A QUALITATIVE EXPLORATION OF THE PROSPECTIVE IMPLEMENTATION OF A PRIMARY CARE CLINICAL REFERRAL DECISION TOOL FOR PATIENTS WITH SUSPECTED HEAD AND NECK CANCER

PAULA BRADLEY

November 2022

Acknowledgements

Using poorly designed and implemented digital health tools is like giving someone shoes that are too small. Yes they can walk, but will they get far? Do they enjoy it? And will they do it again?

Pritesh Mistry. Fellow, Digital Technologies, Kings Fund - seen on Twitter

Thank you to all (too many to mention individually) who have contributed to this pandemic infused PhD journey.

Firstly I would like to thank my three main supervisors who have supported me from the beginning, Professors Scott Wilkes Dean of University of Sunderland Medical School, Professor Richard Neal Professor of Primary Care of University of Exeter and Professor Vinidh Paleri, Director of the International Centre for Recurrent Head and Neck Cancer, London.

Additions to the group along the way to thank include; Dr Nicola Hall (University of Newcastle) for collaborating on the Framework Synthesis, Dr Emmanuel Ogundimu (University of Durham) for responding to an email from a stranger asking for statistician input and Dr Andrew Sturrock (University of Sunderland) for reading the thesis drafts.

To Dr Gregory Maniatopoulos (Northumbria University) your supervision and enthusiastic discussion about the topic of implementation science in healthcare has been vital to keep me motivated, particularly during the pandemic. Thank you for your pastoral care, the editing, the engagment and the honesty.

Thank you to Val Bryant, Joanne Patterson, Sarah Owen, Joanna Matthan and Jennifer Deane for words, deeds, coffee, cake and company along the way. To mum, dad and Triona for reading the thesis, after a lifetime of head and neck cancer chatter you still managed to consume some more, thank you.

I would like to thank RCGP, CANTEST, CRUK, BAHNO and Oracle Cancer Trust for the funding and academic opportunities during the PhD. Without Health Education England North East I would not

have been able to devote the time during my GP training to academia, so thank you for supporting the local integrated academic training pathway.

Final thanks go to all the participants in the research, to the patients, the healthcare professionals and other academics, too numerous to mention, who continue to strive for improvement in the patient head and neck cancer journey from recognition to palliation and everything in between.

Table of Contents

ACKNOWLEDGEMENTS
TABLE OF CONTENTS
TABLE OF TABLES
TABLE OF FIGURES
GLOSSARY
Abstract
CHAPTER 1: INTRODUCTION
Aim13
Background13
The Problem14
The Intervention15
Objectives
Structure of the Thesis16
CHAPTER 2: SUSPECTED CANCER REFERRAL PATHWAY
The NHS England Two Week Wait Suspected Cancer Referral Pathway
Impact of the Two Week Wait Referral Pathway22
Primary Care Research and Use of Patient Data to Improve Early Recognition and Referral of Suspected
Cancer
Impact of Primary Care Use of the Two Week Wait on Secondary Care
Impact of Covid-19 on Suspected Cancer Referrals31
CHAPTER 3: HEAD AND NECK CANCER TWO-WEEK WAIT REFERRAL PATHWAY IN PRIMARY CARE
Head and Neck Cancer
The Challenge for Primary Care
The Primary Care Two Week Wait Referral Criteria36
Regional Variation in Referral Criteria for Suspected Head and Neck Cancer in England
Head and Neck Cancer Recognition in Primary Care39
Risk Assessment Tool for Laryngeal Cancer42

CHAPTER 4: HEAD AND NECK CANCER TWO-WEEK WAIT REFERRAL PATHWAY IN SECONDARY CARE
Secondary Care Views on the suspected Head and Neck Cancer Two Week Wait Referral Pathway46
Head and Neck Cancer During the Covid-19 Pandemic51
Future of the Suspected Head and Neck Cancer Referral Pathway53
CHAPTER 5: IMPLEMENTATION SCIENCE AND COMPLEXITY
Implementation Science
Normalization Process Theory60
Complexity in Healthcare62
Complex Adaptive Systems
Complexity Frameworks to Explore Healthcare Innovation and Implementation
Non-Adoption Scale up Spread Sustainability (NASSS)68
CHAPTER 6: METHODOLOGY AND METHODS74
Methodological Framework74
Personal Reflections on the Research77
Method78
CHAPTER 7: PROTOCOL FOR THE STATISICAL MODELLING OF SIGNS AND SYMPTOMS OF HEAD AND NECK
CANCER IN A SYMPTOMATIC PRIMARY CARE POPULATION81
Rationale82
Methods
Limitations
CHAPTER 8: FRAMEWORK SYNTHESIS
Method
Results
CHAPTER 9: NON-ADOPTION ABANDONMENT SCALE-UP SPREAD SUSTAINABILITY (NASSS) ANALYSIS106
Method106
Results
CHAPTER 10: DISCUSSION
Aims of the Study
Summary of Results

Interpretation of Results	
The Future of the Suspected Head and Neck Cancer Referral Pathway	
Literature Comparison	
Contribution	
Strengths	
Limitations	
Reflections	
Implications for practice and policy	
Current and Future Research	204
CHAPTER 11: CONCLUSIONS	206
REFERENCES	
Appendices	220

Table of Tables

TABLE 1 SIGNS AND SYMPTOMS OF HEAD AND NECK CANCER ACCORDING TO ANATOMICAL SITE
TABLE 2 SIGNS AND SYMPTOMS OF SUSPECTED HEAD AND NECK CANCER FOR URGENT REFERRAL (FROM
NICE GUIDELINES 2000 AND 2005)36
TABLE 3 REFERRAL CRITERIA FOR SUSPECTED HEAD AND NECK CANCER IN ENGLAND (NICE GUIDELINES 2015
NG12)
TABLE 4 REGIONAL REFERRAL CRITERIA
TABLE 5 MAKE SENSE CAMPAIGN RED FLAG SYMPTOMS OF HEAD AND NECK CANCER
TABLE 6 CPRD CODES (FROM PERSONAL CORRESPONDENCE WITH E SHEPHARD)
TABLE 7 SIGNS AND SYMPTOMS FROM TIKKA (100) STATISTICAL MODELLING
TABLE 8 KEY FEATURES OF COMPLEX ADAPTIVE SYSTEMS (CASS) (145)
TABLE 9 COMPARISON OF SOME KEY CHARACTERISTICS OF IMPLEMENTATION SCIENCE AND COMPLEXITY
SCIENCE AND THEIR INTEGRATION (144)66
TABLE 10 CICI FRAMEWORK GENERIC CHECKLIST
TABLE 11 SIMILARITIES BETWEEN SOCIAL COMPLEXITY THEORY AND PRAGMATISM
TABLE 12 GENERAL TERMS SEARCHED (FULL SEARCHES IN APPENDIX E) 90
TABLE 13 SPICE CRITERIA91
TABLE 14 QUESTIONS ABOUT CCDT FOR EACH OF THE 4 DOMAINS OF NPT
TABLE 15 PARTICIPANT PRACTICE CHARACTERISTICS94
TABLE 16 FORMAT AND DETAILS OF CCDT STUDIED96
TABLE 17 STUDY METHODS AND FINDINGS97
TABLE 18 DOMAINS OF NPT IN RELATION TO CCDT98
TABLE 19 INTERVENTION PRESENTED/USED/ACCESSED FOR EACH INTERVIEW GROUP

TABLE 20 FROM PAPER FROM BRAUN AND CLARKE KEY CONCEPTUALISATIONS AROUND THEMATIC	
ANALYSIS: THEN AND NOW	.114
TABLE 21 SUGGESTIONS TO ENSURE AND COMMUNICATE RIGOR IN PRAGMATIC QUALITATIVE ANALYSIS	;
FOR IMPLEMENTATION SCIENCE	.116
TABLE 22 PARTICIPANT CHARACTERISTICS	.126

Table of Figures

IGURE 1. NASSS FRAMEWORK DIAGRAM71
IGURE 2 THE PRISMA (PREFERRED REPORTING ITEMS FOR SYSTEMATIC REVIEWS AND META-ANALYSES)
DIAGRAM93
IGURE 3. VERSION 1 ORLHEALTH CALCULATOR (V1)109
IGURE 4. VERSION 2 OF ORLHEALTH CALCULATOR (V2)110
IGURE 5. THE EXCEL SPREADSHEET FOR TRIAGE OF NEW SUSPECTED HNC PATIENTS DURING THE FIRST
WAVE OF THE COVID-19 PANDEMIC (V3)111

Glossary

A&E	Accident and Emergency
A&G	Advice and Guidance
CCDT	Clinical Cancer Decision Tool
CCDTs	Clinical Cancer Decision Tools
COVID-19	Covid-19 pandemic
DoH	Department of Health
EBM	Evidence Based Medicine
ENT	Ear Nose and Throat
ENTS	Ear Nose and Throat Surgeons
GDP	General Dental Practitioner
GDPs	General Dental Practitioners
GP	General Practitioner
GPs	General Practitioners
HNC	Head and Neck Cancer
HNCs	Head and Neck Cancers
HNS	Head and Neck Surgeon
HNSs	Head and Neck Surgeons
NG12	National Guidelines 12
NHS	National Health Service
NHSE	National Health Service England
NICE	National Institute of Clinical Excellence
OMFS	Oral Maxillofacial Surgeon
ORLHC	Symptom Based Risk Calculator for Head And Neck Cancer Referral
	(OtoRhinoLaryngology Health Calculator)
PCPI	Patient, Carer, Public Involvement
PPI	Public Patient Involvement
PPV	Positive Predictive Value
TWW	Two Week Wait
UK	United Kingdom

Abstract

Introduction

Recognition of Head and neck cancer (HNC) in primary care is difficult. The HNC two-week wait referral pathway (TWW) is demanding on hospital services because of high volume of referrals with low yield of cancers. HNC specialists have developed a symptom-based risk calculator for HNCs' referrals (ORLHC) to use as a Clinical Cancer Decision Tool (CCDT) for suspected HNC in primary care.

Aims

To identify the complexity integral to the proposed implementation of a CCDT for referral decisions about patients with signs and symptoms of HNC.

Methods

Qualitative methods were used. A Normalization Process Theory framework synthesis of the qualitative data of GPs' experience of CCDTs was undertaken. The results of this informed a semistructured interview study with 53 stakeholders (GPs, surgeons, and patients) to interrogate the potential and emergency pandemic implementation of ORLHC. The data were analysed using the Non-Adoption, Abandonment, Scale up, Spread, Sustainability (NASSS) framework.

Results

Six studies were identified for the framework synthesis, which showed that CCDTs were useful to increase awareness of signs and symptoms of undiagnosed cancer. Concerns centred around clinical acumen, specialists' impression of referrals generated by a CCDT and integration within existing systems. Fifty-three interviews were conducted. Data analysis using the NASSS framework identified complexities that may impede implementation. These included (1) understanding and interpretation of symptoms of HNC, (2) how GPs employ existing CCDTs, (3) financial incentives, and (4) the impact on referral behaviour of national cancer policy priorities. Concerns about the application of ORLHC in the primary care context were identified. Opportunities exist to improve communication between primary and secondary care to triage referrals to the most appropriate clinician.

Conclusion

This rigorous assessment has shown that ORLHC in its current form does not have the evidence base, nor financial support, to justify further work exploring its implementation for use by GPs as part of their referral process.

CHAPTER 1: INTRODUCTION

Aim

The thesis aims to explore the potential implementation of a primary care clinical cancer decision tool (CCDT), a symptom-based risk calculator developed by ENT specialists (ORLHC), for patients with signs and symptoms suspicious of head and neck cancer (HNC). The thesis asks if a CCDT such as ORLHC is a realistic solution to the problems associated with the low yield of cancer diagnosis from the large numbers of patients referred to secondary care on the two-week wait (TWW) pathway.

Background

Head and Neck Cancers (HNCs) arise from a variety of tissue and anatomical sites giving rise to some very commonly encountered symptoms which can be ignored or trivialised by both patients and clinicians. The differentiation of serious/concerning symptoms from the plethora of common symptoms, such as a sore throat, a blocked nose or a lump in the mouth or throat is compounded by the fact that some areas of the head and neck are hidden from view without specialist equipment. HNCs are much less frequently encountered in primary care when compared to cancers of the lung, the gastrointestinal tract and the breast with signs and symptoms presenting often because of the impact of the size of a tumour. HNCs are consequently amongst those commonly diagnosed at a late stage. Efforts to improve earlier recognition and diagnosis of cancers is one of the principles of the National Health Service England (NHSE) Long Term Plan (1).

Currently, in England, if a primary care clinician suspects a patient has signs or symptoms suspicious of a HNC, which fulfil specific referral criteria, they access a TWW referral pathway. This pathway guarantees a patient is assessed by a specialist within 14 days of the date of the referral. Most patients referred via this system to HNC specialists, when examined, do not have a cancer to account for their signs or symptoms. Most of the patients referred, despite their primary care clinicians concern, have signs and symptoms with a very low probability of cancer being the cause. Head and neck surgeons (HNSs) have long lamented the TWW referral pathway for HNC as not fit for purpose. The use of the TWW has not increased the numbers of patients diagnosed at an earlier stage of disease and it presents challenges to the organisation of already stretched hospital out-patient services.

Due to these acknowledged challenges some HNSs in the UK have used data from patients referred to their service as suspected cancers, to undertake statistical predictive modelling. Using this data, a couple of CCDTs have been developed and the hope was that they could be used in primary care. These CCDTs were intended to better differentiate the likelihood of cancer and determine the optimal referral route from primary care. The anticipated outcome was that use of such CCDTs would lead to a reduction in the numbers of patients referred on the TWW pathway. Their implementation was considered, from the specialist perspective, a potential additional triage check to apply to the referral process, redirecting the many patients clinically unlikely to be diagnosed with an HNC to a more appropriate route to access specialist assessment.

One of the statistical predictive modelling exercises from ENT departments in England resulted in the "Symptom Based Risk Calculator for Head And Neck Cancer Referral" (www.orlhealth.com) here on in referred to as ORLHC. Some patient information and referral criteria pertaining to the signs and symptoms of HNC was used to calculate a risk (positive predictive value (PPV)) of an undiagnosed cancer being responsible for a patients' symptoms. This calculator was derived from patient data from secondary care HNC referrals in 2016. The primary aim of the ORLHC was that it could be used as a model for primary care clinicians to triage patients with signs and symptoms suspicious of HNC to make decisions about the referral route to secondary care.

The Problem

Given that a large proportion of the patients referred on the TWW HNC pathway are not diagnosed with a cancer, HNSs speculate that there is room for improvement in the triage of patients by primary care clinicians. The hope was that a predictive risk calculation as part of the referral criteria using ORLHC might fill this gap. This study explores the challenges posed by the proposed intervention (ORLHC) itself and those thrown up by the dynamic and complex environment within which its

implementation is anticipated. This thesis is the first to apply qualitative methods to the topic of a HNC CCDT for primary care to explore and uncover issues surrounding its proposed implementation into the primary care context.

The Intervention

When the PhD began, the ORLHC had not been externally validated, it had not been trialled in any clinical setting nor had it been considered for use by any primary care clinicians. This thesis explores the potential use of the ORLHC and had to be reframed because of the way ORLHC was utilised during Covid 19 pandemic (COVID-19). ORLHC was adapted and used by secondary care to remotely triage TWW suspected HNC referrals that were received from primary care. During the first lockdown period of COVID-19, ORLHC was endorsed nationally, and adopted by numerous HNC specialists in the UK. The results of the use of ORLHC within the NHS during COVID-19 were collected, analysed, and published by the UK ENT HNC group (2).

This thesis benefits from the inclusion of interview data from HNSs around and after the first lockdown period when clinical services were reconfigured in response to the health crisis. Although the ORLHC was not used in the arena for which it was originally intended, its actual implementation and use in clinical practice offered a unique opportunity to pragmatically take the exploration from the theoretical to the practical. During COVID-19 the application of ORLHC to triage TWW HNC referrals emerged as a new way of working. Data from the interviews from this period have been considered (along with the pre-COVID-19 interviews with GPs and specialists, patients and HNC survivors), in the analysis to consider the future uses of ORLHC and its potential role in the primary care triage and referral process.

For the purposes of this thesis, the online first version of the calculator was used pre-COVID-19 in discussions with clinicians (General Practitioners (GP), Ear Nose and Throat Surgeons (ENTS) and Oral Maxillofacial Surgeons (OMFS)) and patients (with no history of HNC) to explore factors shaping the potential implementation of the tool in primary care. Version 2 and its pandemic spreadsheet version

(Version 3) were used in later interviews with some of the HNC patients and HNSs (exclusively ENT) to explore specific implementation issues related to the reconfiguration of services due to the pandemic (the versions of ORLHC are presented in Chapter 9).

Objectives

This qualitative thesis identifies and explores complex challenges associated with the implementation and use of a primary care CCDT for patients with signs and symptoms suspicious of an undiagnosed HNC. The first part of the thesis provides a synthesis of the qualitative data about how existing CCDTs for primary care have been received by those for whom their use is intended (GPs). This work establishes factors that shape the implementation of a CCDT in primary care which were explored in the stakeholder interviews. The synthesis draws upon the work done with GPs to understand previous engagement with existing CCDTs and the potential impact this would have on the proposed implementation of a calculator aimed at GPs to use in situations where they suspect HNC.

The semi-structured qualitative interviews (n=53) were carried out with clinicians (GPs and HNSs) and patients (a group of HNC patients and a group with no history of a HNC) to explore views about the current HNC referral pathway and attitudes to potential changes in the way the pathway operates. The pre-COVID-19 interviews were analysed in parallel with the HNSs pandemic interviews enabling a discussion of the potential for the implementation of a CCDT like ORLHC and what might determine any future work in this area. The results identify factors which might challenge and facilitate the establishment of ORLHC into the referral pathway for suspected HNC from primary care in the future.

Structure of the Thesis

Chapter 2 covers the history of the TWW referral process in the National Health Service England (NHSE) and provides some detail about the primary care research into cancer decision making during and beyond the inception of the TWW. The National Institute for Health and Care Excellence (NICE) provides evidence to develop and support cancer pathway referral criteria to improve the sensitivity for referrals from primary to secondary care to improve early cancer diagnosis.

Chapters 3 and 4 concentrate on HNC; the disease itself, the epidemiology, difficulties faced by primary care clinicians in recognition and referral of HNCs and the evidence for inclusion of signs and symptoms to improve recognition and referrals of suspected HNC from primary care. Chapter 4 outlines the difficulties faced by secondary care from the volume of referrals which drove the development of the ORLHC and presents the variation in referral criteria that exist around the country, and some of the difficulties this might cause for primary care.

Chapter 5 explores the literature in the field of implementation science. The implementation process must be viewed with an appreciation of complexity, particularly in the healthcare context, which exists at an individual, organisation, and political level. Change and innovation do not exist in a static environment and any change in practice and process must always take account of the dynamics of multiple interrelated players, pressures, and power structures. This chapter introduces some of the implementation and complexity theories and frameworks. The thesis uses two frameworks to analyse data; Normalization Process Theory (NPT), in the framework synthesis and the Non-adoption, Abandonment, Scale up, Spread, Sustainability (NASSS) framework which is employed to explore the complexities surrounding the potential implementation of a CCDT (ORLHC).

Chapter 6 sets out the pragmatic approach to research, how the author's background influenced the choice of PhD topic, how it determined the way the research was carried out and the choices of analytical frameworks which were applied to the data.

Chapter 7 sets out the method for the abandoned predictive statistical analysis which was planned but because of COVID-19 could not be completed. The intention was to do some multivariate regression modelling of the signs and symptoms of HNC similar to that used in modelling from the secondary care cohort.

The following chapters are divided into two (Chapters 8 and 9) and report the two different investigation types which made up the PhD. The first (Chapter 8) is the qualitative framework

synthesis. The chapter also details the framework synthesis method used to explore the factors shaping the implementation and use of CCDT by GPs in primary care. NPT is used as the framework, (an established implementation theory which explores the implementation of new technologies using sociological constructs) and is described in the implementation science and complexity chapter (Chapter 5). The Framework Synthesis was used to inform the development of the semi-structured interview topic guide for the second part of the thesis.

Chapter 9 presents the data collected from the stakeholder groups analysed using a reflexive thematic analysis approach and presented using the NASSS framework. NASSS was developed for use in the healthcare field to identify areas of complexity within seven interlinked and dynamic domains which can be used to determine areas of concern before, during and following a new technology introduction (described in Chapter 5). This chapter explores the complexity, using the NASSS domains, related to the potential implementation of a CCDT like the ORLHC into primary care for decisions about referrals to secondary care for suspected HNC. Much of the data presented in this thesis is impossible to view without using the lens of the pandemic. Some of the interview responses would likely be vastly different now compared to those conducted in the pre-pandemic era. The lessons learned from the emergency and immense healthcare reconfiguration during the pandemic, along with the patient, primary and secondary care COVID-19 experience will be important to determine any future work in this arena to refine the suspected HNC referral pathway.

The Discussion Chapter (Chapter 10) brings together the results from the framework synthesis and the NASSS analysis placing them in the context of the current literature. This discussion covers the impact of policy efforts in England to improve suspected cancer pathways, to achieve earlier diagnosis and therefore improved treatment outcomes. Other issues which are discussed include GP's use of gut instinct over protocolisation and how COVID-19 has affected the cancer landscape in England. The Discussion Chapter (Chapter 10) includes reflections on the PhD experience: the strengths and weaknesses of the research and areas for further study. This chapter includes observations about the impact of the pandemic on the researcher, the study, the write up and future research in this area.

The thesis draws conclusions (Chapter 11) from the data and the literature about the need for a CCDT in this clinical arena. It proposes potential areas which require further consideration prior to future effort into the implementation of a CCDT for HNC. In addition, the thesis discusses what contribution this research makes to the future of this area of clinical practice. It proposes other options to address problems associated with how the TWW suspected HNC pathway currently operates and the serious implications that its current format has on resource allocation in secondary care.

This introductory chapter presents the clinical and organisational problem with the referral pathway from primary to secondary care in England for suspected HNC. The ORLHC has been proposed as one solution to the problems perceived with the pathway from the secondary care perspective. Having set the scene; with four chapters covering the cancer landscape in England, that of HNC and an overview of the field of implementation science and complexity, the thesis moves onto present how the data was appproached, collected and analysed. The PhD aims to answer whether the implementation of a primary care CCDT provides a realistic solution to a problem like HNC where high referral rates do not yield many cancer diagnoses. The thesis now moves to the background chapters, starting with a review of cancer pathways in England, a discussion about the issues around early identification and referral in primary care, why it matters and what efforts have been made to improve issues regarding route of referral and earlier recognition of suspicious signs and symptoms for primary care clinicians.

CHAPTER 2: SUSPECTED CANCER REFERRAL PATHWAY

This chapter presents some background to the changes in the approach to suspected cancer in NHSE over the last three decades. The chapter presents the justification for changes in how the pathway operates, the impact of research into how to improve early recognition in primary care and some consequences experienced in secondary care by the establishment of the TWW referral pathway because of the volume of referrals compared to the conversion to cancer diagnosis and impact on service delivery.

The NHS England Two Week Wait Suspected Cancer Referral Pathway

During the 1990s, patients with suspected cancer could potentially wait months for a consultation with a secondary care specialist. This was because of the long waiting times for a routine out-patient appointment or because urgent referrals from a GP were downgraded to a routine referral by the specialist at the receiving hospital. The TWW referral pathway was introduced in 2000 by the Department of Health (DoH) to standardise the care pathway for patient assessment, rapid diagnosis and management within a defined target period (3) and improve communication between GPs and specialists. The pathway introduced referral criteria, a structured pathway, and a waiting time target of two weeks for any patient with suspected cancer referred to secondary care from a GP. The decision about the urgency of the referral sat with the GP who had clinically assessed the patient rather than the purview of the hospital consultant receiving the referral. Prior to the introduction of the TWW referral pathway, patients could be referred to a specialist on a routine basis (routine referral target is currently 18 weeks to be seen) or on an urgent basis and many, more than now, presented as an emergency.

The NICE guidelines are a set of signs and symptoms suggestive of an underlying cancer and latterly, for cancer types, include the addition of imaging and laboratory tests for primary care to use to inform and justify a timely specialist consultation to rule in or rule out a cancer diagnosis. Over the decades there have been several iterations of the NICE guidelines. The most recent referral guidelines (NG12)

have been developed with consensus agreement and draw upon evidence where available. The threshold (PPV) for referral of patients with signs and symptoms associated with a subsequent diagnosis of cancer has fallen to 3%. This threshold change was brought about by a combination of patient (4), charitable bodies and policy (5) pressure. The changes to the cancer referral thresholds aim to improve the cancer outcomes in the UK but as a result means that the numbers of patients referred for investigation and secondary care assessment have increased. The threshold changes have been controversial in terms of the impact on secondary care from referral volumes, the conversion from referral numbers to cancer diagnosis and whether the changes have the desired impact on cancer treatment outcomes and mortality.

For some cancer types, including head and neck, historical changes to the referral thresholds and subsequent increase in referral volumes, has not resulted in increased yield of cancers nor in the numbers of patients who are diagnosed at an earlier stage of their cancer. An editorial at the time of the launch of the 2015 NG12 in the British Medical Journal called for improved "access to investigations and specialist opinion, and to rely on improving clinical skills" (6) rather than a reliance on a new set of referral criteria.

There is enthusiasm to reduce the referral threshold further to 2% even 1% across 11 cancer types with the aim that it will increase those diagnosed at an earlier point. Some modelling of primary care data using the PPV data from the systematic literature review that informed NG12 referral criteria (7) has been done to justify these changes. The research included laryngeal cancer as one of the cancers studied, there is limited data about the predictive clinical signs and symptoms for this type of cancer and the main author used the results of their own research in NG12. Ideally future versions will include some of the secondary care data (8), the reliability and basis of which is discussed in the next chapter. The authors argue that the required increase in resources to respond to a change in threshold for referral from 3% to 2% would be minimal for some cancers, It is questionable that an 8% increase in resource allocation within the NHS could be considered modest in terms of healthcare finances (7)

there are potentially huge resource implications for departments which receive referrals for certain cancer types. One of these cancers is gastrointestinal cancer, where demand for endoscopy services continues to be a huge provision challenge for NHS diagnostic services. These considerations are particularly pertinent to planning and recovery from the impact of the last two years of COVID-19 (9).

Impact of the Two Week Wait Referral Pathway

The most recent (2018) National Cancer Diagnosis Audit (10) demonstrated that 52% of patients who were diagnosed with cancer were referred through the TWW route but that route of referral varied according to cancer type. Of those who presented through Accident and Emergency (A&E) only 26% had not had a previous GP encounter about their symptoms. Avoidable delay in diagnosis was considered to occur in 20% of patients (according to the GP entered data) and these were most frequently attributed to the patient, primary/secondary care clinician and system factors. This audit provides important detail about the routes of cancer referral from data entered by one in 20 English GP practices, a small fraction of practices, those with robust records, reliable record keeping and a willingness for scrutiny. The impact of the use of payments and Clinical Commissioning Group (CCG) incentives which drove this voluntary information sharing is not discussed by the authors. By the time the results were published the NG12 referral criteria had been released for use. The results of the most recent audit (data submitted in 2016) are expected and should reflect the impact of introduction of the 2015 NG12 clinical referral guidelines.

Moller *et al* (11) explored the effect of the TWW referral pathway on cancer survival for a one-year (2009) cohort of primary care patients and found that practices with the lowest use of the pathway had an excess mortality, and that this was consistent for different types of cancer (apart from breast). Data from studies like this have influenced the drive to educate patients and GPs in early recognition of signs and symptoms of cancer and encouraged GPs to use the TWW pathway (justified because it has been demonstrated that the mortality outcomes in practices with lower referral rates are worse). The sentiments expressed in this paper have influenced policy and campaigns aimed at GPs to improve

recognition and referrals for suspected cancers and some of the GPs interviewed for this PhD passed comment about this (discussed in the results presented in this thesis).

A recent analysis of a larger cohort and a longer period between 2011 and 2015 confirmed an association between higher overall practice utilisation of the TWW referral pathway and lower patient mortality for all cancers (12) in an order of magnitude that represents the differences between England and comparable countries. The study found that the total number of referrals via this route has increased over this time, as the numbers diagnosed through the emergency route have reduced. This more up-to-date analysis (12) has shown that a practice with higher TWW referrals (of patients with symptoms suspicious of cancer) confers a positive impact on the treatment and mortality outcomes for patients who are diagnosed with cancer via that referral route. The authors conclude that this work supports the lowering of the thresholds for symptomatic referrals through this route but provides no data on the impact of these changes in referral patterns on secondary care specialties including diagnostics, though at least the lack of evaluation on the healthcare system is acknowledged (7).

Cancer diagnosis after an emergency GP referral or an A&E attendance (analysis between 2006 and 2015) (13) showed that by analysing cancers by type, those more difficult to recognize early and notorious for late stage presentation (such as pancreas, gallbladder and ovarian) were more likely to present via an emergency route. Interestingly the HNC such as laryngeal, oral and oropharynx do not have such strong correlations with emergency presentation and the authors speculate whether this is due to dentists' input, or greater than average involvement of hospital departments' clinics in the diagnosis of certain cancers. An increased use of TWW referral pathway with access to timely clinical assessment and investigations has certainly contributed to this inevitable decrease in emergency presentations of cancers.

Murchie *et al* (14) studied a Scottish cohort of patients with a diagnosis of cancer (6 most common cancers, a slightly different pathway to England but comparable referral criteria) to explore their route to diagnosis and GP compliance with referral criteria (those as a result of bowel or breast screening were excluded). Discussion focused on the difficulties of missed opportunities (19% of patients) and the complex reasons for emergency presentations including recognition, non-adherence to referral guidelines and recognition of the significance of multiple presentations with the same symptoms, but patient and system factors remain important. For some patients who fall between the cracks, then the emergency presentation is their *"best chance of rapid treatment and cure and does not always represent failure"*.

A more recent study (15) which explores GPs compliance with TWW for patients presenting with six cardinal red flag symptoms of concern for cancer (dysphagia, post-menopausal bleeding, rectal bleeding, anaemia, breast lump and haematuria) and demonstrates that only 40% of patients had a TWW or urgent referral within two weeks of their red flag symptom being recorded in the electronic records. The study highlighted that those urgently referred were more likely to have a cancer which substantiates the work that concludes that "gut instinct", the clinical impression and experience is just as important as compliance with guidelines. Nonetheless there was a proportion of patients who were not referred within the two week period who went on to be diagnosed with a cancer in the next year. This study focuses on symptoms with established PPVs. The study considers the elements which appear to play into decisions not to refer, particularly comorbidities. The authors have not commented on how soon following the initial two weeks from recorded symptom those who subsequently were diagnosed with a cancer did have a referral to a specialist, which route this was through (urgent, TWW, emergency, routine) nor were they able to comment on the impact of referral type on stage at diagnosis, treatment outcome or mortality.

There is a lack of data about the sensitivity of some of the signs and symptoms for HNC which remain on some cancer alliance referral guidelines. It would be interesting to be able to explore in a similar

way compliance with HNC NG12 but this would require substantial effort particularly in terms of GDP records which are less sophisticated and integrated than those used in General Practice. Equally GPs would not reasonably expect to refer all neck lumps within two weeks of recording their existence in the notes, there are multiple factors which play into GPs' referral decisions which have been further explored in a systematic review (16). The systematic review suggests that there are non-modifiable factors related to a GP's demographics and experience. There were also what are considered modifiable factors such as an individual GPs' approach to uncertainty, the perspective of their professional role and engagement with continuing medical education. Reconciliation with referral guidelines was highlighted as a factor which contributed to conflict in decision making, this could be mitigated with improved communication channels between primary and secondary care. The review suggests further research is needed to explore how GPs "appraise" symptoms as suspicious or non-suspicious. The work from secondary care in modelling signs and symptoms of HNC seems to be motivated by questions about the reliability of clinicians in primary care to appraise signs and symptoms in the same way as specialists.

Primary Care Research and Use of Patient Data to Improve Early Recognition and Referral of Suspected Cancer

To improve the early recognition of cancer in primary care there have been two major ongoing research projects which have contributed to the growing evidence base behind the inclusion of certain signs and symptoms in the NICE cancer referral guidelines. Risk Assessment Tools (RATs) and QCancer[®] are two decision aids for GPs developed from statistical modelling of data from primary care electronic records and have been influential in determining primary care cancer referral criteria since the inception of the TWW, these will be considered in this chapter.

The first series of studies, CAncer Prediction in ExeteR (CAPER) studies (17) sought to identify the risk of cancer when a patient presents to their GP with certain recognised suspicious symptoms. Each of these CAPER cohort studies is executed in the same way. Starting with a database of patient records from primary care cancer cases which are control matched by five age and sex matched non cancer patients. Symptoms, and combinations of clinical signs and stated symptoms are statistically modelled to assess positive and negative predictive values. These values are presented in such a way that a GP can look at a colour-coded (according to risk: white = 1%, yellow = 1-2%, orange = 2-5% and red >5%) single or combination of symptoms from a chart and use this to help support referral decisions (these numbers have changed in line with the changes in the positive predictive thresholds taken on by NICE of 3%).

