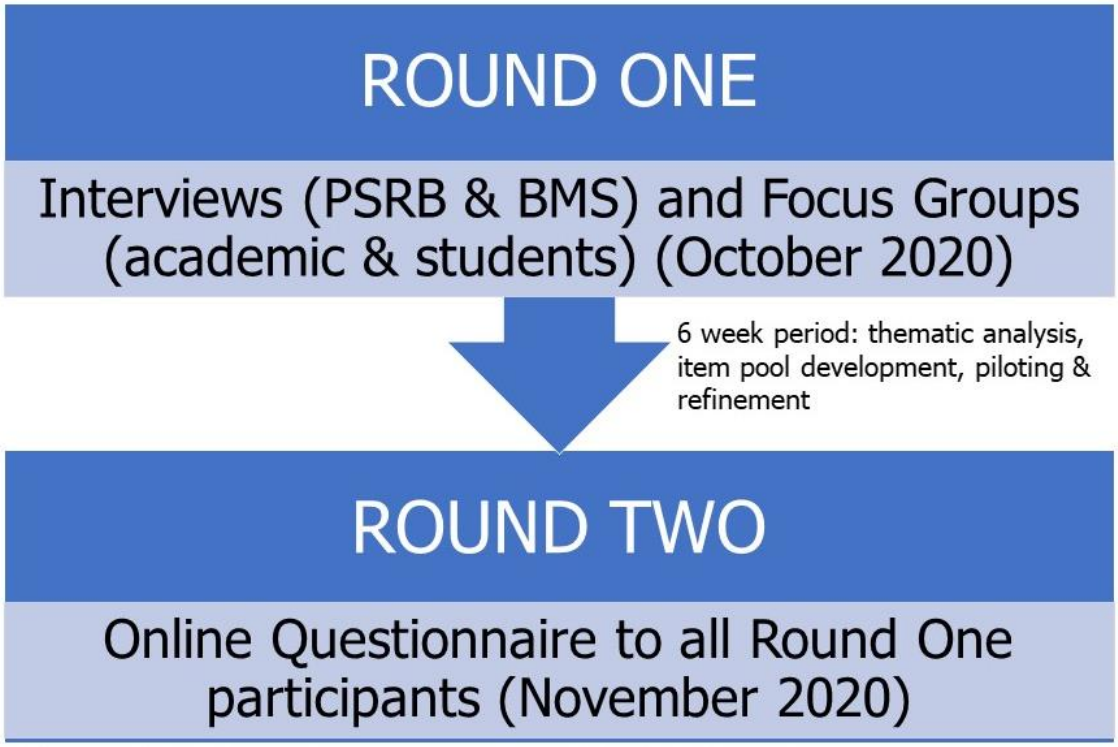


Figure 3.2. Schematic representation of the Delphi study design.

3.3.2 Sampling and Recruitment strategy

The study took place at a large West Midlands university and involved the recruitment of academic staff and students from the BSc Biomedical Science programmes. Some participants in the student group lacked experience in a clinical pathology laboratory, whilst others had completed a placement year in a hospital laboratory and would be eligible to join the HCPC register upon graduation. Practicing BMSs from a local NHS Trust were recruited regardless of level of experience. Academic staff, students and practicing BMSs were invited to participate in three separate focus groups, but unfortunately a focus group proved challenging for the BMS group and individual interviews were preferred. PSRB representatives were invited to participate in online interviews.

Following distribution of participation invitations, a follow up reminder was sent one week prior to data collection. At the local participating NHS Trust, a gatekeeper distributed the participant information sheet and consent form, therefore it is unknown how many potential participants received this information. In the academic group, the participant information sheet was distributed to 22 colleagues via email and in the student group this was sent to 142 final year students via their virtual learning platform. In the BMS, student and academic groups 8 to 20 participants were requested for the initial focus group. Recruitment of PSRB representatives was poor, therefore the invitation was extended to council members with responsibility for guideline development via a gatekeeper at one PSRB organisation, which resulted in the recruitment of an additional PSRB representative.

3.3.3 Sample size

There is no accepted minimum sample size for Delphi methodology (Keeney, Hasson and McKenna, 2011). Possibly due to the COVID-19 pandemic, recruitment numbers were low, but acceptable for carrying out focus groups in the 1st round. Due to pressures of the COVID-19 pandemic, a focus group for BMSs was not convenient and one-to-one interviews were preferred. As a result, 2 PSRB representatives and 5 HCPC registered BMSs were recruited for one-to-one online interviews. Two virtual focus groups were conducted via Microsoft Teams, one with 7 students from the BSc Biomedical Science programmes and another with 5 academics. In total, 19 participants were recruited for the 1st round.

Table 3.1. Method of data collection in round one according to participant group. Participant codes, relevant experience and discipline are presented, unless removal was essential to preserve anonymity.

Participant Group	Data collection method	Participant Codes	Experience of the BMS role	Discipline
Biomedical Scientists (n=5)	One-to-one interviews	BS1	1 year in NHS	Haematology
		BS2	<1 year in NHS	Haematology
		BS3	>25 years in NHS	Immunology
		BS4	>25 years in NHS	Biochemistry
		BS5	5-10 years in NHS	Haematology
Academics (n=5)	Focus group	AC1	HCPC registered	Not disclosed to preserve anonymity
		AC2	No experience as a BMS	
		AC3	No experience as a BMS	
		AC4	HCPC registered	
		AC5	Completed NHS placement	
Students (n=7)	Focus group	S1	Not completed placement	N/A
		S2	Not completed placement	N/A
		S3	Not completed placement	N/A
		S4	Not completed placement	N/A
		S5	NHS placement student	Biochemistry
		S6	NHS employment (non-BMS)	Immunology
		S7	NHS placement student	Histology
PSRB (n=2)	One-to-one interviews	PB1	Experience as a BMS	Not disclosed to preserve anonymity
		PB2	Experience as a BMS	
Total Participants		**19**		

The participants represented a range of organisations and professional backgrounds. Despite appearances as a heterogenous group of participants, they were all stakeholders of the BMS role, and this demonstrates a degree of homogeneity. It is recognised that a homogenous group of stakeholders are more likely to achieve consensus than a heterogenous one (Manley, 2013). To

enhance credibility of the findings, participants should be representative of the population to be influenced by the research, which was an important consideration in this study (Murphy *et al.,* 1998). Small sample sizes draw upon the homogeneity of participants. Although the participants appeared to represent a heterogenous group, the small sample size utilised in this study is supported by the overarching homogeneity of participants as stakeholders of the BMS role, despite representing a range of organisations (figure 3.3). The use of representatives from a single academic institution and a single NHS Trust supported this homogeneity. Both PSRB representatives were HCPC registered BMSs, demonstrating further homogeneity with the BMS group.

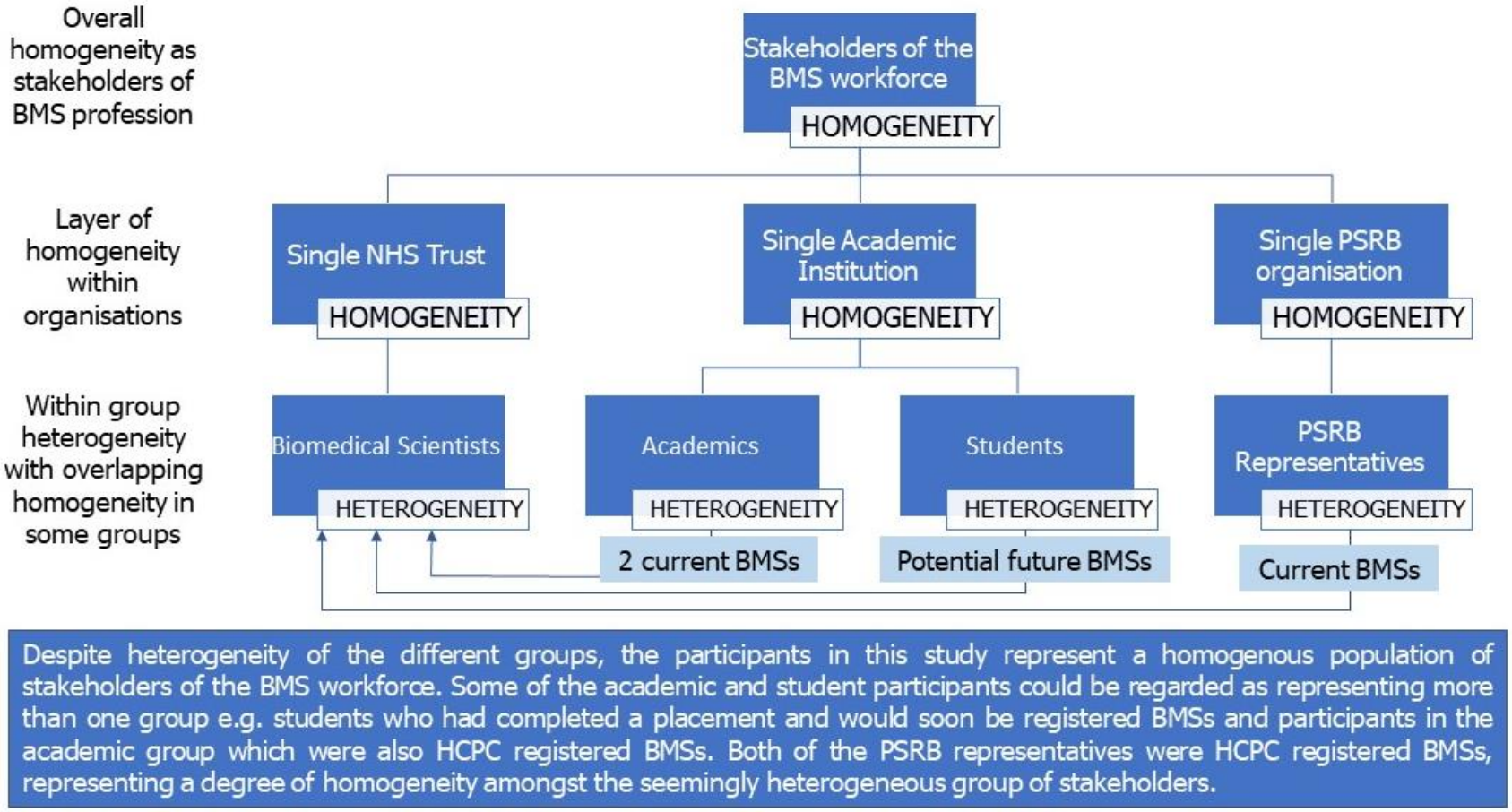


Figure 3.3 Diagram demonstrating the degree of homogeneity and heterogeneity amongst the participants.

Although 19 participants may be considered low and makes reaching definitive conclusions challenging, utilising one-to-one interviews and focus groups in the 1st round meant this was an acceptable number as both methods allow a deep approach to data acquisition (Campbell and Cantrill, 2001). Panel sizes of 10-15 participants are considered acceptable for a Delphi study (Day and Bobeva, 2005). Unfortunately, due to pressures of the COVID-19 pandemic, representatives from the 3 targeted PSRB groups were not recruited. Only representatives from one of the three invited organisations participated, with both PSRB participants representing the same organisation. Section 3.6.3.1 considers the impact of the COVID-19 pandemic upon recruitment. The implications of this will be considered further in chapter 5.

3.3.4 Participant Response rates

The response rate in the 1st round of the study was unknown due to the use of gatekeepers in the NHS Trust to invite prospective participants. Participants from round 1 were invited by email to complete the 2nd round questionnaire using Jisc Online Surveys. Participants had two weeks to complete the questionnaire before a reminder was sent and a final submission deadline was set. Individual respondents in round 2 could not be identified, so a reminder was sent to all round 1 participants. This reminder resulted in a further two students, one academic and one BMS participant completing the questionnaire. Of the 19 participants in the first round, 16 responses were received in round 2. Table 3.2 provides a breakdown of participant numbers by group.

Table 3.2 Participant numbers and response rate in the first and second round of the study.

Participant group	Participants in Round One	Participants in Round Two	Response rate
HCPC Registered Biomedical Scientists	5	4	80%
Academics on BSc Biomedical Science programme	5	5	100%
Students on BSc Biomedical Science	7	7	100%
PSRB Representatives	2	0	0%
Overall Response rate	**19**	**16**	**84.2%**

Between the 1st and 2nd rounds one participant was lost from the BMS group and both PSRB representatives failed to respond. The lack of PSRB representatives in round 2 will be considered in chapter 5. The student and academic groups retained all participants between the 1st and 2nd rounds. The 84.2% response rate for the 2nd round was acceptable for a Delphi study, where response rates of at least 70% are required to maintain rigour (Keeney, Hasson and McKenna, 2011). All non-responses were recorded as this may have resulted from a deliberate choice to omit a response because the participant is unsure of the answer, or from unintentionally missing a response.

3.4 ROUND ONE METHODOLOGY

Within this section, the methodology for the 1st round of the Delphi study is explained including the process of data collection and thematic analysis.

3.4.1 Data collection procedure

The qualitative 1st round was informed by the literature review, which was used to develop the interview schedule. The qualitative 1st round data was analysed using content analysis techniques (Hasson, Keeney and McKenna, 2000; Vázquez-Ramos, Leahy and Estrada Hernández, 2007). Braun and Clarke (2013) thematic analysis was considered the most appropriate data analysis technique for round one because of the flexible nature of the methodology and accessibility to less experienced qualitative researchers. The findings of the thematic analysis were used to develop attitude statements for the 2nd round as outlined in section 3.5.

3.4.2 Developing the interview schedule

The interview schedule was developed using the literature review findings and identifying key themes and unresolved issues to generate the questions. Participants were provided with a vignette that was designed to be accessible to all stakeholders and outlined a case requiring prompt action from a BMS. Data collection began with discussion of the vignette (appendix 14) and the Biomedical Scientist's role within the case, before progressing onto questions informed by the literature review findings. The interview schedule can be found in appendix 14. The questions were refined following a mock interview with a colleague.

It was important to consider trustworthiness in the data collection process and this was based around the criteria of Lincoln and Guba, (1985). It was important to establish credibility of the findings and reduce researcher bias which was

achieved through piloting the interview schedule and carrying out an item pool reduction (section 3.5.2) of the paired statements generated in round 2 to identify those statements with the greatest discriminating power (Hicks, 2004). Delphi methodology lends itself to triangulation of method through combination of qualitative and quantitative data. Using a questionnaire to establish consensus in the 2nd round verified initial observations from the 1st round. To establish applicability of the findings, stakeholders which represented several stakeholder groups were invited to participate. To ensure consistency and neutrality, one of the 1st round transcripts was subject to independent thematic analysis by a colleague and the results were compared for consistency and to ensure appropriate themes had been identified (Lincoln and Guba, 1985).

3.4.3 Transcription

Anonymised audio recordings were made of the interviews and focus groups and transcribed shortly after data collection to preserve key details (Braun and Clarke, 2013). Transcription software 'Express Scribe' was used to reduce recording speed and aid transcription. Verbatim transcription was used to produce an exact record of the discussions. Whilst a transcript is a representation of an interview or focus group, it is not raw data itself. Instead, it is the result of a subjective interaction between the recording and the transcriber, who listens to the recording (Braun and Clarke, 2013). The transcriber must select what to preserve from the recording and how to present this in written form. The transcription notation system used in this thesis is provided in table 3.3.

Table 3.3. Transcription notation system used throughout the participant transcripts. Adapted from Braun and Clarke, (2013).

Feature	Notation and explanation of use
The identity of the speaker	Int: Interviewer is speaking XX1: Participant code used when participant is speaking
Laughter	(Laughs) or (General laughter) if multiple participants are laughing
Coughing	(Coughs)
Pauses	(Pause) signals a moderate pause (3-5 seconds), … signals a short pause, (Long pause) indicates a pause longer than 5 seconds
Inaudible speech	(Inaudible) with best guess presented in parentheses
Non-verbal sounds	'Erm', 'er', 'mmm', 'hmmm', 'uh-huh' represent non-verbal sounds made by participants
[Removed for confidentiality reasons]	Removed to preserve the identity of the participant
[Context]	When the quote requires further information to provide context e.g. The Institute [of Biomedical Science]

During the verbatim transcription, participant responses were presented as stated without correction of sentence structure or spoken word to capture how participants expressed themselves. Punctuation was added during the transcription process and appropriateness of punctuation and tone of voice were confirmed when verifying accuracy of the transcription by replaying the recordings. An example transcript is provided in appendix 15, which is highlighted to demonstrate coding.

3.4.4 Thematic analysis

Thematic analysis is a qualitative research methodology that encompasses data analysis but does not stipulate data collection techniques and can be adopted in a range of ontological and epistemological positions (Braun and Clarke, 2013). As a result, thematic analysis was an appropriate data analysis technique as the

study aimed to influence professional practice aligned with a pragmatist approach. The process of thematic analysis is lacking in the published literature and the process of theme identification is often under-reported (Vaismoradi *et al.,* 2016).

3.4.4.1 Familiarisation and data coding

The first stage of thematic analysis was familiarisation with the transcripts, which began with immersion in the data. This consisted of re-reading the transcripts to identify early discussion points and patterns, identifying only the most obvious themes (Braun and Clarke, 2013). This stage of data analysis involved reading the words analytically and critically to understand the data. Coding was carried out manually and transcripts were colour-coded line by line to identify comments relevant to the research. Complete coding according to Braun and Clarke (2013) ensured that all relevant data was considered. Both data-derived and researcher-derived codes were identified and recorded. Whilst data-derived codes accurately reflected the content of the data, researcher-derived codes went beyond the explicit content of the data and addressed implicit meaning (Joffe and Yardley, 2004; Braun and Clarke, 2013; Vaismoradi *et al.,* 2016). Codes were selected to be concise and capture the key aspects of the data (appendix 15). Selected codes were found frequently or infrequently within the data set and there was no defined boundary for inclusion, but they were chosen to represent data diversity (Braun and Clarke, 2013). Codes were created based upon the participants' narrative but were rarely defined in the same terms the participant had used as they were designed to be informative without the data set and were refined throughout the process.

3.4.4.2 Identifying patterns across the data

Once the codes from all transcripts were identified, patterns within the data emerged. This process was carried out manually by displaying the codes visually and arranging them into themes when commonalities were identified. Themes were considered as specific patterns within the data which conveyed subjective meanings (Joffe and Yardley, 2004; Vaismoradi *et al.,* 2016). Themes were identified with a central organising concept and to provide meaningful data insight and capture the essence of the participant's experiences and opinions (Vaismoradi *et al.,* 2016). The relationships between the themes were considered as either linear or hierarchical and arranged into subthemes accordingly. This was an active process with candidate themes being revised by reviewing the coded data and the entire dataset (Braun and Clarke, 2013). Once complete, illustrative quotes, themes and subthemes were subject to revision to produce the revised thematic map (figure 4.1) which presents a visual representation of the themes and subthemes in chapter 4.

3.5 ROUND TWO

The remainder of this chapter presents the methodology for round two of the Delphi study.

3.5.1 Development of the attitude statements

Attitude statements were developed into an item pool as described by Oppenheim (1992) and Hicks (2004). Following the thematic analysis in round one, statements were developed from quotes taken during the 1st round and

themes identified in the literature review. Development of 94 attitude statements occurred following round one, which consisted of 47 positive and negative paired statements. These were revised through the removal of repetitive statements and rephrasing of ambiguous ones.

Positive and negative paired statements were used to determine the participants' true opinions by minimising satisficing. Satisficing involves selecting responses that are perceived to be acceptable, agreeing with assertions or scoring each question with the same or similar rating (Krosnick, 1990; Daniel, 2011). Statements were designed to be clear, unambiguous and address a single opinion so as not to cause confusion (Oppenheim, 1992; Hicks, 2004). In Delphi methodology, steps should be taken to reduce attrition, therefore, the time between rounds was minimised to maintain participant interest (Keeney, Hasson and McKenna, 2011; Trevelyan and Robinson, 2015).

Participant opinion was scored using a five-point Likert scale consisting of strongly agree, agree, neither agree nor disagree, disagree, or strongly disagree. These responses were awarded a numerical value from 1 to 5. This scoring system was reversed for the opposing version of the statement (Hicks, 2004). For example, strongly agreeing with the positive statement that BMSs work in the best interests of the patient scored 5, and strongly disagreeing with the opposing statement that the desire to work in the best interests of the patient is not shared by all BMSs also scored 5 (see table 3.4). Therefore, a participant who believed that BMSs work in the patient's best interests would score highly

for this pair of statements. The scores were not shared with the participants and were added once responses were received.

Table 3.4. An example of the scoring system employed for paired attitude statements.

Positive statement: Q2. Biomedical Scientists work in the best interests of the patient at all times				
Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
5	4	3	2	1
Negative statement: Q11. The desire to work in the best interests of the patient at all times is not shared by all Biomedical Scientists				
Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1	2	3	4	5

Participants who felt they could not provide an opinion for a statement were asked to omit the question, however, participants may have unintentionally omitted a response. As far as possible, the voices of the participants in round 1 were used to construct the statements used in round 2 as recommended by Keeney, Hasson and McKenna (2011). Participants could select a neutral response to demonstrate 'do not know' if they could not express an opinion (Likert, 1932). Participants may have felt a neutral opinion towards a statement and therefore selected 'neither agree nor disagree', but it was recognised that participants may not have sufficient knowledge or experience to provide a response and may prefer to omit their answer. Removing the option 'neither agree nor disagree' has been shown to increase the number of negative responses recorded (Garland, 1991).

3.5.2 Item pool reduction

The 94 attitude statements in the item pool were reduced before presenting to participants in the round two questionnaire. Delphi studies are associated with attrition between rounds, therefore it was important to include a manageable number of statements in an appropriate timescale to maintain participant interest. Multiple rounds increase the possibility of study fatigue or distractions (Hsu and Sandford, 2007; Keeney, Hasson and McKenna, 2011). To minimise attrition, participation in both rounds of the study was explicit from the outset. Two rounds is the minimum number in a Delphi study, but was appropriate as the study aimed to determine whether consensus existed amongst stakeholders rather than proceeding until consensus was reached.

The item pool reduction was carried out according to Hicks (2004). The draft item pool was distributed to 15 academics in the Department of Biomedical Science and Physiology who had not participated in round 1. The pilot participants were recruited through an email distributing the 94 attitude statements to eligible colleagues who had sufficient understanding of the BMS role to enable them to express an informed opinion on the topic. Although the pilot participants had not participated in round one of the study, they were representatives of one of the participating groups with an understanding of the BMS role. Piloting the statements with academics rather than the round 1 participants was deemed necessary to reduce attrition and facilitate generation of the round 2 questionnaire quickly. In addition, the study was carried out at a time of high pressure due to the COVID-19 pandemic and piloting the statements with the round 1 participants may have reduced engagement in round 2. Hicks

(2004) recommends that the item pool is piloted with a minimum of 20-25 participants, but due to small numbers of participants in round one, 15 participants for the pilot was deemed acceptable. Of the 15 participants who received the pilot questionnaire, 14 responses were received.

To identify statements which demonstrated the greatest power to discriminate between different strengths of attitude, the total score for each respondent in the pilot was calculated (Hicks, 2004). The total scores were arranged from lowest to highest and the five respondents with the highest and lowest scores were identified. The number of participants in the low scoring group who scored each statement with a 4 or 5 were identified, and this process was repeated with the high scoring group. Statements where the difference between the high and low scoring groups was greater than or equal to 2 were included, and those below this value were removed (Hicks, 2004). There were 22 paired statements included in the final questionnaire (44 statements in total), along with one ranking question focused upon priorities of the BMS role.

The statements were randomised to ensure positive and negative statements were interspersed to reduce satisficing (Hicks, 2004). The final questionnaire using Jisc online surveys can be found in appendix 13. Hicks (2004) recommends that the pilot questionnaire is redistributed to the same participants to establish reliability. However, due to the timeframe of the Delphi study and the need to reduce attrition, it was not possible to delay distribution of the round two questionnaire. This was acknowledged as a possible limitation of the study design and is discussed in chapter 5.

3.5.3 Defining consensus

The aim of the 2nd round was to determine whether consensus existed amongst stakeholders regarding the BMS role within patient outcomes and where areas of divergence existed. Delphi studies define consensus as the agreement of an individual participant with a statement, providing a group opinion and the level of agreement amongst participants, both within and between groups (Campbell and Cantrill, 2001; Keeney, Hasson and Mckenna, 2001; Trevelyan and Robinson, 2015; Humphrey-Murto *et al.,* 2017). The percentage of agreement is commonly used to define consensus (Keeney, Hasson and McKenna, 2006; Diamond *et al.,* 2014). In Delphi methodology, there is inconsistency regarding the required level of consensus, leading to a lack of standardisation (Boulkedid *et al.,* 2011; Keeney, Hasson and McKenna, 2011; Diamond *et al.,* 2014). The required level of consensus should be established before data collection begins to remove bias (Campbell and Cantrill, 2001; Keeney, Hasson and McKenna, 2006; Barrett and Heale, 2020). The level of consensus reported in the literature ranges from 51% up to 80% (Hasson, Keeney and McKenna, 2000; Keeney, Hasson and McKenna, 2006; Diamond *et al.,* 2014).

Although a range of consensus levels are quoted in the literature, 70% of participants agreeing or strongly agreeing and disagreeing or strongly disagreeing with a particular statement has been widely applied, despite a small sample size (Keeney, Hasson and McKenna, 2011; Humphrey-Murto *et al.,* 2017). Another Delphi study with limited participants (n=18) adopted a consensus level of 75% (Berger-Estilita, Nabecker and Greif, 2019), suggesting

that the widely applied level of 70% would be appropriate for this study. Although numerous studies have defined consensus, a definition of divergence is elusive. One author suggested that disagreement occurred when 1/3rd of participants had opposing views (scored the lowest available scores 1-3) and another 1/3rd of participants scored the highest available score 7-9 when using a 9-part scoring system (Fitch *et al.,* 2000). Disagreement and divergence are not interchangeable terms, therefore for the purposes of this study the definition of divergence was failure to reach consensus (Moore *et al.,* 2009).

3.6 Ethics

This section provides an overview of the ethical considerations associated with the study, including ethical approval and the impact of COVID-19 upon recruitment.

3.6.1 Ethical Considerations

One key ethical consideration for this study was being an insider researcher, which involves conducting research with populations, communities or groups which the researcher is also a member (Asselin, 2003; Brannick and Coghlan, 2007; Greene, 2014). Insider researchers can also be defined by engaging in research within their own institution, which is applicable as both an employee and student of the research institution (Asselin, 2003). Insider research is often criticised for a tendency by the researcher to believe they know the culture, reducing objectivity in data collection (Brannick and Coghlan, 2007). To minimise this, the literature review findings were used to generate the interview schedule in round 1. If the researcher is known to the participants, there is a risk that

participants will only reveal ideological details and may not express their true opinion. Social desirability bias is the tendency of research participants in qualitative research to promote a desirable trait and suppress those considered undesirable (Nederhof, 1985; Bergen and Labonté, 2019).

Whilst participants may have been known to the researcher, it was also likely that participants would be known to each other through their professional networks. Every effort was made to ensure anonymity of the participants, however, anonymity can be difficult to achieve because participants are invariably known to each other as experts in their field (Barrett and Heale, 2020). This study used online focus groups or interviews in the 1st round. Although participants were given the option to have their cameras off, true anonymity could not be maintained. Participants agreed not to disclose any information they heard in the study when giving consent (Appendix 12).

The benefits of insider research include access to organisational systems and participants more readily. Participants may be more willing to engage with a familiar researcher with whom they have established a rapport, which is relevant when researching colleagues and students (Greene, 2014). Insider researchers can ask meaningful questions and gain a full understanding of the culture under study (Hammack, 1997; Moreno *et al.,* 1998; Ferguson, Yonge and Myrick, 2004). Participants may be more comfortable with an insider researcher and provide honest accounts, or conversely may feel they cannot share information for fear of being judged or impacting their professional relationship with the researcher (Fleming, 2018). This was addressed by invitations and reminder

emails requiring participants to complete the informed consent form, demonstrating an understanding of participation expectations from the outset.

