The use of health information technology in the follow-up of patient test results: an exploration of the experiences and views of primary care staff in the North East of England

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The use of health information technology in the follow-up of patient test results: an exploration of the experiences and views of primary care staff in the North East of England

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Dedication

To my late father, Abdulraouf, who unfortunately had to leave us sooner than expected. To my lovely mother, Thoriah, who kept nagging me to finish my study. To my lovely sister, Abeer, and to my big brother, Abdulrahman, who supported me unconditionally. Finally, to my beautiful, gorgeous, energetic and awesome kids that I have, Abdulrahman & Saif.

To you all, I dedicate this work

Declaration

This work has not been previously submitted for a degree and is not based on joint research.

Statement of Copyright

Abstract

Background

Computerisation in general practices in the UK over the last 30 years has enabled paperless clinical record keeping but the process of ordering tests and receiving results electronically from hospital systems has been a relatively recent development. The Integrated Clinical Environment System (ICE) provides an electronic link between general practices and hospital-based facilities, facilitating the timely transfer of test results across healthcare boundaries. Whilst the existing literature covers the technical aspects of such systems, there is a paucity of information about how these systems function in real life and what views healthcare staff have of using them.

Aims and Objectives

This research sought to ascertain the experiences and views of health care staff in general practice about their use of health information technology (HIT) systems for the ordering, processing and follow-up of test results. The research described the test ordering processes and the subsequent actions taken by healthcare professionals. It provided an understanding of different staff roles in this process, including what obstacles GPs and administrative staff faced and their views on the possible subsequent impact these obstacles had on patient care. The human element in the process of requesting and dealing with test results has not been previously described in detail.

Methodology

The programme of work comprises, in the first section, a narrative and systematic review of the literature, initially from the UK and then, because of a paucity of data, the global setting, on using HIT to order and act on test results. This was followed by a description of the established Donabedian model for evaluating healthcare processes through the stages of structure, process and outcome, with a description of how these components applied to this research.

The third section of the thesis consisted of empirical qualitative research project involving semi-structured interviews with 18 staff members from 13 general practices within the North East of England, to ascertain and explore their experiences, views and perceptions around using HIT systems for the follow-up of test results. A conceptual framework was generated by which these data were labelled and sorted. The analysis process involved identifying recurring themes and concepts.

Results

The reviews indicated that users found the HIT systems easy to use and felt that these systems improved their efficiency compared with the previous paper-based systems, which was confirmed in this study.

A new finding, reflecting aspects of the literature, was that results' management was also perceived to be associated with increased workload, sometimes due to receiving multiple warning alerts about abnormal findings and because of results received from tests done elsewhere.

A further, new finding, was the blurring of responsibility and duties about who should review, interpret and act on certain test results received. This task was sometimes left to administrative staff, whose role was to file 'normal' results but often found themselves in a position of not knowing whether such results had clinical significance. This factor appeared to be related to GP workload and the delegation of tasks. Participants also felt that the numbers of tests ordered and received had increased, an issue highlighted recently in the literature. There also appeared to be an increasing level of dis-continuity in the clinical care provided in practices, related in part to the use of locum and sessional doctors. Tests ordered were not necessarily designated for follow-up by a specific doctor. These factors may also be contributing to the increasing number of tests ordered.

Conclusions and Discussion

This study found that whilst the new HIT systems for tests have been associated with ease of use and efficiency in the transfer and availability of results, there appears to be a number of challenges in processing and actioning these results. Applying the Donabedian model for evaluating healthcare processes through the stages of structure, process and outcome shows how the components of the differing procedures have potential drawbacks and could contribute to compromised patient care. This is largely related to the changing structures of general practice whereby continuity of care can be a problem. There appeared to be no standardised procedures for dealing with tests and a standardised approach might be a necessary way forward.

This work revealed the importance of human factors in the structure and process of tests results' management, and how clarification of responsibilities and maintenance of continuity of care are crucial elements in delivering high quality care.

Acknowledgment

First, I would like to thank all the participants who were included in this study. I am so grateful to them for sharing their views with me and for giving up their time to make this research possible. I would like to acknowledge the support of King Abdulaziz University who funded me throughout my study.

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A special thanks to Professor Amritpal Hungin, who provided critical and constructive reviews throughout my study. His tremendous help, support and guidance throughout my study helped me to produce this piece of work.

Finally, I would like to thank all my friends and family for their enormous support. Whilst completing this work, I faced so much personal and professional challenges, and I am grateful to all of my family and friends for always inspiring me, listening to me and keeping me going.

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Abbreviations used in this thesis

AHRQ	Agency for Healthcare Research and Quality
CASP	Critical Appraisal Skills Programme - Qualitative Checklist
CCG	Clinical Commission Group
DBS	Disclosure and Barring Service
EHRs	Electronic Health Records Systems
FOBT	Faecal Occult Blood Tests
GP	General Practitioner
HIT	Health Information Technology
HRA	Health Research Authority
ICE	The Integrated Clinical Environment System
IRAS	Integrated Research Application System
NECS	North of England Commissioning Support
NHS	National Health Service
PCP	Primary Care Practitioner
PRISMA	Preferred Reporting In Systematic Reviews and Meta-Analyses
VA	US Veterans Affairs

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Chapter 1: Introduction

1.1. History and Background

UK general practice has been computerised since the late 1980s and paperless clinical records are now the norm. However, this has been a long and difficult journey. Practices, in the 1980s and '90s, either developed their own electronic systems or bought into commercial health information technology (HIT) systems for clinical record keeping (1, 2). These early HIT systems posed major problems for the National Health Service (NHS) due to lack of inter-operability or synchronisation between different IT systems. Several previous attempts to achieve harmonisation and effect working between and across systems resulted in expensive consequences such as buying and maintaining expensive servers (3, 4). A major problem has been the difficulty of linking systems from different physical settings (5). Laboratories in the UK also developed, like general practices, their own internal HIT systems for holding test results, but they were not able to link these with test requests from general practices until relatively recently. The reasons were essentially that hospitals and general practices each had their own independent electronic systems, sometimes simply based on PCs connected internally *via* an intranet. Some laboratories developed their own closed systems within their wider hospital setting. Laboratory machines such as Coulter Counters already provided an automated haematological analysis printed electronically. They had the capacity to hold results in electronic format and these could be retrieved from within the laboratory-based IT system but not from elsewhere. Eventually these automated machines were linked with

larger central databases, facilitating results from tests conducted in the laboratory to be linked with a particular patient (5). This enabled batches of results for the patient to be retrievable all at the same time (4). By enabling such systems to link with general practices as well as with systems in other settings, such as out-patient or hospital wards, a wider range of healthcare professionals involved in the patient's care were able to view results remotely using these electronic health records systems (EHRs) (6).

Over the last 30 years general practice consultations and summary records have been computerised and combined into an accessible format using chiefly one of three commercial systems known as SystmOne, Vision and EMIS. Therefore, there is now no need to order tests by hand filing the paper forms to go with the specimens. Previously, most of the results were reported and delivered to general practices in a physical format, such as by a hospital courier service. This prevented an automated audit trail of tests and any subsequent actions (7). As part of this historical procedure each practice had its own administrative method for receiving and reviewing test results. These were usually filed within the patient's paper record, transcribed into the paper-based clinical record or entered manually into the newer electronic clinical record (8).

1.2. Evolution of the electronic health record systems

The last ten years have seen huge progress in the development and implementation of electronic systems which allow the transfer of information between general practices and laboratories in a more convenient format (9, 10). This was an important development because anyone who has access to

this system can now check a patient's test results, providing they have authorisation. Test results can be accessed not only by the staff at the general practice where the patient is registered but also at other settings such as outpatient clinics or wards, where the tests did not originate but may be useful in patient treatment and care (9).

The interlinking system now operating went through various developments: first, laboratories had to find a common system that they could use; and they then had to work out how these systems interacted with those general practices who decided to link with them. In addition, they needed to set up connections with other local hospitals and clinics where the data might be required (11).

1.2.1. The Integrated Clinical Environment (ICE) System

Implementing an electronic system that could be adopted by NHS trusts to connect primary and secondary care posed many different challenges. Some of the challenges were technical but there were also problems of authorisations and security of data. The systems had to be robust, closed and required permissions in terms of access to authorised personnel. The success of the systems' interconnectivity within a secure environment has meant that general practitioners are now able to order tests and receive results electronically. There was a further challenge here as general practices had adopted different systems and the laboratory systems had to be compatible with these. The laboratory reporting system which is commonly in operation and is almost universally accepted in the UK is the Integrated Clinical

Environment System (ICE), brought out by Sunquest Information Systems Inc. in 2008 after the acquisition of Anglia Healthcare Systems (10, 12).

The ICE system is a wide-ranging electronic test requesting system that allows pathology requests to be made from hospitals or GP practices. In addition, it permits GPs to access pathology and radiology results reported by or to the hospital, including results that were not requested by GPs themselves. Figure 1 represents system-to-system connectivity. Some NHS trusts issued manuals to clarify how to use the ICE system, and importantly for this research, the manuals also tried to explain the link between different electronic systems (13).

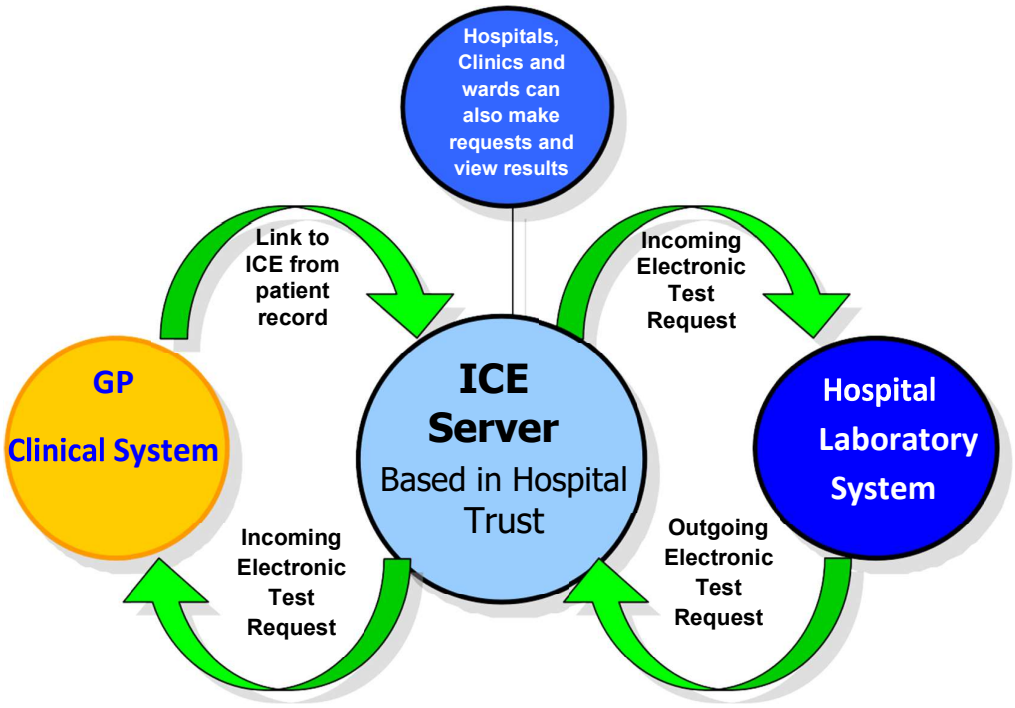


Figure 1: System-to-system connectivity as explained by Newcastle upon Tyne Hospitals NHS Foundation Trust 2015 (13).

The ICE system also creates an environment to ensure that requests are made appropriately, *i.e.,* that each test request is accompanied by a rationale, and that sufficient information is available to the laboratories and to clinicians who did not order the test but who may have to act on the results. The ICE system maintains the electronic record in the patient's file, linked to their clinical record. The system's abilities allow an interface with computers in non-laboratory settings such as phlebotomy clinics so that the specimens can be taken and collected from sites different from the ordering practice itself. The ICE system has been adopted in over 90 trusts within the NHS. This includes all the trusts within the northeast area (14). This represents an enormous advance as this potentially universal availability of test results can contribute to efficiency, maintaining continuity of care and in avoiding repeated tests because the paper-based results might not have been available or were misplaced.

1.3. Information Technology and Continuity of Care

HIT connectivity is an important component in tracking patient information, and therefore aims to contribute to continuity of care. Continuity is important in patient care and access to test results is a component of this. The literature suggests three types of continuity in care terms: relational, informational and management (15). The literature indicates that longitudinal continuity is not just an aspect but a basic part of continuity and that this is measurable (16). Longitudinal continuity is the extent of care over a long period of time and relational continuity is the extent of the interaction between the patient and clinician. Informational continuity covers the documents that enclose the

patient's information in addition to the patient's preferences and values, something of which the clinician might be personally aware. Management continuity refers to constant and supple management of a patient across different healthcare settings (15).

The previous paper-based system had inherent problems such as the potential loss of a result with vital information. The efficiency of the system in receiving and acting on the results was dependent on the level of administration and clinical organisation within each practice. Whilst the new linked up ICE and general practices systems have improved efficiency in the transfer of results, the problems of how best to deal with the incoming results still remains (17).

1.4. Purpose of the study

This programme of work aimed to explore and understand the experiences and views of primary care staff regarding the use of health information technology on the follow-up of patient test result.

The objectives of this research were:

- To describe the process and understand individual staff roles in the follow-up of test results;
- To explore staff perceptions on the impact of health information technology on the ordering of tests, collecting samples, receiving, reviewing and acting on test results;
- To describe different systems' features and how users interact with these systems;

- To explore the benefits and obstacles that individual faced while using the electronic system to order, review and act on test results;
- To explore the perspectives of primary care staff on how these systems could be further improved for the follow-up of test results in the future.

While the research progressed, the objectives shifted more toward investigating the human element in the process of test results follow-up rather than the role of the electronic systems as a part of the structure of the health care system, and the use of electronic systems in the continuity of patient care.

In this thesis, the research is reported in the following manner. Firstly, literature reviews to (a) understand the effects of using electronic systems on test result management and (b) discovering gaps in the literature about healthcare staff opinions about the use of electronic systems for the follow up of test results, are to be found in chapter 2. The initial focus of this systematic review was the UK clinical setting, but this was changed to cover views from around the world because of the limited number of studies from the UK alone. Secondly, as a prelude to doing the research, I explored (Chapter 3) the concept of observing and evaluating clinical systems, particularly the established Donabedian model for health structures, processes and outcomes (18). Chapter 4 of the thesis established which methodologies could be used in the general practice setting, based on the theoretical underpinnings I had explored, and finally, the finding of the fieldwork itself and the context of this research within the existing knowledge base are presented and discussed in chapters 5, 6 and 7.

I did not undertake an outcome evaluation of the impact of HIT relating to test result management, as this was out of the scope of this thesis. The evaluation

of test result outcomes would have required a prolonged longitudinal study geared towards establishing the impact of having done a particular test on patient outcomes. Considering that many patients have multi-morbid conditions, outcomes in terms of clinical success secondary to having a particular test would have been impossible to evaluate within the duration of this research. Moreover, a retrospective study was ruled out due to possible ethical considerations of applicability and patient confidentiality. This would also have meant knowing exactly why a doctor ordered a particular test; the reasons for this are highly variable, ranging for the need to explore pathology, provide reassurance or for monitoring and watchful waiting for the development of a patient's condition (19). There is likely to have been a lack of clarity about this and linking the decision to order a test and the eventual outcome would have been complex and difficult task, if not impossible, within the scope this thesis.

1.5. Personal Impacts

This thesis presented me with the opportunity of studying a health system that was foreign to me. Although it is outside my field of pharmacy, the content and theme of the thesis has parallels with HIT systems in many other fields. The thesis was designed to provide me with experience, not only in conducting research, but also on how people perceive the effect or impact of a given system on their daily activities.

The research was started in April 2015 and the first interview was conducted in June 2017. During these two years, I faced delays in ethics approval and challenges in the recruitment phase, which took time to resolve. I passed the

first progression review in February 2016, and the NHS Integrated Research Application System (IRAS) form was submitted in August that year. In September 2016 a favourable opinion was received, and an initial assessment was received from the Health Research Authority (HRA) in October that year. The HRA Approval was received in February 2017, but I was not able to conduct any interviews until the North of England Commissioning Support (NECS) issued the Confirmation of Capacity & Capability in March 2017 and the Letter of Access in May 2017 (Appendix 4.4). Despite their remit as a facilitation organisation they were unable to help with participant recruitment and I needed to contact practice staff directly to seek their help. This was a trying task for someone new to the UK with no prior exposure to the organisation of the NHS especially general practice. These delays were explicable but frustrating. I completed my fieldwork (essentially interviews) in mid-2018.

The literature and background available in this field has a heavy IT emphasis on how systems operate and connect. However, my aim was to gain insights into how people use and react to the system. As my thesis progressed, I realised that this, the human element, was a key factor in trying to understand the working and the effectiveness of the electronic systems. Thus, the thesis evolved to have a heavy human element rather than an emphasis on the technicalities of the systems themselves.

Chapter 2: Literature Review

2.1. Introduction

Reflecting the issues identified in the previous chapter, and prior to as well as in order to inform development of the study that forms the main body of this thesis, I completed reviews of the literature. The aim of this was to examine the following areas:

1. The effect of using electronic systems on test results managements

2. Health care staff opinions and views about using electronic systems for the follow-up of patient test results.

Two reviews were conducted to examine these issues and areas. The first was broad in ambit, examining the aftereffect and challenges of electronic systems on test results management. The goal of this review was to gain an understanding of the existing body of knowledge and to gather information that would help in forming my main research question. Thus, this review was considered as a narrative review aiming to orient myself within the literature and therefore conducted by moving through the literature following up references within papers and over a wide range of databases. The second literature review, which explored healthcare staff opinions and experiences of use of technology to manage test results arose from this initial work and was constructed to address a well-defined research question and used much more rigorous methods. The aim was to find all existing evidence in an unbiased, transparent and reproducible way. Attempts were made to find all current published and unpublished literature relating the research question. The

process was documented and reported. Reasons for including or excluding studies were explicit and informed by the aim of the research. Also, the risk of bias in individual studies and overall quality of evidence were assessed systematically.

2.2. The effect and challenges of electronic systems on test results managements

In order to understand the effect and challenges associated with the use of electronic systems for the management of test results by health care staff, researchers have tried to identify the stages of the test result management process. The process of test results management has been divided into three different stages (pre-analytic, analytic, post-analytic) (20). The *pre-analytic* stage dealt with the ordering of tests by a clinician or administrative staff, the *analytic* stage involved conducting the test, and the *post-analytic* stage included how the test results are communicated to the clinician or administrator and what actions they took after receiving the results (Figure 2).

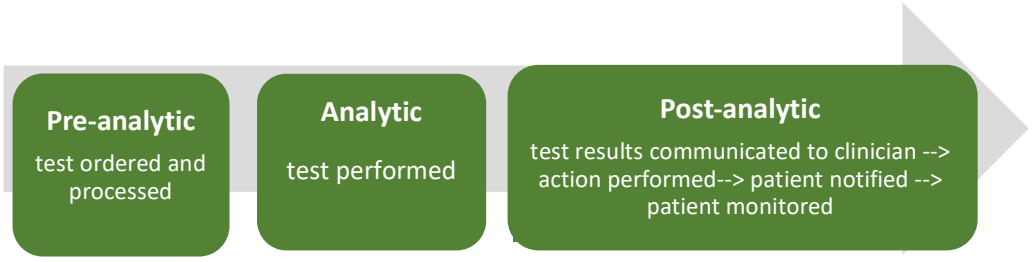


Figure 2: Simple diagrammatic representation of the Test Results Management process (20).

In general, the literature shows that the use of electronic systems can facilitate the process of test result management in a number of ways. In the pre-analytic phase, literature has been shown that electronic systems helped to improve the quality of information recorded, such as the patient's clinical history, and date and time of sample collection (21). Using technologies, such as a custom labelling system such as a barcode system, can also minimise the potential for errors by generating labels with specific patient content that can be directly applied to test tubes, which matched with patient's bar-coded wristbands (22). However, it is unclear from the literature what challenges healthcare professionals face when using systems for ordering and managing test results. Very little has been published on the role of electronic systems in the analytic phase too and whether these systems can provide any benefits. It has been shown that in the post-analytic phase, electronic systems can provide reminders to physicians, in the form of pop-up alerts or automated emails so as to inform them that a particular abnormal test result needs to be followed up or a particular action taken. Electronic systems can also improve the communication of test result information between health care professionals, and help consolidate and store patient-related information in one place (23). Few studies have looked at the challenges that clinicians face when using electronic systems in the follow-up process (post-analytic phase). However, issues have been reported around system design, display, and alerting, but these studies have not been conducted in the UK or explored in great depth (24-29).

Errors can occur at any stage of the test results management process. In the pre-analytic stage, mistakes can occur in the ordering and handling of

specimens. These include, for example, requesting inappropriate tests, losing or incorrectly storing specimens, supplying insufficient amounts of specimens, supplying them in an incorrect container, mislabelling of specimens with the wrong patient information, and supplying inaccurate data about a patient's fasting status which could impact on the accuracy of the results (30, 31). In the analytic stage, errors can occur around equipment failure, sample mix-ups, procedures not followed according to laboratory standards, and failures in the quality process of tests performed (32). In the post-analytic stage, errors can occur around failing to inform a patient of an abnormal test result (33, 34), sending the results to the wrong patient (35), and interpreting the result incorrectly for example when laboratory staff who lack the appropriate expertise misinterpret results (36).

Consequences of such errors can lead to serious situations for patients, such as delayed diagnoses, inappropriate treatment and unpleasant adverse drug events, which all are negative outcomes that probably any health care systems would try to prevent. This is illustrated by a retrospective study that found that the improper follow-up of test results led to two cases of colon cancer being undiagnosed (37). This study investigated 423 positive faecal occult blood tests (FOBT), which were identified over a 10-month period (December 1, 2003 to September 30, 2004) in a tertiary care facility at the Department of Veteran Affairs, US. They reported that they found 15% (63/423) of positive FOBT cases lacked a documented follow-up plan within 4 weeks of the positive result and two of these cases were linked with undiagnosed colon cancer were found (37).

Another study conducted in a university-affiliated U.S. hospital tracked specific radiology reports that had a significant unexpected finding, and found that eight cases were not appropriately followed up by the primary care clinicians (38). This retrospective study investigated 395 possible malignant cases between April 2003 and March 2004 in Emergency Department/urgent care, primary care medicine, non-primary care medicine and surgery in a university affiliated hospital that used a semi-automated system. If a malignancy was found the radiologist contacted the referring clinician or appropriate member of the clinical team by telephone or rarely by secure email, which could be prone to be missed without proper audit trail and closing the loop of the communication (38).

Another third retrospective study carried out at Brigham and Women's hospital in Boston, Massachusetts, reported how six patients were given an insufficient supply of levothyroxine because the primary care physicians did not appropriately follow up laboratory results (39). The study covered 363 outpatients from a large tertiary care hospital receiving levothyroxine therapy over a 1-year period – 2000 to 2001, and the cases were randomly selected.

Health information technology, such as the adoption and use of electronic systems has the potential to assist with the follow-up of patient test results (33), although little research has been conducted comparing pre and post adoption of information technology in test result management process (40).

Little research has been conducted in the UK to explore the challenges of using electronic systems for the follow-up of abnormal test results. One qualitative study involving four general practices in Birmingham conducted

four focus groups (one per practice) to understand how staff communicated test result information with patients as one of the major actions and step in test results management process. It concluded that the main problem facing these practices was the absence of a clear communication protocol, which should describe the communication process and responsibilities of the test results in the test result management process (41). More worryingly, there appeared to be no method of detecting if a test result had been delayed or missed. However, this study only focused on the communication aspects of using the electronic systems in the follow-up of patient test results and not specifically on any other challenges that could accompany the use of electronic systems in the test result management process. A second study surveyed 50 English general practices to get a clearer picture of how test results were managed and found that around 80% of practices relied on the patient to call the practice to see if their test result had been received (42). With few UK studies having been conducted in this area, it is difficult to know if these issues arose in only certain practices or were more common to practices in general across the UK.

Thus far we have seen therefore, that electronic systems can help in numerous ways at all stages of test result management, but it is also the case that new challenges are emerging as a result of adopting electronic systems. The increased use of electronic systems has led to a change in the natures and perspectives of the clinicians (43), which will be discussed thoroughly in the discussion chapter of this thesis.

2.3. Health care staff perspectives on using electronic systems for the follow-up of abnormal test results

Building on this account of the general effect and challenges of electronic systems in the follow-up of patient test results, I completed a more focused systematic literature review that explored users' opinions and views. The intention of this was having first introduced and investigated the general role and challenges of electronic systems, to investigate what health care staff think about the impact of electronic systems in the follow-up of patient test results. User perspective was chosen as the focus due to the absence of such a review. The importance of this question becomes more apparent when we note that in some studies, there is evidence that users may become dissatisfied with electronic system deficiencies, and become more reluctant to use them (44, 45). Due to the nature of the point under investigation; users' perspective; a decision was made to write a qualitative - thematic systematic review, and thus the methods were designed accordingly.

The idea of solely synthesising themes in the literature review, without any statistical methods, is becoming more acceptable in the medical field (46). Moreover, considering thematic analysis as a way to obtain more insights into qualitative research concerning participants' experiences are becoming widely acceptable in the medical field as well (47). With most of the research published within the healthcare paradigm focusing mostly on the quantitative aspects, an alternative approach to investigate the experiences was required.

2.3.1. Methods

The systematic review was conducted according to the Preferred Reporting in Systematic Reviews and Meta-analyses (PRISMA) guidelines; the protocol was registered with PROSPERO (no. CRD42016042944).

2.3.1.1. Eligibility criteria and study selection

Primary research articles published between January 2005 and July 2016 that explored health care staffs' perspectives of using any type of electronic systems in any clinical setting (primary, secondary or tertiary care) for any type of test results were eligible for inclusion. This included how the test results were communicated to the clinician or administrator, and what actions they took on receiving these results (36). Electronic systems were defined as any digital version of a patient's paper chart that allows providers to send and receive information, which included both imaging and laboratory test results (48). Studies that provided only quantitative data, with no discussion of users' opinions, views, experiences or perspectives, or that focused solely on patients' opinions were not included. On the other hand, studies that tried to evaluate users' perspectives quantitatively using feedback, percentages or other methods were included as long as the main outcomes of the research were based on users' perspectives. The search was restricted to English language publications only. Editorials, commentaries, letters and opinion articles were also excluded.

2.3.1.2. Information sources and search

Four large databases were searched for relevant studies, including conference abstracts: OVID – MEDLINE, OVID - EMBASE, Ebscohost - PsycINFO and the Cumulative Index to Nursing and Allied Health Literature (Ebscohost - CINAHL). Search terms were identified and grouped into three sets: 'Electronic Health Records', 'Test Results' and 'Follow-Up'. Further details can be found in Appendix 2.1. Choosing these specific search terms were inspired from other literature review, which aimed to evaluate the impact of electronic systems in the follow-up of patient test results (33, 40, 49). In addition, the academic liaison librarian at Durham University was consulted about these terms and available synonyms that were used in each database. Also, technical or research reports from government agencies such as the Agency for Healthcare Research and Quality (AHRQ), the National Patient Safety Agency, Department of Health, and specific scientific research groups such as Local and Regional Clinical Commission Groups were reviewed. In addition, we used the following two websites (http://etheses.dur.ac.uk) and (https://oatd.org/) to search for relevant doctoral dissertations. The grey literature was also searched for relevant articles using the following website (http://www.opengrey.eu).

2.3.1.3. Study selection

After removing duplicate articles, three reviewers (AAM, AB, AN) independently screened the titles and abstracts for relevant articles before reviewing full text articles. Alaa Bagalagel (AB) and Ahmad Noor (AN) are currently two assistant professors at College of Pharmacy, King Abdulaziz

University. Any disagreements were resolved by discussion, with arbitration by a fourth reviewer, the main supervisor of this research, (SPS) if necessary. An extraction sheet (Appendix 2.2) was used to capture pertinent information from these studies including: author(s), date of publication, title, aim, study type - *i.e.*, whether qualitative, quantitative (surveys with qualitative content) or both, data collection methods, sample size, country, clinical setting, and summary of findings. Data that represented staff opinions, views, experiences and perspectives were added in the findings section of the extraction sheet.

2.3.1.4. Bias assessment

The quality of included studies was also assessed using the Critical Appraisal Skills Programme (CASP) qualitative checklist. It consisted of ten key questions; one point was given for a 'yes' answer to each question, with a maximum score of 10 for each paper (Appendix 2.2, final column) (50).