The RATs from the CAPER studies were piloted in 152 practices in 2010 and were seen to increase the referral rates for suspected cancer. The use of RATs was associated with the diagnosis of 47 extra lung and ten extra colorectal cancers than would have been the case had it not been used by the referring GP. The desktop mouse-mats and flip charts from the study were distributed to all GP practices in 2012 (18) though the national impact of this was not formally measured. Latterly, there are more than a dozen RATs for different cancer types (8, 17, 19-33) including laryngeal cancer. It seems logical that the cancer cases in these series will have higher PPVs for known signs and symptoms for the type of cancer diagnosed. What is perhaps more helpful is the strength in combining the sign and symptom scores to increase suspicion for individual patients.

The studies continue to be published and have replicated the case control cohort method for multiple cancer types and more recently looked at the significance of thrombocytosis in a subsequent diagnosis of cancer (34, 35). Many of these studies have been used to inform the NG12 referral criteria the clinical lead of which was their main author. The case control cohort data is static, and retrospective rather than a dynamically updated risk assessment adapted according to new information and variables like the QCancer[®] series described in the following section. Case control studies are usually to establish link between exposure to risk factors and development of disease. People who are diagnosed with cancer are not exposed to signs or symptoms of cancer these are present because of the cancer. Case control studies allow an opportunity to examine rare events to identify possible predictors of outcome calculating relative risk. These studies are subject to the accuracy of record

keeping and coding and there is no discussion of how the authors dealt with missing data and whether that introduced any bias. The purists in multivariable prediction modelling, do not use case control methods and do not advocate initial univariate analysis to exclude variables (which is a method used in the RAT series) as this can wrongly rule out potentially important predictors of disease.

Hippisley-Cox and colleagues in Nottingham developed and began publishing their series from the QCancer[®] work. QCancer[®] is a CCDT which is integrated into the Electronic Patient Record System EMIS (formerly known as Egton Medical Information System). This CCDT is based on statistical algorithms within the electronic patient record system and uses patient information such as demographics, signs, symptoms, and co-morbidities to assess current and future risk of cancer (36-44). The algorithms are updated annually using research data from those GP practices that contribute data from their practice EMIS records (QResearch). The EMIS clinical system is the most widely used system in the UK but is by no means the only one. The QCancer® 10 years risk scores are available to GPs that use EMIS and calculate individual patient risk of having a current, but unrecognised and undiagnosed cancer, based on their own clinical factors, symptomatology, risk factors such as smoking, comorbidities, and age. The QCancer[®] tools rely on coded information in the patient records, this means GPs need to accurately record signs, symptoms, demographic information, and comorbidities to allow reliable calculations of risk. The QCancer® multivariable prediction models have been validated in an external set of records, the THIN (The Health Improvement Network) datasets by statisticians in Oxford (prior to QResearch® moving to Oxford University) (45-49). The statistical modelling methods used in QCancer® and their validation take account of missing data and use recognised methods to account for these. QCancer® is fully integrated in the electronic records meaning the results of statistical modelling can be regularly updated and create real time risk predictions.

In practical terms, the QCancer[®] scores require multiple answers to detailed questions about an individual patient and in the real world of general practice it is difficult to envisage it being used unless

a doctor has already considered cancer as the reason for the patient presentation. Another consideration is that if secondary care is not aware of these risk scores, then how does a GP communicate this in the referral when, despite the calculated risk, the relevant referral criteria threshold is not reached. The vague symptom rapid access clinics aim to fill this gap between the patient in whom a GP suspects a cancerous process but where a cardinal symptom on the referral criteria is not present (50, 51).

RATs and QCancer[®] were the basis of work within primary clinical record systems by MacMillan Cancer Support, Cancer Research UK and the British Medical Journal. The project embedded a system (eCDS MacMillan electronic Cancer Decision Support Tool) within some of the GP clinical systems (52) between March and November 2013. This tool used Read Code information inputted by GPs along with demographic information to calculate a risk score for a specific patient having an undiagnosed cancer. The tool presented symptom prompts within the electronic system to GPs during consultations so they could consider adding information about six major cancers (lung, colorectal, ovarian, pancreatic, renal, oesophago-gastric) to the risk calculation (52, 53). Some of the qualitative data collected as part of this project is discussed in the framework synthesis chapter of this thesis. The Accelerate, Coordinate, Evaluate (ACE) programme evaluated the use of QCancer[®] and concluded that "More research should be done around this, as due to the limited data collected around this in these projects a solid conclusion cannot be drawn" (54). The eCDS study showed no strong evidence that having access to the tools had any impact on urgent cancer referrals, conversion, or detection of cancer. Outside the confines of research projects, there is little evidence to suggest that electronic decision tools (QCancer[®] and electronic RATs) have made an impact on early recognition and diagnosis of cancers in primary care, nor that they are frequently used in day-to-day clinical primary care practice (55).

The Electronic RIsk assessment for CAncer (ERICA) trial (University of Exeter) (56) aims to evaluate the clinical and cost effectiveness of the eRATs for six cancers (lung, oesophago-gastric, kidney, bladder,

ovary, colorectal) using symptom checkers and prompts generated by the electronic system housed in the MacMillan eCDS system. This trial reduces the threshold of PPV for signs and symptoms suspicious of an undiagnosed cancer even further to 2%. The primary outcome of this randomised control trial (intervention arm supplied with the suite of eRATs, control arm usual care) will be the stage of cancer at diagnosis It is hoped that practices using the eRATs suite intervention can reduce the numbers of cancers diagnosed at later stages of disease severity by 4.6%. This is predicted to improve the outcomes of treatment and prevent approximately 6,000 deaths a year. COVID-19 inevitably interrupted the recruitment to this study. There is no indication from the study website nor the protocol that any secondary care specialists who receive the suspected cancer referrals at the hospital end of the pathway have participated in this trial design nor that any anticipated increase in the referrals has been accounted for in the receiving hospitals nor been subject to any economic or financial impact assessment. The framework synthesis in this PhD analyses GPs' response to and use of CCDTs in relation to their referral patterns and practice. A comprehensive National Institute of Health Research Health Technology Assessment report published during COVID-19 exploring the role of cancer diagnostic tools to aid decision-making in primary care concluded that there is a lack of data supporting clinical effectiveness and therefore ability to make a judgement on the impact on patient outcomes (57). There is a paucity of data to justify NHSE promoting the increase in uptake and use of these CCDTs in primary care GP contracts.

Qualitative data suggests that GPs appreciate the TWW referral pathway as one which is easy to use when patients fit into the specified criteria. Data from 2012-2013 demonstrated that a desire for better communication between primary and secondary care exists when it comes to suspected cancer (58), these sentiments were echoed in a qualitative study of primary care staff around the same time (59).

Impact of Primary Care Use of the Two Week Wait on Secondary Care

Over the last decade, primary care has; had better access to diagnostic tests, extended and improved cancer screening for cancers such as cervical (with Human Papilloma Virus cytology) and colorectal (with Faecal Immunohistochemical Test) and developed non-specific symptom pathways to improve detection and survival outcomes. Questions remain about whether GPs rely overly on clinical referral guidelines to recognise cancers and what this means for the experience of trainee doctors in primary care, for the development of clinical gut instinct (60, 61) and for patient anxiety. There are patient consequences of over investigation and the impact of the volumes referred on secondary care departments which must also deal with the cancers diagnosed at a later stage. This is particularly relevant to those cancer types where the early recognition and diagnosis vanguard has failed to improve either the numbers of cancers picked up through the TWW or impact on survival outcomes. It is particularly pertinent to HNC where a pre referral discriminatory test like a blood test is yet to be identified and where reliance on interpretation and understanding of the relevance of physical signs and functional symptoms are paramount.

Cancer referrals impact on secondary care because despite the fact that over the years the threshold at which patients are referred have become lower the yield of cancers from the volumes referred have also reduced for all cancer types are under 20% (most less than 10%) (62). Conversion rates have decreased from 10.8% (2009-2010) to 6.6% (2019-2020). There is a need for new ways for primary care to prioritise their referrals particularly for cancers like head and neck where there is no laboratory test to contribute to the decision making and one which has one of the lowest conversion rates after brain and central nervous system TWW referrals. An alternative is for the process of triage of referrals to operate at the secondary care end, which is what happened during COVID-19 in some ENT departments in the UK.

A recent systematic review of primary care diagnostic prediction tools for colorectal cancer (63) concluded that none of the many predictive models had been fully validated, none had robust

effectiveness data nor economic impact analysis and so provide limited evidence of their impact on patient outcomes. Colorectal surgeons are calling for improved risk stratification with a combination of structured history and examination and call for the development of online decision support for patients as well as for primary and secondary care (64). As with suspected HNC referrals the increase in the volume of patients referred under the TWW pathway has not been matched by an improvement in the stage of cancer at diagnosis (65). This mismatch between primary and secondary care and the siloed working practice seem inevitably to lead to increased tension between primary and secondary care in efforts to achieve the goal of increasing early cancer diagnosis and improving treatment outcomes. Concerns and calls for improved risk stratification for cancer referrals have come from colorectal surgeons as well as HNCSs. Lowering the threshold for suspected cancer referrals across the board must be subject to enquiry. Increasingly, and in the face of pandemic pressures, secondary care is tightening up on their scrutiny of referrals to check that specified criteria are being met (this is more common for routine referrals than cancer). The increase in the use of electronic advice and guidance (A&G) during the pandemic means primary care can access specialist advice about their patients in the community. This is being recommended as means to manage referrals from primary to secondary care by NHSX (part of NHS Transformation Directorate). Electronic communication could be adapted in numerous ways to help manage the triage of patients in whom a GP suspects a cancer, particularly when there is no appropriate primary care investigation to add to the risk profile and mitigate decision making like HNCs.

Impact of Covid-19 on Suspected Cancer Referrals

The response to COVID-19 has had a deep and lasting impact on healthcare services, how they are delivered and patient expectations. The changes and responses to the pandemic will determine the health of the nation for the next several decades.

During the first month of the lockdown period in England, suspected cancer referrals fell by 60% (66). With the subsequent backlog of referrals there is huge pressure on services to assess and investigate.

The effects of the delays in referrals were modelled by a UK group and they concluded that delays in diagnosis and the inevitable later stage at diagnosis will influence mortality rates and these will not be clinically evident for ten years or longer (67). Early analysis of the COVID-19 cancer service provision and targets (in the first two waves of the pandemic) has shown that the Cancer Wait Time targets in England were not met despite the lower numbers referred compared to prior to the pandemic (68). Unfortunately, more time has passed, and the NHS has been subject to further disruption, this will inevitably have a negative effect on cancer outcomes in England and this will no doubt be replicated around the world. The United Kingdom (UK) government response to the healthcare crisis appears to focus on secondary care resourcing, but without primary care investment, access to diagnostic capacity and improved communication between primary and secondary care timely access to cancer diagnosis will deteriorate (69) particularly for those where the inverse care law exists (70).

This chapter explores the history of the suspected cancer pathway in England. It considers what motivated its development, the primary care evidence that informs it, the role and evolution of the CCDTs which aim to improve recognition in primary care to improve the treatment outcomes via the benefits of an earlier stage at diagnosis. The increase in suspected cancer referrals from primary care is felt by secondary care who must meet the TWW target to assess a patient and there are calls from specialists to respond to the volume of referrals with further methods to prioritise those patients who are most likely to have an underlying cancer.

The next chapter concentrates on the context related to HNC, the difficulties faced by primary care when it comes to this type of cancer, what proposals have been made to address the problems of recognition and triage of patients where an underlying HNC is suspected, how some HNS responded to the COVID-19 healthcare crisis and how this was evaluated.

CHAPTER 3: HEAD AND NECK CANCER TWO-WEEK WAIT REFERRAL PATHWAY IN PRIMARY CARE

This chapter discusses the context within which the new CCDT for the signs and symptoms of HNC has been developed and the primary care environment within which it is expected to be utilised. The epidemiology of the disease is described along with the difficulties which face primary care in differentiating the sinister from the benign when it comes to HNC because of the variety of signs and symptoms which, though usually insignificant can sometimes represent an underlying cancer. The chapter presents the changes to the national referral criteria agreed by NICE, the current regional variations in the referral criteria, and the efforts made in primary care research to identify signs and symptoms which point to an undiagnosed laryngeal cancer.

Head and Neck Cancer

HNC is the 8th most diagnosed cancer in the UK, there are approximately 12,200 new HNC cases in the UK every year, which is an average of 34 HNCs diagnosed every day (2015-2017). The crude incidence rate in 2018 was 25 new HNC cases for every 100,000 males in the UK, and 11 for every 100,000 females (71), therefore in a primary care practice of 10,000 patients there will be approximately two diagnoses per year. There were nearly 4,100 deaths attributable to HNC in the years between 2016 and 2018. (71).

Over the last decade, HNC incidence rates have increased by a fifth (20%) in the UK. Rates in males have increased by a sixth (17%), and rates in females have increased by around a quarter (24%) (2015-2017). HNCs affect mainly adults with an increase in diagnosis in the eighth decade and are more common in males than females. Risk factors for HNCs include alcohol, smoking, precancerous lesions and human papilloma viruses (Human Papilloma Virus (HPV) 16 and 18) (72). The numbers of HNCs diagnosed a year are increasing, this is despite the fall in cigarette smoking there is a rise in the HPV positive cancers of the oropharynx (tonsils and base of tongue) in middle aged non-smokers of both genders (73).

The Challenge for Primary Care

HNC is a term that comprises a large group of cancers that affect many different, often functionally crucial, anatomical sites and tissue types. The majority of HNCs originate in the epithelial mucosa and are identified as squamous cell carcinomas. These cancers develop in the mouth, the larynx, and the pharynx (3 parts: nasopharynx, oropharynx, laryngopharynx), while other rarer forms of HNC develop in salivary glands, thyroid gland, nose, paranasal sinuses, ears and bones of the face and skull. Skin cancers and lymphomas present with signs and symptoms in the head and neck region.

Signs and symptoms of HNC will depend on the anatomical site affected. Signs of HNC are common and include (1) a swelling in a named gland (thyroid, salivary), (2) an increase in the size of a lymph node, (3) a soft tissue or bony change and (4) signs which present to primary care (GPs and GDPs), such as an ulcer in the mouth or oropharynx. Symptoms of HNC present with alteration to function and affect things like chewing, eating, swallowing or speaking, but can also affect breathing and be the cause of weight loss (either because of the metabolic impact of cancer or because of the change in the ability to eat or swallow because of pain or impact of the size of a tumour). Other common symptoms include earache (otalgia), sore throat, facial pain, and nasal obstruction. Because of the complex anatomy of the head and neck, there are signs and symptoms related to its rich and varied anatomical structures, lymph drainage, innervation, and vital bodily functions. A summary of the signs and symptoms of HNC according to anatomical site (see *Table 1*) demonstrates their variety.

Anatomical site	Signs and symptoms
Oral (lips, gums, minor salivary glands, anterior tongue)	Ulcer Lump – local or regional lymph nodes Bleeding White/red patch Cranial nerve palsy Pain - Local or referred (otalgia) Trismus Loose teeth
Oropharyngeal (base of tongue, tonsils, soft palate and posterior pharyngeal wall)	Sore throat Lump – local or regional lymph nodes Pain – local or referred (otalgia) Dysphagia Stertor Change in voice (hot potato, nasal voice) Nasal regurgitation
Sino-Nasal	Lump – local or regional lymph nodes Bleeding Pain Unilateral/bilateral nasal obstruction Anosmia Unilateral/bilateral nasal discharge Tooth instability Ocular signs Cranial nerve palsy Trismus
Nasopharyngeal	Nasal obstruction Bleeding Cranial nerve palsy Lump – local or regional lymph nodes Hearing loss from middle ear effusion Nasal voice Headache
Hypopharyngeal	Pain – local or referred (otalgia) Dysphagia Hoarseness Neck lump (regional lymph nodes) Shortness of breath/stridor Weight loss
Larynx Supraglottis	Pain Hoarseness Swelling/Lump – local or regional lymph nodes
Glottis	Hoarseness – early & late Stridor – late Pain – late Dysphagia – late Swelling/Jump – regional lymph nodes – late
Subglottis	Voice change Stridor Swelling/Lump – regional lymph nodes
Salivary glands	Swelling/Lump – local or regional lymph nodes Pain Cranial nerve palsy
Thyroid	Swelling/Lump – local or regional lymph nodes Stridor Hoarseness Dysphagia
Primary bone tumours	Swelling/Lump – local or regional lymph nodes Pain Ocular changes Trismus Loose teeth
Other symptoms which may be associated	Weight loss Insomnia Shortness of breath

Table 1 Signs and Symptoms of Head and Neck Cancer according to anatomical site

The Primary Care Two Week Wait Referral Criteria

There have been several iterations of the suspected cancer referral guidelines in England since their

inception (Table 2 and Table 3 show the HNC referral criteria over the last two decades).

Table 2 Signs and symptoms of suspected head and neck cancer for urgent referral (from NICE guidelines 2000 and 2005)

Department of Health Guidelines 2000	NICE Guidelines 2005
Ulceration of oral mucosa persisting for >3/52	Ulceration of oral mucosa persisting for >3/52
All red or red and white patches of the oral mucosa	Unexplained red and white patches (including suspected lichen planus of the oral mucosa
Hoarseness persisting for >6/52	Hoarseness persists for >3/52
Unresolving neck masses for >3/52	Unresolving neck lump for 3/52
Unexplained tooth mobility not associated with periodontal disease	Unexplained tooth mobility not associated with periodontal disease
Unilateral nasal obstruction particularly when associated with purulent discharge	Unexplained persistent sore or painful throat
Cranial neuropathies	Persistent swelling in the parotid or submandibular gland
Orbital masses	Unilateral pain in the head and neck area for more than 4 weeks, associated with otalgia but with normal otoscopy
Dysphagia persisting for 3/52	
Oral swellings persisting for >3/52	

The signs and symptoms in NG12 are considered those for which there is a more than 3% chance of a

patient presenting with one of these being subsequently diagnosed with a cancer (as discussed in the

previous chapter). Those selected are derived from a pragmatic list of signs and symptoms and are

largely based on clinical experience and consensus agreement, at the time of the development of the

guidelines there was a lack of robust data from primary care to inform the decisions (74).

Table 3 Referral Criteria for suspected head and neck cancer in England (NICE Guidelines 2015 NG12)

Ulceration of oral mucosa persisting for > 3/52
A red or red and white patch in the oral cavity consistent with erythroplakia or erythroleukoplakia
Aged 45 or above persistent unexplained hoarseness
Persistent unexplained lump in the neck
Lump in the lip or oral cavity

Regional Variation in Referral Criteria for Suspected Head and Neck Cancer in England

The NG12 guidelines have tightened up the broad criteria of previous iterations of the referral criteria

but it is evident from reviewing regional guidelines that, at the time of writing, each of the regional

cancer alliances has slightly or greatly differing clinical referral criteria (see *Table 4*). The criteria often

originates from previous iterations of the NICE guidelines.
England is made up of a 21 regional Cancer Alliances (made up of representatives from primary and secondary care), the criteria are decided upon in consultation with members of the alliance for local implementation. Members include representatives from both primary and secondary care. London (a pan-London guideline is used for three of the alliances) has the widest range of symptoms which includes all the signs and symptoms from previous NICE TWW HNC referral criteria. Only five of the Cancer Alliances in England were solely using the NG12 criteria (75). There may be some discomfort in narrowing the criteria amongst clinicians, be that primary or secondary care. Whatever the reason, it appears that the NG12 HNC criteria is not deemed sufficient for many of the regional cancer alliances. This might reflect secondary care's influence or genuine fear that cancers will not be recognised at the earliest opportunity or that suspicious cases even those that are relatively rare will not be referred in a timely manner without the inclusion of certain signs and symptoms on the list of referral criteria.

Some of the concerns from specialists about HNC are that many are diagnosed via non TWW routes. National Cancer Registration and Analysis Service "Routes to Diagnosis" publication shows that between 2006 and 2014 (76) 46% of diagnoses of HNC came via the TWW pathway, 28% came from GP via routine referral, 16% via an elective route starting with an outpatient appointment (either selfreferral, consultant to consultant or other referral) and 7% via an emergency route (the other 3% are unknown, post mortem diagnosis or via an elective booked or listed admission).

Table 4 Regional Referral Criteria

<u>SIGNS AND</u> <u>SYMPTOMS</u> <u>ALLIANCE NAME</u>	NG12 criteria only	Hoarseness (>6/52)	Sore throat	Referred Earache	Unilateral Otitis Media with Effusion	Dysphagia / Odynophagia	Globus & suspicion of cancer	Oropharynx lump/tonsil abnormality	Parotid / submandibular swelling	Unilateral Nasal Obstruction +/- bloody/purulent discharge	Unexplained cranial nerve palsy	Orbital Mass	Severe Facial Pain/numbness	Poor healing after tooth removal/tooth mobility	Trismus	Mucosa l firm swelling in oral cavity
Northern	х															
Lancashire and	х															
South Cumbria																
West Yorkshire & Harrogate		x	x	x		x			x	x	х	x		x		x
Humber Coast & Vale*		x	x	x		x				x			x		X	
Cheshire & Merseyside			x	x		x		x								
Greater Manchester			x	x		x			x	x	х	x				
South Yorkshire & Bassetlaw	x															
West Midlands			х													
East Midlands			х	x		х				x				х		
East of England North												x				
London (Pan London)			x	x		x			x	x	x	x	x	x		x
East of England South												x				
Thames Valley			х	х			х	х	x							
Wessex		x	х	х		х		х								
Surrey & Sussex	х															
Kent & Medway	х															
SWAG			х	x	x	x		х	x	x				x		
Peninsula				х	x	x		х	x	x				х		

The regional referral guidelines are agreed within the Cancer Alliances; the fact that there are so many variations in the additional signs and symptoms added to the NICE guidelines is concerning and does not appear to be reflected in other cancer site pathways. For some regions, the inclusion of odynophagia or dysphagia at the cervical level in TWW HNC referral criteria is considered justified. Delays may occur if those symptoms are referred via the TWW gastroenterology route, where endoscopy services may be stretched by demands from suspected upper gastrointestinal cancer referrals (which includes dysphagia as one of its referral criteria) and the provision of open access services provided for GP direct referrals.

Head and Neck Cancer Recognition in Primary Care

Only a small (but significant) proportion of patients referred to TWW clinics receive a subsequent diagnosis of HNC (8.8%), and this pathway accounts for 40.8% of diagnosed HNC (77). Some of the areas of the head and neck, from which many of the cancers arise, are not accessible in primary care without an endoscopy (intranasal, nasopharynx, base of tongue, hypopharynx, and larynx). Those areas which are visible such as the oral cavity, familiar to GDPs, are not necessarily viewed with the same confidence by GPs. NICE recommend oral lesions seen by a GP should be subsequently assessed by a GDP. Referral processes from GP to GDP are not well established, many patients do not have a registered dentist, this leaves GPs with difficult decisions about what to do with oral lesions best dealt with by dentists (78). A lack of confidence in head and neck because of lack of clinical exposure (79) and a disconnect between services and inadequate provision of dental care creates unnecessary delays in referrals to secondary care (80). All of this goes some way to explain why some of these cancers remain diagnosed at a late stage despite the lowering of the referral threshold and the numbers referred on the pathway. Confounding issues are that patients often dismiss these common but troublesome symptoms for longer than perhaps they would if it were a change in their bowel habit or waterworks, and so, present to primary care late (78).

Symptoms of HNC are common in general practice. They are sometimes present without any detectable abnormality on examination because, as mentioned, much of the head and neck mucosal areas are inaccessible in primary care (base of tongue, nasopharynx, hypopharynx, larynx, sinuses). The inability to examine these areas can be either a false reassurance or cause anxiety for patient and GP. Less prevalent cancers, by their rare nature are more difficult to predict because the symptoms a patient presents with can be common, and neither sensitive nor specific for diagnosis.

Some of the features particular to the HNC TWW pathway compared to those pathways for other cancer sites include the fact that there are no helpful blood markers for use in primary care to triage suspicious cases into low or high risk for an underlying cancer diagnosis. There is variation in the quality and availability of out-patient diagnostic ultrasound guided fine needle aspiration of neck lumps for diagnostic purposes that is available to primary care. Primary care has been discouraged from requesting ultrasound investigation of neck lumps as it leads to a lot of inadequate imaging of malignant as well as benign pathology in the neck (81) and inevitable delay, therefore, in diagnosis. Appropriate diagnostic imaging and cytology are often limited to specialist radiologists and radiographers working alongside histopathologists.

A retrospective study from Helsinki (82) estimated that one HNC was detected once in every 6,000 symptomatic patient seen in primary care (seen by GP or nurse, figures analysed from 2016). Of a total of 242,211 patients; 11,896 had one of the symptoms potentially caused by HNC coded in their electronic notes (according to the red flag symptoms promoted in the European Head and Neck Society Make Sense Campaign 2013) (see *Table 5*).

1	Sore tongue, non-healing mouth ulcers and/or red or white patches in the mouth
2	Pain in the throat
3	Hoarseness
4	Painful and/or difficulty swallowing
5	Lump in the neck
6	Blocked nose and/or bloody discharge from the nose

Table 5 Make Sense Campaign Red flag symptoms of head and neck cancer

There is a recognition that delay in diagnosis of HNC has many components: patient factors include delay in; recognition of symptom seriousness, seeking help and patient initiated follow up (83-85). Time intervals from first symptom to diagnosis of HNC are important in determining outcome of treatment. A researcher administered questionnaire of 80 patients diagnosed with HNC by Allgar *et al* (86), found that where a patient could recall a date of first symptom and that there was a median total time interval of 111 days to diagnosis (76 patients). Thirty nine percent (31/80) of participants in the study admitted that they felt something was wrong for more than a month before realising that they might need help. Few participants could estimate the help-seeking interval from self-reported first symptom dates, but most had first contact with a GP (85%) rather than a dentist (86).

Clinician factors determining a delay in diagnosis of HNC, include a lack of experience and confidence in head and neck history taking and clinical examination and the relative frequency of benign head and neck signs and symptoms (87, 88). The results of a small questionnaire exploring the views of 27 GPs in the North-West about the referral system for suspected HNC (89) suggests that improved prereferral communication between primary and secondary care would improve referral patterns. There was a perceived time gap between the TWW and the urgent referral where suspicion exists but is not high. In addition, a dialogue with the patient about the impression and the suspected cancer route through which the GP is referring them was seen as important to the clinician receiving the referral in secondary care and something which specialists perceived was being omitted by primary care clinicians. The same study explored reasons for GPs referring patients in whom they do not truly suspect cancer as the reason for their symptoms citing medicolegal implications and defensive medicine as reasons for referral decisions.

Rather than adding to the ever expanding and self-selecting postgraduate education packages one approach could be to admit that there are huge differences between the ability of specialists and generalists to assess head and neck symptoms and find a way to address this by means other than education. Improving communication between these two groups could both improve patient care and offer the most appropriate referral route. This a more realistic approach to the problem of the volume of suspected HNC referrals to secondary care than expecting specialist knowledge and understanding of HNC from generalists. Communication through non written formats is certainly a more efficient means of shared decision making about patient referral. A discussion with a specialist may mitigate the risk a primary care clinician carries, may facilitate easier decision making, and offer options to instigate some initial investigation or management options prior to hospital specialist assessment. Certainly, the way patients were managed in COVID-19 has shown that improved communication helped manage uncertainty and risk. This, at least at the height of the crisis, helped with the triage and flow of patient referrals from primary to secondary care (this is discussed in Chapter 4 in relation to HNC).

Risk Assessment Tool for Laryngeal Cancer

The laryngeal cancer Risk Assessment Tool (8) is a primary care cohort case control study based on the series of studies described in Chapter Two. The study used the now established RAT cohorts (see Chapter One); the team included no secondary care input and used only eight Clinical Practice Research Datalink (CPRD) codes for laryngeal cancer (two of which are carcinoma in situ). The conclusions were that pain and hoarseness are more sensitive symptoms which lead to an eventual diagnosis of a laryngeal cancer.

Pain (throat and or ear), odynophagia and dysphagia combined with hoarseness in the secondary care setting are not associated with a cancer located purely in the vocal cord (larynx) rather those arising from the hypopharynx. These cancers often present at a late rather than early stage (90). *"Hoarseness is often an early presenting symptom of glottic cancers due to vocal cord immobility or fixation, with pain with swallowing and referred ear pain indicating advanced disease. In contrast, pain with swallowing is the most common early symptom of supraglottic cancer, with hoarseness indicating advanced disease extending into the glottis" (91). Hence, the larynx RAT is unlikely to be helpful in early recognition at all as most signs identified as significant are in fact signs of late-stage disease.*

Likewise, clinically manifest/palpable neck lump associated with a HNC implies a cancer outside the vocal cords, again either a late sign or a cancer in the supraglottis or one which has spread to the larynx from another site (hypopharynx) or is extending beyond the vocal cords. Neck nodes are not associated with cancer limited to the glottis, *"Lymphatic involvement is a pathologic hallmark of supraglottic cancers, in contrast to both glottic and subglottic cancers"* (91).

The limited clinical codes related to laryngeal cancer used in this study is likely to explain why the study did not show that the presence of a neck lump was associated with diagnosis of laryngeal cancer, but it also explains why the authors were surprised by this finding as they lack the relevant clinical experience to recognise that this is not surprising at all. The addition of input from clinicians with an interest in HNC might have added to the codes used in the searches, enhanced the results and conclusions made as well as its clinical relevance. The study includes carcinoma in situ of the larynx twice, this is a premalignant not a malignant pathological finding most clinically associated with hoarseness alone. Picking up pre-malignant processes remain nonetheless very important, in terms of management and for subsequent surveillance.

Code	Description	Code	Description
319	Malignant neoplasm of larynx	43111	Malignant neoplasm of laryngeal cartilage
9237	Malignant neoplasm of larynx NOS	50579	Malignant neoplasm, overlapping lesion of larynx
11403	Carcinoma in situ of larynx	53882	Carcinoma in situ of larynx NOS
26813	Malignant neoplasm of larynx, other specified site	97332	Malignant neoplasm of laryngeal cartilage NOS

Table 6 CPRD codes (from personal correspondence with E Shephard)

These types of studies based on electronic patient records are fraught with errors in primary care interpretation of clinical signs, symptoms, and their subsequent coding as well as reflecting a lack of clinical expertise both by the referrers and the coders, as discussed in the previous chapter. The addition of insomnia as one of the signs and symptoms was not explained: this may be significant because some of these patients have some degree of airway compromise which might be apparent in a recumbent position, but that this is the reason is not obvious from the data nor the discussion. There is no exploration of the stage of cancer at diagnosis which is important when this risk assessment tool is proposed to improve earlier recognition of these cancer types. The lack of a more comprehensive code search with the assistance of a HNC expert means this cohort study is potentially missing many laryngeal cancers and other relevant HNCs which present with similar symptoms (hypopharyngeal, the different sites of the larynx and the thyroid). It fails to provide as comprehensive or accurate an evaluation of the signs and symptoms of laryngeal cancers that the authors assert.

There are issues related to recognition and referral of HNC within primary care because these cancers are a relatively uncommon presentation. This is confounded by the fact that the symptoms with which HNCs present are common and can be in anatomical areas that are not easily accessible to examination in primary care. Regional variation of the referral criteria means that some patterns of disease presentation may not be recognised particularly where the referral criteria have been pared down over the years which can create gaps in knowledge particularly for less experienced primary care clinicians. There are additional issues with ability and availability for GPs to make onward referral to and patient access to dental services. The next chapter considers the views of secondary care about the way the HNC TWW referral pathway is working, their efforts to try and influence the future of the clinical criteria for referral and how one solution which was proposed to address the difficulties faced by primary care clinicians. This proposed solution (ORLHC) is the subject of this thesis, was used by secondary care during COVID-19 and this investigation of its proposed and actual use has implications for the future of the suspected HNC pathway.

CHAPTER 4: HEAD AND NECK CANCER TWO-WEEK WAIT REFERRAL PATHWAY IN SECONDARY CARE

This chapter presents some of the secondary care work exploring which of the signs and symptoms of HNC, alone and in combination, are most predictive of an outcome of a cancer diagnosis from a referral on the HNC TWW pathway.

Solutions have been proposed by secondary care to try and reduce the volume of patients referred via the TWW pathway and improve the reliability of the referral criteria to more accurately identify those patients most likely to have an underlying cancer as the source of their symptoms. Some statistical modelling of predictor signs and symptoms has been conducted to achieve this (ORLHC) and it was originally considered as a potential decision tool for use in primary care. During the period that this research was conducted, ORLHC was used in a way that the authors had never predicted, to remotely triage patients referred from primary to secondary care on the TWW pathway during COVID-19. It is this CCDT (ORLHC) for use in primary care for suspected HNC referrals which is the example under consideration in this thesis.