The inclusion of students in the study creates a power imbalance where the student's ability to freely decide whether to participate is compromised (Hammack, 1997). Researchers and academics must ensure that no coercive pressure is applied to students or colleagues, but even when no coercive pressure is applied, colleagues may feel obliged to participate and students may falsely perceive participation to provide an academic advantage (Hammack, 1997; Moreno *et al.,* 1998; Ferguson, Yonge and Myrick, 2004). Trust between the academic researcher and research participants is important for addressing this power imbalance and academic staff have a moral duty to function in the best interests of their students (Ferguson, Yonge and Myrick, 2004). The use of online focus groups and an anonymous questionnaire in round 2 helped to address this power imbalance. Online focus groups which allow participants to turn off their video camera help to increase anonymity and support participants to feel more comfortable and engage in the discussion, which is beneficial for reducing the power imbalance (Flayelle, Brevers and Billieux, 2022). Participants in round 2 were identifiable only by their participant group, providing a further sense of anonymity. To minimise perceived pressure, recruitment was requested electronically, and participants were invited to complete the informed consent form. Once this was completed, a participation invitation was sent only to those who had consented. One week prior to data collection, a single reminder email was distributed to all participants to prevent undue pressure on those who did not wish to participate.

The research was carried out in accordance with the University's ethical requirements and General Data Protection Regulation (GDPR) (Information Commissioner's Office, 2018; Research Policy Unit, 2020). The only identifiable data collected from participants was their name and email address, which was required to arrange the focus group or interview. This information was stored on a password protected, encrypted file on the University's secure network. Participants were asked to treat any information, including participant identities, confidentially because the use of focus groups in the 1st round meant that participants could not be truly anonymous. Prior to participating, stakeholders were informed what the study involved, and informed consent was taken for both rounds of the study. Expectations of the participants were explicit, the time between the rounds was minimised and participants attended online focus groups or interviews during round one to facilitate participation and increase response rates (Keeney, Hasson and McKenna, 2011; Trevelyan and Robinson, 2015).

Participants were informed of their ability to withdraw from the study, and the importance of doing so within two weeks of data collection, in the participant information sheet (appendix 11). Due to the nature of the Delphi methodology, notification of intention to withdraw was required prior to data analysis. Once data analysis from the 1st round had taken place, it was impossible to withdraw an individual participant's responses, but they were advised to omit their 2nd round responses if they wished to withdraw. Participants were made aware that they could omit responses in lieu of 'do not know' as this was an important ethical

consideration. Missing data is important in survey-based research and can occur due to a unit nonresponse, where an entire participant's data is lost due to non-participation, or through item nonresponse which is failure to obtain a response for a question (de Leeuw, 2001). Failure to record missing data items introduces a risk of bias during data analysis, particularly as round 2 aimed to determine whether consensus existed amongst stakeholders. None of the participants requested withdrawal from the study, but 3 participants were lost between rounds, which is discussed further in chapter 5.

3.6.2 Ethical Approval

Ethical approval was obtained from the Faculty of Education, Health and Wellbeing (FEHW) ethics committee on 18th March 2020 (Appendix 1). Ethical approval from the NHS Health Research Authority (HRA) was obtained on 13th May 2020 (IRAS ID: 273632, REC reference: 20/LO/0675) (Appendix 2). According to the HRA decision tool, this study was classified as research (Health Research Authority, 2020). HRA approval was subject to an amendment being submitted for the 2nd round questionnaire, which was not available until completion of round one data collection. Approval for the 2nd round questionnaire was received on 24th of November 2020 (Appendix 6). As the study involved staff and students from the Faculty of Science and Engineering (FSE), advice from the Chair of the Life Sciences ethics committee was obtained (Appendix 7). Confirmation of capacity for the study was provided by Research and Development (R&D) at a local NHS Trust on 7th August 2020 (Appendix 5).

3.6.3 Recruitment Procedure

Once ethical approval was obtained, data collection began in September 2020. Recruitment of participants was arranged through a gatekeeper at the participating NHS Trust. Initially, one Trust was selected for ease of carrying out data collection. In hindsight, online data collection would have facilitated participation from more than one NHS Trust, which may have increased recruitment. For staff and students on the BSc Biomedical Science programmes, permission to conduct the research was requested from the Head of the Department of Biomedical Science and Physiology and was received on 18th August 2020 (Appendix 8). The prospective participants received an email providing a brief overview of the study and instructions for participation (appendix 9 and 10). The participant information sheet (appendix 11) was distributed alongside the invitation email containing the link to the online consent form (appendix 12). Participants were then contacted individually to arrange a date and time for data collection. Each participant was allocated a code to anonymise their responses (see table 3.1). The participant codes were not shared with the participants and in round 2, participants were only identified by their participant group. Any section of the transcript which may have identified the participant has been removed and this was noted in the transcript.

3.6.3.1 The Impact of the COVID-19 pandemic on the research

The NHS HRA announced in March 2020 that continuing with research during the pandemic required COVID-safe measures to be introduced, meaning face-to-face data collection moved online. Amended paperwork to reflect these changes was submitted to FEHW ethics committee and ethical approval was

obtained on 6th August 2020 (Appendix 3). Confirmation was received from HRA on 19th July 2020 that amendments were not required (Appendix 4). NHS Trust R&D approval issued on 7th of August 2020 (appendix 5) reflected these changes in data collection.

The COVID-19 pandemic impacted recruitment as there was significant pressure on the BMS workforce, which resulted in arrangements for an online focus group being unsuccessful. To facilitate participation for this essential stakeholder group, the online focus group was replaced with online one-to-one interviews. Recruitment from the PSRB groups was also impacted, with some invited stakeholders responding to say they were too busy to participate. The implications of this will be discussed in chapter 5.

The Delphi methodology is more successful when the researcher builds a rapport with participants, minimising attrition between rounds (Keeney, Hasson and McKenna, 2011). Conducting the research online meant that building a rapport with participants was more challenging. However, utilising online video call technology in data collection has been considered 'the next best thing' to face-to-face interactions and participants prefer this to using the telephone (Archibald *et al.,* 2019). Although these changes were essential to allow data collection to continue, the potential implications are discussed in chapter 5.

3.7 Summary

This chapter has presented the methodology of both rounds of this Delphi study. It has outlined the rationale for methodology selection, recruitment of

participants and the process of thematic analysis. Development of the attitude statements was also described, along with the technique of piloting and reducing the item pool. Selection and justification of consensus levels have been described. In chapter 4, the results of the 1st and 2nd round will be presented, including illustrative quotes from the 1st round of data collection along with a discussion of findings and implications for practice.

CHAPTER 4. FINDINGS AND DISCUSSION OF ROUNDS ONE AND TWO

4.1 Introduction

This chapter presents the findings from both rounds of this Delphi study and puts these into context using published literature. In the qualitative 1st round, respondents participated in semi-structured interviews and focus groups, as outlined in chapter 3. The findings of the 1st round of the study, including illustrative quotes and the results of the thematic analysis are presented. In the 2nd round, participants were asked to score their agreement with a series of statements generated from round one. Round 2 findings are presented in a series of tables illustrating consensus levels by participant group. To aid data interpretation, statements are presented as pairs of positive and negative statements arranged according to round 1 themes. These statements were randomised when presented to participants to minimise bias.

4.2 Findings of Rounds One and Two

The round 1 thematic analysis identified several themes and subthemes (figure 4.1). The first theme was 'putting the patient at the centre', which consisted of two subthemes: patient in context and supporting patient care. The second theme was 'safety of the patient' which consisted of three subthemes: minimising harm, accreditation and registration and pressures of the role. The final theme was 'the multi-disciplinary team' which consisted of three subthemes: unseen healthcare workforce, misunderstood role and team working. Some overlap between the themes was evident and these are indicated by arrows on the thematic map. The themes and subthemes are presented, along with illustrative

quotes used to identify the themes. Illustrative quotes are presented in separate, indented paragraphs alongside the participant's code (Braun and Clarke, 2013).

Each of the 44 consensus statements in round 2 are presented in tables 4.1 to 4.9 and are colour coded with red representing consensus disagreement, green consensus agreement and grey for consensus not achieved. These are presented in pairs of positive and negative attitude statements according to the themes and subthemes in round 1 to aid data interpretation. In round 2, participants scored their agreement using a 5-point Likert scale, with the option to omit their response. In the remainder of this chapter, statements from the item pool will be presented to identify consensus or divergence of opinion. In response to some statements, one participant failed to provide an answer, which is indicated within tables 4.1 to 4.9. Important findings or observations considered relevant for practice will then be outlined in detail.

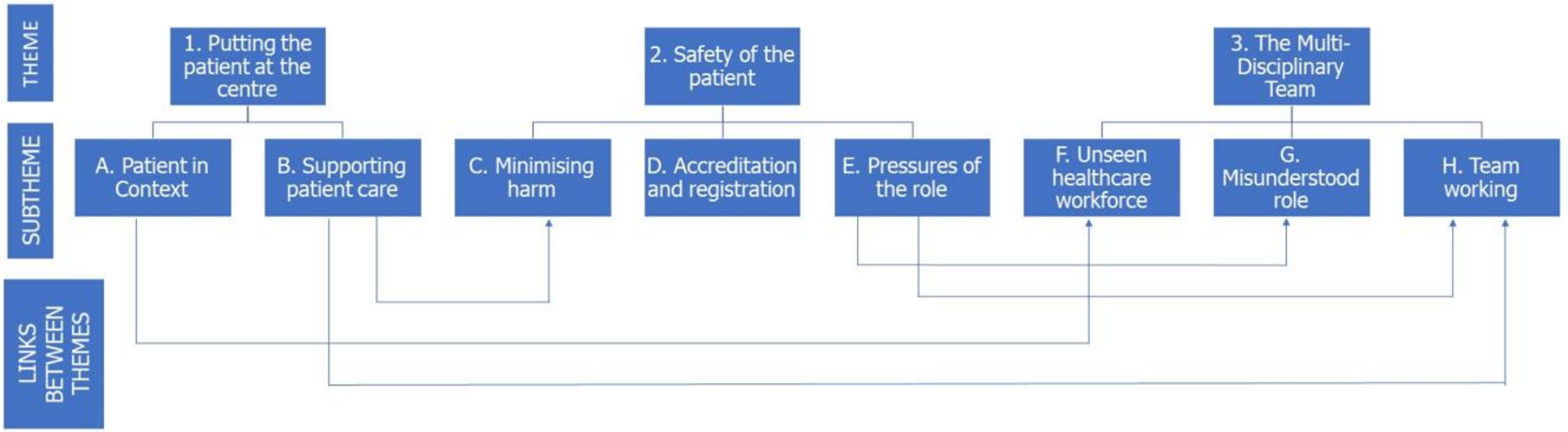


Figure 4.1. Flow chart to represent the three main themes and eight subthemes identified during the thematic analysis of round one. There is some overlap between the subthemes which are indicated by arrows.

4.2.1 Theme One: Putting the patient at the centre

Putting the patient at the centre captured an important aspect of the BMS role. Participants spoke passionately about the BMS role within healthcare and how this is integral for patient care. Participants perceived the motivation for the BMS role was to achieve patient outcomes and several participants discussed the importance of the patient, rather than the sample being analysed.

4.2.1.1 Theme One, Subtheme A: Patient in context

4.2.1.1.1 Round One Findings

Within the subtheme, 'patient in context', several participants expressed the importance of the patient within the BMS role and the desire to provide the best outcome. One of the BMS participants (BS1) stated:

> If you're in blood bank and there's a big, you know, massive major haemorrhage and a patient's needed unit after unit after unit, it's nice to know that the patient's still having a full blood count done two days later.

This statement reflected the desire to ensure their actions in the blood transfusion laboratory have contributed to a positive patient outcome. By processing a full blood count specimen at a later stage, the participant suggested that the patient's survival meant the BMS had positively influenced the patient's outcome. This reflects the isolated nature of the BMS role, whereby survival is perceived to equate clinical benefit, yet the clinical condition of the patient cannot be fully understood based solely upon a full blood count result. Participants also

commented upon the importance of recognising there is a patient behind every specimen:

> BMS (BS4):
>
> If you don't see the patient at the end of it you almost think 'well I'll take my time over that, I won't worry about doing it particularly quickly', whereas, you know, you could have a patient sat in the emergency department or the theatre waiting for a particular result and they're not getting it.

This extract highlights that, despite the lack of patient contact, stakeholders felt the need to focus upon the importance of the patient within their role. Phrases such as 'putting the patient first' were used frequently, but what this means from a BMS perspective has not been previously explored. Participants recognised the pathology laboratory played an important role in patient care, with delays in testing negatively impacting the clinical team, preventing diagnosis and treatment. This evidenced the crossover between this subtheme and the subtheme 'unseen healthcare workforce'. As BMSs lack patient contact, it is difficult for patients and other healthcare professionals to recognise the importance of the role. When asked how BMSs can evidence the importance of patient outcomes within the role, one BMS participant (BS4) explained that BMSs should be:

> Aware that there's a patient at the end of what they do, and they are working to a high standard. 'Erm', that they're working as per standard

> operating procedures in their lab, they're doing things properly, they're not taking any shortcuts and they're practicing to a high standard within their profession.

This demonstrated that by practicing to a high standard and following correct procedures, BMSs consider they are putting the patient first and contributing to patient outcomes. Participants outlined the importance of adherence to defined protocols and communicating results urgently to work in the patients' best interests. The laboratory must act to prevent errors which negatively impact patient care and should ensure all abnormal laboratory findings are acted upon (Hilborne, Lubin and Scheuner, 2009; Birse, 2010; Otto, 2011; Morris, Otto and Golemboski, 2013; Hallworth *et al.,* 2015). Participants discussed the need to ensure adherence to procedural aspects of the role, such as ensuring specimens are appropriately labelled and performing quality control checks. Processing correctly labelled specimens is essential for patient safety and has been discussed extensively in the literature (Brent, 2016; IBMS, 2016; Dunbar *et al.,* 2021).

One NHS placement student (S5) stated the importance of the patient was a key motivation for entering the profession:

> You're becoming a Biomedical Scientist because you want to help people, particularly in a hospital setting because you're going into pathology to run patient tests. You've kind of got to have a reason for doing that.

This quote demonstrated that contributing to patient outcomes was considered important for job satisfaction. One student employed in an NHS laboratory in a non-BMS role (S6) supported this viewpoint when discussing whether education or practice-based training should deliver the patient-focused aspects of a BMS role:

> It should be continuous rather than just one bit that we learn and then it's forgotten about because, I think, the patient is sort of overall the reason why we do the job anyway, and they should be the focus.

Student expectations were that the patient-focused aspects of the role were a requirement of their undergraduate education. However, these requirements are not explicit within course accreditation requirements, with graduates of an accredited BSc Biomedical Science award requiring knowledge of the clinical pathology of human disorders, disease processes, investigation and the contribution of these to patient care (IBMS, 2021a). There is currently no requirement for the patient-centred aspects of the BMS role to be delivered in undergraduate education, placing the burden on laboratories.

Although not previously discussed in the BMS role, in nursing, supporting PCC demonstrated significant improvements in job satisfaction (Pol-Grevelink, Jukema and Smits, 2012; Boer, Nieboer and Cramm, 2017; Huang *et al.,* 2020). In the UK, the BMS workforce is under strain due to high staff turnover, a lack of experience and development opportunities (Osaro and Chima, 2014). This was evidenced in round 2 where stakeholders expressed that BMSs should be better

integrated into the MDT and that follow-up on patient cases increased job satisfaction.

When discussing how BMSs can evidence they are striving to achieve patient outcomes, another PSRB representative (PB1) remarked:

> OK. I found those quite difficult. I feel quite ashamed of myself because you'd think, after all these years of me talking to people (pause) but it's just one of those things you take for granted.

This PSRB representative expressed that the importance of patient outcomes within the BMS role was taken for granted. This comment and the implications for practice will be discussed in chapter 5. Conflicting opinions were expressed within the academic group for this subtheme, and these opinions were not aligned with those of other stakeholder groups. One academic participant (AC2) stated:

> I still think a Biomedical Scientist would do the tests accurately, even if they didn't think about the patient, you'd hope, because that's the scientist part of it.

This suggests the participant felt the Biomedical Scientist's motivation was to achieve a scientifically accurate result and to excel in their role. The importance of patient outcomes was not considered an important factor, instead focusing upon the importance of achieving an accurate result. One HCPC registered

academic participant (AC4) expressed the BMS role was increasingly pressured, which detracted from the importance of patient outcomes:

> When you get that many specimens, it's difficult to devote… the same amount of attention to each one, but yeah, you're striving to have the patient's 'erm' interests at heart and their outcomes… I think the size of modern labs almost, they've turned into sausage factories if you will… Patients are almost viewed as a number.

This participant highlighted the challenges of the BMS role and recognising the importance of the patient due to significant numbers of specimens received. The opinions of the academic participants conflicted with the opinions of other stakeholder groups. Academic stakeholders with experience of working in an NHS laboratory discussed the volume of samples making it difficult to focus upon patient outcomes, whereas other stakeholder groups felt that this was essential. This demonstrated conflicting opinions between the academic group and other stakeholders.

4.2.1.1.2 Round Two Findings

Following analysis of the 2nd round data, key findings were identified in relation to the consensus rates across the participant groups. In response to statement 11, 'the desire to work in the best interests of the patient at all times is not shared by all BMSs' there was divergence of opinion and this statement failed to reach consensus in any participant group (table 4.1). Whilst the academic group demonstrated a tendency towards agreement, the student group demonstrated

a tendency towards disagreement. In the BMS group, there was evidence of a split opinion. One participant in the academic and student groups strongly agreed with this statement, which conflicts with an agree consensus being achieved across all groups for the opposing version of the statement, that 'BMSs work in the best interests of the patient at all times' (Q2).

There was greater divergence in the student responses than in the BMS group and an increased reliance upon the 'neither agree nor disagree' option on the Likert scale. This indicated a discrepancy between stakeholder responses which could indicate the desire to agree with statements that highlight the profession or respondent in a positive light. One recognised limitation of questionnaire research is that participants can agree with an assertion regardless of content (Krosnick, 1990). Reducing questionnaire length can minimise this as participants are more likely to give the same response to excessive numbers of questions (Daniel, 2011). In addition, social desirability bias can result in participants selecting responses they believe are socially acceptable, rather than their true opinion (Nederhof, 1985; Bergen and Labonté, 2019).

In response to question 25, 'despite a lack of proximity to the patient, BMSs put the patient at the centre of what they do', most participants demonstrated agreement. The statement reached consensus within the student group, BMS group and overall, but failed to reach consensus in the academic group (table 4.1). Two academics and one student disagreed with this statement, suggesting that some participants believed patients were not at the centre of the BMS role.

Question 3, 'it is easier for staff providing direct patient care to prioritise patient outcomes' achieved an agree consensus in the student and academic groups but demonstrated divergence in the BMS group. This suggested that participants considered the Biomedical Scientist's input in patient outcomes a key motivation for the role. This was an observation made by MLS participants in Canada, supporting the importance of patient outcomes in the laboratory scientist role (Birse, 2010). Failure to achieve consensus in the academic group for the positive version of the statement (Q25) conflicted with an agree consensus in the academic and student groups for Q3. Academic responses demonstrated divergence of opinion compared to the practicing BMSs, which is important since academics influence student understanding through curriculum content and delivery.

Analysis of the 1st and 2nd round data demonstrated the presence of a theory-practice gap, although it is important to note that the small number of participants in round 2 makes reaching definitive conclusions challenging. The theory-practice gap has been described extensively in nursing and relates to the divide between theoretical ideals generated in academic environments and professional practice (Zieber and Wojtowicz, 2020). In nursing, this gap is greatest for newly qualified professionals due to the physical separation of academic studies and clinical practice, contributing to difficulties relating theory and practice (Monaghan, 2015; Greenway, Butt and Walthall, 2019). This was particularly relevant to the student group, as only a small proportion of students on the BSc Biomedical Science award complete a healthcare laboratory placement. The theory-practice gap has been described in paramedic science

(Michau *et al.,* 2009), pharmacy (Pittenger *et al.,* 2019), medicine (Wright and Homer, 2017) and extensively in nursing (Bradshaw and Merriman, 2008; Scully, 2011; Monaghan, 2015; Greenway, Butt and Walthall, 2019). However, this has not been previously described in relation to the BMS workforce, illustrating a contribution to knowledge. By identifying this gap, strategies to address this can be developed and curricular changes introduced.

Not all students studying a degree in Biomedical Science aspire to work as a healthcare BMS. Graduates may pursue careers in teaching, research or pursue further education, which is challenging when designing the curriculum. Placements within industry or within the NHS are open for all 2nd year BSc Biomedical Science students to apply, but annually only a handful of placements are available. The benefit of placements for students and their future employability are well recognised (Yorke and Knight, 2006; Brooks, 2012; Cunningham and Gallacher, 2013). Laboratory experience is often required when applying for graduate positions, therefore a lack of experience in a healthcare laboratory makes graduate employment challenging (Demaria, Hodgson and Czech, 2018). Unfortunately, Biomedical Science placement availability is limited, and this is a barrier to obtaining HCPC registration.

The theory-practice gap in the academic group was also evident within this subtheme and is a key finding of this study. There was a discrepancy between the responses in the BMS group and the academic group for the subtheme patient in context, suggesting a lack of understanding of the BMS role in the academic group. To meet the requirements of HCPC accreditation of the Applied

Biomedical Science award, a HCPC registered BMS should have overall responsibility for the award (HCPC, 2017). Academics on the BSc Biomedical Science programme may not have experience of NHS pathology laboratories and HCPC registration is not mandatory, unlike in other healthcare courses where practitioners deliver most of the content. Therefore, a lack of understanding or personal experience of the BMS role amongst academics may influence student responses. The QAA Benchmark Statements are not designed to be a prescriptive syllabus, allowing academics to influence degree content, learning and assessment (Quality Assurance Agency, 2019). This highlights the importance of practitioner involvement in courses linked to professional practice to ensure students develop a real-world view. Practitioner lecturers are aware of the knowledge and skills required in the professional workforce and can instil these skills into students (McEwen *et al.,* 2003). The use of visiting lecturers who remain in practice is essential for ensuring professional currency and an important requirement for PSRB accreditation of the award (IBMS, 2020b).

Statement 43 that 'it is possible for a BMS to do their job well without considering the needs of the patient' demonstrated divergence of opinion. All BMS participants disagreed with this statement but the student and academic groups failed to reach consensus. This suggests that some participants felt it was possible for a BMS to do their job well without considering the needs of the patient, which is an important finding. This finding does not comply with the professional and regulatory body guidelines, which require BMSs to work in the best interests of patients and service users at all times (HCPC, 2014; 2016; IBMS, 2018a). There was also divergence of opinion for whether lack of patient contact

impacted upon the ability of BMSs to achieve patient outcomes. As this statement achieved consensus in the BMS group only, it further evidenced a theory-practice gap (Monaghan, 2015; Greenway, Butt and Walthall, 2019).

The response to Q43 conflicted with participant responses to question 35, 'a BMS should recognise the importance of each individual sample by considering the needs of the patient behind the sample', which reached consensus within all groups and overall (table 4.1). This provided further evidence of conflicting responses by participants to positive and negative versions of the statements, which may suggest that lack of a clear definition of the BMS role in patient outcomes leads to differing interpretations amongst stakeholders. Students and academics failed to reach consensus on the negative version of the statement, which is significant because the importance of patient outcomes are not explicit in the BSc Biomedical Science curriculum (Quality Assurance Agency, 2019), meaning that these essential concepts must come through professional and statutory body guidelines.

Table 4.1. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme A: Patient in Context

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
PUTTING THE PATIENT AT THE CENTRE, SUBTHEME A: PATIENT IN CONTEXT									
2. Biomedical Scientists work in the best interests of the patient at all times.	6/7 (85.7%) Agree 1/7 (14.2%) Neutral	4/4 (100%) Agree	4/5 (80%) Agree 1/5 (20%) Disagree	14/16 (87.5%) Agree 1/16 (6.25%) Neutral 1/16 (6.25%) Disagree	11. The desire to work in the best interests of the patient at all times is not shared by all Biomedical Scientists	3/7 (42.9%) Disagree 3/7 (42.9%) Neutral 1/7 (14.2%) Agree	2/5 (50%) Disagree 2/5 (50%) Agree	3/5 (60%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree	6/16 (37.5%) Disagree 4/16 (25%) Neutral 6/16 (37.5%) Agree
25. Despite the lack of proximity to the patient, Biomedical Scientists put the patient at the centre of what they do	6/7 (85.7%) Agree 1/7 (14.2%) Disagree	4/4 (100%) Agree	2/5 (40%) Agree 1/5 (20%) Neutral 2/5 (40%) Disagree	12/16 (75%) Agree 1/16 (6.25%) Neutral 3/16 (18.75%) Disagree	3. It is easier for staff providing direct patient care to prioritise patient outcomes due to their proximity to the patient.	5/7 (71.4%) Agree 1/7 (14.2%) Neutral 1/7 (14.2%) Disagree	2/4 (50%) Agree (2/4) 50% Disagree	4/5 (80%) Agree 1/5 (20%) Disagree	11/16 (68.75%) Agree 1/16 (6.25%) Neutral 4/16 (25%) Disagree

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
35. A Biomedical Scientist should recognise the importance of each individual sample by considering the needs of the patient behind each sample	6/7 (85.7%) Agree 1/7 (14.2%) Disagree	4/4 (100%) Agree	5/5 (100%) Agree	15/16 (93.75%) Agree 1/16 (6.25%) Disagree	43. It's possible for a Biomedical Scientist to do their job well without considering the needs of the patient	3/7 (42.9%) Disagree 2/7 (28.6%) Neutral 2/7 (28.6%) Agree	4/4 (100%) Disagree	2/5 (40%) Disagree 1/5 (20%) Neutral 2/5 (40%) Agree	9/16 (56.25%) Disagree 3/16 (18.75%) Neutral 4/16 (25%) Agree
Key	Consensus (>70%) reached agree or strongly agree				Consensus (>70%) reached Disagree or strongly disagree	Failed to reach consensus			

4.2.1.2 Theme One, Subtheme B: Supporting patient care

4.2.1.2.1 Round One Findings

Within the subtheme supporting patient care, participants discussed the BMS role and expectations of pathology service users. One of the BMS participants (BS4) stated the BMS role was to:

> Ensure the results are reported in a timely manner to the correct people that need to take action, and also have the knowledge that this patient might require further testing so it might not be just the tests that the GP requested.

This participant's response highlighted the integral role of the BMS within healthcare, but also demonstrated the requirement for autonomy. BMSs must recognise and action abnormal results and provide further testing to facilitate timely clinical decision making, using their education and training. Another BMS participant (BS2) commented:

> We're the ones giving the doctors and the clinical staff the information they need to base their decisions on, 'erm' so if you didn't spot the blasts for example, they might have just treated it completely differently.

In this response, the participant recognised BMSs highlighted abnormalities in laboratory results, (including visual abnormalities in blood or tissue seen

microscopically) to allow clinical staff to achieve an informed diagnosis and treatment strategy. This subtheme of supporting patient care demonstrated overlap with the subthemes minimising harm and team working, as participants recognised the importance of the BMS role for supporting healthcare.

Focusing upon achieving patient outcomes was considered an important aspect of patient safety. Stakeholders felt BMSs were responsible for highlighting urgent and abnormal findings to clinicians to prevent them being overlooked. One academic participant (AC2) described the BMS role as essential for initiating treatment decisions:

> It is the first step that is required to find out what's wrong with them, and if you don't know what's wrong with them, you can't treat them.

This highlighted the importance of the BMS role for supporting patient care, the MDT and clinical decision making. The participant continued, stating that working to achieve patient outcomes was an essential aspect of PCC:

> I completely agree with patient centred care and patients should be the centre of it because, 'erm', it, it's not just a number. The patient isn't a number, so they need to treat each sample as an individual person.

The term PCC was not phrased in the question, suggesting the participant felt PCC demonstrated putting the patient at the centre of the role. PCC is considered an important aspect of healthcare and features heavily throughout the nursing literature. However, this concept has not been discussed in relation to the BMS workforce. In healthcare, PCC relies upon a therapeutic relationship between the healthcare professional, the person being cared for, and their significant others (McCormack and McCance, 2017). For BMSs, this therapeutic relationship is difficult to establish due to a lack of patient contact.

In the education of BMSs, there is a predominant focus upon the biomedical aspects of disease and patient-centred decision making is rarely covered (Homberg, Oberhauser and Kaap-Fröhlich, 2019). The HCPC standards which BMSs must comply with use terminology such as "understand the need to act in the best interests of service users at all times" (HCPC, 2014 p. 7). Whether acting in the best interests of service users constitutes PCC and whether PCC was a tangible aim for BMSs was discussed by the participants in the 1st round of the study. It is likely that the PCC definition should be revised to recognise that non patient facing roles, including BMSs, can practice in a person-centred way.

One BMS participant (BS5) spoke passionately about supporting patient care being a key motivation for entering the profession:

> So that's why I took the role as a Biomedical Scientist, because in my role, I'm still helping the patient and I'm still helping to find out what's wrong with the patient.