FINDINGS OF THE REVIEW:

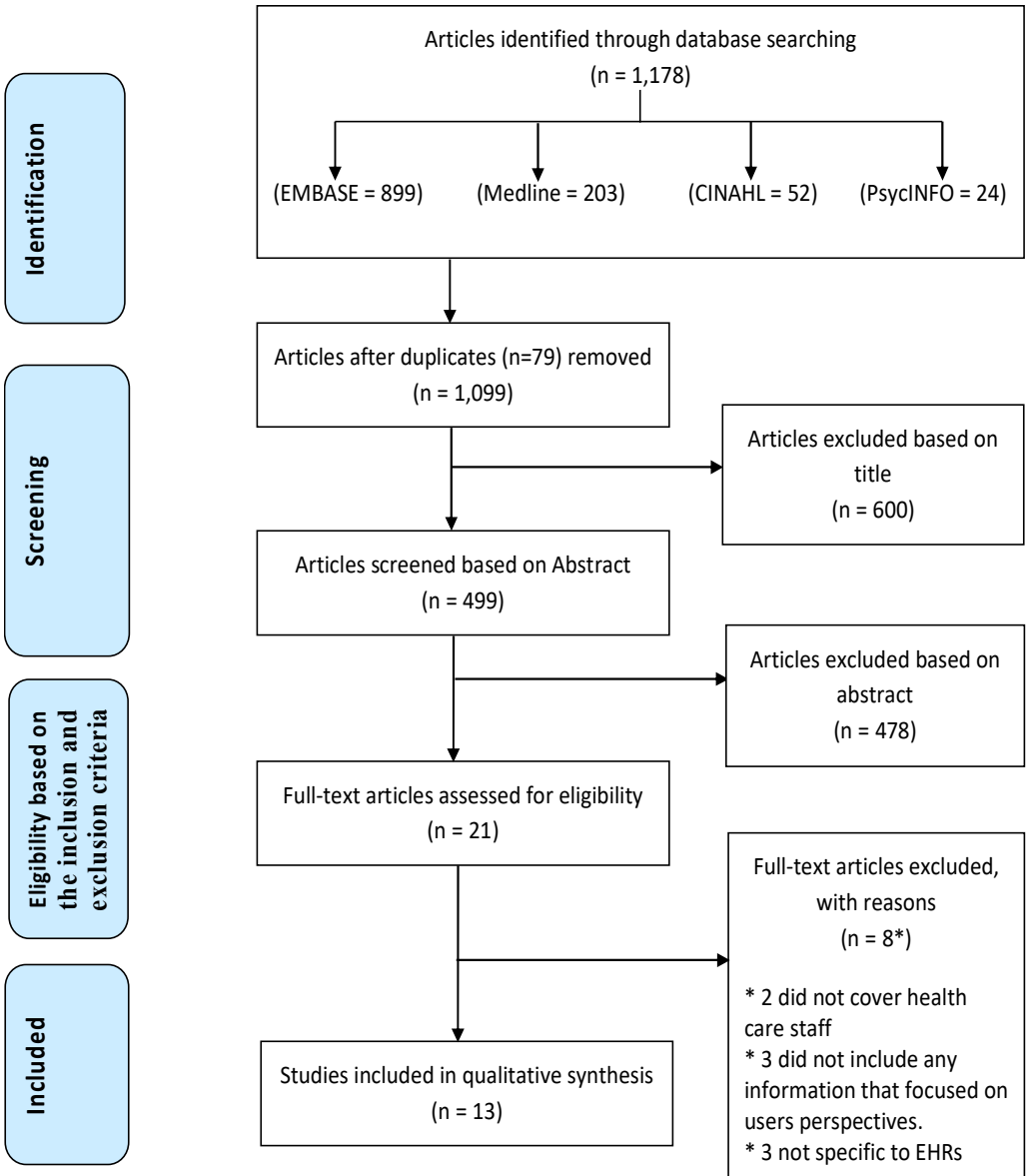


Figure 3: PRISMA Flow diagram for the systematic review

2.3.2. Results

2.3.2.1. Study characteristics

Our search returned 1,178 publications, of which 79 were duplicates. One thousand and eighty-six articles were eliminated at the title (600), abstract (478) and full text (8) stages. Twelve full papers and one conference abstract met the inclusion criteria. The conference abstract and two full articles reported results from the same survey, but each source presented a different analysis of the data (27, 28, 51). The majority of studies were undertaken in the US (n=9) (27, 28, 51-57), with six of these studies conducted using the Veterans Affairs (VA) electronic system (27, 28, 51, 55-57). A variety of different methods were used, including surveys (n=6), focus groups (n=1), interviews (n=3), or mixed methods (n=3).

2.3.2.2. Descriptive themes

Twelve sub-themes emerged solely from the data gathered from all included literature using the extraction sheet, and these were grouped under five main themes. The main themes were formed based on the similarity and nature of those subthemes and based on what they were represent (Figure 4). The five main themes relating to users' perceptions and experiences of EHRs were: (1) Alert Notification (Quantity of alerts, alerts' content, alerts' presentation and alerts monitoring.). (2) Accessing patient information and test results (Time to access, time to send results/inquiries). (3) Responsibility for acting on patient test results (Polices of responsibilities, surrogate's role). (4) Communication of

patient information and test results between health care staff (Communication methods and documentation.), (5) User training (training content and the effect of training). Figure 4 illustrates the subthemes that emerged and synthesised from the included studies.

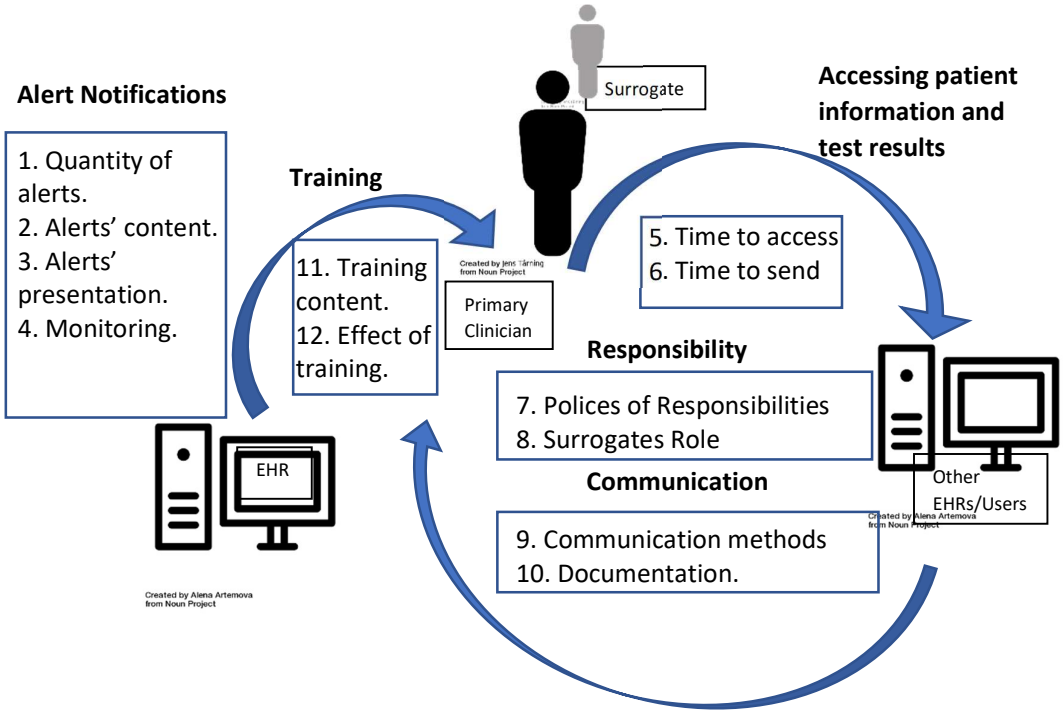


Figure 4: Descriptive themes from the systematic review

Alert Notifications

Clinicians received electronic 'alert' notifications from the electronic system that informed clinician about the arrival and the content of the test results. Alert notifications affected users' experiences and mainly related to the quantity of alerts received, their content and presentation, and how organisations monitored staff actions after receiving these alerts.

Users reported receiving too many alerts from EHRs, with the majority of Primary Care Providers (85.6%, n=2,218) in a survey by Singh *et al.* receiving 'too many' alerts, with the median number of alerts received each day reported to be 63 (27, 28). The study conducted a cross-sectional, web-based survey of all primary care practitioners (PCPs) within the Department of Veterans Affairs, US, with 5001 PCPs invited, and 2590 (51.8%) responded. These alerts included clinical information related to test results but also referrals, medication-refills, messages and orders using the VA electronic system. Sixty-nine percent (n=1,803) of respondents felt that this number*, i.e.,* 63 alerts/day, exceeded what they could effectively manage with Primary Care Providers more likely to miss test results due to this high volume (Odds Ratio, 2.20 [95% CI, 1.37-3.52]) (27).

Similar findings were found in another qualitative study, with one Primary Care Provider explaining how they encountered up to "*sixty to seventy alerts per day"* from their VA system with each alert taking about *"two to three minutes"* to deal with (55). The same Primary Care Provider explained how *"there's no time allowed for alerts... I've just finished seeing patients. I have to go back and handle all the alerts. Some people actually come in on weekends."*(55). In the survey by Singh *et al*. 85% (n= 2,218) of respondents reported staying after hours or having to work at weekends to address and follow-up alerts (28).

The content of alert notifications was also raised as a factor impacting on users' experiences. According to Singh *et al*. the majority of respondents (80%, n=2071) felt that they received too many 'For-Your-Information only alerts' that contained clinical information unrelated to test results, where no

action on their part was required (28). Furthermore, two thirds of respondents (61.8%, n=1601) in the same study were unsure why they had received these alerts (28). A similar finding was reported by Hysong *et al*. with one general practitioner questioning why he had received alerts that in his view should have been directed to secondary care staff: *"He [the surgeon] needs to take care of his stuff, and if every department did that, I mean, that would cut down our workload by fifty percent."*(55). Although these two examples related to users of the VA electronic system, the problem of alerts content seem to affect providers using other systems too. Users of an electronic system at an HIV clinic in Kenya questioned the accuracy of some alert content, with some users ignoring some alerts that in their opinion were not clinically justified or based on outdated results (58).

Another issue related to how the alert notifications were displayed on the system's screen. Participants in one study felt that users should have the ability to customise the electronic alert notifications without seeking approval from their managements, *i.e.*, the VA in this study, so as to receive only high priority alerts (55). Dalal *et al*. investigated the addition of a new electronic tool, which allowed users to 'acknowledge' when they had viewed or acted upon a particular alert at integrated healthcare delivery network in the US (52). Of the 72 general practitioners who were surveyed, 48 (67%) said that they always used this tool and 33 (45.8%) reported that it had improved workflow efficiency (52).

Another sub-theme related to how organisations monitored staff responses to alert notifications. In a study conducted by Menon *et al*. at the VA, one

participant explained how meetings were arranged with users who had not acknowledged or acted upon alert notifications that they received: "*Unacknowledged alerts go to the supervisor, then higher up. It escalates up the line (…) they provide a report of any progress notes or encounters or all that stuff that's not been signed off on.*"(56). Around 83% (n= 33) of the institutions using VA's electronic system in this study monitored the follow-up of certain test results only when they considered them life threatening; these processes were highly inconsistent between centres with some conducting random chart reviews of critical test reports and others referring to automatically generated monthly evaluation reports of unfollowed alerts (56). About half (n=1,264) of general practitioners respondents in one survey were in favour of getting feedback from their supervisors about their alert management performance (28).

Timely Access to Patient Test Results

Some of the included literature showed a general trend that health care staff are believing that electronic systems provided them with timely access to patient test results (54, 59, 60). Gordon *et al*. interviewed 29 providers in the Emergency Department of a tertiary hospital in the US, and noted how the system gave one respondent timely access to his patient's *"echocardiogram report from her most recent cardiology visit and her most recent ED visit."*(54). Seventy-eight percent (n=54) of survey respondents working at two public hospitals in Turkey also believed that electronic systems reduced the time needed to send and receive radiology reports, and the number of orders for repeated tests (60). In the same study, around 80% (n=55) of respondents

believed that the system helped them make consultations more time efficient by allowing instant review of the results during the ward round and cutting down on patient waiting time (60).

Health care staff seemed to be in favour of electronic systems over paper-based systems when it came to sending results to the ordering/responsible clinicians. Prior to electronic system implementation, one radiologist in a study conducted by Georgiou *et al*. recounted spending *"a lot of time previously chasing up the clinicians [ordering or responsible clinician] . . . they're not that easy to locate at all times*" (59). Post electronic system implementation, the responsibility appeared to shift away from the individual radiologists to the Radiology Notification System's operator, whose role was to deliver the test results to the ordering physician or the patient's care team if the clinician was unavailable: *". . . it has greatly reduced the time that's needed to find the referring doctor. . . I could just report the case and I'll give (the RNS operator) the message and then I can leave it and go on to the next study. So time efficiency (is) great."*(59).

Responsibility for Acting on Patient Test Results

The absence of clear positions of responsibility for follow-up was also expressed in the literature. This issue emerged as a theme as studies showed that tests ordered in the hospital could not have a clear description of who should follow them, and what should clinicians do while covering non-available clinicians (28, 49, 56, 57).

Some Emergency Department physicians interviewed in one Australian study believed that it was the duty of the ordering physician to act on the test results

received: *"If you order a test you should be checking the results."*(49). Other physicians in the same study felt it was the primary care provider responsibility (who may or may not have ordered the test): *"So with us the delineation of who is going to follow-up the result is much clearer – it's not us because we are an isolated emergency visit. (…) We won't be seeing you again. Whereas they have an ongoing relationship with the GP."*(49). Singh et.al described how because of a software configuration issue, the results of Positive Faecal Occult Blood Tests were only sent to a preconfigured 'ordering' provider in the lab at one large VA facility and not to the patients' general practitioners (57). As a result, there was a low rate of follow up by general practitioners, who were possibly unaware of some of their patients' abnormal test results (57). When these results were sent electronically to the patient's healthcare provider, the rate of missed follow-ups decreased from 29.9% to 5.4% (57).

Another study conducted by Menon *et al*. highlighted uncertainty around whether the alert would go to one individual or the team caring for the patient: *"The ordering provider or whoever is set up in a team of some sort will get those alerts. It could go to a team if a team is assigned, but if not, it will go to the ordering provider. When we have trainees and if team is not assigned, it is frustrating."*(56). When patients were not seen by their primary care providers for a certain period of time, this study also highlighted how they became 'unassigned' by the electronic system, *i.e*., dissociated with the Primary Care Provider, and created uncertainty around who was now responsible for acting on their test results (56).

Delegation of follow-up responsibilities also appeared as a sub-theme. Only 58.9% (n= 1,525) of surveyed participants in Singh *et al*. study agreed or strongly agreed that they assigned a surrogate to take care of test result notifications when they were out of the office (28). This survey also showed that 60% of participants (n=1,555) would like the ability to assign more than one surrogate on the electronic system, if needed (28). However, 51.7% of survey participants (n=1,339) believed that using surrogates for test results follow-up created new safety concerns, although it was unclear from the study what these specific concerns might be (28). One participant in Menon *et al*.'s study highlighted how not all surrogates documented the actions that they made (56), *"…Sometimes the surrogate writes notes in EHR but other times the surrogate just takes care of it and moves on, and you don't know what happened until the next time you see the patient. Not really a safety concern because the surrogate does the appropriate thing, but it is a communication problem."*(56).

Communication of Patient Information between Healthcare Staff

Primary care providers liked the electronic system functionality that allowed them to communicate patient test results to other providers electronically, and some clinicians electronically communicated what actions they took after receiving a particular patient test result to their colleagues (56). Almost all inpatient physicians (96%, n=67) who participated in a study conducted by El-Kareh *et al*. preferred to be notified by email of any normal or abnormal microbiology test results following their patient's discharge (53). The majority of primary care providers (70.5%, n=1,826) surveyed by Singh *et al*. agreed or

strongly agreed that they would like to have a messaging system as part of their electronic system that would allow them to communicate with other physicians about their patient's management (28). This survey did not elaborate on what types of information they wanted to communicate or how exactly this feature would differ from emails external to the EHRs (28). Only 24.2 % (n=628) of participants stated that their current electronic system had 'convenient features' for notifying patients of their test results (28). Although not specified, these 'convenient features' may have related to the ability to generate patient letters electronically from the electronic systems (28).

User Training

The content and duration of the training provided to users was also discussed in the literature as some users mentioned how they had received insufficient training before using the system. For example, primary care providers in the focus groups conducted by Hysong *et al*. commented on the lack of adequate training that they received on the use of their electronic system, with one primary care provider describing it as *"pretty lackluster."*(55). Another primary care provider stated how *"you can do it [sort] by patient also, so mine were all mixed up. (…)... That's something which I learned today after eight years of being at the VA."*(55). More than half of the survey participants (n=1,406) in Singh *et al*.'s study also considered the training on using their electronic system to be "insufficient."(28). Menon *et al*.'s study reported how staff in five (13.5%) VA facilities had two hours or less training in the use of the electronic system, with almost half (n=13) of respondents having no more than 10 minutes' training on how to view and manage alerts in their EHR system (56).

Menon *et al*. also showed that facilities with a low-risk of missed test results tended to have more training than high-risk facilities (56). Almost 38% (n=982) of survey respondents in Singh *et al*.'s study felt that they needed further support on how to use their electronic system to notify patients of their test results, with over 60% (n=1,565) of participants asking their colleagues (rather than IT personnel) for help when using the system specifically for test result management (28). Only a small percentage of participants (n=355, 13.7%) reported any refresher training (28). Noormohammed *et al*. reported how refresher training and explaining the rationale and algorithms behind the clinical decision support system to users contributed to a decrease in the rate of missed reminders for specific tests in their Kenyan study (58).

2.3.3. Discussion

This review explored healthcare staff perspectives of using electronic systems for the follow-up of patient test results. Based on the published literature, five main themes emerged: alert notifications, accessing patient information and test results, responsibility for acting on patient test results, communication of patient information and test results between staff, and user training. User experiences were largely affected by the quantity of electronic alert notifications received, content of these alerts, how the alerts were presented, and how organisations monitored staff responses to these alerts. Users believed that electronic systems appeared to be more time efficient for accessing and receiving test results, but that there was also opportunity for improving communication to the patient through the systems. Uncertainty around who was responsible for acting on abnormal test results and the

training users received on the system seemed to both influence users' experiences.

The review showed how clinicians depended heavily on use of EHR as a communication tool (28, 53). We found examples of how electronic systems improved the communication of information between physicians and nurses (61), enhancing its readability and reporting (62, 63). Lacson *et al*. examined the effect of an innovative software feature at an academic medical centre, which facilitated radiologists to communicate critical results to the ordering provider and allowed them to acknowledge receipt (64). The wider literature also discussed how electronic systems could have a negative effect on clinician–patient relationship, with patients in one study reporting a lack of eye contact and reduced discussion time when the doctor was using their computer to access patient information and patient test results during their consultation (65).

Users reported ambiguity around who was responsible for the follow-up and acting on test results, especially when several clinicians were involved in the management of a patient's care. The British Medical Association published guidance in 2012, which was later updated in 2016, to help address this issue and recommended that the ordering provider should always be responsible for the follow-up, unless it was explicitly stated that it was responsibility of a different individual or team caring for the patient (66). The guidance also highlighted how when physicians received the test result, without any direction from the ordering clinician, they were often unsure whether any action had been taken (66). The guidance concluded that even though electronic systems

can enable rapid access to test results, they can also present hazards if clear processes for taking action are not available (66). The Medical Council of New Zealand issued a guidance that was similar to the British Medical Association's guidance, but also highlighted how if the ordering clinician was off duty, he/she should have a system in place to notify another clinician that there were results outstanding (67). Also, the VA issued a new policy in 2015, which emphasised the time frame within which test results should be communicated to patients (68). The policy also highlighted how each ordering provider should assign a qualified designee to receive test results when he/she was unavailable (68). It seems that other countries and health systems should follow similar principles as they implement electronic systems for test results communication.

It was clear from this review that healthcare staff relied heavily on electronic systems for communication and executing tasks. It follows that settings and organisations must also adopt methods to anticipate downfall of electronic systems as well. SAFER guides are newly developed tools intended to help settings recognise weak points in their adopted electronic systems and help put strategies in place to combat them (69). These guides, which were developed by safety researchers, were promoted by the Office of the National Coordinator for Health Information Technology to encourage a safer working environment when using EHRs (70). Settings must recognise that adopting electronic systems can present challenges, some of which we have explored in this review, and that staff may need to reconsider the ways in which they work so as to provide safer patient care.

2.3.3.1. Limitations

Most of the included studies were conducted in the US, with the majority of these obtaining users' perspectives on the VA system. Nevertheless, the VA's electronic system has been widely used for more than a decade and helps facilitate care for more than 9 million patients. Many of the features of electronic communication described in VA settings have recently emerged in non-VA settings (71, 72). Although the aim of this review was to cover healthcare staff experiences, most of the data covered those of clinicians.

Also, it was difficult from the included literature to identify challenges that could appear in each stage. The review was able only to illustrate some challenges based on what were discovered based on users' perspective in general. As a result, there were no cover to any specific challenges that would be unique to the stage of the follow-up.

2.3.4. Conclusion

Users' experiences mainly involved reviewing and acting on results that appeared as alert notifications, time needed to send and receive results, defining the responsibilities for acting on test results and documenting these actions, and how training improved users' experiences on the follow-up of test results. Inconsistency in the views about who was responsible for follow up and action on test results, especially when several clinicians were involved in the management of a patient, can cause potential patient safety risks. Even though electronic systems can enable rapid access to test results, they can also present hazards if clear processes for responsibility and taking the

necessary actions are not in place. This review intended to explore users' perspectives in detail, but with a limited number of published papers, the need for more elaborating data derived from different healthcare staff seem to be important to address this matter properly. Furthermore, there were very limited data regarding what healthcare staff perspective about the role of electronic systems in each stage of test results process, which could help in better understanding of both process and systems.

The intent of this thesis was to provide a discourse around some unanswered questions about the structure and process of test results management when electronic systems are used, with an exploration of staff views and experiences in the follow-up of results. The aims, objectives, theoretical foundation, methods and the results are detailed in the following chapters.

Chapter 3: Development of the theoretical approach to the evaluation of users' perspectives on electronic systems.

3.1. Introduction

This chapter introduces the theoretical underpinnings for the evaluation of users' perspectives on electronic systems in the follow-up of patients' test results. It is based on a classical theoretical model developed for the evaluation of healthcare systems and outcomes. As this thesis developed, becoming reliant on interviews with primary care staff in general practice, I realised the need for a formal approach to evaluate the particular component of the healthcare systems I was studying.

Evaluating systems in healthcare is a complicated process, which requires researchers first to understand the reasons behind the intended implementation, before trying to evaluate it, and to study the system structure and environment. An understanding of both the structure and the original intent of the system are essential as an evaluation of the system needs to be designed to capture any unintended consequences. In order to assess a system, researchers usually investigate whether the system accomplishes its goal and to study how and why it could fail to succeed, by understanding and appraising the systems' stress/failing points (73, 74). Evaluation is a systematic attempt to learn from experience, which enables making sense of the system and thus understand how it works and how it could achieve the desired outcomes. The understanding that comes from careful interpretation of the link between the structure and outcomes also allows researchers to

probe in a systematic way. This also helps in learning how the system could fail, by understanding what the possible failing/stress points are – this requires a rigorous understanding of the system in place. As described in the previous two chapters, the reasons behind implementing electronic systems in primary care include the minimisation of missed test results, accelerating the process of ordering and acting on test results and improving communication. These are all designed to lead to improvements in the quality of care (75). Quality of care is a broad term, and is therefore difficult to evaluate without using specific parameters or outcomes. Moreover, it is inappropriate to evaluate the quality of a system based only on one outcome, and it is also hard to evaluate multiple outcomes at the same time (76). Instead of studying only outcomes to evaluate quality of care, researchers can study the process of any given system, break it down to its essential steps, evaluate stress points at each step, investigate the possible occurrence of these stress points, understand how each step would affect the whole process and find room for improvement.

This chapter aims to map the system in which tests, investigations and test results are ordered, conducted, reported, received and acted upon. This will enable us to identify potential points of stress and failure during the whole process and to draw up a model to reduce and eliminate failures. In order to achieve that, a system analysis technique will be used. Focusing only on improving individual sectors of the process of analysis has the potential to decrease errors even though it may be also efficient to study and improve the system as a whole (77). The design of an apparently flawless system could easily include design mistakes which are hard to notice. By identifying and studying stress points, *i.e.*, points where errors could occur, researchers can

get a better understanding of the effectiveness of the whole model proposed. The primary purposes of any system designed for healthcare field are (1) to eliminate any possibilities of errors to occur, and (2) to help in the discovery of any potential errors and make it possible for further improvement before harm take place (78).

In any given healthcare system, whether an information system is ‘successful’ or not is decided by workflow, efficiency and by eliminating errors (17). On the other hand, it is also possible to set success measures outside an organisation's own measures of success (for example, the proportion of professionals using the system, which is probably not an outcome but rather a measure of the success of the structure and process of that system) (17). Ongoing discussions about what could mark a system a success should, at the very least, consider the multidimensional nature of the concepts of ‘success’ and ‘failure’ (79). For example, a system can be a success financially; the implementation of a project may have low expenses, or management may have succeeded in reducing the administrative workforce by a set target (17). On the other hand, success in lowering the cost might not lead to better patient outcomes. Alternatively, success could be measured based on the results at each stage of the system being in place. For example, a specific success measure could be a reduction in errors in ordering tests (80) even if this is not actually associated with improved care on the whole.

System analysis is a problem-solving procedure that breaks down a system into its primary sections and components. This helps to understand how those sections work and inter-operate to accomplish their purpose (81). Drawing a

series of actions that represent each step or action's inputs, outputs and management helps to understand the whole process, evaluate results, and make it possible to propose an improved system that overcomes the known and undiscovered stress and failure points. In this chapter, data flow diagrams are used for this - these represent a model where the test journey will be displayed from ordering tests to their follow-up actions.

This chapter is based on the classical approach of assessing and evaluating quality of care in healthcare setting. This was introduced by Avedis Donabedian as early as 1966 (18). Donabedian was a Professor of public health and he famous of proposing the use of a model that breaks down systems in healthcare into its three main components, which are Structure, Process and Outcome. His work and contributions influence health services globally (82). His proposal of understanding the health care setting based on his model is recognised in most countries and researchers still use his model to assess quality in healthcare (83). This model is one of the most used analysis models and it is well known and understood among healthcare professionals concerned with systems organisation (84). Donabedian defined structure as the physical equipment, staff (*e.g.* clinicians and non-clinicians), and organisational features; process as the all actions that will lead to the outcomes; outcome as the effects of healthcare on patients or community (74).

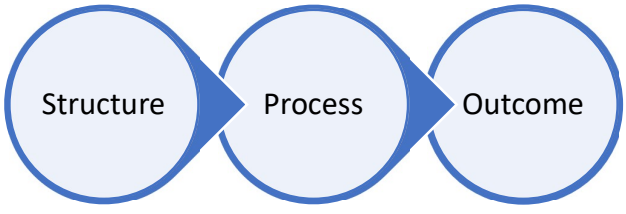


Figure 5: The Donabedian Model

3.2. Phases of test result management

As elaborated in the earlier chapter, some of the existing research has clustered the test result process into three different stages (pre-analytic, analytic, post-analytic) (20). In this instance the pre-analytic stage deals with the ordering of a test, the analytic stage involves conducting the test and the post-analytic stage includes receiving and following up results.

To understand the current process and system in a more detailed way, the steps of test results management will be detailed based on the series of factors. These factors are designed to understand all three components in the Donabedian Model by seeking answers to a list of questions. Questions include the following: how would the practice place the test request/order? Who would place the order for the test? Who would conduct the test and how will the sample will be analysed and reported? How would practices receive results? What does the practice do after receiving the results? Who will act on and follow up the results? Questions focused on the 'who' and 'where' are intended to examine the structure component, which includes physical equipment, staff and organisational features; questions focused on 'how' are intended to investigate how structural elements will act and lead to the outcomes, which is the process; questions with 'what' are intended to explore the outcomes by understanding the purpose of each stage.

Based on these questions, and what has been published, the test results management process can be divided into five main stages 1) the ordering step 2) the conducting step 3) the reporting step 4) the receiving step and 5) the acting step, which are represented in table 1.

3.3. Phases of Test Results Management: (Donabedian Model)

Table 1:

Step	Structure	Process	Outcomes
The Ordering step	The clinical staff staff Room The patient Electronic system	Staff knowledge Type of the test Communication channels	Order the right test for the right patient
The conducting step	The staff The patient The settings The tools Electronic system	Time of collection Place of collection Order clarification	Conduct the right test at the right time and send it for the appropriate analysis
The reporting step	The Lab The Practice The Result Electronic system	Analysing the sample Reporting the results	Reporting the right results to the right practice as soon as possible
The receiving step	The practice Electronic system The staff	Staff schedule	Deliver the results to the appropriate GP
The acting step	The staff The Results The patient Electronic system	Filing or contacting patients	All test results must be acted upon appropriately.

The ordering step is when the general practitioner orders or delegates a staff member to organise the test, *i.e*., a member from the reception team or the nursing team to perform or organise the test. Factors affecting this step could include how the electronic system displays the ordering screen and how the tasks appeared on the screen. The importance of this issue is illustrated by the need to know who asked for the test. This is important because locums or part-time GPs could affect the management process at this step by not being familiar with the way tests are ordered and by not knowing the process whereby they are conducted and by whom, and importantly, by not knowing who will act on the results.

The conducting step is where the test sample is taken, either in the practice or at an alternative setting, *i.e*., the laboratory or the hospital. How will the patient be instructed to provide the specimen and how can it be checked that the patient delivered the sample? Also, how can it be checked that the laboratory received the specimen and performed the appropriate test?