Secondary Care Views on the suspected Head and Neck Cancer Two Week Wait Referral Pathway

Data from NHSE shows that TWW referrals to ENT are increasing (92). The creation and promotion of the TWW referral route encourages primary care clinicians to endeavour to detect cancers at an early stage to improve treatment outcomes and facilitate timely assessment. In HNC, the cancer stage at diagnosis (how extensive a cancer is in terms of local, regional, and systemic impact) has not improved with the use of the TWW referral pathway (77). Significant numbers of cancers are still diagnosed through routine, emergency, and referrals from other departments. Several datasets suggest that the outcome of cancer treatment is not dependent on the route through which the patient accesses specialist input and in fact those who receive a diagnosis of HNC via a non-TWW route do not have worse survival outcomes than those who come through this pathway (93, 94).

Data collected from Yorkshire demonstrated that TWW referrals to one ENT department had increased by 84% between 2009 and 2014 (93). One reason cited for this is that "referring and diagnosing patients based on head and neck symptoms can be challenging as other benign head and neck disease can also present in a similar way" (93). Though this is a very small study it emphasises the difficulties which secondary care consider primary care clinicians face in differentiating cancerous from non-cancerous presentations. There is no further exploration of this aspect within this study as the main aim was to look at the clinical outcomes of the patients diagnosed with HNC. They did conclude that, "The current TWW referral system for suspected HNC patients does not identify early cancer nor lead to better overall survival. Patient and primary care education on cancer awareness is essential to ensure early diagnosis" (93). Expanding medical education is only one solution to the problem of "inappropriate" referrals, it provides an ideal world solution to a real-world problem where a more imaginative, realistic, and collaborative approach might be a better one.

There is similar data from oral and maxillofacial surgical departments (95-98) of low cancer diagnostic yield from high volume of referrals (mostly from GPs rather than perhaps expected, from GDPs) with suggestions that better communication between GPs and GDPs and online referral tools encompassing scoring systems could be adopted in an effort to take pressure off departments to deliver the 14 days target for lower risk patients.

Appendix A demonstrates some of the most common symptoms which present to a TWW HNC clinic and the yield of a cancer diagnosis from these referrals. These tables are composites of several audits from secondary care (94, 99-103). These types of audits are motivated by the secondary care specialists' belief that the volume of referrals coming from primary care via this route reflects poor use of the HNC TWW criteria and that the criteria used are not good at differentiating those patients most likely to have a cancer causing their symptoms from those unlikely to have cancer. Some HNSs want to reinstate of some of the more sensitive red flag symptoms from previous iterations of the referral guidelines like unilateral ear pain (otalgia) and persistent unilateral sore throat (102, 104) and

there is mounting data that a combination of symptoms strengthens the predictive value of referrals (105). These arguments may fuel the resistance by some cancer alliances to instigate the NG12 referral guidelines.

The results of several statistical predictive modelling (100, 101, 106), development of web-based tools (107) and a machine learning algorithm (108) have been published from HNC teams within secondary care. The hope is these will provide some evidence from secondary care to establish an evidence-base for future versions of the referral criteria and to aid primary care when deciding the referral route for a patient with head and neck signs and symptoms. The impetus is to reduce pressure on hospital resources from the volume of suspected HNC referrals the majority of which are not diagnosed with cancer.

Tikka *et al* (100) have used the previous iterations of the TWW criteria in their retrospective analysis of nearly 5,000 patients and concluded *"refinement of the current NICE referral guidelines is possible and will increase diagnostic efficacy"*. The study modelled signs and symptoms of HNC showing that some combinations of signs and symptoms coupled with age and sex variables are more predictive of cancer diagnosis as an outcome from a suspected HNC TWW referral with *"greater diagnostic efficacy"* (100).

The statistical modelling in this study was flawed in that it omitted to account for incomplete data (367 patients were omitted from the analysis) rather than adjusting for that by some recognised statistical method (109). Rare symptoms were omitted, smoking status, long regarded as a risk factor strongly associated with the development of a squamous HNC, was missing in half the patients, and therefore not included in the analysis. Well established statistical approaches to missing data were not used in this study. There is little information about the ethnic make-up of the patients which questions its application in a different population group. It is not clear whether the chosen clinical signs and symptoms are based on the primary care clinical assessment upon which the referral was

based, or the secondary care specialist clinical findings. The study (100) does offer some encouraging data in terms of the predictive value of signs and symptoms, and when compared to the NICE criteria of 2005 and 2015 are more sensitive for this cohort of patients. It should be considered that the input of a more comprehensive specialist history and examination findings may have influenced this sensitivity rather than the information the original referral contained. The model was used to design a symptom-based risk calculator that is freely available on the internet (<u>www.orlhealth.org</u>). *Table 7* from Tikka *et al* (100) shows recommended changes to the current guidelines following statistical predictive analysis of signs and symptoms associated with an outcome of cancer from patients referred to TWW clinics.

Table 7 Signs and symptoms from Tikka (100) statistical modelling

Recommended referral criteria
Persisting hoarseness for > 3/52
Unexplained oral ulceration or mass >3/52
Unexplained persistent swelling in the parotid or submandibular gland >3 weeks
Unexplained neck mass > 3 weeks or recently appeared neck mass
Dysphagia >3/52
Odynophagia >3/52
Unexplained otalgia with normal otoscopy
Sensation of lump in throat with presence of blood in mouth
Sensation of lump in throat with unexplained otalgia with normal otoscopy

The model was externally validated in a Scottish cohort of 2,000 patients who had been referred to the rapid access clinic for suspected HNC (106). On this occasion only two cases were excluded because of missing data (rather than considering using statistical methods to include cases with missing data). The external validation showed that the symptom calculator had a strong predictive power. The external validation reports the significance of the symptom of unintentional weight loss in the patients who were diagnosed with cancer. This predictor variable was not reported in the results of the derivation cohort. It is not clear if weight loss was an addition to the external validation modelling or whether it was an omission in the first model because of the incomplete data. This cohort had a more complete dataset probably because the intention for the collection of the data was specifically to externally validate the model. The model was further refined with another Scottish cohort of 3,650 patients (101) seen in all types of head and neck clinics (not only the urgent suspected cancer referrals) so as to include those cancers diagnosed via routes other than the suspected cancer route. There were 307 cancers diagnosed and the sensitivity (to predict the true positive cancers) of the model increased to 88.6%. This is not a screening test (like a faecal immunochemical test or a representative of human tissue like a cervical cytology sample) so it is a false attribute of the calculator. The optimism with which a prediction model can accurately predict a particular outcome, should be expressed in terms of the calibration and discrimination (110). The use of this calculator is subject to human experience and error plus the interpretation of what a patient means when they describe their symptoms, as is shown in the analysis of the interviews with HNSs during its use during COVID-19. The authors celebrate the AUROC (Area under the receiver operator characteristic) but make no mention of the intercept nor calibration associated with the model, these two parameters are essential in reporting the reliability of prediction models (111). The authors also do not make it clear whether the signs and symptoms modelled were those with which the primary care doctor referred the patient or whether these were the result of a specialist interpretation of a patient history and informed by the results of a clinical examination. The authors originally propose that this calculator be used as a CCDT within the range of decision tools used in primary care or used as a triage tool at the secondary care end to assess the urgency of the two-week wait referrals received from primary care. This second model, unlike the first version (which is presented on the internet site orlhealth.org as Version 2), includes details of some of the predictor symptoms such as their persistent, intermittent, unilateral, bilateral nature, presence of unintentional weight loss and some lifestyle factors such as smoking (current, ex, never) and alcohol history (previous excess, more or less than 14 units a week).

The secondary care population data upon which the examples of the multivariable prediction modelling is based (100, 101, 106, 107), by their nature, have a higher prevalence of HNC within them than would exist in a primary care cohort.

Symptom risk calculators developed from secondary care, theoretically, cannot be applied to the general primary care population within which the prevalence of HNC will be lower because of the spectrum effect (112). The spectrum effect refers to the phenomenon where tests that are developed in a population with the disease more prevalent, can be less accurate in identifying disease when applied to another population where the disease is less prevalent. The signs and symptoms are common but subject to interpretation by the clinician depending on their experience and confidence with them. More extensive model derivation and validation in different cohorts, at the very least, is needed before a pilot of the symptom calculator for TWW referrals from primary care is launched, let *al*one before such a CCDT can be implemented for widespread use. An anticipated problem with this will be that the small numbers of HNC TWW referrals per practice/GP will make such a proposal very difficult to execute.

Head and Neck Cancer During the Covid-19 Pandemic

The impact of COVID-19 has already been described in the previous chapter. Early in the pandemic, hospitals reconfigured their services to help manage their response to the crisis. In terms of suspected HNC referrals, several triage methods were deployed, from simple telephone assessment to the use of the ORLHC (113, 114). Out-patient departments pivoted to initial telephone assessment to prioritise patients into those requiring an investigation, a face-to-face assessment, or a deferred assessment, for patients referred from primary care with signs and symptoms of HNC. Clinical assessment of patients with head and neck signs and symptoms during COVID-19 was further compromised by the need for protective equipment from the aerosol generating procedures which are required for thorough examination of the mucosal surfaces of the head and neck. Concerns about asymptomatic patients harbouring potential high viral loads, meant that judicious decisions about examination and investigations had to be made (115).

An amended version of the ORLHC, which was generated from secondary care data as described above, was used during COVID-19 to remotely triage the TWW referrals for suspected HNC from

primary care (116). This was driven by the imperative to reduce the numbers of face-to-face encounters. Participants (HNSs in secondary care) were asked to use the adapted calculator (shown in Chapter 6) along with a telephone assessment of a patient to determine whether he or she would proceed with: immediate investigation, an urgent face to face assessment, a deferred face to face assessment, telephone follow up or a discharge. The participants collected data on diagnostic outcome at the six-month point following referral (considered an appropriate time within which an undiagnosed cancer would be likely to have clinically manifested). The triage tool was endorsed by ENTUK and BAHNO, and its use by HNSs is qualitatively assessed in later chapters.

Data was collected during a time when the use of the calculator in telephone triage of suspected HNC TWW referrals was adopted and data submitted by 41 centres in the UK. Data was collected for a period of 16 weeks with the intention that the patient outcomes would be monitored for six months. Almost 70% of referrals were considered low risk after remote telephone assessment. Interestingly, nearly 50% of the HNSs (no clinical experience level information was provided in the analysis) overrode the calculator outcome, this was included in the initial ENTUK report but not mentioned in the publication (2). Nearly 40% of those patients considered low risk were still seen and assessed urgently, this may reflect the novelty of using this new approach and some degree of discomfort with it, but this has not been discussed by the authors. Nearly half (45.3%) of the patients had urgent investigation or assessment. Three quarters (75%) of those who had an investigation organised were subsequently discharged without a cancer diagnosis. It is not clear whether this was because the clinical history gave some additional clues to the specialist or whether there was unease with reliance on the calculator during this period. Of those referred, there was a cancer yield of 5.6% (254 of 4557), with 5.0% of patients referred on the TWW pathway diagnosed with a cancer (227 of 4568) with 0.6% in the followup period. Oropharyngeal cancers were the most common of the cancers diagnosed during this period and there were a larger than expected proportion of cancers where the primary was outside the head and neck region (32.8% 86/254). Twenty-seven of the cancers included in the analysis were diagnosed

outside the cancer target periods because after initial assessment, using the combination of ORLHC and remote telephone consultation, for 19 patients their presentation was regarded as low risk and so assessment was deferred. Specialists who were contacted about these 27 cases considered that only 11 of these had suffered any adverse effect from the late diagnosis. This based solely on the specialists' clinical opinion and may not reflect the views of those patients and their families for whom a delay in a cancer diagnosis may have had significant impact on their quality of life from the symptoms and the eventual cancer diagnosis. There is an omission in the paper of any analysis of the seniority of those who participated in the data collection therefore carried out the remote assessment of the patients and made the decision about which category of risk the patient was place in. There appears to be some non-HNC specialist level (trainees) input into the application of the calculator, it would be interesting to see whether further analysis reveals any further details about how successful the calculator was in the hands of a non-HNC consultant and whether this had any bearing on those cases of cancer which were diagnosed late.

This thesis will present data (Chapter 8) from some of the HNSs who used ORLHC during this period as well as some specialists who chose not to use it to explore its potential future use in primary care.

Future of the Suspected Head and Neck Cancer Referral Pathway

There is little doubt that the feeling amongst HNSs is that the rationalisation of the HNC referral criteria since their inception in 2000 has increased the numbers referred via the TWW pathway yet has failed to increase the yield of cancers (77).

The total triage approach mandated by COVID-19 means that patients referred with a suspected symptom of a HNC have been remotely assessed by a specialist as opposed to an automatic face to face appointment in an outpatient clinic. For the specialists this has meant that they have been able to make a clinical (albeit remote) assessment and make decisions based on their expertise using the patient history. This meant that HNSs were able to; organise investigations without the need to see a patient face to face, provide clinical advice, adopt a watch and wait approach for those patients in

whom a non-significant problem will likely resolve and reserve those scarce face-to-face clinic appointments for those in whom they have a genuine suspicion that a cancer is causing symptoms. This COVID-19 experience may well transform how the cancer pathway in England for suspected HNC operates in the future.

Input from both primary and secondary care will contribute towards efforts to improve the patient pathway and the diagnosis of HNC. What is not clear is; if there is a need for a CCDT for HNC for use in primary care, how to fill gaps in education of both clinicians and patients about the signs and symptoms which are most predictive of an underlying HNC or whether earlier recognition of this rarely encountered type of cancer (in terms of primary care) can be improved (74). A paper from Usher-Smith's concludes thus: *"Ideally new tests should be developed and evaluated using data from the population(s) in which they are intended to be used"* (112). Some more robust statistical modelling of the signs and symptoms of HNC from the primary care population would avoid the spectrum effect and might provide evidence leading to improved decision making about who to refer via the suspected HNC route and could also support the development of alternative clinical pathways such as speech and language therapist assessment of functional problems with voice and swallowing.

Considering the data generated from use of the ORLHC in secondary care during COVID-19, the role of ORLHC (or something like it) in primary care may well be considered obsolete as secondary care consider the future application of more strict risk assessment triage to the TWW referrals on their receipt in hospital. These issues are considered in later chapters which analyse the qualitative data from the interviews with clinicians.

This chapter introduces some background to the challenges faced by secondary care when it comes to the HNC TWW referral pathway. There is a sense from HNSs that the TWW system is flooded with referrals which they consider clinically unjustifiable. This puts huge pressure on hospital services to meet the cancer TWW targets. Both primary and secondary care researchers have developed CCDTs

which they believe could help select those most likely to have an underlying cancer and therefore justify a referral. There is increasing evidence from secondary care about which signs and symptoms alone and in combination are more predictive of a patient having an undiagnosed HNC, how this evidence will be used in the future is subject to debate. The COVID-19 experience with ORLHC and the relatively recent publications from both primary and secondary care will determine the future criteria that inform the next iteration of the NICE primary care TWW referral criteria for patients with suspected HNC.

The next chapter considers some of the methods by which implementation of healthcare innovation is evaluated. Many implementation models, theories and frameworks have been developed since the dawn of Evidence Based Medicine (EBM) which propose to better understand, plan, implement and embed technological innovations within healthcare. As the field has developed proponents have become concerned with consideration of and engagement with the complex context within which innovative practices and technologies are proposed. The next chapter introduces NPT, which frames the experience of GPs use of CCDTs in primary care in the framework synthesis chapter of the thesis, and the NASSS framework which is the lens through which the analysis of the stakeholder interviews exploring the prospective implementation of a primary care CCDT for suspected HNC is considered.

CHAPTER 5: IMPLEMENTATION SCIENCE AND COMPLEXITY

The thesis aims to explore the potential implementation of a primary CCDT for patients with signs and symptoms suspicious of HNC. It asks if this is a realistic solution to the problems associated with the low yield of cancer diagnosis from the large numbers of patients referred to secondary care on the TWW pathway. To do this, two frameworks, drawn from the world of implementation science, NPT and NASSS, have been selected. This chapter presents some background to implementation science and the field of complexity and why these two frameworks were chosen to frame the qualitative analysis in the thesis.

This chapter focusses on some of the work over the last two decades in the field of implementation and complexity in healthcare innovation. This field has emerged in response to the evolution of EBM and seeks to understand the ways in which individual behaviour, system culture and organisational practices influence the implementation of innovation in healthcare. Implementation science aims to explore and/or analyse responses to and plan better interventions in healthcare. The chapter describes some approaches to implementation and complexity concentrating on NPT and NASSS which have been used to present the qualitative work in this thesis. The framework synthesis using NPT allows the exploration at a practice or individual GP level of the factors determining how GPs interact with CCDTs at a practice level. The use of NASSS enables a broad approach to the social, cultural, economic, and political landscape unique to healthcare implementation with a particular emphasis on the NHS. NASSS offers a means to explore the complexities and interactions between complex entities which are essential to acknowledge and address in the process of development of any new approach to the HNC TWW referral pathway which includes a CCDT like ORLHC.

Implementation Science

Implementation science is born out of a desire to understand more about the complex interaction of key players and the context within which innovation and implementation of evidence-based practice are enacted in healthcare. It is defined as *"the scientific study of methods to promote the systematic*

uptake of research findings and other evidence based practices into routine practice to improve the quality and effectiveness of health services and care" (117). Implementation science combines theories from several disciplines most notably psychology, sociology, and organisational theory and has developed in response to the need to make sense of and facilitate the implementation of innovation. Innovation in healthcare is described by Greenhalgh *et al* as: "*a novel set of behaviours, routines and ways of working, which are directed at improving health outcomes, administrative efficiency, cost-effectiveness, or the user experience*" (118). The issues surrounding the adoption of innovations in healthcare have been summarised by Fitzgerald *et al* (119) and concentrate on the role of evidence (its credibility), the nature of adoption decisions, those involved and their complex interactions within context. All these aspects interact in the process of adoption of new technologies.

Implementation science has emerged over the last 20 years to plan, explain, and explore responses from individuals, organisations and systems to innovations which are rooted in evidence-based practice. In so doing, the overall aim of implementation science is to formalise the study of the implementation of "evidence- based" research findings into practice with the aim of improving the quality and effectiveness of healthcare. The spread and diffusion of innovations were conceptualised by Rogers in 1962 (120) as being determined by more than simply the evidence of success of the innovation. In the context of healthcare, the EBM movement, and efforts to mobilise new knowledge into practice drove the interest and development in the field of implementation science. Bauer *et al* (121) describe the aims of implementation science as 1) to identify uptake barriers and facilitators across multiple levels of context (individuals in treatment, providers, organisation and other stakeholder groups) and 2) to develop and apply implementation strategies that overcome these barriers and enhance the facilitators to increase the uptake of evidence-based clinical innovations. Checkland *et al* (122) suggested that the metaphor of "*barriers to change*" may underestimate the multiple factors influencing the implementation of complex interventions. It is a more

multidimensional enterprise which involves multiple actors and deserves a broader approach to understand how to successfully introduce and ultimately embed something new into routine practice.

There are multiple stakeholders in the NHS ranging from commissioners, GPs, those within secondary care, (doctors and managers both hospital and departmental) as well as patients themselves and Social Care (123). These in turn are influenced by DoH policy, politics, the financial climate, budget constraints and incentives, amongst many others. There are complex and multi-layered relationships at play which influence how innovation in healthcare plays out in terms of implementation; an appreciation and attention to these multidimensional interactions is essential when planning any activity that will disrupt the status quo. A systematic review of "change in primary care" exposes the gap between evidence and practice and highlights the importance of context (124). The authors consider context as a four-level framework made up of, external context, organisation, professionals, and intervention.

For an intervention to be successfully implemented it is critical to consider the "fit", i.e., does the intervention achieve what is intended for those who are expected to use it. Over the last two decades, to improve the understanding of the implementation process in the complex world of healthcare, many approaches have been proposed. Drawing upon distinctive theoretical foundations, each approach offers a different analytical lens (ranging from the macro policy level and the organisational responses at a meso level to the micro-level setting of individual action) and often contrasting explanations about the nature and trajectory of innovation and its implementation (125). These approaches can be regarded as theories, models, and frameworks. Nilsen has attempted to categorise them into process models, determinant frameworks, classic theories, implementation theories and evaluation frameworks (126) and are described below.

1. *Process models* describe the process of implementation and aim to provide a practical guide to the implementation of research into practice. An example of a process model is quality

implementation. Some of these models are derived from authors own experience of implementation (127) and others are the result of literature reviews in the area (128).

- 2. Determinant frameworks describe the influences over implementation, these are often multilevel, multi-dimensional and interrelated barriers and facilitators. Many of these frameworks highlight the context and its impact on the outcome of a particular intervention. These are again derived from data produced from research projects or from aspects derived from a particular academic discipline or literature reviews.
- 3. Classic theories are those applied from disciplines like behavioural psychology and organisation theory. The most influential theory from this category is Rogers's diffusion of innovations theory seeks to explain the adoption of new ideas and technologies. Rogers viewed diffusion as a social process in which actors create and share information through communication. He described the roles of opinion leaders, change agents and gate keepers working within social structures and systems and influencing the trajectory of innovation (129).
- 4. *Implementation theories* have been developed to understand and explain certain aspects of implementation. NPT (130) is one of these and describes four domains which determine the embedding of complex interventions in practice (coherence, cognitive participation, collective action and reflexive monitoring).
- 5. *Evaluation frameworks* aim to guide the evaluation of implementation projects. Some approaches from previous categories (such as NPT) include elements of evaluation within them but these specify elements that should be considered as outcomes.

There are multiple options when considering theories and frameworks with which to plan, carry out, analyse, and evaluate complex interventions from the realm of implementation science. Optimal use of these theories and frameworks can structure effective planning, delivery and analysis of implementation projects, their use allows a shared language and are purported to facilitate and build the evidence base in this arena (131). One theory to understand and explain implementation, popular

in the healthcare setting, is NPT. NPT is considered a good way of exploring social determinants of engagement with a novel way of working.

Normalization Process Theory

NPT provides a framework "for understanding and evaluating the processes (implementation) by which new health technologies and other complex interventions are routinely operationalized in everyday work (embedding) and sustained in practice (integration)" (132). This framework, devised by May *et al* (130, 132, 133), proposes to aid development, evaluation, and implementation of complex interventions. NPT has evolved in response to the need for improved health and healthcare and the complexity of implementation and integration of healthcare interventions.

NPT framework allows analysis of the work that people do to interact with a new intervention; it examines the impact of the intervention on the context within which it is intended to operate. NPT additionally aims to scrutinise the complex interactions between the intervention and individuals who work with or fail to work with it, the individuals championing it and how it impacts on the dynamics between those enacting it and the individuals for whom the intervention is intended to benefit. In so doing, the NPT framework seeks to evaluate the effect on established work practices as well as the disruption to the norm which is ultimately the aim of complex interventions (how an intervention becomes or fails to become the norm). Importantly, NPT aims to evaluate how individuals and groups of individuals appraise the work; to make sense of its impact and value, this in turn reinforces commitment to its integration into daily practice.

The NPT framework emerged out of work in the telemedicine arena. It was formulated in an effort to explain factors that promote or inhibit the implementation of complex interventions with particular attention to cooperative and collective work of individuals to normalise a complex intervention (133) in the particular forum of the health care setting. This initial theory was called Normalisation Process Model (NPM) and was designed to explain routine embedding with reference to social processes. NPM has evolved over time to become NPT and has been championed by a group of UK sociologists

but latterly has become an international collaborative work which includes academics from France, Australia and USA (132).

NPT is made up of four main constructs which are described below:

1. <u>Coherence</u>

Coherence refers to how individuals make sense of the work of implementation of a complex intervention. It also takes account of the interaction between the participants and the intervention within the context of the existing system where they enact this work.

2. <u>Cognitive participation</u>

Cognitive participation refers to the factors which drive and inhibit commitment and participation in the implementation and integration of an intervention.

3. <u>Collective action</u>

Collective action refers to the work individuals and organisations do to make an intervention function. This domain also explores how the intervention impacts on work practices, and analyses impact on training, resources, labour, and the organisational support aspects.

4. <u>Reflexive monitoring</u>

Reflexive monitoring refers to the appraisal of the effects of using the new intervention, how is the impact measured, whether there have been any alterations to the use of the new intervention, other than those envisaged intentions of the researchers or those that developed the intervention.

A recent systematic review (134) of the use of NPT in feasibility studies and complex healthcare interventions demonstrated widespread use of the framework in the evaluation as well as the planning of complex interventions. One hundred and thirty papers were identified that reported using the framework in areas ranging from, diagnostic point of care testing (135) to the management of

constipation in primary care (136) and was used by teams from South Africa to Abu Dhabi. The authors advocate exploring the context within which an innovation in healthcare is to be introduced before embarking on a trial of that intervention. A thorough consultation with the stakeholders about a planned or potential implementation of a new intervention or innovation provides a background, highlights perceived threats to current position and relationships, but also explores potential benefits from the implementation of an innovation or intervention. Exploration of attitudes, values and beliefs can challenge deeply entrenched tenets and behaviours to encourage trial and adoption of a new practice or technology. Engagement with stakeholders can uncover deficits in knowledge and understanding. In this context, analysis using NPT can help to establish training and competency issues as well as changes in current care pathway, workforce patterns or labour division.

Murray *et al* (137) discuss the use of NPT in the continuum of implementation of an intervention from design of trial to evaluation of the data. The authors (members of the NPT Peer Learning Group funded by the National Institute of Health Research) advocate using the framework to plan as well as to implement research into practice. NPT is used to present the framework synthesis part of the thesis. The subject of the synthesis is GPs, their practice and interaction with CCDTs. In the context of implementation studies this research is at the level of the individual and practice rather than at an organisation or system level, it can be considered a micro aspect in the micro, meso, macro continuum (138). As such, NPT was considered an appropriate tool with which to examine factors shaping the experience of GPs using CCDTs.

Complexity in Healthcare

Complexity in healthcare innovation particularly in the EBM era was focussed on the complexity of the innovation rather than an appreciation of the complexity of the individuals, organisations, and institutions. More recently the complexity of context has received attention from researchers calling for a paradigm shift in healthcare innovation. Those calling for a fourth paradigm, highlight the necessity to explore, analyse and consider the environment within which a new intervention is intended to be implemented (139). There has been criticism that the implementation models, theories, and frameworks were considered too abstract and inappropriate for systematic reviews and health technology assessments (140). The positivist approach to scientific inquiry controls for as many elements as possible, this scientific approach cannot by applied to real life where boundaries are blurred, relationships are messy and interactions evolving and subject to change. Responding to unknown, the uncertain, the unpredictable and the emergent demands tenacity, flexibility, and inclusivity. Through an approach that considers complexity proponents anticipate the results will force researchers to face uncomfortable truths, to negotiate good compromises and to embrace creative, reflexive and collaborative ways of working and thinking (139).

Theories are generally specific and predictive with directional relationships between concepts making them suitable for hypothesis testing as they may guide what may or may not work (141) whereas frameworks organise, explain or describe information and the range and relationships between concepts, including some which delineate processes and are therefore useful for communication (131).

To consider innovation, implementation, and adoption in healthcare an approach to the interaction between multiple systems and multiple agents is essential. The broad church of individuals and groups interested in change, innovation, and implementation in the healthcare environment is drawn from multiple schools of thought, disciplines, and motivations. The field draws upon expertise from many areas and relies on collaboration and pragmatism to drive change (142).

This chapter will now consider the theory of Complex Adaptive Systems and a couple of the frameworks which aim to offer a comprehensive approach to innovation and implementation drawing on the business world (as opposed to the public sector) and reflecting more of the contextual setting within which change is proposed, planned, and carried out. A greater exploration of the micro (individual, practice), the meso (organisation level) and the macro (political, cultural) context, their

interrelatedness, and appreciation of the blurred boundaries, has the potential to offer greater opportunity for a successful innovation.

Complex Adaptive Systems

Complex Adaptive Systems (CAS) is an approach to the phenomenon of complexity. This school of thought recognises that behaviour patterns and interrelationships are unpredictable in what is a constantly adapting environment (143). CAS has been applied to multiple arenas including physics, education, business, and economics. There are several characteristics of a complex adaptive system; it is composed of a large number of elements which interact dynamically, any element in the system is affected by and affects several other systems, it is made up of non-linear interactions, which means small changes can have large effects, it may be difficult to define system boundaries, a constant flow of energy is required to maintain the organisation of the system are not aware of the behaviour exists that helps to shape present behaviour and elements in the system are not aware of the behaviour of the system as a whole and respond only to what is available or known locally (143). Proponents of CAS propose that it offers a theory to apply to implementation which moves away from the linear step by step approach (144). Table 8 shows the key features of complex adaptive systems. Considering change in healthcare by using a broader approach such as CAS highlights the multiple players, the policy context, challenges assumptions and takes account of the dynamic properties of healthcare systems.

Table 8 Key features of complex adaptive systems (CASs) (145)

Embeddedness/nested systems: CASs are embedded within a wider context and other CASs Fuzzy boundaries: System boundaries are permeable and hard to define Distributed control and self-organisation: System patterns are not created by top-down control; instead, autonomous agent interact to create outcomes. Thus, organisation in a CAS emerges naturally from local rules held by agents Emergence: Interactions between agents create system outcomes that are not directly intended and are greater than the sum of the individual agent behaviours Unpredictability: The behaviour of a CAS cannot be predicted due to its non-linearity, sensitivity to initial conditions, and historicism Non-Linearity: the magnitude of system input and agent interactions is not linearly related to the magnitude of changes in the system. A CAS can react suddenly to minor inputs or fail to change despite overwhelming external pressure Phase changes: Where a small change in the system inputs results in a qualitative change in the systems state Sensitivity to initial conditions and historicism: Future agent actions are affected by past changes in the system, leading initial conditions to exert a strong influence on system behaviour Non-equilibrium: CASs are characterised by continual change and do not reach equilibrium Adaptation and co-evolution: Agents and systems evolve together, reacting to changes in the context to ensure optimal functioning and survival A focus on complexity demands a move away from the controlled environment of a scientific

experiment and explanation of the system level outcomes related to the context within which the intervention exists and what may determine its longevity. As Braithwaite concludes (144) "we must grapple with the world we actually inhabit, not the one we wish we did". Implementation science coupled with appreciation of complexity science offers an approach to this real-world reality (*Table 9*) where, though there is an appreciation of it, there is no approach that makes it possible to eradicate uncertainty. The messiness of the reality of healthcare systems has been acutely demonstrated with the transformation of healthcare systems in the face of COVID-19 over the last two years. Healthcare systems have gone from a status of relative stability, (in the case of the NHS) into a chaotic period which demanded unprecedented levels of individual, community, systems and political responsiveness and adaptation to an ever-changing landscape.

Approach / Features	Implementation Science	Complexity Science	Complexity science and implementation science
Task	The task is specific, getting evidence into clinical practice in an understandable way	The task is context dependent: properties of complexity apply to biology, ecology, physics, computer science, human social systems	Tailored solutions and iterative processes
Theoretical assumptions	Heterogeneous and diverse – numerous theories, frameworks, and models	Homogenous – core assumptions of complexity science are characterised by "universally" (i.e., they apply across all complex systems)	Different theories, frameworks and models require an understanding of complexity features such as unpredictability, uncertainty, emergence, interconnection
The Intervention	To be standardised to permit generalisability	To be adapted to meet needs	Factoring in complex interventions and complex settings
The context	Full of confounders, a "problem" to be solved for successful implementation	An intrinsic part of a complex system: a dynamic environment that must be factored in for any intervention to be successfully taken up	For improvement to be realised the context must be re-etched or re- inscribed such that its culture, politics and characteristics are altered
Historical underpinnings	Evidence-based practice movement, statistics, and the scientific method	Systems theory, chaos theory; emanating from diverse scientific disciplines	More sophisticated change models can be encouraged to arise over time
Aims within health services research	Describing or guiding the process of translating research into practice (process models) Understanding or explaining what influences implementation outcomes (determinant frameworks, classic theories, implementation theories) Evaluating implementation (evaluation frameworks)	Description of complex system Understanding context Relationships among agents Dynamics How rules and governance structures emerge, i.e., self- organisation For prediction rather than implementation	Ensure that turning evidence into practice is accomplished without too many unintended negative consequences; improvement might be sustained, potentially through the adaptation of the intervention to different settings Implementation is not merely based on effective planning but anticipation of a range of possible outcomes
Tools and methods	Randomised controlled trials, behaviour change interventions, step-wedge designs	Causal loop diagrams, system dynamics modelling, network articulations	Realist evaluation, long term case study, participatory research, stakeholder analysis, systems mapping, social network analysis

Table 9 Comparison of some key characteristics of implementation science and complexity science and their integration (144)

Complexity Frameworks to Explore Healthcare Innovation and Implementation

Many frameworks have been proposed to address the issue of complexity. The background and the healthcare system within which they have been developed influences where they are best applied. Two of these frameworks are EPIS (Exploration, Preparation, Implementation, Sustainment) and Context and Implementation of Complex Interventions (CICI). EPIS is described as a process and determinant framework with its focus on inner and outer context determinants (146). It was developed in Australia and has been used internationally to plan and execute implementation projects in healthcare settings. EPIS offers an opportunity to explore factors which might be important prior to an implementation project and during its evolution but is a process driven framework with users

expected to move through the phases of a project. It does offer an examination of outer and inner factors but not as a means by which to assess whether a proposed intervention is a good fit to the context. It is not designed to expose the obstacles which might pose challenges to implementation, it is focused on the implementation activity as opposed to identifying resisting forces or obstacles that might make an implementation project more difficult or doom it to failure.