The literature lacked discussion of how BMSs work to achieve patient outcomes. Therefore, it was considered essential to articulate this within the scope of this study. When asked how they interpreted 'putting the patient at the centre' of their role, one NHS placement student (S5) remarked:

> Just turning up at the hospital, doing your thing, doing your job, continually training to get better, that's you helping the patient in some small way.

Acting in the 'patient's best interests' was discussed by several participants. As previously described, these terms have not been defined in the literature, demonstrating a contribution to knowledge of this study.

4.2.1.2.2 Round Two Findings

Following on from analysis of the 2nd round findings (table 4.2), noteworthy trends in the consensus data were identified. Statement 26, 'job satisfaction is not determined by the perceived importance of the patient within the BMS role' showed divergence of opinion. The BMS group reached a disagree consensus however, the academic and student participants demonstrated greater divergence of opinion, with some participants agreeing with the statement.

Except for one student response, all participants agreed or strongly agreed that 'by focusing upon the outcome of the individual patient BMSs achieve greater job satisfaction' (Q42). This supported the emerging trend that positive statements reached consensus more often than negative statements.

When discussing the importance of achieving patient outcomes within the BMS role, participants stated that the primary role was to process specimens and initiate diagnosis and treatment pathways. This underpins the work of other healthcare professionals by ensuring results are reported and indirectly influences patient outcomes (DoH, 2006; 2008). Stakeholders considered the BMS role as essential for achieving patient outcomes, with several participants remarking that without BMSs to support diagnosis and treatment, patient outcomes would be unachievable. Participants in the BMS group suggested it enhanced their role to have follow-up in cases where they had influenced patient care. This suggested the importance of achieving patient outcomes was perceived to increase a Biomedical Scientist's job satisfaction, a concept which has been previously described in nursing (Castaneda and Scanlan, 2014).

To date, the published literature has failed to address the BMS role in achieving patient outcomes and the contribution made by this professional group to patient care, demonstrating the original contribution of this research. Across all stakeholder groups, consensus was achieved for the statement 'without BMSs, initiating diagnosis and treatment decisions for patients would be impossible' (Q12). Both the positive and negative versions of this statement achieved consensus across all groups, indicating that stakeholders felt BMSs were

essential for initiating diagnosis and treatment decisions. This is reflected by the estimate that pathology laboratories are responsible for 70% of diagnosis and treatment decisions (DoH, 2006; Hallworth, 2011; Ferraro, Braga and Panteghini, 2016).

Table 4.2. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme B: Supporting Patient Care

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
PUTTING THE PATIENT ARE THE CENTRE, SUBTHEME B: SUPPORTING PATIENT CARE									
42. By focusing upon the outcome of the individual patient, the Biomedical Scientist achieves greater job satisfaction	6/7 (85.7%) Agree 1/7 (14.3%) Neutral	4/4 (100%) Agree	5/5 (100%) Agree	15/16 (93.75%) Agree 1/16 (6.25%) Neutral	26. Job satisfaction is not determined by the perceived importance of patients within the Biomedical Scientist role	2/7 (28.6%) Disagree 2/7 (28.6%) Neutral 3/7 (42.9%) Agree	4/4 (100%) Disagree	3/5 (60%) Disagree 1/5 (20%) Neutral 1/5 (20%) Agree	9/16 (56.25%) Disagree 3/16 (18.75%) Neutral 4/16 (25%) Agree
12. Without Biomedical Scientists, initiating diagnosis and treatment decisions for patients would be impossible	7/7 (100%) Agree	4/4 (100%) Agree	4/5 (80%) Agree 1/5 (20%) Disagree	15/16 (93.75%) Agree 1/16 (6.25%) Disagree	44. Without the Biomedical Scientist role, point of care testing delivered by other clinical staff would be a suitable replacement	6/7 (85.7%) Disagree 1/7 (14.3%) Neutral	4/4 (100%) Disagree	5/5 (100%) Disagree	15/16 (93.75%) Disagree 1/16 (6.25%) Neutral

4.2.1.3 Overview of Theme One

Within the theme patient in context, participants recognised the role BMSs have within patient outcomes and the healthcare system. The student, BMS and PSRB representatives agreed the importance of patient outcomes within the BMS role should be implicit, however academic stakeholders expressed difficulties in focusing upon the importance of individual patients due to workload. Ways in which BMSs can evidence they are striving to achieve patient outcomes involved recognising the importance of the patient and producing high-quality results within a suitable timeframe. The BMS role was recognised by all stakeholder groups as essential for supporting clinical decision making and high-quality care. Consensus rates were high across all participant groups for theme one, but positive statements reached consensus more often than negative statements.

4.2.2 Theme Two: Safety of the patient

Within safety of the patient, participants discussed the importance of appropriate action to ensure patient safety. All stakeholder groups recognised the importance of accreditation and registration for preventing patient harm. The academic group discussed role pressures, but this subtheme did not feature in the BMS group and may reflect the heterogeneity of stakeholder groups.

4.2.2.1 Theme Two, Subtheme C: Minimising harm

4.2.2.1.1 Round One Findings

Participants discussed patient safety, challenging inappropriate decisions and the importance of the BMS role in advocating for the patient and preventing harm. One BMS participant (BS3) remarked:

> If you know that something's wrong, to be able to whistle blow and stand up and say 'this is wrong', so for example if you saw someone who wasn't following an SOP[1] you should be free to say 'that SOP isn't being followed therefore the results may be incorrect'.

This participant recognised that BMSs and clinical staff follow SOPs to ensure patient safety and prevent harm. The importance of being able to report deviations from procedure was considered key to this. The importance of minimising harm was supported by one of the PSRB representatives (PB1) who stated:

> Starting with the receipt of the sample, 'erm', ensuring that it's got the right (pause) 'erm' correct (pause) information on it 'erm' so 'erm'… procedural requirements, it's a suitable test for the indication and then that it is processed in accordance with standard operating procedures.

This comment recognised the importance of following standard procedures to minimise harm and ensure patient safety. Processing correctly labelled specimens was considered an important aspect of the BMS role, and central to ensuring high-quality results. One HCPC registered academic (AC1) explained the BMS role in achieving patient outcomes:

[1] Standard Operating Procedures (SOPs) are a set of instructions describing the relevant steps of a procedure or technique designed to ensure standardisation of the technique across operators.

> There's the checks, the QC[2], making sure that the specimen actually does belong to that patient, 'erm' and that you've got the correct sample as well.

This participant referred to the importance of quality control checks and ensuring specimens are adequately labelled prior to analysis. Without these essential steps, any reported results have little clinical benefit. One student employed in an NHS laboratory in a non-BMS role (S6) explained BMSs have a duty to ensure that other clinical staff have not made an error which might compromise patient care:

> Obviously, GPs and clinicians and consultants can sometimes miss things, 'erm' so if you just go along the lines of 'well I've done this test, that's all they've requested' then you're not getting the bigger picture and they could ultimately diagnose the patient incorrectly.

This comment highlighted that the BMS role requires application of knowledge and skills and autonomous decision making to ensure high-quality patient care. Participants from all stakeholder groups discussed the BMS role in ensuring patient safety and preventing harm. This is linked with the subtheme of supporting patient care. All stakeholder groups felt BMSs were key to ensuring

[2] Quality Control (QC) are materials with known concentrations of specific substances which can be used to ensure equipment or manual tests are functioning correctly. This helps to ensure the quality of the results reported by a laboratory.

procedures were correctly followed, and in facilitating safe patient care by supporting and challenging clinical decisions. Many of the discussion points within this subtheme considered procedural aspects of the BMS role.

Participants felt it was necessary to look beyond the samples received in the laboratory and to consider the needs of the patient behind the specimen. This was discussed by participants from all groups:

> BMS (BS4):
>
> Because we only see samples, and sort of in some labs it can almost seem like a bit of a production line, you have to keep reminding yourself that there's a patient at the end of this. I think on the whole that the majority of people do realise that and work to that end.

> Student (S4):
>
> When you're looking at just the lab results, 'erm', as a Biomedical Scientist so you need to have that in mind, that there is a patient on the other side of that 'erm' test result and it… ultimately, what you decide, well… will affect their lives.

These comments highlight the importance of focusing upon patient outcomes within the BMS role, a concept which has not previously been explored.

4.2.2.1.2 Round Two Findings

Following analysis of the 2nd round data for subtheme C (table 4.3), several key findings were identified. The statement 'the BMS plays an essential role in patient safety' (Q27) was agreed or strongly agreed with by all participants in the BMS and academic groups. There was greater divergence of opinion in the student group, with two participants expressing a neutral opinion, but consensus was reached overall. The opposing version that 'it is not within the Biomedical Scientist's remit to question clinical decisions' (Q45), generated disagree or strongly disagree responses across the BMS and academic groups, but the student group showed greater divergence of opinion with participants in this group expressing opposing opinions, which may indicate a lack of understanding of the BMS role. The greater degree of divergence identified in the student group may be related to a theory-practice gap and reflects the limited clinical exposure amongst some students on the BSc Biomedical Science award.

Students on the BSc Applied Biomedical Science programme complete a one-year clinical placement, rather than a 3-year integrated placement, common in other healthcare professions. In paramedic students, there was criticism of clinical placement for failing to expose students to a variety of clinical situations (Michau *et al.,* 2009). For Biomedical Science students, only a small proportion of students will gain experience in a clinical laboratory which widens the theory-practice gap. Morris *et al*. (2013) identified that MLS students in Canada were poorly prepared for meeting the IOM aims and the patient-centred aspects of their role and suggested curricular changes were required to address this, supporting the findings of this study.

The discrepancy between the BMS group and the student and academic groups further supported the presence of a theory-practice gap. In the student group, this theory-practice gap was evident in the subtheme *minimising harm* (table 4.3). Academics may have theoretical knowledge of a subject area without professional experience to apply the theory to real-world situations (Wright and Homer, 2017). To reduce the theory-practice gap, students require theoretical knowledge from academic staff and practical knowledge from clinical educators. This relationship is intertwined and key for developing practitioners with a suitable level of knowledge (Scully, 2011). Biomedical Science awards without an integrated placement may include less input from practicing BMSs, highlighting the requirement for practitioner input into professional courses.

Table 4.3. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme C: Minimising harm

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
SAFETY OF THE PATIENT, SUBTHEME C: MINIMISING HARM									
27. The Biomedical Scientist plays an essential role in patient safety	5/7 (71.4%) Agree 2/7 (28.6%) Neutral	4/4 (100%) Agree	5/5 (100%) Agree	14/16 (87.5%) Agree 2/16 (12.5%) Neutral	45. It is not within the Biomedical Scientist's remit to question clinical decisions that put the patient at risk	3/7 (42.9%) Disagree 2/7 (28.6%) Neutral 2/7 (28.6%) Agree	4/4 (100%) Disagree	5/5 (100%) Disagree	12/16 (75%) Disagree 2/16 (12.5%) Neutral 2/16 (12.5%) Agree
36. Biomedical Scientists are able to draw upon their own personal experiences as a patient or carer which allows them to empathise with the patient	6/7 (85.7%) Agree 1/7 (14.3%) Neutral	4/4 (100%) Agree	2/5 (40%) Agree 2/5 (40%) Neutral 1/5 (20%) Disagree	12/16 (75%) Agree 3/16 (18.75%) Neutral 1/16 (6.25%) Disagree	4. Biomedical Scientists do not require empathy for patients to do their job effectively	4/7 (57.1%) Disagree 1/7 (14.3%) Neutral 2/7 (28.6%) Agree	4/4 (100%) Disagree	4/5 (80%) Disagree 1/5 (20%) Agree	12/16 (75%) Disagree 1/16 (6.25%) Neutral 2/16 (12.5%) Agree

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
13. Biomedical Scientists must question inappropriate clinical decisions	4/7 (57.1%) Agree 2/7 (28.6%) Neutral 1/7 (14.3%) Disagree	4/4 (100%) Agree	5/5 (100%) Agree	13/16 (81.25%) Agree 2/16 (12.5%) Neutral 1/16 (6.25%) Disagree	5. Patient safety is the responsibility of others in the clinical team and it is not appropriate for a Biomedical Scientist to question their decision making	5/7 (71.4%) Disagree 1/7 (14.3%) Neutral 1/7 (14.3%) Agree	4/4 (100%) Disagree	5/5 (100%) Disagree	14/16 (87.5%) Disagree 1/16 (6.25%) Neutral 1/16 (6.25%) Agree

Participants scored their agreement with the statement 'BMSs are able to draw upon their own experiences as a patient or carer to empathise with the patient' (Q36). The BMS and student groups agreed or strongly agreed with this statement. However, in the academic group there was greater divergence of opinion, with one participant disagreeing with the statement and two participants expressing a neutral response. The negative statement 'BMSs do not require empathy for patients to do their job effectively' (Q4) showed divergence of opinion in the student group, but consensus was achieved in the BMS and academic groups and overall (table 4.3). There was evidence of inconsistencies in the responses to the paired statements in both the academic and student groups. This suggests evidence of satisficing, whereby participants choose the first response deemed to constitute an acceptable answer (Krosnick, 1990). There was evidence of participants agreeing only with statements with positive connotations in some cases, which will be discussed further in chapter 5.

The statement 'BMSs must question inappropriate clinical decisions' (Q13) was agreed or strongly agreed with by all BMS and academic participants. The student participants demonstrated divergence of opinion, with one participant disagreeing with the statement and two participants expressing a neutral response. Consensus was achieved within the BMS and academic groups, and overall. The negative version of the statement 'patient safety is the responsibility of others within the clinical team, and it is not appropriate for BMSs to question their decision making' (Q5) reached a disagree consensus in all groups and overall (table 4.3). However, caution is required when interpreting the 2nd round data due to small participant numbers.

4.2.2.2 Theme Two, Subtheme D: Accreditation and registration

4.2.2.2.1 Round One Findings

Accreditation and registration recognised the highly regulated nature of the BMS profession. Laboratories are subject to accreditation by United Kingdom Accreditation Services (UKAS) against ISO 15189, as well as accreditation of training laboratory status by the IBMS. Within this subtheme, participants commented that accreditation and professional registration were essential for ensuring service quality. One PSRB representative (PB1) commented:

> It comes down to the regulatory frameworks that we're working within that if there are errors that lead to the HCPC doing investigations then people can be struck off. The unfortunate side, 'erm' outcome, of that is that the patient could be compromised.

This demonstrates that statutory registration was considered evidence that BMSs met the required standards for practice and this could be withdrawn in the event of malpractice or unprofessional behaviour (HCPC, 2016). The importance of working within their scope of practice and referring cases to appropriate clinicians was also discussed by the participants. The same PSRB representative (PB1) recognised that failing to focus upon patient outcomes can negatively impact the BMS professionally:

> It can seriously affect the patient and also contravenes the regulatory, 'erm' the regulations by which we are registered which can lead to disciplinary action and, 'erm', people being taken off the register so there are professional consequences as well as consequences for the patient.

This PSRB representative recognised the importance of professional registration but noted that unsafe deviation from procedure could lead to removal of registration. The impact of this upon patient outcomes and patient safety was acknowledged. The importance of adhering to professional guidelines is evident for registered healthcare professionals and malpractice has significant negative implications for their professional future (Maben *et al.,* 2021). The HCPC have fitness to practise procedures and a mechanism to remove practitioners from the register to protect the public from negative actions (HCPC, 2018a). Professional registration was considered favourably by stakeholders. One BMS participant (BS5) stated that professional registration and accreditation standards were important for patient safety:

> I wouldn't want myself or a family member to come into a hospital that 'erm' doesn't have these regulatory bodies or these legal aspects to them because then I wouldn't feel safe.

This comment demonstrated that participants recognised the importance of patient outcomes within the role and meeting the needs of the patient. There

was acknowledgement of the patient as a person through comparison to the care of a family member. Participants agreed that professional standards and regulation were important to underpin safety and high-quality services. This subtheme featured less prominently in the student and academic groups.

4.2.2.2.2 Round Two Findings

Once the 2nd round data had been analysed, important findings were identified (table 4.4). Participant responses to the statement 'HCPC registration for BMSs provides confidence for patients and others about the quality of the Biomedical Scientist's practice' (Q28) achieved consensus within all groups and overall (table 4.4). The negative version of the statement 'statutory registration for BMSs has no meaning to patients and others in the clinical team as they lack an understanding of the role' (Q14) showed greater divergence in responses. BMS and academic groups demonstrated conflicting views within their groups. Consensus was achieved only in the student group. However, in the student group, 71.4% of participants agreed with both opposing versions of the statement, demonstrating inconsistency and a potential lack of understanding of the importance of statutory registration, further evidencing a theory-practice gap. This lack of understanding within the student group may relate to the assumption that statutory registration confers an implied benefit. This theory-practice gap was also identified in the academic group for the subtheme accreditation and registration suggesting a poor understanding of these concepts within both the academic and student groups.

Participants scored their agreement with the statement 'statutory HCPC registration ensures BMSs feel empowered to make autonomous decisions' (Q37) and demonstrated divergence of opinion in the academic and student groups, with several participants expressing a neutral opinion. Consensus was reached in the BMS group only. Participant responses to 'BMSs are not required to make autonomous decisions' (Q15) achieved a disagree consensus in the BMS group only. The academic and student groups demonstrated greater divergence of opinion. These paired statements evidenced divergence of opinion within and across the groups, suggesting a lack of understanding of the BMS role. However, naming the statutory body in the positive version of the statement, but not in the negative version may have influenced responses, which will be discussed in chapter 5.

Table 4.4. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme D: Accreditation and registration

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
SAFETY OF THE PATIENT, SUBTHEME D: ACCREDITATION AND REGISTRATION									
28. Statutory HCPC registration for Biomedical Scientists provides confidence for patients and others in the clinical team about the quality of the Biomedical Scientist's practice	5/7 (71.4%) Agree 2/7 (28.6%) Neutral	4/4 (100%) Agree	4/5 (80%) Agree 1/5 (20%) Disagree	13/16 (81.25%) Agree 2/16 (12.5%) Neutral 1/16 (6.25%) Disagree	14. Statutory registration for Biomedical Scientists has no meaning to patients and others in the clinical team as they lack an understanding of the role	5/7 (71.4%) Agree 1/7 (14.3%) Neutral 1/7 (14.3%) Disagree	2/4 (50%) Disagree 2/4 (50%) Agree	3/5 (60%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree	10/16 (62.5%) Agree 2/16 (12.5%) Neutral 4/16 (25%) Disagree
37. Statutory registration with the Health and Care Professions Council (HCPC) ensures that Biomedical Scientists feel empowered to make autonomous decisions	2/7 (28.6%) Agree 5/7 (71.4%) Neutral	3/4 (75%) Agree 1/4 (25%) Disagree	2/5 (40%) Agree 1/5 (20%) Neutral 2/5 (20%) Disagree	7/16 (43.75%) Agree 6/16 (37.5%) Neutral 3/16 (18.75%) Disagree	15. Biomedical Scientists are not required to make autonomous decisions	4/7 (57.1%) Disagree 1/7 (14.3%) Neutral 2/7 (28.6%) Agree	4/4 (100%) Disagree	3/5 (60%) Disagree 1/5 (20%) Neutral 1/5 (20%) Agree	11/16 (68.75%) Disagree 2/16 (12.5%) Neutral 3/16 (18.75%) Agree

4.2.2.3 Theme Two, Subtheme E: Pressures of the role

4.2.2.3.1 Round One Findings

The perceived pressures within the BMS role, particularly TATs and volume of specimens received, was identified only within the academic group. Within this subtheme, participants commented upon the challenges of the BMS role. One HCPC registered academic participant (AC4) commented:

> Yeah, I feel that in the lab that I came from, that if you imagined those two poles apart, quantity and quality, I feel it's moving slightly from the quality towards the quantity... As a result, the quality of the work is not as good as it should be because they are focusing upon quantity.

Academic participants expressed BMSs experienced external pressures which prevented them focusing upon patient outcomes. Pressures of the role demonstrated some overlap with the misunderstood role and team working subthemes within theme 3, recognising that external pressures can be applied to the laboratory to meet the needs of the clinical team. Another HCPC registered academic participant (AC1) remarked:

> You've always got people breathing down your neck, haven't you? Where is the result for this? 'Erm' the consultant's coming, and I need this out today.

This comment reflected the pressures of the BMS role, but also demonstrated an 'us and them' perception, which may relate to BMSs not feeling part of the MDT.

The participant expressed that the consultant's workload was considered more important than the Biomedical Scientist's. The perceived pressures of the role highlighted by the HCPC registered academic participants may have been motivation for entering academia. Another academic participant with experience of an NHS placement (AC5) reflected upon their own experiences and commented:

> When I was being trained up, I was trained like 'you do it this way because this is the fastest way to do it', not like 'you should do it this way because it's the most accurate' or 'this is the way you'll get the result you need', it's like 'you do it this way because this is the fastest way to do it'.

This comment highlighted the pressure that some BMSs may feel to process and report high specimen volumes.

The pressures of the role were perceived to influence the quality of the laboratory service by academic stakeholders. This subtheme featured exclusively in the academic group which suggested that the perceived pressures of the role were less evident in the practicing BMS group. Time and workload pressures were considered to detract from the importance of achieving these outcomes. This has been discussed in the nursing literature, where high workloads are known to result in reduced quality care and impact upon patient safety (Aiken *et al.,* 2013; Ball *et al.,* 2014). Participants felt that BMSs who were not working to

achieve patient outcomes made mistakes and displayed a lack of care and attention. Healthcare professionals working under pressure, stress, lacking sufficient information, failing to take precautions and a lack of care and attention have historically been attributed to errors in patient care (Green, Tsiroyannis and Brennan, 2016; Ugur *et al.,* 2016).

4.2.2.3.2 Round Two Findings

Following analysis of the 2nd round data, a number of key findings were identified. In response to 'pressures of the BMS role do not detract from the importance of the individual patient' (Q17) an agree consensus was achieved amongst the student group, whilst the BMS and academic groups demonstrated greater divergence, with one academic omitting a response (table 4.5). Participants in the academic group expressed conflicting opinions, with one participant agreeing and two participants disagreeing with the statement. The small participant numbers in round 2 means that caution is required when reaching definitive conclusions and assuming wider application of the findings. The statement that 'other pressures of the BMS role detract from the importance of the individual patient' (Q29) demonstrated divergence of opinion, failing to achieve consensus in any group. This is an interesting finding and suggested that participants were unsure whether the pressures of the role detracted from the importance of the patient.

PCC for healthcare professionals is defined as 'a focus on treating people as individuals; respecting their rights as a person; building mutual trust and understanding; and developing therapeutic relationships' (McCormack and

McCance, 2017 p. 1). For BMSs this therapeutic relationship with patients may prove challenging due to a lack of direct contact, but this does not prevent the BMS from timely result reporting and escalating findings appropriately. Prompt reporting and initiation of treatment can positively influence patient care (Plebani, Laposata and Lundberg, 2011; Epner, Gans and Graber, 2013; Hallworth *et al.,* 2015). This requires BMSs to appropriately alert clinical teams to abnormal results to ensure patient care is not delayed. Participants in the academic group acknowledged focusing upon patient outcomes was challenging due to the volume of specimens that were received. Participants felt focusing upon patient outcomes increased the perceived importance of the specimen being tested. By focusing upon a specimen as an inanimate object, it was considered less important than considering the specimen as an essential element of patient care.

The motivation to provide quality patient care is reflected in the literature across several healthcare professions (Kjellström *et al.,* 2017). However, despite good patient care being considered important for job satisfaction, many aspects, including building a relationship with patients, establishing a human connection and receiving praise from patients (Castaneda and Scanlan, 2014) cannot be applied to the BMS role due to a lack of therapeutic relationship. This has not been previously explored in relation to the BMS profession, which demonstrates the contribution to practice of this study.

The statement 'BMSs must be prepared to put in extra hours to meet the needs of the service and the patient' (Q18) achieved consensus in both the student and

BMS groups but failed to reach consensus in the academic group or overall (table 4.5). Participants in the academic group expressed conflicting opinions for this statement. For the negative statement 'time pressures often impact upon a Biomedical Scientist's ability to do their job well' (Q6), the academic and BMS participants reached an agree consensus, whilst the student group showed greater divergence of opinion. This statement achieved consensus overall but failed to reach consensus in the student group (table 4.5). This pair of statements demonstrated divergence of opinion across the stakeholder groups, suggesting that to understand the pressures of the role required some first-hand experience.

The academic group failed to reach consensus on several statements which achieved consensus in other stakeholder groups and overall (table 4.1 to 4.9). The lower rate of consensus in the academic group was reflected by greater divergence in responses and increased rate of omissions. The academic group were less able to express an opinion for some statements than the student group, suggesting problems relating university content to clinical practice (Greenway, Butt and Walthall, 2019). The subtheme 'pressures of the role' was exclusively identified by academic participants. This suggests that HCPC registered BMSs may seek roles in higher education due to the challenges of their healthcare role or to seek a better work-life balance. This has been identified as motivation for entering academic careers in nursing, but not in relation to the BMS role (Magpantay-Monroe, 2009).

Table 4.5. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme E: Pressures of the role

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
SAFETY OF THE PATIENT, SUBTHEME E: PRESSURES OF THE ROLE									
17. The pressures of the Biomedical Scientist role do not detract from the importance of the individual patient	6/7 (85.7%) Agree 1/7 (14.3%) Neutral	2/5 (50%) Agree 2/5 (50%) Neutral	2/5 (40%) Disagree 1/5 (20%) Neutral 1/5 (20%) Agree 1/5 (20%) Omitted	9/16 (56.25%) Agree 4/16 (25%) Neutral 2/16 (12.5%) Disagree 1/16 (6.25%) Omitted	29. Other pressures of the Biomedical Scientist role detract from the importance of the individual patient	3/7 (42.9%) Disagree 3/7 (42.9%) Neutral 1/7 (14.3%) Agree	2/4 (50%) Disagree 2/4 (50%) Neutral	3/5 (60%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree	6/16 (37.5%) Disagree 6/16 (37.5%) Neutral 4/16 25% Agree
18. Biomedical Scientists must be prepared to put in extra hours in order to meet the needs of the service and the patient	5/7 (71.4%) Agree 2/7 (28.6%) Neutral	3/4 (75%) Agree 1/4 (25%) Neutral	3/5 (60%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree	11/16 (68.75%) Agree 4/16 (25%) Neutral 1/16 (6.25%) Disagree	6. Time pressures often impact upon a Biomedical Scientist's ability to do their job well	4/7 (57.1%) Agree 1/7 (14.3%) Neutral 2/7 (28.6% Disagree	3/4 (75%) Agree 1/4 (25%) Neutral	5/5 (100%) Agree	12/16 (75%) Agree 2/16 (12.5%) Neutral 2/16 (12.5%) Disagree

4.2.2.4 Overview of Theme Two

Within the theme 'safety of the patient', participants recognised BMSs minimised patient harm by ensuring procedures and protocols were correctly followed. All stakeholders recognised the importance of statutory registration and accreditation for ensuring a high-quality laboratory service and underpinning patient safety. In the academic group, participants discussed pressures of the BMS role which impacted upon achieving patient outcomes. This theme was absent in other stakeholder groups. Within the subtheme, minimising harm, consensus was more readily achieved across all stakeholder groups. However, there was greater divergence of opinion within the accreditation and registration and pressures of the role subthemes.

4.2.3 Theme Three: The Multi-Disciplinary team

The theme multi-disciplinary team demonstrated that BMSs did not feel part of the MDT. Participants discussed the difficulties in BMSs being isolated from the patient and wider healthcare team and the perceived lack of recognition as part of the MDT. Stakeholders felt clinical teams lacked an understanding of the BMS role, which made it challenging to justify decisions such as sample rejection. All participants expressed that BMSs should be recognised within the MDT and receive feedback when they had influenced patient care.

4.2.3.1 Theme Three, Subtheme F: Unseen healthcare workforce

4.2.3.1.1 Round One Findings

Participants felt BMSs were not recognised within the MDT due to a lack of face-to-face contact with patients and healthcare professionals. Stakeholders felt

there was a lack of understanding of the BMS role within healthcare. Despite the BMS role underpinning 70% of all diagnosis and treatment decisions, BMSs and the wider impact of pathology services on patient care is poorly understood (Ferraro, Braga and Panteghini, 2016). This was identified by participants who discussed feeling separated from other clinical teams:

> BMS (BS5):
> I think because we're hidden, like we're in the labs and we don't get any sort of patient face-to-face care or receive patients face-to-face, so I think a lot of people forget that we are there, and we do help in the decision making.