The reporting step is when the laboratory department sends the results to the medical practice. Questions include: how will urgent results be reported and what is the role of the laboratory personnel in reporting the results?

Receiving results is concerned with how the general practices get the result and ensure that the appropriate clinician will see it. Results for tests ordered by locum or part-time clinicians and how practices act on these results is an important component of this step. Also, how staff deliver information regarding urgent test results to the appropriate clinician could have an impact on this step.

Acting on test results is a component of the process. Who receives the result and decides what to do further? The action could be simply filing the result as “normal”, changing the course of treatment, asking for further tests and/or informing the patient about the results. When and how GPs decide to contact the patient also has a role in the shape of this step.

Flow chart diagram of the process

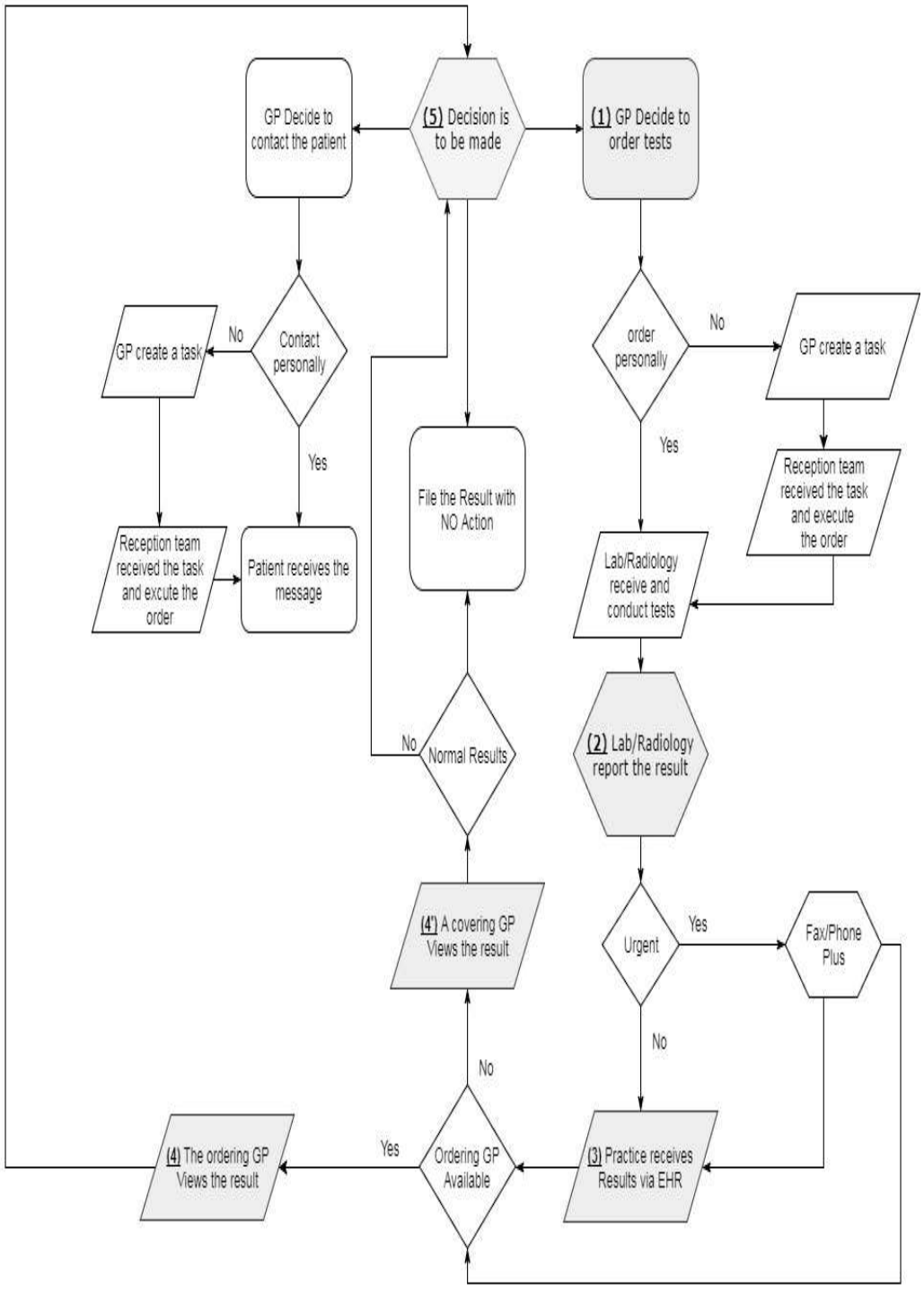


Figure 6: Flow chart diagram of test results managements

Process mapping is the visual representation of all the steps based on what could actually happen. The flowchart is simply the mapping of the process steps and was designed to cover different scenarios that might occur in each step. Each step will be considered to have five main factors: input, input agent, processing, output, and output agent (85). Input is the information entered into the step or the system; processing is the procedure of transforming input information into the output; output is the results provided after processing.

Summary of the steps

Table 2:

step		Input	Input agent	Processing	Output agent	Output
1	- Clinician decides to order tests	- Patient History	- Clinician - electronic systems	- Clinician entered the order - Clinician sent a task	Electronic system	- Order was sent to the lab
2	- Lab/Radiology report the result	- Order received from the practice	- Lab/Radiology personnel - Electronic system	- The sample collected - Sample analysed - Result Sent	Electronic system	- Results Received to the practice
3	- Practice received the results and divides them	- Results received based on the urgency	- Electronic system	- Body system - divide evenly - On call (Urgent)	Electronic system	- Results ready to view by the clinician
4	- The GP Views the result	- Viewing the results for decision	- Electronic system	- Ordering GP / Covering - The familiarity with the patient - Result's status	Electronic system	- Decisions will be made based on the results
5	- Executing the decision	- The result - Patient History and Status	- Ordering clinicians	- Clinician is aware of the patient condition. - Access Electronic system for extra Info - Method of communication will be based on the situation	Electronic system	- Change in medication - Repeat Test - Have an appointment - No action
			- Covering clinicians	- Files Normal results or leaves them in the system - Only view abnormal in detail		

3.4. Potential Stress Points (failure points)

As shown in Chapter 2, errors may occur at any step of the test management process. In the *pre-analytic* stage, errors can occur in the ordering and handling of samples. These include, for example, requesting incorrect tests (30), losing or imperfectly storing samples (30), providing deficient volumes of sample(s) (30) or supplying them in an inappropriate container (30). In the *analytic* stage, examples of errors include sample mix-ups and procedures not followed according to laboratory standards (32). In the *post-analytic* stage, errors can occur around failing to inform a patient of an abnormal test result (33, 34) or sending the result(s) to the wrong patient (35).

From the flowchart presented, more specific areas are prone to produce errors unintentionally. For example, not knowing who ordered the test will make it difficult assigning the result to the appropriate GP*, i.e.*, the one who knows precisely why the test was ordered. Not knowing why the test was ordered risks the possibilities of acting on a test result inappropriately, leading to potential harm. This might occur because the normal result has provided false reassurance whilst another test might be indicated. For example, viewing a thyroid function test with a normal value might make the covering provider file it as “healthy”, when instead further investigations for alternative problems is indicated. Errors could occur when the reason for the test being ordered is not linked with the result. Also, not having a safety net that oversees tests and ensures they were reported and received at the practice could lead to losing results. The same safety procedures should be available to ensure that all results are seen by the ordering provider, or at least the covering one. This

should minimise the risk of missed test results. Moreover, a procedure needs to be in place to ensure that all results had the appropriate actions carried out and no results were left for later actions which were not carried out. Also, more effort should be in place to ensure that patients are informed about their results – this is likely to have the effect of minimising the chance of missing test results and errors.

All these stress points with associated missed or inappropriate further actions can lead to possible adverse events for patients such as delayed diagnoses, inappropriate treatment and unpleasant adverse drug events.

3.5. Discussion

As the aim of any system is provide successful and effective throughput and outcomes, a clearer definition of the practical translation of ‘success’ is needed. The success of electronic system implementation has many angles: effectiveness, efficiency, commitment, and user satisfaction. It is hard to agree on only one element as the representative of the success or failure of the system. Also, the costs and benefits ratio needs to be included in the evaluation of a system's efficiency, especially from administrative points of view (79, 86). As a result of such complexity, quality of care can become lost as the most important outcome because cost savings may drive the decision to use the system (87). Any management plan should ideally be preceded by a careful system analysis, keeping in mind the aims of the intended implementation. If that is not possible, an analysis of the system or process can be conducted to review its shortcomings and to help improve the system – this can be achieved only with evaluations (18). For the purpose of this

thesis, which was to explore the use of health information technology in the follow-up of test results, based on healthcare professionals' narratives, the main outputs will be experiences and views on the track of tests and results from ordering to action on results. That, in essence, means ordering the right test for the right patient, and acting correctly on its result within the right context.

The system analysis suggested in this chapter is based essentially on the process component of the Donabedian model. Studying outcomes in terms of patient outcomes is a challenge and cannot be covered properly without an extensive study of clinical cases, almost certainly needing a prospective observational survey. Equally, it is not possible to ascertain outcomes from a retrospective assessment as this would depend on precise recordkeeping and also be subject to bias in recall as well as patient selection and need a very large sample size (88, 89). Moreover, records' access would require extra procedures to ensure confidentiality if the researcher was not a member of the healthcare team. It would certainly be difficult to assess structure and process item of the system using retrospective analysis. This approach was thus out of the scope of this thesis. The approach in this chapter provided the basis for studying the HIT system, based on interviews, including the identification stress points which could lead to errors or failings.

Donabedian's three-part dimensions makes quality of care assessment possible as structure will influence process which in turn influences outcome. Focusing only on the outcomes alone will fail to provide insights into the deficiencies or strengths of the system to which the outcomes might be

attributed (90). Likewise, variations in the structure or process could lead to differences in outcome (91). A measure of quality of care that includes all key aspects of the concept under consideration is more valid than one that only includes one of these dimensions (92). On the other hand, disadvantages of Donabedian's model include the difficulty in forming the relationship between structure, process, and outcome (90). Furthermore, there may be difficulty defining whether some factors are firmly part of structure and/or process or outcomes, as overlap between them may occur.

This chapter introduced the classical, but still applicable Donabedian model. By following this, it was possible to study the existing procedures for ordering and reviewing tests and to work out where problems and weaknesses might occur. Based on an understanding of the procedures for the follow-up of test results, as well as the literature findings, I planned to carry out interviews with GPs and practice staff using a series of questions to understand their perspectives and opinions about HIT.

Chapter 4: Research Methods and Methodology

4.1. Introduction

This thesis aimed to explore the use of health information technology in the follow-up of patient test results by ascertaining the perceptions and experience of primary care staff. The research also intended to discover staff perspectives on how current electronic systems could be improved to enhance the follow-up of test results in the future. It was demonstrated in the review of literature, discussed in chapter 2, that there is a significant gap in the level of understanding and perceptions about the impact of health information technology amongst different staff working within the same clinical setting. This probably reflects the situation across the NHS. The research was conducted using a semi-structured interviews, after which the data were analysed to understand the experiences and perception of staff about how the systems work, and where possible vulnerable areas existed, as outlined in chapter 3.

This chapter addresses the theoretical and practical concerns involved in conducting the empirical research that lies at this heart of the thesis. It describes the methodological standpoint in order to define and describe the processes utilised to answer the primary research questions. It also details the rationale for choices made in research implementation, with reference to the evaluation of strengths and weakness of available alternatives, and the relationship of the methods to the researcher's ontological and epistemological position.

This chapter initially describes the so-called ‘research onion’ as an organising concept, the ontological and associated epistemological assumptions that underpinned the research methodology and most appropriate methods of data collections. Then, the research strategy, research choice, design and techniques are illustrated. Also, sampling and recruitment, and the ethical considerations raised in this research including protecting confidentiality, safety and wellbeing of persons involved in the study are addressed. Finally, the chapter discusses the process of data analysis adopted by explaining the procedure for analysis, the process of generating analytic codes, the list of initial codes appeared which while the researcher was collecting the data and, lastly the final list of themes as appeared from the data.

This chain of thought and means of structuring this chapter were adapted from the research methodology reported by Saunders *et al*. in 2007 in the ‘Research Onion' (Figure 7). Saunders presented a model that aims to reflect the understanding of research methodology, with each step of thinking and planning presented as the layer of an onion (93). The research onion was developed to illustrate the phases involved in developing a research strategy and the progression from an overarching philosophy to research techniques and procedures. it has been demonstrated as applicable and adoptable for almost any type of research methodology, and the concept can be used in a wide range of situations (94).

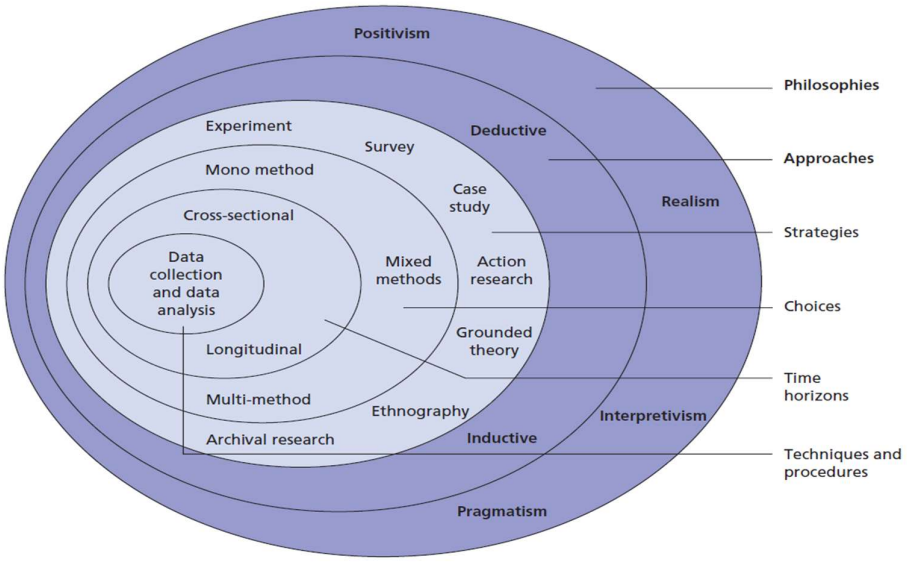


Figure 7: The Research Onion (93)

4.2. Research Philosophies and Approaches

Based on the concept of onion model, two main aspects define and shape the philosophy and approaches behind any research, which are ontology and epistemology.

Ontology is concerned with the nature of knowledge and reality. Key ontological issues are concerned with whether there is a reality that exists independently of human perception, and whether there is a shared social reality and knowledge. Generally, realism and idealism are identified as the two principal ontological positions available to researchers. Realism is based on the idea that there is an external reality which exists independently of people's beliefs and understanding. Idealism, on the other hand, states that reality is fundamentally mind-dependent. Under these broad situations, more perspectives can be identified.

Numerous styles of realism have had an important effect on the philosophy and methodology of the social sciences (95-98)

Lakoff states this difference between 'objectivist' and 'realist' views:

> *"Scientific objectivism claims that there is only one fully correct way in which reality can be divided up into objects, properties, and relations. . . . Scientific realism, on the other hand, assumes that "the world is the way it is," while acknowledging that there can be more than one scientifically correct way of understanding reality in terms of conceptual schemes with different objects and categories of objects."* (1987:265)

Terms used for such versions of realism include 'critical' realism (95), 'constructive' realism (99), 'subtle' realism (100).

The philosophical approach used in this research lies within the school of realism, which is known as 'subtle realism' (100, 101). Subtle realism means that the researcher views reality as something that exists independently of those who observe it but is only accessible through the perceptions and interpretations of individuals (100). The critical importance of participants' specific interpretations of the issues researched was recognised and their personal views were believed to help in development of a more holistic understanding. There are three main reasons that led me to adopt this position. First, the reality and the importance of the 'sense' of the phenomena, as well as the 'physical' phenomena are important, where the interpretation is based on understanding of themes. Second, the context of the phenomena is far more important, rather than pursuing only an overall understanding

independent of specific conditions. Third, the importance of investigating the processes of forming the phenomena is supported under this school.

For instance, although the impact of electronic systems on the follow-up of test results is something that exists materially and outside of people (as demonstrated in Chapter 3), investigating users' opinions and listening to their perspectives will build a holistic picture of the impact of the systems on the follow-up of patient test results. This paradigm recognises the critical importance of participants' interpretations of the matters researched and believe that these interpretations can yield different types of understanding.

Epistemology is the study of knowledge and justified belief, and is concerned with the following questions: What are sources of knowledge? And, how we can learn about reality? It is suggested, as reflected in the Saunders' 'onion', that epistemological position and their associated assumptions can best be considered as distributed along a continuum ranging from beliefs that knowledge is acquired through induction to beliefs that are acquired through deduction. One view believes that knowledge is based on deduction, a 'top-down' process, where reasoning starts out with a general statement, or hypothesis, and examines the possibilities to reach a conclusion. In contrast, those who argue that knowledge is acquired through induction, a 'bottom-up' process, believe patterns are derived from observations of the world (102, 103).

In other words, 'induction' implies a process in which patterns are derived from the data. In contrast, 'deduction' assumes knowledge acquisition is derived from propositions or hypotheses that are tested against observations.

Blaikie, among others, claimed that there is no such thing as ‘pure’ induction or ‘pure’ deduction (101). For example, when a researcher used an inductive view to generate and interpret data, the researcher cannot approach this with a completely blank mind. The questions, which a researcher could have asked participants and the logical categories, will have been influenced by assumptions deductively derived from previous work in their field. Likewise, deductive researcher aiming to test a hypothesis will have drawn on a body of theory which in turn has been inductively derived from prior observations.

For the perusal of this research and its proper ontology, as explained previously, the views of Blaikie and other researchers who believe in the balance between inductive and deductive approaches, the importance of understanding peoples’ viewpoints in the context of the conditions and circumstances of their lives were followed. At the start of this research project, the existing theories and research were used to help developing plan and design of the study and create information-gathering instruments.

4.3. Research Strategies

The Onion model illustrates some strategies that could be adopted in any given research depending on the overarching philosophical orientation and positioning. These include but were not limited to (a) Ethnography, which focuses on exploring a culture-sharing group by describing the shared patterns of a group and how a group works (b) Case study, which focuses on developing an in-depth analysis of a case or multiple cases; and finally (c) Grounded Theory, which focuses on developing a theory grounded in data from the field and moving beyond description to generate a theory which

comprehensively explains the data (104).

A framework approach in general tries to create an explanation of a process derived from the opinions of participants, but it does not aim to build a theory in contrast to grounded theory (104, 105). Besides, the framework approach allows the researcher to use inductive and deductive reasoning and not going blind into the data, which is not supported by classical grounded theory (104, 105).

The 'Framework approach' is considered as an analytical tool developed at NatCen Social Research, an independent UK-based centre for social research (105, 106). Researchers who adopted this approach were mainly concerned with social policy and had an interest in applied sciences, which can be applied in this research. This approach was developed to enable NatCen Social Research to be commissioned and funded by ensuring that evidence was systematically generated and analysed (105). Also, the framework approach reflects the original explanations and observations of the participants studied (inductive), but it starts deductively from pre-set aims and objectives. The process of data analysis tends to be more explicit and informative, and consists of five general steps/stages: organising the data, reading and memoing, developing codes and themes, interpreting data, and representing data (104, 105, 107).

4.4. Research Choice

On the basis of the philosophical orientation for this study reported in the thesis, which in turn was derived from the research question, a number of

choices emerged about appropriate and aligned research methods. It is important to select the appropriate methods to address specific research questions, and it is often necessary to utilise and combine different research methods for answering research questions.

Rather than the quantitative approach, which facilitates the testing of a hypothesis, investigating frequencies of events and quantifying relationships between clearly defined variables, a qualitative methodology was chosen. This is manifested in using individual interviews as the source of data. Due to the nature of the research question and also due to the busy schedule of most of the healthcare professionals, the observation was not implemented as a main method to collect data. In addition to the interviews, field notes were also used to help in the data analysis but are not part of the data presented. The notes were primarily used to record information about the researcher's experience of the interviews and participant reaction, behaviour and interaction (108).

The reason for choosing qualitative methods was in order to achieve alignment with the main objective of this study, which is exploring participants' experiences. Information of this kind is difficult to present clearly and meaningfully with numbers and in statistics. Due to some faced obstacles including data access, limited-time and shortage of funds, the possibilities to adopt a mixed qualitative and quantitative methods or to include, for example, focus group discussions as qualitative methods were reduced. This research is sponsored by King Abdulaziz University, Jeddah, Saudi Arabia. The Scholarship covers a monthly allowance and tuition fees, but not any expenses for participants' reimbursement.

4.5. Study Design and Time Horizon

The data collection was carried out using semi-structured interviews. Semi-structured interviews are characterised by open-ended questions, which aim to explore people's knowledge, beliefs and perceptions and are a way of discovering participant's voices on matters that are important to them. Consequently, they are particularly well-suited to this research. In addition, a semi-structured interview helps junior researchers, such as the main researcher in this study, by providing rich data with some borders that prevent deviation from the main topic. Both structured interviews and unstructured interviews were considered unsuitable, as the former would limit participants' discussion and the latter might lead to participants covering issues not related to the purpose of this research (109, 110).

4.6. Participant Eligibility

All individuals whose jobs involve using an electronic system in the follow-up process of test results in primary care, within the Northeast area of England, were eligible to be invited to participate in this study. This included both health care professionals (*e.g.*, GP, nurses) and non-medical staff (receptionists and practice manager), with participants recruited until thematic saturation was reached in the overall sample.

The North of England Commissioning Support (NECS), which cover all the member practices in the 11 Clinical Commission Groups (CCGs) in North East and Cumbria, contacted general practices to participate in this research. At the beginning of the study, only the NECS was in charge of contacting general

practices. Then, because of the low recruitment rate, an amendment to the study protocol and its appendices sought to the Research Ethics Committee to approve direct contact with general practices by email and telephone calls to introduce and explain the research to key members at the practice without the help of NECS.

Participants were invited to take part in a single, semi-structured interview. An invitation letter was sent to all potential participants (Appendix 4.1). Participant information sheets detailing the purpose of the interview (Appendix 4.2), the format of the interview (*e.g.*, approximate length of the interview), and confidentiality of information were enclosed with the invitation letter. In case that potential participants had any questions, the contact details were provided with the supervisor's contact information. Also, all participants were informed that all their potential questions or inquires that they might have prior to the interviews would be answered.

The letter of invitation was written in a friendly tone explaining what the participants are requested to do and outlining the information enclosed in the participant information sheet. The participant information sheet simply tried to answer few, but important questions such as: What does the study involve? Why have I contacted the participant and why they have been chosen to take part? Do participant have to take part? What do participant have to do? Will participants' responses in this study be kept confidential? What will happen to the results of the research study? What if something goes wrong? / How to make a complaint? Who is organising and funding the research? And, who has reviewed the study?

4.7. Recruitment

Identifying eligible participants was more challenging than expected. Participants were reluctant to allocate the interview time without reimbursement. The research did not have any direct fund for data collection. This meant I spent a significant amount of time attempting to identify the eligible, willing participants. Although this specific issue remains a challenge to many postgraduate students, it was more challenging for me as I am an international student with limited connections with peers in UK.

The research was a cross-sectional study, which provides an understanding of user's perspective at one point of time. The proposed plan aimed to include at least nine practices, and three interviews from each practice, which preferably would include a general practitioner, a nurse and a receptionist/practice manager. Nine practices and three interviews from each was proposed as a requirement for the IRAS and Ethics Committee, but it was also indicated that the data collection would continue until thematic saturation is reached. The Health Research Authority (HRA) approved approached all GP practices within the 11 CCGs that represent the Northeast commission service. Unfortunately, the recruitment process of health care professionals did not go as smoothly as anticipated. As a result of that, practices were identified from two large CCG's websites due to transportation issues. A list of GPs registered in both Darlington CCG (11 practices) and Newcastle Gateshead CCG (65 Practices) were printed from these both websites: https://www.darlingtonccg.nhs.uk, and http://www.newcastlegatesheadccg.nhs.uk. I tried to advertise my research to

practices within these two CCGs. The recruitment methods varied from sending emails, which contained the participant information sheet, to direct recruitment methods such as calling and visiting practices. I also tried to use the snowballing effect by asking participants to promote the research for more future participants. Snowball sampling is where early participants would promote the research trying to help the main researcher by recruiting other participants. It is a method used to increase the sample size and to overcome obstacles in knowing, reaching and meeting more potential participants(111). The addition help was offered by one of the professors in primary care. The major problem faced during recruitment was reimbursing participants for their time as the study did not have any direct funds for the recruitment.

4.8. The Interview

Using semi-structure interviews allow participants to express their opinions freely. The interview schedule provided an outline of the critical topics to be discussed. Semi-structured interviews would also allow me to probe for more specific information when needed, thus helping to understand particular issues in more depth and exploration of emergent issues.

The process and stages of test results management and the how staff are using the electronic systems on each step was the major aspect that forms the interview schedule. The aim was to design a list of questions that would help to explore the experiences and views of primary care staff about the impact of health information technology on the follow-up of patient test result. To achieve that, the interviews included items to help to fully understand and describe the process of test results managements, individual staff roles, investigate

different systems' features and how users' interface with these systems. The design allows us to explore obstacles that individuals face while using the electronic systems and how these systems could be further improved based on the basis of what was published in literature. After drafting a schedule, a pilot interview was conducted with a GP who was affiliated with Durham University.

The interview consisted of eight major questions with a possibility to prompt based on the flow of the interview. After the common introduction, a question aimed to explain the process of test results, based on the participant's words, was introduced. After that question, the focus shifted to cover participant's role in the process and their experiences. After investigating the role and the experiences, questions regarding systems' advantages and disadvantages were asked and how the system could be improved. Before ending the interview and ask the final question regarding any other comments, a question about how practices contact patient to deliver the results was asked. The question regarding patient communication was decided to be asked separately to investigate if any mechanisms are presented to ensure that results are communicated with the patient (Appendix 4.3).

4.9. Ethical Considerations

All research generates ethical considerations and it is incumbent on researchers to weigh these and identify potential risks and harms to participants and take steps to avoid them and if and when they do, to mitigate them. Due to the nature of the study aims, participants' status (employees of general practices), and the lack of any patient identifiable information or any

classified information in general, the study did not raise a huge number of ethical issues. On the other hand, since it involved human participants, ethical approval is needed before starting any data collection (112). How to interact with the participants, confidentiality and handling the data are the main issues that were addressed. The interview questions did not include any question that could have sensitive material in general. Before starting any interview or visiting any practice, a research passport – letter of access, which was issued by NECS after providing a letter from Occupational Health and confirmation of a successful Disclosure and Barring Service (DBS) check was shown. Moreover, it was explained to all participants that this research was a part of a postgraduate study.

This study was reviewed and approved by the School of Medicine, Pharmacy and Health Ethics Committee - Durham University, and the Research Ethics Committee London – Stanmore. REC Reference Number: 16/LO/1551.

When the school of Medicine, Pharmacy and Health moved to Newcastle University, an amendment was applied and approved.

Each member of staff was given the opportunity to ask questions about the study and, was also asked to complete a consent form (Appendix 4.4). The researcher explained to the interviewees that entry into the study was entirely voluntary and that they could withdraw at any time.

All individuals who agreed to participate in the semi-structured interviews gave their written consent. The Consent Form was signed and dated by the participating member of staff before they entered the study.

The interviews were recorded using a digital recorder (with participants' consent), and then these recordings were deleted once they had been successfully transferred over to a password-protected computer. I transcribed the recordings verbatim and a unique participant identification number was placed on each electronic file. The contact details for the interviewee was not included on the transcript.

Data collection took over ten months (from June 2017 to March 2018). Interviews were conducted by the researcher and were scheduled at a convenient time and place chosen by the participants. Interviews varied in length from 25 to 75 minutes. During the whole period of the data collection, the only ethical issues that arose was the change of the sponsor from Durham University to Newcastle University, which was due to the transfer of the School of Medicine, Pharmacy and Health to Newcastle University. This was resolved by applying for an amendment that was approved to contact practices directly. *Appendix 4.5* displays the ethical approval documents.

4.10. Study Participants

All practices within both Newcastle Gateshead CCG and Darlington CCG (n=76) were contacted in various ways (telephone call, emails, and personal drop off where the researcher visits the practice to promote the study). Eighteen interviews were conducted. Thirteen practices were included in the study with different primary care practice staff, including GPs (n=9), receptionists (n=8) and a practice manager (n=1). The interview process failed to include head nurses in the study because all practices declined to free a nurse for the interviews. Out of the thirteen practices, five practices offered two

participants, which include a GP and a receptionist/practice manager. The first interview was conducted with a GP by telephone in June 2017 and lasted for around 35 minutes, and the last one was with a receptionist in March 2018 and lasted for approximately 25 minutes. Interviews were conducted either face-to-face (n=16) or by telephone (n=2) based on the participant's choice and preference. The interviews lasted between 20 – 75 minutes. Seventeen of the eighteen interviews were digitally recorded with informed consent, with one receptionist preferring not to have the interview recorded.