Another framework which proposes to facilitate the structured and comprehensive conceptualisation and assessment of context and implementation of complex interventions has been developed called the Context and Implementation of Complex Interventions (CICI) (140). The CICI framework (140) was developed iteratively by an international group of academics and applied to health technology assessments and systematic reviews. It is considered both a determinant and an evaluative tool (see *Table 10*). CICI is a structured and formal checklist and would be challenging to use in a pragmatic way for the planning stages of a project. These two approaches are dogmatic and appear to be focused on success and failure of implementation rather an approach to whether an intervention is appropriate and the challenges the context may pose to its implementation. Table 10 CICI Framework generic checklist

Intervention	Which intervention characteristics interact with the setting, the context and the implementation?						
	How do these intervention characteristics interact with the setting, the context and the						
	implementation?						
Context	Which aspects of the context interact with the implementation of the intervention?						
	How do these aspects of the context interact with the intervention?						
Implementation	Which theoretical underpinning guides the implementation?						
theory	How does this theory interact with the setting and the context?						
	How does this theory interact with the intervention?						
Implementation	Which stages of the implementation process are passed through during implementation?						
process	How does the implementation process interact with the setting and the context?						
	How does the implementation process interact with the intervention?						
Implementation	Which implementation strategies are employed during implementation?						
strategy	How do these implementation strategies interact with the setting and the context?						
	How do these implementation strategies interact with the intervention?						
Implementation	Which implementation agents are involved in the implementation effort?						
agents	How do these implementation agents interact with the setting and the context?						
	How do these implementation agents interact with the intervention?						
Implementation	Which implementation outcomes are reported?						
outcomes	How do these implementation outcomes interact with the intervention outcomes?						
Setting	Which aspects of the setting interact with the intervention?						
	How does the setting interact with the intervention?						
	How does the setting interact with the context?						
	How does the setting interact with the implementation?						

Recent theoretical developments have attempted to explore further the multiple forms and manifestations of complexity in health technology-supported change projects. The Non-Adoption, Abandonment, Scale-up, Spread, Sustainability framework (NASSS) provides an opportunity to ask pertinent questions of the context within which an innovation or health technology is proposed. In so doing, it provides an opportunity to explore the context into which a technology is intended to be implemented, so that areas of complexity are identified and addressed with a view to increase the chances of successful implementation.

Non-Adoption Scale up Spread Sustainability (NASSS)

Greenhalgh's work on innovation and diffusion (147-149) highlighted the many components, moving parts and shifting relationships and convoluted, imprecise, and uncertain routes to success or failure. Greenhalgh's most recent work, NASSS (150) draws on individual theories of technology adoption. In the healthcare setting the complexity does not only lie in the intervention and the way the actors interacting with it respond to it, but in the context within which it is implemented and, no technology project in health and social care is simple. Challenges in technology implementation projects come from those factors which Greenhalgh classifies as simple (straightforward, predictable, few components), complicated (multiple interacting components or issues) or complex (dynamic, unpredictable, not easily disaggregated into constituent components). Greenhalgh *et al* suggest that projects with high levels of complexity within multiple domains of NASSS rarely succeed.

This novel framework can be used in the planning, analysing or writing up projects or initiatives which involve a technology (151). A NASSS framework analysis provides a rich narrative of the context into which a technology is intended to be implemented, so that areas of complexity are identified and addressed with a view to increase the chances of successful implementation. This framework encourages an exploration of these multiple, interacting, and evolving factors over the duration of a project. It is intended to be used reflexively and flexibly to guide conversations and help generate ideas. The authors do not intend that it is used as a checklist (150).

NASSS (150) is derived from several theories. The developers of the NASSS framework built on their previous work done on diffusion of innovation, in the early 2000's (147-149). The framework was developed using a combination of hermeneutic systematic reviews of the literature and empirical case studies of technology implementation which allowed exploration, testing, and improvement of the framework. The NASSS framework (150) is an attempt to "produce an evidence-based, theory-informed, but also accessible and usable framework that would enable those seeking to design, develop, implement, scale up, spread and sustain technology-supported health or social care programs to identify and help address the key challenges in different domains and the interactions between them". In this context, Greenhalgh et al consider that NASSS has "several potential uses: (1) to inform the design of a new technology; (2) to identify technological solutions that (perhaps despite policy or industry enthusiasm) have a limited chance of achieving large-scale, sustained adoption; (3) to plan the implementation, scale-up, or rollout of a technology program; and (4) to explain and learn from program failures" (152).

The NASSS framework is comprehensive, made up of seven domains and is intended as a tool to help all stakeholders involved in implementation of complex interventions in health care (see *Figure 1*).

The Seven Domains of NASSS

- 1) *Illness or condition*: the complexity occurs when the condition is unpredictable, poorly understood, influenced by age or socioeconomic factors
- 2) Technology: complexity exists when there are issues with how the technology works (i.e., functionality), its dependability and speed; other aspects that are important are how much knowledge is required to use it, are there alternatives and are there issues with intellectual property
- 3) *Value proposition*: this is the value to the developer, the patient, the healthcare system, taxpayer, or insurer, is there a suitable business plan to justify its use in terms of cost effectiveness, efficacy
- 4) Adopter system: this refers to the staff, patients and carers who will be expected to use the technology, does the technology threaten traditional or professional roles and practices
- 5) Organisations: complexity can be related to capacity to innovate (this would be related to leadership, resources, clinician-managerial relationships) and readiness too for this technology, the nature of the adoption and funding decision (interorganisational agreement and speculative cross-system savings), potential disruption to existing routines and extent of work needed to implement changes (buy-in, delivery, evaluation)
- 6) *Wider system*: this includes issues like policy context, support from regulatory or professional bodies and public perceptions, as well as inter-organisational networking (with the aim of quality improvement for example) which can be utilised to spread organisational level innovations
- 7) *Embedding and adapting over time*: complexity in this domain may arise from an inability to adapt to changing context or from a lack of resilience

Greenhalgh's group have devised worksheets (NASSS-CAT tools) to help guide, monitor and research technology implementation projects in health and social care to evaluate the application of innovative technologies in the real world and their work is ongoing (153).





Applicability of NASSS Framework

For the purposes of this thesis the NASSS framework brings a dynamic and multidimensional perspective to explore the potential implementation of a primary care CCDT for patients with signs and symptoms suspicious of HNC. In the constantly evolving backdrop to this research, demonstrated so cogently by the impact of COVID-19 on English healthcare, its application to this innovation and to this context was apt. The NASSS framework was developed by a group led by an English primary care clinical academic, and this may be the reason that it is more digestible and intuitive to an NHS

healthcare worker. The use of NPT for the framework synthesis demonstrated that it was not as the most suitable framework for analysis of the stakeholder interviews compared to NASSS. The experience of using NPT for the framework synthesis motivated the decision to move to use NASSS for the analysis of the stakeholder interview data as it was considered more instinctive in terms of language and application to real world healthcare in the NHS. A pragmatic decision was taken to use NASSS in favour of NPT for the second part of the thesis analysis. The author's familiarity with the multifaceted and interacting nature of the NHS, work in both primary and secondary care, different stakeholder priorities, the internal healthcare market, healthcare policy and patient need, influenced the preference to use NASSS as the analytical framework over NPT.

Drawing on NASSS framework, this thesis explores the motivations behind the desire from secondary care to change the pathway and the issues that clinicians have with the current model of suspected HNC referral. The thesis considers the factors that determine how ORLHC could be used and where ORLHC might sit in the pathway so that it might be best able to determine a change in primary care referral practice. Using NASSS to analyse the stakeholders' views additionally enables an understanding of the differences between the perceptions of how the HNC TWW is used by primary care and whether GPs consider that it requires any adaptation to its current form. In addition, a broad and multidimensional approach to the data using NASSS allows an exploration of the policy and cultural context within which changes to cancer pathways can occur. The NASSS approach provides the organisational context to innovation and implementation, how commissioners, managers, governing bodies and special interest groups might shape innovation and implementation. Clinician groups often determine change in healthcare practice, but without consideration to the other stakeholders, the organisations, the political and the financial context efforts to change clinical pathways can be futile. On an individual level one needs to understand how changes in the pathway might impact on the day-to-day work of primary care, reflect on the failure in uptake of use of the CCDTs that have been developed over the years and what improvements could be made, what lessons
can be taken from this to initiate successful innovation, execution, and implementation of a new pathway. Integrating patient views and opinions in how such a change to normal practice would be received is important, as any changes will impact on their interaction with healthcare. An appreciation of the personal (healthcare professionals and how they do their job) as well as the general population (patients, healthcare resources, cancer diagnoses) impact can be gleaned from this work in terms of the greater good for the NHS and the population as well as the personal impact in terms of workload, decision making and managing risk.

In this thesis, the analysis of the interview data from stakeholder groups with interest in the suspected HNC referral pathway is mapped onto the NASSS framework (described above) to explore the potential implementation of a primary care CCDT for suspected HNC. The NASSS framework offers a dynamic and flexible approach with an appreciation that implementation cannot be considered in isolation as part of a research project but should be embedded from the inception of an intervention to enable adaptation and multilevel approach from the start.

This chapter completes the background to the thesis in terms of the state of primary care cancer recognition and referral to secondary care in England, the difficulties with the recognition and referral of suspected HNC and the problems in terms of clinical resources to assess those referred from primary care with suspicious signs and symptoms. The background concludes with a summary of the state of implementation science in healthcare and a consideration of the complexity of the context within which innovations are proposed.

The next chapter presents the methodological approach and a description of the method used to meet the aims and objectives of this thesis.

CHAPTER 6: METHODOLOGY AND METHODS

This chapter explores the philosophical standpoint and the influences over the decisions made about the methods used in this thesis. This chapter builds on the previous chapter about implementation providing a description of the methods employed and reflections on the role of the author in the data collection and approach to analysis. This chapter presents the methods employed to undertake the systematic qualitative framework synthesis using NPT which explores the factors shaping the implementation and use of CCDT by GPs in primary care. This is followed by a discussion of the methods used to explore stakeholders' views on the implementation of a primary care CCDT for suspected HNC referrals using the NASSS framework.

Methodological Framework

Before stating the methodological stance of this research study, consideration is given to the research paradigm underpinning the thesis, and which informs the exploration of the potential implementation of a primary care CCDT for suspected HNC. Paradigms in research (Kuhn (154)) are philosophical standpoints that determine the types of questions asked and how the answers are understood. The paradigms recognised in the social sciences are referred to as positivist, interpretivist, critical and pragmatic.

Ontology is the philosophical study of the nature of being, becoming and reality. Epistemology considers knowledge in terms of its nature, origin, and scope. The scientific pursuit and production of knowledge through quantitative hypothesis testing methods is rooted in positivism (Comte 1798-1857). This paradigm is founded on the belief that research can uncover a truth about the real world (that there is one reality that exists). In the positive paradigm the researcher is independent of the subject matter.

The interpretivist ontological perspective is that there are multiple realities rather than one true reality (universalism), that knowledge is created by individuals and groups and that these multiple realities are interpreted to provide the meaning to activities and events (155, 156). Every researcher

can be considered biased (157) and the interpretivist researcher reflects on their role in the research, their own prior experience and knowledge determines or at least influences their interpretation of and the values they impose on the data.

The critical researcher's ontological position is one that realities are socially constructed, at its core, the critical paradigm is focused on power, inequality, and social change. For the critical researcher reality is subject to constant internal influence. This positioning implies that the realities are understood with reference to the power relationships in society (158). The researcher can never be objective. Examples of research in this paradigm are those that address social justice and human rights. Critical realism is one framework that has emerged from this philosophical world view. Pragmatists are criticised as not being concerned with value whereas critical realists are interested in the power structure and interaction. In reality considering one without the other makes change, particularly in the NHS, difficult.

Pragmatists decide what they want to study based on what is important to them with reference to their own personal value systems (159). The pragmatic researcher is goal orientated and the data generated often has societal consequences (160) this approach can be considered as action research, where change is the outcome.

To define oneself as a pragmatist is not to reject the premise of ontology and epistemology but to be more flexible and concede that there can be no resolution to the broad philosophical arguments. A pragmatist is comfortable in the belief that meaning is inseparable from human experience and needs and is dependent upon context (161). Pragmatic epistemology does not view knowledge as reality, knowledge is constructed with a purpose to better manage one's existence and to take part in the world. Pragmatic inquiry is driven by a desire to elicit practical change. What is important to the pragmatic researcher is that the research, the analysis, and the outcomes are informed by their personally lived experience and held values. The pragmatist is interested in the results of research that will have societal consequences. Pragmatists "judge the value of knowledge (and our ways of knowing) by its context-dependent, extrinsic usefulness for addressing practical questions of daily life, knowledge is meaningful only when coupled with action" (145).

Long et al proposed similarities between social complexity theory and pragmatism (Table 11) (145).

Table 11 Similarities between social complexity theory and pragmatism

Aim to create "useful" knowledge Reject reductionist science in favour of the study of whole systems, in context Understand research as a continual learning process Focus on the social consequences of research and intervention Value the democratisation of knowledge and research, valuing all stakeholders' input Prioritise understanding over theoretical or methodological purity, encouraging the use of multiple methods

Pragmatists use both inductive and deductive logic in a cyclical way to inform their data collection. This iterative approach requires reflection on complex interrelated structures and relationships which are ever present and crucial to the functioning of health services, an appreciation and analysis of these enormous and complicated interrelated factors can go some way to planning and executing innovations in healthcare (162). Hammersley (163) states *"indeed it seems to me that all research involves induction and deduction in the broad sense of those terms; in all research we move from ideas to data as well as from data to ideas"*.

The pragmatic approach is considered appropriate to applied research such as in the context of complex healthcare systems. The driver in pragmatic research is the question rather than the paradigm (164). A pragmatic approach to qualitative research requires flexibility to answer healthcare needs through enquiry and exploration of experience of those involved in decision making and those affected by the decisions. The pragmatic approach has been referred to as the fourth paradigm, welcoming a flexible, real world approach with emphasis on multiplicity of resources for research conducted in real time (139).

This fourth paradigm in the arena of healthcare research advocates the use of multiple modalities of investigation, resources, experience in real time and teams to influence change in the ever-changing

world of health services (139). The real world of healthcare demands real time changes, resource reallocation, moral and ethical decisions in the face of dynamic circumstances (relationships, cultural shifts, hierarchies, economic conditions) and this approach is the one used (often unconsciously) in the NHS as in any complex system.

Pragmatism in healthcare service research encourages cross boundary working through the research itself and analysis of systems and complexity, this can enhance healthcare services via stakeholder collaboration, uncovering and exploring assumptions, challenging siloed working and has potential to improve communication, resource allocation and ultimately patient satisfaction and outcomes (165).

A pragmatic approach to research responds to frequent goal posts changes and multiple small or major alterations in priorities. In so doing, it requires tenacity and adaptation to changing challenges. Pragmatism is more associated with applied disciplines than the pure traditional disciplines such as empirical science, it is associated with mixed methods research where both quantitative and qualitative methods are applied to explore a particular phenomenon, but it can be applied to purely qualitative pursuits.

The response to COVID-19 has required an abundance of adaptation, flexibility and tenacity from the NHS, clinical researchers, patients, and doctors (amongst countless others in society) just like the pragmatic approach taken in this research. The agile response to the data collection for this thesis required in early 2020 was made easier because of this predetermined perspective.

Personal Reflections on the Research

The researcher and their relation to the participants is important to reflect upon. I knew all the HNSs apart from three who were interviewed during the pandemic, and I knew half the GPs involved because I had worked with them (166, 167). This, of course may have influenced the answers to the questions leading to more openness and honesty or indeed reluctance because of perceived interest and motivation about the topic. My dual experience in both fields lends some balance and a unique

perspective bringing a deeper understanding of the issues faced. I am conscious that another researcher without this personal experience of working in both the primary and secondary care settings may not have reached the same conclusions nor accessed specialist participants quite so easily.

When healthcare research is undertaken by healthcare professionals it is impossible to remove the subjective voice in the narrative. The influence of working in healthcare, bearing witness to the impact of resource allocation, poor practice, rationing, regional and local inequality is brought to bear on the researcher's perception and interpretation of data.

As a doctor who has been involved in both providing healthcare at the primary and secondary care level (both as a GP and as a surgical trainee providing healthcare for HNC patients) and as a patient receiving care from the NHS, I have a unique perspective (as do all individuals). As such, I could be considered an "insider" in terms of my personal perspective in terms of the disease and its impact on patients, their families, and their healthcare team; this is a valuable and privileged position. My perspective is influenced by both good and bad experiences from the perspective of patients, doctors, and the population at large giving me insights into the significant impact of the disease on patients, on the doctors who are expected to recognise it, those who see the referrals in the hospital and reallife experience of how these clinical pathways operate in this field. This experience and perspective have motivated my interest in this area and research into this clinical problem. The challenges of COVID-19 and the devastating impact it has had on the healthcare services, the population, the economy, and the world in general has accelerated the need to optimise clinical pathways.

Method

Qualitative Research

Qualitative researchers "go beneath the surface of superficiality to expose how the world manifests itself and operates, by describing behaviours, practices, motivations, attitudes, and values, rather than describing statistical means, modes and medians, standard deviations, t-tests and p-values.

Qualitative researchers try to understand real-world activities rather than abstract numbers, and they seek to ask questions about the world of the subject rather than to statistically test hypotheses" (162).

Qualitative research is a flexible method of research which allows the application of an interpretative approach to explore and understand phenomena. The role of the researcher in the phenomenon under investigation is an important element of qualitative research in the context of how the individual views the reality of the world (ontology) and what is the basis of knowledge (epistemology). Qualitative research aims to add the human voice to the scientific empirical perspective. There are well established methods to generate data concerning questions of "what", "why" and "how" like semi-structured, in-depth interviews and focus groups providing rich interpretations and analysis. One to one interview offers the opportunity to converse in depth about an individual's reflections, motivations, and beliefs about a general or a specific area of interest. Semi-structured interviews mean that an interview observations or allow novel ideas to emerge during a conversation. Implementation science has established a role in gathering data from multiple perspectives about the experience of healthcare can help to shape future innovations and their application which is where.

Pragmatic qualitative research can bring solutions to practical problems in healthcare, it can reveal work processes and patterns of working that support the design of effective improvement interventions. Understanding the culture of an organisation or a team may also assist in determining the barriers and enablers associated with implementing new procedures (162). For qualitative researchers the social world is open to interpretation formed by experience and context and cannot be constrained by fixed identifiable rules. Hammersley argues "distinctive features of qualitative research is far from straightforward" (163).

Ritchie and Lewis (168) recommend a flexible approach because from their perspective, there is no "right" way to conduct qualitative research as it provides contextual, explanatory, evaluative and

generative data. The aim of this research was not to generate theory but to explore the views of some of the stakeholders about a potential change to an accepted clinical referral pathway. This thesis provides analysis of how the complex healthcare environment might influence and shape changes in how the suspected HNC pathway changes by considering the landscape within which it is situated. The pragmatists' lack of methodological fundamentalism means that there are a variety of ways to collect data for analysis and a more creative approach can be taken by the researcher.

The next chapter is the protocol for the multivariate regression modelling. This aspect of the PhD was not completed because of COVID-19 but has been presented in the thesis as it constitued a major part of the academic work during the PhD period.

CHAPTER 7: PROTOCOL FOR THE STATISICAL MODELLING OF SIGNS AND SYMPTOMS OF HEAD AND NECK CANCER IN A SYMPTOMATIC PRIMARY CARE POPULATION.

This chapter sets out the protocol which was intended as a quantitative study of what had been a multi methods PhD project. The protocol was developed alongside the other work which is presented in this thesis, unfortunately the COVID-19 intervened and it was not possible because of travel restrictions and time to execute this.

There were multiple obstacles which were overcome in the first two to three years of this PhD to gain access and secure funding for the data. To not complete this part was frustrating but I learned a lot about research in multivariable regression analysis and its critical, yet often unsuccessful place in healthcare (169-172).

At the time of protocol development there was no evidence generated from primary care to support the referral guidelines in the field of HNC (during the PhD the larynx RAT study was published (8)). There reamain questions as to whether there is a better way to determine probability of HNC in patients presenting in primary care and whether there is untapped information from primary care data about the complex interaction of patient factors affecting referrals. The aforementioned spectrum effect (112) suggests that models developed in a context different to that for which it is intended to be deployed is problematic. This project was intended to overcome this.

The protocol was developed with the help of Dr Emanuel Ogundimu (statistician formerly of Northumbria University now University of Durham) who has experience working with electronic patient health care databases and developing multivariate regression prediction models. The data was to be purchased from University of Birmingham who hold a licence for the The Health Improvement Network database (THIN) data for £10,000) with input from Professor Tom Marshall (Public Health and Primary Care). The protocol is presented in the future tense as it did not happen and this is how it was written and presented to funders and Professor Marshall.

Rationale

This will be an opportunity to produce this much needed work to add to the evidence base for future guideline adjustments. Using a database derived from primary care electronic patient records will allow modelling of a wide variety of variables including signs and symptoms as well as comorbidities not appreciated or recorded in the secondary care data, modelling from a richer data-source may highlight some complex interactions and result in more sensitive risk assessment data. It will also influence further development, validation and implementation of a risk assessment tool to be used in the primary care setting to assist in decisions about route of referral for suspicious symptoms of HNC. Primary care epidemiological data does not exist for the signs and symptoms of head and neck cancer in the UK.

The evidence from both primary and secondary care will contribute towards a valuable body of work and further improve the patient pathway and the diagnosis of HNC. The lack of evidence for PPV for symptoms of HNC is an area which requires development and there has been a call for evidence from primary care from symptomatic patients in more rare cancers, this study aims to answer this call (173). Less prevalent cancers, by their rare nature, are more difficult to predict because the symptoms with

The recent analysis of HNC 2WW referrals to two secondary care centres has produced a refined version of the referral guidelines which purports to "demonstrate greater diagnostic efficacy than the current NICE guidelines" (100). To use such evidence in a primary care population requires some modelling and validation within this population.

which a patient presents are common and not sensitive nor specific for diagnosis.

The secondary care population (within which the modelling by both Tikka and Lau (100, 107) was carried out) will by their nature have a higher prevalence of HNC, this modelling cannot be applied to the general primary care population within which the prevalence of HNC will be lower. Nonetheless

the signs and symptoms are common and so some statistical modelling and validation within this population is necessary before a tool can be developed.

Statistically modelling the signs and symptoms of HNC in the primary care population avoids the spectrum effect. The spectrum effect refers to the phenomenon where tests that are developed in a population where the disease is more prevalent can be less accurate in identifying disease when applied to another population where the disease is less prevalent. The paper from Usher-Smith's paper concludes "Ideally new tests should be developed and evaluated using data from the population(s) in which they are intended to be used" (112).

Methods

Design and Setting

A open cohort study using primary care records in primary care in the UK, practices registered and contributing to THIN between 1/1/2009 and 31/12/2019.

Participants

Patients registered in a practice contributing to the database between 1/1/2009 to 31/12/2019 aged over 18 years old who have been registered in a contributing practice for at least a year, after acceptable mortality reporting.

The entry to the study will be the date of the first consultation with one of the prespecified predictor symptoms using the Read Codes from the patient records (Appendix B) within the study period.

The end date is 12 months from the entry to the study with first symptom consultation unless before this period there is a diagnosis of HNC, death or the patient leaves the practice or because the practice stops contributing data. This period was chosen because by this time most HNC would be clinically apparent (time to event) for the patients in the study any of the other predictor symptoms recorded in the study period will be captured.

Variables

The study outcome is a diagnosis of HNC (mouth, the larynx and the pharynx [3 parts; nasopharynx, oropharynx, laryngopharynx], salivary glands, nose and sinuses, thyroid and primary bone tumours of

the jaw) recorded in the patient's GP record using diagnostic Read Codes (Appendix B) in the 12 months from entry to the study. This is dichotomous outcome, whether a HNC was present, yes or no. (Appendix C)

The signs and symptom variables are to be included if they are recorded at any time up to diagnosis of a HNC or until the end of the study period.

Patients will be excluded if; they have a history of HNC at baseline, have a TWW HNC referral recorded in the 12 months preceding the study entry date, those without a deprivation banding and those who presented with any of the predictor symptoms in the previous 12 months (neck lump, salivary gland swelling, thyroid swelling, change in voice, dysphagia, odynophagia, cranial nerve palsy, unilateral otalgia, unilateral nasal symptoms, anosmia, haemoptysis, noisy breathing, oral lesion, oral pain, red or white patch in the mouth, jaw symptoms, halitosis, weight loss, shortness of breath, insomnia).

Baseline socioeconomic variables will include; age, deprivation banding and sex (categorical). Lifestyle related factors at baseline will include (if recorded), continuous variables like body mass index (BMI) and categorical variables; excess alcohol (yes no, <14 units/week, >14 units/week), smoking history (never, ex, current - light smoker (1–9 cigarettes/day); moderate smoker (10–19 cigarettes/day); heavy smoker (≥20 cigarettes/day)).

A previous diagnosis of cancer apart from HNC (exluded at baseline) and HPV status (positive, negative) will be included.

Symptoms

Predictor variables focus on symptoms some of which might raise alarm for a HNC (Table 1). The list includes symptoms have been included in NICE guidelines (Table 2 & Table 3) or identified from other predictive modelling studies (75, 100), a review of the literature (73, 95, 102, 105, 174-182) as well as recent secondary care statistical modelling of signs and symptoms predictive of an outcome of a HNC from cohorts referred as suspected cancer through the TWW referral pathway (100, 101, 106, 107).

Predictor variables are composites made up of multiple codes (Appendix C) reflecting different manners in which the clinical information may be recorded. The variables will be time varying, so if a baseline symptom is recorded again or any of the other variables recorded during the study period they will be measured so that combinations of symptoms can be included in the analysis.

Data access and cleaning methods

A stochastic simple imputation method will be used. It will be created as the first of a series of multiple imputations using Multivariate Imputation by Chain Equations method to impute missing values.

Statisitcal methods

Proposed analytical approach for the study will present descriptive statistics for all risk factors included in the study. It is envisaged that potential interaction effects will be identified and explored.

The method is based on QCancer[®] studies, validated by Collins et al using the THIN database (36-49, 183-185) and the TRIPOD guidelines which makes recommendations on reporting of multivariable prediction model for individual prognosis or diagnosis (111).

The linearity of continuous variables with outcomes using fractional polynomials or linear splines in addition to collinearity between variables will be assessed.

We intend to use a multivariable logistic regression model to describe the relationship between the binary outcome variable and a set of predictors and derive the model.

The model development following linearity assessment will follow two steps:

1) A stochastic simple imputation

2) A series of multiple imputations using Multivariate Imputation by Chain Equations method to impute missing values.

Although the most common approach to variable selection is the use of backward elimination method, we intend to use a more modern approach based on regularisation techniques. Regularisation methods shrink parameter estimates towards zero. An example of a regularised method that selects

variable is the LASSO (least absolute shrinkage and selection operator). These methods add a little bias into the parameter estimates to gain reduction in the variance. In addition, the least significant predictors are shrunk quicker and subsequently, the predictors which the method deems insignificant have their coefficients shrunk to zero. For this project, we intend to use the Adaptive LASSO. We chose this method because it has the oracle property- loosely speaking, *"it knows the truth and will select the true variable that relates to the outcome"*.

To check the internal validity of the model, 200 bootstrap samples will be used to adjust for optimism. These will be randomly drawn, with replacement including all predictor variables, from the final model. Predictive ability will be assessed by examining measures of discrimination and calibration. Discrimination will be assessed using the concordance statistic c (this value varies between 0.5 and 1.0 for sensible models, where 1 represents perfect discrimination), this measure is equivalent to the area under the Receiver Operating Characteristic (ROC) curve. In addition to the ROC curve, we intend to evaluate predictive accuracy using the Brier Score and calibration using the calibration slope.

Stata software for statistical data science will be used to perform the modelling of the data.

If a prediction model aims to guide referral decisions, a cut-off is required to classify patients as either low risk (no referral or alternative route) or high risk (referral is indicated). We aim to use decisioncurve analysis to evaluate the clinical usefulness of our model. The aim is to make better decisions with a model than without.

Limitations

The accurate coding of signs, symptoms and HNC diagnosis in the electronic patient record was expected to limit this study as with any study of electronic patient records. Efforts within the statistical modelling endeavoured to account for any missing data.

This work was unfortunately not completed during the PhD and the funding was returned to BAHNO and Oracle Cancer who both generously contributed to purchase the data. Examiners requested that

the protocol was added as an additional chapter to the thesis following successful defense in the viva voce as it was a substantial part of the work done during the PhD and they recognised this.

The next chapter moves to present the method and results of the framework synthesis which set the scene for, and was essential to construct the questions asked in the semi-structured interviews which followed.

CHAPTER 8: FRAMEWORK SYNTHESIS

The following chapter is a description of the method and the results of the NPT framework synthesis of the qualitative literature exploring the factors shaping the implementation and use of CCDTs by GPs in primary care.

To provide some context to the implementation of a new CCDT for HNC signs and symptoms for use in primary care, I wanted to evaluate the work done on GPs experience of implementation and use of CCDTs in primary care. I wanted to evaluate studies that sought to understand GPs' prior use and engagement experience with CCDTs in their practice either as part of a qualitative assessment or as part of a cohort study. For the purposes of this framework synthesis, CCDTs are defined as any intervention (be that digital, paper, electronic, mouse-mat) that is used within general practice to provide a numerical value or a recommendation to consider an underlying cancer diagnosis as the cause of a patient's symptoms or supporting a referral to secondary care for investigation for suspected cancer. This study aims to synthesise qualitative research on GPs' attitudes to, and experiences of CCDTs (186). Drawing upon a framework synthesis approach, it aims to provide a comprehensive analysis of factors shaping the implementation and use of CCDTs informed by NPT (6). This framework allows the exploration of how individuals (GPs) respond to the CCDT in the healthcare context, how the CCDT affects their normal working practice, how it affects their consultations with patients, how they engage with the new way of working, how they maintain their commitment to the work and how they evaluate the CCDT and its impact on their work.

The NPT framework (described in Chapter 5) was chosen as the most appropriate framework to evaluate and analyse the existing qualitative literature to expose the factors influencing the implementation of CCDT in primary care from the perspective of GPs. The framework synthesis attempts to assess how individuals make sense of a new process, the "buy in", the engagement in and the legitimacy of a new practice.

A framework synthesis was considered most appropriate to meet the aims of this work. This method of qualitative synthesis offers "a highly structured approach to organising and analysing data by utilising an **a priori** "framework" – informed by background material and team discussions – to extract and synthesise findings" (187). Booth et al (188) consider that this method allows a comprehensive sampling of resources and can be performed by a qualitative researcher who is not an expert. A framework synthesis is regarded as achievable in terms of time scales and appropriate for a relatively junior researcher (189).

Method

The framework synthesis protocol was published in PROSPERO International Prospective register of systematic reviews (<u>https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=90717</u>, see *Appendix D*).

Data Sources and Search Strategy

Included studies contained data from GPs (in the form of telephone, questionnaires, focus groups, interviews) or direct observation of GPs using any form of qualitative method to describe participation with and/or the barriers and facilitators determining engagement with CCDTs in primary care. GPs based in the UK and included those based in Western countries with a similar health service system to the UK (one with a primary care gatekeeper determined access to consultation with secondary care specialists).

Original qualitative studies, studies involving secondary analysis of qualitative data, qualitative studies that are part of a mixed methods study (the study could also have a quantitative component but include a qualitative component and a qualitative methodology is described) were included. Analysis, discussion, and conclusions were included as well as direct quotes and raw data from studies. Studies using the following methods were excluded: systematic reviews or meta-analyses. Commentary articles written to convey opinion or stimulate discussion with no research component were not included but were used to identify any literature not found in other searches. With the assistance of a Liaison Librarian, a search strategy was defined. Terms used in the search are listed as Medical Subject Headings (MeSH) (seeTable 12).