Stakeholders in all groups felt that BMSs were not recognised as part of the MDT or patient care pathway by the public. Several comments reflected a lack of external awareness of the BMS role. The laboratory workforce is often described as an inanimate object 'the lab'. This fails to recognise the knowledge and skills required to maintain the service and isolates BMSs from the clinical setting (Ferraro, Braga and Panteghini, 2016). Communication with other healthcare professionals and patients is predominantly over the telephone, further distancing BMSs from the MDT. Many participants perceived that BMSs contributing to patient care provided increased job satisfaction. There was some overlap between this subtheme and supporting patient care, as participants discussed the importance of laboratory results for diagnosis and treatment. Communication was identified as an important aspect of the BMS role, as one PSRB representative (PB2) stated:

> Communication of those results as well, whether they need to communicate those results urgently by something other than the usual paper or electronic reporting mechanisms.

This comment reflected the autonomy of BMSs to equate clinical presentation, laboratory findings and pathophysiology and determine whether results needed to be communicated urgently or routinely. The importance of urgent result communication, without over-alerting was considered an important skill for BMSs. This is a recognised requirement of the MLS role (Adams *et al.,* 2011; Hallworth *et al.,* 2015). Both verbal and non-verbal communication are considered essential features of PCC (McCormack and McCance, 2017). Despite communication being an essential element of the BMS role, communication directly with patients is limited, making it challenging to evidence PCC. Many participants felt the BMS role was crucial for timely patient management as BMSs would often be aware of a patient's diagnosis before the requesting clinician. By escalating urgent findings or laboratory results, the BMS provides the initial step required for diagnosis and treatment, which impacts patient outcomes.

The same PSRB representative (PB2) then discussed the historical BMS role, which traditionally included phlebotomy and face-to-face patient contact, recognising that this aspect of the BMS role is largely absent:

> There's not many Biomedical Scientists now who do phlebotomy, so they've got a lack of understanding of what patients are going through.

> When I trained, we went round, especially as trainees, to bleed the patients and you get a huge understanding of what patients are actually going through that I don't think modern Biomedical Scientists get.

This participant suggested that patient contact was beneficial to be able to prioritise patient outcomes within the BMS role. As the BMS role has evolved due to workload pressures, BMSs have become less integrated into the healthcare team and increasingly utilised telephone or written communication. Stakeholders felt that BMSs were not regarded as part of the MDT and felt separated from the wider healthcare team. There was also a perception that patients and healthcare professionals lacked understanding of the BMS role, with some participants suggesting there was little awareness of the duties undertaken. This subtheme was evident within all stakeholder groups.

4.2.3.1.2 Round Two Findings

Analysis of the 2nd round data demonstrated a number of noteworthy findings. The statement 'despite the lack of patient contact, BMSs can focus upon achieving outcomes for each individual patient' (Q30) demonstrated consensus in the BMS and student groups and overall, but divergence and conflicting opinions within the academic group (table 4.6). The negative version of the statement 'lack of patient contact makes it difficult for BMSs to recognise their role within an individual patient's outcome' (Q38) failed to achieve consensus within all groups. However, the academic participants largely agreed with this statement, whilst the student group and BMS groups had a larger proportion of

participants disagree with the statement. Within this subtheme, the student group reached consensus on one of the six statements, further supporting the presence of a theory-practice gap with respect to the BMS role in the MDT. There was divergence of opinion in all groups, demonstrating that respondents could not agree whether patient contact impacted upon a Biomedical Scientist's ability to prioritise patient outcomes, which is a key finding. In nursing, a physical nearness to the patient and an understanding of the patient's situation are considered important to feel a responsibility for patient care (Hillman, 2016). As this physical proximity cannot be achieved for the majority of BMSs, their education and training must reflect the importance of patient outcomes, a concept which is not currently included in the BSc Biomedical Science curriculum.

There is a national drive within England for consolidation of pathology services and reduction of on-site services to an essential core 'emergency service', with a central hub to process the regional workload (NHS Improvement, 2018). The consolidation of pathology services is ongoing and the impact of this on the BMS role is unknown. Nationally, less urgent services have relocated to centralised hub sites, whilst a reduced haematology and biochemistry service serves acute services, with 97% of NHS Trusts having progressed towards networked pathology services (NHS England and NHS Improvement, 2019).

In response to the statement 'centralisation of pathology services into 29 hubs across England is unlikely to impact the Biomedical Scientist's desire to focus upon patient outcomes' (Q19) there was divergence of opinion. The statement failed to achieve consensus in the student group, academic group and overall,

but achieved a disagree consensus amongst the BMS group (table 4.6). This may result from a lack of first-hand experience of the role in some stakeholder groups. The opposing statement that centralisation of pathology services will make it more challenging for BMSs to put the patient first (Q7), achieved an agree consensus in both the BMS and academic groups but failed to reach consensus in the student group and overall (table 4.6). One participant in the academic group failed to provide a response. The student group demonstrated divergence of opinion, with at least one participant selecting most options on the Likert scale.

There was divergence of opinion amongst stakeholders on whether centralisation of pathology services would impact upon the BMS role and make it more challenging to recognise the importance of the patient. Proximity to patients is thought to compel healthcare professionals to carry out their moral responsibilities (Hillman, 2016). Increasing separation of the BMS from the patient was perceived to make recognition of patient outcomes more challenging. This further physical separation may increase the divide between BMSs and other healthcare professionals, which may influence the perception that BMSs are not regarded as part of the MDT.

Table 4.6. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme F: Unseen healthcare workforce

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
THE MULTI-DISCIPLINARY TEAM, SUBTHEME F: UNSEEN HEALTHCARE WORKFORCE									
25. Despite the lack of patient contact, Biomedical Scientists can focus upon achieving outcomes for each individual patient	7/7 (100%) Agree	4/4 (100%) Agree	3/5 (60%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree	14/16 (87.5%) Agree 1/16 (6.25) Neutral 1/16 (6.25%) Disagree	38. Lack of patient contact makes it difficult for a Biomedical Scientist to recognise their role within an individual patient's outcomes	3/7 (42.9%) Disagree 2/7 (28.9%) Neutral 2/7 (28.9%) Agree	2/4 (50%) Disagree 2/4 (50%) Agree	3/5 (60%) Agree 2/5 (40%) Disagree	7/16 (43.75%) Disagree 2/16 (12.5%) Neutral 7/16 (43.75%) Agree
19. Centralisation of pathology services into 29 hubs across England covering a wider geographical area is unlikely to impact the Biomedical Scientist's desire to focus upon patient outcomes	3/7 (42.9%) Disagree 4/7 (57.1%) Agree	3/4 (75%) Disagree 1/4 (25%) Agree	3/5 (60%) Disagree 2/5 (40%) Agree	9/16 (56.25%) Disagree 7/16 (43.75%) Agree	7. Centralisation of pathology services into 29 hubs across England covering a wider geographical area will make it more challenging for Biomedical Scientists to put the patient first	3/7 (42.9%) Agree 2/5 (28.9%) Neutral 2/7 (28.9%) Disagree	4/4 (100%) Agree	4/5 (80%) Agree 1/5 (20%) Omitted	11/16 (68.75%) Agree 2/16 (12.5%) Neutral 2/16 (12.5%) Disagree 1/16 (6.25%) Omitted

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
47. Biomedical Scientists are well integrated within the healthcare team, despite a lack of patient contact	4/7 (57.1%) Disagree 2/7 (28.6%) Neutral 1/7 (14.3%) Agree	2/4 (50%) Disagree 1/4 (25%) Neutral 1/4 (25%) Agree	4/5 (80%) Disagree 1/5 (20%) Neutral	10/16 (62.5%) Disagree 4/16 (25%) Neutral 2/16 (12.5%) Agree	20. The nature of the Biomedical Scientist role makes it difficult for them to feel part of the healthcare team	2/7 (28.6%) Disagree 2/7 (28.6%) Neutral 2/7 (28.6%) Agree 1/7 (14.3%) Omitted	4/4 (100%) Agree	3/5 (60%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree	9/16 (56.25%) Agree 3/16 (18.75%) Neutral 3/16 (18.75%) Disagree 1/16 (6.25%) Omitted

4.2.3.2 Theme Three, Subtheme G: Misunderstood role

4.2.3.2.1 Round One Findings

Misunderstood role recognised that the public and healthcare professionals lacked understanding of the BMS role. Participants commented that the BMS role is more complex than other healthcare professionals recognise, with one BMS participant (BS4) commenting:

> People don't always appreciate that there's a laboratory behind that and the extent of the work, and even when it does come into the lab it's not always a case of just putting a sample on an analyser and pressing a button and 5 minutes later you get the results.

This quote demonstrated participants felt the role was undervalued and there was a lack of recognition amongst other healthcare professionals who failed to recognise the work involved in producing laboratory results. Unless the BMS role gains recognition from other healthcare professionals, public recognition will remain challenging. Participants felt the lack of recognition for the BMS role made them feel undervalued. The fragmented nature of healthcare systems can make it challenging for professionals to provide a holistic approach to patient care. Historically, pathology services have operated in a professional silo physically separated from other aspects of clinical care (DoH, 2006). The BMS role needs wider publicity to enable better understanding of what this involves. However, the lack of recognition and public understanding of the role was thought to impact engagement of BMSs with the public and other healthcare professionals (DoH, 2006; Ferraro, Braga and Panteghini, 2016).

Participants expressed that the BMS role was simplified by clinical colleagues who did not appreciate the technical requirements of reporting pathology results. It was also suggested that the laboratory could be seen as a scape goat and was blamed by clinical teams if things went wrong:

> BMS (BS3):
>
> The likes of GPs and that will blame labs for not getting the results back to the patient… so the patient gets the perception that the labs aren't doing their job.

The perception that BMSs and laboratories were blamed for missing samples or unreported results highlighted that the nature of the BMS role may prevent exploration of these issues with patients or the clinical team. It was suggested the BMS role was not highly regarded by patients or clinical teams:

> BMS (BS4):
>
> I don't know that we're always as highly regarded as we should be, although, you know, obviously we do contribute to a high percentage of diagnoses and treatments for the patient. I don't think we shout loud enough about what we do.

Participants expressed a lack of appreciation of the BMS role amongst the public and healthcare team, with one participant suggesting BMSs needed to publicise their expertise. There was some overlap with the subtheme 'pressures of the

role' as the misunderstood nature of BMS duties contributed to perceived external pressures. Overall, participants expressed that the BMS role was misunderstood and unappreciated which made the role more challenging. Participants felt that clinical teams became frustrated when specimens were rejected rather than recognising this as a key aspect of patient safety.

4.2.3.2.2 Round Two Findings

Following on from analysis of the 2nd round data, some key findings were identified. In response to the statement 'the BMS role is well understood by other healthcare professionals' (Q21), there was divergence of opinion across participant groups. Only the student group reached consensus, disagreeing with the statement, whilst within all other groups, consensus was not achieved (table 4.7). The opposing statement 'the role of the BMS in healthcare is poorly understood by other healthcare professionals', demonstrated greater agreement, with consensus reached overall, in the student and BMS groups (table 4.7). In the academic group, participants expressed opposing opinions and all statements in this subtheme failed to reach consensus within the academic group, further supporting the presence of a theory-practice gap. The degree of consensus for the negative statement conflicted with the divergence of the positive statement demonstrating inconsistencies in responses.

Rejection of incorrectly labelled specimens by the laboratory is considered important for ensuring patient safety and minimising harm (Plebani, 2014; Brent, 2016). However, in response to the statement 'Clinical teams respond positively if the laboratory rejects a patient's sample due to incorrect labelling' (Q22) both

the student and BMS groups reached a disagree consensus. The statement 'clinical teams often suggest that the laboratory is negatively impacting patient care if an incorrectly labelled sample is rejected' (Q39) reached an agree consensus in the BMS and student groups. Rejecting incorrectly labelled specimens is essential for ensuring patient safety, but stakeholders felt this was not understood by the MDT. Incorrectly labelled specimens are a major cause of wrong blood in tube (WBIT) incidents and patient harm, therefore, BMSs strive to ensure only appropriately labelled specimens are processed (Plebani, 2014; Brent, 2016). This contributed to a perceived lack of understanding of the BMS role amongst healthcare professionals.

The need for adherence to procedural requirements is highlighted in the professional documentation (HCPC, 2014; IBMS, 2018b). Providing recommendations for further testing was considered important to minimise further delays in patient care and reduce patient anxiety and discomfort. Professional guidelines were recognised as providing the basis for BMSs to evidence they are working to achieve patient outcomes. These guidelines were considered to ensure the quality of a Biomedical Scientist's work and ensure respect for the patient. The guidelines were considered essential for patient safety, a key aspect of statutory registration and requirement to use the protected title 'Biomedical Scientist' (HCPC, 2015).

Table 4.7. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme G: Misunderstood role

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
THE MULTI-DISCIPLINARY TEAM, SUBTHEME G: MISUNDERSTOOD ROLE									
21. The role of the Biomedical Scientist in healthcare is well understood by other healthcare professionals	5/7 (71.4%) Disagree 1/7 (14.3%) Neutral 1/7 (14.3%) Agree	2/4 (50%) Disagree 1/4 (25%) Neutral 1/4 (25%) Agree	3/5 (60%) Disagree 2/5 (40%) Agree	10/16 (62.5%) Disagree 2/16 (12.5%) Neutral 4/16 (25%) Agree	31. The role of the Biomedical Scientist in healthcare is poorly understood by other healthcare professionals	7/7 (100%) Agree	3/4 (75%) Agree 1/4 (25%) Neutral	3/5 (60%) Agree 2/5 (40%) Disagree	13/16 (81.25%) Agree 1/16 (6.25%) Neutral 1/16 (6.25%) Disagree
22. Clinical teams respond positively if the laboratory rejects a patient's sample due to incorrect labelling	6/7 (85.7%) Disagree 1/7 (14.3%) Neutral	3/4 (75%) Disagree 1/4 (25%) Neutral	2/5 (40%) Disagree 1/5 (20%) Neutral 1/5 (20%) Agreed 1/5 (20%) Omitted	11/16 (68.75%) Disagree 3/16 (18.75%) Neutral 1/16 (6.25%) Agree 1/16 (6.25%) Omitted	39. Clinical teams often suggest the laboratory is negatively impacting patient care if an incorrectly labelled sample is rejected	5/7 (71.4%) Agree 1/7 (14.3%) Neutral 1/7 (14.3%) Disagree	3/4 (75%) Agree 1/4 (25%) Neutral	2/5 (40%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree 1/5 (20%) Omitted	10/16 (62.5%) Agree 3/16 (18.75%) Neutral 2/16 (12.5%) Disagree 1/16 (6.25%) Omitted

4.2.3.3 Theme Three, Subtheme H: Team working

4.2.3.3.1 Round One Findings

Team working recognised the interconnected nature of the UK healthcare systems, which relies upon collaborative working to support patient care. Participants across different stakeholder groups recognised the importance of team working:

> Student (S2):
>
> If this was a member of my family that was, 'erm', being tested, would I be happy just leaving it like 'I'm doing my job OK'? If we all work together as a team then, like everyone that's involved in the patient pathway, then it will, 'erm', I think achieve a better outcome for the patient.

The importance of team working to achieve the best outcome for the patient was evident in the participants' comments, as was the desire to positively influence patient care. Participants in the BMS group discussed the desire to receive follow-up from clinical teams:

> BMS (BS4):
>
> It's very nice when you get feedback from the clinicians, and you get to know how you've influenced that patient's treatment and diagnosis, but you don't always get that.

This comment supported the perceived difficulty of BMSs to feel part of the MDT as participants remarked that being informed of a patient's outcome was desirable, but rarely achieved. One of the PSRB representatives (PB2) spoke passionately about the BMS role within healthcare:

> The Institute [of Biomedical Science] keep saying 70-80% of diagnoses rely on Biomedical Scientists. You haven't got a healthcare service, an integrated healthcare service, without Biomedical Scientists.

This recognised the importance of individuals within the healthcare system completing their role effectively, but also recognised that BMSs may not always see the bigger picture. Teamwork is essential in healthcare, but participants expressed BMSs could utilise their knowledge and skills to support clinical colleagues if better integrated into the healthcare system. There was some overlap between this subtheme and supporting patient care and pressures of the role. BMSs expressed a desire to receive follow-up for clinical situations they have had input into, and this is linked to the desire to be a recognised member of the healthcare team.

4.2.3.3.2 Round Two Findings

Following analysis of the 2nd round data, several key findings were identified. There was divergence of opinion for the statement 'BMSs are regarded as an essential part of the MDT by the wider healthcare team' (Q8). No group reached consensus for this statement, suggesting that BMSs struggle to feel part of the

MDT. In the opposing statement participants demonstrated divergence of opinion that 'BMSs are not considered part of the MDT by the wider healthcare team' (Q32). In the BMS and academic groups there were opposing opinions amongst participants. Table 4.8 demonstrates that consensus was not achieved within any participant group for this pair of statements, which demonstrated divergence of opinion regarding the BMS role within the MDT.

When considering the BMS role within the MDT the statement 'BMSs are well integrated within the healthcare team, despite a lack of patient contact' (Q47) reached a disagree consensus in the academic group only. The opposing statement 'the nature of the BMS role makes it difficult for them to feel part of the healthcare team' (Q20) reached an agree consensus in the BMS group only. In the academic group, discussions regarding the MDT were limited, suggesting a lack of understanding of both the BMS role and the integrated nature of the healthcare system. It is essential that staff delivering professional courses understand the role to deliver effective teaching. This has previously been described in relation to the occupational therapist profession (Murray and Lawry, 2011), but has not been identified with respect to the BMS role. In the theme, 'the multi-disciplinary team' very few statements achieved consensus, although the small sample size means caution is required when considering the wider implications.

In round 2, participants were informed that if they could not express an opinion on a particular statement, to omit their response. None of the BMS participants omitted a response to any of the statements, whilst in the student group two

responses were omitted in table 4.8 (Q20 and Q40, omitted by different participants). In the academic group, four responses were omitted in tables 4.5, 4.6 and 4.7 (Q17, Q7, Q22 and Q39), but these were omitted by the same participant, suggesting this participant felt unable to express an opinion on these topics. Three of the omissions in the academic group and two in the student group occurred within the theme 'the multi-disciplinary team'. This suggests that in the academic and student groups, it may be difficult to gain an understanding of how the BMS role contributes to the wider healthcare system.

Stakeholders discussed how to recognise a BMS working to achieve patient outcomes and the physical disconnect between BMSs, patients and clinical teams. The importance of recognising the needs of the patient and service user, despite this disconnect was discussed. The concept of moral proximity has been described as the automatic responsibility felt for others due to their proximity (Bauman, 1990). The moral responsibility for others does not exclusively rely upon physical or emotional proximity, but some knowledge of the other person elicits a response (Hillman, 2016). In healthcare, it is essential that patient care is prioritised over other tasks, but the relationship between a patient and their healthcare professional is an essential element of this (Nortvedt and Nordhaug, 2008). For BMSs a lack of proximity to the patient may reduce moral responsibility, suggesting this should be addressed in their education and training. Although BMSs cannot demonstrate a typical healthcare professional and patient relationship, this does not prevent BMSs from empathising with the patient's situation.

The lack of patient contact was highlighted as making it more challenging to recognise the importance of patient outcomes. Physical separation of the patient and healthcare professional reduces the moral demand to address the needs of a faceless patient (Bauman, 1991). For BMSs achieving patient outcomes for an unknown, faceless patient may reduce moral responsibility. In patient-facing roles, the impact of a healthcare professional upon patient care is evident from assessing the patient's clinical symptoms, something which a BMS is not able to do. Hillman (2016) recognised that ED nurses found it challenging to meet their moral responsibilities due to the increasing demands placed upon them. It is possible that BMSs thrive on demonstrating moral responsibility for a patient that they will not encounter, and this may be a key motivation for entering the profession, as articulated in this study.

Table 4.8. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group for subtheme H: Team working

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
THE MULTI-DISCIPLINARY TEAM, SUBTHEME H: TEAM WORKING									
8. Biomedical Scientists are regarded as being an essential part of the multi-disciplinary team by the wider healthcare team	4/7 (57.1%) Agree 1/7 (14.3%) Neutral 2/7 (28.6%) Disagree	2/5 (50%) Disagree 1/5 (25%) Neutral 1/5 (25%) Agree	3/5 (60%) Disagree 2/5 (40%) Agree	7/16 (43.75%) Agree 2/16 (12.5%) Neutral 7/16 (43.75%) Disagree	32. Biomedical Scientists are not considered part of the multi-disciplinary team by the wider healthcare team	3/7 (42.9%) Agree 3/7 (42.9%) Neutral 1/7 (14.3%) Disagree	2/5 (50%) Agree 2/5 (50%) Disagree	3/5 (60%) Agree 2/5 (40%) Disagree	8/16 (50%) Agree 3/16 (18.75%) Neutral 5/16 (31.25%) Disagree
33. Biomedical Scientists must recognise when referral to a consultant or member of the medical team is required to ensure the best outcome for a patient	5/7 (71.4%) Agree 2/7 (28.9%) Neutral	4/4 (100%) Agree	5/5 (100%) Agree	14/16 (87.5%) Agree 2/16 (12.5%) Neutral	40. Biomedical Scientists are not responsible for referring a patient case for a consultant to review	3/7 (42.9%) Disagree 2/7 (28.6%) Neutral 1/7 (14.3%) Agree 1/7 (14.3%) Omitted	4/4 (100%) Disagree	3/5 (60%) Disagree 1/5 (20%) Neutral 1/5 (20%) Agree	10/16 (62.5%) Disagree 3/16 (18.75%) Neutral 2/16 (12.5%) Agree 1/16 (6.25%) Omitted

4.2.3.4 Overview of Theme Three

The final theme was the multi-disciplinary team, which was strongest in the practicing BMS group. The student group evidenced a basic understanding of the MDT, perhaps linked to a lack of clinical laboratory experience. In the academic group there was little discussion of the importance of the MDT, which indicates a lack of understanding of the wider healthcare system. Participants across all stakeholder groups expressed the BMS role was poorly understood, which participants felt related to the physical distance between BMSs, the laboratory and patients or clinical teams. Within this theme, few statements reached overall consensus, demonstrating divergence of opinion across the stakeholder groups.

4.2.4 Key Findings from 'Technical and Analytical aspects of the role'

In the literature review, many of the articles focused upon the technical and analytical nature of the BMS role. In response to 'the technical and analytical nature of the BMS role does not detract from the importance of the individual patient' (Q34), an agree consensus was reached in the BMS and academic groups and overall. In the student group, there was greater divergence of opinion. The opposing statement 'the technical and analytical nature of the BMS role makes it difficult to recognise the importance of the individual patient' (Q10) reached a disagree consensus for the BMS group (table 4.9). There was divergence of opinion in both the student and academic groups. Adams *et al.* (2011) suggested that technical and analytical skills and softer skills such as empathy were mutually exclusive and that healthcare professionals were likely to struggle to display both qualities. This was something that stakeholders did not evidence in their responses, although there was divergence of opinion on whether the

technical and analytical nature of the BMS role made it difficult to recognise the importance of the patient. In the academic group, consensus was only achieved in two of the six statements for technical and analytical aspects of the role, supporting the presence of a theory-practice gap.

The importance of softer skills was discussed, which were considered more challenging to teach than technical skills (Adams *et al.,* 2011; Fraser *et al.,* 2013). Working autonomously, taking responsibility for their actions and recognising their role within the MDT were considered important to demonstrate a focus upon patient outcomes. Participant responses to 'softer skills such as empathy are important aspects of the training and education of BMSs' (Q41) demonstrated an agree consensus in the BMS and student groups and overall. The academic group failed to reach consensus and participants expressed conflicting opinions, with one participant strongly disagreeing with this statement (table 4.9). Conversely, the statement BMSs do not require soft skills because their priority is processing specimens in a timely fashion (Q24) demonstrated a disagree consensus in all participant groups. It is possible that strong disagreement with Q41 by one of the academic participants was made in error. In response to questionnaires, participants can exhibit questionnaire fatigue, particularly when under time pressures, and their response may not reflect their true opinion (Krosnick, 1990; Daniel, 2011). Stakeholders in this study identified empathy as an important skill for BMSs.

The importance of empathy for BMSs was considered in round 2. Empathy is a central concept in PCC and requires an understanding of the needs, feelings and

situation of the patient (Irving and Dickson, 2004; Petrucci *et al.,* 2016). Despite empathy being considered an essential skill in healthcare professionals, time-pressures, inadequate training and over medicalisation can conflict with empathetic healthcare (Moudatsou *et al.,* 2020). With respect to the Canadian MLS workforce, Price (2015) identified EI was key for success when working in a clinical laboratory, which supports the importance of this concept for BMS training. Petrucci *et al.* (2016) recognised that EI was a key aspect of empathy, suggesting that laboratory staff who evidence EI would also be empathetic.

Table 4.9. Consensus rates of the paired statements used in the 2nd round questionnaire by participant group: Technical and analytical aspects of the role

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
LITERATURE REVIEW: TECHNICAL AND ANALYTICAL ASPECTS OF THE ROLE									
23. Measures of the quality of the laboratory service, such as specimen turn-around time are good measures of care for the patient	5/7 (71.4%) Agree 2/7 (28.9%) Neutral	1/4 (25%) Agree 2/4 (50%) Neutral 1/4 (25%) Disagree	3/5 (60%) Disagree 2/5 (40%) Agree	8/16 (50%) Agree/ 4/16 (25%) Neutral 4/16 (25%) Disagree	9. Measures of the quality of the laboratory service, such as specimen turn-around time are not important indicators of quality care from the patient's perspective	5/7 (71.4%) Disagree 2/7 (28.9%) Neutral	2/4 (50%) Disagree 1/4 (25%) Neutral 1/4 (25%) Agree	3/5 (60%) Disagree 2/5 (40%) Agree	10/16 (62.5%) Disagree 3/16 (18.75%) Neutral 3/16 (18.75%) Agree
34. The technical and analytical nature of the Biomedical Scientist role does not detract from the importance of the individual patient	4/7 (57.1%) Agree 2/7 (28.9%) Neutral 1/7 (14.3%) Disagree	4/4 (100%) Agree	4/5 (80%) Agree 1/5 (20%) Disagree	12/16 (75%) Agree 2/16 (12.5%) Neutral 2/16 (12.5%) Disagree	10. The technical and analytical nature of the Biomedical Scientist role makes it difficult to recognise the importance of the individual patient	4/7 (57.1%) Disagree 1/7 (14.3%) Neutral 2/7 (28.9%) Agree	4/4 (100%) Disagree	2/5 (40%) Disagree 1/5 (20%) Neutral 2/5 (40%) Agree	10/16 (62.5%) Disagree 2/16 (12.5%) Neutral 4/16 (25%) Agree

Positive statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)	Negative statements	Students (n=7)	Biomedical Scientists (n=4)	Academics (n=5)	Overall (n=16)
41. Softer skills such as patient empathy are important aspects of the training and education of Biomedical Scientists	5/7 (71.4%) Agree 1/7 (14.3%) Neutral 1/7 (14.3%) Disagree	4/4 (100%) Agree	3/5 (60%) Agree 1/5 (20%) Neutral 1/5 (20%) Disagree	12/16 (75%) Agree 2/16 (12.5%) Neutral 2/16 (12.5%) Disagree	24. Biomedical Scientists do not require soft skills such as empathy, as their priority should be analysing specimens in a timely fashion	6/7 (85.7%) Disagree 1/7 (14.3%) Neutral	4/4 (100%) Disagree	4/5 (80%) Disagree 1/5 (20%) Neutral	14/16 (87.5%) Disagree 2/16 (12.5%) Neutral

4.3 Overview of 2nd round findings

As demonstrated in table 4.10, more positive statements reached consensus than negative statements (59.1% and 31.8% respectively). Overall, 45.5% of statements achieved consensus across all groups. The degree of consensus was highest in the BMS group, with 72.7% of statements achieving the 70% consensus level. In the student group, 54.5% of statements achieved consensus, whilst this was 40.9% in the academic group. This demonstrated divergence of opinion amongst the stakeholder groups and more statements achieved consensus in the BMS group compared to the academic group. However, it is important to be cautious when interpreting this data due to the small number of participants in round 2.

This is the first time a theory-practice gap has been identified in the education of BMSs, demonstrating a contribution to knowledge. In nursing, the theory-practice gap can be reduced by effective collaboration between the university and clinical educators (Scully, 2011). However, in Biomedical Science, many graduates aspire to a BMS career but cannot obtain clinical laboratory experience prior to graduation. Therefore, the theory-practice gap is likely to be increased for students without this experience. Changes to teaching and learning of Biomedical Science are required to support development of capable practitioners. Following the identification of a theory-practice gap, strategies to address this are required.

Table 4.10. Overall consensus rates according to the themes and subthemes generated from round one data analysis.