Practices belonged to various CCGs within the Northeast area (n=5). Different primary care practices were involved (n=13), including two practices located in Northumberland, one in Darlington, one in Eaglescliffe, one in Guisborough, two in Newcastle, four in Middlesbrough and two in Stockton. Summary and detailed information were provided in Table 3 and Table 4.

All the identifiable data were anonymised by assigning a code name for each interview. The name consists of three parts; the practice code, participant's code, and the CCG code. With that three elements, each interview have a unique name that cannot lead to any identification of the participants. GP, RM, PM represent General Practitioner, Receptionist and Practice Manager respectively. The CCG code presents the location of the practice, which I added later to display a possible laboratory or hospitals affiliations. The detailed codename indicates some clarification of the code name, which also was sure not to show or identify any participant.

Table 3: Summary of the Interviews

Total Number of Interviews	18
Total Number of recorded Interviews	17
Total Number of Full Transcripts	17
Number of Included CCGs	5
Number of Included Practices	13
Number of GPs	9
Number of Receptionists	8
Number of Practice Managers	1

Table 4: Interviewees' details

#	Participant Code	Practice Code	Location of the Practice	Number of GPs at the Practice	Participant	Interview Date	Duration (min)
1	GP1_P1_CCG1	P1_CCG1	Village	6	Partner	Jun-17	~ 35
2	GP2_P2_CCG2	P2_CCG2	Small town	8	Partner	Jun-17	~ 35
3	PM1_P3_CCG3	P3_CCG3	Large town	6	Admin	Jul-17	~ 35
4	RM1_P4_CCG4	P4_CCG4	Small town	8	Admin	Sep-17	~ 35
5	GP3_P5_CCG1	P5_CCG1	Village	6	Partner	Sep-17	~ 25
6	RM2_P6_CCG5	P6_CCG5	Inner city	7	Admin	Sep-17	~ 50
7	GP4_P7_CCG4	P7_CCG4	Inner city	5	Partner	Sep-17	~ 55
8	RM3_P7_CCG4	P7_CCG4	Inner city	5	Admin	Sep-17	~ 25
9	GP5_P6_CCG5	P6_CCG5	Inner city	7	Partner	Oct-17	~ 30
10	RM4_P2_CCG2	P2_CCG2	Small town	8	Admin	Nov-17	~ 30
11	RM5_P3_CCG3	P3_CCG3	Large town	6	Admin	Nov-17	~ 30
12	GP6_P8_CCG2	P8_CCG2	Large town	8	Salaried GP	Nov-17	~ 25
13	GP7_P9_CCG5	P9_CCG5	Inner city	6	Partner	Nov-17	~ 45
14	GP8_P10_CCG4	P10_CCG4	Inner city	7	Partner	Nov-17	~ 75
15	RM6_P11_CCG2	P11_CCG2	Large town	5	Admin	Nov-17	~ 20
16	GP9_P11_CCG2	P11_CCG2	Large town	5	Partner	Nov-17	~ 35
17	RM7_P12_CCG4	P12_CCG4	Small town	6	Admin	Mar-18	~ 30
18	RM8_P13_CCG4	P13_CCG4	Inner city	5	Admin	Mar-18	~ 25

4.11. Data Analysis

Field notes regarding the interviews were written which included a general description of the settings, and participant reaction, the interaction between me the participant. This information was not used in the analysis directly but helped to provide a context and prompt to recall and hence data analysis.

All data collected were coded, analysed and continuously compared. The first preliminary report was written after only three interviews. Logically, the current node and codes are different from that one, and have cover more area than the first report. Also, at the middle of data collection phase and during the coding of the available interviews, a GP was consulted to evaluate the direction of the questions. Points were agreed that need more investigation were: (1) test result context, and how is it for a second/different GP to follow up a patient test results? And what if the second GP would not typically order and therefore didn't value the test? (2) the feedback loop, as the GP could not know whether these tests have been carried out or missed either by the patient or lost (3) using HIT and competing demands (4) the role of technical supports. Relevant topics and issues arising from the findings were incorporated into subsequent interviews, and the emerging findings/themes influenced the development of the topic guide used for the interview.

In general, there are five steps to analyse data in a qualitative study: organising the data, reading and memoing, developing codes and themes, interpreting data, and presenting data (107). This study applied a robust and complete analysis using the 'five stage' framework approach.(104, 105)

4.11.1. Procedure for analysis

As explained earlier, a framework analysis was used for the analysis. The main idea behind using a framework is to form an organised analytical framework. Analytical framework could be defined as assigning a group of codes to the data that gathered into clusters that have been cooperatively developed by the researcher. The framework aims to create a new order for the data, which helps in organising the data in a way that can support answering the research questions (113). This process helps the researcher to identify similarities and differences in the qualitative data. After finding relations between the codes and themes, the researcher will draw descriptive conclusions, which collected around themes. Therefore, all data were broken down and looked out for different codes sentence by sentence. I used words from the actual interviews and as used by the participant. I used NVivo qualitative data analysis Software; QSR International Pty Ltd. Version 11, 2015 for coding, which was particularly helpful as this research was my first interaction with a qualitative study. NVivo does not assist the researcher in undertaking the analysis but offers an efficient, systematic way of managing the data. Although the data was uploaded into the software, the process of coding and identifying themes must still be done by the researcher. The personal field notes helped to go back to the interview and hereafter achieve better and more accurately recall of who said what and how they expressed themselves. Participant's laughter and long pauses were included in the transcripts to help me understand participant's expressions.

4.11.2. Initial Coding

The initial coding was done as a starting point to provide the analytical leads for further exploration. Establishing inter-rater reliability is mostly used and a recognised method of ensuring the reliability of the study when multiple researchers are involved with coding. Therefore, a postgraduate student qualitative data group at Newcastle University was contacted to help assign a second person to review and comment on the initial coding. To speed the process, a colleague with experience in qualitative analysis was asked to comment on coding process, and after discussions, a list of the twenty-eight codes was identified. As my colleague lives at my hometown in Saudi Arabia, it was difficult to have face to face meetings to discuss the codes. His contributions were mainly commenting on my codes and if the codes really represented the corresponding sentences. It is impossible to quote every sentence that support the findings, and thus representative quotes are included, where I cite one or two representative quotations that could best represent the code and support the theme and my analysis. I have also used quotes that are especially interesting and introduce unique terminology.

4.11.3. The process of generating analytic codes

Initial list of codes

After reading and memoing the interviews, the initial list of codes was developed. The initial codes were reduced to twenty-eight, by removing duplicates and preserve ones that better expressed the themes derived from the data collected. This step aimed to simplify code structure by merging codes

that have the same meaning. For example, the two codes, `screen' and 'user interface', which both relate to how the user would interact with the system were combined under 'user interface' as it best clarifies how the user would communicate with the operating system. The final list of codes was grouped by looking at all possible and logical relations among them, *i.e*., nodes that dealt with the same topic, concept, idea or experience were categorised to form a 'theme'. For example, 'looking for more information' is a code, which could be related to the type of the test, but not all clinical staff tend to look for further information. As a result, it was decided to add that code under the 'individual' rather than the 'results'.

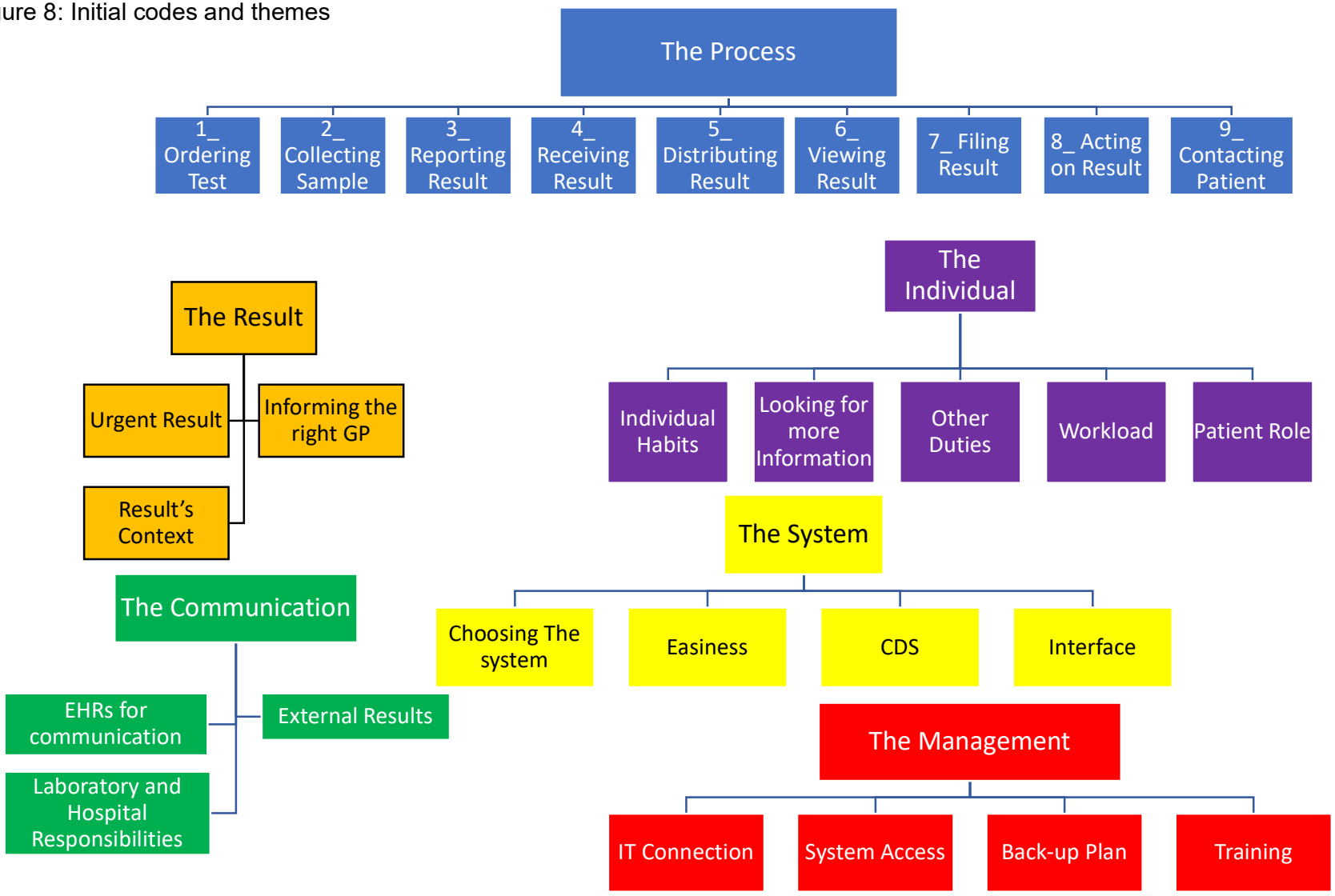
Six main categories or themes were identified: (1) the process of test results management – from ordering the test to communicating the result with the patient; (2) the status of the result and staff perspectives on using the electronic systems for the follow-up of patient test results could be affected based on the type of results, *e.g*., normal, abnormal or urgent, and how the result's context could change how staff would use the systems; (3) the user's habits and how specific personal attributes could affect the experience for each user; (4) the electronic system's capabilities and features, which also could shape users opinions; (5) how using electronic systems as the method of communication between healthcare personnel regarding test results management could form their perspectives; (6) the management and how organisational factors, such as providing access to the specific electronic system, the availability of a backup plans in case of a problem with the IT connection and the evaluation of the training could also influence the

experience. All of these codes and themes were presented in Table 5 and in Figure 8.

Table 5: List of codes used to label the data

Codes	Ordering Test	Individual Habits	Choosing The system	IT Connection	Urgent Result	EHRs for communication
	Collecting Sample	Looking for more Information	Easiness	System Access	Informing the right GP	External Results
	Reporting Result	Other Duties	CDS	Back-up Plan	Result's Context	Laboratory and Hospital Responsibilities
	Receiving Result	Workload	Interface	Training		
	Distributing Result	Patient Role				
	Viewing Result					
	Filing Result					
	Acting on Result					
	Contacting Patient					
Themes	The Process	The Individual	The System	The Management	The Result	The Communication

Figure 8: Initial codes and themes



4.12. Final codes

Translating sentences into codes is a process that expresses the growing understanding of the ideas within the data. While writing about the first chosen theme, *i.e*., 'process', I noticed that it would be unrealistic to study each stage of the test result process in isolation from the other factors (codes). Also developing a theme that only fixated on the process of test results management is unsuitable. The main reason for that is the process theme ended up as a description of the chronological order of activities stated in the interviews rather than the insights of the impact of the electronic systems on the test results management process based on user opinions. As a result, I decided to rerun the coding process in a way that would not just describe the order of events, but also allow me to investigate and understand the experience at each stage of the test results management process.

As mentioned previously in Chapter 2 and 3, the literature divided test results process into three main stages (pre-analytic, analytic, and post-analytic) (20). The pre-analytic stage deals with the ordering of tests by a clinician or administrative staff. The analytic stage involves conducting the test, and the post-analytic stage includes how test results are communicated to the clinician or administrator and what actions they took on receiving this result. Logically, the proposed order of events presented as codes under the process in Table 5*, i.e.,* ordering test, collecting sample, reporting result, receiving result, distributing result, viewing result, filing result, acting on result and contacting patient could be divided among the three stages presented in the literature. I divided the process into four main stages, which consist of ordering tests,

collecting samples, receiving results and acting on results. As all the interviewees in this research were staff in General Practice settings, information regarding the analytic stage presented in the literature, *i.e.*, conducting the test, was mainly regarding how practices collect samples and how practices would receive results. It is more representative to demonstrate the test results management process as a cycle rather than a chain of action, which I tried to illustrate in Figure 9. Elements in the figure do not represent codes or theme, but they only represent the stages and could interfere with the cycle.

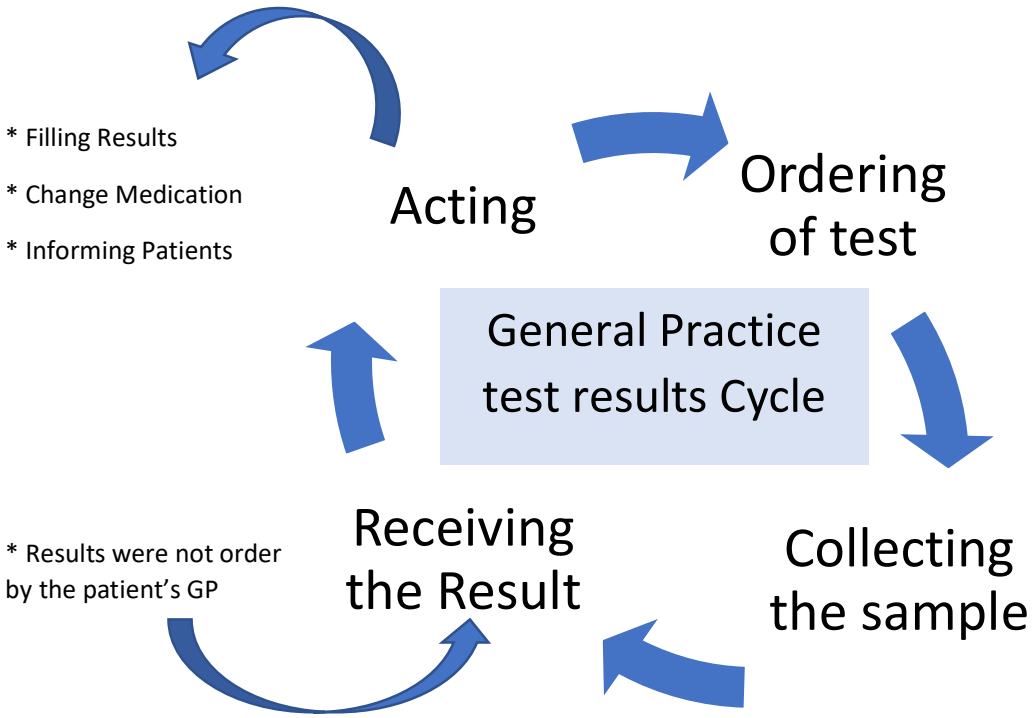


Figure 9: The test result cycle

During the rerun of the codes, each sentence from the interviews was linked to the most appropriate stage that the sentence talked about. After that, each sentence in the specific stage was linked to a code that best represented the opinions about the impact of the electronic system in that specific stage. The experience of using the electronic system in each stage of the process was discussed separately as each stage could have its own attributes and then codes, which could be only appropriate to the specific stage.

Chapter 5: Staff perceptions of the impact of health information technology on ordering of tests, collecting samples and receiving results

5.1. Introduction

This chapter describes the experiences and perspectives of primary care staff on how electronic systems are used in general practices to order tests and the impact of the systems on the staff and the practice. It covers the progression of the order after it has been placed on the HIT system by someone in the practice, how the laboratory receives the sample, links it with the request and the ways in which practices handle the results.

The use of thematic framework analysis was used based on pragmatic reasoning. Also, It helps in emphasis research findings where themes are presented sufficiently in a more focused way to inform policy planning and can be done in a shorter period of time (105, 114). I felt that a thematic framework analysis, where the interview contents were linked, was the most appropriate way of bringing together respondents' texts in a coherent way. This enabled a framework of narratives to be created and examined systematically.

5.2. Benefits and problems of using electronic systems to order tests

Sunquest Information Systems Inc., a U.S. developer of medical laboratory and diagnostic information solutions, introduced an electronic system that enables clinical settings to communicate with each other and with services that

contribute to the patient pathway and they labelled it the Integrated Clinical Environment System (ICE) (115).

All practices included in this research used only the ICE system to order a selection of tests based on what the system provides. The ICE system provides some features that are believed to facilitate placing an order into it, but some participants expressed the view that these features introduce challenges as well. Also, developing the themes based on the interviews showed that users were likely to use the same system or features differently, based on what they were looking to execute. These are detailed below.

5.2.1. A Tale of Two Systems: using a universal tool

Although all the included practices, at the current time, do not have any electronic systems alternative to the ICE system to place an order, participants' perspectives were highly positive towards it. As one GP considered it as *"a universal tool"* while describing how he could "*see test of that patient that had been done elsewhere on systems that use ICE"* (GP2_P2_CCG2).

It is also worth mentioning that all GP practices that participated in this research adopted two different systems simultaneously; one to order test (ICE) and one to review and act on the results (SystmOne or EMIS). Therefore, practices must request permission from whichever laboratory each practice is linked to, for each user to access the ICE system. This process was described by one practice manager as *"quite frustrating"* (PM1_P3_CCG3) as it was *"something extra they have to do, so you have to give them* (new member of

staff) *access to SystmOne, but they* (The laboratory via ICE) *have to give them access to ICE system as well"* (PM1_P3_CCG3). Although it is an extra step, one head receptionist believed that it is for *"security, so that people can't just come in and have access to taking blood and things like that*" (RM2_P6_CCG5). The ICE system also allowed users to access patient information and results that were taken outside the practice, such as those who *"may have attended out-of-hours at the weekend"* (RM2_P6_CCG5).

Both clinical and administrative staff praised the ICE system and its features. For example, a head receptionist described how the design of the system and its interface helped her to do her job:

> *"It's very specific. It's very ordered, there's no black and white. It's what we need, this request, and this is what we need to do […] It's very instructive in what we need to request"* (RM4_P2_CCG2).

Also, a GP from a different practice described the system as *"so practical you probably wouldn't want to change it"* (GP1_P1_CCG1). Moreover, one GP explained how it was *"a nightmare"* and *"really problematic"* when *"ICE had gone down"* as they *"had to go back to using the paper form and ticking the boxes on the brown paper form"* (GP6_P8_CCG2). The GP explained that the ICE system relied on a continuous internet connection and when the internet is down, the system will not work.

5.2.2. The services menu (navigating the screen)

The ICE system used a menu tool that included most of the common tests, with a search box for other tests. This feature was described by one GP *as "Pretty good. So ninety percent of the tests I would require will be on the first page of the menu. And then, there is a search box on that for everything else*" (GP2_P2_CCG2). He *"like[d] being able to select a blood test off a menu. It means I get the right test done more of the time, coz there is no confusion about it"* (GP2_P2_CCG2). The head receptionist at the same practice, P2_CCG2, also shared a similar view by describing how *"common requests. Swabs, urine, stool, all the other bits and pieces. There's my condition sets […] the doctors would just say, 'Do whatever Microbiology, immunology'. They're all just there*" (RM4_P2_CCG2). She also explained that if a GP wanted to make a referral or order a test for somebody who had a specific health condition or disease, the menu had a pre-programmed set list of blood tests for that condition, which she described it as "*great*" as she said:

> *"They have a set request, as well. If you're wanting to do a healthy heart check, you can just select the condition set for that. That will give you all of the blood tests. It is simple to use, it's easy"* (RM4_P2_CCG2).

This view on the ease of use of the pre-set request was also shared by a GP from another practice who described it as *"handy"*:

> *"You can tick the annual diabetic check box and it tells you the standard things you want, and you can do 'select all', or*

> *I think it will ask you some questions sometimes. That will automatically fill all those ones in for you. So it gives you an idea [of] what you might want for various things, following up abnormal liver or whatever else it will be" (*GP8_P10_CCG4).

The same GP described the ordering as *"relatively simple"* (GP8_P10_CCG4) explaining how *"I've tick those [boxes], I then say continue and then I write in the reason, whatever that will be and then I print the form"* (GP8_P10_CCG4).

On the other hand, another GP, from another practice, explained how it might be advantageous to "*have more set groups of test results for certain conditions"* (GP6_P8_CCG2).

Some clinical and administrative staff described how it is useful that more tests have been added to the ICE system over time: *"they [are] increasing what we can request on ICE on the computer, like now we can request ECGs in the computer which is helpful"* (GP1_P1_CCG1). One of the administrative staff members from a different practice also explained how the request screen had been amended "*I think they've just added ferritin onto it and B-12 which didn't used to be on there. There's a main screen that it gives you the common tests"* (RM4_P2_CCG2).

5.2.3. Search tool

Regarding the search tool provided in the ICE system for uncommon tests, one GP explained how *"occasionally if you are looking for something obscure, it might take you a couple of goes to find it"* (GP2_P2_CCG2). He felt that *"the*

*trick is [was] to know what the test is called in the system" (*GP2_P2_CCG2*).* Another GP at a different practice also described how *"you may find it [a specific test] difficult to find"* (GP7_P9_CCG5). He seemed to agree with the previous GP, GP2_P2_CCG2, as he explained *"you're testing rheumatoid factor, but you can't remember the name of anti TTG and you certainly can't remember what TTG stands for, then you've got a problem"* (GP7_P9_CCG5). Also, the practice manager at Practice 3 explained how it would be *"more useful if it picked up in a different variation [of the words] when you searched" and gave the example of* "*X-ray electronically you searched it, do you do an X and dash R, or just X R"* (PM1_P3_CCG3).

5.2.4. Placing the order (creating an electronic test request)

Before finally placing the order, the ICE system also provides the option of picking the time to collect the sample such as "*sample can be taken later", which means that it "will stay in the computer and then phlebotomist take the sample she prints out the request that I request online"* (GP1_P1_CCG1). A head receptionist at different practice also described this option as *'helpful, [as] it makes it difficult to lose a test as it is entered in the system"* (RM8_P13_CCG4). Another head receptionist from different practice explained how this request could be on the system "*two days later or whatever"* (RM2_P6_CCG5). In this case, when the nurses see the patient *"they don't create a request, the request is already there - by the person who saw them in the first place. They will then pick that request up"* (RM2_P6_CCG5).

5.3. Transforming orders into results (Collecting Samples)

Features and capabilities of the electronic system used by the practices to place tests, the ICE system, seemed to have little effect of the impact on how the order would become a result based on users' perspectives. The major features, as per participants' perception, were the ability to print the electronic form with all required information and hand that to the patient. This could help the limited number of times transporters would collect samples daily, and how the ICE system provided an audit trail of the test. Participants also talked about how their responsibilities toward the test, at this stage, are limited to place the order via the system and provide the request form to the patients.

5.3.1. Trusting the electronic systems

The exact technicality and mechanism of how the order would be recognised by the laboratories' electronic systems was not investigated in depth as it was unclear in the narratives from all the participants. One GP explained *"It sends to lab. At the lab, they log that and deal with it, I don't quite know what they do"* (GP8_P10_CCG4). A practice manager at a different practice had some difficulty explaining the actual electronic linkage between the practice and the laboratory as she said, "*it's different system but they talk to each other, sorry I am not very technical"* (PM1_P3_CCG3). However, participants in general tried to express their perception about the impact of the electronic systems on the collecting phase by talking about the procedure of collecting the samples. It is also seemed that participants had a great trust in the credibility of this link between their system and the laboratory system, which made their perspectives mainly focused on the clinical aspects provided in the system.

5.3.2. Printing the electronic forms

One GP explained that one of the advantages of using electronic systems is the ability to print a form that included all the required instructions for collecting the sample, which enabled the patient to have the choice to take the printed form and to hand over the sample at different locations *"Lots of different places. It's here and the next-door surgery, where they accept patients from any surgery for blood test […] they can choose where they go"* (GP6_P8_CCG2). The head receptionist from another practice explained how this form made her work easier as she clarified that if a clinician ordered different tests *"haematology, microbiology, and biochemistry - all on one request"* there will not be all in only one form, but *"There will be three of these which come out"* (RM2_P6_CCG5). She also explained that the form will have instruction on *"whatever colour bottle, to put [the label] on which bottle. That comes off, and it sticks on the bottle"* (RM2_P6_CCG5).

5.3.3. Time to collect samples

Participants' narratives addressed the issue that the action of collecting the sample was not entirely controlled by the capabilities of the electronic systems. For example, if the patient provided the sample in the practice, these samples were picked by carriers at specific times of the day. One GP explained how they would need to send a patient to the hospital if they came after "*3 o'clock [as that] would be the last time we can do a blood test"* (GP1_P1_CCG1). Although the responsibility was now with the patient to attend the hospital to get the blood test done, producing a printed form would make it easier for the patients. One GP explained how *"If I do give a patient a blood form today, I*

suppose they could choose not to have it done if they don't want to. That's their choice. I wouldn't follow them up on it" (GP6_P8_CCG2). However, in this particular practice, she also described how *"one of the receptionists will have a look to see whose review is still outstanding [in the system every month]. If they haven't had it done, they'll contact the patient to say, 'You still need to do this'"* (GP6_P8_CCG2). All the included practices, except for P8_CCG2, tended to believe that providing the sample for the test is the patient's responsibility alone. For example, one head receptionist believed that *"Otherwise, you spoon-feed a lot of them"* (RM5_P3_CCG3). But she also mentioned that their *"patients are quite good, really. We don't really get anything that's not sent back [from the laboratory as the sample was not collected from the patient] or anything like that"* (RM5_P3_CCG3). Moreover, one GP tended to *"print off a form which is for the patient as a reminder"* (GP8_P10_CCG4). He *"tended to make the patient an appointment [to collect the sample] and then they will come in tomorrow or next day or whatever it may be"* (GP8_P10_CCG4).

5.3.4. The audit trail (managing requests)

While practices do not tend to print a report of missed tests or missed results in general, the system itself provided an audit trail of the test and its status. One GP told a story of a patient that was asked *"to have some blood tests and he hadn't come back and had them done. I then went on to reorder them [at the next appointment] and the order from the previous time was still down here, this last one. It comes down as, 'Didn't turn up'"* (GP8_P10_CCG4). Moreover, another GP from different practice explained although they *"don't as yet have*

a formal system to check if patients don't go for their blood test or their pathology tests", missed orders will be caught as a *"part of the follow-up of the clinical case [during each patient's appointment]"* (GP9_P11_CCG2). He explained that *"In the actual record we will have a follow up plan, but we don't search for pathology requests that have not been done. Rather, we wait and review the patient as planned in the clinical assessment"* (GP9_P11_CCG2).

5.4. The process of receiving results: opportunities and demands

Implementing electronic systems to deal with test results helps in decreasing the time needed to receive a result, but it forces practices to establish new techniques and methods in order to handle this change of process. This could be one of the reasons that led to the increase in the number of results received daily. For example, participants were satisfied with the results' turnover time, but they tried to developed procedures to ensure that all results were distributed among working GPs efficiently. Also, some practices delegated some GPs' duties to administrative staff to prevent clinical staff from being overwhelmed. Participants also mentioned how their procedures are controlled by the outcome of the results and how the laboratory / hospitals would report the results, *i.e.*, reporting urgent results.

5.4.1. The impact on the time needed to receive the result

There was agreement amongst all participants that adopting electronic systems shorten the time required to receive a test result. One GP explained that "*The current system surpasses dramatically what we used [to be] able to*

do. I think it really very useful" (GP2_P2_CCG2). He explained that adopting an electronic system which is linked to the laboratory's system helped in making "*results back as soon as the results known pretty much"* (GP2_P2_CCG2). On the other hand, another GP from a different practice felt that the current synchronisation between both systems, the laboratory and the practice, was not optimal yet as results *"seems to be on a pull basis that our system contacts the labs, postbox and it pulls them down"* (GP8_P10_CCG4). He explained that results transported to the practice's electronic system via what he called *"a run"* where results "*went to a mailbox, and if there was something in the mailbox, it came to us"* (GP8_P10_CCG4). He expressed that what he hoped to achieve is not just to have a forced run to get the results, but to have a continuous synchronisation between laboratory system and practices' systems "*What ideally would happen is when the result comes off the labs computer system […] It's automatically filed a bit like an email goes"* (GP8_P10_CCG4). In general, all participants had a perception that as soon as the laboratory analysed the sample, they would send it to the practice's electronic system. One GP explained how they knew when to expect most of the results depending on the nature of the test:

> *"For blood tests, next day, usually. X-rays normally a week, and ultrasounds same day as the test, but that depends on how long it takes to do the test, and that could be up to six weeks. The X-rays will often be done within a day or two of request. Histology, about two weeks, and microbiology normally a couple of days"* (GP3_P5_CCG1).