Table 12 General terms searched (full searches in Appendix E)

Malignant neoplasm/Malignancy	Cancer
Oncology	Neoplasm
Tumour/Tumor	General practice
Family practice	Family medicine
Family physician	General practitioner
Primary healthcare	Risk assessment
Risk assessment tool	Decision support system
Decision making	Computer assisted diagnosis
Decision making	Medical decision making
Prediction	Predictive modelling
Model	Statistical model

The databases used were considered the most relevant databases for the subject matter (medical as well as qualitative research) and the publications which would likely house references to relevant material. Boolean operators and combinations of search terms were applied, and the database searches were applied on 15th July 2020 (see *Appendix E*). A systematic electronic literature search from inception to July 2020 in MEDLINE, CINAHL, Web of Science and EMBASE databases was undertaken.

Selection Criteria

A comprehensive pre-defined search strategy was developed by PB using the SPICE approach (Setting Population Intervention Comparison Evaluation (190)Table 13). No publication type, language or date limits were applied to the searches. Online searches via Google for grey literature were performed using combinations of the terms from the electronic database searches. The initial screening of titles was conducted from the search results. The second screening of titles and abstract was conducted independently by another researcher. The final screening was conducted, following the extraction of the full articles, and checked for consistency. The screenings were guided by the inclusion and exclusion criteria as defined in the protocol. Differences were discussed and agreement between reviewers achieved. Email contact was made with two authors to establish that multiple publications were from the same study and another author was contacted to obtain a copy of their PhD thesis. Manual searches were undertaken by reviewing the reference lists of relevant identified literature

from the database search results.

Table 13 SPICE criteria

Setting General Practice/Primary Care in NHS/Western type public healthcare system (Primary Care gatekeeper)
Population Constal Practitioners /Primary Care doctors /Family doctors
Intervention
Cancer Clinical Decision Tools – paper, electronic, desktop, mouse-map, electronic decision aid/system
Normal practice/no comparator
Other form of risk assessment
Evaluation Qualitative – face to face interviews. Telephone interviews, questionnaires, focus groups, direct observation

Data Extraction and Critical Appraisal

Data extraction was carried out using a comprehensive data extraction template which was designed based on the specific characteristics of the review. The Critical Skills Appraisal Programme (CASP) checklist was used to assess the quality of included studies along with a critical assessment of study bias was performed. The quality appraisal was carried out independently by the two reviewers with a high level of agreement.

Data Synthesis

For each article, all text from 'Results/Findings' and 'Discussion' were extracted and imported into Nvivo V.11[®] software (Nvivo Qualitative data analysis Software; QSR International, V.11, 2016). Study characteristics were also extracted into a spreadsheet to explore potential associations between specific themes and studies.

An emergent approach to coding was taken and resulting codes were then mapped to the four NPT constructs: coherence, cognitive participation, collective action, and reflexive monitoring (*Appendix F*). In order to aid with analysis of the data using NPT, a table of questions for each of the four domains of NPT was adapted from an article by Murray el al (137), in relation to CCDT (be they risk assessment tools or electronic clinical decision systems) (see *Table 14*).

Table 14 Questions about CCDT for each of the 4 domains of NPT

Coherence (Meaning and sense making of participants) How they make sense of the work of implementation and integration in order to promote/inhibit routine embedding of a practice.	Is the CCDT easy to describe? Do GPs understand what the CCDT is? Do GPs understand how the CCDT should be implemented? Is the CCDT clearly distinct from other practices? Do GPs express understanding of how the CCDT is distinct from other practices? Does the CCDT have a clear purpose for GPs/patients? Do GPs report a shared understanding of the purpose/benefit/value of the CCDT? What benefits do GPS feel the CCDT will bring and to whom? (GPs/patients)? Are these benefits valued by GPs? Does the CCDT fit with the overall goals and activity of the organisation (practice/NHS)? Do GPs feel the CCDT fits with their own responsibilities/ roles?
Cognitive participation (Commitment and engagement by participants) Process and work go through to enrol individuals to engage with new practice	Do GPs think the CCDT a good idea – "buy in"? Do GPs see the point of the CCDT easily? Are GPs willing to drive implementation? Are GPs able to/willing to sustain involvement? Do GPs feel is it "right"/legitimate they are involved? Do GPs feel using CCDTs is a legitimate part of their role?
Collective action (The work participants (individuals and organisations) do to make the intervention function) How they enact it	What effect does the CCDT have on the work of GPs (how the intervention affects the consultation)? Does the CCDT promote or impede GPs work? How compatible is the CCDT with existing work practices? Does it make work easier? How does it affect their roles/responsibilities/training needs? Do GPs require extensive training before they can use the CCDT? Is there organisational support for the CCDT? Is there confidence in the new practice when they are using/enacting it? What impact does the CCDT have on division of labour, resources, power and responsibility between professional groups? Is there confidence in the new practice when they are using/enacting it?
Reflexive monitoring (Participants reflect on or appraise the intervention) How they appraise its effects – informal and formal appraisal of new practice to assess its advantages and disadvantages	How do GPs perceive the CCDT once it has been in use for a while? Is the CCDT perceived as advantageous for patients or staff? Are effects on them and their work clear? How do they judge this? Is it clear what effects the CCDT has had? What are the effects on GPs and their work? How do GPs appraise/evaluate this? Can GPs contribute feedback about the CCDT once it is in use? How are benefits or problems identified or measured? Can the CCDT be adapted or improved on the basis of experience? Has its use been altered while in use?

Results

The PRISMA diagram (see *Figure 5 The PRISMA* (*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*) shows the results of the searches (full search strategies and results are in *Appendix E*). There were four published peer reviewed articles, two reports and one PhD thesis which were considered eligible for analysis (*52, 53, 191-195*). Because two of the published papers came from the same study these have been considered together (*194, 195*). Similarly, another of the published articles and one of the reports were based on the same study data (*53, 193*).



Figure 2 The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) diagram.

Characteristics of included studies

Characteristics of the practices from which the 107 GPs were selected for interview and included in

the studies are presented in Table 15.

Study	Number of GPs	Setting
Hamilton (195) Green (194)	23	175 practices from 7 cancer networks, participants selected to include areas of affluence and poverty and practices with non-white population ranging from 2-50%, UK
Dikomitis(53, 193)	23	Diversity of practices located in deprived to affluent area, UK
Chiang (192)	15	Purposeful sample of GPs to cover a range of geographical location within Victoria, Australia
Moffat (52)	28	A mix of rural, suburban, and urban areas and a range of affluent/deprived patient populations, UK
Akanuwe (191)	4	Lincolnshire (large rural county), England
Pannebakker (196)	14	Practices Central and Eastern Clinical Research Networks, England
TOTAL	107	

Table 15 Participant Practice Characteristics

The CCDT assessed were either the RATs derived from the CAPER studies (53, 193-195), QCancer[®] (192) or a mix of the two (52, 191) (see *Table 16*). The interventions were presented in different forms, from mouse mats, to integrated computer prompts for symptoms suspicious of cancers, the use of the QCancer[®] tool which is embedded within the EMIS web electronic patient record system and presented vignettes followed by videoed simulated cases (192).

The studies were heterogeneous in design (see *Table 17*). One study was from Australia (192) the others were from the UK.

One study used actor simulated cases and QCancer[®] (192) whereas the other studies interviewed GPs after using the tools in practice with real patients. Two of the studies used semi-structured telephone interviews (52, 53, 193), the Australian study (192) undertook face-to-face interviews and Akanuwe (191) undertook a focus group with four GPs (see *Table 17*). The interviews with GPs were conducted at variable time intervals after use of the tools.

Data were analysed using the framework method in most of the studies (52, 192, 194, 195). Normalization Process Model (an earlier version of NPT) was used in one study (53, 193) and another used a deductive approach using the Consolidated Framework for Implementation Research and an inductive approach using the Risk Communication Framework (197) (see *Table 17*).

In the Australian study (192) there was a \$300 incentive for participants, this was not discussed in terms of its impact on the participants' engagement nor their responses to simulated cases or interview questions. Practices were given some financial support via the Cancer Networks for participation in another study (194, 195).

All the studies lacked an exploration of the role of the interviewer in relation to the interviewee and the impact this could have on the data (reflexivity) (198). This failure to reflect on the objectivity of the interviewer and any assumptions that they may have brought to the study means that there was no exploration of the relationship between the interviewer and the participants and the impact this could have on the data (described as potential bias and influence in the CASP checklist) (199).

Synthesis of Results

The analysis is presented using the four domains of NPT with selected quotes and commentary from the selected sources.

The emergent coding of the data focused on the CCDT, the role of the doctor, the consultation, the impact on cancer investigation and referrals, and the implications and influence of secondary care cancer services. Each theme (code) was considered and assigned to the most relevant domain of NPT (130).

Table 16 Format and details of CCDT studied

Study	ТооІ	Cancer Type	Тооl Туре	Description
Green et al (194) Hamilton et al (195)	RAT	Lung Colorectal	Desk-based (mouse mats and A5 desk easels)	Quantifies risk of cancer in symptomatic primary care patients. Consists of risk score for high-risk symptoms in isolation, for repeat presentation of the same symptom and in combination with one other symptom. Positive Predictive Values for symptoms of cancer, developed through series of population-based case-control studies in primary care setting. Derived from the Cancer Prediction in Exeter (CAPER) (17)
Dikomitis et al (53, 193)	Electronic RAT (eRAT)	Lung (non-smokers) Lung (smokers) Colorectal	Electronic Using the British Medical Journal Informatica Clinical Audit Platform (iCAP) a software programme compatible with clinical packages in GP (EMIS, VISION)	Electronic version of clinical decision RAT (194, 195) described above.
Chiang et al (192)	QCancer®	Lung Colorectal Gastro-oesophageal Pancreatic Blood Renal Prostate Various others	Electronic web-based version, simple single browser page version	Prototype QCancer [®] software implemented into a web-based version interface designed as a simple browser page. QCancer [®] algorithms can be used to calculate the percentage probability of having an undiagnosed cancer. Developed using QResearch [®] database in a series of prospective cohort studies, it incorporates a range of risk factors.
Moffat et al (52)	QCancer [®] and RAT	Lung Colorectal Oesophago-gastric Pancreatic Ovarian	eRAT described in Dikomatis et al (53, 193)	Participating GPs were presented with either scores from the eRAT or QCancer® (described above) depending on network allocation.
Akanuwe (191)	QCancer [®] and RAT	Not clear	Not clear	Not clear which versions
Pannebakker et al (196)	Electronic clinical decision support (eCDS) 7 Point Check List	Melanoma	Electronic (integrated into primary care clinical system)	eCDS Support for assessment of pigmented lesions. Integrated into EMIS clinical system. A validated diagnostic checklist of 7 weighted features of a pigmented lesion. A score of 3 or more is suspicious of a diagnosis of melanoma.

Table 17 Study Methods and Findings

Study	Data collection method	Qualitative Analysis	Findings
Green et al (194) & Hamilton (195)	Telephone interviews	Pragmatic, emergent themes	Beneficial Credibility to decisions Referral that may not otherwise have happened Instructive but did not supersede clinical judgement
Chiang et al (192)	Face to face interviews	Framework	Clinical experience and belief in clinical intuition determined use difficult to introduce into workflow of consultation Avoidance of revealing potentially confronting information Variable interpretation of patients' symptoms led to widely different cancer risk assessments
Dikomitis et al (53, 193)	Telephone interviews	Emergent Themes mapped to Normalisation Process Model	Variable degrees of use Danger of prompt overload/"prompt fatigue" Increased awareness of cancer symptoms Evidence base questioned Complemented NICE guidelines Need more comprehensive training Use dependent on individual GPs recording behaviour Most perceived a future for electronic aids Concern about impact on the patient doctor interaction Medicolegal implications Dichotomy of financial pressures limiting referrals
Moffat et al (52)	Telephone interviews	Framework	Increased awareness of non-red flag symptoms Prompted earlier diagnosis Individual preferences Might suit group practices rather than smaller GP/single GP practices Limited by recorded read codes Training issues to understand the tools components Awareness by secondary care Variable interpretation of risk
Akanuwe (191)	Focus Group	Consolidated Framework for Implementation Research (CFIR) & Risk Communication Framework	Enablers Supports decision making Identify and modify health risk behaviours Improve process & speed of assessment & treatment Personalise care Easy to use Barriers Additional time requirement Worry or anxiety related to referral for investigations Potential over referral Conflict with existing guidelines Symptoms suggestive of cancer will need referral whatever the quantified risk Need to evaluate effectiveness of tools against current practice Integration into IT system Involvement of secondary care
Pannebakker et al (196)	Face to face Semi-structured	Thematic iterative approach, themes mapped onto the CFIR framework	Easy to use Time-efficient Useful for borderline cases Facilitate communication Might improve timely diagnosis of melanoma Concern will increase or lead to unnecessary referrals Better implementation could enhance its uptake and usefulness

Key factors affecting the implementation of CCDT were identified within the included papers and organised under the four NPT constructs (*Table 18*). The quotes are followed by the reference of the study they are taken from.

	Evelopetion	Thomas
NPI Domain	Explanation	Inemes
Coherence	The impact of CCDT on role of GP	Communicating sharing and understanding risk Collaboration and involvement with secondary care and existing guidelines The one size fits all approach to training
Cognitive	Elements determining	Clinical acumen versus protocol
Participation	GPs use of CCDTs	The medico-legal implications of using a new CCDT
Collective	Impact of the CCDT on	Increasing awareness
Action	the work of the GP	Prompt fatigue (CCDT generated prompts) Impact of IT integration Time as a resource
Reflexive Monitoring	GPs reflections on using a new technique	Unintended consequences Investigation and referral patterns "Think Cancer"

Table 18 Domains of NPT in relation to CCDT

Coherence: The impact of Clinical Cancer Decision Tool on the role of the GP

Coherence refers to how participants make sense of the intervention (18).

Communicating, Sharing, and Understanding Risk

A key result was that GPs were often expected to communicate the pros and cons of a course of action,

investigation, treatment, and the likelihood of signs and/or symptoms being serious or benign and this

was influenced by different expectations in terms of the potential reaction to them from patients.

Different levels of comfort were experienced when using CDDTs within consultations (191, 192) this

was because of the perceived impact of the information for the patient, how it was communicated

and what effect it might have.

If someone was very worried and they scored zero then I might be able to say, "Look, this is a scoring system that's been developed," and it might just aid reassurance. Equally, if I was worried ... I might just say, "Look, this is the scoring system, you've got quite a lot of points on this. It doesn't mean it's anything serious, but it does mean we need to look into it more closely (196)

Some GPs had concerns that using the CCDT would increase anxiety so did not share the cancer risk

even keeping it hidden from the patient's view or feeling using the percentages in the discussion with

the patient would be challenging (52, 192). Others were comfortable using the CCDT to reassure patients (191).

Sometimes I hide it, just in case I cause an alarm, but I will start to cover it during the consultation if there is any risk, yes. It depends because, you know, some patients, if they're anxious, when they see something like that, they become more anxious. (52)

There was a lack of understanding about the intended role of the CCDT or how to use the results that it generated (52, 53, 191, 193). This "sense making" aspect in these studies may reflect a lack of knowledge of interpretation of the results and the need for training in the use of the CCDT. Understanding how the CCDT fits within the current cancer pathway, how the cancer risk figures were calculated might improve confidence in the validity of using the CCDT (53, 191-193). This might encourage its use and integration into the consultation.

Collaboration and Involvement with Secondary Care and Existing Guidelines

A common theme across studies was the reported need for the CDDT to be integrated within existing referral pathways and endorsed by secondary care (52, 53, 191, 193). The perception that their referral behaviour would change by using the tools evoked a fear that without knowledge and awareness by the hospital specialty teams, the GPs would feel less confident in using them.

My concern is that the tools are not known to the secondary or hospital setup. So, I referred some patients, and I am concerned they may not recognise my QCancer[®] referral ... So, when I am thinking, if they see the patients I referred using QCancer[®], they will ask - who is this? Is this a new doctor, a new GP? (191)

This made some participants uneasy about using the tool to make decisions about referrals.

There are criterion boxes often and very occasionally a patient doesn't quite fit one of the boxes and you tend to worry ... but I think if you can justify whether actually they've got 38% chance of colorectal cancer on this [tool] then I don't think they would argue with that (52)

Having secondary care doctors' endorsement of the CCDT appears to be an important aspect to promote its routine use. To justify referrals of suspected cancer using the percentages generated by the CCDT would require some knowledge of the CCDT by secondary care (52, 53, 191, 193).

The 'One Size Fits All' Approach to Training

Use of the intervention by GPs was determined by their involvement in a research study (53, 191,

193), the training they had prior to using the CCDT and the support that they received whilst using the CCDT.

Although the tool itself doesn't look that bad on the training, in terms of the implementation and making it work in every single practice, I feel that the training was not bespoke (52)

Training is essential in determining coherence (52), how GPs understand the CCDT, how CCDT are

distinct from other practices.

Finally, data certainly highlighted that GPs might decide to refer on the basis of a holistic approach and, as many respondents emphasized, the approach of the individual GP and his/her level of clinical experience also plays a crucial part in the decision-making process (53, 193)

By understanding the benefits for both the doctor and patient CCDT may be more likely to be integrated into practice. Any training should aim to demonstrate how the CCDT fits with the responsibilities and role of the doctor as well as the overall goals of the NHS.

Cognitive Participation: Elements Determining GPs Use of CCDT

Cognitive participation refers to the commitment and engagement with the intervention (18).

Clinical Acumen Versus Protocol

Some participants commented on their discomfort with using the CCDT to aid their decision making rather than it being an instruction that had to be obeyed. Other GPs made it clear that they did not want to have their clinical acumen challenged by a CCDT (52, 53, 191-193, 195). Protocolisation was one of the most discussed factors affecting implementation within included papers (52, 53, 191-193, 195). GP responses suggest a reluctance to be protocol driven in their decision making. This questions the perceived legitimacy of the use of CCDT's when GPs do not feel it "right" that they should be used (194, 195).

I don't think you can ever protocolise... make a risk schedule that is better than... experience (194, 195)

The CCDT was used to back up "instinct" and ignored if it did not (52). Despite this theme being a dominant one, there was little exploration in the studies of whether the CCDT was used by GPs to justify not taking further action in terms of investigations in those with a low risk of symptoms being caused by cancer and only one interviewee was quoted alluding to this (192).

Without the checklist I already know what to look for. I know that if it's changed in size, if it's irregular, that those are all serious ... So I would have already gone through it anyway, with or without the [list] in front of me, so does it really matter? Probably not. It's in my head like any other medical problem, I mean, I consult all day long (196)

This could be because the underlying agenda is early recognition and diagnosis rather than an appreciation that CCDT might actually contribute to a reduction in over investigation and improved selection of patients for two-week wait referral pathways (192). Some GPs did overrule the outcomes generated by the CCDT if these were not consistent with their clinical impression. (52, 191, 192).

The Medico-Legal Implications of Using a New CCDT

Medico-legal implications were highlighted by one study (53, 193). Sustaining and driving involvement

and "buy in" could be impeded if GPs felt there was a medico-legal threat to their decision making.

Quite a few partners were worried about any medical legal implications with that ... what would be the implications? That was probably a point that put people off, really (53, 193)

This could occur if GPs felt they may be potential medico-legal implications associated with the

response from patients who were later diagnosed with cancer after the CCDT had highlighted an

increased risk, but a decision was made not to investigate or refer.

If that's the NICE guidance and that's in the CCG 2-week wait form, if you've got a score of 4 and you don't refer, I think the lawyers would say that you're not following guidance and they could sue you (196)

Collective Action: Impact of the CCDT on the Work of the GP

Collective action is the work individuals and organisations do to make an intervention work (137).

Increasing Awareness

GPs found that using the intervention benefitted them as it increased their cancer symptoms

awareness. For some GPs, the CCDT acted as a reminder of suspicious signs and symptoms and was

considered an aide-memoire (52, 53, 191-195). There was an appreciation that some patients may

not otherwise have been referred so promptly to cancer services.

Normally I'd get a few investigations, get the results back and then based on that say do we need to do something, or I refer this on based on that. But I guess if I have a calculator saying it's higher risk, it might prompt me to make a referral to a specialist a bit earlier (192)

The use of the CCDT increased awareness of NICE guidelines in some cases, again building confidence

in the use of the CCDT (52, 53).

It probably made us more aware than NICE guidance ... it's probably made me more aware of symptoms which I may have not been as aware of in the past (52)

Prompt Fatigue (CCDT Generated Prompts)

Prompt fatigue was mentioned by several studies (52, 53, 193). The electronic interruptions impacted

on the work of the GP and the flow of the consultation.

we have all sorts of prompts coming at ... it gets a little bit distracting ... you're trying to sort out and you've got all these messages flashing up at you (52)

The prompts were regarded, in some studies, as a nuisance making work more difficult (53, 193).

I suppose the prompt of a photo to be added would be helpful if they need to look through it (196)

Impact of IT Integration

A major component of how easy it was for GPs to engage with the CCDT appeared to be software

integration with the existing clinical systems. GPs commented on clunky integration, lack of support,

and lack of training on how to use the CCDT (52, 53, 191, 193).

There was a problem of accessing the tools as they are not integrated in our IT system. It was not easy downloading or googling the tools during patient consultation (191)

Integration into the clinical IT system was an issue which had the potential to "make or break"

implementation and integration. When participants encountered problems with using the CCDT it

was sometimes met with frustration with some GPs choosing to abandon use (52).

so much hassle ... we had to spend so much time ... trying to install it in every single desktop ... I couldn't do it. I just gave up (52)

Time as a Resource

Time was one of the most discussed factors for successful implementation (52, 53, 191, 193-195). Recognition of the benefits of using a CCDT was needed to justify the additional time required for its use. This impacts on consultation, time required to train users, and the additional effort to keep using the CCDT. Time is at a premium in general practice: the pressures of the 10 minutes appointment, to keep up to date, to attend training.

if it's actually going to make life easier ... is it going to improve care for the patient? Or is it ... time really spent in filling up proformas? (194, 195)

Participants reported that adjusting to new work practices and integrating new techniques could take additional time, attention, and commitment. However, there was also recognition that initial investment would be worth it for improved patient care (191).

I thought it was going to be time consuming using the tool. But ... that will only be the case in the short term ... it will be time saving in the long term, as the consultation, the assessments, investigations and referral processes will be faster (191)

Reflexive Monitoring: GPs Reflections on Using a New Technique

Reflexive monitoring is the appraisal work those individuals utilising the CCDT acknowledged (18).

Unintended Consequences

It was recognised that the CCDT could be valuable as an intervention to identify at risk patients or

those suitable for screening (191, 192, 194, 195). In terms of the NPT framework, this highlights how

the use of a complex intervention is adapted based on experience.

there is a potential for using the tools for screening ... They could also be modified for asymptomatic patients (191)

Another recognised benefit of using the CCDT was in identifying patients' modifiable lifestyle factors

(191, 192). This information was used in consultations with patients to try and encourage change of

behaviours like smoking, weight, or alcohol consumption. GPs recognised their positive role in

encouraging modification of behaviour as well as general health awareness.

Your chest X-ray is perfectly normal. Your cough settles ... I still have to try and convince you to stop smoking, to exercise, to lose weight ... it should be used as a relationship tool (192)

Investigation and Referral Patterns

It was acknowledged that the CCDT could reduce over-investigation and over-referral to secondary care of those cases where a patient's symptoms are below the positive predictive threshold (52, 53, 191, 193-195).

we were thinking that using the tools in consultation could result in unnecessary ... over-referrals ... I don't think there will be over-referrals (191)

Conversely others worried that CCDT would increase the referral rates but reflected that this was not always the case and could be auditable (191, 194, 195). It was reported that the use of CCDT may reduce referrals to secondary care in some cancer types and that this would have an impact on the stretched secondary care services.

I think our referral thresholds for lower GI have definitely gone down (194, 195)

"Think Cancer"

All studies demonstrated that the interventions prompted them to "think cancer" (52, 53, 191-195). In so doing, they improved and heightened their awareness of relevant signs and symptoms. The CCDT were a means to improve the speed of diagnosis of cancer and prompt action whether that be to initiate investigation, referral, or counselling of a patient.

Yes, I must admit ovarian didn't come so high up ... This really said "hey, consider ovarian as well" (192)

The data revealed that some GPs felt the CCDT prompted earlier review for patients with vague symptoms or alerted them to the possibility of an underlying cancer-causing symptoms prompting investigation or referral (194, 195).

If I had a patient with a vague set of symptoms, then finding and using the tool showed that it was an amber ... I might have followed up the patient in a different way ... I'd like to see you again, just to see how these symptoms are, um, rather than leaving it to the patient to contact us (194, 195)

Comprehensive co-operative working between primary and secondary care in planning, designing, and implementing CCDTs will benefit clinicians, patients, quality of health care and take account of scarce resources. Stakeholder consultation and involvement should be regarded as essential aspects of health care innovation and implementation.

The value that clinicians place on their clinical acumen and their desire for this to be recognised makes them wary to rely solely on protocol driven decision-making. There will always be clinicians who find decision aids reassuring, those who find them helpful as an aide-memoire and those that find them a nuisance and will not use them at all. An ideal tool is one that does not undermine clinical instincts but supports and enhances them.

CCDTs are a helpful adjunct to clinical work in primary care, but without careful development legitimising their use particularly from secondary care, training, and IT integration they may remain superfluous to clinical acumen and experience. These new insights into the understanding of GPs' experiences of using CCDTs directly informed the questions posed during the stakeholder interviews exploring the potential implementation of ORLHC in primary care for suspected HNC.

The next chapter is the study exploring stakeholder views on the ORLHC based on some of the work presented in this chapter.

CHAPTER 9: NON-ADOPTION ABANDONMENT SCALE-UP SPREAD SUSTAINABILITY (NASSS) ANALYSIS

This chapter presents the method and an analysis of the interview data collected from stakeholders using the NASSS framework, about the potential and real use of ORLHC and its role in the suspected HNC TWW referral pathway. The themes which have been developed within the data are presented within the seven domains of NASSS: (1) condition, (2) technology, (3) adopters, (4) value proposition, (5) organisations, (6) wider systems and (7) adaptation and embedding.

Method

Semi-structured interview was chosen as the method of data collection as the intention was to explore both individuals' perceptions related to the potential implementation of a primary care CCDT for suspected HNC as well as the influence of the context within which the intervention would or could be implemented. This, it was hoped, would allow exploration of what impact ORLHC might have, whether it was considered an appropriate intervention and what might determine its success or failure. By adopting this method, it allowed a broad but multifaceted and dynamic approach to explore the potential implementation of a primary care CCDT for suspected HNC which was considered most appropriate and intuitive to this aspect of the research. The topic guide was developed in consultation with supervisors and Val Bryant (Patient and Public Involvement representative) and was informed by the results from the framework synthesis (see *Appendix G*).

By developing questions which explored the broad contextual complexity within which ORLHC was intended to be implemented it was possible to present the analysis using the NASSS framework. Interviewing in this way allowed the development of familiarity and confident reflection on some of the complexities of healthcare, particularly the NHS context, the political agenda, the internal market, the work of GPs, HNS, and the patient journey from primary to secondary care.

Addressing how and why a new intervention might succeed or fail through a contextual lens can shape how an intervention is developed, delivered, and determine engagement with it. Of course, it could also expose complexities in both the intervention and the context that are insurmountable and require a rethink of the intervention. For the groups pushing for any new intervention the latter is less desirable, but the exercise can lead to revelations in understanding that save effort and resources being deployed into projects doomed to failure. This work can inform potential changes in the TWW pathway for suspected HNC such as the ORLHC. In the NHS, evidence based, and scientifically robust interventions too often fail because of assumptions and siloed thinking. This approach has historically prevailed over stakeholder consultation and consideration of system complexity.

Qualitative interviews with stakeholders who could be involved in the implementation of the intervention are undertaken to provide context and explore factors that would determine and shape any innovative change to the suspected HNC referral pathway. In this study ORLHC was used as an example of a proposed change. Qualitative research as part of pragmatic implementation science research is critical to *"support the examination of the dynamic context and systems into which evidence-based interventions are integrated – addressing the "hows and the whys" of implementation"* (200).

The intervention being considered in this research is the ORLHC and it is based on quantitative data. It has been developed using statistical methods but its application in real world decision making was untested at the start of the research. Before COVID-19 there had been no formal assessment of how clinicians would engage with it, how patients would respond to it, how it is presented, or whether it does what it is designed to do (quantitative) which is safely (without impacting on actual numbers of cancer diagnoses from this pathway) reduce the volume of referrals for suspected cancer. This changed because of the pandemic response demanding that a remote approach to patients was taken whenever possible to reduce the potential spread and exposure. As a result of this, a large number of HNS in the UK adopted the adapted ORLHC for use in telephone assessment of patients referred as suspected HNC during the first lockdown period in the UK.

Because the interviews tended to be grouped sequentially (with the set of HNS carried out first and the HNC patient interviews most latterly) rather than concurrently, some themes were explored more with some groups than others as the interviews progressed. An iterative approach was taken reflecting the analysis of the interviews and inevitable recognition of areas to explore with subsequent interviewees and groups.

The Intervention (ORLHC) (Potential and Real)

Through the course of the PhD the format and statistics underpinning the predictive calculator for HNC changed. At the start of the PhD (February 2018) the ORLHC website (www.orlhealth.com) hosted the first version of the calculator based on the work by Tikka *et al* (100), there were a number of omissions like smoking status because of missing data as discussed in the HNC chapter (Chapter 4). This online calculator was the one which was shared with participants (so that they could familiarise themselves with it prior to the interview and was sent along with the participant information sheets *Appendix H*) during the early part of the study (with HNS pre pandemic, GPs and the PCPI participants). The intention from the outset of the PhD was to include GDPs but this proved challenging.

The thesis refers to ORLHC when discussing the idea of a CCDT for HNC in principle unless the analysis is specific to one version in particular, henceforth these are V1 (version 1 of ORLHC Figure 2), V2 (version 2 of the ORLHC Figure 3) and V3 (the amended ORLHC used by specialists in the form of an Excel spreadsheet during the first wave of COVID-19 *Figure 4*).
Please select YES or NO I obtain the probability valu threshold point for this mo	based on presence or al le for head and neck car odel. The abstract of the	sence of given symptoms in your patient a cer. An urgent referral will be recommende paper on which this calculator is based ca	as appropriate. Press "Calculate" to d if probability is ≳8%, the optimal n be found here.
ease enter patient Age *	🗘 e.g. 21		
Please select Gender*		Male Female	
Hoarseness (more than 3 weeks)	No Yes	Sensation of lump in throat	No Yes
Oral ulcer (more than 3 weeks)	No Yes	Recent mass in neck (less than 3 weeks)	No Yes
Oral swelling (more than 3 weeks)	No Yes	Unexplained otalgia (with normal otoscopy)	No Yes
Dysphagia (more than 3 weeks)	No Yes	Intermittent hoarseness	No Yes
Neck mass (more than 3 weeks)	No 🔵 Yes	Odynophagia	No Yes
Presence of blood in mouth	No Yes		
Calculate			

1: Tikka T, Pracy P, Paleri V. Refining the head and neck cancer referral guidelines: a two-centre analysis of 4715 referrals. Clin Otolaryngol. 2016 Feb;41(1):66-75. doi: 10.1111/coa.12597.

Figure 3. Version 1 ORLHealth Calculator (V1)

By the time of the pandemic there were two versions available online and it was data from the second version (101) that was used for the service evaluation during the first wave of the pandemic. The signs and symptoms were displayed with a drop-down option (yes, no, persistent, intermittent) along with gender and age data in the form of an excel spreadsheet and data was entered and submitted to the INTEGRATE group (the UK Ear Nose and Throat trainee surgical research network www.entintegrate.co.uk) for analysis (116).

HaNC-RC v.2 (2019)

Symptom Based Risk Calculator for Head And Neck Cancer Referrals v2

Please select options from the list based on presence or absence of given symptoms, signs, demographics and social history in your patient as appropriate. All symptoms should be present for 3 weeks or more, apart from stridor which is an acute presentation. Press "Calculate" to obtain the probability value for head and neck cancer. An urgent suspicion of cancer (2 weeks) referral will be recommended if probability is 2-7.1%, the optimal threshold point for this model. Routine referral is recommended for thresholds less than 2.2%. For moderate risk probabilities (2.2%-7.0% an urgent-6 weeks referral is recommended). The abstract of the paper on which this calculator is based can be found here.

lease select Gender		Male	Female		
Unintentional Weight loss	No Yes		Odynophagia	No Yes	
Smoking status	Never Smoked	\$	Oral Ulcer	No Yes	
Alcohol status	≤ 14units/week	٥	Oral Swelling	No Yes	
Hoarse voice	No	\$	Unexplained unilateral otalgia	No Yes	
Sore Throat	No	\$	Stridor	No Yes	
Dysphagia	No	\$	Persistent Head and Neck Skin Lesion	No Yes	
New Neck Lump	No	\$	Feeling of Something in Throat (FOSIT)	No Yes	
Calculate					
ates a field that is require	ed in order to obtain a calc	ulation.			