Theme and Subtheme	Positive statements achieving overall consensus	Negative statements achieving overall consensus
Theme One: Putting the patient at the centre, Subtheme A: Patient in Context	3/3 statements (100%)	0/3 statements (0%)
Theme One: Putting the patient at the centre, Subtheme B: Supporting Patient Care	2/2 statements (100%)	1/2 statements (50%)
Theme Two: Safety of the patient, Subtheme C: Minimising Harm	3/3 statements (100%)	3/3 statements (100%)
Theme Two: Safety of the patient, Subtheme D: Accreditation and Registration	1/2 statements (50%)	0/2 statements (0%)
Theme Two: Safety of the Patient, Subtheme E: Pressures of the Role	0/2 statements (0%)	1/2 statements (50%)
Theme Three: The MDT, Subtheme F: Unseen Healthcare Workforce	1/3 statements (33.3%)	0/3 statements (0%)
Theme Three: The MDT, Subtheme G: Misunderstood Role	0/2 statements (0%)	1/2 statements (50%)
Theme Three: The MDT, Subtheme H: Team Working	1/2 statements (50%)	0/2 statements (0%)
Technical and analytical aspects of the role	2/3 statements (66.6%)	1/3 statements (33.3%)
Total	**13/22= 59.1%**	**7/22= 31.8%**

4.4 Priority ranking exercise

In the final question, participants ranked the importance of aspects of the BMS role, including accuracy, patient safety, taking appropriate action, volume of samples processed and speed from 1 to 5 (one being least important, 5 being most important). The range of participant responses can be found in figure 4.2. There was a range of participant responses across all groups.

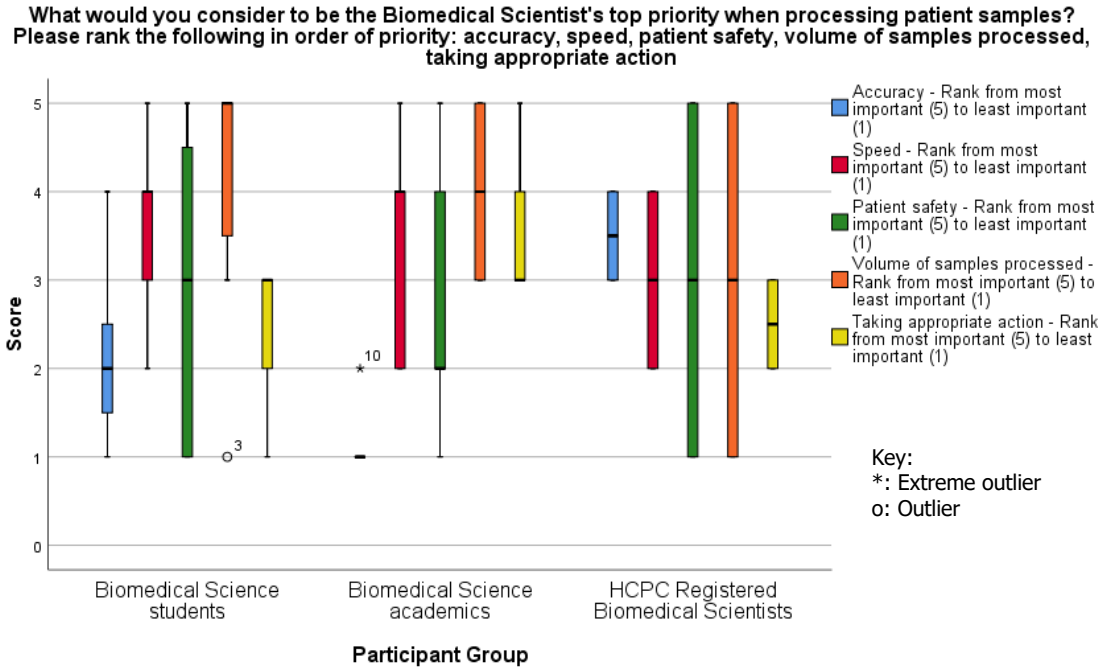


Figure 4.2. Box and whisker plots for the priority ranking exercise. Participants considered the Biomedical Scientist's priority when processing samples including accuracy, speed, patient safety, volume of samples processed and taking appropriate action. Participants ranked 5 as the most important and 1 as the least important.

4.4.1 Accuracy

Figure 4.2 demonstrates that accuracy was considered least important in the student and academic groups and was considered of higher importance in the BMS group. This was an unexpected finding as accuracy frequently features in the BSc Biomedical Science curriculum and accurate testing is regarded as an essential aspect of diagnosis and treatment.

4.4.2 Speed

Figure 4.2 demonstrates that speed was considered important in all stakeholder groups, with most participants ranking it as 3rd or 4th most important priority within the BMS role.

4.4.3 Patient Safety

There was greater divergence on the importance of patient safety within the BMS role. In the BMS group, two participants scored patient safety as 5 (most important) whilst two participants scored it as 1 (least important). This divergence of opinion was also demonstrated in the student group, suggesting stakeholders found it difficult to prioritise patient safety within the BMS role (figure 4.2).

4.4.4 Volume of samples processed

The importance of volume of samples processed within the BMS role was considered by many of the student and academic participants as the most important aspect (figure 4.2). In the BMS group, there was divergence of opinion, with two participants suggesting it was most important (5) and two participants suggesting it was least important (1). This is a key finding and will be explored further. The conflicting opinions within the BMS group may be related to the small sample size.

4.4.5 Taking appropriate action

In the academic group, taking appropriate action was considered a priority within the BMS role, scoring 4 or 5. The BMS group ranked this as a lower priority, scoring 2 or 3. The student group also ranked this a lower priority, scoring 1, 2 or 3. Overall, taking appropriate action was considered a lower priority by the stakeholder groups (figure 4.2).

4.4.6 Summary of Priority Ranking Exercise

Stakeholders recognised BMSs must work with accuracy and precision, reporting and communicating results in a timely fashion and escalating abnormal findings appropriately. However, the ranking exercise demonstrated divergence of opinion, with accuracy ranked higher in the BMS group and lower in the academic and student groups, which is surprising as accuracy is a key feature of diagnostic testing (Leeflang and Allerberger, 2019). The divergence within all groups with regards to patient safety was unexpected as this is considered a key aspect of the role (Hilborne, Lubin and Scheuner, 2009; Birse, 2010). The BMS group selecting taking appropriate action as a lesser priority within their role was also unexpected. This question may have been mis-interpreted by participants, or the small BMS participant numbers (n=4) may have reduced effectiveness of the exercise.

4.5 Free text responses

The final section of the questionnaire allowed participants to include a free text response up to a maximum of 250 characters. These responses are presented in table 4.11. Free-text comments were submitted by two academic participants and one student participant. It was important to capture free-text responses in the 2nd round to allow participants freedom to express themselves. Free text responses were utilised to highlight difficulty with the ranking exercise as the importance of a number of tasks was noted. Other responses demonstrated that a lack of first-hand experience of the role made this exercise challenging for

some participants and further demonstrates the presence of a theory-practice gap.

Table 4.11. Summary of free-text comments following the round two questionnaire.

Participant Group	Comment
Academic	I have no experience of working as a Biomedical Scientist so some of these answers were guesswork, based on second-hand information, or my idea of an ideal situation
Academic	Ranking question was difficult as I assume they needed to be ranked 1-5, but 3 would have been a '5' for me, speed and volume are important but not at the cost of accuracy (which affects patient safety and potentially… [incomplete statement]
Student	Some questions could be clarified by use of the word "generally", as there are exceptions to very many scenarios

4.6 Addressing the Exploratory Aim

This study explored whether there is shared understanding within stakeholder groups of how the BMS role contributes to patient outcomes and whether these concepts should be defined to reduce ambiguity. This has not previously been considered in the literature, with few published articles considering the importance of the UK BMS role in healthcare. The key contribution of this study was to identify how BMSs evidence that they are striving to achieve patient outcomes. This is something that has not been previously outlined in the professional or statutory guidelines or in the QAA Benchmark statements (HCPC, 2014; 2016; IBMS, 2018a; Quality Assurance Agency, 2019).

Although stakeholders expressed some similarities in their 1st round responses of how BMSs contribute to patient outcomes, the consensus data in the 2nd round

demonstrated greater divergence. Participants in the 1st round discussed the importance of achieving patient outcomes rather than analysing specimens and this was considered motivation for a more fulfilling role. This has previously been described in nursing, where PCC is thought to increase job satisfaction (Pol-Grevelink, Jukema and Smits, 2012; Boer, Nieboer and Cramm, 2017; Huang *et al.,* 2020).

Whilst the definition of PCC identified by McCormack and McCance (2017) requiring a therapeutic relationship with the patient may not be applicable to the BMS role, stakeholders recognised that BMSs could focus upon the needs of the patient, a quality that has also been described in radiographers (Shrestha, 2015). Mead and Bower's (2000) definition of the patient-centred approach recognises the individual needs of the patient and provides them with the ability to make informed decisions about their own health. According to this definition, BMSs report laboratory data allowing patients to make decisions about their own health and allowing other healthcare professionals to practice PCC. Changes to PCC terminology are required to recognise that healthcare professionals without patient contact can also evidence they are working in the best interests of the patient. This is a key recommendation from this study and demonstrates a contribution to practice, as the literature does not define how BMSs can meet the relevant HCPC standards (HCPC, 2014; 2016).

It is important to recognise that the BMS role allows patient-facing healthcare professionals to practice PCC. The Health and Social Care Act (2008) states that

all healthcare professions must comply with 'enabling and supporting relevant persons to make, or participate in making, decisions relating to the service user's care or treatment to the maximum extent possible' (The Health and Social Care Act, 2008 p. 8). This is applicable to the BMS role in supporting PCC within the MDT. The BMS role within healthcare is essential for clinical decision making and supporting quality care (DoH, 2006; 2008). Several participants expressed that focusing upon achieving patient outcomes and supporting patient care was an important motivation for entering the profession.

The professional standards have not defined how BMSs can evidence the patient-centred aspects of the role. This study demonstrated that stakeholders believed these are essential skills for practicing BMSs and defined how stakeholders believed these aspects could be evidenced within the BMS role. The BMS role in healthcare should be explicit within the education of the future BMS workforce. It should also be defined within the BSc Biomedical Science programme how BMSs can evidence that they meet the standards set by the professional and statutory bodies and this is a key recommendation from this study.

One important finding was the difference in the consensus data according to stakeholder group. Overall, more positive statements reached consensus than negative statements (as shown in tables 4.1 to 4.10). The number of statements that reached consensus was lowest in the academic group and highest in the BMS group. In the student group, more positive statements achieved consensus than negative statements, suggesting evidence of social desirability bias. Participants may choose to present themselves in a socially acceptable way,

regardless of whether it reflects their true opinion, to conform with expectations (Bergen and Labonté, 2019). This may be related to the power imbalance between students and academic researchers and the desire to appear knowledgeable within the field (Ferguson, Yonge and Myrick, 2004). This is a recognised limitation of including students as research participants and will be discussed further in chapter 5.

As seen in table 4.10, some themes reached consensus more readily. Within the theme 'putting the patient at the centre' all positive statements achieved consensus, whilst only 20% (1/5) of negative statements did. This supports the presence of satisficing as participants agreed with positive assertions due to the perception that the researcher also agreed with the statement (Krosnick, 1990). Within theme 2 'safety of the patient' 57.1% (4/7) of the positive and negative statements achieved consensus, with the subtheme 'minimising harm' reaching consensus on all statements. This suggested preventing harm and the BMS role in patient safety were considered important by stakeholders. The importance of laboratory testing in preventing harm and supporting patient outcomes has been recognised in the literature (Birse, 2010; Epner, Gans and Graber, 2013; Hallworth *et al.,* 2015). However, the subthemes of accreditation and registration and the MDT demonstrated greater divergence of opinion and a poorer understanding of these concepts.

This study has articulated how BMSs can evidence they are working to achieve patient outcomes. This has not been previously discussed in the literature. After

the final interview question, one PSRB representative stated that the importance of patient outcomes within the BMS role was taken for granted. Guidelines for healthcare professionals need to be explicit and free of misinterpretation to ensure patient safety (Manski, 2013; Gurses *et al.,* 2014). This statement supported the rationale for the research to develop professional guidelines outlining the qualities expected of students and qualified BMSs. Outlining how BMSs can evidence compliance with the HCPC standards is essential for ensuring high-quality patient care and supporting education and training of the BMS workforce.

4.7 Summary

This chapter has presented the findings of the Delphi including thematic analysis of the qualitative 1st round responses and analysis of consensus of the attitude statements. The degree of consensus in round 2 was highest amongst the BMS group and lowest amongst the academic group, suggesting divergence of opinion across stakeholder groups. These findings have been contextualised within the published literature related to the BMS profession and wider professional literature. In chapter 5, the impact of the study, strengths, limitations and recommendations for practice will be considered as well as the contribution of the study to knowledge and practice.

CHAPTER 5. CONCLUSION

5.1 Introduction

In this chapter, the key findings of the study will be presented, along with discussion of the contribution of this study to knowledge and professional practice. Recommendations for practice will be made, along with recognition of the strengths and limitations of the study and suggestions for further work. Reflections upon the doctoral research journey are included. The way in which the study has addressed the research aims is also presented.

5.2 Research Aims and Key Findings

This study aimed to determine how stakeholders expected BMSs to contribute to patient outcomes and considered the factors that may impact upon the contribution of BMSs to PCC and patient outcomes. To date, this concept had not been discussed, despite the importance of working in the best interests of the service user being a requirement of professional guidelines (HCPC, 2014; 2016). Ways of meeting the patient focused aspects of the BMS role are not explicitly defined within the professional guidelines (HCPC, 2014; 2016; IBMS, 2018a). This Delphi study utilised a panel of stakeholders, including academics and students on the BSc Biomedical Science programmes, PSRB representatives and practicing BMSs to explore perceptions of the BMS role in patient outcomes.

Stakeholders described how BMSs can evidence they are working to achieve patient outcomes, which was not outlined in professional body guidelines (IBMS, 2018a). Patient outcomes were considered key motivation for entering the

profession. Outlining how BMSs work to achieve patient outcomes allows BMSs to demonstrate the essential knowledge and skills delivered through the completion of the IBMS Certificate of Competence. Stakeholders felt that empathy and the BMS role within the MDT were essential components of the education and training of BMSs, but this is not a requirement of the QAA Benchmark Statements.

PCC as previously defined by McCormack and McCance (2017) was not deemed appropriate for the BMS workforce due to a lack of patient contact. Changes to PCC guidelines to include those healthcare professionals without direct patient contact who must work in the best interests of the patient are required. Stakeholders expressed that the BMS role lacked recognition by patients and other healthcare professionals. The research demonstrated a theory-practice gap in both the student and academic groups in some aspects of the BMS role. This gap had not been identified in relation to the BMS workforce and demonstrates a contribution to knowledge. This re-enforced the importance of having HCPC registered practitioners delivering course content to evidence real-world applications of the programme, although the presence of the theory-practice gap in the academic group suggested that this input may not be sufficient (HCPC, 2017; IBMS, 2020b).

5.3 Addressing the Research Questions

The extent to which each of the research questions in the study have been addressed will now be outlined.

5.3.1 Research Question 1: Is there consensus between stakeholders regarding the role of BMSs in contributing to patient outcomes?

Participants discussed how the BMS role contributed towards patient outcomes and the importance of this within the role. Whilst there was largely consensus regarding the impact of the BMS role upon patient outcomes, whether BMSs strive to work in the best interests of the patient demonstrated greater divergence. Stakeholders failed to reach consensus upon whether all BMSs work in the patient's best interests at all times, which contradicts both professional and statutory guidelines (HCPC, 2014; 2016; IBMS, 2018a).

5.3.2 Research Question 2: Is there a shared understanding amongst stakeholders of recognising how BMSs work to achieve patient outcomes?

Participants agreed that a BMS focused upon achieving patient outcomes demonstrated this through the standard of their work, adherence to SOPs and professional guidelines and demonstrating a professional attitude. Stakeholders described using the professional guidelines and standards to prevent harm and standardise care. Participants discussed fitness to practise and keeping knowledge and skills up to date as essential for maintaining patient safety and ensuring high-quality laboratory results.

5.3.3 Research Question 3: What are the opinions of stakeholders regarding the importance of achieving patient outcomes in the BMS role?

Achieving patient outcomes within the BMS role was recognised as processing specimens to initiate diagnosis and treatment pathways. This underpins the work of other healthcare professionals by ensuring results are reported and indirectly influences patient outcomes (DoH, 2006; 2008). There was consensus amongst stakeholders that the BMS role was essential to underpin many aspects of clinical care and therefore achieving patient outcomes as part of the MDT was essential.

5.3.4 Research Question 4: Can stakeholders identify how it can be recognised that BMSs are working to achieve patient outcomes?

This was recognised as processing specimens accurately, in a timely fashion, communicating results in a clinically appropriate timeframe, working to underpin the actions of other healthcare professionals in the MDT, working within the Biomedical Scientist's scope of practice and recognising when appropriate referrals were required. These actions were considered essential to underpin the work of the wider MDT, and this demonstrated a desire to achieve patient outcomes.

5.4 Contribution to knowledge

The BMS role in achieving patient outcomes has not been previously detailed in the published literature or professional guidelines. One PSRB representative described these qualities as 'taken for granted'. By recognising and outlining

these concepts, these can be incorporated into the education and training of the BMS workforce, demonstrating a contribution to knowledge and professional practice. The understanding of the BMS role within patient outcomes and the contribution of BMSs to PCC should be introduced into the curriculum to ensure that BMSs are prepared for practice and remove the burden for delivering these key concepts from laboratory-based trainers.

The identification of a theory-practice gap in the student and academic groups demonstrated changes to the BSc Biomedical Science curriculum are required to ensure that students are adequately prepared for practice. An understanding of the complexities of the BMS role were lacking in the student and academic responses. There was also poor understanding of key concepts such as quality management and laboratory accreditation. For practicing BMSs, these concepts were a key aspect of their role, and therefore students need a good understanding of these after completing their degree and work-based training.

5.5 Recommendations for practice

Based upon the 1st and 2nd round findings of this Delphi study, the following recommendations for practice are made:

5.5.1 Recommendations for PSRB organisations

- The relevance of PCC for non-patient facing roles should be reconsidered. The current accepted definitions of PCC are not appropriate for those roles without patient contact and should be updated. Working in the best interests of the patient is more appropriate terminology as this does not

require the healthcare professional to develop a therapeutic relationship with the patient.

- Guidelines relevant to the profession, including the IBMS good professional practice for Biomedical Science professionals, should be updated to suggest how BMSs can meet the patient-focused requirements of the HCPC (IBMS, 2018a).
- The professional and statutory guidelines should be updated to reflect the addition of the key concepts identified by stakeholders. The patient-focused aspects of the BMS role, such as empathy, the importance of working in the patient's best interests and how these can be achieved, as well as the BMS role within healthcare should be delivered as part of the BSc Biomedical Science programme to better prepare students for practice.

5.5.2 Recommendations for Service Providers

- The BMS role within the MDT was not well recognised and stakeholders expressed that BMSs were undervalued in healthcare. Promotion and publicity of the BMS role in healthcare is required to highlight the importance of the BMS role within the MDT. This should be delivered in collaboration between healthcare organisations and higher education institutions.
- BMSs must be better integrated into the healthcare system to gain recognition for their professional skills and knowledge. Their role within the MDT should be facilitated through representation at MDT meetings,

which will also develop understanding of the BMS role within the wider healthcare system.

5.5.3 Recommendations for Higher Education Institutions

- Following the identification of a theory-practice gap for BMSs, strategies for reducing this gap should be identified and tested to ensure graduates are prepared for their role. The evidence of a theory-practice gap in the academic group demonstrates the importance of practitioner involvement in professional courses (McEwen *et al.,* 2003).
- Academics teaching on the BSc Biomedical Science programme without experience of working in healthcare laboratories should be exposed to this 'real-world' setting to support delivery of the holistic aspects of the BMS role. It is essential that the patient-centred aspects of the curriculum are delivered by practitioner lecturers with professional experience of these concepts. Course content should be updated to include a wider overview of the BMS role within the MDT and integration with other healthcare professionals and students on other healthcare courses would be beneficial.

5.5.4 Recommendations for Students

- The benefits of integrated placements in higher education programmes are well recognised (Yorke and Knight, 2006; Brooks, 2012; Cunningham and Gallacher, 2013). Students should be further encouraged to engage with opportunities to join integrated or Applied Biomedical Science programmes if this is appropriate for their career aspirations.
- Students must recognise the importance of the BMS role within the wider MDT and how this facilitates patient outcomes and supports patient care.

Understanding of this should be assessed through integration into module learning outcomes.

5.6 Reflection upon the Research Journey

The completion of this thesis has instigated my research journey and allowed personal and professional development. Through the completion of this study, I have developed as a practitioner and a researcher and developed a passion for promoting the BMS role within healthcare (Smith *et al.,* 2020). I have developed my confidence as a researcher to allow me to justify the decisions I have made and identify recommendations for professional practice (Bryan and Guccione, 2018). I am better prepared to support my own students through their research projects following the development of my own knowledge and skills (Leonard, Becker and Coate, 2005).

I have been fortunate to have several opportunities for research dissemination, but due to the ongoing COVID-19 pandemic, these dissemination opportunities have been virtual and research outputs to date are presented in Appendix 16. I have developed my competence and confidence as a presenter through dissemination of my research (Dinham and Scott, 2001). In March 2022, I presented a poster in the IBMS biannual Congress conference which allowed my research to be reviewed by experts in the field. Inclusion of PSRB representatives in the study and dissemination of a study summary to all participants ensured that PSRB organisations were aware of the research findings and recommendations for practice. This provides a mechanism by which the study

can influence curriculum content both locally and nationally for the BMS profession.

5.7 Limitations of the study

Although the study was successful in addressing the research aim, several limitations were recognised. To continue data collection during the COVID-19 pandemic, focus groups and interviews took place online. Online platforms such as Microsoft Teams are preferred to telephone interviews as they facilitate a rapport between the researcher and participants more readily (Archibald *et al.,* 2019). This was important for a Delphi study, where establishing a relationship between the researcher and the participants is known to reduce attrition (Keeney, Hasson and McKenna, 2011). The dynamic of an online focus group is different to face-to-face and it can be more challenging to generate discussion between participants, with online focus groups typically covering less content than face-to-face (Kite and Phongsavan, 2017). However, this was balanced against the need to conduct the research at a challenging time for the profession.

Participant numbers were low, particularly in the BMS group. Whilst there is no accepted minimum sample size for Delphi methodology, a panel size of 10-15 participants is considered acceptable (Day and Bobeva, 2005; Keeney, Hasson and McKenna, 2011). However, recruitment in this Delphi study was lower than anticipated and the limitations of drawing conclusions based upon a small sample size must be recognised (Hackshaw, 2008). This was possibly related to the difficulties of researching during a pandemic when laboratories experienced increased workloads and staff absences (IBMS, 2020a). In hindsight, it may have

been advisable to attempt a further stage of recruitment or seek ethical approval to approach multiple NHS Trusts for participation.

Initially, data collection in the BMS group was planned as a focus group, but this was changed to individual interviews due to participant availability. Although the one-to-one interviews generated high-quality, rich data from the BMS participants, the lack of a dynamic between the participants was a recognised limitation (Kite and Phongsavan, 2017). Participants in a focus group engage in discussion and clarify responses in the context of other participants, but this was not possible in a one-to-one interview (Krueger and Casey, 2009).

Following analysis of the 2nd round data, it became evident that revisions to some questionnaire statements would have been beneficial. Positive and negative statements were not a direct mirror image of each other in some cases, which may have resulted in some inconsistencies in responses. Table 5.1 presents the statements which required revisions, highlighting the problem with the statement and suggested appropriate wording.

Table 5.1. Statements used in round 2 identified as needing rewording to ensure they were clear and unambiguous.

Statement(s)	Identified problem	Suggested changes
12. Without Biomedical Scientists, initiating diagnosis and treatment decisions for patients would be impossible.	The positive (12) and negative (44) statements are not direct mirror images of each other.	12. Unchanged
44. Without the Biomedical Scientist role, point of care testing delivered by other clinical staff would be a suitable replacement.		44. The Biomedical Scientist role is not required for initiating diagnosis and treatment decisions.
41. Softer skills such as patient empathy are important aspects of the training and education of Biomedical Scientists.	The positive (41) and negative (24) statements are not direct mirror images of each other.	41. Biomedical Scientists are required to demonstrate empathy for patients to do their job effectively.
24. Biomedical Scientists do not require soft skills such as empathy, as their priority should be analysing specimens in a timely fashion.		24. Unchanged
37. Statutory registration with the Health and Care Professions Council (HCPC) ensures that Biomedical Scientists feel empowered to make autonomous decisions.	Use of the PSRB organisation in the positive (37) but not the negative (15) statement may have unduly influenced some participants to agree with the positive statement.	37. Biomedical Scientists are required to make autonomous decisions based upon their education and training.
15. Biomedical Scientists are not required to make autonomous decisions.		15. Unchanged

It is possible that ambiguity in the statement wording resulted in consensus being achieved for more positive statements than negative statements. As

previously discussed, this could have contributed to the degree of satisficing seen in round 2 (Krosnick, 1990).

The success of Delphi relies upon reducing attrition rates between rounds and the steps taken to reduce attrition have been previously outlined (chapter 3). One of the strategies for reducing attrition was to minimise the time between rounds (Keeney, Hasson and McKenna, 2011). Therefore, the piloted questionnaire developed for round 2 was not redistributed to the pilot participants. Hicks (2004) recommends that the refined item pool is redistributed to the same participants to establish reliability. However, due to the timeframe of the Delphi study and the need to reduce attrition, it was not possible to delay distribution of the 2nd round questionnaire. This is a recognised limitation of the study but was considered necessary to maintain participant interest (Keeney, Hasson and McKenna, 2011). In hindsight, it may have been better to contact the participants and provide an update on the study to maintain participant interest, providing time for the 2nd round questionnaire to be re-distributed to the pilot participants.

There are implications of being an insider researcher conducting research upon students and colleagues. This raises a power imbalance between the researcher and participants who may feel pressure to participate in a study due to their professional relationship with the researcher (Moreno *et al.,* 1998; Ferguson, Yonge and Myrick, 2004). To minimise this, it was explicit in the participant information sheet that taking part in the study would not provide an academic advantage. Insider research is often criticised as the researcher may impose their

pre-conceived ideas onto the participants (Brannick and Coghlan, 2007). This was minimised by utilising the literature review to develop the interview schedule for round 1. In addition, the 2nd round questionnaire was developed following a thematic analysis of the 1st round responses and the literature review themes to minimise researcher influence (Braun and Clarke, 2013).

One of the strengths of the study was the participation of PSRB representatives. Representatives of 3 PSRB organisations were invited to participate, but only 1 organisation did so. Unfortunately, both PSRB representatives in the 1st round were lost in round 2. PSRB involvement in professional courses is essential to ensure that degree content is appropriate and that staff delivering the award have the required knowledge to ensure learning outcomes can be achieved (Churchman and Woodhouse, 1999). Participation of PSRB representatives was considered essential to influence guidelines and professional policies relevant to the BMS profession, therefore losing both PSRB representatives in the 2nd round was a recognised limitation.

5.8 Strengths of the study

This study was potentially the first to consider the importance of the BMS role within patient outcomes and the qualities BMSs exhibit to demonstrate prioritisation of these. One key strength is the inclusion of a range of stakeholders of the BMS profession. The use of focus groups and one-to-one interviews allowed participants to articulate their opinion without the constraints of pre-defined questionnaire responses (Krueger and Casey, 2009). This generated rich, high-quality data which was used to develop the 2nd round

statements. This richness of data would not have been achieved without using qualitative data collection methods in round 1 (Mansell *et al.,* 2004).

The inclusion of PSRB representatives in the study provided the potential to influence professional guidelines and policies relevant to the BMS profession. Both PSRB representatives failed to respond in the 2nd round (which is described as a limitation in section 5.7). However, all participants received an overview of the study findings and recommendations for practice, providing potential to influence professional guidelines. PSRB representation was considered essential to influence professional guidelines and deliver curricular change.

5.9 Further research

Initially, it was proposed that the Delphi would include a 3rd round using Twitter as a data source and presenting the 2nd round statements to a wider audience of BMSs using the monthly IBMS discussion group, #IBMSChat. Following round 1, the data contained rich and in-depth perspectives from the participants. Within the scope of this thesis, it was not possible to conduct a 3rd round of the Delphi using Twitter and do justice to the findings and implications for practice. As a result, data collection was halted after 2 rounds. The data collected from the 2nd round highlighted a divergence of opinion amongst the stakeholder groups and demonstrated that the final round of the study will be worthy of completion at a later stage. This study also considered the perspectives of a small number of stakeholders in a single academic institution and a single NHS Trust. To verify the findings, the Twitter round would consider the opinions of a wider audience.