With more results coming throughout the day, some practices tried to develop strategies where they could manage to follow-up results without being overwhelmed. One of these strategies and reasons for them were explained by one head receptionist:

> *"You can't sit there watching the results coming in non-stop. We pick a particular time that we look at them. We try and look at 10:00, then we'll try and look at lunchtime. We tend to move around desks on an afternoon after lunch. So the next girl that goes on to that desk will look about 2:00 and then probably before they finish, 4:00, something like that*" (RM1_P4_CCG4).

5.4.2. Dealing with the received results and the impact of Discontinuity of Care

After receiving the results, different practices used different methods to distribute them among the available GPs. Ideally, each result would be sent to the one who requested it, but with the current GP practices' situation where many of the clinicians are not full-time partners, it is difficult to do so. One GP explained the reasons why more GPs were becoming part time rather than full time partners, and felt that this impacted on how practices follow-up test results. The GP explained that when most of the GPs in a practice are locums or part time, it *"means that there is a dwindling pool of people who do have the responsibility and they have to live with the bad decision-making [where staff should take responsibility for the decisions they're making regarding both*

becoming part-time GPs, and ordering tests that they will not review due to their schedule] of other bits of the system around them. That's a big problem" (GP7_P9_CCG5). He explained that the implication of this situation is that most of the locum GPs, especially the young, are using defensive treatment methods where they ordered a lot of unnecessary test, and others will receive them and act on them:

> *"The youngsters who are locuming practice defensive medicine. In practicing defensive medicine to think that running off eight different blood tests on 60% of the people that they see is a good way of defending yourself from charges of having missed something. As a result, you get a massive number of completely useless tests coming through where others will review them"* (GP7_P9_CCG5).

As a result, practices tried to adopt methods to distribute results among available GPs so that all results would be reviewed properly. The first method is what they call 'the buddy system' where a specific GP will cover the unavailable one. In the buddy system, the GPs will not only receive the results that come back for their own patients, but they'll also receive results for another specific unavailable GPs or as described by one GP: *"So, there are four doctors in the practice, and so we work on two sets of two. So, we take it in, we have a link between two of us that, yes, we cover each other that way"* (GP3_P5_CCG1). On the other hand, in Practice 1, results were distributed evenly among all available GPs:

> *"A member of staff will distribute them [results] accordingly to ideally the people who requested them or because of our [five GP] staff are part time those would be distributed evenly amongst the GPs and some for the nurses who requested them. (…) There is no specific persons they would goes to*" (GP1_P1_CCG1).

The third method is what they called the duty doctor, where there is an allocated GP who will only handle the abnormal or urgent results of the unavailable GP.

> *"Duty doctor in this practice is, one doctor each day is responsible for all urgent requests, all requests for medication, all requests for urgent appointments goes to the duty doctor. So you are responsible for, if a patient rings up and says, 'I need to be seen,' or there is an urgent problem you are the Duty doctor. And also any faxes that come through from the hospital that require immediate same day action"* (GP9_P11_CCG2).

5.4.3. Accommodating the high number of results

Some practices tried to assist GPs by decreasing the number of normal results that they received in their inbox, so they would focus more on the abnormal results. In one practice, for example, a member of the admin team would go through results, especially swab and urine results, and identify those that were abnormal and place a yellow flag next to them using the practice electronic

system so that the GP would be easily able to recognise the abnormal one. The head receptionist at practice 6 explained how there is an ability, on her results screen, to flag some results manually. She explained that the reason for that because some results, such as urines or swabs, do not come with any alerts or flags when it is abnormal, whereas abnormal blood results got a red flag.

> *"I would go into each result [urines], put a little yellow flag on so the doctor knows instantly - when they look at their screen - that all the results with a red arrow are abnormal. Also, C&S [Culture and Sensitivity], bacteria, if a swab has been done, I would put a little yellow sticker on those on the screen. Then, that alerts the doctor, straight away, that all of those are abnormal. They can concentrate on those ones before they do the normal results, in case we need some antibiotics or in case we need to call a patient in - if it's a high result*" (RM2_P6_CCG5).

Other GPs in other practices, P7 for example, believed that it was important for a GP to cover all results equally as sometimes *"normal test doesn't mean that that is the end of the problem. The patient may need more investigations. Even if your patient has got a problem and their test is normal, it doesn't mean that everything is okay"* (GP4_P7_CCG4). As a result, he "[*doesn't] particularly like the system because, even though they are flashed red, there are some other results, which could be equally important even though they may not be flashed. Then, you can miss that, you see. My aim, usually, is to go through*

the whole of the list" (GP4_P7_CCG4). To support his opinion, he gave two examples of results where the abnormal value should be linked to the patient's characteristics such as the age:

> *"The results come, and the abnormal ones are highlighted [if they were outside normal range] but, you see, sometimes, you have results like HbA1c for diabetes. Now, the normal could vary, it depends on how old the patient is and what your target level is, so that doesn't give you that. PSA results, for example: although the normal is before 4, it depends on the age range. It doesn't give you that, you see"* (GP4_P7_CCG4).

5.4.4. Status of results: Normal, Abnormal or Urgent

Laboratory and radiology report results as either normal, abnormal or urgent. Normal results were reported in a black colour and some practices delegate the filing of such a result to a member of the administrative staff (when no action is required) as explained above. Abnormal results usually were reported in a red colour, which helped the viewer to distinguish them from the normal ones. One head receptionist described how the system help the administrative staff to file the normal:

> *"Some come back normal and we can tell because they're colour coded, what's normal and what isn't. We also have a list of results that we're allowed to file, so the full blood counts, liver function results. (…) we have a list of them*

upstairs, exactly the ones that we can and can't file" (RM1_P4_CCG4).

The problem with any abnormal results is that they only get flagged if it have numeric value, *i.e.*, it's a quantitative abnormal rather than qualitative abnormal. For example, a complete blood count has a normal range whereas swabs do not. Furthermore, results would get flags even if they are slightly above or under the normal range, which believed to be a disadvantage by one of the GPs:

> *"It is a bit of a frustration when a lot of the just outside the normal range get flagged up as abnormals. There can be discrepancies between the ICE's use of the normal range and the clinician's use of a normal range. (…) In full blood counts, in particular, you see a lot of minimally outside the normal range that are flagged up as abnormal results and actually they're all normal results. That's a bit of frustration sometimes"* (GP7_P9_CCG5).

The urgent radiology and laboratory results were reported differently. One GP believed that their local radiology department were very anxious to make sure that the practice received and acted upon the urgent results, which was describe as *"belt [and] braces and a bit more protection than what we actually need" (*GP2_P2_CCG2). He explained his opinion by describing the process:

> *"It will come to us in three different paths. It will get faxed, it will come with the electronic message within the ICE*

*system, and it will also appear in our inbox as well. […] on the ICE screen where we order test, you can see it, they call it ICE mail […] Two methods fine, but a third one really" (*GP2_P2_CCG2).

For the laboratory, they only add a telephone call. The reason for the telephone call according to one GP is to speed the process *"up by a couple of hours"* (GP6_P8_CCG2). After receiving urgent results, practices seem to have similar protocols, which was best described by one of the GPs who worked at Practice 5:

"Urgent Results tend to come in by phone, and are written down. So, the receptionists have a policy on how they record the details of the phone call, so that they know that they've got the right person's details checked from the laboratory, and they check a couple of times to make sure they've got all the numbers right. If they haven't been electronically sent through yet, and those are then sent as an electronic task straightaway to the GP that most likely knows that patient. Or if there's only one on duty, the GP on duty, to then decide on what to do. So, again, there will be an audit trail available, because it's been electronically recorded" (GP3_P5_CCG1).

It was clear from the interviews that adopting electronic systems for test results management shifted the worries from ensuring that the results were received

to methods for handling the increase in results received on a daily basis. The use of the electronic systems to produce tasks in order to deal with the results, and what staff perception were on the impact of the electronic systems on the acting stage will be discussed in the next chapter.

5.5. Summary and Conclusions

- The implementation of electronic systems at general practices in UK has become established, where staff now consider them as the main method to order and to process test results.
- Staff in general practices believed that using electronic systems improved the level of daily activity compared with the old paper-based systems.
- Participants did not fully understand the linkage between the ICE and their systems, or how their systems were linked with the laboratory/hospital system.
- Although the ICE system is universal, it had to interface and integrate with the practices' own system, which required extra steps in order to have access to it.
- Due to security and confidentiality reasons, providing access to the ICE system for each new member was frustrating.
- In general, most respondents felt that the system worked well, but in cases of internet or system breakdown, it is a huge problem going back to the paper-based systems even for a few days.
- The menu features seemed to be easy to use and the pre-set list of tests provided help to the users and made the work faster, but the test order search tool could be frustrating.

- The electronic systems provided the option of printing the orders, which enabled patients to provide their sample at different sites.
- An audit trail provided advantages as it allowed staff to track any order and to know what occurred to the test order at each step.
- Although the electronic systems allowed the flagging of the results to minimise the GP's workload, this could represent a patient safety challenge if the responsible GP was not aware of all the results.
- The interpretation result needs to be linked to patient's characteristics and not disregarded based only on being at the normal range.

Chapter 6: The impact of health information technology on reviewing and acting on test results based on staff perceptions

This chapter analyses and discusses the views of primary care staff in general practice about the impact of health information technology on the reviewing and acting stage, which is the last stage of the test results management cycle. The process of acting on test results is summarised, and the workload associated with using electronic systems to act on results is explored based on participants' perspectives. Health care practitioners' opinions on how the systems facilitate the daily activities related to test results follow-up are discussed. Also, general practices staff perceptions about the role of the hospital and laboratory staff in test result management in the era of electronic systems is discussed.

6.1.1. Adopting a specific electronic system

All practices included in this research used either SystmOne or EMIS at the time of the interviews. Some practices formerly used the Vision as their electronic system for test results managements, but they changed it to one of the other two systems. Two practices (P5_CCG1 and P10_CCG4) changed their system in the six months prior to the interviews and were asked about the reasons for this change.

One GP at practice 5 explained how the decision was related to NHS policy 'politics', and was not due to any problems they faced while using the old electronic system, or because of any advantages regarding the new system.

> *"The area we're working in wanted people to work on SystmOne. So, we held out for quite a long time, but we were the last practice, and we thought we should, so we did it for politics rather than anything else."* (GP3_P5_CCG1).

The GP at Practice 10, which was located at different Clinical Commissioning Group (CCG), also conveyed a similar perception as he explained the reason was not that there were any problems with Vision, but the general trend was toward SystmOne.

> *"There was a lot of pressure on people to move to SystmOne, despite the fact that all systems were of equal standing. Because our system was not time-expired, we didn't reach a time when we had to change because Vision continues and has always continued. We never faced a decision of having to change, it was a voluntary decision. Quite a lot of people came to us saying we need something new, and that's what they were persuaded to go for"* (GP8_P10_CCG4).

While discussing reasons behind adopting a specific system with GP8_P10_CCG4, the GP explained that part of the reasons was the presentation given by the Vision system prior to adoption:

> *"We got them both [Medittel and Vamp] to come and present to us, and the person who presented the Medittel, which is what everybody else was using, was so abysmal at the presentation […] and we went with the other people who came across. We stuck with them […] and it became Vision"* (GP8_P10_CCG4).

The interview results highlighted that there were no particular reason related to the system itself for the adoption of one system or another within the practice. The decision seemed to be based on local factors. The important issue was that whichever practice system was selected, it needed to be compatible with the ICE system, which is essentially hospital laboratory based.

6.1.2. Electronic systems and managing test results

Regardless of the electronic system's trade name, it is worth noting that all interviewees believed in the huge advantages that the electronic systems offer in making their daily tasks of following up test result easier than what used to be with paper-based systems.

6.1.2.1. The electronic systems and acting on high number of results

As mentioned previously, the number of results increased, but this theme discusses how the electronic systems could help in decreasing the workload. For instance, one GP mentioned that *"in average day and first thing in the morning I might have 30 results to look at"* (GP1_P1_CCG1), and he also mentioned that it would reach *"60 or 70 and get 100 results each day some time"* (GP1_P1_CCG1). He also mentioned that reviewing and following up

these results would take him around half an hour, and his perception was this is "*not very long [.] In an average day, I really guessing I had never timed it. Less than half an hour"* (GP1_P1_CCG1). One GP expressed his opinion regarding the advantages of using electronic systems as he described a GP who is not using them to execute tasks as living in the dark ages:

> *"I have a friend in other practice […] She was still doing everything on paper, and the results were coming in if someone to sign they should look out there. That's just out of the dark ages now, isn't it?"* (GP6_P8_CCG2).

6.1.2.2. Efficiency of the electronic systems and results handling

The perception of how electronic systems made acting on, and filing results, especially normal results, more easier and faster was shared by a GP as he said:

> *"Its probably two clicks to say normal. As it comes up yea it's in fact one click / two clicks, two clicks to say something is normal. If they are normal you can move them fairly quickly"* (GP2_P2_CCG2).

In addition to the easy to use and file in normal results, he also viewed the automated system as "*a big step forward"* as it helped him as a GP to

> *"Set up your referral to the gastroenterology for instance, a letter template can be setup that has all automatically draws through blood test"* (GP2_P2_CCG2).

In addition, he also believed that using the electronic system helped him to follow-up results in more convenient fashion:

> *"It's a nice little simple way doing it without passing some paper work, having to remember to catch somebody in the corridor to do something for you. You can get through to the 100 test results and actions what need to happen relatively quickly"* (GP2_P2_CCG2).

Although this GP's perception would indicate an improvement in patient safety by not having to catch somebody in the corridor, he mentioned this point in the context of the convenience rather than safety.

The perception of the advantages provided by the electronic systems in performing the work efficiently and more timely than the previous paper-based system was also shared by administrative staff. One practice manager said that she believed that the electronic system is *"pretty good. I think it's quite efficient, it's easy to use, it's certainly is much better than paper. Much better than paper, Much better than paper"* (PM1_P3_CCG3). She elaborated that the reasons for this superiority over paper-based systems is that the paper system is time consuming and may lead to loss of test results "*you have to wait for the paper to arrive, you may lose it, it might be settle in somebody's desk somewhere that we don't know where is it"* (PM1_P3_CCG3). Whereas, she perceived the electronic systems as integrated system *"all in one place, it' all automatically, integrated into the patient's record, we don't have to do that manually but with the paper you do. Amm it's quick, it's efficient"* (PM1_P3_CCG3). In addition to the convenience and improved patient safety,

the context of the later quotation was the perception of how much quicker and more efficient the electronic systems were in comparison to the paper-based system.

Another GP from a different practice shared a similar opinion on how the electronic systems would improve patient safety by decreasing the chances of losing a result. He compared what used to happen with paper-based systems and how they "*had a pile of paper results. Things can get lost, results can get lost" (*GP9_P11_CCG2). Whereas he felt the electronic system helped to make the daily work more "*organised […] we just have to make a comment and that get passed to reception." (*GP9_P11_CCG2).

The perception that the electronic systems would help in improving the daily task was also shared by one of the GPs who adopted a new system recently, P5_CCG1. This GP mentioned that one of the system's capabilities he liked was giving the GPs the freedom to either act on the test or to ask other members, clinical or administrative, to act on the results:

> *"I can either file it with no action, or I can file it with an action, and the action could be to generate a prescription, or to get somebody in, or to repeat a test, or to do further tests. Those actions are electronic tasks that can be done by me, or can be sent to a receptionist to, again, deliver the next step in the chain"* (GP3_P5_CCG1).

The practice manager at P3_CCG3 mentioned that she liked some specific system's capabilities. She mentioned that the system they adopted in the

practice had a lot of automated capabilities, such as assigning specific GP's results to another one in case the first one is not on duty, *i.e.,* automated buddy system. This helped her doing her tasks in addition to decreasing the risk of missing test results at follow-up:

> *"Within our system that there is a way to redirect pathology results, which is fantastic. Because that's used to be, you know that's could be quite difficult. One GP not realising that somebody is off and didn't pick the results so have to remind him versus this way we can just send it off automatically which is quite good. I really don't have any dislikes to it"* (PM1_P3_CCG3).

Moreover, another head receptionist at another practice emphasised that the electronic systems provided her with a clear view of what she needed to do:

> *"It makes our job easier, in that it's very specific. It's very ordered, there's no black and white. It's what we need, this request, and this is what we need to do. To meet our needs, it's just very specific, there's no black and white. It's very instructive in what we need to request, or what we need to tell the patients (….) we just act in with instructions from the GPs. Then it's there, all the information that we need to do, what we've been asked or told, is there for us to do"* (RM4_P2_CCG2).

Executing daily tasks appeared to become easier, quicker and more convenient in comparison to what used to be with the paper-based systems. The interviewees did not only focus on the patient safety aspects and how the systems would help to potentially decrease the risk of errors but also improve the care provided. The participants believed that making tasks easier to conduct led to better patient care. Some of the emphasis on workload was thought to be realistic and practical as GPs could be overwhelmed with the number of results received on a daily basis. This specific point of comparing what is optimal in terms of patient care and what is efficient in relation to the significant volume of results received was mentioned by one GP when he said:

> *"There are a lot of things that you could argue would involve us in care of our patients, but it is about being efficient as well. Ultimately our workload is ever increasing and it seems to be everybody in hospital who is in doubt will send the job for the general practitioner as we have nothing else to do"* (GP1_P1_CCG1).

Another GP clarified that although he preferred to go through all the results regardless of their status (as some normal results may sometimes require further investigations), it was difficult to review them all and to contact all patients. He also emphasised that a GP must be realistic as he explained that *"[GPs] don't have the physical time to deal with all these queries. You just have to deal with them the best way you can"* (GP4_P7_CCG4).

6.1.3. Electronic systems workload and handling normal results

Some GPs believed that reviewing normal results would increase their daily workload and preferred other members in the practice to have the authority to file them. For instance, one GP believed that having *"somebody for example in the administration team who is able to file normal results confidently, completely normal results, and yea that I suppose will be fine"* (GP1_P1_CCG1). Although Practice P1_CCG1 did not give this authority to the administration staff, another practice, P4_CCG4, used the electronic systems to give the reception team the responsibilities to file normal results, which led to a decrease in GPs' daily work:

> *"Because the staff are filing the normal the doctors don't get that many to deal with in the day, so they usually get through them"* (RM1_P4_CCG4).

As mentioned in the last chapter, other GPs at different practices believed that reviewing all normal results could be as crucial as the abnormal ones. One GP explained that he preferred to review all the results by himself. He did not like the electronic system *"because even though [Results] flashed red, there are some other results which could be equally important even though they may not be flashed. Then, you can miss that, you see. My aim, usually, is to go through the whole of the list*" (GP4_P7_CCG4). This indicates the importance of reviewing the normal results in the context of the patient's condition and symptoms.

Another GP at another practice believed that one of the problems with the electronic systems is the flagging of a lot of clinically normal results, which might be slightly abnormal but do not have any clinical effect. He described this as *"a bit of a frustration when a lot of the just outside the normal range get flagged up as abnormals"* (GP7_P9_CCG5). He admitted that *"clearly that's always going to be the case. Wherever you set your range, there will be results come point one of a place outside that range and therefore reflect up as abnormal"* (GP7_P9_CCG5).

Another GP explained that filing normal test results is relatively quick, but the problem appeared when filing normal results that he did not order. He needed to know at the least why these tests were ordered:

> *"So for instance, if I did my bone blood test I would know the background. I would know the reason for the test. I can check it quickly. However, we also get results from the nurses. So the nurses may arrange for a blood test. Or I may get, for some reason another doctor may have arranged the blood test, but the result has come to me. In that situation, I have to go into the clinical record and read the history, find out why the test was requested, and then make a decision about action. So yes, if I have arranged it, it's straight forward. Somebody else has arranged it, takes more time"* (GP9_P11_CCG2).

Regarding who should review normal results, some practices try to stay at the middle ground by asking the help of the administrative staff, but not in filing any

results. For example, some practices asked for administrative staff to go through results and put a flag on abnormal results that do not appear as abnormal. This could include but were not limited to urine tests, swabs and antibiotic sensitivities. Thus, as these type of results do not have normal values, the electronic system does not flag the abnormal one with red, and someone needs to go through them to find if any abnormality is presented. This increases the workload of the GP according to one head receptionist:

> *"Before we flagged, obviously, the doctor would have to go into each single result. They may have 10 urines. Only 2 of them might be abnormal, but they would have to go into each result. This way, we put a little yellow flag next to the result and they can instantly see which ones they need to go into. That works well because it alerts the doctor to all their abnormal... So they would do all of the little yellow ones first, and all of the bloods that have a little red arrow on. (…) Anything with nothing next to them is a normal result. On a very busy day, they know that if they get their abnormal results done the normal results can maybe sit there until the next day - or later that day"* (RM2_P6_CCG5).

Also, other practices allocated some patients and results to a nurse to deal with especially for long term conditions and annual checks. One GP said that in his practice *"If the nurse has got competence to look at the results, they look at the results"* (GP4_P7_CCG4). He mentioned that they *"If [the nurse] get an abnormal result and they're not sure what action to take, the nurses will send*

me a task about the abnormal result. 'Can you have a look at it and advise?'" *(*GP4_P7_CCG4).

In summary, although healthcare providers would consider patient safety as their ultimate goal, but it seemed that some of them consistently point to workload as the primary risk factor for patient safety and that they use the context of convenience to address the positive impact of electronic systems on patient care.

6.1.4. Staff habits and electronic systems

In general, GPs seem to have different techniques when they have to act on complicated results using the electronic systems. Some GPs tended not to file these kinds of results until they decided what to do, as one GP explained this method:

> *"I tend not to file it until I'm ready to file them. Sometimes it happens when you look at the result, 'Not sure what to do with that.' I will leave it for a day, speak with colleagues and then file it the next day"* (GP6_P8_CCG2).

Another GP mentioned that he used to not file the complicated result but leave it on the system, so it would be there as a reminder for him to recheck it, but he had changed his method and now he *"send a task [to himself] saying look at this abnormal results"* (GP1_P1_CCG1). He explained that he changed his method to let the reception staff know that he looked at the results but needed more time in case the patient called:

> *"If the patient was to call and want to know the results, will at least they would know it was abnormal and they need to discuss with me. But if they don't call then it will [be] left with me to sort out."* (GP1_P1_CCG1).

Also, some would send and transfer the complicated results to other GPs for their opinions, especially if someone else ordered them. One GP explained this method:

> *"If the tests are looked at by somebody else and they're not sure what action to take, it can be sent to somebody else to have a look at. Sometimes, you send it to a colleague and say, 'Look at this result. What do you think? Should we do anything?'"* (GP4_P7_CCG4).

Other GPs preferred to discuss difficult results with other GPs in person, so they would leave it unfiled until they meet. One GP explained that he used this method as the staff tend to gather almost every day for a meal and to discuss such matter:

> *"We sometimes, I will see a result and I will say I have no idea what to do with this and we'll have a talk. We tend to meet about 10:30 every day. The part, the people, the doctors that are here tend to meet and we normally talk about some systemic issues about something I'm concerned about this or what do you think of that or I've had*

*this failing result, what do you think I should do with it?" (*GP8_P10_CCG4).

It appeared from the previous quotations that the electronic systems provided features that allowed GPs to choose the most suitable action when they were dealing with complicated results, and that some GPs would change their technique after using the system for a while.

6.1.5. Familiarity and efficiency: linking results with patient records

One GP mentioned that although the system provided some important features, he also believed that getting in and out of the patient record from the results page was not that easy:

> *"I think it's fairly speedy. Easy to look at old results and compare, I think that's an important thing, and not that difficult to then organise follow up messages or tasks after that. Slightly more difficult getting in and out of somebody's records from the results page"* (GP3_P5_CCG1).

Part of the reason for his opinion may be due to the fact that his practice implemented a new electronic system a few months prior to the interview. He hinted that once he got used to it, it became easier to use:

> *"I think it could be a little bit easier to get into the individual person's notes. Yes, so, rather than being seamless, to go backwards and forwards between things is slightly tricky,*

*but it's not hard. Once I've got used to it, it doesn't feel difficult at all to do that" (*GP3_P5_CCG1).

The same perception of familiarity with the system was also shared by another GP, who worked at two practices, which adopted two different electronic systems. As he said: *"Now admittedly, I'm always going to prefer the system I'm more familiar with"* (GP7_P9_CCG5).

6.1.6. Using the ICE system to overcome practices' electronic system limitations (for more precise and productive outcomes)

While practices adopted their electronic system to view and follow-up results, some GPs felt the need to access the ICE system (the hospital system) to have more accurate context of the results and to compare them with previous ones. One GP mentioned that if he *"was in a patient note or wanted to. He would view them on ICE on the computer system that [their] hospital used"* (GP1_P1_CCG1). He explained that the main reason for this is to know all the tests that have been done for the patients outside the practice, which would help him to compare the current one with old results from the hospital system:

"Our system on the computer only would have direct view of the test we requested, so we don't have direct view of test that [was] done by other clinician on our patients. So we have to actively go looking for those […] I think it good for use that I can have a results, for example, if I check kidney function and somebody GFR is low. If I just highlight this

GFR, it would tell me what all previous results are, so it would be useful" (GP1_P1_CCG1).

Using both systems was also done regularly by one GP, who worked at different practices:

"Because ICE system a universal tool we can see the blood test of that patient that had been done elsewhere on systems that use ICE […] I can see the blood test that they had done in the hospital during the admission so I can compare, contrast and compare what I have got with what was actually found 2 weeks previously by somebody else and you can see changes, which was all was very cool beforehand" (GP2_P2_CCG2).

The same GP also believed that this capability not only helped him to sort out the result in the right context, but also to decrease the need for unnecessary repeated tests:

"you are looking at and thinking well I have got haemoglobin here that said it 8 now ... something gone on in last two weeks,,, We can do that now and we also don't have to repeat things that already" (GP2_P2_CCG2).

One of the reasons for relying heavily on the ICE system could be as explained best by one head receptionist, who worked at different practice, as she said that it does not feel really like 'two systems' rather than it feels like *"ICE is*

integrated into our system, so it's not really two systems. It's all part of the same thing" (RM5_P3_CCG3).

6.1.7. Finding the results' trend

Some GPs felt the need to go through old results as they are not familiar with the patients or why the current test was ordered. One GP explained that most of the results they handled were ordered by someone else, which needed to be reviewed thoroughly

> *"What I don't like is I get an awful lot of tests. And a lot of them, I don't organise. I don't order not many tests, but I seem to get an awful lot. I think a lot of it comes from the nurses, a lot of it comes from the hospital. Other tests come from other doctors"* (GP9_P11_CCG2).

Another GP, who worked at different practice, also believed that knowing the '*trend*' of the results would help her not to take any unnecessary actions for some results:

> *"If some patients have abnormal liver function but that's normal for them. Sometimes, you want to go back a few results to see if it worse than usual or if this is normal for that patient."* (GP6_P8_CCG2).

She also mentioned that the system provided a handy search tool, which enabled to track old results straightforwardly and made knowing the result's context an easy task:

"It's very handy. For example, if I'm looking for a set of liver tests that are abnormal, if I go into the patient's journal and to put, 'liver' in the search box, it'll bring up everything about liver function tests. That makes it quite easy to look back." (GP6_P8_CCG2).

Other GPs from different practices believed that some improvement in system capability to retrieve old results could help in making their job easier. One GP mentioned that knowing the right context of the results when covering for somebody else, and making decisions on tests are not that easy:

"The main difficulty is getting somebody else's results, so you're not aware of the patient. You might know of them, but you don't know exactly what's happening. So you're having to spend more time, and also not always clearly understanding what the test has been done for, and I think that is always a slight problem." (GP3_P5_CCG1).

Another GP from different practice agreed that the electronic systems helped him in knowing the right context of the results by viewing and graphing old ones easily, but he considered not having results prior to 2008 is a negative issue:

"I suppose the not useful thing is if you want any results prior to that (2008), they're not accessible on the computer system. It's only really relevant if it's a histology result or someone says they had an abnormal smear test many

years ago and that might not be on the system. We can't access them very easily" (GP6_P8_CCG2).

6.1.8. Electronic Systems and Staff Responsibilities

As the clinical staff responsibilities differ from the administrative staff, the system provided a different screen interface and authorisations based on what the specific user needs to do. One head receptionist explained this issue as she said *"they'll* (the GPs) *just see it for theirs, because they can look at it slightly different"* (RM1_P4_CCG4). This was also mentioned by another head receptionist at different practice, when she explained that her screen is different from others in the reception team as she is the head of the team:

> *"Only I get the results. The rest of the staff won't get the results. They only get tasks, I get the ICE but I go into ICE to get that. It's called Workflow Manager. In Workflow Manager [which is a tab that appeared only to the reception manager] you have a higher level to be able to action results and action things that"* (RM2_P6_CCG5).