1: Tikka T, Kavanagh K, Lowit A, Jiafeng P, Burns H, Nixon U, Paleri V, MacKenzie K. Head and Neck Cancer Risk Calculator (HaNC-RC) - v.2. Adjustments and addition of symptoms and social history factors. Clin Otolaryngol. 2020 Jan 27. doi: 10.1111/coa.13511. [Epub ahead of print]. PMID: 31985180

PubMed

Figure 4. Version 2 of ORLHealth Calculator (V2)

Remove data be	fore submission	Demog	raphics		General		Voice	Airway		Swall	owing		0	ral		Misc				Outco	mes		
Dete		Age	Gender	Smoking	Akohol	Unintentional weight loss	Hoerseness	Stridor	FOSIT	Sore Throat	Odynophagla	Dysphage	Oral swelling	Oral uker	Unexplained unifet otalgie	Neck lump	Skih lesion	Celcresult	Clinidan advice	Patient choice	Triage outcome	ActMty outcome	Follow up
Date of triage	Patient ID	Age	Gender	Do you smoke?	Do you drink alcohol?	Have you lost any weight without trying?	Do you have a hoarse volce?	Do you have notry breathing?	Do you have a feeling of something stuck in your throat?	Do you have a pain in your throat?	Do you have pain when you swallow?	Do you have any difficulty swellowing?	Do you have a new swelling in your mouth?	Do you have a new ulcar in your mouth?	Do you have any new ear pain?	Do you have any new lumps in your nesk?	Do you have a new growth on your sidn on your H&N?	Outcome	Patient advised for neview or b2	Patient agrees to/ preferences review or IX?	Review or bx arranged?	Outcome of review or bx	Cancer at 6 months?
05-Apr-2020	Example	45	Male	No	s14 units/week	No	No	No	No	No	No	No	No	No	No	No	No	Low risk	No	Yes	Urgent Investigation offered	investigated then Followed up only	

Figure 5. The Excel Spreadsheet for triage of new suspected HNC patients during the first wave of the COVID-19 pandemic (V3)

Those head and neck patient participants who accessed the website prior to an interview would have seen both the original and the second version of the calculator presented online. The HNS who were interviewed during COVID-19 (some were interviewed before) had some knowledge of the calculator in its various forms and those who had used it during the pandemic had engaged with the excel spreadsheet version.

When the thesis refers to ORLHC, it is one of these formats depending on the timing of the interviews (see *Table 19*). These aspects were beyond the control of the researcher but provide dynamic and valuable insights, nonetheless.

Group	No	Dates	Location	V 1	V 2	V3			
HNS	11	6 March 2019 – 19 July 2-19	North East	\checkmark					
GP	12	14 June 2019 – 5 December 2019	North East	\checkmark					
РСРІ	12	21 August 2019 – 13 December 2019	North East	\checkmark					
HNSC	12	16 July 2020 – 25 August 2020	National	\checkmark	\checkmark	\checkmark			
HNCP	7	23 November 2020 – 25 January 2021	North East	\checkmark	\checkmark				
(HNS = Head and Neck Surgeons, GP = General Practitioners, PCPI = Patient, Carer, Public Involvement Group Sunderland University, HNSC = Head and Neck Surgeons interviewed during									

Table 19 Intervention presented/used/accessed for each interview group

Covid-19, HNCP = Head and Neck Cancer Patient)

This qualitative research aims to make a pre-emptive assessment of the thoughts of those for whom the ORLHC is intended to benefit and explore aspects which might determine whether, despite its intended clinical impact, it would be used in the way that its developers hope, and whether there would be recognition that something similar might aid GPs in identifying those patients who might otherwise have a delay in the recognition that an undiagnosed cancer is the cause of their symptoms. Questions that this research hopes to answer are about where the ORLHC fits in the pathway and how it might best be implemented so that it could become embedded in practice. To do this the thesis aims to explore the key stakeholders' views and experiences of the existing HNC TWW pathway and use of the ORLHC in secondary care triage of suspected HNC referrals during COVID-19. Any change in healthcare service impacts upon a whole range of individuals, groups and systems and the appreciation of these interrelated and complex entities can aid implementation of change into day-to-day practice. Secondary care specialists question the low yield of cancer diagnoses from the TWW pathway and audit of practice has resulted in a call for change to the current suspected HNC TWW pathway. Changes to a clinical pathway will not only impact on this group of individuals, and careful consideration of the stakeholders' views could also influence how best to adjust the pathway to the benefit of all stakeholders and uncover issues around how that change might be facilitated.

The experience, views, and perspective of those who must use an innovation, and those for whom the outcome is designed to benefit, is important in determining its use.

Qualitative Analysis

For the analysis of the in depth semi structured interviews a thematic analysis approach was taken (201). Thematic analysis is a flexible method which "can be used to answer almost any type of research question and analyse almost any kind of data" (202). It is not a prescriptive approach but allows analysis to a phenomenon or to explore assumptions and attitudes. Braun and Clarke refer to thematic analysis as reflexive thematic analysis (203). They recently reflected that the method has been used and published extensively in research since their original publication without appropriate attention to the fact that qualitative research needs to be creative, reflexive and subjective rather than confined by rigid protocol and process. They refer to their approach as making room for the researcher to articulate their assumptions, their approach and reflect upon how that informed their research. *Table 20* displays their reflections on how thematic analysis has been used since inception and what they consider it to be currently (203). Braun and Clarke argue being dogmatic in approaching analysis risks limiting appropriate and necessary adaptations and innovations in methods (204).

113

Table 20 From paper from Braun and Clarke Key conceptualisations around thematic analysis: Then and now

Then	Now
Not 'getting it' (them) versus 'getting it' (us)	There are several clusters of TA approaches, each with different philosophical assumptions and procedural practices that reflect these assumptions (we call these coding reliability TA, codebook TA and reflexive TA)
TA is theoretically flexible	In specific iterations of TA, flexibility is more or less constrained by paradigmatic and epistemological assumptions around meaningful knowledge production; reflexive TA procedures reflect the values of a qualitative paradigm, centring researcher subjectivity, organic and recursive coding processes, and the importance of deep reflection on, and engagement with, data
Themes are themes	There are different conceptualisations of a theme – domain summaries versus patterns of shared meaning, underpinned by a central meaning-based concept
Searching for themes	We now prefer the term 'generating (initial) themes' to emphasise that themes are not 'in' the data, pre-existing analysis, awaiting retrieval

Ramanadhan *et al* (205) suggest measures to ensure rigor in pragmatic qualitative analysis for implementation science which, though published since my research data was collected, has been helpful in ensuring that I demonstrate awareness of, and guidance by these principles (*Table 21*).

The Framework Synthesis presents analysis of the existing qualitative research with GPs involved in using CCDTs. This work focused on the individual interaction with the intervention, how they made sense of it, how it fitted into their work and how they reflected on its efficacy over time. The synthesis of the data revealed that there were influences from external factors over how GPs interacted with the CCDTs, these were things like national policy, their relationships with hospital specialists and medicolegal implications on their practice. It became clear that these factors would be important in determining future engagement with CCDTs beyond the research when GPs benefitted from incentives and support to use the CCDTs. NPT was used in the framework synthesis as a conceptual tool to explore the nature of the interaction of the individual and new working practice, but NASSS was more appropriate to explore the wider range of factors shaping the implementation. When considering the implementation of a novel intervention one approach is to consider the individual, the organisation, and the system as social levels under consideration. These can be thought of as the micro, the meso and the macro levels in sociology which act with degrees of interdependence (138). In the case of healthcare, the micro level under consideration is at the individual practice (as considered in the framework synthesis Chapter 8), the meso level is the organisation (hospital trust

or primary care) and the macro level can be considered the government healthcare policy which determines the priorities of the NHS led by political, cultural and financial determinants. In the context of this thesis, COVID-19, and the response to it can be considered one of the broadest and far-reaching influences over NHS healthcare delivery in its history. The application of the NASSS framework was a logical approach to explore the challenges surrounding the potential implementation of the ORLHC reflecting the complexities in the healthcare system from individual groups to systemwide issues.

Though this research does not have a definitive or 'hard' technological intervention to implement and adopt, the NASSS framework allows the crucial consideration of practice, organisation and institution level factors at play which would determine how and what changes can be brought to bear on the current suspected HNC pathway. Applying the NASSS framework to the analysis of the interview data additionally enables the identification of gaps in the knowledge and understanding that ideally should be considered for any future work in this area. To explore whether a hitherto unused and untested intervention was likely to succeed better than the CCDTs previously studied requires a deeper exploration of the wider context prior to any implementation which this thesis provides. Enthusiasm for the technology from a charismatic leader and a group of eager HNSs with their own motivations to try and reduce the volume of referrals into their clinics is not enough to guarantee a successful implementation, adoption, and integration into routine primary care practice.

Data Collection

Setting

Most of the interviews were with clinicians, public and patient participants resident in the North East of England. Clinicians interviewed during the pandemic were recruited from the wider UK so there were participants from outside the North East. Clinician interviews during COVID-19 discussing V3 and remote assessment by secondary care clinicians took place over the phone or via Teams or Zoom. The HNC patient interviews took place during the pandemic, so these were also conducted by remote means (i.e., phone or via Zoom).

Table 21 Suggestions to ensure and communicate rigor in pragmatic qualitative analysis for implementation science

Consideration	Description
Demonstrate the link between research goals, analytic approach, findings, and broader literature	Researchers should explain how and why they are incorporating procedures from different approaches. By explicitly justifying their decisions and connecting these pieces of the overall research design, the team can ensure internal coherence as they combine procedures from approach that may have distinct underlying principles and assumptions
Ensure transparency around data analysis	Researchers should provide sufficient details about which procedures from which analytic approaches have been used and how they were combined or adapted to enable readers and users of the research to understand and evaluate the utility of the work. Details may include, e.g., the coding structures and how conceptual frameworks influenced analysis. Additionally, for data collected among diverse participant groups (e.g., evidence-based intervention recipients vs implementers) or sites, details about if/how data were analysed separately and, then, holistically are critical. Ongoing documentation of the analytic process, including description of decision-making and mediation of disagreements, also supports transparent reporting
Triangulate data	The analysis can be strengthened by comparing results from different methods of inquiry (e.g., participant observation and focus group discussions) or different sources (e.g., implementers and leaders) to gain a more comprehensive and nuanced view of the implementation science concerns at hand.
Integrate reflexivity	The researchers should describe how their background, experience, and positions (particularly in terms of being grounded in research or practice) may influence their analysis of the data. Relevant details may include experience with the implementation effort, setting implementers, an evidence-based intervention of interest
Use member reflections	Sharing early findings with members of participant groups to get feedback offers an opportunity to strengthen the analysis and help to meet practice goals. This could include sharing early interpretations with an advisory group or key implementation stakeholders to gather suggestions to further refine/develop analysis
Consider divergent roles	It is important to identify and investigate not only the broadly consistent themes but the deviant cases as well. This ensures a wide range of 'explanations' have been considered, and the bulk of the cases have been included in the summaries offered. For example, this might prompt attention to an implementation site with a vastly different experience implementing a new innovation compared to others in its network

Sampling

A mix of purposive and convenience approaches to sampling was employed to select key stakeholders with insights into the head and neck TWW process. For the specialist and GP groups, a snowball approach was adopted. These approaches reflect issues of practicality. The pre-pandemic HNS group was made up of a range of years of experience and ratio of ENT to OMFS. There was more scope and potential within the GP group to sample participants who had roles in commissioning, leadership roles (such as Primary Care Networks), specific primary care cancer roles as well as those with no additional specific role outside their day-to-day clinical work. HNC patient and PCPI sampling were more difficult, given the nature of the project, limitations included access to patient records and reliance on voluntary participation, so a convenience sampling approach was taken. The pandemic sample of HNS was limited initially to those who engaged with V3, but further participants were recruited to explore the opinions of those who had chosen not to use V3 in the first wave of COVID-19.

Recruitment

To capture the opinions about the suspected HNC pathway and an intervention to change how it operates, recruitment was sought from clinician groups; GPs, GDPs, ENT and OMFS and to voices to represent patients and the public. *Table 19* shows the numbers interviewed in each group and the period during which the interviews were conducted.

Clinicians

Recruitment of GPs, GDPs and HNS clinicians pre COVID-19 was limited to those who were currently working within NHSE in the North East of England. All clinicians were to be working in a post Certification of Completion of Training capacity. During COVID-19 one ENT consultant asked if his trainee could observe the interview and it became apparent that he had been utilising ORLHC under supervision during COVID-19 and his offer to complete an interview himself was accepted.

Head and Neck Surgeons (ENT and OMFS) pre COVID-19

Recruitment for the first group of surgeons was via email communication. Invitations were sent to each of the HNC multidisciplinary team leads in the North East of England (4). Head and neck consultant surgeons (ENT and OMFS) were invited to contact the interviewer if they were interested in participating in the study in the form of a recorded interview. Thirteen HNSs in the region emailed the interviewer to organise an interview. One who initially expressed interest in participating failed to respond to an invitation to book an appointment, and another booked an appointment but had to cancel and failed to book a further interview, these were both, unfortunately, OMFSs. Volunteers received a copy of the participant information sheets (see *Appendix G*), along with a link to the

"symptom-based risk calculator for HNC referral" website (www.orlhealth.org) via email and were invited to provide availability and preferred location for a face to face interview. The interviewer travelled to the participant's preferred location at the time arranged to conduct the interview. The interview commenced after the participant had an opportunity to ask any questions and sign a consent form.

General Practitioners

GP recruitment was via several routes, including personal email approach to regional and local GP cancer leads (via Northern Cancer Alliance), GPs with a Clinical Commissioning Group (CCG) role, a PCN (Primary Care Network) chair and GPs without a formal leadership role. GPs involved in CCG activity were contacted via email with an invitation to recommend other GPs who might be interested in participating. The emails had the participant information sheet as an attachment (*Appendix G*). As recruitment proved so challenging in this group I sent email requests to GPs working in practices in which I had a training role. Those who responded to email invitations were invited to provide availability and preferred location for the interview, once arranged the interviewer travelled to the location. Before the start of the interview the participant was invited to ask any questions and sign a consent form (*Appendix H*).

A local GP confederation education administrator was contacted to consider allowing the promotion of the study at a teaching event for GPs. In return for this opportunity to promote and possibly recruit GP participants, I provided some teaching in an ENT topic (dizziness) teaching sessions to approximately 60 GPs. GPs attending the dizziness teaching were invited to provide an email address if they were interested in participating in an interview. Following the event the interviewer contacted those who provided an email address with the Participant Information Sheet (*Appendix G*) and they were invited to respond if they were prepared to volunteer to provide availability for an interview. There was one response to this invitation.

118

Any GPs who delcared an interested in participating were contacted by email by the interviewer to arrange the interview location, date and time. The interviewer travelled to the specified location undertake the interview unless a telephone interview was the preferred mode (one GP participant). The participant was invited to ask any questions and complete a consent form (*Appendix | H*) prior to start of the interview, for the telephone interview the consent form was completed and sent attached to an email to the interviewer.

General Dental Practitioners

The interviewer contacted an academic dentist at the University of Newcastle (Dr David Holliday) who was the director of the Northern Dental Practice Based Research Network and arranged a telephone call to discuss recruitment of GDPs. The interviewer was invited to present at a meeting at the Dental School University of Newcastle at a meeting of the aforementioned network (February 2020). Following this presentation the information about the project and contact details were added to the network's website. One GDP responded to the invitation to participate, the participant information sheet (*Appendix G*) was shared with them and an appointment for a remote interview was organised. A signed consent form (*Appendix H*) was returned electronically, there was an opportunity to ask any questions and a technically difficult interview was conducted.

PCPI

PCPI recruitment was via the University of Sunderland Senior Lecturer Dr Lesley Scott and her team who coordinate the group. An email invitation was sent by Dr Scott to members of the group to volunteer to participate, the PCPI team coordinated with the participants and arranged face-to-face interviews in a prebooked room located in the department of Health and Wellbeing at the University of Sunderland. Participants were sent the participant information sheets (*Appendix G*) by Dr Scott. When the the participants were met they were invited to ask any questions they had about the study and each participant signed a consent form (*Appendix H*) before the interview commenced.

Head and Neck Cancer Patients

Inclusion criteria for this group was a history of treatment for a HNC in the previous five years but patients were excluded from recruitment if they had not passed the two-year post completion of treatment (at this point a HNC is less likely to recur).

HNC patients were recruited with the help of the consultant surgeons and clinical research nurses in two Hospital Trusts (Newcastle Upon Tyne and Sunderland) after a trust R&D procedure was followed and approval granted. The clinical research nurses gave the participant information sheets to interested patients. The patients were free to then contact the interviewer via her University email address or telephone number if they were interested to participate. The patients were provided with the participant information sheet (*Appendix G*) and voluntarily contacted the researcher via university telephone number or email. The participants chose a time and mode of communication that was preferable to them (telephone or video). When a date and time was agreed a link to the video platform or telephone numbers were exchanged. Prior to the interviews the participants were invited to have a look at the ORLHC website and a link to it was provided for them in an email for them to access it prior to the interview if they wished. For those who had not completed the consent form and returned via email prior to the interview, verbal consent was taken during the recording of the interview. After answering any questions the participants had about the study the interviews commenced.

Head and Neck Surgeons during COVID-19

The response to COVID-19 warranted a huge shift in priorities by the whole health service in the UK. This included the way referrals from primary to secondary care with suspected HNC were managed. There was a national endorsement of a spreadsheet version of the ORLHC (V3) by ENT-UK and many HNC units opted to use this in their remote assessment of patients referred under the suspected HNC TWW pathway. A useful and iterative pragmatic adjustment was made in response to the pandemic and the way head and neck services adjusted to the reduced footfall in the hospitals. A plan was formulated to interview consultant surgeons about their approach to remote assessment of suspected cancer referrals during the pandemic. A further group of HNS was recruited for interview, these were from around the UK as opposed to only surgeons working in the North East. Professor Paleri sent an email to members of the ENT-UK head and neck interest group (a national body) in June 2020 inviting members to email the interviewer to participate in an interview. Participants had to have been involved in their HNC departmental response to COVID-19 but did not need to have used the triage tool (V3) and could be of any level of training or years post completion of certificate of training.

Incentives

£25 to PCPI volunteers, no other incentives were offered.

Informed Consent

Informed consent was written in most cases (*Appendix H*) and obtained at the time of the face to face meeting to conduct the interview. When COVID-19 meant that face-to-face interviews were not possible two of the HNC patients consented to participation verbally as part of the recorded interview (an appropriate method during COVID-19 <u>https://www.hra.nhs.uk/covid-19-research/seeking-consent-covid-19-research/</u>) the others completed the consent forms and emailed them to the interviewer ahead of the interview. Face-to-face, telephone and video conference facilities were all used for interviewing purposes and were dependent on interviewee preference, this was particularly pertinent after March 2020.

Data Collection

Interviews were conducted between March 2019 and January 2021. The topic guide was developed in consultation with supervisors and Val Bryant (Patient and Public Involvement representative) and was informed by the results from the framework synthesis (see *Appendix F*). The interviews were all conducted individually by me either face-to-face or remotely using telephone or video platform option (Microsoft Teams or Zoom video conferencing). One interview had an observer (an ENT registrar) who did contribute to the interview as they had used the V3 during the pandemic and so a further interview was arranged with this participant.

121

The pre-pandemic HNS interviews concentrated on issues with the referral pathway, the potential for change and impressions of the ORLHC. The GP interviews explored issues around the use of decision tools and knowledge of CCDTs. There was an opportunity to discuss challenges of HNC diagnoses, their impression of the ORLHC (V1) and its place in the pathway as well as how they discussed risk with patients. Interviews with the PCPI participants centred around consultations with GPs and the use of computers and computer aided decision tools by GPs. During the interview I demonstrated the ORLHC (V1) and explored the participants responses to it including discussion of risk. The HNC patient interviews were largely focussed on their cancer journey, discussion of their diagnostic pathway, the role of their GP and impressions of the ORLHC (V1 and V2 available on website if accessed).

The pandemic interviews were conducted with clinicians some of whom had used the V3, some who had not; the interviews centred around their experience of remote assessment of patients referred on the TWW pathway during the pandemic, impressions of V3 and its potential future use. The aim was that interviews were conducted sequentially but this was not always possible because of issues with recruitment. After completing two or three interviews from each group the transcriptions were shared with GM and or VB and initial impressions from these helped inform future interview topics.

Recording and Transcription

All clinician interviews were recorded on an encrypted electronic device and uploaded to Express Scribe software for transcription purposes. Interviews with clinicians were typed verbatim by the researcher; the interviews were subject to a further listen to check for transcription accuracy. A named university approved professional transcriber (Dr Phil Hodgson, Northumbria University Newcastle) signed a confidentiality agreement and was employed to type the PCPI and HNC patient interviews which had been recorded using an enctypted electconic device. The recorded interview files were transferred in an encrypted format via wetransfer.com and the interviews were transcribed verbatim and returned in word files. Unique identifiers were used to protect the anonymity of the participants and identifiable personal information removed. The returned professionally typed transcripts were read (by me) along with the recordings for accuracy and amended where required. Field notes were taken to reflect upon the interviews and to help inform future ones. These were commonly just single words or notes on surprising, confirmatory comments that interviewees had made or areas to explore further in subsequent interviews.

Data Analysis

The analysis was carried out using an iterative approach as the data was collected (interviews conducted). After three interviews from each group the transcripts were coded using a micro, meso, macro approach (138). This was followed by discussion with a supervisor, followed by further data collection informed by some of the coding of the initial interviews (inductive and deductive). When each group of interviews were completed the coding of the data recommenced. Coding and theme development was ongoing as the data was collected and influenced the interview schedules for the subsequent interviews.

All transcripts were read through at least twice before analysis commenced; this was in addition to the transcription and checking transcription process (familiarisation). NVivo 12 software was used to manage the coding of the interview transcripts. Initial coding was open on a line-by-line basis and the transcripts for each group were coded together and then holistically analysed. Codes were grouped into themes that were developed using the thematic approach (201). New themes and those anticipated from the framework synthesis were further re-evaluated in a deductive inductive cycle. Drawing upon the multilevel nature of context (125, 206) these themes were categorised into areas of practice, organisation, and the wider system (a micro, meso, macro approach). Comparative analysis within groups and between groups was conducted. The themes were refined with a supervisor to create a rich narrative which was mapped onto the NASSS framework (Appendix K).

123

Saturation

Saturation in the context of a small scale, time and resource limited project is impossible (207), as is full representation of all anticipated stakeholders. The notion of saturation is questionable and harks to a positivist approach to a non-positive pursuit, akin to a sample size in a randomised control trial and not necessarily appropriate for qualitative work (208). Despite the small sample there is power in the information collected because of the breadth of experience that the participants have (209). Problems with recruitment and the interruption by COVID-19 means that there are limitations to the conclusions that can be drawn which will be discussed in later chapters.

Generalisability and Transferability

I do not propose to offer an analysis of the data that is generalisable but there are aspects which can be considered transferable. Some of the findings are applicable to other CCDTs, clinical decision tools and cancer types within the context of the NHS and the dramatic changes imposed on it by COVID-19. This thesis offers an interpretation, informed by the researcher's understanding of the problem and approach to the data from the perspective of clinicians and patients about the current and proposed changes to the suspected HNC TWW pathway. The thesis discusses some of the complexities (identified from the data) related to; the condition, the way individuals practice, the organisations which guide practice and the political and healthcare system within which the pathway operates. The thesis considers the proposed intervention (ORLHC) and factors which could affect its implementation.

Ethics

As the clinician interviews were considered a pathway assessment, an application for University Ethics for HNS and GPs (ref 007592) was submitted. The recruitment of the University of Sunderland Patients Carers Public Involvement group was approved by University Ethics (ref 004547). A further application was approved by the University for post Covid-19 HNS interviews about the triage of suspected HNC referrals during the pandemic (ref 006992).

Ethical approval was sought and granted from the Newcastle North Tyneside Research Ethics Committee for HNC patients (20/NE/0098 278313 *Appendix J*). Four hospital Research and Development (R&D) departments agreed to be named as participant identification centres in the application, all four hospitals were approached for R&D approval following the approval from Health Research Authority, two of the hospital trust R&D completed the process and commenced identification of HNC patient participants.

This chapter sets out my pragmatic methodological stance and methods used for my research. I adopt a pragmatic qualitative approach to the study of a prospective implementation of a primary care CCDT for HNC. Firstly, I describe the method used to perform a framework synthesis of existing literature, informed by NPT. This initial work informed the method adopted to undertake a series of semistructured in-depth interviews with multiple stakeholders which was thematically analysed and mapped onto the NASSS framework. This work explores the complexities associated with the potential implementation of ORLHC and consider the factors which might frame any future work.

Results

Semi-structured in-depth interviews were conducted with 53 participants between March 2019 and January 2021 (see *Table 22*). Clinical participants were purposively selected according to their role and involvement in delivery and commissioning of healthcare services.

Participants were made up of five groups: head and neck surgeons, general practitioners, Public Carer Patient Involvement volunteers from the University of Sunderland, a second group of head and neck surgeons (all ENT specialists) and individuals with a history of diagnosis and treatment of a HNC.

Table 22 Participant characteristics

Head and neck surgeons (HNS)	Age	Years as consultant	Specialty	National Head and Neck Cancer		
HNS-1	41	75	FNT	Kole Ves		
HNS-2	39	1	ENT	No		
HNS-3	58	23	ENT	No		
HNS-4	63	30	ENT	Yes		
HNS-5	40	3.5	ENT	No		
HNS-6	45	9	ENT	Yes		
HNS-7	50	12	ENT	Yes		
HNS-8	48	11	ENT	No		
HNS-9	46	6	OMFS	Yes		
HNS-10	38	3	OMFS	No		
HNS-11	61	25	UMFS	Yes		
General Practitioners (GP)	Age	Years of experience	Clinical Commissioning Group or Primary Care Network or local/regional cancer role	Clinical experience in ENT		
GP-1	56	28	No	Yes		
GP-2	47	17	Yes (Cancer Lead)	No		
GP-3	55	25	Yes (Cancer Lead)	No		
GP-4	55	26	Yes (CCG Clinical Director)	No		
GP-5	45	12	Yes (CCG Locality Director)	No		
GP-6	46	16	Yes (CCG Medical Director)	No		
GP-7	41	12	No	Yes		
GP-8	44	13	No	No		
GP-9	51	20	Yes (CCG governing body)	No		
GP-10	57	31	Yes (Primary Care Network Clinical Director)	No		
GP-11	31	1.5	No	No		
GP-12	49	21	No	No		
Public Carer Patient Involvement (PCPI)	Age	Gender	Personal history of cancer (of any type)			
PCPI-1	55	F	No			
PCPI-2	54	M	Yes			
PCPI-3	63	М	Yes	-		
PCPI-4	66	F	No			
PCPI-5	59	F	No			
PCPI-6	57	F	NO			
	59	M	No			
	44 50	IVI E	No			
PCPI-10	72	M	No			
PCPI-11	72	F	No			
PCPI-12	62	M	No			
Head and Neck	Age	Years as	Use of Triage Tool during first	Region	UK National	Interviewed
Surgeons during	, s	consultant	wave of Covid-19	5	Head and	in first group
Covid-19					Neck Cancer	
(HNSC)					Role	
HNSC-1	57	20	Yes	West Midlands	Yes	No
HNSC-2	50	14	Yes	Yorkshire	Yes	No
HNSC-3	53	18	Yes	West Midlands	No	No
HNSC-4	57	21	Yes	London	Yes	No
HNSC-5	47	10	Yes for follow up not for triage	Uxtord	Yes	No
HNSC-6	49	12	Yes	North East	NO	Yes
	40	Z Trainaa	NU Voc	North East	NO	res
	20		Voc	West of Scotland	No	No
HNSC-10	39	4	No	Vest of Scotianu	No	No
HNSC-11	47	10	Ves	North Fast	Vos	Ves
	40	12		North East	103	103
Head and neck Cancer patients	Age	Gender	Cancer type			
(HNCP)						
HNCP-1	67	М	Oropharyngeal			
HNCP-2	56	М	Nasopharyngeal	1		
HNCP-3	50	F	Oropharyngeal	1		
HNCP-4	69	M	Oropharyngeal	4		
HNCP-5	65	M	Uropharyngeal	4		
HNCP-6	54	F	Oropharyngeal	4		

Condition

The first domain of NASSS is condition. This domain refers to complexities in the illness or disease studied. Where a disease is regarded as simple, such as a bacterial tonsillitis, there is a clear clinical, diagnostic and treatment pathway. For more complex diseases where the presentation, investigation and management are not so straightforward, the application of what is considered a simple intervention to solve a clinical problem is challenging and therefore more difficult to implement.

When considering HNC the discussion with participants centred around how often the disease is encountered, how well it is recognised in primary care and how this influences how the pathway is used. Questions were posed about whether the ORLHC intervention might be applied in primary care as a way of addressing secondary care concerns about referral patterns. This section benefits from the experience of some HNSs working during COVID-19, some of whom used ORLHC to triage patients during the first lockdown period in the UK.

Themes identified that pertain to the complexity of the condition HNC, centre around the differences between specialists and generalists in terms of how confidently they deal with signs and symptoms of HNC relative to their clinical exposure to the disease. The differences identified are put down to perceived deficiencies in education and training. Complexities exist in relation to the condition of HNC because of primary care clinicians' lack of familiarity with the existing referral pathway criteria. There appears to be an absence of shared language and understanding of the condition leading to concerns from specialists about the clinical interpretation of the signs and symptoms by clinicians in primary care. The complexity inherent in the understanding and exposure to the condition means consequently there is variability in the quality of referrals from primary care. Specialist experience of the ORLHC during COVID-19 raise questions related to whether it can be used reliably for all types of HNC in such a way that it would be useful in the primary care context.

Exposure to Head and Neck Cancer

GPs admit that their exposure to and experience of diagnosing HNCs in their day-to-day practice is limited. This lack of familiarity with the disease is acknowledged by GPs and specialists which make early recognition difficult.

I think ... the issue is still that from a general practice point of view, you're talking about small numbers of small numbers of people. So, you know if you are a part time GP say how many head and neck referrals do you do in year never mind monthly (GP 2)

when you say the number that you would expect in a GPs lifetime, I suppose across all of us then it is that's small a number (GP 10)

Most GPs interviewed remembered specific cases of HNC that they had seen and referred into

secondary care. The presentations were so distinctive and memorable because of their rarity.

I saw one a long time ago, but I haven't seen anything recently. (GP 5)

Specialists did express sympathy with primary care and the difficult job they have as generalists to

identify the cases most likely to be cancers. Despite this they voiced their frustrations with the low

volume of patients from the large numbers referred on the cancer pathway who are ultimately

diagnosed with a HNC.

that's something you can't teach someone who sees one case in a million years ... or in their whole career, you can't teach that set of symptoms. (HNS 7)

The rarity of the problem cancer generally or head and neck cancer ... They don't see a lot of as an individual GP and that's always been the issue, (HNS 8)

One GP remarked that their limited secondary care clinical experience and exposure to ENT, not only

HNC, but to the management of benign conditions affecting the head, neck, and oral cavity, led to a

lack of confidence and hence deference to secondary care expertise.

I do think that most GPs that I know aren't very confident with ENT and the fact that it's a higher referral thing ... I don't really feel particularly skilled with it ... we all know that ENT is a weak point (GP 11)

This was echoed amongst some of the specialists who consider that primary care clinician inexperience leads to discomfort and a reliance on referral pathways to access expert input.

whereas a GP doesn't feel quite as many necks ... They are a little more likely to go 'oh maybe there's a lump lets push it through anyway' when there isn't one. (HNSC 6)

Even patients could see the benefits of the ORLHC for GPs without experience of a particular specialty.

Well, as a GP... You're lucky because you've done ENT... But if you were a GP without ENT experience, this is probably... Oh, it's a game changer. So, there is a risk. However that risk, for me... If I went to see a GP without experience of ENT, I think it's... It is a game changer for them. (PCPI 12)

Deficiencies in Education and Training

Most specialists admitted that their skills are very different to that of a generalist, an opinion for which

patients seemed to have more sympathy.

When you go and see a GP, you expect them to know a little bit about most things that you would approach them about. But they can't be experts all the time. You know... You know, you won't have certain diseases or illnesses presenting in patients all the time. (PCPI 7)

Specialists could rationalise that a lack of experience, and training influenced the associated anxiety

that GPs expressed about the burden of missing and being considered responsible for a late diagnosis

(of what might be a more difficult to treat cancer) which could lead to referrals for conditions which

when subjected to a specialist assessment are considered obviously benign by those with accumulated

expertise.