Whilst the presence of a theory-practice gap with respect to the BMS workforce was identified for the first time in this study, strategies to address this gap have not been considered. It would be worthwhile verifying that this gap exists across multiple institutions and then considering pedagogic strategies that can be introduced to address this gap. Changes to the curriculum and professional and statutory guidelines will influence curricular content and align teaching methods more closely to practice.

5.10 Summary

This study aimed to consider stakeholder perceptions of the BMS role within patient outcomes and how stakeholders believed that BMSs can evidence they are working in the best interests of the patient. The study identified a divergence of opinion in key areas related to the BMS role, including the BMS role in the MDT and patient care and the importance of accreditation and registration, demonstrating a theory-practice gap in the student and academic groups. This has not previously been described in the education of BMSs. Changes to the education of the future BMS workforce are required to reduce this theory-practice gap and support the development of capable practitioners.

REFERENCES

Adams, A., McCabe, K., Zundel, C., Price, T. and Dahl, C. (2011) 'Perceived emotional aptitude of clinical laboratory sciences students compared to students in other healthcare profession majors', *Clinical laboratory science,* 24(3), pp. 167-171.

Agee, J. (2009) 'Developing qualitative research questions: a reflective process', *International journal of qualitative studies in education,* 22(4), pp. 431-447.

Aiken, L.H., Sloane, D.M., Bruyneel, L., Van den Heede, K. and Sermeus, W. (2013) 'Nurses' reports of working conditions and hospital quality of care in 12 countries in Europe', *International journal of nursing studies,* 50(2), pp. 143-153.

Alderwick, H., Dunn, P., McKenna, H., Walsh, N. and Ham, C. (2016) *Sustainability and transformation plans in the NHS. How are they being developed in practice?* London: The King's Fund. Available at: www.kingsfund.org.uk (Accessed: 24/06/20).

Almalkawi, I., Jester, R. and Terry, L. (2018) 'Developing a consensus-based scoring rubric to enhance practice-based assessment of student nurses' clinical competence: A Delphi study', *Nurse Education Today,* 69, pp. 95-103.

Al-Saadi, H. (2014) *Demystifying Ontology and Epistemology in Research Methods.* Available at: https://www.researchgate.net/publication/260244813_Demystifying_Ontology_and_Epistemology_in_Research_Methods (Accessed: 02/05/20).

Angen, M.J. (2000) 'Evaluating Interpretive Inquiry: Reviewing the Validity Debate and Opening the Dialogue', *Qualitative health research,* 10(3), pp. 378-395.

Archibald, M.M., Ambagtsheer, R.C., Casey, M.G. and Lawless, M. (2019) 'Using Zoom Videoconferencing for Qualitative Data Collection: Perceptions and Experiences of Researchers and Participants', *International journal of qualitative methods,* 18, pp. 1-8. doi: 10.1177/1609406919874596.

Asselin, M. (2003) 'Insider Research: Issues to Consider When Doing Qualitative Research in Your Own Setting', *Journal for Nurses in Staff Development (JNSD),* 19(2), pp. 99-103.

Aveyard, H., Payne, S.A. and Preston, N.J. (2016) *A Post-graduates Guide to doing a Literature Review in Health and Social Care.* Oxford: Oxford University Press.

Ball, J.E., Murrells, T., Rafferty, A.M., Morrow, E. and Griffiths, P. (2014) "Care left undone' during nursing shifts: associations with workload and perceived

quality of care', *BMJ quality & safety,* 23(2), pp. 116-125. doi: 10.1136/bmjqs-2012-001767.

Barrett, D. and Heale, R. (2020) 'What are Delphi studies?', *Evidence-based nursing,* 23(3), pp. 68-69. doi: 10.1136/ebnurs-2020-103303.

Bauman, Z. (1990) 'Effacing the Face: On the Social Management of Moral Proximity', *Theory, culture & society,* 7(1), pp. 5-38.

Bauman, Z. (1991) 'The Social Manipulation of Morality: Moralizing Actors, Adiaphorizing Action', *Theory, culture & society,* 8(1), pp. 137-151.

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

Becich, M.J., Gilbertson, J.R., Gupta, D., Patel, A., Grzybicki, D.M. and Raab, S.S. (2004) 'Pathology and patient safety: the critical role of pathology informatics in error reduction and quality initiatives', *Clinics in Laboratory Medicine,* 24(4), pp. 913-943.

Bennett, A., Garcia, E., Schulze, M., Bailey, M., Doyle, K., Finn, W., Glenn, D., Holladay, E.B., Jacobs, J., Kroft, S., Patterson, S., Petersen, J., Tanabe, P. and Zaleski, S. (2014) 'Building a laboratory workforce to meet the future: ASCP Task Force on the Laboratory Professionals Workforce', *American journal of clinical pathology,* 141(2), pp. 154-167.

Bergen, N. and Labonté, R. (2019) '"Everything Is Perfect, and We Have No Problems": Detecting and Limiting Social Desirability Bias in Qualitative Research', *Qualitative health research,* 30(5), pp. 1-10. doi: 10.1177/1049732319889354.

Berger-Estilita, J., Nabecker, S. and Greif, R. (2019) 'A Delphi consensus study for teaching Basic Trauma Management to third-year medical students', *Scandinavian journal of trauma, resuscitation and emergency medicine,* 27(1), pp. 1-11. doi: 10.1186/s13049-019-0675-6.

Birse, R. (2010) 'Patient Safety Climate in the Canadian Medical Laboratory Science Profession', *Canadian journal of medical laboratory science,* 72(6), pp. 158.

Boer, J., Nieboer, A.P. and Cramm, J.M. (2017) 'A cross-sectional study investigating patient-centred care, co-creation of care, well-being and job satisfaction among nurses', *Journal of Nursing Management,* 25(7), pp. 577-584.

Boulkedid, R., Abdoul, H., Loustau, M., Sibony, O. and Alberti, C. (2011) 'Using and Reporting the Delphi Method for Selecting Healthcare Quality Indicators: A Systematic Review', *PloS one,* 6(6), pp. e20476. doi: 10.1371/journal.pone.0020476.

Bowling, A. (2005) *Measuring Health: A review of quality of life measurement scales.* 3rd edn. Maidenhead: Open University Press.

Bracken, S. (2010) *Discussing the Importance of Ontology and Epistemology Awareness in Practitioner Research.* University of Worcester. Available at: https://www.openaire.eu/search/publication?articleId=core_ac_uk__::da85dcc931e863655005c423498b55c4 (Accessed: 22/01/2018).

Bradshaw, A. and Merriman, C. (2008) 'Nursing competence 10 years on: fit for practice and purpose yet?', *Journal of clinical nursing,* 17(10), pp. 1263-1269.

Brady, S.R. (2015) 'Utilizing and Adapting the Delphi Method for Use in Qualitative Research', *International journal of qualitative methods,* 14(5), pp. 160940691562138. doi: 10.1177/1609406915621381.

Brannick, T. and Coghlan, D. (2007) 'In Defense of Being "Native": The Case for Insider Academic Research', *Organizational research methods,* 10(1), pp. 59-74.

Braun, V. and Clarke, V. (2013) *Successful Qualitative Research: A Practical Guide for Beginners.* London: SAGE.

Brent, M.A.Z. (2016) 'OR Specimen Labeling', *AORN journal,* 103(2), pp. 164-176.

Brooks, R. (2012) *Evaluating the impact of placements on employability.* University of Huddersfield Employability, Enterprise and Citizenship in Higher Education Conference. 27/03/2012.: University of Huddersfield. Available at: http://eprints.hud.ac.uk/id/eprint/13202/ (Accessed: 22/08/21).

Bryan, B. and Guccione, K. (2018) 'Was it worth it? A qualitative exploration into graduate perceptions of doctoral value', *Higher education research and development,* 37(6), pp. 1124-1140. doi: 10.1080/07294360.2018.1479378.

Campbell, N., Eley, D.S. and McAllister, L. (2014) 'Investigating personality and conceptualising allied health as person or technique oriented', *Australian health review,* 38(1), pp. 86-92.

Campbell, S.M. and Cantrill, J.A. (2001) 'Consensus methods in prescribing research', *Journal of clinical pharmacy and therapeutics,* 26(1), pp. 5-14.

Castaneda, G.A. and Scanlan, J.M. (2014) 'Job Satisfaction in Nursing: A Concept Analysis', *Nursing forum (Hillsdale),* 49(2), pp. 130-138.

Chen, C., Su, W., Chiang, Y., Shu, Y. and Moons, P. (2017) 'Healthcare needs of adolescents with congenital heart disease transitioning into adulthood: a Delphi survey of patients, parents, and healthcare providers', *European journal of cardiovascular nursing,* 16(2), pp. 125-135. doi: 10.1177/1474515116643622.

Chichetti, J. (2011) 'A two-round Delphi study examining consensus of recommended clinical practices for patients with ventricular assist devices as

destination therapy', *Progress in transplantation,* 21(1), pp. 15-26. doi: 10.7182/prtr.21.1.v32706724w42k277.

Churchman, R. and Woodhouse, D. (1999) 'The Influence of Professional and Statutory Bodies on Professional Schools within New Zealand Tertiary Institutions', *Quality in higher education,* 5(3), pp. 211-226. doi: 10.1080/1353832990050303.

Cooke, A., Smith, D. and Booth, A. (2012) 'Beyond PICO', *Qualitative Health Research,* 22(10), pp. 1435-1443.

Critical Appraisal Skills Programme (2018) *CASP Qualitative Checklist.* Available at: https://casp-uk.net/casp-tools-checklists/ (Accessed: 30/03/2020).

Croal, B. (2017) *The Communication of Critical and Unexpected Pathology Results.* London: Royal College of Pathologists. Available at: https://www.rcpath.org/resourceLibrary/the-communication-of-critical-and-unexpected-pathology-results-pdf.html (Accessed: 13/11/2018).

Cunningham, S. and Gallacher, D. (2013) 'Learning beyond the classroom: biomedical science students' narratives of volunteering and developing employability skills', *Journal of Learning Development in Higher Education,* (6), pp. 1-19. doi: https://doi.org/10.47408/jldhe.v0i6.217.

Daniel, S. (2011) *Satisficing in Survey Design.* Deakin University, Melbourne Burwood Campus, Burwood: Deakin University. Available at: https://www.researchgate.net/profile/Scott-Daniel-2/publication/327539913_Satisficing_in_Survey_Design/links/5ef2beb2458515ceb207ede1/Satisficing-in-Survey-Design.pdf (Accessed: 31/03/21).

Dawson, J. (2021) 'Medically optimised: healthcare language and dehumanisation', *British journal of general practice,* 71(706), pp. 224. doi: 10.3399/bjgp21X715829.

Day, J. and Bobeva, M. (2005) 'A Generic Toolkit for the Successful Management of Delphi Studies', *Electronic Journal of Business Research Methods,* 3(2), pp. 103-116.

de Leeuw, E.D. (2001) 'Reducing Missing Data in Surveys: An Overview of Methods', *Quality & quantity,* 35(2), pp. 147-160.

Demaria, M., Hodgson, Y. and Czech, D. (2018) 'Perceptions of Transferable Skills among Biomedical Science Students in the Final-Year of Their Degree: What are the Implications for Graduate Employability?', *International Journal of Innovation in Science and Mathematics Education,* 26(7), pp. 11-24.

Diamond, I.R., Grant, R.C., Feldman, B.M., Pencharz, P.B., Ling, S.C., Moore, A.M. and Wales, P.W. (2014) 'Defining consensus: A systematic review recommends methodologic criteria for reporting of Delphi studies', *Journal of clinical epidemiology,* 67(4), pp. 401-409.

Dinham, S. and Scott, C. (2001) 'The Experience of Disseminating the Results of Doctoral Research', *Journal of further and higher education,* 25(1), pp. 45-55. doi: 10.1080/03098770020030498.

DoH (2006) *Report of the Review of NHS Pathology Services in England.* London: Available at: https://www.networks.nhs.uk/nhs-networks/peninsula-pathology-network/documents/CarterReviewPathologyReport.pdf (Accessed: 10/05/2018).

DoH (2008) *Report of the Second Phase of the Review of NHS Pathology Services in England.* London: Available at: https://webarchive.nationalarchives.gov.uk/20090428021020/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_091985 (Accessed: 20/08/2020).

DoH (2015) *The NHS Constitution.* Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/480482/NHS_Constitution_WEB.pdf (Accessed: 31/08/2020).

DoH (2016) *Operational productivity and performance in English NHS acute hospitals: Unwarranted variations. An independent report for the Department of Health by Lord Carter of Coles.* London: Department of Health. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/499229/Operational_productivity_A.pdf (Accessed: 20/10/2021).

Drennan, J. (2008) 'Professional and academic destination of masters in nursing graduates: A national survey', *Nurse education today,* 28(6), pp. 751-759. doi: 10.1016/j.nedt.2007.12.003.

Dreyfus, S.E. (1981) 'Formal Models vs. Human Situational Understanding: Inherent Limitations on the Modeling of Business Expertise', *Operations Research Centre,* 81(3), pp. 1-52.

Dunbar, N.M., Delaney, M., Murphy, M.F., Pagano, M.B., Saifee, N.H., Seheult, J., Yazer, M. and Kaufman, R.M. (2021) 'Emergency departments are higher-risk locations for wrong blood in tube errors', *Transfusion,* 61(9), pp. 2601-2610. doi: https://doi.org/10.1111/trf.16588.

Epner, P.L., Gans, J.E. and Graber, M.L. (2013) 'When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine', *BMJ Quality & Safety,* 22(Suppl 2), pp. ii6-ii10. doi: 10.1136/bmjqs-2012-001621.

Epstein, R.M., Fiscella, K., Lesser, C.S. and Stange, K.C. (2010) 'Why The Nation Needs A Policy Push On Patient-Centered Health Care', *Health Affairs,* 29(8), pp. 1489-1495.

Feilzer, Y.M. (2010) 'Doing Mixed Methods Research Pragmatically: Implications for the Rediscovery of Pragmatism as a Research Paradigm', *Journal of mixed methods research,* 4(1), pp. 6-16. doi: 10.1177/1558689809349691.

Ferguson, L.M., Yonge, O. and Myrick, F. (2004) 'Students' Involvement in Faculty Research: Ethical and Methodological Issues', *International journal of qualitative methods,* 3(4), pp. 56-68.

Ferraro, S., Braga, F. and Panteghini, M. (2016) 'Laboratory medicine in the new healthcare environment', *Clinical Chemistry and Laboratory Medicine (CCLM),* 54(4), pp. 523-533.

Fincham, J.E. (2008) 'Response Rates and Responsiveness for Surveys, Standards, and the Journal', *American Journal of Pharmaceutical Education,* 72(2, article 43), pp. 1-3. doi: https://doi.org/10.5688/aj720243.

Fitch, K., Bernstein, S.J., Aguilar, M.D., Burnand, B., Lacalle, J.R., Lazaro, P., van het Loo, M., McDonnell, J., Vader, J.P. and Kahan, J.P. (2000) *RAND/UCLA Appropriateness Method User's Manual.* Santa Monica, CA: The RAND Corporation.

Flayelle, M., Brevers, D. and Billieux, J. (2022) 'The advantages and downsides of online focus groups for conducting research on addictive online behaviours', *Addiction (Abingdon, England),* 117(8), pp. 2142-2144. doi: 10.1111/add.15944.

Fleming, J. (2018) 'Recognizing and resolving the challenges of being an insider researcher in work-integrated learning', *International Journal of Work - Integrated Learning,* 19(3), pp. 311-320.

Fraser, M., Lew, K., Martindale, R., VanSpronsen, A. and Ward, C. (2013) 'Defining the Next Generation of Medical Laboratory Technologists', *Canadian Journal of Medical Laboratory Science,* (Winter), pp. 14-18.

Garland, R. (1991) 'The mid-point on a rating scale : is it desirable?', *Marketing bulletin,* (2), pp. 66-70.

Goleman, D. (1996) *Emotional intelligence.* 1st edn. London: Bloomsbury.

Golemboski, K. (2011) 'Improving patient safety: lessons from other disciplines', *Clinical laboratory science,* 24(2), pp. 114-119.

Golemboski, K., Otto, C.N. and Morris, S. (2013) 'Using performance tasks employing IOM patient safety competencies to introduce quality improvement processes in medical laboratory science education', *Clinical laboratory science,* 26(4), pp. 205-211.

Grant, C. and Osanloo, A. (2014) 'Understanding, Selecting and Integrating a Theoretical Framework in Dissertation Research: Creating the Blueprint for your "house"', *Administrative issues journal: education, practice, and research,* 4(2). doi: 10.5929/2014.4.2.9.

Grant, M. (2009) 'Patient Safety: Part 1: The Case for the Laboratory's Role', *Canadian journal of medical laboratory science,* 71(1), pp. 9-11.

Greaves, R.F., Bernardini, S., Ferrari, M., Fortina, P., Gouget, B., Gruson, D., Lang, T., Loh, T.P., Morris, H.A., Park, J.Y., Roessler, M., Yin, P. and Kricka, L.J. (2019) 'Key questions about the future of laboratory medicine in the next decade of the 21st century: A report from the IFCC-Emerging Technologies Division', *Clinica Chimica Acta,* 495, pp. 570-589.

Green, B., Tsiroyannis, C. and Brennan, P.A. (2016) 'Human factors - recognising and minimising errors in our day to day practice', *Oral diseases,* 22(1), pp. 19-22.

Greene, M.J. (2014) 'On the Inside Looking In: Methodological Insights and Challenges in Conducting Qualitative Insider Research', *Qualitative report,* 19(29), pp. 1-13.

Greenway, K., Butt, G. and Walthall, H. (2019) 'What is a theory-practice gap? An exploration of the concept', *Nurse education in practice,* 34, pp. 1-6.

Guba, E.G. and Lincoln, Y.S. (1994) 'Competing paradigms in qualitative research', in Denzin, N.K. and Lincoln, Y.S. (eds.) *Handbook of Qualitative Research* Thousand Oaks, CA: SAGE, pp. 105-117.

Gurses, A.P., Seidl, K.L., Vaidya, V., Bochicchio, G., Harris, A.D., Hebden, J. and Xiao, Y. (2014) 'Systems ambiguity and guideline compliance: a qualitative study of how intensive care units follow evidence-based guidelines to reduce healthcare-associated infections', *Quality and Safety in Health Care,* 17(5). doi: 10.1136/qshc.2006.021709.

Hackshaw, A. (2008) 'Small studies: strengths and limitations', *The European respiratory journal,* 32(5), pp. 1141-1143.

Hallworth, M.J. (2011) 'The '70% claim': what is the evidence base?', *Annals of clinical biochemistry,* 48(6), pp. 487-488.

Hallworth, M.J. (2015) 'Improving clinical outcomes – towards patient-centred laboratory medicine', *Annals of clinical biochemistry,* 52(6), pp. 715-716.

Hallworth, M.J., Epner, P.L., Ebert, C., Fantz, C.R., Faye, S.A., Higgins, T.N., Kilpatrick, E.S., Li, W., Rana, S.V. and Vanstapel, F. (2015) 'Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine', *Clinical chemistry,* 61(4), pp. 589-599.

Hammack, F.M. (1997) 'Ethical issues in teacher research', *Teachers College record,* 99(2), pp. 247-265.

Hanafin, S. (2004) *Review of literature on the Delphi technique.* Dublin, Ireland: Available at: https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.521.4998&rep=rep1&type=pdf (Accessed: 14/05/21).

Hand, T. (2007) 'The evolution of the healthcare assistant in primary care', *British journal of healthcare assistants,* 1(2), pp. 89-91. doi: 10.12968/bjha.2007.1.2.23375.

Hasson, F., Keeney, S. and McKenna, H. (2000) 'Research guidelines for the Delphi survey technique', *Journal of advanced nursing,* 32(4), pp. 1008-1015.

Haughton, T. (2011) *Does Positivism really 'work' in the Social Sciences?* Available at: http://www.e-ir.info/2011/09/26/does-positivism-really-%E2%80%98work%E2%80%99-in-the-social-sciences/ (Accessed: 23/10/2017).

HCPC (2014) *Standards of Proficiency- Biomedical Scientists.* London: Health and Care Professions Council. Available at: https://www.hcpc-uk.org/resources/standards/standards-of-proficiency-biomedical-scientists/ (Accessed: 09/08/2019).

HCPC (2015) *The Making of a Multi-Professional Regulator: The Health and Care Professions Council 2001-15.* London: Health and Care Professions Council. Available at: https://www.hcpc-uk.org/globalassets/resources/reports/the-making-of-a-multi-professional-regulator---the-hcpc-2001-2015.pdf (Accessed: 27/06/2020).

HCPC (2016) *Standards of Conduct, Performance and Ethics.* London: Health and Care Professions Council. Available at: https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/ (Accessed: 09/08/2019).

HCPC (2017) *Standards of Education and Training Guidance.* London: Health and Care Professions Council. Available at: https://www.hcpc-uk.org/standards/standards-relevant-to-education-and-training/set/ (Accessed: 09/08/2019).

HCPC (2018a) *Fitness to Practise- How to raise concerns.* Available at: https://www.hcpc-uk.org/concerns/raising-concerns/ (Accessed: 20/08/2021).

HCPC (2018b) *Misuse of title.* Available at: https://www.hcpc-uk.org/concerns/what-we-investigate/misuse-of-title/ (Accessed: 03/09/21).

Health Innovation Network (2017) *What is person-centred care and why is it important?* London: Available at: https://healthinnovationnetwork.com/wp-content/uploads/2016/07/What_is_person-centred_care_HIN_Final_Version_21.5.14.pdf (Accessed: 25/02/22).

Health Research Authority (2020) *Is my study research?* Available at: http://www.hra-decisiontools.org.uk/research/ (Accessed: 02/09/21).

Healthcare Costing for Value Institute (2016) *Introduction to health outcomes.* Bristol: Healthcare Costing for Value Institute. Available at: https://www.hfma.org.uk/docs/default-source/our-networks/healthcare-

costing-for-value-institute/institute-publications/introduction-to-health-outcomes (Accessed: 10/07/20).

Hicks, C.M. (2004) *Research methods for clinical therapists.* 4th ed edn. Edinburgh: Churchill Livingstone.

Hilborne, L.H., Lubin, I.M. and Scheuner, M.T. (2009) 'The beginning of the second decade of the era of patient safety: Implications and roles for the clinical laboratory and laboratory professionals', *Clinica Chimica Acta,* 404(1), pp. 24-27.

Hill, K.Q. and Fowles, J. (1975) 'The methodological worth of the Delphi forecasting technique', *Technological forecasting & social change,* 7(2), pp. 179-192.

Hillman, A. (2016) 'Institutions of care, moral proximity and demoralisation: The case of the emergency department', *Social theory & health,* 14(1), pp. 66-87.

Homberg, A., Oberhauser, H. and Kaap-Fröhlich, S. (2019) 'Clinical reasoning - an approach for decision-making in education and training for biomedical scientists', *GMS journal for medical education,* 36(6), pp. 1-10. doi: 10.3205/zma001289.

Hong, Q.N., Pluye, P., Fabregues, S., Bartlett, G., Boardman, F., Cargo, M., Dagenais, P., Gagnon, M., Griffiths, F., Nicolau, B., O'Cathain, A., Rousseau, M. and Vedel, I. (2018) *Mixed Methods Appraisal Tool (MMAT).* Available at: http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/127916259/MMAT_2018_criteria-manual_2018-08-01_ENG.pdf (Accessed: 08/04/2020).

Hsu, C. and Sandford, B.A. (2007) 'The Delphi Technique: Making Sense of Consensus', *Practical Assessment, Research, and Evaluation,* 12. doi: https://doi.org/10.7275/pdz9-th90.

Huang, C., Weng, R., Wu, T., Hsu, C., Hung, C. and Tsai, Y. (2020) 'The impact of person-centred care on job productivity, job satisfaction and organisational commitment among employees in long-term care facilities', *Journal of clinical nursing,* 29(15-16), pp. 2967-2978.

Humphrey-Murto, S., Varpio, L., Gonsalves, C. and Wood, T.J. (2017) 'Using consensus group methods such as Delphi and Nominal Group in medical education research', *Medical teacher,* 39(1), pp. 14-19. doi: 10.1080/0142159X.2017.1245856.

IBMS (2016) *Patient Sample and Request form Identification Criteria.* London: Institute of Biomedical Science. Available at: https://www.ibms.org/resources/documents/patient-sample-and-request-form-identification-criteria/ (Accessed: 09/08/2019).

IBMS (2018a) *Good Professional Practice in Biomedical Science.* London: Institute of Biomedical Science. Available at:

https://www.ibms.org/resources/documents/good-professional-practice-in-biomedical-science/ (Accessed: 09/08/2019).

IBMS (2018b) *Registration Training Portfolio for the IBMS Certificate of Competence. Laboratory Training Logbook.* London: Institute of Biomedical Science. Available at: https://www.ibms.org/resources/documents/ibms-registration-training-portfolio-guidance-candidates-and/ (Accessed: 09/08/2019).

IBMS (2020a) *COVID-19- recommendations for laboratory work.* Available at: https://www.ibms.org/resources/news/covid-19-recommendations-for-laboratory-work/ (Accessed: 12/02/21).

IBMS (2020b) *Criteria and Requirements for the Accreditation of BSc (Hons) Degrees in Biomedical Science.* London: Institute of Biomedical Science. Available at: https://www.ibms.org/resources/documents/criteria-and-requirements-for-the-accreditation-and-re/ (Accessed: 22/08/21).

IBMS (2021a) *Criteria and Requirements for the Accreditation of BSc (Hons) Degrees in Biomedical Science.* London: Available at: https://www.ibms.org/resources/documents/criteria-and-requirements-for-the-accreditation-and-re/ (Accessed: 08/08/22).

IBMS (2021b) *University Information.* Available at: https://www.ibms.org/education/university-information/ (Accessed: 15/07/22).

Imenda, S. (2014) 'Is There a Conceptual Difference between Theoretical and Conceptual Frameworks?', *Journal of social sciences,* 38(2), pp. 185-195.

Information Commissioner's Office (2018) *Guide to the General Data Protection Regulation.* Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/711097/guide-to-the-general-data-protection-regulation-gdpr-1-0.pdf (Accessed: 06/05/21).

Institute of Medicine (2001) *Crossing the Quality Chasm: A New Health System for the 21st Century.* Washington: National Academy Press.

Irving, P. and Dickson, D. (2004) 'Empathy: towards a conceptual framework for health professionals', *International journal of health care quality assurance,* 17(4), pp. 212-220.

Jason, L.A. and Glenwick, D.S. (2016) *Handbook of methodological approaches to community-based research.* 1st edn. New York: Oxford University Press.

Joffe, H. and Yardley, L. (eds) (2004) *Content and Thematic Analysis.* London: Sage Publications; Series number, .

Keeney, S., Hasson, F. and McKenna, H. (2006) 'Consulting the oracle: ten lessons from using the Delphi technique in nursing research', *Journal of advanced nursing,* 53(2), pp. 205-212.

Keeney, S., Hasson, F. and McKenna, H. (2011) *The Delphi Technique in Nursing and Health Research.* 1st edn. Chichester: Wiley-Blackwell.

Keeney, S., Hasson, F. and Mckenna, H.P. (2001) 'A critical review of the Delphi technique as a research methodology for nursing', *International Journal of Nursing Studies,* 38(2), pp. 195-200.

Kite, J. and Phongsavan, P. (2017) 'Insights for conducting real-time focus groups online using a web conferencing service', *F1000 research,* 6(122), pp. 1-12. doi: 10.12688/f1000research.10427.2.

Kivunja, C. (2018) 'Distinguishing between Theory, Theoretical Framework, and Conceptual Framework: A Systematic Review of Lessons from the Field', *International journal of higher education,* 7(6), pp. 44-53.

Kjellström, S., Avby, G., Areskoug-Josefsson, K., Andersson Gäre, B. and Andersson Bäck, M. (2017) 'Work motivation among healthcare professionals', *Journal of health organization and management,* 31(4), pp. 487-502. doi: 10.1108/JHOM-04-2017-0074.

Kmet, L.M., Cook, L.S. and Lee, R.C. (2004) *Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields.* Alberta, Canada: University of Alberta Libraries. Available at: https://era.library.ualberta.ca/items/48b9b989-c221-4df6-9e35-af782082280e (Accessed: 08/04/2020).

Kroft, S.H. (2018) 'The Evolution of the Clinical Pathologist', *American Journal of Clinical Pathology,* 150, pp. 283-284.