Some GPs complained about the workload associated with following-up test results, especially when the work seems unnecessary or the responsibilities are somehow ambiguous. One GP criticised how the Radiology Department sent a lot of repeated results, in addition to the results that would be handled entirely by the radiologists at some stage. For the repeated results, he believed that this could not only cause extra work, but also affect patient safety.

> *"With radiology, for some reasons we get two copies of electronic reports. I have no idea why. And that unnecessary works and as I said you could question it as it could lead to safety risk (….) If I have 100 results in a day I don't want 20 of those to be repeat and test unnecessary time spent doing something like that, so that a frustrating […] sometime the duplicate results can come back two days later, so I could get one work on report and then two days later another reports"* (GP1_P1_CCG1).

Also, another GP from different practice believed that laboratory could do more work, especially with swab results and results without numbers, which the system does not flag automatically:

> *"That could be an abnormal swab result. If there were some way that they could highlight that it needs attention or it needs particular attention, but I think that would require somebody there, on the other end, making that note. So, it's going to be time-consuming at the other end. Yes."* (GP9_P11_CCG2).

6.1.9. Methods to deliver urgent results

One of the respondents, a practice manager, believed that laboratories and hospitals would call if urgent results appeared. This made the practice feel that although they often received abnormal results, they were not urgent unless there was a call from the hospital:

> *"If there were an urgent result, the lab will ring us. So, we don't have to worry so much about the inbox being completely empty every day. because if there is something that needed to be acted upon immediately, we will receive a phone call from the hospital to let us know immediately and there is protocol to follow for that"* (PM3_P3_CCG3).

Calling to inform practices about urgent results allowed GPs to act on the results right after the telephone call, even if the results are still not in the system as one GP explained:

> *"Adapt on their results anyway. If I've spoken to the lab and they tell me haemoglobin is four, I won't wait for it to come back. I'll contact the patient and I'll organise something*" (GP6_P8_CCG2).

Using means other than the electronic flags to ensure that the practice was informed about urgent results would indicate that the current automated systems may need some improvement in this area.

6.1.10. Reducing errors (safety net)

Some interviewees explained how the electronic systems helped to minimise clinical errors through reducing the number of missing test results by providing a safety net. One of the prime procedures that electronic systems offer is how they help in preventing accidental filing. One GP explained that *"It only become*

filed if I resulted [picked the proper action] as normal – no action, or normal action or whatever. It can't be filed accidentally" (GP1_P1_CCG1). Also, another GP mentioned that results will stay in the GP's screen unless a decision is made *"they can't actually be cleared out from somebody's inbox unless he viewed them"* (GP2_P2_CCG2). According to him, and based on this feature, his practice does not run a review to explore if any tests were missed, and they rely on the fact that everyone knew that results must be checked by GP. This led to the absence of clear guidelines that put a timeframe/deadline to act on results:

> *"I don't think we can routinely see ones that haven't been viewed, but we don't need to. (short laugh) because they all get viewed […] We never needed to make it a role, let's put it that way... I think everybody leave their path link clear at the end of the day, and you just accepted that that's what you do, that a part of your day's work is to make sure at 5 o'clock all the Path link had been looked at which is relevant to you and any action had been taken"* (GP2_P2_CCG2).

This perception was also shared by a GP at another practice as he explained that although the practice did not have a written policy, everyone knows the procedure and what should be done:

> *"We don't have a written policy, I don't think. Yes, but I think everybody is aware of the procedure. Everybody is aware of their role, and everybody is aware that it is important for tests not to go astray, that they all should be looked at by a*

clinician, and then followed up properly if they need to be followed up" (GP4_P7_CCG4).

From the administrative point of view, the practice manager explained that although the responsibility to act on the results is part of a GP's daily work, it is also part of her job as practice manager to make sure that GPs will check all results and manage them on a daily basis:

"My particular role is making sure that all the results that come back to the practice are acted upon on a daily basis. To make sure whether they being abnormal or normal results" (PM1_P3_CCG3).

This was also a job for the reception team in other practices. One head receptionist explained how she tended to run a report every few days to check if any results are still pending in the system:

*"If doctors haven't looked at the pathology results for a few days then I tend to send a reminder or one of the reception staff will send a reminder saying, 'There are still a few results there, please can you check them.' We follow up on that in the background as well" (*RM1_P4_CCG4).

Also, another head receptionist at another practice explained how the outdated results appear in a different colour so the reception team would catch the old ones; she said: *"Anything that isn't today, it puts the date as red"* (RM4_P2_CCG2).

6.1.11. Using the system for communication and using the audit trail

One of the common trends among the interviewees was how they used their practice's electronic system as the main method of communication between each other regarding test result management. Practices' electronic systems provide what they called a 'task system', where staff sent patient-related inquires to share with others. One GP explained that he used the tasking system to communicate with the reception team about what they should do with the results:

> *"Usually if something action is needed then we send message to the appropriate team for example, I may send a message to the administration staff say please contact patient X and advise them that they need to have a phone call with me or please could you arrange for patient X to have a repeat blood test within however long that would be a kind of thing we did"* (GP1_P1_CCG1).

As mentioned earlier in this chapter, some GPs use the tasking features as a self-reminder by sending a task to themselves. One GP stated that GPs would *"task ourselves to do something with that results"* (GP2_P2_CCG2).

Another GP explained that the system provided the option to either write the original task, or use one of the readymade templates:

> *"On the task thing, you can use a standard form that says the result is normal, or abnormal, and then you can also have a free text box. Which gives you the chance to write*

something down, to say, 'This is what you're going to tell to the patient'" (GP3_P5_CCG1).

Also, another GP explained that the tasking system allowed the sending of tasks either as normal or as urgent, and either to a specific person or a group of people:

"Actually if I want to make it urgent, I would just click that box... I'll send it to me and you can see what happens at the other end. (clicks) okay, task created about a patient, I am gonna send it to me, but it could be to anybody or group of people, he clicks send and my tasks have appeared here, and you can see that there are three tasks and one of them has been marked as urgent" (GP2_P2_CCG2).

From administrative point of view, as the system enabled tasks to be sent to a group of people, and due to the high number of tasks, one head receptionist believed that more than one person could end up working on the same task. One head receptionist explained that although the tasking system tried to prevent this issue by indicating that someone else is currently working on the exact task, duplicates still existed.

"Because we can both be doing it at the same time. We have had that where we're sending letters out and we've both got the same letter. You can't if you put the ICE request on. If you put the request for the bloods or whatever sample it may be, you can see that on there. You can see that

someone's actually done that so I won't do that one. But we do manage to swap over occasionally" (RM4_P2_CCG2).

To overcome this possible problem, some practices allocated a specific desk to act on the tasks. One head receptionist from another practice expressed how the reception team had to allocate a specific desk to execute actions that come as tasks from GPs:

"We have one desk that's allocated for it upstairs that somebody deals with the results and the actions and does a little bit of paperwork. That's their main job on that particular desk" (RM1_P4_CCG4).

This quotation indicates that some practices needed to modify their daily activities and job description to accommodate the way the ICE system and the practice's system normally deliver the results.

One GP explained how GPs are relying more on what they called 'the tasking system'. The tasking system is the feature of the electronic systems whereby the practice's staff can communicate with each other internally regarding test results:

"It's very easy. It's just opened-- We have a group called reception, it goes to the reception group and then all the receptionists or intern take turns to check that and make sure all the tasks are completed by the end of the day" (GP6_P8_CCG2).

To illustrate how practices rely on the tasking system, another GP from a different practice expressed that even though the partners in the practice are very close and could meet daily over lunch time and discuss patients' situation, they still used the task system to communicate with each other regarding patients test results:

> *"We are a very close practice in terms of the partners. We tend to communicate with each other quite a lot. We know that some doctors are good at some areas, but have their own interests.* […] *If the tests are looked at by somebody else and they're not sure what action to take, it can be sent to somebody else to have a look at.'"* (GP4_P7_CCG4).

Part of this attitude could be explained by the fact that the task is connected to the patient records, which made it easier to view patient results. One head receptionist expressed that the task system provided an audit trail, which documented all the actions that have been made to the request, and the patient in general:

> *"If you do it as a task it's connected to the patient's name and there is an audit trail. We can see that the doctor requested reception to ring the patient on Monday. Then the receptionist, maybe, has tried to ring the patient and there is no answer. They'll put, 'No answer' and continue that task. By Friday, if that patient then turns up poorly, the doctor may say, 'I asked you to contact the patient, why wasn't that done?' We can say that there is a clear request,*

and then the receptionists have tried to contact the patient, but they got no answer. There is a clear audit trail that we can go on" (RM2_P6_CCG5).

Another GP expressed that having a clear audit trail for actions is one of the most useful things about having an electronic system in general, and using the tasking feature in specific:

"The most useful, there's an audit trail. So if I leave a message, I know it's on the system. It's not on a piece of paper and it will get lost. So there is a clear audit trail, it's clear who's responsible. If I've done the test, my name is on it, it will come to me. I have to action that test. If somebody else does it, I know who did it. I know who actioned the test. So it is clear who ordered it, who actioned it and I like that. I like the clarity and the responsibility is clear. I like all those things" (GP9_P11_CCG2).

Although using the tasking system comes with huge advantages, another GP mentioned that a new problem of 'over use' of this service could appeared:

"The system is quite good when we're using the IT for communicating, but you can end up overusing the task system (…..,.) it's very easy for some people to just send a task and then it's out of your domain" (GP4_P7_CCG4).

Also, as the interviewees expressed earlier, the tasking system is used to communicate actions, which mainly are orders to contact patients. One head receptionist expressed that most of the requests to contact a patient came in a form of tasks, which also showed how urgent the contact should be:

> *"Mainly contacting patients is done by the task. […] If a doctor wants it to be done straight away then they'd red-flag the task. It would come up in red so that the girls know which to look for them first, and obviously they stand out so we do them first. We work in order priority and they get checked every day from when we open at eight until we close at six o' clock."* (RM5_P3_CCG3).

6.1.12. Working without an internet connection

Some participants mentioned that one of the things that the electronic systems would offer is that the system would provide some functionalities even with no internet connection, which limited the need to return into the actual paper system. One head receptionist explained how their system would still allow them to see a patient's record, but not to add or alter any information:

> *"Even if the internet is down, and you've got no web at all, you can go into - what we call - PC mode. That lets you see a patient's record. You can't add to it, and you can't alter it, but you can see a patient's record" (*RM2_P6_CCG5).

The practice manager explained that most of problems with the connection would be resolved quickly:

> *"Generally, if we face any problem with the system working, it has to do with the network connection or so rather than the actual program itself (….) it can resolved immediately. If there is a problem we ring the IT help desk if it is with the computers"* (PM1_P3_CCG3).

Also, some practices tried to continue their services, even without any internet connection, by providing continuity plans by going back to the paper system. One GP explained that although they try to provide clinical services with no internet connection, they would not be able to do it for a long period.

> *"We just have to stick with our continuity plan which we go and fall back on hand-written prescriptions paper records. We can manage that up for a few days, but we probably couldn't manage it for very long because we do need to be able to access test results and act on them"* (GP6_P8_CCG2).

6.1.13. Contacting patients after receiving a test result

In general, several elements would influence how GPs would contact a patient regarding a specific test. The patient's attitude, the type of the result and the severity of the result would induce how GPs would deliver the news. Although the electronic systems provided features to help practices in contacting a

patient, due to the high number of results received in the practice, most practices rely on the patients to call the practice. One GP explained this procedure in general:

> *"If it's a normal result we will usually mark it as normal and to file. We usually request the patient to ring, to check their blood results. The default position is the patient rings for the result. Occasionally, if I know the patient and they are very anxious I will tick the box for the patient to be contacted and told that the result is normal. But usually, the default is the patient has to ring in. If there is an abnormal result, we usually will contact the patient. There is a box to tick to contact the patient. I usually send a task to the reception or the admin requesting them to contact the patient."* (GP9_P11_CCG2).

Another GP said that although patients wanted GPs to contact them about all results, it is difficult to contact all the patients regarding all the results: *"calling every patients having slightly abnormal is not realistic. So some time patient demands could be difficult"* (GP1_P1_CCG1). He explained that even with the abnormal results, methods to contact a patient is related to the severity of the results:

> *"If it is something with great concern then I would contact the patient by myself as soon as I seen the results. If it is something like I mentioned slightly abnormal function and*

maybe need to be adjusted I would send a message to the reception team" (GP1_P1_CCG1).

The seriousness of the results also controls the content of the message as some GPs preferred to deliver bad news face to face and not over the telephone. One GP explained that although the first contact with the patient would be via the telephone, sometime he would ask the patient to visit:

"Some time, if it can be dealt with over the phone, we leave a message to the reception 'get me/ the urine sample did show you got a urinary tract infection here is the prescription' and that would be a handover to the patient. Occasionally I will phone the patient and say 'we need to see you now'" (GP2_P2_CCG2).

One head receptionist at different practice also explained that some GPs would contact the reception team to contact a patient for urgent results, in case the GP could not get the patient on the telephone:

"If it's something particularly urgent they will try and phone the patient from the room. If they, say, can't get hold of the patient, then they'll send an urgent." (RM1_P4_CCG4).

The practice manager at a different practice noted that sometimes it is difficult to get hold of the patient by the telephone, then they would send a text message:

"What we tend to do, is we tend to use telephone first. Ring them first, we tried ring them straight away on the day. If we don't get a response, we send a text message and nine times out of ten, the patient will actually ring us back within an hour" (PM1_P3_CCG3).

Also, practices tend to send letters in case they are busy, or they could not reach the patient as one head receptionist at another practice explained:

"Depends how busy our phone system is. If the phones are busy, then we'll tend to do letters. If they're a bit quiet, then we'll tend to ring. I would say we do more letters than actual ringing, but if it's an urgent request, we'll always, always ring. The only time we'll ever send a letter is we've had a few attempts of ringing the patient over a day or so, and we're not having any luck" (RM4_P2_CCG2).

One GP at another practice expressed how the electronic systems helped in generating the letters and that's could be part of the reasons why practices tend to use letters for slightly abnormal results:

"We have a patient result template letter, which I might have generated. The result might be abnormal, I'll go to flick into the record, create a document, patient results letter, flick into that, it populates the letter with the address and the name and there's a drop-down box that says we have had the following and it will be a blood test result hospital letter

that come up with how the things are and it would say, 'This is not an urgent matter but please, could you book in for.'" (GP7_P9_CCG5).

6.2. Summary and Conclusions

- Although electronic systems represent a step forwards in test results management, they also presented challenges, such as the increasing number of results received daily.
- It was mentioned that adopting the electronic systems was not the only cause for this increment and that the current status of general practice in the UK with increasing numbers of locum GPs also plays a role.
- There was no apparent justification for why a specific practice would adopt a precise electronic system.
- GPs and administrative staff admired the electronic systems due to its convenience and ease of use, while they assumed that patient safety will be the consequence results.
- Staff are relying heavily on the electronic systems for communication due to its capabilities of providing the audit trail and linking the task to the patient file.
- The current status of using electronic systems could indicate the over use of the ordering features, which may lead to the test being viewed, but not in necessary in the right context.

Chapter 7 Discussion, Conclusion and Recommendations

7.1. Introduction

The main aim of this research was to ascertain the experiences and views of primary care staff in general practices about health information technology and the follow-up of patient test results, and to provide a synopsis of the electronic systems used in general practices. This was done by investigating both clinical and administrative staff perceptions and views based on narratives of their experiences of using these electronic systems. This research used a qualitative approach with semi-structured interviews to obtain an understanding of the process and participants' perspectives, to support the research objectives. The main research objectives were:

- to describe the process and to understand individual staff roles in the follow-up of patients' test results
- to describe different systems' features and setup and how users interface with these systems
- to explore obstacles faced by individuals whilst using the electronic system for follow-up of test results
- to explore the perspectives of primary care staff on how these systems could be further improved for the follow-up of test results in the future.

7.2. Main Findings

The main findings were as follows.

1. The experience of primary care staff (both medical and administrative) confirmed reports in the existing literature about the ease of use and improved efficiency with the newer electronic systems, compared with the previous paper-based systems. This research added information about the way tests results are handled in the practice setting.
2. A new finding, reflecting and adding to the existing literature, was that test results' management was associated with additional workload, sometimes due to multiple electronic alerts about abnormal results. This included the challenge of dealing with results from tests conducted outside the practice as well as results from tests requested by locum and sessional GPs not normally part of the practice.
3. A finding, not previously highlighted, was the frequent disconnect between tests ordered and the issue of responsibility of acting on them.
4. A key finding was around the handling of results by non-clinical administrative staff. There was a blurring of responsibility and duties as to who should interpret the results and act on them. In the event of "normal" results being reported, administrative staff, in most circumstances, were unlikely to flag them for possible further clinical action. This issue was also related to the large volume of results to be dealt with daily (see below).
5. Whilst the electronic system created efficiency in the ordering of tests and receiving results, there was a clear perception that this had been accompanied by an increase in the number of tests ordered. This factor

has been confirmed in a recent study measuring the volume of tests over time (19), and this qualitative study highlights that.

6. A previously unreported finding was that there is an increasing level of discontinuity within practices causing problems with test results. Tests ordered by staff are rarely designated for follow up by a specific individual. Responsibility for acting on results has become compromised, and by inference, this is a barrier to the continuity of care of patients as well as a potential threat to patient safety. This is largely related to the changing structures of general practice whereby continuity is frequently difficult to maintain. There are no standardised procedures for dealing with tests and results and practices vary in how they manage this.

7.2.1. Evaluating health systems based on the Donabedian Model

The Donabedian model is a theoretical model that provides a framework for investigating and evaluating health services and the quality of health care (116). According to the model, information can be gathered in three categories: “structure,” “process,” and “outcomes" (117). Structure describes the actual context and physical setting in which care is delivered including buildings, staff, software and hardware. Process represents the contacts between patients or patient information and providers throughout the delivery of healthcare, *i.e.*, how the structure was utilised to achieve the outcomes and how care is delivered. Outcomes refer to the effects of the system in place under investigation (117). Outcomes deal with the effects on patients or populations,

which include but not limited to, changes in health status as well as patient satisfaction and health-related quality of life.

As described in chapter 3, the structure and process of each stage of the management of test results' follow-up was not identical between the practices but they shared common grounds. Dissecting the structure of the system adopted by each practice for the follow-up of results revealed that it comprised primary care staff in general practices, the actual health care settings, the patients and the previous electronic systems. The process included actions by healthcare staff utilising the structure to achieve the desired outcomes. These actions might have included chasing missing results and ensuring the accuracy of information in order to deliver optimum care.

The structure and process of ordering, processing, and following up results in the practices studied had similarities. For example, they all used the same electronic system to order tests, the ICE system, for laboratory or radiology requests. The use of the ICE system enabled samples to be collected either at the practice or at different places such as hospital clinics and phlebotomy clinics. The participants shared similar perceptions about the superiority of the electronic system over the old paper-based system and they felt that most of their requests in the area of test results managements were met. On the other hand, some participants complained that the ease of use was, amongst other factors, accompanied by an increase in the number of results they received daily. Some also complained that a large proportion of the results they needed to review were ordered by someone else with little information available about the context, *i.e.*, why the test had been requested and what was to be done

about the result. On the whole, although some felt that some aspects of the system and its use could be improved, most believed that the systems were providing the expected and required functionalities.

The process underpinning the organisation of ordering and managing test results can be thought of as being part of a cycle rather than a linear sequence of events in which the final product is the patient being informed of the result. Based on the interviews it was evident that structures varied between practices and thus the process of ordering, receiving and acting on the results would differ also. The cycle contained four main stages, *i.e.,* the ordering of tests, collecting samples, receiving the results and acting on the results. There are several actions that could spin off from the receipt of the results, ranging from clinical action to the silent filing of the result.

The research thus revealed that participants were reliant on the electronic systems to act on results and were using the systems and their capabilities differently according to their personal roles in results management. This was based on the processes of working and organisation within each practice. Staff had differing responsibilities and duties regarding receiving and reviewing the results – in some practices this was entirely clinically led whilst in others there was involvement of the reception or administrative staff. For example, some practices adopted an approach whereby clinical staff ordered a test but non-clinical staff were reviewing and possibly interpreting the results, sometimes taking older test results into account. This might happen when monitoring long-term conditions such as thyroid function. This qualitative research did not allow a comparison of the effectiveness of the different procedures in the practices

but a common factor, as mentioned previously, was that practices were aiming to cope with a very large number of results received daily. In practical terms this meant that the GPs themselves were unlikely each to review every result and that some sort of filtering was needed. Thus, it is safe to assume that the actual outcomes from a test result, with regard to follow up, was dependent upon the structure and process components of the system or procedures in each practice. This varied between the practices and there was no standardised approach.

7.2.2. Summary of the empirical study

This qualitative research involved eighteen semi-structured interviews in equal number between clinical and administrative staff from thirteen general practices scattered within five Clinical Commissioning Groups in the Northeast area of England. Data consisted of seventeen full literal transcriptions of participants' narratives and one script of a participant's opinions and views prepared me immediately after the interview. Narratives were analysed using framework analysis. This enabled groups of codes to be created to form an order for the data. This helped in organising the data in a way that would reveal insights and help answer the research questions (113).

The predominant themes in relation to the process of ordering tests and receiving results are summarised in table 7.1 below.

Table 6: The predominant themes emerging from the empiric study

Theme	**Commentary based on narratives**
A. Benefits and challenges of using the electronic system to order tests	
Using a universal tool	The availability of a system that connects all practices with laboratories and hospitals was considered the cornerstone of interconnectivity. Practices were able to order tests electronically and view current and previous results including those ordered elsewhere.
The services menu, a tool for navigating on the screen	The menu helped to reduce the time require to order tests
Search tool	The search tool, which enabled tests and results to be unearthed from the clinical record, but terms used in the search needed to match the system's vocabulary
Creating an electronic test request	The system provided flexibility for when the test was performed – the nurse or phlebotomist taking the specimen could access the system at another time or site
B. Transforming orders into results	
Trusting the electronic systems	Staff were not focused on the technical aspects of connectivity, but they trusted that the link was working adequately and confidentially
Printing the electronic request forms	The system provided flexibility regarding the place chosen to collect the sample
Time to collect samples	Although practices used electronic systems, the timings around when the carrier would pick-up samples could affect how and when staff place the order
The audit trail (managing requests)	Having an audit trail enabled staff to track requests and results
C. The process of receiving results: opportunities and demands	
Potential delays in receiving results	Using electronic systems shortened the time needed to report results.

Dealing with the received results and the impact of lack of continuity of care	A crucial point was how practices would handle the results arriving daily, based on the practice's procedures.
Accommodating the high number of results	One of the crucial points discovered was the challenge of handling the high number of results which arrived daily
Status of results: normal, abnormal or urgent	Practices relied on the labs and hospitals to call in case of urgent results.
D. Reviewing and acting on test results	
Adopting a specific electronic system	Practices were not looking for specific features in the system: the decision to select a particular system was based on local circumstances
Electronic systems and acting on a high number of results	The system was easy to use, which made the processing high number of results possible providing the practice had a good administrative approach
Electronic systems: workload and handling normal results	Delegation of responsibilities helped in decreasing the workload.
Staff habits and electronic systems	The systems allowed different users to use different methods to look for further information.
Familiarity and efficiency: linking results with patient records	The efficiency was linked to how familiar the user was with the system
Using ICE system to overcome practices' electronic system limitations (for more precise and productive outcomes)	Putting the results in the right full context required users to access the ICE system as well as the clinical records
Finding the results' trend	Graphs helped staff
	Rapid shifting of clinical personnel where practices were depending on locum GPs and replacements compromises continuity of care

Electronic systems and staff responsibilities	Different screen interfaces for different members of the practice team
Reducing errors (safety net)	Accidental filing of previous paper results now in the past – electronic enabled integrated recording
Using the system for communication and using the audit trail	The system became the prime method of communication regarding test results actions within the practice.
Working without an internet connection	Practices could survive without the internet connection for only a short time
Contacting patients after receiving a test result	Practices depend on an audit trail to acknowledge that the patient has been contacted

The list of the predominant themes formed in this research were similar to some of those in the wider literature. For example, from this empirical study, primary care staff were pleased with how the electronic systems facilitated access to all their patients' files. This is covered in the literature, *i.e.*, that electronic systems can help in accessing patients' clinical history, and the date and time of sample collection (21). Participants complained about the high number of results they received daily and this was also highlighted in the literature (27). Also, our participants were pleased with the system as the communication tool for test result information between health care professionals and this point was mentioned in the literature (23).

7.2.3. The literature reviews

Before starting the qualitative part of this research, I undertook two literature reviews which addressed the following two subjects: the effect of using

electronic systems on test results management and staff opinions about using the systems for the follow-up of results.

The first review aimed to scope the field and to develop an understanding of potential focal topics and questions for the thesis, by understanding the effect and challenges of electronic systems. This review showed that electronic systems can help in facilitating access to patient information, such as the clinical history, and date and time of sample collection (21). The review also indicated that a custom label system could improve safety by minimizing errors by electronically generating labels with specific patient and sample information applied to specimen containers (22). On the other hand, the literature also showed that errors could occur with mislabelling, incorrect patient information, or inaccurate data about a patient's fasting status. This could impact on the accuracy of the results and it would be hard to detect if staff were totally reliant on the information provided in the electronic systems (30, 31). Electronic systems can provide reminders that a particular abnormal test result needs to be followed up (118) but the problem with these alerts is that they can exceed the numbers of results that the clinician can deal with in a single day (27) and this was confirmed in this thesis.

Electronic systems can also improve the communication of test result information between health care professionals and store patient related information in one place, with an audit trail (23) but the literature has reported that features like system design, display and alerting could benefit from further improvement (24-29). Errors can occur around failing to inform a patient of an abnormal test result (33, 34) or conveying the results to the wrong patient (35).

Published data has also shown that certain system deficiencies, such as poor information displays can influence the timely follow-up of abnormal test results, with possible negative clinical consequences (43). Users may thus become dissatisfied with the system and be reluctant to use it (44, 45).

Previous systematic reviews have attempted to investigate the challenges that users face when implementing a new electronic system as well as factors that may encourage adoption (50, 119-122). Other reviews have tried to measure the quantitative impact of EHRs in different clinical settings, focusing in particular on the numbers of missed test results (33, 123, 124). However, little is known about users' experiences of these systems post-implementation for the follow-up of patient test results, and in what ways these systems could be improved. This research attempted to do this.

The second review was intended to cover clinical staff opinions about the impact of electronic systems on the management of results. The review identified five main areas in relation to users' experiences of reacting to and responding to test results while using electronic systems. These were alert notification, timely access to test results, responsibility for acting on test results, communication of patient information between staff, and user training.

The systematic review also reported on a recurring theme, *i.e.*, the large quantity of electronic alert notifications received by healthcare professionals, the content of these alerts and how they presented. Staff responses to these alerts appeared to affect user experiences. At the same time users thought that electronic systems improved and shortened the time required to receive test results. The findings in this thesis also indicated that although participants

complained about the number and content of the alerts, adopting electronic systems to process results reduced the time needed to receive and act on a result. It seemed, though, that practices might be forced to establish new procedures in order to handle this shift of speed, which they were managing with difficulty. A comparison of different processes was not possible in this thesis. For example, we have no data to ascertain if practices which adopted a buddy system to distribute results would be better than practices who distributed results equally among available GPs. Some of our respondents criticised the techniques adopted by other practices, such as the delegation of some clinical tasks to non-clinical members*, e.g.,* flagging abnormal results, or even filing normal results, as they believed this could compromise patient care if the context of the results was not appreciated. These methods used by some practices could also compromise continuity of care if the clinician was not aware of the results. Importantly, this research revealed more reasons for the high number of tests and results other than the adoption of electronic systems, such as locum GPs ordering “unnecessary “tests.

From of the literature review users thought that electronic systems shortened the time required in receiving and accessing test results. The literature also indicated that some clinicians complained about the uncertainty around who was responsible for acting on abnormal test results and that the communication between staff using the electronic systems would benefit from improvements. The review also concluded that proper training could help to improve user awareness of existing features. These factors were reflected in the empiric research in this thesis which found that similar issues were raised by the participants. Participants indicated that that the electronic systems

brought advantages such as enhanced connections between staff within the same practice and in line with previous literature, they also felt that electronic systems shortened the time to access results. However, the uncertainty around who was responsible for acting on results needed clarification. This applied particularly to results from sources outside the practice.

7.3. Strengths and weaknesses of the of the research

This research delivered insights into the perceptions and views of primary care staff in general practices regarding health information technology in the follow-up of test results. The research showed that respondents believed that using electronic systems in their daily activities enhanced the turnover speed, improved communication between staff within the practice and helped clinical staff to deal with the results within the right context, if they were able to link the results with the patient's situation.

However, there were a number of important limitations which need to be acknowledged. Firstly, although this qualitative study had approval to cover all eleven CCGs in northeast England, only five were included. Also, although the study set out to include three primary care staff from each practice (a GP, a nurse and a member of administrative staff), but nurses were difficult to recruit. However, the responses of the participants were considered measures of how practices handled test results even for long term conditions, for which nurses are frequently responsible. The study had to focus on developing themes and conclusions based on GP and staff who provided both clinical and administrative viewpoints. The interviews (18 in all) produced a pattern of

views with much similarity, and it was felt that thematic saturation was reached, as detailed in chapters 5, 6.