If I were a GP, the ivory towers consultant wagging their finger and saying, "well really you should have", would drive me up the wall. ... They are just dealing with a whole different set of problems to the ones we're dealing with ... I can see a wry smile from a GP when you say, "No really, this should all be coming our way" ... you can almost hear GPs going, "fine, we'll send them all, there you go, have the whole lot" (HNS 2)

The recognition of the significance of signs and symptoms of HNC by non-specialists, is considered

poor because of a lack of training, experience with, and exposure to patients with benign disease as

well as HNC.

if they haven't done much head and neck in their training then they won't have seen ... enough to actually get any experience of It ... not entirely sure what it is they are looking for (HNS 8)

This lack of experience and exposure to signs suspicious of HNC was highlighted by a comment a HNCP

made

One of the practice doctors. It was a locum ... had a look and said, "Yeah, I don't think it's anything major. We'll get an ultrasound. That'll take about six or eight weeks." ... two days later I got a phone call from ... my doctor saying ... "We see you've been in for a lump on the neck. We're going to put you into an emergency situation and we'd like you to come in the following week to see a specialist (HNCP 1)

Secondary care attribute the problems associated with the ability of primary care clinicians to

differentiate the signs and symptoms suspicious of HNC and therefore the quality of the referrals on

a deficit in education in medical schools and in post graduate training.

I think education is important because, at the moment, even routine simple polyps and granulomas are being sent in as two week wait cancers. Standardising education is going to be difficult (HNS 10)

Not all specialists considered that improvement in training and education was the answer to the

problems with recognition and referral of suspected HNC, admitting that this was a simplistic and

unrealistic solution to the problems associated with generalists dealing with specialist areas of clinical

practice.

ENT is 20% of General Practice, so is rheumatology and so is orthopaedics and so is general surgery and so is psychiatry ... you'll get up to about 300% ... be realistic about that. ENTUK [Ear Nose and Throat United Kingdom – specialist association with interest in ENT in UK] have written and published a curriculum that has been sent round to all medical school deans and the GMC [General Medical Council] with negligible or no response. (HNS 3)

Familiarity with Current Referral Pathway Criteria

GPs commented that the TWW cancer referral criteria were subject to change and as a result they

admitted that they had to check this each time they considered a referral. This behaviour reinforces

that, despite the impression at the receiving end of the pathway, it is not a referral pathway which is

used frequently by individual GPs.

I can never remember them all. So, I'll go ... "we can do a two week wait shall we just have a look and see if you fit it" ... go through the criteria with them, because ... I can't remember it all (GP 12)

I find I often have to open the two week wait referral form with the patient there with me, and just go through some of the questions ... I do have to remind myself quite regularly about that (GP 9)

Several GPs mentioned that they so seldom referred on suspected HNC pathway, that they had not

had the need to look at the referral criteria for some time.

one of the problems ... the two week wait pathways change ... I don't have the time to go into each one as it changes ...you just can't ... keep going through them and you can't keep up with the changes sometimes (GP10)

One patient even commented that their own GP took a little time to decide on the course of action,

But the lump on the neck, he wasn't happy with. So... He said, I'm going to refer you, probably, for an ultrasound. He didn't know whether to do an ultrasound or send me to ENT. Because he didn't know... Because I was having the nasal problems. I might've started getting a bit of a hearing problem in my left ear, and a lump on the left side of my neck. So, he hadn't... I think he might've asked for advice or whatever. He hadn't made a decision. I rang him back and he said, I'm just going to refer you to the ENT (HNCP 2)

One GP was surprised to find that the criteria they were expecting for suspected HNC was no longer

part of the referral pathway.

It's interesting that's three weeks, because I always remember that being six ... how long has it been three? (GP 9)

Several GPs were aware of signs and symptoms that would alert them to suspect a cancer, but which

were no longer part of the two-week wait guidelines. This admission tended to be made by the older

more experienced GPs with memory of previous versions of referral guidelines.

I referred a lady the other day whom, I was always taught unilateral bloody nasal discharge is a red flag, so I had a lady in with a history of polyps. We didn't know whether it was a nosebleed, it looked very odd in the right nostril ... So, I just ... wrote urgent referral required and lo and behold she was seen just actually three days later (GP 1)

The complexity of the condition and how rarely it presents in primary care poses a clinical challenge

for GPs. Patients present with more of the uncommon signs and symptoms which require more

"detective" work, diagnostic work up based on clinical acumen and grounded in medical knowledge.

This contrasts with something like a breast lump which requires more straightforward clinical thought

processes.

some head and neck tumours ... are quite challenging ... the sinus area. But I've only had one in my career ... I'm using experience rather than assessment tools ... it presented with a change in smell ... you ... go through your basic physiology (GP 5)

The inherent complexity which resides in the condition HNC, and its infrequent presentation means that GPs use the HNC referral guidelines so rarely that they do not recognise any need to be familiar with them.

Shared Language and Interpretation

Several GPs admitted that they were not familiar with one of the words used in ORLHC, odynophagia (a term meaning painful swallowing). This is a commonly used and understood word amongst specialists but not, it appears, amongst GPs. This further highlight GPs' lack of familiarity with, understanding of and subsequently the interpretation of terms associated with the clinical presentation of HNC.

Odynophagia ... I had to look that up. I suspect there's a lot of GPs who would need to (GP 9)

A couple of the surgeons recognised that this lack of shared language and understanding of this complex set of cancers could be a potential problem for primary care using ORLHC which has been created by specialists using language which it is assumed means the same thing to the non-specialist as it does to the specialist.

I know what ... dysphagia means, you cannot swallow, and odynophagia means it hurts to swallow. But I see an awful lot of globus referred in with "can't swallow" ... actually, they can swallow ... you'll just ask them ... "If I was to give you a sandwich right now, can you eat it?" "Yes, no problem" ... it's that whole understanding ... making the lingo work ... you'll never get round that, even with a calculator (HNS 7)

Specialists commented that what a GP, a surgeon and a patient mean by, and their interpretation of certain words influences how they view the significance of certain symptoms. These distinctions were noted by specialists, particularly when it came to a swallowing symptom (dysphagia; disordered swallowing), odynophagia (painful swallowing) and globus (the feeling of a lump in the throat). This misinterpretation has an influence on how the referral pathway is used and therefore impact on the potential use of ORLHC.

Despite their frustration with the common misinterpretation of symptoms, specialists recognised that these were difficulties inherent in recognition of HNCs for primary care. These inherent difficulties were considered a challenge to the use of ORLHC in primary care.

it's always going to be ... dysphagia ... we think of it ... different to the GPs ... you need to really drill down and actually work out what it is ... we have enough experience to understand that. I could feel a lump in my throat, isn't a problem ... it needs a proper assessment (HNSC 12)

The issue of swallowing symptoms was particularly irksome to the specialists in the North East where a swallowing problem, be that painful or dysfunctional swallowing, was actually no longer part of the HNC referral criteria (in compliance with NG12), but part of the Upper Gastrointestinal cancer pathway. Swallowing problems are amongst the symptoms in ORLHC. GPs observed this inconsistency between the regional guidelines and the ORLHC which would have implications for how successfully it could be implemented into the HNC pathway when its criteria includes symptoms which were not part of the regional referral guidelines (at least in the North East).

when it comes to dysphagia, that's actually an upper GI (gastrointestinal) symptom ... It's not on ... our pathway form but it is on the upper GI one. ... I think dysphagia ... and the pseudodysphagia ... I think people do struggle with. Unless you are used to seeing endless globus patients and you can tell which ones are the ones that have a risk and the ones that don't (HNSC 3)

Other examples where complexity exists when it comes to a shared understanding and language in the realm of HNC, pertains to lumps in the neck. For some specialists there is a perception that for some primary care practitioners, a lump in the neck appears to have become synonymous with a complaint of a sensation of a lump in the throat (globus). This is an interesting observation as it shows confusion amongst some clinician groups about the differences between signs and symptoms.

Even neck lumps ... there is a confusion between lump in the neck and lump in the throat ... we put the patient on to a neck lump clinic to do an ultrasound and biopsy and then the patient comes in and says, "well I just feel a lump in the throat" (HNSC 2)

the assumption of us all thinking the same is not true. ... feeling of lump as opposed to, an actually palpable lump, that you can definitely feel, are very definite different things ... it is confidence, we feel a lot of necks, we are confident that if I haven't felt something, it's because it's not palpable. (HNSC 6)

A shared language and interpretation of that language are essential to the development of something like ORLHC paying particular attention to the audience for whom its use is intended, primary care.

Referral Variability

Specialists voiced concern about the quality of the referrals coming from GPs, particularly the oral lesions referred to OMFS which once again they put down to deficits in training, experience, and exposure. Issues were raised about the appropriateness of GPs clinically assessing areas outside their clinical expertise like the oral cavity which was leading to inappropriate TWW HNC referrals.

We are not trained as medics, to actually examine mouths ... I think there should be a change in pathway, especially in mouth problems, they should go to the dentist (HNS 10)

Other OMFS, when discussing TWW referrals, considered there was variability in quality and considered at times better from GPs when compared to some GDPs.

There is huge variation in how much people know ... looking at referrals, the GPs clearly know their stuff and they have got the diagnosis right and others just seem to be utterly clueless about what's inside ... once the patient opens their mouth ... it's just some pink stuff and some white stuff (HNS 9)

The OMFS who would be expected to receive more TWW referrals from GDPs than ENT specialists

were no more complementary about referrals received from this group of clinicians. GDPs have

greater depth of training and experience specific to the mouth, jaw and salivary glands in their

undergraduate and post graduate years compared to medically trained GPs.

I think ... GPs are not the worst offenders. General dental practitioners send some of the worst two week wait referrals in and I think some of that is because they never take their loops off (HNS 11)

Even within one practice there were different levels of concern about a patient's presentation by

different GPs albeit a week apart

I mean the first one ... checked the lump ...said it didn't seem like anything sinister - but if it's still there next week, come back ... the second doctor]... I think she's been my GP for donkey's years. And she said, no, I'm going to... I'm going to refer you straightaway (HNCP 7)

Reliability

During COVID-19, when ENT used ORLHC to triage TWW referrals, it became clear that the outcomes of the triage calculation could not be relied upon for all signs and symptoms with which patients were referred. ORLHC was not able to offer a reassuring individual patient risk calculation for all the different types of HNC. This was a problem which was identified as a potential issued in the pre-COVID-19 interviews. This will be a major challenge to the use of ORLHC in primary care.

The realities of and challenges to the use of ORLHC by non-specialists were exposed when it was used by HNC specialists during COVID-19, albeit in the remote rather than the face-to-face setting where it was originally intended to be used. When questioned prior to COVID-19 it was OMFS who raised concerns that ORLHC had few discerning questions about oral lesions. OMFS commented that the jaw, face, and oral cavity was more amenable to direct visual inspection and verbal or written description than some of the ENT areas like the tongue base, pharynx, and larynx. There were further areas of the head and neck where, during COVID-19, ENT specialists found ORLHC was not a suitable triage tool.

When you trying to use it on salivary glands or skin or thyroid it doesn't work. Therefore, you don't tend to ... use it ... So mainly ENT, oropharynx and larynx is actually a very good tool ... All the other more complex cancers it's obviously not of good use (HNSC 4)

Several ENT surgeons who used ORLHC during COVID-19 discovered it was not something that they found helpful to determine a reliable risk score when used for younger adults referred with neck lumps.

we diagnose a significant amount of lymphoma which presents as a neck lump, which on the calculator comes in as low risk ... the majority of the ones that we overrode ... were young people with neck lumps, because they also complain of fatigue some soft B symptoms [symptoms such as fever, weight loss and night sweats] ... so we would then say "well I am going to see you" ... Because the calculator is all based on head and neck squames [squamous cell carcinoma] ... it doesn't take into account lymphoma (HNCS 9)

Referrals of thyroid and parotid lumps were also considered as lower risk for urgent assessment by

specialists than the ORLHC risk calculation would suggest. Overriding a risk calculation was based

upon clinical experience which would be impossible to emulate in primary care because of the

complexity inherent in the condition which have already been discussed.

a thyroid lump is very rarely clinically high risk, but as soon as you have a persistent neck lump its high risk ... A thyroid lump, you do an ultrasound on all of them whether its low risk or high risk, so I don't know whether it applies to thyroids ... a new onset lump in the left anterior triangle for six weeks ... is much more worrying than a ... lump in the parotid for ... 3 months ... it's different to that new onset persistent lump (HNSC 7)

you speak to most head and neck surgeons, and you mention thyroid cancer, yeah, that can wait ... I think this is a pleomorphic salivary adenoma ... that can sit on the waiting list for six months before that gets done (HNSC 9)

During COVID-19 it became apparent that ORLHC had not been useful to OMFS to use to triage their

referrals. None of the ENT surgeons interviewed knew of any OMFS who had used ORLHC. The lack

of uptake was put down to the importance of visual appearance of the lesions which had already been

identified as an issue facing these types of lesions by OMFS participants in the pre-C19 interview data.

because for them ... it's a question of just looking in the mouth ...erythroplakia [red patch], leucoplakia [white patch], an ulcer on the tongue, a bobble on the tongue, a nodule ... ours are all about the symptoms rather than any signs ... theirs' is a much more sign orientated thing so ... there isn't anything pictorial that is going to be terribly useful in ENT (HNSC 1)

Some speculated about possible further exploration of the use of ORLHC in the primary care context.

One HNS considered that ORLHC would have to be carefully assessed in terms of how to assess its

reliability when used by different healthcare professionals admitting that the same experience,

training, and exposure to HNC would influence interpretation and understanding. The risk calculation

is dependent on the information inputted by a clinician so is subjective.

What I think would be interesting is if a GP and an ENT doctor took the same history from the same patient and worked out what they had clicked. If they had clicked the same things ... If generally they are clicking the same things that we would click, then, I don't see why it can't be used as a screening tool for which clinic to refer to in primary care. (HNSC 8)

Other ENT specialists, questioned that it would actually be useful in primary care, admitting that primary care clinicians are right to feel a certain degree of discomfort managing clinical risk in specialist areas. Accurately predicting a risk of cancer demands a high degree of understanding and experience of the nuances of a condition. Some of the questions are nebulous, and you've got to know how to drill into them. I think it would be ... appropriate for... primary care to use it, maybe ... I just think they go "no that's for someone else to decide I have decided that it's reached my threshold for somebody else seeing it", you know for a specialist opinion, and I think that's appropriate (HNSC 12)

For most specialists questioned after experience of COVID-19 use, a high level of clinical experience of and training in HNC was repeatedly highlighted as a pre-requisite to use ORLHC to make reliable clinical decisions about suspected HNC and as a result, overall, it was largely used by senior HNS during COVID-19.

I think the triage tool can help you decide if you are going to see them face-to-face, or you are going to discharge them, or you are going to give telephone follow up. I think you get a feeling from the patient ... about their anxieties ... as what the score tells you, but that's an experience thing. I guess it's different if someone is less experienced and they are using it (HNSC 12)

As a disease, HNCs arise from several anatomical sites and tissue types. These can be difficult to recognise and diagnose for primary care clinicians who encounter them so seldom. The interview data suggests that specialists and GPs recognise that difficulties in the interpretation of signs and symptoms are influenced by education and clinical training in, and exposure to HNC. The interview data suggests that the primary and secondary care clinicians do not share the same understanding or language with which to assess risk associated with the signs and symptoms of HNC using ORLHC. This lack of a shared vocabulary adds to the challenge of recognising those patients most likely to have an underlying cancer as the cause of their clinical presentation. The use of ORLHC in primary care is unlikely to impact on the more difficult to recognise HNCs and for referrals for those patients with signs like neck, thyroid, and salivary lumps. Expert HNS using remote assessment during COVID-19 have demonstrated that with or without ORLHC they can quickly and accurately make decisions about the urgency of assessment for a suspected HNC referral. Clinical experience and exposure to patients with HNC appears to be crucial in the successful application of ORLHC in confidently making an individual patient risk assessment. The versions of the ORLHC presented as a potential CCDT in this study do not adequately address the complexity of the disease even to the satisfaction of specialists who used it during the first wave of th COVID-19.

Technology

Domain 2 refers to complexity in the features of the technology itself. In the context of this study it is more difficult to define, as the format of the technology used changed through the course of the study (Chapter 6). An example of a simple technology is a telephone call, this intervention is thought of as reliable and affordable. A more complex intervention such as a decision aid that is integrated into a primary care IT system, has more potential to be unreliable, expensive, and subject to change. This aspect of the NASSS framework is the sole domain over which innovators can exert the most influence to try and minimise complexity. With regards to ORLHC it is important to place it within the context of how primary care engages with existing decision aids particularly the ones aimed at early recognition of cancer signs and symptoms.

Experience with Existing Electronic Decision Tools

The GPs thought that ORLHC appeared to be easy to use, they commented that there were a reasonably small number of questions with yes/no answers. When considering the decision tools that they were currently using, GPs said that they were less likely to use one housed in an external website and more likely to use one if the outcome was a prerequisite for a referral. Existing decision tools that GPs were more likely to use were evidence-based, specialty endorsed and were straightforward to use. Embedding decision tools within clinical pathways, coupled with a seal of approval from secondary care was seen as the best way to embed something like ORLHC and making it a mandatory part of the referral process would ensure that it was used.

it needs to be easily findable; I am a particular fan of referral forms ... which include or incorporate the pathways ... You could put the risk assessment as part of the referral process ... built in as part of the referral process (GP 4)

Some GPs mentioned that they would find it reassuring to use an electronic aid like ORLHC when deciding whether to proceed with a referral for suspected cancer. ORLHC would enable a decision to be based upon a specialty endorsed calculator with the additional benefit that it would provide a way to document the justification for the decision either way.

If you can say that you've used an evidence-based pathway and you stratified the risk you considered it, then that forms part of your decision, that kind of takes some of the responsibility or it gives you a bit more clinical reassurance. (GP 11)

Examples of the use of pre-existing electronic decision aids for risk assessment-based decision making were given. GPs used the example of calculating a Wells Score, a clinical risk assessment for likelihood of a deep vein thrombosis, when considering referral to hospital for further investigation and treatment.

None of the non clinician participants could recall an electronic decision tool being used in a consultation with a GP but were comfortable with GPs using computers during their consultation to aid their decision making, be that looking up previous consultations or "googling" for additional information.

having those tools to hand, I think, is very, very important and I wouldn't think anything less of a GP who ... looked at something for...for more information...for me ... it would give me more reassurance (HNCP-3)

Lack of Utility of Existing CCDTs

The CCDTs available to GPs for use in cancer referral decisions (QRisk[®], RATs previously described) and the reception from GPs considered in the framework synthesis) did not feature at all in the regular clinical practice of any of the GPs interviewed. When discussing one existing CCDT (QCancer[®]) in primary care, one GP commented that,

Hardly anybody uses it because of the two week rule ... The problem is the more of these things that come out, the less you tend to use them ... So, I don't think anything else will, actually get used that much (GP 1)

Another GP, specifically referring to QCancer[®] (Chapter Three) reiterated some of the concerns identified in the framework synthesis about the incompatibility of the CCDTs with the TWW referral

guidelines.

If they fit the two week wait criteria they go, if they don't fit and you are worried you would do a routine referral. So, I don't use it [QCancer®] because actually I just use whatever the criteria is for the two week wait as my risk assessment tool ... if ... QCancer® said they don't have a risk of it, and they were one of the unlucky ones, I wouldn't have a leg to stand on. I'd be seen to be not following current guidance. (GP 12)

Most of the GPs interviewed recognised the example of the colorectal RAT which was shown to them. The main reason for their familiarity with this picture was because some of them had seen it on a desk top mouse mat (recall from Chapter Two that these were distributed to all practices in 2012 and the electronic versions along with QCancer[®] and eCDS have been available within electronic patient records for years).

The ones that have been available for cancer? I don't think we have had as much uptake for in primary care, partly cos they are outside the clinical system ... in EMIS you can do QCancer[®] ... but because it is not very specific, I don't know whether that's sort of put people off a little bit ... Well, how often do you use it? (GP 2)

One or two GPs had used a version of the RAT table sometime in the distant past (via the mouse-mat).

Yeah, those ones, I can't remember what they are called, but those ones. Although, to be absolutely honest, I haven't used them for a very long time (GP 8)

Only one GP had used it or any of the other versions of RAT or QCancer® for any cancer type to make

decisions about the management of or referrals for suspected cancer in their practice and this was

one of the GPs with an interest in cancer. GPs conceded that CCDTs had potential for use in clinical

consultations where a patient was convinced that a cancer was the reason for their symptoms and the

GP was convinced it was not, but none of the GPs had ever used an existing CCDT in this way.

Yes, I have heard of it, and I think I have seen it at times but I have not used it one of our registrars actually was quite into QCancer[®] and I think we did have at one point we had mouse mats (GP 10)

Clinical Utility and Accessibility

There were some clinical decision tools for a variety of conditions which were integrated into the clinical patient record systems and used on a regular basis by the GPs interviewed. Clinical utility was an important driver in the engagement with clinical decision aids, GPs said that they would be put off using clinical decision aids that were long winded, too difficult to locate when using a search engine or which gave an ambiguous answer to the clinical question meaning that it did not directly influence the management of a patient.

the easiest thing is either have it embedded in a two week wait where you can kind of just click on it ... which I think would make it really easy. The other thought I had was ... whether there is some sort of protocol or some sort of template you could easily put into EMIS ... a single template ... If it's easy to find stuff, people will use it (GP 12)

GPs could see ways in which the ORLHC could be modified to fit the way in which they worked to manage risk and ensure patients would consult with a GP should symptoms not settle, become worse or develop new worrying features. GPs thought that ORLHC could be adapted for the way they worked to help the GP so that they could provide additional information in terms of verbal and documentation about safety netting. GPs wanted additional functions adding to ORLHC which could generate specific and accurate patient advice about what to do if their symptoms changed, if symptoms persisted and within what timeframe they could expect their symptoms to completely resolve.

if ...it generates a leaflet that you then give to a patient ... for safety netting "I've printed of the safety netting advice" ... It just gives an extra sort of thing to round off your consultation ... it might make you feel a bit more comfortable that you have backed it up (GP 11)

For patients anything which has been developed to enhance the consultation and aid decision making

was a positive addition, one participant commented on the ubiquity of algorithms, software outside

the consulting room meaning it was acceptable in this arena too as long as it was from a reliable

source.

We all use algorithm-generated pieces of software on the computer, whether it's online or on the hard drive of the computer. Now we do it on our phones or whatever. So, if there's a little bit of substance behind it ... the research has been done ... brief explanation by the GP to the patient (HNCP-2)

Another said

So if he or she had said to me ... this is the sort of thing that I need to consult, and as far as I'm concerned it's just pressing keys on a keyboard, I would be more than happy with that .. whatever a doctor needs to do is, the way I look at it, fine (HNCP-4)

Clinical Acumen

The ability to override a calculator generated clinical recommendation was important. GPs were

theoretically willing to engage with a CCDT like ORLHC even as a mandatory part of the referral

pathway if it could be overridden when they felt clinically the generated risk assessment was incorrect.

It was clear that for the GP their clinical acumen had to remain the dominant factor in their clinical decision-making process.

You should still use your clinical judgement and not just be guided by what the computer says ... If there was something nagging you that this isn't quite right, you still have the option to refer and say I know it's low risk but because not everything fits in within the guidelines (GP 4)

GPs wanted to retain the flexibility allowing them to communicate concerns when the calculation generated conflicted with their clinical impression that a cancer was a real possibility. No matter what the calculation result indicated, GPs needed to retain the ability to overrule a recommendation generated from an online calculator. This way of working reflects their experience of using the two-week wait criteria at the time of interview (amongst GPs in the North East). If a GP's clinical impression was that an underlying cancer causing the patients' signs and symptoms, they could communicate that impression to secondary care so even when a set of prescribed clinical referral criteria were not met a GP could use the TWW suspected cancer referral pathway.

I mean you are just doing your medicine, and you come across a person that you think "oh it might be, I've got to think about cancer" ... there's often some latitude in what you can put in ... "this is not a two week wait thing, but I am concerned about this ... please will you see them urgently" and I think in those cases they seem to get seen as if they were a two week wait, they seem to be very good at responding to that (GP 9)

Non clinicians were concerned about protocolisation and reliance on algorithms as much as the GPs

as one of the PCPI participants said

statistics are good, but only up to a point ... you've got the lies, lies and statistics – that quote as well ... as long as it doesn't mean that the GP's own ... personal knowledge ... they don't go, like, all computerised. Because you do need that personal touch. And you need someone there for to reassure you as well. (PCPI 9)

Integration into Existing Systems

The ORLHC format that was used by specialists during COVID-19 (an excel spreadsheet shown in

method and methodology chapter) was described by some as initially clunky to use. Its presentation

in this format was enough to put some specialists off using ORLHC at all during COVID-19.

The other reason I haven't really used it is because, just the way that the spreadsheet is laid out ... It doesn't help ... it's really clunky, it's not it's not designed well to run through a two week wait consultation referral (HNSC 10)

Those clinicians that adopted it said that they quickly became familiar with using it within their remote clinical assessment of patients, this was at least during the period within which the data was being collected by ENTUK. Some clinicians did adapt how they used it, integrating it into their entirely new way of working, using telephone consultation alongside ORLHC calculation of risk assessment to determine decisions about further investigation and assessment.

I mean teething problems, well maybe for a day or two getting used to it ... after two clinics people realised ... you can do it on the spreadsheet. (HNSC 2)

One clinician described having several clinical programmes in use simultaneously and found it

irritating to have to toggle between them.

You've got three things, you've got to keep your notes, unless and you can't really dictate notes as you are talking to someone though so ... if you perhaps maybe had a version of the tool where you did it and then it printed out ... you could embed it as a web page ... (HNSC 12)

Interestingly this situation was described by a secondary care consultant in the pre-COVID-19

interviews as being a working practice with which they assumed GPs were familiar and comfortable.

Yet it was an annoyance and a hindrance to smooth working for secondary care.

GPs are used to it having everything on it, they'll have two screens up, they'll have EMIS [EMIS WEB electronic clinical record system used in primary care] on one screen, they'll have pathways on the other screen, and they'll just go backwards and forwards between the two. (HNS 8)

Adoption and Uptake of Pre-Existing Technology

When considering a new technological intervention, it is useful to consider how clinicians use the already accepted technology within the same arena. This includes simple means of communication like simple telephone or electronic communication. OMFS felt ORLHC was not the best way to assess risk in terms of the visible oral lesions, they considered images and descriptions of suspicious lesions were more useful. The use of digital photography and video pre-COVID-19 was limited and employing these simple methods to communicate between primary and secondary care seemed to be beset by

quality issues. Pre-COVID-19 photography and video were seen as potential adjuncts to clinical triage particularly by the OMFS specialists.

I think where you can mitigate some of that is digital technology ... like recordings, clinical photographs... I think verbal descriptions, the human race finds extremely difficult. (HNS 10)

Right now, for technology to take a good quality image and send, that is in everybody's pockets. (HNS 9)

Image quality was an issue for specialists who did not feel that they could rely on photographic assessment even during the remote triage in COVID-19. This was despite the adoption of photography and video consultation in primary care which initially at least, were increasingly used as an alternative to face-to-face consultations. This adoption happened at pace with rapid innovation and growth in reliable, easy to use technology and was driven by need in the face of a global emergency yet secondary care appeared to lag behind in adapting to this expansion in digital communication.

if the technology was there and the pictures were useful enough then that would be handy. (HNSC 8)

Despite the expansion in the use of remote communication options for both primary and secondary care during the pandemic some ENT surgeons remained sceptical about the role of remote visual clinical assessment of patients as part of the communication between primary and secondary care.

GPs often send us photos and its incredibly difficult to work out a neck lump on a photo. You can't examine someone's nose and nasopharynx or larynx on a photo or on video link because you need to scope them. So, I don't think having the video is actually that helpful because ... a lump is tactile. (HNSC 9)

As a proposed risk assessment calculator for referrals for suspected HNC from primary to secondary care, ORLHC even in its evolution during the study period still requires development to meet the needs of GPs and the way in which they work. There are many lessons to take from the existing CCDTs, how they have failed to integrate with electronic records and that they are so rarely used for decision making in the recognition and referral of suspected cancers in primary care. Experience of the way in which ORLHC was used in COVID-19 will be useful for future versions of the decision aid but can only reflect its use by one clinician group (ENT) in extraordinary circumstances.
Value Proposition

The third domain of NASSS refers to the value proposition of the technology. Those interventions

designed with a clear justification and good return on investment are less complex than those without

a clear business case or evidence to support them.

Purpose of the Two-Week Wait Clinical Assessment

The proposed use of ORLHC in the primary care decision making about referrals on the suspected HNC

TWW pathway is driven by clinicians in secondary care. Many head and neck surgeons consider the

"yield" of cancer from two-week wait clinics as the sole measure of its worth.

We get about 60% of the cancers now coming through two week wait, used to be about 50%. So, it's still not particularly good at early identification, there are so many of them, I think the hit rate here is about 6 or 7%. So, we are doing a lot of consultations and virtually all of the non-cancer have, essentially, nothing much wrong with them. So, we're displacing a lot of normal referral patients, which is increasing the waiting time for routine referrals (HNS 4)

Patients who have obviously not got head and neck cancer get referred in on that pathway which leads, as we all know, to the two week wait pathway being swamped (HNS 11)

Some of the HNSs think that the two-week wait clinics are resource heavy and inefficient because they

do not consider the valuable role in ruling out cancer and the benefits that patients and primary care

clinicians derive from this, others, however, appreciate this benefit to patients and clinicians.

I think that's got tremendous value, bearing in mind most of the disease we are treating is, well 96-97% of the patients, haven't got cancer (HNS 9)

Some of the specialists identify that clinical assessment in the TWW clinics can address patients'

reversible swallowing and voice dysfunction and that this can be neglected on occasion because of

the pressure to work to targets.

Do you want a service to pick up cancers? ... that's not the only function of the two week wait. It's not just to pick up cancers, it's also to reassure patients, and patients who are anxious are a big drain ... It's not why we went into the job, to make patients anxious, they use a lot of resources ... they have a problem that needs help ... the problem with thinning things down and saying my only priority is to pick up cancers (HNS 2)

Assuming they are seen by a senior clinician, but that means you tying up a senior clinician, spending a significant amount of time saying to patients "actually there is nothing wrong with

you". Now that, I accept, is part of our role, to do that, and it's an important part of our role (HNS 11)

One of the specialists went as far to comment that when it comes to managing symptoms, some practice is far from ideal. Patients without an underlying cancer present with troublesome symptoms, sometimes these patients are discharged with no plan to manage these. For some surgeons the sole outcome of the two-week wait clinic is a diagnosis or not of cancer.

I don't know any other specialty, you've got raging COPD and you can't walk up a flight of stairs and you can't breathe, you come to see the radiologist, the respiratory doctor, and they go "you haven't got lung cancer, off you go". (HNSC 9)

Evaluation of Success

When ORLHC was used by specialists during COVID-19 its success was judged on the numbers of missed or delayed cancer diagnoses in those patients who were judged to be low risk (via a combination of remote telephone assessment and use of ORLHC). Success was also judged in terms of the reduction in the number of patients that needed to be seen face-to-face and the number of investigations that were successfully avoided by an expert triage.

Of the ones that were high risk, 14% of them had cancer. None of the low-risk ones that we have seen, or have been re-referred, have had cancers. So, we're looking at thinking ... this is pretty sensitive, from what we can see, so we are a fan of this (HNSC 9)

The value of using ORLHC during COVID-19 was that clinicians could calculate and document an

individual risk for each patient to justify decisions about how to manage the next steps in their clinical

journey. Some of the specialists that had used the calculator commented that they had not relied on

it completely and overrode the outcome if their personal impression from a history did not tally with

the calculated risk (low or high) from ORLHC.

So ... you have to be sensible in what you put down. Every now and again it would say low risk and I would be concerned. So, I would always override it when that happened if I was concerned ... I ever got an unexplained high risk it was normally due to something stupid like putting exsmoker in or something like that (HNSC 8)

Other specialists admitted that no matter what the outcome of the ORLHC calculator their own remote clinical assessment was ultimately the opinion that they trusted, they relied on experience and clinical acumen over a statistical prediction which reflected how the GPs had responded to the theoretical reliance on the outcome of ORLHC to make referral decisions.

I can't think of a single case where the tool changed my management (HNSC 3)

There was only one non clinician who expressed anything about ongoing assessment of a decision tool like ORLHC in terms of it updating in light of new information, any system should be live and new data concerning clinical outcomes added so that any decision aid was regularly informed, improved and made more sensitive.

You also check the data and have a way of improving it and putting input back in to see whether or not the diagnosis was right or wrong... is there any way of incorporating and analysing secondary care stuff so that the ones that have not been referred and who may have developed things (PCPI-12)

Funding

Interviews with CCG member participants pre-COVID-19 revealed that they had experience with

expensive, ill thought through and poorly adopted pathway decision tools in other clinical areas. This

previous experience meant that questioned how financially justifiable any efforts to develop,

disseminate and implement a decision aid for suspected HNC referrals would be.