Krosnick, J.A. (1990) *The impact of satisficing on Survey Data Quality.* Washington D.C.: U.S. Government Printing Office. Available at: https://pprg.stanford.edu/wp-content/uploads/2-The-impact-of-satisficing-on-survey-data-quality.pdf (Accessed: 31/03/2021).

Krueger, R.A. and Casey, M.A. (2009) *Focus groups.* 4th edn. Los Angeles: SAGE.

Leeflang, M.M.G. and Allerberger, F. (2019) 'How to: evaluate a diagnostic test', *Clinical microbiology and infection,* 25(1), pp. 54-59.

Leonard, D., Becker, R. and Coate, K. (2005) 'To prove myself at the highest level: The benefits of doctoral study', *Higher education research and development,* 24(2), pp. 135-149. doi: 10.1080/07294360500062904.

Liberati, A., Altman, D.G., Tetzlaff, J., Mulrow, C., Gøtzsche, P.C., Ioannidis, J.P.A., Clarke, M., Devereaux, P.J., Kleijnen, J. and Moher, D. (2009) 'The PRISMA Statement for Reporting Systematic Reviews and Meta-Analyses of

Studies That Evaluate Health Care Interventions: Explanation and Elaboration', *PLoS medicine,* 6(7), pp. e1000100. doi: 10.1371/journal.pmed.1000100.

Likert, R. (1932) *A technique for the measurement of attitudes.* New York: The Science Press.

Lincoln, Y.S. and Guba, E.G. (1985) *Naturalistic Enquiry.* California: SAGE.

Maben, J., Hoinville, L., Querstret, D., Taylor, C., Zasada, M. and Abrams, R. (2021) 'Living life in limbo: experiences of healthcare professionals during the HCPC fitness to practice investigation process in the UK', *BMC Health Services Research,* 21(1), pp. 1-14. doi: 10.1186/s12913-021-06785-7.

MacArthur, A., Klugarova, J., Yan, H. and Florescu, S. (2015) 'Innovations in the systematic review of text and opinion', *International Journal of Evidence Based Healthcare,* 13(3), pp. 188-195.

Magpantay-Monroe, E.R. (2009) *The attraction of nursing academia to practicing nurses: A phenomenological study.* Doctor of Education in Educational Leadership: University of Phoenix. Available at: https://search.proquest.com/docview/520390133 (Accessed: 22/08/2021).

Manley, R.A. (2013) 'The Policy Delphi: A Method for Identifying Intended and Unintended Consequences of Educational Policy', *Policy futures in education,* 11(6), pp. 755-768. doi: 10.2304/pfie.2013.11.6.755.

Mansell, I., Bennett, G., Northway, R., Mead, D. and Moseley, L. (2004) 'The learning curve: the advantages and disadvantages in the use of focus groups as a method of data collection', *Nurse researcher,* 11(4), pp. 79-88. doi: 10.7748/nr2004.07.11.4.79.c6217.

Manski, C.F. (2013) 'Diagnostic testing and treatment under ambiguity: Using decision analysis to inform clinical practice', *Proceedings of the National Academy of Sciences - PNAS,* 110(6), pp. 2064-2069.

Marseu, A., Santaguida, P.L., Moore, G.P. and McDonald, S.D. (2022) 'An e-Delphi study on mode of delivery and extremely preterm breech singletons', *Journal of Perinatology,* . doi: 10.1016/j.jogc.2020.02.064.

McArthur, A., Klugarova, J., Yan, H. and Florescu, S. (2015) 'Innovations in the systematic review of text and opinion.', *International Journal of Evidence Based Healthcare,* 13(3), pp. 188-195.

McCance, T., McCormack, B. and Dewing, J. (2011) 'An exploration of person-centredness in practice', *Online journal of issues in nursing,* 16(2), pp. 1-10. doi: 10.3912/OJIN.Vol16No02Man01.

McCormack, B., Borg, M., Cardiff, S., Dewing, J., Jacobs, G.C. and Janes, N. (2015) 'Person-centredness – The 'State' of the Art', *International practice development journal,* 5(Suppl), pp. 1-15. doi: 10.19043/ipdj.5SP.003.

McCormack, B. and McCance, T. (2017) *Person-Centred Practice in Nursing and Health Care Theory and Practice.* 2nd edn. Chichester: Wiley Blackwell.

McCreanor, G. (2017) *1.6% A target set in stone?* Available at: https://thebiomedicalscientist.net/science/16-%E2%80%93-target-set-stone (Accessed: 20/10/2021).

McEwen, L., Haigh, M., Smith, S., Steele, A. and Miller, A. (2003) 'Real World Experiences?', *Planet,* 10(1), pp. 18-22.

McKenna, H.P. (1994) 'The Delphi technique: a worthwhile research approach for nursing?', *Journal of advanced nursing,* 19(6), pp. 1221-1225.

McMillan, S.S., King, M. and Tully, M.P. (2016) 'How to use the nominal group and Delphi techniques', *International Journal of Clinical Pharmacy,* 38, pp. 655-662.

Mead, N. and Bower, P. (2000) 'Patient-centredness: a conceptual framework and review of the empirical literature', *Social science & medicine,* 51(7), pp. 1087-1110.

Michau, R., Roberts, S., Williams, B. and Boyle, M. (2009) 'An investigation of theory-practice gap in undergraduate paramedic education', *BMC medical education,* 9(1), pp. 1-7. doi: 10.1186/1472-6920-9-23.

Monaghan, T. (2015) 'A critical analysis of the literature and theoretical perspectives on theory–practice gap amongst newly qualified nurses within the United Kingdom', *Nurse education today,* 35(8), pp. e1-e7. doi: 10.1016/j.nedt.2015.03.006.

Moore, S.A., Wallington, T.J., Hobbs, R.J., Ehrlich, P.R., Holling, C.S., Levin, S., Lindenmayer, D.B., Pahl-Wostl, C., Possingham, H.P., Turner, M.G. and Westoby, M. (2009) 'Diversity in Current Ecological Thinking: Implications for Environmental Management', 43(1), pp. 17-27.

Moreno, J., Caplan, A.L., Wolpe, P.R. and the Members of the Project on Informed Consent, Human Research Ethics Group (1998) 'Updating Protections for Human Subjects Involved in Research', *JAMA : the journal of the American Medical Association,* 280(22), pp. 1951-1958.

Morgan, D.L. (2014) 'Pragmatism as a Paradigm for Social Research', *Qualitative inquiry,* 20(8), pp. 1045-1053. doi: 10.1177/1077800413513733.

Morris, S., Otto, C.N. and Golemboski, K. (2013) 'Improving Patient Safety and Healthcare Quality in the 21st Century- Competencies Required of Future Medical Laboratory Science Practitioners', *Clinical Laboratory Science,* 26(4), pp. 200-204.

Morton, S.M.B., Bandara, D.K., Robinson, E.M. and Carr, P.E.A. (2012) 'In the 21stCentury, what is an acceptable response rate?', *Australian and New Zealand journal of public health,* 36(2), pp. 106-108.

Moudatsou, M., Stavropoulou, A., Philalithis, A. and Koukouli, S. (2020) 'The Role of Empathy in Health and Social Care Professionals', *Healthcare,* 8(1). doi: 10.3390/healthcare8010026.

Murphy, M.K., Sanderson, C., Black, N.A., Askham, J., Lamping, D.L., Marteau, T. and Mckee, C.M. (1998) 'Consensus development methods, and their use in clinical guideline development', *Health Technology Assessment,* 2(3).

Murray, C. and Lawry, J. (2011) 'Maintenance of professional currency: Perceptions of occupational therapists', *Australian occupational therapy journal,* 58(4), pp. 261-269.

Nederhof, A.J. (1985) 'Methods of Coping with Social Desirability Bias: A Review', *European journal of social psychology,* 15(3), pp. 263-280.

NHS Digital (2022) *NHS Workforce Statistics, November 2021 Staff Group, Care Setting and Level.* London: NHS Digital. Available at: https://digital.nhs.uk/data-and-information/publications/statistical/nhs-workforce-statistics/november-2021 (Accessed: 11/03/2022).

NHS England (2014) *National Pathology Programme Digital first: Clinical Transformation through Pathology Innovation.* London: Available at: https://www.england.nhs.uk/wp-content/uploads/2014/02/pathol-dig-first.pdf (Accessed: 10/07/2020).

NHS England (2018) *Pathology Networks.* Available at: https://www.england.nhs.uk/pathology-networks/ (Accessed: 20/10/2021).

NHS England and NHS Improvement (2019) *NHS England and Improvement pathology networking in England 2019: the state of the nation.* NHS England and NHS Improvement. Available at: https://improvement.nhs.uk/resources/pathology-networks/ (Accessed: 10/07/2020).

NHS Improvement (2018) *NHS Improvement pathology networking in England: the state of the nation.* Available at: https://improvement.nhs.uk/documents/3240/Pathology_state_of_the_nation_sep2018_ig.pdf (Accessed: 10/07/2020).

NICE (2016) *Patient experience in adult NHS services: improving the experience of care for people using adult NHS services.* NICE. Available at: https://www.nice.org.uk/guidance/cg138 (Accessed: 02/09/2020).

Nortvedt, P. and Nordhaug, M. (2008) 'The principle and problem of proximity in ethics', *Journal of medical ethics,* 34(3), pp. 156-161. doi: 10.1136/jme.2006.020230.

Oppenheim, A. (1992) *Questionnaire Design, Interviewing and Attitude Measurement.* London: Pinter.

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

Otto, C.N. (2011) 'Patient safety and the medical laboratory an introduction', *Clinical laboratory science,* 24(2), pp. 105-107.

Petrucci, C., La Cerra, C., Aloisio, F., Montanari, P. and Lancia, L. (2016) 'Empathy in health professional students: A comparative cross-sectional study', *Nurse Education Today,* 41, pp. 1-5.

Pittenger, A.L., Dimitropoulos, E., Foag, J., Bishop, D., Panizza, S. and Bishop, J.R. (2019) 'Closing the Classroom Theory to Practice Gap by Simulating a Psychiatric Pharmacy Practice Experience', *American Journal of Pharmaceutical Education,* 83(10), pp. 2102-2110.

Plebani, M. (2002) 'Charting the course of medical laboratories in a changing environment', *Clinica Chimica Acta,* 319(2), pp. 87-100.

Plebani, M. (2013) 'The CCLM contribution to improvements in quality and patient safety', *Clinical chemistry and laboratory medicine,* 51(1), pp. 39-46.

Plebani, M. (2014) 'Laboratory-associated and diagnostic errors: a neglected link', *Diagnosis,* 1(1), pp. 89-94.

Plebani, M. (2016) 'Harmonization in laboratory medicine: Requests, samples, measurements and reports', *Critical reviews in clinical laboratory sciences,* 53(3), pp. 184-196.

Plebani, M., Ceriotti, F., Messeri, G., Ottomano, C., Pansini, N. and Bonini, P. (2006) 'Laboratory network of excellence: enhancing patient safety and service effectiveness', *Clinical Chemistry and Laboratory Medicine (CCLM),* 44(2), pp. 150-160.

Plebani, M., Laposata, M. and Lundberg, G.D. (2011) 'The Brain-to-Brain Loop Concept for Laboratory Testing 40 Years After Its Introduction', *American journal of clinical pathology,* 136(6), pp. 829-833.

Pol-Grevelink, A., Jukema, J.S. and Smits, C.H.M. (2012) 'Person-centred care and job satisfaction of caregivers in nursing homes: a systematic review of the impact of different forms of person-centred care on various dimensions of job satisfaction', *International journal of geriatric psychiatry,* 27(3), pp. 219-229.

Price, T.M. (2015) 'Emotional Intelligence in Medical Laboratory Science', *Clinical laboratory science,* 28(3), pp. 178-185.

Quality Assurance Agency (2019) *Benchmark Statement for Biomedical Sciences.* London: Quality Assurance Agency. Available at: https://www.qaa.ac.uk/docs/qaa/subject-benchmark-statements/subject-benchmark-statement-biomedical-sciences.pdf?sfvrsn=2bf2c881_4 (Accessed: 22/06/2020).

Research Policy Unit (2020) *Code of Good Research Practice.* Available at: https://www.wlv.ac.uk/media/departments/research/documents/Code-of-Good-Research-Practice-(2020-21).pdf (Accessed: 06/05/21).

Royal College of Pathologists (2011) *Code of Practice for Clinical Biochemists/ Chemical Pathologists and Clinical Biochemistry Services.* London: Royal College of Pathologists. Available at: https://www.rcpath.org/resourceLibrary/g027-clinbiocodeofpractice-mar11-pdf.html (Accessed: 13/11/2018).

Royal College of Pathologists (2013) *Key Performance Indicators in Pathology.* London: Available at: https://www.rcpath.org/resourceLibrary/key-performance-indicators-in-pathology---recommendations-from-the-royal-college-of-pathologists-.html (Accessed: 13/11/2018).

Ryan, A.B. (2006) 'Post-Positivist Approaches to Research', in Antonesa, M. (ed.) *Researching and Writing Your Thesis: a guide for postgraduate students* MACE: Maynooth Adult and Community Education, pp. 12-26.

Schmeer, K. (1999) 'Stakeholder Analysis Guidelines '*Policy Toolkit for Strengthening Health Sector Reform* Bethesda, MD: Abt Associates, Inc, pp. 1-48.

Scholl, I., Zill, J.M., Härter, M. and Dirmaier, J. (2014) 'An Integrative Model of Patient-Centeredness – A Systematic Review and Concept Analysis', *PloS one,* 9(9), pp. e107828. doi: 10.1371/journal.pone.0107828.

Scotland, J. (2012) 'Exploring the Philosophical Underpinnings of Research: Relating Ontology and Epistemology to the Methodology and Methods of the Scientific, Interpretive, and Critical Research Paradigms', *English language teaching (Toronto),* 5(9), pp. 9-16.

Scott, M.G., Rifai, N., Smith, B., Oellerich, M., Panteghini, M., Apple, F., Sikaris, K. and Young, I. (2015) 'The Changing Face of Laboratory Medicine: A More Service and Less Academically Oriented Profession?', *Clinical chemistry (Baltimore, Md.),* 61(2), pp. 322-329.

Scully, N.J. (2011) 'The theory-practice gap and skill acquisition: An issue for nursing education', *Collegian (Royal College of Nursing, Australia),* 18(2), pp. 93-98.

Shrestha, R.B. (2015) 'The race for the care: A vision for patient-centered care', *Applied radiology,* 44(9), pp. 34-37.

Smith, J., Billot, J., Clouder, L. and King, V. (2020) 'Juggling competing activities: academic staff as doctoral candidates', *Higher education research and development,* 39(3), pp. 591-605. doi: 10.1080/07294360.2019.1685945.

Souza, M.T.d., Silva, M.D.d. and Carvalho, R.d. (2010) 'Integrative review: what is it? How to do it?', *Einstein (São Paulo, Brazil),* 8(1), pp. 102-106.

Starfield, B. (2011) 'Is Patient-Centered Care the Same As Person-Focused Care?', *Permanente journal,* 15(2), pp. 63-69.

Stewart, J. (2001) 'Is the Delphi technique a qualitative method?', *Medical education,* 35(10), pp. 922-923.

Sullivan, E. and Brye, C. (1983) 'Nursing's future: use of the Delphi technique for curriculum planning', *The Journal of nursing education,* 22(5), pp. 187-189.

Sutrisna, M. (2009) *Research Methodology in Doctoral Research: Understanding the Meaning of Conducting Qualitative Research, Working Paper.* Liverpool: Liverpool John Moores University. Available at:(Accessed: 27/01/2018).

Sutton, K.L. (2014) 'The laboratory's role in patient centered health care', *AMT events,* 31(2), pp. 82-83.

The Health and Social Care Act (2008) *(Regulated Activities) Regulations 2014.* London: House of Commons. Available at: https://www.legislation.gov.uk/ukdsi/2014/9780111117613/contents (Accessed: 02/09/2020).

Toronto, C.E. and Remington, R. (2020) *A Step-By-Step Guide to Conducting an Integrative Review.* 1st edn. Cham: Springer International Publishing AG.

Trevelyan, E.G. and Robinson, P.N. (2015) 'Delphi methodology in health research: how to do it?', *European journal of integrative medicine,* 7(4), pp. 423-428.

Turoff, M. (2002) 'The Policy Delphi', in Linstone, H.A. and Turoff, M. (eds.) *The Delphi Method Techniques and Applications*. 1st edn. Newark, New Jersey: New Jersey Institute of Technology, pp. 80-96.

Ugur, E., Kara, S., Yildirim, S. and Akbal, E. (2016) 'Medical errors and patient safety in the operating room', *Journal of the Pakistan Medical Association,* 66(5), pp. 593-597.

Vaismoradi, M., Jones, J., Turunen, H. and Snelgrove, S. (2016) 'Theme development in qualitative content analysis and thematic analysis', *Journal of Nursing Education and Practice,* 6(5), pp. 100-110. doi: 10.5430/jnep.v6n5p100.

Vázquez-Ramos, R., Leahy, M. and Estrada Hernández, N. (2007) 'The Delphi Method in Rehabilitation Counseling Research', *Rehabilitation counseling bulletin,* 50(2), pp. 111-118.

Whittemore, R. and Knafl, K. (2005) 'The integrative review: updated methodology', *Journal of advanced nursing,* 52(5), pp. 546-553.

Williams, M. (2016) *The Philosophy of Social Research.* 1st edn. London: SAGE Publications Ltd.

Wright, S.R. and Homer, M. (2017) 'Addressing the theory-practice gap in assessment', *Perspectives on medical education,* 6(1), pp. 7-9.

Yorke, M. and Knight, P.T. (2006) *Learning & Employability: Embedding employability into the curriculum.* York: The Higher Education Academy. Available at: http://www.employability.ed.ac.uk/documents/Staff/HEABriefings/ESECT-3-Embedding_employability_into_curriculum.pdf (Accessed: 22/08/21).

Zieber, M. and Wojtowicz, B. (2020) 'To dwell within: Bridging the theory–practice gap', *Nursing philosophy,* 21(2), pp. e12296-n/a. doi: 10.1111/nup.12296.

APPENDICES

Appendix 1: Ethical approval from FEHW ethics committee obtained 18th March 2020

Ethical approval letter removed for confidentiality reasons.

Appendix 2: Ethical approval from NHS HRA obtained 13th May 2020.

NHS HRA ethical approval letter redacted for confidentiality reasons
(page one)

NHS HRA ethical approval letter redacted for confidentiality reasons
(page two)

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
One participating NHS organisation, conducting the activities as per A18 of the IRAS form. Therefore, one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used.	No funding is being provided to sites by the sponsor.	Local collaborator.	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to hold Letters of Access if focus groups were held in clinical areas. Letters of Access would not be expected if focus groups were held in non-clinical/administrative buildings.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
This study has not been put forward for adoption to the NIHR Portfolio. An amendment should be submitted for approval for the Delphi questionnaire, which will be generated following the focus group discussions.

Appendix 3: Ethical approval paperwork from FEHW ethics committee following minor amendments in data collection due to the COVID-19 pandemic, obtained 6th August 2020.

Revised ethical approval letter from FEHW ethics committee redacted for confidentiality reasons

Appendix 4: Confirmation from HRA that resubmission of documents to reflect study changes due to COVID-19 was not required. Received 19th of July 2020.

Dear Kathryn

Many Thanks for your email. As this amendment would be made to Change how or when participants are seen to avoid exposing them to COVID-19 or to reduce the burden on clinical services, it would be considered Non-Substantial, Non notifiable which means it would not need HRA Approval or R&D agreement. You could implement this change without having to submit an amendment as it just involves switching the focus group to being held remotely in light of the pandemic.

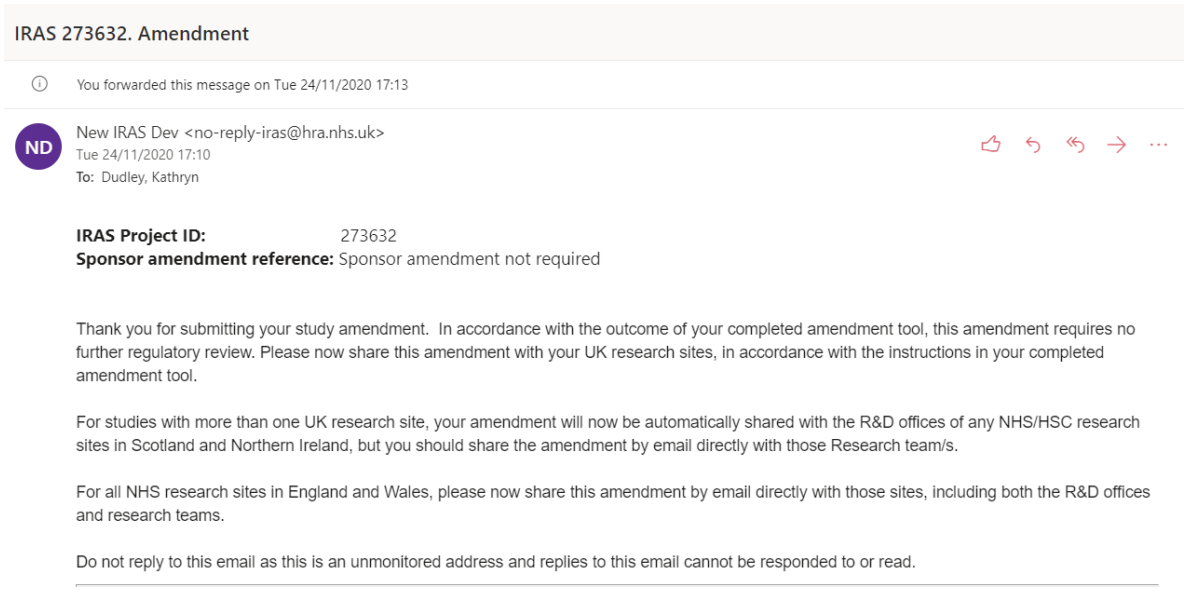
Further guidance for this is provided on the following link, https://www.hra.nhs.uk/covid-19-research/covid-19-guidance-sponsors-sites-and-researchers/#patients

Kind Regards

Appendix 5: Trust R&D confirmation of capacity for study. Received 7th August 2020.

NHS R&D permission to carry out the study redacted for confidentiality reasons

Appendix 6: NHS HRA approval for round two Delphi questionnaire received 24th of November 2020.



IRAS 273632. Amendment

You forwarded this message on Tue 24/11/2020 17:13

ND

New IRAS Dev <no-reply-iras@hra.nhs.uk>
Tue 24/11/2020 17:10
To: Dudley, Kathryn

IRAS Project ID: 273632
Sponsor amendment reference: Sponsor amendment not required

Thank you for submitting your study amendment. In accordance with the outcome of your completed amendment tool, this amendment requires no further regulatory review. Please now share this amendment with your UK research sites, in accordance with the instructions in your completed amendment tool.

For studies with more than one UK research site, your amendment will now be automatically shared with the R&D offices of any NHS/HSC research sites in Scotland and Northern Ireland, but you should share the amendment by email directly with those Research team/s.

For all NHS research sites in England and Wales, please now share this amendment by email directly with those sites, including both the R&D offices and research teams.

Do not reply to this email as this is an unmonitored address and replies to this email cannot be responded to or read.

Appendix 7: Evidence of approval for commencing the study from the Head of the FSE Life Sciences Ethics Committee (LSEC).

Email evidence of approval to commence the study redacted for confidentiality reasons

Appendix 8: Evidence of approval for commencing the study from the Head of Biomedical Science and Physiology

Emails confirming approval for commencing the study redacted for confidentiality reasons

Appendix 9: Email invitation sent to participants to recruit for the online focus groups for the BMS group, academic group and student group.

Dear Biomedical Scientist,

I am currently completing a doctoral thesis which is researching the role of the Biomedical Scientist within patient outcomes. I am aiming to recruit approximately 10 participants from each of the following groups: practising Biomedical Scientists, BSc Biomedical Science students and academic staff delivering the BSc Biomedical Science programme, along with representatives from the professional and regulatory bodies.
This study aims to determine whether there is agreement amongst stakeholders on the BMS role in achieving patient outcomes. The study will use a Delphi technique and consists of two 'rounds'. The study will involve participation in an online focus group lasting a maximum of 90 minutes followed by completion of an online questionnaire which will take a maximum of 30 minutes to complete.

If you would like to participate, please read the attached participant information sheet and click here to complete the online consent form.

You will be prompted to enter a password which is **BMS2020**.
The online focus group will be scheduled for the week commencing the 21st of September at a mutually convenient day/time which will be agreed if you decide to participate. In order to participate, you will need access to Microsoft Teams, internet access and a microphone, but a webcam is not required.

In order to allow time for the focus group to be arranged, the deadline to consent for participation if you wish to take part is **Friday 18th of September**.

I sincerely hope you will agree to participate and if you have any questions, please email [REDACTED].
Thank you for your time and any help you may be able to offer to this study.
Yours Sincerely

Kathryn Dudley,
Biomedical Scientist & Doctoral Research Student,
University of Wolverhampton

Appendix 10: Email invitation sent to representatives from the professional, statutory and regulatory bodies, including the IBMS, HCPC and DoH.

Dear [organisation] representative,

My name is Kathryn Dudley and I am a Biomedical Scientist by background and currently working as a lecturer in Biomedical Science, specialising in haematology and transfusion at the University of Wolverhampton. As part of my Professional Doctorate course at the University of Wolverhampton, I am proposing to conduct a research project which will focus upon the importance of the Biomedical Scientist's role in patient outcomes.

I require your support to contact representatives within your organisation with responsibility for establishing professional policies relevant to the Biomedical Scientist profession. I would be grateful if you could distribute the attached information to staff within your organisation who influence policies for the Biomedical Scientist profession. The study will adopt a Delphi methodology comprising 2 rounds. Round 1 will comprise an initial telephone interview regarding the role of the Biomedical Scientist in achieving patient outcomes. The telephone interview will last for approximately 60 minutes and will be followed by round 2 which requires completion of an e-questionnaire 4 weeks later and will take no longer than 30 minutes to complete.

If you agree that I can approach the staff within your organisation, then I would ask that you forward the attached email and participant information sheet on my behalf requesting participation of interested parties in the study. The potential benefits of this research include the influence of future policy, education and practice. The importance of achieving patient outcomes is not explicit in the Quality Assurance Agency (QAA) Benchmark Statements for Biomedical Science and this is something this research may seek to change.

I am therefore writing to seek your permission to contact representatives of your organisation and ask that you kindly forward the attached information to suitable participants. I enclose a copy of the research protocol for your information.

I am happy to have a discussion about this via telephone or an online meeting platform to explain my research further if required.

I look forward to hearing from you.

Yours sincerely

Kathryn Dudley
Biomedical Scientist & Doctoral Research Student, University of Wolverhampton

Appendix 11: Participant information sheet which was distributed to prospective participants

Participant Information Sheet
Version 4.2, 27/07/20

Study title

A Delphi study exploring stakeholder perceptions of the role of the Biomedical Scientist in patient outcomes.

Invitation

You have been invited to participate in a research study based upon your professional knowledge and experience as a Biomedical Scientist. This research is being undertaken as part of a doctoral research project at the University of Wolverhampton. Before you decide whether you wish to participate it is important for you to understand why the research is being done and what it will involve in terms of your time. Please take time to read the following information carefully and discuss it with others before you decide whether you wish to take part. Ask us if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this information.

What is the purpose of the study?

Many Biomedical Scientists work behind the scenes and have little patient contact. Previously published research suggests that the role of the Biomedical Scientist is poorly understood by patients and healthcare professionals and that many patients are unaware that the role exists. Documents issued by the HCPC make frequent references to the importance of the 'service user' within the role of the BMS. This research study aims to elicit the views of stakeholders on the role of the BMS within patient outcomes. This is worthy of investigation because there are over 23,000 Biomedical Scientists registered with the HCPC.

Why have I been chosen?

You have been selected to participate in this study because you are a Biomedical Scientist and your experience and opinions can contribute to this research study. Within your group of participants there will be approximately seven other Biomedical Scientists, some of which have a responsibility for training. Other groups within this study will include BSc Biomedical Science students and academics who deliver the BSc Biomedical Science programme at the University of Wolverhampton, as well as policy makers from the IBMS, HCPC and Department of Health (DoH).

Do I have to take part?

Participation in this research study is voluntary. It is up to you to decide whether or not to take part. If you decide to take part, you are free to withdraw up to 2 weeks following participation in the interview. After this it will not be possible for you to withdraw your anonymised responses.

What will happen if I decide to take part?