In the absence of observed use of the systems, there was no information other than interviews with which to confirm whether electronic systems actually work in terms of patient safety. Participant observation, as a methodology, could have provided real time observations but could not be used due to difficulties in the recruitment phase and was out of the scope of this research. The methodology I used was based on the need to ascertain users' perspectives and the semi-structured interviews did this.

Finally, outcomes are sometimes seen as the most important indicator to evaluate the quality of any proposed system in aimed enhancing patient health status. However, the measurement of outcomes that can be attributed solely to the system in place is challenging (125). Donabedian, in his model, proposed that evaluating the process component could be equivalent to evaluating quality of care as the process would contain actions for the delivery of quality. This process component can be ascertained *via* interviews – my research method – amongst alternative methods such as record reviews (74). It was impractical to investigate actual outcomes for this project and my decision was to seek a different approach, whereby information about 'process' was ascertained *via* interviews. This research focused on health information technology and the follow-up of test results and was related to 'structure and process' rather than the 'outcomes.'

Additionally, actual clinical outcomes from a study such as this would have represented a study of the effect of the test result on the patient's care. This

was clearly beyond the scope of this study as it would have meant following each patient's situation against the background of complex interacting factors. These would have involved a long-term, longitudinal study with clinical follow up.

7.4. Reflexivity and the Role of the Researcher

The nature of qualitative research inevitably means that there is a degree of subjectivity on the part of the observer, or the researcher, and that the coding of the participants' responses and narratives will have been influenced by. Thus, my own inner perceptions and interpretation of what the participants were saying and what they were meaning had that effect to some extent. It could be argued that a different researcher might have ascertained a different set of themes and drawn conclusions that were similar, but not completely identical, to the ones that I have drawn. However, the consistency of the perceptions and opinions obtained during this empiric research convinces me that the main points have been discovered, obtained and described.

Inevitably a degree of repetitiveness in the quotes drawn from the participants' responses occurs and this could be interpreted as an indication of the emphasis and strength of feelings. This repetition provides an indirect measure of the priorities that the respondents had in mind. In formal quantitative research, this would be more specifically measured but in this qualitative work it has been possible, at least to some extent, to evaluate what the participants' main concerns and issues were – repetitions of specific themes were illustrative of their main concerns. My use of specific quotes was, of course, also influenced by my reflexivity in my role as the researcher.

I have experience of working as a pharmacist at two tertiary hospitals in Saudi Arabia, which involved mainly working as drug information pharmacist. Also, I had a significant experience in the area of biosimilar medications and conducted, with a research team in the US, several literature reviews on the clinical efficacy and safety of newly approved medications (126-130). These experiences and knowledge influenced my mind-set as a clinical researcher who was familiar with quantitative research methodologies. I needed to handle a paradigm shift when starting this postgraduate research by adopting a qualitative research methodology. The use of qualitative research, which helps to develop more full-bodied and comprehensive knowledge capable of answering questions about meaning and experience in context-specific ways was entirely new to me. Therefore, the understanding of the philosophical and theoretical underpinnings of qualitative research encouraged me to value and use this approach and to become aware of the role of participants' opinions in the construction of knowledge. My background as an overseas pharmacist with no previous interaction with any of the electronic systems adopted by health care settings in UK allowed me to draw a holistic picture of the impact of these systems based on participants' perspectives. Whilst this was a difficult process it provided a degree of objectivity that might have not been available to a UK-based researcher.

As a result, I tried to make my own thoughts and interpretations clearer during the data collection and analysis stages for validity and reliability purposes. This was useful especially when I returned to the data during the analysis stage to understand the context of the quotations from the interviews and this allowed

me to address my own thoughts that may have influenced the interpretations made.

7.5. The role of the specific electronic systems in the process of test results management

Although electronic systems help in making the follow-up of results safer and timely, the usage of these systems also had weaknesses.

7.5.1. The ICE system

All the participants and practices were using the ICE system. The ICE system offers an integrated approach to requests and reports and communicates between GPs and hospitals. The system links the patient's identity in the practice's electronic system with the laboratory system *via* a secure NHSNet connection. This allows participants to use the ICE system to order and to view past results and tests ordered outside their practice, such as from a hospital or community clinic. Participants in this research indicated their satisfaction with using the ICE system was down to multiple factors, including the availability of the drop-down menu that contained a list of possible tests. It was also thought by some of the participants that the additional search tools for less commonly used tests were easy to use and that the continuous update of the system with newer tests made work more efficient.

Although the ICE system requires specific permission for use by each GP, this point was brought out only by administrative staff, probably because they were responsible for obtaining these authorisations for their practice. It was clear, in relation to the functionalities of the system that staff were focusing on those

aspects and obstacles which related directly to their duties. For example, whilst they could work with the system, they were not aware of or interested in the deeper complexities of the system or how it functioned technically as long as the connection was smooth and uninterrupted.

Whilst the ICE system provided a dropdown menu to pick the desired test, and also provided a search feature, the system requested extra steps to prevent and minimise accidental orders. The system asks all users to provide free text reasons for each order. The search engine for this was felt by some to be frustrating; they complained that an exact dash, hyphen or spelling had to be used to identify the desired test. With many confusing and alike looking medical terms, this made the search for the desired test cumbersome even though it was aimed at reducing errors in test ordering.

In addition, the ICE system provided pre-set request forms for tests for common, long-term conditions and some of the participants expressed the view that these could be extended to more groups of tests for common conditions.

Overall, participants were pleased with the ICE system as they believed it made their job of ordering tests simpler and they could link this with improved efficiency and patient care. The ability to review older results and tests ordered elsewhere was appreciated even though the reason and the context for these was not always clear.

Some of the satisfaction with the ICE system could also be related to the comparison staff made with the old method, *i.e.,* the paper-based system. Participants' responses frequently reflected their prior experiences,

particularly when asked about the advantages of the new system. This could have compromised their ability to critique the ICE system more objectively. This is understandable as the level of satisfaction with any service will be higher if expectations are met or exceeded compared with past experiences (131). This issue could have potentially limited suggestions for improvements within the ICE system.

7.5.2. The practices' electronic systems

As mentioned in the results chapters, there were no specific features related directly to the electronic systems that led practices to adopt a specific system for themselves. The decision was essentially based on local factors and the three main systems in use were thought to be equivalent in functionality.

A better understanding of the results' context was seen as important. The need to have the patient's history and background in relation to the test was a major factor. The staff, in particular GPs, were increasingly handling results for tests that were ordered by other practitioners and this was seen as an obstacle to continuity of care. Thus, the practices' own IT systems for record keeping and consultations needed to be easy to use and to link with tests and results via the ICE system.

7.6. Continuity of Care

The association between tests, results and continuity of care was a key, unexpected finding in this thesis.

There is more than one definition of the term ‘continuity of care’. This was best described in a report published by the National Co-ordinating Centre for NHS Service Delivery and Organisation (132). The report defined continuity of care as longitudinal or provider continuity, which means seeing the same professional each time a patient visits a general practice (132). It also includes the continuity of information through records, either written or electronic. This could be said to be facilitated by the ICE system which, at least, provides information continuity even if not clinical records.

The importance of continuity of care is mentioned in the literature where it is documented that when a patient has to access several professionals, especially for the same complaint, there is likely to be unavoidable duplication of the patient narratives, a risk of unresolved diagnoses and potential for contradictory recommendations. This could lead to loss of trust by the patients (133). It is also documented that continuity of care can increase patient satisfaction (134) and can be linked to lower hospital admission rates (15, 135).

Having clear physician responsibility for a specific test, and therefore the patient, is a key element to the continuity of care (136). Collusion of anonymity is a term introduced in the 1950s, which described the situation where both general practitioners and specialists assume that the patient is the other’s problem (137). Although some guidelines in the UK and worldwide addressed this issue, the literature indicates that the problem exists within the relationship between doctor and patient. Continuity has not been a key focus in policy until recently even with the high value put on it by many patients, especially those

with chronic and complex problems (16, 138, 139). The British Medical Association published guidance in 2012, updated in 2016, to help address this issue and recommended that the ordering provider should always be responsible for follow-up, unless it was explicitly stated that it was the responsibility of a different individual or team caring for the patient (66). The Medical Council of New Zealand issued guidance that was similar to British Medical Association's guidance, but also highlighted that clinicians must always have plans in place to ensure proper and successful continuity of care (67). For example, the guidance even indicated that in the event of a clinician retiring, a plan of transfer arrangements should be in place and that patients should know before these arrangements take effect (67).

7.6.1. Continuity of care in UK general practices

Based on the qualitative part of this research, the current situation in the practices in this study does not provide an optimal picture for relationship continuity, even though it provided continuity of information. This issue, discovered as the thesis progressed, has the potential to affect patient outcomes if appropriate action is not taken upon the receipt of the results. Whilst the practices may have a good system for processing the results the question of responsibility and ownership remains.

The participants mentioned that although distributing results to the people who requested them is the optimal situation, practices could not achieve this as it is difficult to provide the relationship continuity where most of the clinical staff is part time. It was also mentioned that in some settings the system does not provide proper continuity because it delivers results only to certain GPs such

as the senior or managing partner. The electronic system does provide information about who requested the test and to some extent, why, and whether it has been acted upon. The problem is that this requires a proactive approach to prevent errors or messing actions.

Information obtained from the interviews indicated that there are two main reasons contributing to a lack of continuity in patient care. Firstly, the current status of general practice in the UK means that practices are depending massively on locums and part time GPs, as touched on previously. Secondly, there is a continuity issue when the electronic system sometimes failed to identify the appropriate, responsible GP. The latter situation seemed to be happened often, with the senior or managing GP partners receiving a large volume of test results even when they had not ordered them, and they were not sure who should take further action.

7.6.2. Electronic Systems and Continuity of Care

Electronic systems, in particular the ICE system, seemed to help in providing a context for recording and sharing patients' information, a feature not possible with the previous paper-based systems or practices' own, individual electronic record systems. Adopting a 'universal system' such as the ICE system elevated expectations around the content and quality of patients' information available to view. With the current status of general practice in UK, past medical information, such as the patient's previous medical history, has become an increasingly important part of supporting GPs' decisions with respect to a specific test result. The patients' information available in the systems has become the primary tool for enabling continuity in practices as

well as in hospitals. Mining the ICE system for detailed information can be a problem especially when GPs receive results for tests they did not order, *e.g.*, from the hospital. This means having to spend more time trawling though the records, not always clearly understanding why the test has been done. GPs sometimes have to make a decision based on what is available in the records, based on their knowledge of the patient. Decisions in urgent situations where quick action is needed can cause problems and is important in clinical care.

The ICE system provides aids to maintain information continuity to a limited extent. For example, the system requires staff to enter reasons for ordering the specific test. If a reason is not provided an electronic prompt appears. This mandatory feature is important as it is not only useful for the laboratory staff but also for the GP to understand or remember why a test was ordered. Nonetheless, the system could provide better service in terms of continuity by enabling the ordering GP, especially if a locum, to choose who should receive the results of this order.

7.7. Electronic systems in the current era

Although the adoption of the electronic systems by general practices provides advantages in communication and continuity of care, recent literature has expressed the view that problems have accompanied this adoption. The most recent reported problem was the increase in the number of tests ordered by GPs in the UK. One study reported that the time-based change in tests ordered by the GPs increased markedly from an average of 1.5 test per year in 2000/1 to an average of five tests per year in 2015/16 (19). Many factors can be attributed to this increase in the number of tests ordered, such as the

increasing number and duration of consultations with GPs (140). Moreover, patients possibly believe that ordering of tests by GPs is related to better care (141). Also, the literature shows that clinicians overestimate the benefits whilst underestimating the harms of tests (142). Although all these factors probably contribute to this increase in the use of tests, this could be also related to the adoption of electronic systems (28, 43, 143). Electronic systems can enable rapid access to test results, but they can also inadvertently create hazards if clear processes for taking action are not in place. Clinicians can enable relationship continuity by ensuring that they have procedures that enable successful and flexible access to complete patient histories so that results can be efficiently and appropriately interpreted and acted on. GPs and practices face a challenge around the importance of relationships and coordinated care.

7.8. Systems theory and management of test results

This was a qualitative research study that used a thematic analysis framework to create an explanation of the process, derived from participants' opinions. The aim of the qualitative research, as indicated previously, was to explore the perceptions, experiences and views of primary care staff in general practices about health information technology in the follow-up of test results. The study tried to describe the process and to understand individual staff roles in the follow-up of results; to describe different systems' features and how users interface with them; to explore obstacles that face individuals while using the ICE system and, to explore the perspectives of staff on how these systems could be further improved. To achieve that, as described previously, the Donabedian model was adopted (83, 84).

The model allowed me to understand the use of an IT system adopted by NHS trusts involving general practices, by dissecting the systems into the three main components, *i.e.,* structure, process and outcomes. Based on primary care staff opinions desired it was perceived that outcomes could be compromised because of a lack of connected and continuous care and the Donabedian approach helped to identify and appreciate this factor.

7.9. Recommendations and Conclusions

This study contributes to the small body of qualitative research which has examined health information technology in the follow-up of patients' test results. As discussed in Chapter 2, the evidence base is small and did not focus primarily on this issue. The findings from this research could be used by those with an interest in this area, such as policy makers, GPs, clinical safety officers and others.

The issue of compromised continuity of care and its association with electronic test ordering was an unexpected finding but one which highlights the current state of general practice and the complex factors that influence connected care. This also highlights the interlocking factors within the complexities of providing medical care in which tests are an important component.

This thesis adds to the literature in that it explored and described primary care staff and practices' experiences and views around the use of health information technology in the follow-up of test results. The thesis offers a more profound understanding of the process of results' management in general practice. Whilst the research was based in NE England, the findings are likely

to be applicable thought the UK and in settings where there is similar health care organisation. This research revealed that a major issue is the compromise of continuity of care and that electronic test ordering and the handling of results has placed strains on practices as well as easing matters. Although the term ‘continuity of care’ does not appear in participants’ narratives, they were anxious about how the current situation contributes to a lack of continuity. This was partly because results can be received out of clinical context and also because lines of responsibility in dealing with the results can become blurred. In addition, this work describes how users were highly dependent on the electronic systems as the method for primary-secondary care communication about tests. Although this could be seen as a positive attribute, with electronic systems providing an audit trail around tests, the over-use of the electronic systems might affect personal interactions with patients because of reduced personalised care. It was clear from this study that the adoption of electronic systems in general practices has had multiple outcomes, including an increase in the number of tests performed. In the future, the increasing role of locums and sessional doctors may exacerbate this problem.

This body of work highlighted that communication between hospitals and general practices has improved with the ICE system, but that in-practice procedures need more attention. HIT provides a secure channel that enables staff to provide more detailed information from the patient record and doing this may lead to a better understanding of why the test was ordered. This could aid general practices to improve information flow and their ability to react faster to the results. These advantages were missed in the communication between

primary care staff in general practices, as in this study, and this is likely to have affected continuity of care.

This was reflected in the participants'' narratives whereby some GPs, especially locums, were not documenting the full justifications for their test requests, making it difficult for the reviewing doctors to put the results into the right context. We therefore recommend creating policies and procedures with guidelines that clarify responsibilities toward ordering tests and their results' management. This is likely to improve efficiency as well as continuity and may well have a positive effect on the increasing number of tests being ordered.

7.10. Areas for further research

The empiric research in this thesis highlighted the point that continuity of care can be compromised if test results are not dealt with appropriately. This includes actions and decisions taken by clinical and non-clinical staff. This area needs further research with a possible view to standardising procedures.

Different practices have adopted varying methods for dealing with test results. There was no evidence to favour one over approach over another. Little is known about the efficiency of these methods. For example, "normal" results might require further investigations to ensure that an alternative diagnosis is considered. There is a need for further studies on possible missed diagnoses or compromised monitoring of care – this is also tied up with care continuity problems.

Moreover, the effect of "over-ordering" of tests and the impact of false positive results has been a source of discussion in the recent literature and further

research into any associations with electronic ordering systems would be useful.

Further research on the impact of an electronic test ordering and its direct or indirect impact on clinical care would be helpful - this thesis this was based on participant narratives and it was not be able to investigate outcomes. Tracking tests to the point where the result is received and studying how staff actually act on them would provide insights into the appropriateness of tests and identify barriers preventing optimal management.

A further interesting area for research is the linking of test results with prescribing. This applies particularly in long-term conditions such as hypertension or diabetes. In these conditions management requires long term monitoring in association with medications - these are frequently adjusted based on test results. With the arrival of pharmacists working directly with patients in practices this would seem timely.

Appendices

Appendix 2.1. Search Strategy for the Systematic Review

Medline		
EHR	**Test Results**	**Follow-up**
exp Medical Records Systems, Computerized/	abnormal test result*.mp.	follow up OR follow-up OR followup.
Medical Informatics/	test result*.mp.	exp Professional-Patient Relations/
Decision Making, Computer-Assisted/	Diagnostic Imaging/	exp "Continuity of Patient Care"/
Decision Support Techniques/	Magnetic Resonance Imaging/	discharge summar*.mp.
Decision Support Systems, Clinical/	X-Rays/	Drug Monitoring/
Reminder Systems/	abnormal imaging.mp.	Delayed Diagnosis/
Nursing Informatics/	Diagnostic Tests, Routine/	
Electronic health record*.mp.	exp Hematologic Tests/	
Electronic patient record*.mp.		
= 61,784	= 654,577	= 1,226,896
203		

EMBASE		
EHR	**Test Results**	**Follow-up**
electronic medical record/	abnormal test result*.mp.	follow up/
medical information system/	test result*.mp.	"evaluation and follow up"/
decision support system/	diagnostic test/	doctor patient relation/
reminder system/	laboratory test/	patient care/
electronic health record*.mp	blood examination/	diagnostic error/
nursing informatics/	diagnostic imaging/	hospital discharge/
medical informatics/	nuclear magnetic resonance imaging/	monitoring/
Electronic patient record*.mp.	X ray/	delayed diagnosis/
	abnormal imaging.mp.	follow up OR follow-up OR followup
= 82,980	= 989,778	= 1,570,679
899		

CINAHL		
EHR	**Test Results**	**Follow-up**
Medical Informatics	abnormal result*	follow up OR follow-up OR followup
Nursing Informatics	test result*	Physician-Patient Relations
Computerized Patient Record	Diagnostic Imaging	Nurse-Patient Relations
Medical Record Linkage	Diagnostic Tests, Routine	Professional-Patient Relations
Health Information Management	X-Rays	Patient Discharge Summaries
Health Information Systems	Magnetic Resonance Imaging	Drug Monitoring
Decision Support Systems, Clinical	Hematologic Tests+	delayed diagnosis
Patient Record Systems	“abnormal imaging”	
Reminder Systems		
= 24,438	= 73,865	= 141,670
52		

PsycINFO		
EHR	**Test Results**	**Follow-up**
Computer Mediated Communication	test result*	follow up OR follow-up OR followup
Cloud Computing	abnormal test result*	Disease Management
Decision Support Systems	diagnostic test*	Client Treatment Matching
Information Technology	Magnetic Resonance Imaging	Clinical Judgment (Not Diagnosis)
Medical Records	laboratory tests	“discharge summar*”
electronic health records	“abnormal imaging”	“delayed diagnosis”
= 17,022	= 65,424	= 105,008
24		

Appendix 2.2. A Table Summarising the Main Findings of the Included Articles in the Systematic Review

Title	Authors	Date	Source	Aim	Methods	Location	Setting	Summary of findings	CASP Marks
Information overload and missed test results in electronic health record-based settings.	Singh H. Spitzmueller C. Petersen N.J. Sawhney M.K. Sittig D.F.	2013	JAMA Internal Medicine. 173 (8) (pp 702-704), 2013. Date of Publication: 22 Apr 2013.	examining the "sociotechnical" predictors of missed test results	Survey	US	VA Primary Care settings	(29.8%) reported missed results that led to care delays. PCPs who reported information overload were more likely to report having missed results	08/10
Primary care practitioners' views on test result management in EHR-enabled health systems: a national survey.	Singh H Spitzmueller C Petersen NJ Sawhney MK Smith MW Murphy DR Espadas D Laxmisan A Sittig DF	2013	Journal of the American Medical Informatics Association. 20(4):727-35, 2013 Jul-Aug.	understand the broad range of social and technical factors that affect test result management	Survey	US	VA Primary Care settings	55.5% EHRs did not have convenient features for notifying patients. 37.9% asked staff for support. 46.1% relied on the patient's next visit to notify them for normal and 20.1% for abnormal results. 45.7% received adequate training 60.4% got help from colleagues. 85.6% stayed after hours or came in on weekends to address notifications 30.1% received protected time. PCPs strongly endorsed several new features to improve test result management, including better tracking and visualization of result notifications.	09/10

Understanding the management of electronic test result notifications in the outpatient setting.	Hysong SJ Sawhney MK Wilson L Sittig DF Esquivel A Singh S Singh H	2011	BMC Medical Informatics & Decision Making. 11:22, 2011.	understand barriers, facilitators, and potential interventions for management of abnormal test result using EHRs	Focus groups	US	VA Primary Care settings	Large number of unnecessary alerts Providers lacked proficiency in use of certain EHR features. Improving display and tracking processes for critical alerts in the EHR, redesigning clinical workflow, and streamlining policies and procedures related to test result notification could be have benefits.	08/10
Perceptions of alert fatigue by PCPS using an integrated electronic health record.	Singh H. Spitzmueller C. Sawhney M. Espadas D. Modi V. Sittig D.F.	2011	Journal of General Internal Medicine. Conference: 34th Annual Meeting of the Society of General Internal Medicine Phoenix, AZ United States.	evaluate the extent of EHR- notifications on causing PCPs to perceive too much information or to feel overwhelmed by the quantity of information they receive.	Survey	US	VA Primary Care settings	68.7% of PCPs reported perceived information overload and 67.3% alert fatigue. 81.1% believed managing alerts took too much time away from normal duties 87.3% reported that they used personal time	08/10
Changing course to make clinical decision support work in an HIV clinic in Kenya.	Noormohammad SF Mamlin BW Biondich PG McKown B Kimaiyo SN Were MC	2010	International Journal of Medical Informatics. 79(3):204-10, 2010 Mar.	To determine reasons for failure to adhere to the reminders of the new EHR system.	Mixed method	Kenya	Primary Care Clinic	reasons for failure: not considering delayed data entry; inadequate training of providers resource issues	06/10

Linking acknowledgement to action: closing the loop on non-urgent, clinically significant test results in the electronic health record.	Dalal AK Pesterev BM Eibensteiner K Newmark LP Samal L Rothschild JM	2015	Journal of the American Medical Informatics Association. 22(4):905-8, 2015 Jul.	to determine how often nonurgent clinically significant test results are acknowledged, verify typical actions taken after acknowledging test results, assess reported use and satisfaction with the tool.	Survey	US	Primary Care Clinics	Rate of acknowledgment of non-urgent results was 78%. 64% were satisfied with the tool.	09/10
How context affects electronic health record-based test result follow-up: a mixed-methods evaluation.	Menon S Smith MW Sittig DF Petersen NJ Hysong SJ Espadas D Modi V Singh H	2014	BMJ Open. 4(11):e005985, 2014.	to identify contextual factors associated with facility-level variation in missed test results.	Mixed method	US	VA Primary Care settings	Facilities strategies were linked with low risk. Qualitative analysis identified three high-risk scenarios: alerts on tests ordered by trainees, alerts 'handed off' to another covering clinician alerts on patients not assigned to a PCP. Policies and procedures to address these high-risk situations varied across facilities	09/10
Impact of health information exchange on emergency medicine clinical decision making.	Gordon B.D. Bernard K. Salzman J. Whitebird R.R.	2015	Western Journal of Emergency Medicine. 16 (7) (pp 1047-1051), 2015. Date of Publication: 2015.	to understand the immediate utility of HIE on ED providers.	Interviews	US	Tertiary Care Hospital	Reasons to requests for outside information; Unexpected information; historical lab values; providing context in decisions making process; improved confidence of provider; and changes in decisions for diagnostic imaging.	07/10

Physicians' views and assessments on Picture Archiving and Communication Systems (PACS) in two turkish public hospitals.	Top M.	2012	Journal of Medical Systems. 36 (6) (pp 3555-3562), 2012. Date of Publication: December 2012.	to determine the physicians' views and assessments on picture archiving and communication system PACS	Survey	Turkey	Two public hospitals	94% agreeing that PACS had been a useful advance for their hospitals users must expect continuous learning about new updates and improved functionality	06/10
Effective notification of important non-urgent radiology results: a qualitative study of challenges and potential solutions.	Georgiou A Hordern A Dimigen M Zogovic B Callen J Schlaphoff G Westbrook JI	2014	Journal of Medical Imaging & Radiation Oncology. 58(3):291-7, 2014.	to investigate the views of the medical imaging department staff about: the results follow-up problem encountered by the medical imaging department what changes occurred following implementation of the Radiology Notification System RNS suggestions for improving the RNS.	Interviews	Australia	Teaching Hospital	Test management systems can have a part in Improving safe and effective communications between wards and hospital departments. RNS provides time efficiency, and improved documentation	09/10
A qualitative analysis of Emergency Department physicians' practices and perceptions in relation to test result follow-up.	Callen J Georgiou A Prgomet M Paoloni R Westbrook J	2010	Studies in Health Technology & Informatics. 160(Pt 2):1241-5, 2010.	exploring physicians' perceptions, practices and suggestions for improvements of follow-up of test results in an ED.	Interviews	Australia	Teaching Hospital	Responsibility for test follow-up; the unique ED environment and time pressures, and the role of the family physician in test result follow up. The key suggestion for improvement was a complete integrated electronic information system with on-line result endorsement	08/10

Improving follow-up of abnormal cancer screens using electronic health records: trust but verify test result communication.	Singh H Wilson L Petersen LA Sawhney MK Reis B Espadas D Sittig DF	2009	BMC Medical Informatics & Decision Making. 9:49, 2009.	determining if technical and/or workflow-related aspects of automated communication in the electronic health record could be linked lead to the response rate.	Mixed method	US	VA medical center and its Primary Care settings	Electronic communication of abnormal results should be monitored to avoid limiting screening. Robust quality assurance and oversight systems are needed.	08/10
Impact of automated alerts on follow-up of post-discharge microbiology results: a cluster randomized controlled trial.	El-Kareh R Roy C Williams DH Poon EG	2012	Journal of General Internal Medicine. 27(10):1243-50, 2012 Oct.	design, implement, and evaluate an automated system to improve follow-up of microbiology results that return after hospitalized patients are discharged	Survey	US	Academic Hospital	The alerting system improved the proportion of important post-discharge microbiology results with documented follow-up.	07/10

Appendix 4.1. Main Study Invitation Letter

Durham Version

Mr. Abdulaziz Mohammed
School of Medicine, Pharmacy and Health,
Durham University,
Room number: C107a, Holliday Building,
Queen's Campus University Boulevard,
Stockton-on-Tees, TS17 6BH, UK
Tel: +44 191 334 0368
email: abdulaziz.a.mohammed@durham.ac.uk

{Date}

Dear Participant (name)

Study Title: Follow-up of Abnormal Patient Test Results in Primary Care

Durham University are currently conducting a study to explore staff experiences of where breakdowns might occur in the follow up of abnormal patient test results.

We would like to hear your thoughts on the current results management process and in what way(s) it could possibly be improved. We hope that being part of this study will not only provide useful feedback to the research team but also help improve the experience for patients.

Please find enclosed an information sheet that explains the background to the study, and what would be expected of you should you agree to participate. Please email abdulaziz.a.mohammed@durham.ac.uk indicating whether or not you would be interested in participating by <date>. It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time in the future. All information supplied is treated in confidence. Thank you for your consideration. If you have any questions regarding this study or require further information, please do not hesitate to contact me by e-mail or on the telephone number above.

Thank you for your time and consideration. We look forward to hearing from you.
Yours sincerely,

Mr. Abdulaziz A Mohammed,
Doctoral Candidate, Durham University,
Co-investigator

Dr. Sarah Patricia Slight,
Reader in Pharmacy Practice, Durham University / Honorary Researcher Newcastle upon Tyne Hospitals NHS Foundation Trust
Chief Investigator.

Mr. Abdulaziz Mohammed
Institute of Health & Society
Baddiley-Clark Building
Newcastle University,
Newcastle upon Tyne
NE2 4BN
Email: a.mohammed6@newcastle.ac.uk

{Date}

Dear Participant (name)

Study Title: Follow-up of Abnormal Patient Test Results in Primary Care

Newcastle University are currently conducting a study to explore staff experiences of where breakdowns might occur in the follow up of abnormal patient test results.

We would like to hear your thoughts on the current results management process and in what way(s) it could possibly be improved. We hope that being part of this study will not only provide useful feedback to the research team but also help improve the experience for patients.

Please find enclosed an information sheet that explains the background to the study, and what would be expected of you should you agree to participate. Please email a.mohammed6@newcastle.ac.uk indicating whether or not you would be interested in participating by <date>. It is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time in the future. All information supplied is treated in confidence. Thank you for your consideration. If you have any questions regarding this study or require further information, please do not hesitate to contact me by e-mail or on the telephone number above.