If you decide to participate in this study, you will be asked to attend an initial interview. This initial meeting will be at a mutually convenient day and time and will take place online or via telephone to minimise inconvenience to you as a participant. This initial session will run for circa one hour. The session will be audio recorded for the purposes of accurately transcribing the discussions that take place, but participants will not be identifiable from the data they provide or from their professional role. Within four weeks of this first round, you will receive a questionnaire via email which will ask you to score your agreement with a number of statements which have been generated by analysis of the results of the initial interviews and which will take you a maximum of 30 minutes to complete.

What are the potential benefits and risks of taking part?

Though there are no direct benefits for you as an individual if you take part, by participating in this research study you will help to influence future policy, education and practice of the Biomedical Scientist profession. There are no risks to you in taking part but if you become distressed during the study you will be able to choose whether you wish to proceed with the study. At the end of the session there will be an opportunity for debrief and you will be signposted to sources of support if required.

Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be confidential. The transcription of the session that you participate in and the audio recordings will be stored on a password protected, encrypted computer file on the secure University network. Consent will be taken using a password protected link within an email. Only the researchers working on the study will have access to any identifiable information. The identifiable data that will be collected is your name and email address, and this will be required to invite you to participate in round 2 of the study, and this will be received by Kathryn Dudley who is leading this study. Once responses for the 2nd round of the study have been received all data will be anonymised by allocating a participant number. This means that identifiable data will be stored securely for a maximum of 12 weeks. You will not be identifiable in any publication or report as all identifiable information will be removed. All participants will be asked to keep all of the information you hear within this session confidential and not to discuss the information with anyone outside of the session. The only exception to this is if something is disclosed during the interview or questionnaire responses that would be considered a potential safeguarding issue or that indicates that poor practice has taken place. In the unlikely event of such a disclosure taking place, the researcher will be

required to inform the manager of the organisation who will deal with the disclosure in line with local policy.

The data controller for this project will be The University of Wolverhampton. The University will process your personal data for the purpose of the research outlined above. The legal basis for processing your personal data for research purposes under GDPR is a 'task in the public interest'. You can provide your consent for the use of your personal data in this study by completing the consent form that has been provided to you. You have the right to access information held about you. Your right of access can be exercised in accordance with the General Data Protection Regulation. You also have other rights including rights of correlation, erasure, objection and data portability. Questions, comments and requests about your personal data can also be sent to the University of Wolverhampton's Data Protection Officer (dataprotection@wlv.ac.uk). If you wish to lodge a complaint with the Information Commissioner's Office, please visit www.ico.org.uk.

What will happen at the end of the research study?

This research is part of a doctoral thesis which will be published and disseminated in relevant journals. Participants will be provided with a short summary of the findings once the data analysis has taken place, prior to publication.

What if I have a problem or concern?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. The person to speak to if you are concerned about the conduct of this study is [REDACTED] Dean of Research, [REDACTED] and she can be telephoned on [REDACTED].

Who has reviewed the study?

This study has been reviewed by the Faculty of Education, Health and Wellbeing (FEHW) Research Ethics Committee and the NHS Integrated Research Application System (IRAS) ethics committee.

Contact for further information

If you require further information about the study or wish to clarify any information, then please contact Kathryn Dudley [REDACTED] or telephone on [REDACTED].

Additional information:

If you wish to request that your data is removed from the study, please contact Kathryn Dudley using the contact details above. Please bear in mind that although you can withdraw, after the first-round data has been analysed it will not be possible to withdraw the data after this point.

The research team thank you for taking the time to read this information sheet and thank you for considering whether you wish to participate in this study.

Appendix 12: The Survey Monkey online questionnaire which was used to obtain consent for participation in the study.

Consent form for 'A Delphi study exploring stakeholder perceptions of the role of the Biomedical Scientist in patient outcomes'.

Delphi Study Consent form. IRAS ID 273632

Please ensure that you have read and understood the participant information sheet before completing this consent form.
If you have any queries or need any further information please contact Kathryn Dudley
[redacted]

1. I confirm that I have read and understand the information sheet dated 27/07/20 (version 4.2) for the above study. I have had the opportunity to ask questions and have had them answered satisfactorily.

- ◯ Yes
- ◯ No

2. I am willing to participate in both rounds of this modified Delphi study.

- ◯ Yes
- ◯ No

3. I understand that my participation is voluntary and that I am free to withdraw prior to data analysis from round one, without giving a reason.

- ◯ Yes
- ◯ No

4. I understand that my data will be stored securely and confidentially and that I will not be identifiable in any report or publication. Please note: the only exception to this is any safeguarding or malpractice concerns being discussed which will be escalated accordingly.

- ◯ Yes
- ◯ No

5. I understand that the researcher may wish to publish this study and any results found, for which I give my permission.

- ◯ Yes
- ◯ No

6. I agree for my participation to be audio recorded and for the data to be used for the purpose of this study.

- ◯ Yes
- ◯ No

7. I agree not to disclose any information that I am privy to as a result of this study.

- ◯ Yes
- ◯ No

8. I agree to participate in the above study

Full Name

Email Address

Done

Appendix 13: The Jisc online surveys questionnaire demonstrating how the questionnaire was presented to participants.

Page 1: Welcome

Welcome to the second round of this Delphi study considering stakeholder perceptions of the Biomedical Scientist role in patient outcomes.

You are asked to score your agreement with a number of statements using a Likert scale. Please select the option that you feel most closely represents your views on each statement. You are provided with the option 'neither agree nor disagree' but please only use this if it truly reflects your opinion of the statement.

If you do not feel you can express your opinion on one of the statements, please do not select an answer and move onto the next question. Please only do this if you feel that you cannot answer the question.

The questionnaire should take a maximum of 15 minutes for you to complete.

Thank you for taking the time to complete this questionnaire and for supporting this research study.

Next >

Page 2: Participant group

Please select the group of participants to which you belong from the list below. If you belong to more than one group of participants, please select the group that you were interviewed or attended the focus group as part of. * *Required*

Biomedical Science students

< Previous

Next >

Page 3: Questions 1-10

Biomedical Scientists work in the best interests of the patient at all times.

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

It is easier for staff providing direct patient care to prioritise patient outcomes due to their proximity to the patient.

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists do not require empathy for patients to do their job effectively

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Patient safety is the responsibility of others in the clinical team and it is not appropriate for a Biomedical Scientist to question their decision making

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Time pressures often impact upon a Biomedical Scientist's ability to do their job well

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Centralisation of pathology services into 29 hubs across England covering a wider geographical area will make it more challenging for Biomedical Scientists to put the patient first

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists are regarded as being an essential part of the multi-disciplinary team by the wider healthcare team

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Measures of the quality of the laboratory service, such as specimen turn-around time are not important indicators of quality care from the patient's perspective

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The technical and analytical nature of the Biomedical Scientist role makes it difficult to recognise the importance of the individual patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The desire to work in the best interests of the patient at all times is not shared by all Biomedical Scientists

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Page 4: Questions 11-20

Without Biomedical Scientists, initiating diagnosis and treatment decisions for patients would be impossible

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists must question inappropriate clinical decisions

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Statutory registration for Biomedical Scientists has no meaning to patients and others in the clinical team as they lack an understanding of the role

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists are not required to make autonomous decisions

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The pressures of the Biomedical Scientist role do not detract from the importance of the individual patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists must be prepared to put in extra hours in order to meet the needs of the service and the patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Centralisation of pathology services into 29 hubs across England covering a wider geographical area is unlikely to impact the Biomedical Scientist's desire to focus upon patient outcomes

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The nature of the Biomedical Scientist role makes it difficult for them to feel part of the healthcare team

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The role of the Biomedical Scientist in healthcare is well understood by other healthcare professionals

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Page 5: Questions 21-30

Clinical teams respond positively if the laboratory rejects a patient's sample due to incorrect labelling

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Measures of the quality of the laboratory service, such as specimen turn-around time are good measures of care for the patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists do not require soft skills such as empathy, as their priority should be analysing specimens in a timely fashion

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Despite the lack of proximity to the patient, Biomedical Scientists put the patient at the centre of what they do

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Job satisfaction is not determined by the perceived importance of patients within the Biomedical Scientist role

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The Biomedical Scientist plays an essential role in patient safety

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Statutory HCPC registration for Biomedical Scientists provides confidence for patients and others in the clinical team about the quality of the Biomedical Scientist's practice

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Other pressures of the Biomedical Scientist role detract from the importance of the individual patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Despite the lack of patient contact, Biomedical Scientists can focus upon achieving outcomes for each individual patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The role of the Biomedical Scientist in healthcare is poorly understood by other healthcare professionals

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Page 6: Questions 31-40

Biomedical Scientists are not considered part of the multi-disciplinary team by the wider healthcare team

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists must recognise when referral to a consultant or member of the medical team is required to ensure the best outcome for a patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

The technical and analytical nature of the Biomedical Scientist role does not detract from the importance of the individual patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

A Biomedical Scientist should recognise the importance of each individual sample by considering the needs of the patient behind each sample

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists are able to draw upon their own personal experiences as a patient or carer which allows them to empathise with the patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Statutory registration with the Health and Care Professions Council (HCPC) ensures that Biomedical Scientists feel empowered to make autonomous decisions

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Lack of patient contact makes it difficult for a Biomedical Scientist to recognise their role within an individual patient's outcomes

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Clinical teams often suggest that the laboratory is negatively impacting patient care if an incorrectly labelled sample is rejected

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists are not responsible for referring a patient case for a consultant to review

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Softer skills such as patient empathy are important aspects of the training and education of Biomedical Scientists

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Page 7: Questions 41-47

By focusing upon the outcome of the individual patient, the Biomedical Scientist achieves greater job satisfaction

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

It's possible for a Biomedical Scientist to do their job well without considering the needs of the patient

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Without the Biomedical Scientist role, point of care testing delivered by other clinical staff would be a suitable replacement

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

It is not within the Biomedical Scientist's remit to question clinical decisions that put the patient at risk

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

Biomedical Scientists are well integrated within the healthcare team, despite a lack of patient contact

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

What would you consider to be the Biomedical Scientist's top priority when processing patient samples? Please rank the following in order of priority:

	Rank from most important (5) to least important (1)
Accuracy	Please select
Speed	Please select
Patient safety	Please select
Volume of samples processed	Please select
Taking appropriate action	Please select

If you have any other points that you feel you would like to make with regards to this study, please include them in the comments box below (maximum 250 characters)

Your answer should be no more than 250 characters long.

Final page

Thank you very much for participating in this study and for taking the time to answer these questions.

You will receive a brief summary of the findings of the study in due course.

If you have any comments or queries following your participation please email k.dudley2@wlv.ac.uk

Once again, thank you for your time and for supporting this study.

Appendix 14: The interview schedule used in round one of the study.

<u>Presentation of the clinical vignette and any discussions that arise following the vignette.</u>

Vignette:

A 65-year-old woman presents to her GP complaining she feels tired all of the time and has no energy. She has noticed some bruising and bleeding when she brushes her teeth. The GP is concerned so requests urgent blood tests and sends an urgent biochemical profile, full blood count and coagulation screen to the local hospital. The results of the patient's full blood count reveal a very low haemoglobin, high white blood cells with immature forms known as blasts, and dramatically low platelets which is the likely cause of her bruising and bleeding.

What do you perceive to be the Biomedical Scientist's role in contributing to this patient's outcomes? What would a good outcome be for this patient?

What role does the Biomedical Scientist play within a multi-disciplinary team in terms of achieving outcomes for this patient?

a. Participants will be asked what they feel the Biomedical Scientist's role is within the vignette.

b. What does putting the patient at the centre of the Biomedical Scientist role mean to you? [Could you provide examples from your own practice of how you have done this?]

c. What do you think is the Biomedical Scientist's role is achieving patient outcomes?

d. What do you understand by a Biomedical Scientist working to achieve patient outcomes?

e. The IBMS 'Good Professional Practice in Biomedical Science' (2019) states:

   "Biomedical science professionals must exercise their professional duty of care and work within the legal, ethical and regulatory frameworks that govern and affect practice."

   What is the importance of these professional requirements and how can Biomedical Scientists achieve them?

f. What is the potential impact upon patient care if Biomedical Scientists are not focused upon patient outcomes?

g. How would you identify a Biomedical Scientist who is or isn't focused upon achieving patient outcomes?

Appendix 15: Sample transcript along with identified codes used for the thematic analysis

Int: OK so I'm going to talk to you briefly about the case study to start with, but as I've already mentioned I'm not looking for any specific details relating to the case I'm just more interested in erm the sort of the Biomedical Scientist role within that case. So, a 65-year-old woman presents to her GP complaining that she feels tired all of the time and has no energy. She has noticed some bruising and bleeding gums when she brushes her teeth and the GP is concerned so requests urgent blood tests and an erm urgent biochemical profile, full blood count and coagulation screen that are sent to the local hospital. The results of the patient's full blood count reveal a very low haemoglobin, high white blood cells with immature forms known as blasts, and dramatically low platelets which is the likely cause of her bruising and bleeding. OK so the first question then is what you perceive to be the Biomedical Scientist's role in contributing to this patient's outcomes?

BS4: OK I would expect the Biomedical Scientist role to be, to ensure that the tests are correct, erm that's the most important thing and obviously to do this they're going to have to have knowledge of what to do, of how to make sure that it's the correct patient that's been tested erm that the correct analyses are selected, that it's correctly booked into any computer systems along the way, that quality control material is used to ensure that the testing is correct and that the results are reported in a timely manner to the correct people that need to take action and also to have knowledge that this patient might actually require further testing so it might not just be the tests that the GP has requested, it might be that more tests are required erm to enable a decision to be made and a diagnosis for the patient. And then also, if the diagnosis is made there might be further testing to manage the patient along the way.

Int: So, what be a good outcome for this patient?

BS4: That the patient gets the correct results in a timely fashion and that they are acted upon quickly and any further testing is done quickly so that the patient can get the best treatment to get the best outcome.

Int: So, could you tell me what role the Biomedical Scientist plays within a multi-disciplinary team in terms of achieving outcomes for this patient?

BS4: Well, I mean as you've said in the case study, erm they've had various tests including a biochemical profile erm there might be abnormalities in the biochemical profile erm so they'd be working with colleagues on results of that. There could be other testing that's done in different laboratories, there could be other testing that's been requested from different disciplines erm, maybe not necessarily in this case but in other cases it might not just be down to laboratory results that are required. You know if it was for say an abnormality in bone function, you might need the X-ray department to have an input so it's looking at lots of different things together to make a bigger picture erm for the clinician to actually diagnose what's going on and treat it.

Int: Thank you, so would you say that Biomedical Scientists are er widely regarded as being part of the Multi-Disciplinary team in healthcare?

BS4: I would like to say yes to that, but I do feel that a lot of the time erm we're not really seen. We seem to be the unseen health service. I think because we don't actually have that one-to-one erm consultation with the patient. As I say sometimes, we only see bits of the patient! I don't know that we're always as highly regarded as we should be, although you know obviously we do contribute to, to a high percentage of diagnoses and treatments for the patient. I think we don't shout loud enough about what we do.

Int: Thank you. So, could you tell me er what you think is meant by putting the patient at the centre of the Biomedical Scientist role?

BS4: I think it erm, from my perspective it's, that's your reason to be. Erm we're here to do a job for the patient. We're here to make sure that we get the right results at the right time on the right sample for the patient erm so that they get the best treatment possible. Erm, and I think that sometimes working in the laboratory we kind of have to remind staff about that over and over. I think because we only see samples and sort of in some labs it can almost seem like a bit of a production line, you have to keep reminding yourself that there's a patient at the end of this. I think on the whole that the majority of people do realise that and work to that end.

Int: So if somebody, if like you say you know the vast majority of people do work in that way, for those that don't is there anything that you do or anybody else can do to support them to develop that?

BS4: I think when we get, particularly students into the lab at the start of their training, it's part of what we do. I mean as you know from working in the University, we have placement sessions for the students of workshops where we get patients in to talk to them about the lab testing that they've had done as part of their diagnosis and treatment. Erm, and I always try and get my students to go out possibly with the phlebotomy team if I can, so that they see, particularly working in a [names hospital] hospital how difficult it can be to get those samples sometimes so that you've actually got a respect for the sample and for the patient.

Int: Thank you so, what do you think is the Biomedical Scientist's role in achieving patient outcomes?

BS4: I think it's; you know as I said, it's to get the right results on the right sample at the right time for the patient. Erm, so I think people assume that for every test that we do, we, that the sample goes to the lab, don't even know that they're aware that it's going to a lab sometimes you know. Doctors quite often, or nurses will say we're taking this sample and we'll get it tested people don't always appreciate that there's a laboratory behind that and the extent of the work and even when it does come into the lab it's not always a case of just putting the case of putting a sample on an analyser and pressing a button and 5 minutes later you get the results. With a lot of the testing, it's quite highly complex stuff that goes on and I think we probably need a bit more education about that so that the public may perceive us better. I think I might have gone off track on that question!

Int: No it's OK.

BS4: (laughs)

Int: So, what do you understand by a Biomedical Scientist who is working to achieve patient outcomes?

BS4: I would say that it's a Biomedical Scientist who is aware that there's a patient at the end of what they do and that they are working to a high standard erm that they're working as per all the standard operating procedures in their lab, they're doing things properly, they're not taking any short cuts and they're practicing to a high standard within their profession, erm adhering to codes of conduct. And obviously, part of that is to be ever increasing your knowledge of what's going on.

Int: So, if someone was to say to you that erm the clinical team will worry about the patient and Biomedical Scientists just need to do what they do well, how do you feel about that statement?

BS4: I think that's probably quite correct erm I think we should be worrying about what we're doing I mean it's very nice when you get feedback from the clinicians and you get to know how you've

influenced that patient's treatment and diagnosis, but we don't always get that. Erm, but I think that, you know, we need to do what we need to do and we need to be assured that what, what we're doing is correct for the patient and that we are producing good quality data from the laboratories for the clinicians to act on.

Int: Thank you. I'm just going to read erm a couple of lines from the IBMS 'Good Professional Practice in Biomedical Science'. So, it states that "Biomedical science professionals must exercise their professional duty of care and work within the legal, ethical and regulatory frameworks that govern and affect practice." OK so would you tell me what you think the importance of these professional requirements is?

BS4: I think they're very important. Erm, obviously we are governed by our HCPC registration erm we have codes of conduct from the Institute of Biomedical Science our professional body and also we are governed by UKAS and we're accredited by them and certainly in other laboratories there are regulations like the human tissue act and blood transfusion practice, sorry I don't know that one. Erm, but I think it's important that, that we adhere to these because that ensures the quality of our work erm, it makes us the professionals that we are and obviously in adhering to all this it's going to give the correct results at the right time for the patient and good quality outcomes for the patient hopefully.

Int: So how can Biomedical Scientists achieve these requirements?

BS4: I think by having an understanding of them, you can't really achieve these unless you know they're there and you are expected to behave in that way and that comes through training and education at an early stage in your career. And I think it is also a lot, in to keep in mind that the patient is at the centre of what we do and having respect for the patient. I know a lot of the time, you know, when you're teaching students, when you get students in to the laboratory I certainly try and emphasise to them you know imagine that patient is your child or you know your grandparent or your parent and you know quite often I say to them you're going to be the generation that's going to be doing my blood tests when I get a bit older and more decrepit and I want to make sure you're doing it right for that purpose! Bit of a selfish purpose really but it gets the message across sometimes.

Int: OK, so what is the potential impact upon patient care if Biomedical Scientists are not focused upon patient outcomes?

BS4: I think it, not always, but sometimes it can erm people might get a little bit sloppy in their attitude to the work you know certainly we've got turn-around times that labs are supposed to adhere to, to get the patient results back. If you don't see the patient at the end of it you can almost think well I'll take my time over that, I won't worry about doing it particularly quickly whereas you know you could have a patient sat in the emergency department or the theatre waiting for a particular result and they're not getting it (pause). I do have to say that on the whole the majority of biochemists, or Biomedical Scientists that I've encountered do put the patient at the heart of it and they go over and above what is actually required of them. You know, working extra hours to make sure that something's done, putting extra effort in to make sure the patient gets the result.

Int: OK, so, how would you identify a Biomedical Scientist who is or isn't focused upon achieving patient outcomes?

BS4: I think it will show in the standard of their work erm and I think you know when you get somebody that, that, that's struggling potentially, you can, there are ways in place that you can

follow to actually get them to the standard that you want. Erm, you know you do it via your trust's capability policies. I mean, obviously you'd start very informally by sitting down and chatting to them because there can be lots of reasons why people aren't performing the way they should and it's kind of trying to get to the bottom of what's going on for them and supporting them.

Int: So how would you assess their standard of work, what do you mean by standard of work sorry?

BS4: For example if a person's working on a particular test for example and their constantly not getting results that you would expect of a good quality which you can obviously see through your quality control material or something like that, you need to look at it and look at the process and see what's going on with the process. Erm, to try and support them to improve, you know it could be that their pipetting skills are not what they should be in which case you'd go back to basics and say well look, let me watch you pipetting, let me see if I can see you doing something that's not quite right.

Int: Yeah

BS4: And giving support that way.

Int: And what sort of qualities would you expect in somebody who, who is erm is focused upon achieving patient outcomes?

BS4: Erm I'd expect them to be professional erm and have a high standard themselves and have a you know, you can usually see that people want to do a good job and I think that the majority of people want to come in and do a good job, it's just that sometimes people don't, not everybody can get to the same standard at the same time so some people need that extra bit of support to get there and it's more about, you know, you can see the people that are achieving what you want them to achieve because their work's done in a timely fashion, erm you know you get good quality control results with their testing and they're competent basically.

Int: Yeah. OK, well that's actually it for all of the questions that I wanted to ask you.

BS4: Oh, OK

Int: Is there anything that you would like to add or anything that you think perhaps I haven't covered?

BS4: Erm, no I don't think there is really. I think it, other than from a training perspective

Int: Yeah

BS4: You know, there's a lot of effort that goes into training Biomedical Scientists and on the whole they are very keen and eager to learn and want to learn more and they're continually looking to improve and do things in a better way and then when you get the odd one or two that are struggling it's all about giving them support to get them to where you want them to be.

Int: So from a training perspective, where do you think students should get these sorts of erm should get these sorts of qualities and should it, you know, is it something that comes through placement or work based learning or through education do you think?

BS4: I think it's both. I think obviously there's the education around what they're doing and why they're doing it as part of degree courses, but I think placement is a very good opportunity and I'd like to think that in the majority of labs, the majority of staff are actually modelling these characteristics that we want to see in our students as they come in. You know, I'm a firm believer in it should be do as I do, not do as I say. Erm, and we should be modelling these values and standards to the people that are coming in. I always say training and managing staff is a bit like parenting, you're going to get the behaviours that you exhibit.

Int: OK, brilliant. Is it, if, is it OK if I stop the recording now or do you have anything else you'd like to add?

BS4: No, I don't think so. That's fine.

Table A2. Codes and associated colours for specimen transcript used in the thematic analysis.

Colour	Code
	Accuracy
	Education and training
	Urgent/timely processing of specimens
	Initiating diagnosis/treatment decisions
	Importance of the role within the MDT
	Unseen healthcare workforce
	Lack of patient contact
	Unappreciated role
	Importance of patient central
	Importance of professional polices
	Measures of laboratory quality
	Going above and beyond

Appendix 16: Research outputs and dissemination opportunities.

Date	Type of Dissemination	Conference
15-16th June 2020	Poster entitled 'A Delphi study exploring stakeholder perceptions of the role of the Biomedical Scientist in Patient Outcomes'.	Annual Research Conference (ARC) 2020, University of Wolverhampton
9th December 2020	Presentation entitled 'A Delphi Study to identify the Biomedical Scientist's role in achieving patient outcomes'	The 4th International Online Conference on Pharmacy, Biomedical Science and Health Research: Challenges and Solutions for Future Generations. Joint University of Wolverhampton and Al Kitab conference.
May 2021	Short methodological reflection published in Journal of Health and Social Care Improvement.	N/A
June 2021	Poster and PowerPoint presentation entitled 'A Delphi Study to identify whether Biomedical Scientists are adequately prepared for practice'.	Annual Research Conference (ARC) 2021, University of Wolverhampton
2nd September 2021	Poster and presentation entitled 'A Delphi Study to identify whether Biomedical Scientists are adequately prepared for practice by their undergraduate studies and professional training'.	Networking in Healthcare Education (NET) 2021 Conference
March 2022	Poster presentation entitled 'How important are patient outcomes for Biomedical Scientists?'	Institute of Biomedical Science Congress 2022

Appendix 17: The Strengths and Weaknesses of the Delphi methodology

Strengths	Weaknesses
The Delphi technique is useful in areas which can benefit from subjective judgements made collectively, for which there is no definitive answer (McKenna, 1994).	The use of 'experts' has been criticised, recognising that non-experts can also be beneficial in research. McKenna (1994) recommends the use of 'informed individuals' due to difficulties in defining what constitutes an 'expert'.
Large and heterogenous samples can be used for data collection and utilising online platforms means that geographical distribution is not a barrier to participation (Hsu and Sandford, 2007).	Poor response rates are common in Delphi studies due to attrition between rounds and a loss of interest in the study as it progresses. Face-to-face involvement in the 1st round has been shown to reduce attrition (McKenna, 1994; Hsu and Sandford, 2007).
Delphi studies can be administered easily and quickly, with many scenarios considered by participants in a short timeframe (Hsu and Sandford, 2007).	The anonymity of the participants in a Delphi study may result in a lack of accountability for participants (McKenna, 1994). As a result, quasi-anonymity where participants are known to each other, but their responses are confidential is recommended. Full anonymity cannot be maintained during a Delphi so steps should be taken to ensure participants treat information confidentially (Keeney, Hassan and McKenna, 2011).
	The Delphi technique has been criticised for a lack of standardisation (Keeney, Hassan and McKenna, 2011) and has been described as unscientific (McKenna, 1994).
	Delphi methodology is time-consuming and can be laborious (Hsu and Sandford, 2007).
	There are no pre-defined guidelines for the size of the expert panel used within the Delphi study, further contributing to a lack of standardisation (Keeney, Hassan and McKenna, 2011).
	The definition of consensus varies in Delphi studies (as described in section 3.5.3). It is essential to define this at the outset to ensure reliability (Keeney, Hassan and McKenna, 2011).

Appendix 18: Steps taken to ensure methodological rigour of this Delphi study through optimising trustworthiness and validity. Assessed according to Hill and Fowles (1975).

Consideration	Steps taken to address the issue
Clarity of questions: a well-designed questionnaire with unambiguous statements	Questions were subject to refinement throughout their development. The questionnaire statements were piloted and non-distinguishing statements were removed (Hicks, 2004).
Choice of respondents: selection of panel respondents for a Delphi has an impact upon reliability.	The selection of 'informed individuals' (McKenna, 1994) was adopted and participants were given the option to omit any responses in the 2nd round if they were unsure of the answer. The opportunity to provide free-text comments also allowed participants to express if they had difficulty responding to a question.
Attrition: Delphi methodology is associated with high attrition rates (Keeney, Hassan and McKenna, 2011).	To reduce attrition, informed consent was taken for both rounds at the beginning of the study. Data transcription, thematic analysis and piloting of the 2nd round questionnaire took place over 6 weeks to maintain interest within the study.
Character of round one: selection of the round one statements can be based upon initial data collection or pre-selected responses sent to participants.	The 1st round used qualitative interviews and focus groups with a semi-structured series of questions. This allowed participants to provide in-depth responses without restrictions and to guide the discussions themselves.
Administration of the questionnaire: the Delphi questionnaire is self-administered and therefore response rates can be low	The time between rounds was minimised to reduce attrition. Email remainders were distributed to all participants one week before the questionnaire closed and again on the deadline day which resulted in extra responses.
Research topic: not all topics are suitable for a consensus methodology such as Delphi	Delphi is particularly beneficial in areas where little empirical data exists (McKenna, 1994) meaning it was considered appropriate for this field. The first round allowed participants to guide the discussions and therefore allowed generation of themes for 2nd round.
Consensus: topics may reach consensus due to social desirability bias or individuals feeling pressurised to respond in the same way as other participants.	Round 2 data collection was anonymous and completed by individual participants asynchronously, meaning the responses of other participants could not be influenced.

Appendix 19: Permission from Wiley-Blackwell to use the Person-Centred Practice Framework re-presented (McCormack and McCance, 2017).

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NEW WORK DETAILS

Title	A Delphi Study Exploring Stakeholder Perceptions of the role of the Biomedical Scientist in Patient Outcomes	Institution name	University of Wolverhampton
		Expected presentation date	2022-12-31
Instructor name	Kathryn Dudley		

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