Thank you for your time and consideration. We look forward to hearing from you.
Yours sincerely,

Mr. Abdulaziz A Mohammed,
Doctoral Candidate, Newcastle University,
Co-investigator

Dr. Sarah Patricia Slight,
Reader in School of Pharmacy, Newcastle University / Honorary Researcher Newcastle upon Tyne Hospitals NHS Foundation Trust
Chief Investigator.

Appendix 4.2: Main Study Participant Information Sheet
Durham Version

Study Title: Follow-up of abnormal patient test results in primary care.

Participant Information Sheet

Names of Investigators: Dr. Sarah Patricia Slight and Mr. Abdulaziz A Mohammed.
IRAS Project ID: 168736

Invitation paragraph

You have been invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If there is anything that is unclear or if you would like more information, please ask. Thank you for reading this.

Background

Pathology laboratories in the U.K. send approximately 50 million electronic results reports to GPs annually. Most tests are normal and do not require follow-up. However, the management of abnormal patient test results is a complex process. Failure to appropriately follow-up these results in a timely manner can have direct clinical consequences for patients, including missed diagnoses and delayed treatment. The aim of this study is to explore GP practice staff experiences of where breakdowns might occur in the follow up of abnormal patient test results.

What does the study involve?

We would like to hear your thoughts on the current results management process in your workplace and in what way(s) it could possibly be improved. We hope that being part of this study will not only provide useful feedback to the research team but also help improve the experience for patients.

Why have I been chosen to take part?

Your GP practice is likely to deal with the follow-up of one or more of the following clinically important patient tests (e.g., mammograms, pap smears, PSAs, and INRs). You have been chosen because you work in a GP practice (e.g., doctor, manager, pharmacist, nurse, administrator) and may be able to provide useful feedback on how these abnormal test results are followed up.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part in either the interview or observation, you will be given this information sheet to keep and will be asked to sign and return the consent form. You are also free to withdraw at any time and without giving a reason.

What do I have to do?

By agreeing to take part, you may be required to participate in an interview. This interview will be conducted by a member of our research team at a mutually convenient time and place, and will take approximately 30-40 minutes. We would like to hear your thoughts on the current results management process and in what way(s) it could possibly be improved. If you agree, the interview will be digitally recorded; if you object to this, however, we will just take notes. You can ask that the digital recorder be switched off at any time during the interview if you prefer. The observation will take place at a suitable time in the future once the interview has taken place. There will be no observation of patients or review of patient data as part of this work.

Will my taking part in this study be kept confidential?

All information supplied will be kept confidential. Any information reported from the interview will not enable you to be recognised. You will not automatically be expected to take part in any future research. All information, which is collected about you during the course of the research, will be kept on a password-protected database and held securely in accordance with the regulations. Access to the information will be limited to the study staff and investigators only. Any personal data will be destroyed as soon as is practical and reasonable to do so (approx. 4 weeks after the date of interview). Any information about you, which leaves the research unit, will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

We plan to submit the findings of this study to medical journals (papers) for publication. The findings will also be presented in a PhD thesis, and will be used to inform future research studies. You will not be identified in any report/publication.

What if something goes wrong? / Who can I complain to?

In case you have a complaint on your treatment by a member of research staff or anything to do with the study, you can approach the chief investigator, **Dr. Sarah Patricia Slight**, School of Medicine, Pharmacy and Health, Wolfson Research Institute, Durham University, Queen's Campus, University Boulevard, Thornaby, Stockton-on-Tees, TS17 6BH. Phone: +44 (0191) 334 0394. Email: s.p.slight@durham.ac.uk

Who is organising and funding the research?

This study is funded by the Durham University.

Who has reviewed the study?

This study has been reviewed and approved by the SMPH Ethics Committee Durham University, and the Research Ethics Committee London – Stanmore. REC Reference Number: 16/LO/1551

Contact for Further Information

Mr. Abdulaziz A Mohammed, School of Medicine, Pharmacy and Health, Durham University, Room number: C107a, Holliday Building, Queen's Campus University Boulevard, Stockton-on-Tees, TS17 6BH, UK. Tel: +44 191 334 0368, email: abdulaziz.a.mohammed@durham.ac.uk
Dr. Sarah Patricia Slight, School of Medicine, Pharmacy and Health, Wolfson Research Institute, Durham University, Queen's Campus, University Boulevard, Thornaby, Stockton-on-Tees, TS17 6BH. Email: s.p.slight@durham.ac.uk

Thank you very much for considering taking part in this research study.

Study Title: Follow-up of abnormal patient test results in primary care.

Participant Information Sheet

Names of Investigators: Dr. Sarah Patricia Slight and Mr. Abdulaziz A Mohammed.

IRAS Project ID: 168736

Invitation paragraph

You have been invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If there is anything that is unclear or if you would like more information, please ask. Thank you for reading this.

Background

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Your GP practice is likely to deal with the follow-up of one or more of the following clinically important patient tests (e.g., mammograms, pap smears, PSAs, and INRs). You have been chosen because you work in a GP practice (e.g., doctor, manager, pharmacist, nurse, administrator) and may be able to provide useful feedback on how these abnormal test results are followed up.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part in either the interview or observation, you will be given this information sheet to keep and will be asked to sign and return the consent form. You are also free to withdraw at any time and without giving a reason.

What do I have to do?

By agreeing to take part, you may be required to participate in an interview. This interview will be conducted by a member of our research team at a mutually convenient time and place, and will take approximately 30-40 minutes. We would like to hear your thoughts on the current results management process and in what way(s) it could possibly be improved. If you agree, the interview will be digitally recorded; if you object to this, however, we will just take notes. You can ask that the digital recorder be switched off at any time during the interview if

you prefer. The observation will take place at a suitable time in the future once the interview has taken place. There will be no observation of patients or review of patient data as part of this work.

Will my taking part in this study be kept confidential?

All information supplied will be kept confidential. Any information reported from the interview will not enable you to be recognised. You will not automatically be expected to take part in any future research. All information, which is collected about you during the course of the research, will be kept on a password-protected database and held securely in accordance with the regulations. Access to the information will be limited to the study staff and investigators only. Any personal data will be destroyed as soon as is practical and reasonable to do so (approx. 4 weeks after the date of interview). Any information about you, which leaves the research unit, will have your name and address removed so that you cannot be recognised from it.

What will happen to the results of the research study?

We plan to submit the findings of this study to medical journals (papers) for publication. The findings will also be presented in a PhD thesis, and will be used to inform future research studies. You will not be identified in any report/publication.

What if something goes wrong? / Who can I complain to?

In case you have a complaint on your treatment by a member of research staff or anything to do with the study, you can approach the chief investigator, **Dr. Sarah Patricia Slight**, School of Pharmacy, King George VI Building, Newcastle University, Newcastle upon Tyne, U.K. Phone: +44 (0191) 20 82358. Email: sarah.slight@newcastle.ac.uk

Who is organising and funding the research?

This study is funded by the Newcastle University.

Who has reviewed the study?

This study has been reviewed and approved by the SMPH Ethics Committee Durham University, and the Research Ethics Committee London – Stanmore. REC Reference Number: 16/LO/1551

Contact for Further Information

Mr. Abdulaziz A Mohammed, Institute of Health and Safety, Baddiley-Clark Building, Newcastle University, Newcastle upon Tyne, U.K. Email: a.mohammed6@newcastle.ac.uk

Dr. Sarah Patricia Slight, School of Pharmacy, King George VI Building, Newcastle University, Newcastle upon Tyne, U.K. Phone: +44 (0191) 20 82358. Email: sarah.slight@newcastle.ac.uk

Thank you very much for considering taking part in this research study.

Appendix 4.3. Main Study Participant Interview Schedule

Durham Version

Study Title: Follow-up of Abnormal Patient Test Results in Primary Care

Participant Interview Schedule

A common introduction will be used as follows:

As a member of staff in this GP practice, we would like your help in understanding the process of following up abnormal patient test results. We are interested in your impressions and thoughts whether these are positive or negative. If there are any questions you do not feel you can answer, we can easily skip over that question. This interview will be recorded using a digital recorder with your permission. All data will be stored anonymously and you will not be identifiable from any uses of these data.

QUESTIONS

1. *Could you describe the process of ordering, processing, and following up test results in this practice?*
    a. **Prompt:** What are the specific steps involved?
2. *What is your role in this process?*
    a. **Prompt:** How are responsibilities delegated?
3. *What are your experiences using the electronic IT system for the results management process?*
    a. **Prompt:** What were your likes and dislikes about using the system?
4. *How has the system met your individual needs?*
    Prompt: What is most useful? Not so useful?
5. *Have you experienced any difficulties?*
    Prompt: Difficulty placing orders, receiving lab results, finding particular information? How do you deal with these difficulties?
6. *How do you think this electronic system could be improved?*
    Prompt: What about other factors that could affect your experiences (managerial level – availability of computers, printer - training)?
7. *Could you describe the process of communicating the results with the patient, once received?*
8. *Do you have any other comments?*

Concluding remarks will end the interview:

That was the last question on this interview. If you would like any further information about the study, please don't hesitate to contact me. My details have been provided on the information sheet. Thank you for taking part in this interview.

Study Title: Follow-up of Abnormal Patient Test Results in Primary Care

Participant Interview Schedule

A common introduction will be used as follows:

As a member of staff in this GP practice, we would like your help in understanding the process of following up abnormal patient test results. We are interested in your impressions and thoughts whether these are positive or negative. If there are any questions you do not feel you can answer, we can easily skip over that question. This interview will be recorded using a digital recorder with your permission. All data will be stored anonymously and you will not be identifiable from any uses of these data.

QUESTIONS

1. *Could you describe the process of ordering, processing, and following up test results in this practice?*
    a. **Prompt:** What are the specific steps involved?
2. *What is your role in this process?*
    a. **Prompt:** How are responsibilities delegated?
3. *What are your experiences using the electronic IT system for the results management process?*
    a. **Prompt:** What were your likes and dislikes about using the system?
4. *How has the system met your individual needs?*
    Prompt: What is most useful? Not so useful?
5. *Have you experienced any difficulties?*
    Prompt: Difficulty placing orders, receiving lab results, finding particular information? How do you deal with these difficulties?
6. *How do you think this electronic system could be improved?*
    Prompt: What about other factors that could affect your experiences (managerial level – availability of computers, printer - training)?
7. *Could you describe the process of communicating the results with the patient, once received?*
8. *Do you have any other comments?*

Concluding remarks will end the interview:

That was the last question on this interview. If you would like any further information about the study, please don't hesitate to contact me. My details have been provided on the information sheet. Thank you for taking part in this interview.

Appendix 4.4: Main Study Consent Form

Durham Version

Study Title: Follow-up of abnormal patient test results in primary care.

Participant Consent Form

Ethical Approval Ref: (REC London – Stanmore. Reference Number: 16/LO/1551)

IRAS Project ID: 168736

Name of Researcher: _____

Name of Participant: _____

Please initial box

1. I confirm that I have read and understand the information sheet version number .....dated..... for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
4. I understand that the interview will be recorded and that anonymous direct quotes from the interview or observational notes may be used in the study reports, PhD thesis and publications. ☐
5. All information supplied will be kept confidential. Any information reported will not enable me to be recognised. ☐
6. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

2 copies: 1 for participant and 1 for the project notes

Study Title: Follow-up of abnormal patient test results in primary care.

Participant Consent Form

Ethical Approval Ref: (REC London – Stanmore. Reference Number: 16/LO/1551)

IRAS Project ID: 168736

Name of Researcher: _____

Name of Participant: _____

Please initial box

1. I confirm that I have read and understand the information sheet version number .....dated..... for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐
3. I understand that should I withdraw then the information collected so far cannot be erased and that this information may still be used in the project analysis. ☐
4. I understand that the interview will be recorded and that anonymous direct quotes from the interview or observational notes may be used in the study reports, PhD thesis and publications. ☐
5. All information supplied will be kept confidential. Any information reported will not enable me to be recognised. ☐
6. I agree to take part in the above study. ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

2 copies: 1 for participant and 1 for the project notes

Appendix 4.4. Main Study Ethical Documents

4.4.1. HRA Favourable Opinion

NHS
Health Research Authority
London - Stanmore Research Ethics Committee
Ground Floor
NRES/HRA
80 London Road
London
SE1 6LH

Telephone: 020 7972 2554

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

28 September 2016

Dr Sarah Slight
School of Medicine, Pharmacy and Health,
Wolfson Research Institute,
Durham University, Queen's Campus, University Boulevard, Thornaby,
TS17 6BH

Dear Dr Slight

Study title:	**Follow-up of Abnormal Patient Test Results in Primary Care**
REC reference:	**16/LO/1551**
Protocol number:	**1**
IRAS project ID:	**168736**

Thank you for your letter, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Julie Kidd, nrescommittee.london-stanmore@nhs.net . Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents
The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Proof of Indemnity]		01 August 2016
Interview schedules or topic guides for participants [Participant Interview Schedule_Appendix B]	1.4	12 July 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Application Form XML file [IRAS_Form_04082016]		04 August 2016
IRAS Checklist XML [Checklist_04082016]		04 August 2016
Letter from statistician [Documentation of Statistical Advice]		
Letters of invitation to participant [Invitation Letter to Participants_Appendix C]	1.4	12 July 2016
Other [Observation Schedule_Appendix F]	1.4	12 July 2016
Other [Data Collection Form_Appendix A]	1.4	12 July 2016
Other [HRA_statement of activities]	4.0	30 March 2016
Other [HRA_schedule of events]	3.2.2	
Other [Proof of Indemnity_02]		01 August 2016
Other [Data Collection appendix form]		22 August 2016
Participant consent form [Participant Consent Form_Appendix E]	1.4	12 July 2016
Participant information sheet (PIS) [Participant Information Sheet_Appendix D]	1.4	12 July 2016
Research protocol or project proposal [Protocol_Follow Up of Abnormal Patient Test Results]	1.4	02 June 2016
Response to Request for Further Information		22 August 2016
Summary CV for Chief Investigator (CI) [CI_CV]		06 July 2016
Summary CV for student [Student's CV]		30 June 2016
Summary CV for supervisor (student research) [supervisor's CV]		06 July 2016
Summary, synopsis or diagram (flowchart) of protocol in non-technical language [Lay Summary]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research

Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/1551	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely
PP

Mrs Rosemary Hill
Chair
Email: nrescommittee.london-stanmore@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Dr. Russell Hill*
Dr Shona Haining , North of England Commissioning Support (NECS)

Appendix 4.4. Main Study Ethical Documents

4.4.2. Letter of HRA Approval

NHS
Health Research Authority

Dr Sarah Slight
School of Medicine, Pharmacy and Health,
Wolfson Research Institute,
Durham University, Queen's Campus, University Boulevard,
Thornaby,
TS17 6BH

Email: hra.approval@nhs.net

08 February 2017

Dear Dr Slight,

Letter of HRA Approval

Study title:	**Follow-up of Abnormal Patient Test Results in Primary Care**
IRAS project ID:	**168736**
Protocol number:	**1**
REC reference:	**16/LO/1551**
Sponsor	**Durham University**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators"*, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **168736**. Please quote this on all correspondence.

Yours sincerely

Thomas Fairman
HRA Assessor

Email: hra.approval@nhs.net

Copy to: *Dr. Russell Hill, Durham University, (Sponsor Contact)*
Dr Shona Haining , North of England Commissioning Support (NECS), (Lead NHS R&D Contact)

NIHR CRN Portfolio Applications Team

IRAS project ID	168736

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Proof of Indemnity]		01 August 2016
Interview schedules or topic guides for participants [Participant Interview Schedule_Appendix B]	1.4	12 July 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
Letter from statistician [Documentation of Statistical Advice]		
Letters of invitation to participant [Invitation Letter to Participants_Appendix C]	1.4	12 July 2016
Other [Data Collection appendix form]		22 August 2016
Other [HRA Statement of Activities]	1	08 February 2017
Other [HRA Schedule of Events]	1	08 February 2017
Other [Observation Schedule_Appendix F]	1.4	12 July 2016
Other [Data Collection Form_Appendix A]	1.4	12 July 2016
Other [Proof of Indemnity_02]		01 August 2016
Participant consent form [Participant consent form - Participant Consent Form_Appendix E]	1.5	08 February 2017
Participant information sheet (PIS) [Participant information sheet (PIS) - Participant Information Sheet_Appendix D]	1.5	08 February 2017
Research protocol or project proposal [Research protocol or project proposal - Protocol_Follow Up of Abnormal Patient Test Results]	1.5	08 February 2017
Response to Request for Further Information		22 August 2016
Summary CV for Chief Investigator (CI) [CI_CV]		06 July 2016
Summary CV for student [Student's CV]		30 June 2016
Summary CV for supervisor (student research) [supervisor's CV]		06 July 2016
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Lay Summary]		

IRAS project ID	168736

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Dr Russel Hill
Email: dirres.ssh@durham.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The sponsor has submitted the HRA Statement of Activities and intends for this to form the agreement between the sponsor and study sites. The sponsor is not requesting, and does not require any additional contracts with study sites.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for external funding has been made.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable Opinion was issued by the Stanmore Research Ethics Committee on the 28th September 2016 Amended documents were submitted on by the researchers to comply with HRA Approval standards. These were classified by the sponsor as a non-substantial amendment.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
All participating NHS organisations will undertake the same study activities. There is therefore only one study site 'type' involved in the research.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
NHS organisations in England that are participating in the study **will be expected to formally confirm their capacity and capability** to host this research. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Principal Investigator should be appointed at study sites. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
As a non-commercial study undertaken by local staff, it is unlikely that letters of access or honorary research contracts will be applicable, except where local network staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, network staff (or similar) undertaking any of the research

activities listed in A18 or A19 of the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 4.4: Main Study Ethical Documents

4.4.3. NECS Confirmation of Capacity and Capability

RE: IRAS 168736: Confirmation of Capacity and Capability at North of England Commissioning Support (NECS)

RIDING, Helen (NHS NORTH OF ENGLAND COMMISSIONING SUPPORT UNIT) <helenriding@nhs.net>

Wed 15/03/2017 16:50

To: DIRRES-SSH D.0. <dirres.ssh@durham.ac.uk>; MOHAMMED, ABDULAZIZ A. <abdulaziz.a.mohammed@durham.ac.uk>; s.p.slight@durham.ac.u <s.p.slight@durham.ac.u>;

Cc: HAINING, Shona (NHS NORTH OF ENGLAND COMMISSIONING SUPPORT UNIT) <s.haining@nhs.net>; MOSS, Sebastian (BELFORD MEDICAL PRACTICE - A84008) <sebastian.moss@nhs.net>;

2 attachments (335 KB)

HRA_statement of activities.docx; 168736 HRA Approval Letter 08.02.2017.pdf;

Good afternoon all,

RE: IRAS 168736: Confirmation of Capacity and Capability at North of England Commissioning Support (NECS)

Full Study Title: Follow-up of Abnormal Patient Test Results in Primary Care

This email confirms that North of England Commissioning Support (NECS) on behalf of the 2 CCGs listed on the IRAS form and the 9 CCGs specified in Non Substantial amendment 1 (AM01) has the capacity and capability to deliver the above referenced study. Please find attached our agreed Statement of Activities as confirmation.

We agree to start this study as soon as Letters of Access are in place for all study personnel involved in the activities listed in Question A18 of the IRAS form.

To confirm NECS can support communications to practices, but we cannot ensure that practices are involved. It is the responsibility of the individual GP practice to assess if they have ability to support the project.

Please note:

- Stepwise recruitment approach with 11 CCGs starting with Northumberland CCG.
- Dr Sebastian Moss has been identified as a local collaborator for the study. NECS have agreed to initially approach practices and signpost them to the study team.
- If the study moves onto other CCGs a local collaborator for each CCG will be required to be identified prior to recruiting practices

If you wish to discuss further, please do not hesitate to contact me.

Kind regards

Helen

Research Manager (Research and Evidence)
North of England Commissioning Support (NECS)
2nd floor
Riverside House, Goldcrest Way
Newburn Riverside,Newcastle, NE15 8NY

Tel: 0191 217 2586 / 07920 565 429
Email: helenriding@nhs.net

Please note my working days are Tuesday, Wednesday and Thursday

www.necsu.nhs.uk

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Appendix 4.4: Main Study Ethical Documents

4.4.4. NECS Research Access Assurance Letter

NHS

North of England
Commissioning Support Unit

Thursday 18th May 2017

Abdulaziz Mohammed
24 Anchorage Mews
Stockton-on-Tees
Teesside
TS17 6BG

NECS Research and Evidence Team
2nd Floor
Riverside House
Goldcrest Way
Newburn Riverside
Newcastle upon Tyne
NE15 8NY

Tel: (0191) 217 2586
E-mail: NECSU.researchanddevelopment@nhs.net

Dear Abdulaziz

Study Title: **Follow-up of Abnormal Patient Test Results in Primary Care**

IRAS REF: **168736**

The information supplied about your role in the above research has been reviewed by the North of England Commissioning Support Unit. We provide research assurance to Primary Care Providers in Northumberland Tyne and Wear, County Durham and Tees Valley and North Cumbria.

I can confirm that evidence of checks, as deemed commensurate with your research activity, has been provided and deemed acceptable.

This letter provides assurance that the necessary checks and clearances as required for your research activity in the following CCGs are in place:

NHS Cumbria CCG
NHS Darlington CCG
NHS Durham Dales, Easington & Sedgefield CCG
NHS Hartlepool & Stockton on Tees CCG
NHS Newcastle Gateshead CCG
NHS North Durham CCG
NHS North Tyneside CCG
NHS Northumberland CCG
NHS South Tees CCG
NHS South Tyneside CCG
NHS Sunderland CCG.

This assurance is valid for the duration of the research or until expiry of any Occupational Health or DBS clearance (duration 3 years), whichever is earlier. Evidence of updated clearances should be provided to Research and Evidence to ensure your assurance continues.

Should your role in the research change, it may be necessary to review these checks and assurances.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act and any local or regulatory requirements whilst on GP Practice premises.

Your substantive employer remains responsible for your conduct during this research project.

NB: NECS/Health Research Authority assurance for the research study must be in place prior to commencement of your role.

This letter does not place any obligations on Primary Care Providers to allow you access to staff, patients, information or premises.

If you require advice in relation to the conduct of the research within the above organisations please contact the NECS Research and Evidence Office.

May I take this opportunity to wish you well in your research role.

Yours sincerely

Shona A Haining

Shona A Haining BSc PhD
Head of Research & Evidence
North of England Commissioning Support

NHS
Health Research Authority

London – Stanmore Research Ethics Committee
Health Research Authority
Skipton House
80 London Road
London
SE1 6LH

Telephone: 020 7972 2561

30 November 2017

Mr Abdulaziz Mohammed
PhD student
Newcastle University
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP

Dear Mr Mohammed

Study title:	**Follow-up of Abnormal Patient Test Results in Primary Care**
REC reference:	**16/LO/1551**
Protocol number:	**1**
Amendment number:	**1 (Our ref AM02)**
Amendment date:	**17 October 2017**
IRAS project ID:	**168736**

Thank you for submitting the above amendment, which was received on 29 November 2017. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*
Interview schedules or topic guides for participants	1.5	21 September 2017
Letters of invitation to participant	1.5	21 September 2017
Notice of Substantial Amendment (non-CTIMP)	1	17 October 2017
Other [Observation Schedule Appendix F]	1.5	21 September 2017
Other [IRAS 29112017]		29 November 2017
Participant consent form	1.6	21 September 2017
Participant information sheet (PIS)	1.6	21 September 2017
Research protocol or project proposal	1.6	21 September 2017

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our Research Ethics Service Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/1551:	Please quote this number on all correspondence

Yours sincerely

Patrick Walsh
REC Manager

Email: nrescommittee.london-stanmore@nhs.net

Copy to: *Dr Shona Haining, North of England Commissioning Support*

NHS
Health Research Authority
London – Stanmore Research Ethics Committee
Health Research Authority
Skipton House
80 London Road
London
SE1 6LH

Telephone: 020 7972 2561

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

02 January 2018

Mr Abdulaziz Mohammed
PhD student
Newcastle University
Queen Victoria Road,
Newcastle upon Tyne
NE1 4LP

Dear Mr Mohammed

Study title:	**Follow-up of Abnormal Patient Test Results in Primary Care**
REC reference:	**16/LO/1551**
Protocol number:	**1**
Amendment number:	**1**
Amendment date:	**17 October 2017**
IRAS project ID:	**168736**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Interview schedules or topic guides for participants	1.5	21 September 2017
Letters of invitation to participant	1.5	21 September 2017
Notice of Substantial Amendment (non-CTIMP)	1	17 October 2017
Other [Observation Schedule Appendix F]	1.5	21 September 2017
Other [SoA]	3.4	21 September 2017
Other [IRAS 29112017]		29 November 2017
Participant consent form	1.6	21 September 2017
Participant information sheet (PIS)	1.6	21 September 2017
Research protocol or project proposal	1.6	21 September 2017

Membership of the Committee

The members of the Committee who took part in the review are listed below.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

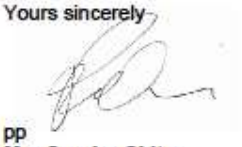
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/1551:	Please quote this number on all correspondence

Yours sincerely



pp
Mrs Sunder Chita
Vice-chair

E-mail: nrescommittee.london-stanmore@nhs.net

Copy to: *Dr Shona Haining , North of England Commissioning Support (NECS)*
Mr Abdulaziz Mohammed, Newcastle University

Attendance of the London - Stanmore Research Ethics Committee at Sub-Committee meeting on 15 December 2017

Name	*Profession*	*Present*	*Notes*
Mrs Sunder Chita	Health Service Research Manager	Yes	
Mrs Marion Cumbers	Retired Librarian	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Patrick Walsh	REC Manager

Appendix 4.4: Main Study Ethical Documents

4.4.7. HRA Approval Letter for the Substantial Amendment

Abdulaziz Mohammed (PGR)

From:	AMENDMENTASSESSMENT, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendmentassessment@nhs.net>
Sent:	04 January 2018 11:09
To:	Abdulaziz Mohammed (PGR)
Cc:	Sarah Slight; dirres.ssh@durham.ac.uk; Kay Howes; HAINING, Shona (NHS NORTH OF ENGLAND COMMISSIONING SUPPORT UNIT); AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)
Subject:	RE: IRAS 168736. SA01 HRA Assessment of Amendment Complete

Dear Dr Mohammed,

Further to the below, I am pleased to confirm **HRA Approval** for the referenced amendment.

You should implement this amendment at NHS organisations in England, in line with the conditions outlined in your categorisation email.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Kevin Ahmed
Assessor
Health Research Authority
Room 001 | Jarrow Business Centre | Rolling Mill Rd, Jarrow | NE32 3DT
T. 0207 104 8171
E. Kevin.Ahmed1@nhs.net
W. www.hra.nhs.uk

Sign up to receive our newsletter HRA Latest.

From: nrescommittee.london-stanmore@nhs.net [mailto:nrescommittee.london-stanmore@nhs.net]
Sent: 30 November 2017 16:44
To: A.Mohammed6@newcastle.ac.uk
Cc: sarah.slight@newcastle.ac.uk; dirres.ssh@durham.ac.uk; kay.howes@ncl.ac.uk; s.haining@nhs.net
Subject: IRAS 168736. Amendment confirmation of REC Validation, categorisation and implementation information

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Mr Mohammed

Thank you for submitting an amendment to your project. Please find attached a copy of the REC validation letter for the submitted amendment.

1

If you have participating NHS/HSC organisations in any other UK nations we will forward the information to the relevant national coordinating function(s).

Please note that you may only implement changes described in the amendment notice.

What Happens Next?

When available, please forward any other regulatory approvals that are expected for this amendment to hra.amendments@nhs.net. However, you do not need to forward the REC favourable opinion as we will be able to access this through our systems.

Information Specific to Participating NHS Organisations in England

1. You should now share your notice of amendment and, if applicable, amended documents, together with this email, with all participating NHS organisations in England. In doing so, you should include the NHS R&D Office, LCRN (where applicable) as well as the local research team. A template email to notify participating NHS organisations in England is provided on the HRA website.
2. The participating NHS organisations in England should prepare to implement this amendment.
3. Your amendment will be reviewed by the REC, as per the attached letter. In parallel to this, an assessment against HRA standards will take place.
4. Once the REC Favourable Opinion is issued, any other regulatory approvals are in place and the HRA assessment has been successfully completed, you will receive an email confirming that your amendment has HRA Approval.
5. You may implement your amendment at all participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this email and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner), so long as you have HRA Approval for your amendment by this date. **NHS organisations do not have to confirm they are happy with the amendment.** If HRA Approval is issued subsequent to this date, you may implement following HRA Approval.
6. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
7. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

IRAS Project ID:	168736
Short Study Title:	Abnormal Patient Test Results Study
Date complete amendment submission received:	29 November 2017
Amendment No./ Sponsor Ref:	1
Amendment Date:	17 October 2017
Amendment Type:	Substantial
Outcome of HRA Assessment	**HRA Approval for the amendment is pending.** The HRA will separately confirm HRA Approval for the amendment by email.
Implementation date in NHS organisations in England	35 days from date amendment information together with this email, is supplied to participating organisations **(provided HRA Approval for the amendment is in place and conditions above are met)**
For NHS/HSC R&D Office information	
Amendment Category	A

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