You've got to think of the work behind this ... getting an electronic tool like this built ... is a massive amount of roll out work for somebody who is going to cost money ... we haven't got resources here to spend money on projects that won't save money (GP 6)

From the primary care perspective, the investment, in terms of effort and financial burden, would

have to come from secondary care or one of the regional bodies like the cancer alliance.

We need a very tight focus on cash and where we spend our money. We are obviously most likely to spend any resource we have got on where the overspend is ... this needs to be funded and backed by ... Northern Cancer Alliance ... or Health Education North East, but I honestly can't see CCGs funding this to be honest (GP 6)

The TWW referrals are a route of referral into hospital without a negative impact on practices in terms

of financial disincentive as there is no ceiling on the numbers of TWW referrals per practice unlike

outpatient referrals. In the North East (at least in the case of HNC) the patients referred via the TWW

pathway are automatically assigned an outpatient appointment (at least at the time of the pre-

pandemic interviews) and so, whether conscious or not, GPs know that patients are a guaranteed a specialist opinion by virtue of using this pathway.

The point of the two week wait referral, I think there is certainly an argument for trying to reduce, unnecessary is such an irritating word, because no referrals are unnecessary, to optimise the correct referrals in the two week wait referrals ... The two week wait referral has got a huge amount of impact from the resource point of view, as well and the temptation sometimes when you are looking at when you are likely to get a referral accepted or not in ... Referring to the two week wait because those can't be declined ... It comes down to funding (GP 8)

There is encouragement to use the TWW pathway from agencies like Cancer Research UK and

MacMillan Cancer who work with the Royal College of General Practice which monitor practice cancer

referrals relative to cancer diagnoses. Practices receive feedback if they are "underusers" of

suspected cancer referral pathways. Though the financial burden on secondary care from TWW

referrals is appreciated by both sides (specialists and GPs) the financial burden falls on secondary care.

The impact on secondary care from the numbers of referrals creates an inevitable tension.

I mean the risk is with all this stuff is that, if you don't if you are referring too liberally you are consuming resources and people who need those diagnostic resources are not able to get them because the waiting list grows. So, it really is a balance to be struck here (GP 9)

I think being honest with you, if there was enough resources, I don't think secondary care would complain either. The problem is that everyone is so busy that they want to not do the things that they don't have to do ... we knew that life would be so much easier but we are not clever enough to do that today (GP 3)

Specialists recognise that for GPs there is no incentive to reduce the numbers of referrals because

they do not come with a financial penalty for volumes referred but they also concede that GPs are

influenced by public and health agency pressure to increase suspected cancer referrals.

I think if revenues are attached, it attracts more input because it's clearly infrastructure tie in and effort. We work in a health economy where nobody sees money. Nobody sees the value of time. They just take it for granted it will happen and the second people start valuing money and time, then that will influence behaviour change. I think until that is done, behaviours and habits will be very difficult to change. (HNS 10)

I suppose the reason why we are looking at risk calculators is purely to try and reduce the burden on secondary care, though, it's never going to stop a GP referring them in unless there's so much financial constraint on them not to refer (HNS 1)

Resources

Concerns about efficient use of resources in the NHS was consistently mentioned by the Patient Carer Public Involvement (PCPI) participants interviewed. For patients and members of the public in general there is a desire to carefully consider the use of scarce resources which is appropriate to clinical need. This, however, is not necessarily applied when considering decisions about referrals when it comes to cancer because of the accepted premise that the earlier it is diagnosed the better the outcome.

Poor resources, waste and efficiency were considered as essential considerations in efforts to improve allocation of health care from the point of view of the PCPI participants. PCPI and HNCP participants were all supportive (hardly surprising) of any efforts to improve efficiency and ease pressures anywhere in the healthcare system. For patients it is important that clinicians make sensible decisions about use of the funding and assets of a poorly resourced NHS and consider the economic implications of choices when contemplating innovations which aim to improve clinical outcomes.

at the moment, services are so over-stretched (PCPI 1)

And especially I'm very aware of the cost that the NHS ... And the pressures that it's under (PCPI 4)

Several of the non clinician participants were concerned that the introduction of clinical decision tools

like ORLHC might be perceieved as being a means to save money by reducing referrals

I would like to know if it's a cost-cutting exercise, or whether it is for the... Promotion of good health, you know (PCPI-1)

It could be looked at in that way. Because if it shows a low result that's not sufficiently high enough to go to the hospital... So, yes, they are cutting their... Aren't they? So, they are making budget cuts, then, that way. But it could have been serious (PCPI-6)

Potential Benefits

Some HNSs had concerns about the quality of referrals from GPs and GDPs and they expressed frustration related to the TWW referrals. Some thought (at least pre-C19) the application of ORLHC (either at the point of referral or to triage) might alleviate some of the pressures in terms of reducing the numbers of patients referred under the assumption that using ORLHC would mean GPs would feel confident to choose a non TWW referral pathway for more patients with signs and symptoms of HNC.

Specialists thought that there were valuable practical and health benefits for patients when they were assessed remotely using ORLHC. During COVID-19 patients did not have to attend a face-to-face appointment, this meant that they did not have to pay for transport costs or parking expenses. Patients did not have to negotiate time off work (if working) or organise alternatives for any caring responsibilities. Some benefits were specific to the COVID-19 including those associated with risk of exposure to the virus from visiting potentially dangerous healthcare facilities.

And certainly, in lockdown period I think these people who were worried they may have cancer were really pleased for someone to contact them and they didn't have to come into the hospital (HNSC 7)

Lack of Evidence and Research to Support Clinical Application in Primary Care

For a new technology there is a presumption that it has been proven to work in the way it is intended.

For all participant groups this was a universally identified as a prerequisite. Participants with a

personal history of HNC were confident that something like ORLHC backed up with evidence that it

worked in the way intended could potentially be used by GPs in a consultation with patients

presenting with signs and symptoms of HNC.

if there's a little bit of substance behind it ... and the research has been done ... "Right, what I'm going to do is use this piece of software - it's going to help me make some choices. And we'll go through it together. It's been devised by experienced medical professionals. People who are more specialist than I am. And who are more experienced than I am. There's been a huge amount of research with patients who've gone through the process that we want you to go through. And therefore, this is why it's been developed" (HNCP 2)

HNCP and PCPI participants discussed the things that they would want to know about ORLHC if it was to be used and discussed how it could be introduced by a GP into a consultation with patients in the primary care setting. It was assumed that if ORLHC was intended for clinical use, it was something which was based on rigorous evidence and research demonstrating its accuracy in determining cancer risk.

"Look, I just want to run through a little advisory tool, like, you know, if you're willing to. And we'll see what it comes with." I'm sure you could sit there in front of the patient, asking the questions verbatim from the screen. And I wouldn't see any objection to it at all ... I would have thought it would all be very good. (HNCP 1) The benefits of ORLHC, if implemented and it worked as intended in the primary care setting, would be derived by secondary care because with effective use the aim is that it will reduce the volume of referrals to be seen within two weeks in hospital outpatient departments. GPs and the organisations that commission primary care services have no financial implications from HNC referral numbers, in fact the GPs considered that the current pathway works well. All stakeholder groups interviewed expect an evidence base to justify any application of ORLHC in primary care which currently does not exist. The use of ORLHC by specialists during the first lockdown period was a pragmatic response to COVID-19 based neither on evidence that it would work nor any economic evaluation, its success was evaluated and measured by those who used it.

Adopters

Domain 4 refers to the capacity or willingness of the end user to adopt the technology. A less complex technology will have users that are ready and willing to use it, whereas a more complex technology might involve users who lack capability or willingness, or perhaps choose not to use it for professional or personal reasons.

Integration into Complex Decision-Making Processes

Specialists predict that if a decision aid like ORLHC has their endorsement and their support its dissemination, that GPs will engage with it as part of their referral process.

Well, if we think it's a good thing and we think it will help patients and help our workload, we will advertise it and recommend it ... Local encouragement by interacting with the GPs is going to help more (HNS 3)

The GPs, who are ultimately expected to use the decision aid, said much more about the factors that would make them more likely to use a decision aid like ORLHC. GPs were more considerate about the practicalities and effort required to embed and adopt a new decision aid in primary care. One GP commented that complex discussions about cancer risk with patients are challenging.

"ok you don't fulfil the criteria for a two week wait referral but you do have some symptoms which at some point may end up being a cancer" ... that's just communication, just working out whether someone is willing to sit tight for a few weeks and see if it gets worse or gets better or repeat the blood tests in a month or whatever. (GP 5)

Other GPs agreed that ORLHC might be helpful for use with patients who had a higher level of concern about the significance of their own symptoms than the GP. GPs recognised that something like ORLHC could theoretically be used to provide reassurance and support a GP's decision not to refer as a suspected cancer. For some GPs ORLHC could support communication with patients about the low risk of a particular sign or symptom being caused by an undiagnosed cancer.

when you actually say ... "you don't need to be referred" that's when the problems actually arise. So, something like this which says you have a very low probability of cancer ... I think it would be very useful ... It's more to say that," ok you don't need a two week rule", that's where I would actually see that much more (GP 1)

Only one GP described that they had used QCancer[®] (existing CCDT) with a patient in this way albeit

only rarely.

I have done this couple of times, not with this tool obviously but with the QCancer risk. Just to show them the low risk ... these are usually the more anxious patients. It's ... a way of supporting things ... That can be helpful, I have to say I've done that only, top of my head 2 or 3 times in the whole 10 years I've been here (GP 3)

GPs considered that the existing referral pathway for HNC was more than adequate for their needs.

GPs tended to use the NICE Clinical Knowledge Summaries of referral criteria or regional guidelines to inform their referral decisions and to back up discussions with patients about that choice (urgent, routine or two-week wait).

I always use the two week wait criteria as my decision (GP 11)

Using interventions like ORLHC and CCDTs challenge the traditional role of the doctor, for some it threatens the importance the clinician attaches to their communication style and diagnostic skills. Some HNSs who did not use ORLHC during COVID-19 felt that though remote consultation over the phone was unfamiliar, aspects of this were familiar and comfortable and the thought of introducing an additional element like ORLHC felt too prescriptive. Some specialists decided during COVID-19 that because the use of ORLHC within the telephone assessment did not enhance the interaction or the

decision-making process, not to use ORLHC at all. This specialist considers the patient doctor interaction as complex and using ORLHC threatened to destabilise that relationship.

It perhaps felt like one change too many, to change the way that we were speaking to patients. I suppose one of my concerns is almost, I have never ever been a fan of sort of protocolisation of histories and examinations. Because it stops, it inhibits thinking and as soon as you start to do that you sort of disempower clinicians from just thinking ... I think a history isn't ... a list of points to tick then ... that takes away from the therapeutic interaction. Because it's more than just ticking off whether you have got cancer or not. It's about speaking, listening to a patient's story and sort of and helping them it ... "my story is broken, how can I fix it?". For me personally to crystalise down a reasonably complex patient doctor interaction into a tick box list is a shame. I feel that it does us a disservice for what we provide to our patients. (HNSC 10)

For patient participants and GPs the discussion of risk with patients was not a simple prospect,

explaining risk is a much more difficult concept in primary care setting without instruments to examine

and imaging techniques at a GP or GDP's disposal. Personal risk for a patient is even more tricky to

navigate, explain and make sense of even when not related to cancer

he mentioned about a percentage of where it could go... and he said ... you'd be surprised of the percentage of how many does go wrong. And I just thought, why would you say that? what percentage. Because, like, when he said a percentage of... And I went... But a percentage of what? Is that the North East? Is that this hospital? Is this, you know, of this year? ... That was a bad thing to say ... We walked out, and I just burst out crying (HNCP 6)

One HNS recounted his own experience of contemplating risk

I got told 1% once when I had broken my neck ... I remember the neurosurgeon cominc through and told me a chance of having a stroke and I was 19 ... 1% ... that's huge and in that situation 1% ... I couldn't believe it 1% so I had to get another scan ... I do remember that feeling of 1% being massive (HNS 2)

Discussion of risk including percentages and numbers with doctors evoked a variety of responses from

a personal 1% risk being too high to live with, to reassurance from numbers and statistics. The

understanding and evaluation of risk is an individual response and probably determined by the context

and the relationship and communication between the patient and the clincian.

I would be flipping it around ... I've got a 99% chance of not having it. I'm not the 1%. ... it's 80% chance of survival ... to me, 80% is... four out of five make it to the five years ... I look on the positive side (HNCP 7)

Others were more likely to be concerned by the lower risk outcomes and would even question the

risks below 1%

You put in the symptoms, and it doesn't quite come up with the threshold, and therefore you don't actually refer. When, in actual fact, they have got cancer (PCPI 4)

You would want to know absolutely, wouldn't you? Because it's always going to be at the back of your mind. They say it's only 0.45, but what if? You don't know. So, I would want to be referred (PCPI 6)

Comfort/Discomfort Using ORLHC for Clinical Decisions

None of the specialists who undertook remote triage of two-week wait cancer referrals using ORLHC

during the COVID-19 period expressed any anxiety related to their clinical decisions about who to see

and not to see face-to-face. Several mentioned that for their non head and neck colleagues (other

ENT specialists) there was more discomfort about taking on the decisions about patients referred to

secondary care with suspected HNC via remote assessment.

So, what the guys who were less confident about discharging them were finding was that basically the sore throat referrals for the patients where the GP ticked pain in throat or pain on swallowing, they were nearly all being brought into for a face-to-face appointment (HNSC 10)

Non HNC surgeons (specialists trained in ENT Surgery but not specialising in HNC Surgery) struggled

with triaging two-week wait HNC referrals remotely during the pandemic despite their post graduate

training in ENT surgery which covers HNC.

We gave that role to non-head and neck surgeons, and I think they found it quite hard to sort of put their neck on the block and say actually you know this is nothing ... I don't think they had quite the confidence to sort of say "Right do nothing" (HNSC 5)

a lot of my colleagues who don't or didn't see a lot of head and neck cancer patients they've really struggled to erm with the telephone triage so we obviously we've changed practice now where everyone is getting a telephone call and what we are finding is a lot of patients getting phoned are also then needing to be seen anyway and that I think is because they are being phoned by non-head and neck specialists and then they don't have the confidence to discharge them so maybe there is a role for the tool in the other guys (HNSC 10)

Many specialists described that the work of the remote triage of two-week wait suspected HNC

patients was only done by consultant or senior trainee cancer specialists during the pandemic.

We are lucky that we are in a position where we the only people who deal with two week waits are the head and neck team and really only people post CCT [Certificate of Completion of Training – when a junior doctor completes their higher training to register as a specialist] have anything to do with them at that stage (HNSC 3)

Some considered that doing anything else would have been inappropriate and that only clinicians of

a certain seniority and with specialist interest were suitable to remotely triage the TWW referrals

during this period.

I think fellows [senior doctors doing specialist training before becoming a consultant] would be fine, registrars [junior doctors in specialist training at different stages of training], it would entirely depend on the registrar and the grade and their level of experience you know there's a big difference between an ST3 and an ST8 (HNSC 9)

Acceptability to Patients

Patient participants, both with a history of HNC and those without a history of cancer, were

enthusiastic supporters of any electronic support to assist the GP manage or make decisions about

clinical presentations with which they were less familiar. There was a general acceptance that

electronic decision aids are an established part of the doctor patient consultation. There appeared to

be a tacit approval from patients to use decision aids under the assumption that anything accessed

for the purposes of helping a GPs make clinical decisions is from a trusted source.

Well, this is the way things are now ... if they can put the risk in and come up with the answer, that it needs to be dealt with quick or it's not too serious ... I think it would be better, yeah (PCPI 11)

Yeah, I think I'd be quite happy if they did something like that. It's just, you know, I'm of the mindset of, you know, anything that helps somebody get to the right care or whatever - you know, the diagnosis quicker... You know, then it can only be a good thing, can't it? (HNCP 7)

Exclusive Specialist Evaluation of ORLHC During COVID-19

The service evaluation of ORLHC during Covid-19 was exclusively from the point of view of HNSs.

There was no consideration given to how the patients referred on the TWW during COVID-19 found

the experience of remote clinical assessment and the use of a personalised risk of a cancer calculation

to make decisions about their care. One specialist who was aware of the ORLHC use in COVID-19 but

who had chosen not to participate said:

a lot of things we do ... in medicine ... and in research ... are very clinician and researcher centric ... measured by outcomes that we have dictated The success or otherwise of an intervention is dictated by our outcomes, but at the same time we trumpet this whole ... patient centred, we want to share decisions ... and those two don't go hand in hand. I don't think ... it's a patient centred interaction to ask a list of questions and then because your risk is low ... say that I therefore don't need to see you ... I don't like that whole idea if I am being completely honest. I think we are a lot more than a flow chart and if you look at that, it's fascinating to read that report, I mean it's the most doctor centric report you could ever consider. I mean every single outcome is based on ... doctor centred outcomes, not a single patient has been asked (HNSC 9)

HNS participants who had used ORLHC made no attempt to assess patient or primary care impressions

of how it was used during the pandemic or what impact it had on their clinical journey or any consequences on the subsequent patient consultations with their GP. The assumption was made that the method of remote assessment was acceptable to all parties. This was without doubt an emergency response but the evaluation gives a biased view so is not enough to conclude that it is an appropriate decision aid which can be used in the future in the primary care setting. When specialists were asked about the patients' impression of the remote assessment and the use of ORLHC it was clear that little attention was paid to their experience.

Not about the tool really, they well, accept ... no sort of specific reaction ... they seem, the tone is reassuring and pleased that we are doing it (HNSC 7)

Very much, "well you're the doctor you tell me", sort of rule applies there for most people. So, they just kind of went along with it most of them ... I don't ever remember anyone asking anything more specific about the tool we were using ... most people were reassured and said "that's good that that says low risk". I think, would generally be the only thing they would say (HNSC 8)

Some of the specialists who used ORLHC did not mention to the patients that they were using it as

part of their clinical evaluation, others used the opportunity to discuss this in the context of a remote

consultation. Such was the novelty of the intervention that the assumption was made that patients

were, initially at least, prepared to accept remote assessment over a face-to-face assessment.

No, they just accept it's a thing ... it's a tool that we are using ... No one ever really said anything about it ... I have absolutely no evidence of what they feel about it ... You know, do they feel more reassured or less by someone turning round and saying to them "yes we have done this on a scientifically evidence basis", I have no idea (HNSC 6)

Patient participants discussed being presented with figures and risk and any future work would have to unpick this aspect and make effort to present any risk calculator in a way that was acceptable to patients, it may require a variety of options in how the outcome was presented to pateints.

I think that would probably scare a patient. Seeing a percentage like that (PCPI 8)

you could have it on a number – a bit like one to ten, or one to nine. And people are not all clever on percentages, are they? (PCPI 4)

GPs interviewed did not recognise any need to change how they used the existing suspected HNC pathway. Patient participants were supportive of any intervention which could improve the patient route to cancer diagnosis. Patient and public participants were cognisant of the need for efficiency within an economically challenged service. The enthusiasm for adoption of ORLHC emerged and is maintained by ENT HNC specialists, those who developed it and utilised it in the COVID-19 first wave. Evaluation of the use of ORLHC was only done from the perspective of the diagnostic outcomes, the service evaluation explored the experience of only the surgeons who used it in their remote assessment of suspected HNC referrals. Specialists sought no feedback from the other stakeholders in terms of how it was received by and impacted on their diagnostic journey (patients).

Organisations

Domain 5 refers to the complexity associated with whether the technology is a good fit for the system and considers relevant constraints, such as budgets and infrastructure.

Essential Organisations to Facilitate Change

The regional cancer network and local Clinical Commissioning Groups (CCG) were considered by

clinicians as essential for the dissemination and endorsement of any changes to the referral pathway.

Network perspective, they would be the people who would probably roll it out, but I don't know how much that means to people within primary care. If they actually go "woah this is network driven it's really important, we should do this" or actually "oh god we're being asked to tick yet another box" and I suspect it's probably a little bit like that, so it's that engagement and coming together to try and share something (HNS 7) The role of the Northern Cancer Alliance and the local CCGs, in communicating change in practice was

evident in the data from both primary and secondary care participants. Both bodies were seen as

conduits of communication between primary and secondary care.

Sending out directives to the GPs from the CCG saying, "These referral criteria, you have to stick to them" (HNS 4)

Only through engagement with these bodies as well the stakeholders including GPs, were changes to

the pathway, including potential use of a decision aid like ORLHC, possible.

I think if you were going to change, embed it into the two week wait referral, obviously you would have to speak to the cancer teams and they are probably your best ... the best way to make sure it actually would work would be exactly what you are doing now, which is asking the GPs that are going to be doing it. (GP 8)

Inconsistencies in Practice and Procedures

Secondary care highlighted issues with primary care use of out-of-date referral forms, issues with the means of referral communication of suspicious cases from dental practitioners and adherence to the clinical referral criteria. There was frustration that despite organisational drivers for consistency and communication of changes to pathways via the cancer alliance, specialists received out-of-date referral forms which made use of out-of-date criteria. Specialists noted considerable difficulties with variability in the dissemination and use of new versions of the referral forms accessed from the electronic patient record system by clinicians or secretarial staff in individual primary care practices, even within this one region.

So, at the moment I think there is more than one face for the ... two week wait form. So, there's still the paper form, there's still the online form and there's the dentists (other spectrum) still write on a piece of paper or a letter head paper. So, it's not universally adopted, there's a widespread of how these two week wait referrals filter through (HNS 10)

One specialist expressed concern that despite efforts to communicate with primary care through the cancer alliance there remain confusion from GPs about the alternative routes of referral to the TWW route.

I know that a lot of the GPs that I was teaching recently are a little bit confused about the new forms because a lot of them are going, "what happens to these other symptoms, if we find these

other symptoms, what do we do?". They are supposed to refer them on the six-week urgent criteria [where a cancer is not suspected but the signs or symptoms warrant a soon assessment rather than a routine wait on an outpatient list], but many of them don't do that (HNS 5)

OMFSs mentioned that some of the ways GDPs referred to their suspected clinics were more variable compared to the GPs who tended to use electronic referral forms. Dentists were noted, on occasion, to refer with a handwritten letter or continued to use fax machines rather than electronic forms of communication. One consultant described the situation in a different region highlighting the regional differences in practice into which the ORLHC would have to be delivered. These specialists commented on referral management services, an intermediary organisation who assess the clinical suitability of referrals from primary care into secondary care for a specialist opinion.

They were sending pretty much all of their ENT referrals as two week wait because it was quick but also because they bypassed the intermediary service that was on down there. So, they didn't get patients bounced back to them from the intermediary ... they have these private companies that prevent GP referrals they were sending. They just bypassed them by using two week wait (HNS 4)

Other regional differences were discussed by another specialist, demonstrating that a top-down approach and a presumption that one size fits all which is difficult to achieve in the complex NHS setting, no matter the good intentions of all involved.

I think you can't generalise services ... you tailor it to your population. Clearly, the incidence of head and neck cancer is quite high in the North East, there's no doubt about that. We would be fooling ourselves if you don't ... unfortunately we just work on a national figure. We don't work on a regional figure; I think centralisation of services will come but I think we have to work for the local population but use national statistics to back it up (HNS 10)

Collaborative Working

A few of the interviews with GPs highlighted practical organisational issues when it comes to reconfiguration of clinical pathways involving both primary and secondary care. A narrow unilateral perspective and siloed working leads to the failure of expensive and important clinically driven projects. The recent changes to and work to improve the regional gastrointestinal referral pathway came up several times from the CCG GPs. One CCG GP lauded the project as a great success.

The new upper and lower GI [Gastrointestinal] pathways, which we think makes it dead easy to decide if a patient needs to be a two week wait or a routine or semi-urgent referral. We've made the upper GI one electronic already so that has a tool, a bit like yours in a way. You go through a system checklist, it works with SystmOne [one of the electronic patient record systems used in primary care] ... it pops up and says "two week wait required. "Do you want to make a referral? - Yes" and it populates the form (GP 6)

Another GP in a neighbouring CCG was vociferous in his criticism of the failures to communicate and collaborate which had created chaotic and ultimately failed project delivery. This highlights the complexity that exists within and between organisations within the NHS which are difficult to navigate even for those in whom there is an assumption of experience in overseeing and communicating clinical pathway improvement.

It's fine having these fabulous regional pathways and having time out sessions educating all the GPs ... nobody had actually mentioned to the secondary care commissioners, so they hadn't changed the referral forms ... so many different versions of the same referral form ... So, it's the fine detail making sure that you've got everybody using the right referral form, that everybody in the whole chain from beginning to the end knows about it ... don't assume anything don't assume that the ... trust actually know that this regional group have recommended this and that all the local GPs are doing that because they probably don't know (GP 4)

It is interesting to note that despite the work which the CCG boasted had been done in educating

clinicians about the new pathway and SystmOne changes that a GP working as a lead for informatics

for a group of practices had never heard of the changes and was unaware of any communication about

the changes which had been instigated in the CCG where they worked.

One GP summarised the situation well in terms of collaborative work, communication, and

stakeholder involvement in future efforts to improve the HNC referral pathway.

It's not great if it's one sided, uni-direction, because ENT consultants have never been a GP and in the majority of cases vice versa. So, I think if you have specialists creating all these amazing tools they maybe wouldn't recognise the limitations in primary care ... Similarly for GPs creating it, I suppose do they know enough about it all ... they are not the ones getting all of these referrals ... so, I think collaboration sounds the ideal (GP 11)

Changes to the Primary Care Workforce

Several specialists commented that the medically qualified workforce in primary care was changing

and was being supplemented with nurse practitioners, they understood this to be because of poor GP

recruitment and retention in certain areas. The changes were considered to be a contributory factor

in terms of the volume of what specialists consider "inappropriate" referrals on the suspected cancer

pathway.

You've seen a change in structure in general practice ... a lot of experienced people have probably retired due to pensions ... You've now got a largely more junior led service or locum service ... we get an awful lot more two week wait referrals. (HNS 1)

Quite a lot of the two week rule referrals come from nurse practitioners ... there's definitely a knowledge or comfort of knowledge ... I don't know how you resolve that but they think as soon as you get a neck lump they tick the box and send them in (HNS 3)

Patient participants were conscious of the changes in terms of continuity of doctors rather than in the

skill set or professional groups utlised in primary care.

I saw a couple of different GPs. That wasn't the best process because the pressures on GPs are obviously time constraints, so there wasn't any joined-up thinking (HNCP-2)

Some participants were concerned about a deterioration in the lack of continuity.

So, there's two that I would actually... Unless it was something trivial, that could be sorted. But anything serious, I would wait and put off and put off (PCPI-11)

Others were quite phlegmatic about it

Never having seen the GP before - because my practice has got quite a number of doctors - and unless you particularly request somebody, you see whoever is available. Which is fine by me. But it does mean that, you know, you haven't got that... Sort of, one-to-one relationship. That when I was younger I would... You know, all my family saw the same GP and that was that (PCPI-7)

Some praised the "younger" doctors who they considered have superior communication skills while

others preferred the familiarity of a regular GP.

You know, you normally get used to a GP and you try to see them if you can ... they're extremely busy and there's a shortage (PCPI-10)

None mentioned nurse practitioners in the context of their primary care practice one did mention a

pharmacist as a healthcare professional who could utilise ORLHC (but this pateint was involved in a

research project exploring this particular topic).

There are well documented problems with patient access to dental practitioners, presentation to GP

services for oral and dental issues and the lack of robust referral processes to GDPs for GPs. These

deficits in service and lack of integration impacts on the volume of patients referred and is confounded

by some of the issues explored in the condition domain earlier in this chapter.

Think there should be a change in pathway especially in mouth problems. They should go to the dentist and then be referred in ... If we have an opportunity to triage them, we will just say "listen this can be seen by a dentist in two weeks" (HNS 10)

Communication Between Primary and Secondary Care

Pre-pandemic work revealed that when it came to suspected HNC the channels of communication between primary and secondary care, other than through the TWW referral form was poor. This situation led to frustration and tension between professional groups, this was mostly expressed by specialists. There is the impression that better and more open channels of communication between primary and secondary care would be helpful at least in the opinion of specialists.

The other thing ... that's missing ... is the personal telephone contact with consultants ... in the old days, a GP would ring you up and you would say yup that sounds like there'll be nothing wrong with them ... GPs don't contact me now as much as they used to 20 years ago. Most people know who I am. I was always happy to ... if a GP rings me up about something and they say they want to be seen I will see the patient even if it's bollocks. But GPs don't do that at all now they don't interact with the hospital (HNS 3)

The electronic advice and guidance (A&G) system is a relatively recent addition to communication options for primary care to consult with secondary care with clinical management questions regarding patients under their care. These patients could already be under specialist care, or the GP could have a query regarding a patient that they were considering referring for a specialist opinion. In the COVID-19 era this service has become even more crucial for patient management in primary care and communication channels between primary and secondary care have been used more frequently. At the time of the pre-COVID-19 interviews A&G was not new but was not used in the manner which it is post pandemic.

Specialists were open and enthusiastic about the relatively novel A&G pre-COVID-19. However, when questioned about using A&G for suspected cancer cases, GPs did not think using this route of communication was a feasible option. For GPs they felt that by the time that they had made a decision that this was a suspected cancer that to delay a referral via this route was not desirable, and further

discussion with a specialist was not warranted. The waiting time for a response from a submitted electronic advice and guidance request, was the reason that one GP said would make them reluctant to use this option prior to a suspected cancer referral because of the fact that the emphasis has always been on the importance of a timely assessment, any delay could have a devastating impact on treatment options.

If I had a ... real concern about cancer I don't think I would do the advice and guidance really because normally it's a maybe you do the letter on a Thursday or a Friday and you get a reply at the end of the following week or the week after well then that's the two weeks over so if I was truly concerned about cancer I'd maybe pick the phone up (GP 10)

Specialists had a mixed experience of A&G with most explaining that the cases that GPs wanted to

discuss tended not to be those in whom the GP suspected a cancer. The use of A&G to discuss

potential suspected cancers, at least in the pre pandemic period when the interviews were conducted

was mostly speculative as for most participants it tended not to be used to discuss these types of

cases.

We've got this advice and guidance thing, which GPs can email in, and you respond on email and ... they might say "I'm not sure this fits the two week rule criteria or not?" and usually you'll say "don't think it does just try this this and this and if that works, that's fine, if not refer in as a routine or as an urgent" (HNS 3)

This was true of GPs a few of whom could see the potential benefit of an electronic consultation prior

to a suspected cancer referral. Some considered it would be a useful adjunct to ORLHC.

That could be useful I suppose ... If you are really worried, then I just stick it on the two week wait ... That would be a good advice and guidance one - just to say "this is what the score says, these are the symptoms, what do you reckon? Urgent referral two week or just GP management". That could be really useful. I think if it's barn door two week wait, then they don't need advice and guidance (GP 11)

On the whole though GPs felt that because a suspicious case of HNC is so rarely encountered, they

would feel more comfortable making the referral rather than communicating about their uncertainty

and having to wait for a response. This was not necessarily the case for all types of cancer particularly

those which they encounter or at least those that they refer more often or which they consider

clinically are less straightforward than suspected HNC.

I do for cancer but not head and neck, so for a lot of colorectal, colorectal is a very complicated pathway. That's really complicated one to look at and some people just don't quite meet it and therefore, I refer up to the hospital and they will say yes or no. But do this, head and neck, I have to say, I think ... it's more black and white and therefore I haven't needed to use it, from that point of view. But I do refer people up who I think have got low risk to go through the process? Yeah (GP 3)

Again, the rudimentary communication methods used by GDPs was considered a potential barrier, one OMFS specialist even questioned whether they had access to the A&G service. The electronic patient records, communication and infrastructure that exists in dental practice is different to that in GP and creates another set of challenges within this clinical setting. It is concerning that even OMFS are not confident that GDP are able to access A&G from a specialist.

Well, we have an advice and guidance system ... I'm not actually quite sure...whether that's accessible to GDPs but it certainly is to GPs (HNS 11)

Methods of referral and communication between primary and secondary care head and neck services are not standardised even within the one region. This is even more stark when considering the differences between GDP and GP and the use of electronic records, electronic communication, and the correct referral forms. These differences exist despite cross organisation working and cancer alliance activity to communicate changes and update practices about referral criteria, referral options and communication options. There are lessons to be learnt from previous failures to collaborate and communicate aims and objectives of clinical pathway improvement projects effectively to positively influence future projects.

Wider Systems

Domain 6 considers complexities within the broader systems and contexts that might limit the technology implementation. Some understanding of the complexities implicit in NHSE cancer referral policy is crucial to plan changes to how the pathway operates.

Aspirations of the Suspected Cancer TWW Referral Policy

The aspiration to achieve early recognition and diagnosis of cancer in primary care was a well understood concept expressed by all participants. There is no question that this is desirable for patients, healthcare, policy makers and society in general. There are external influences on cancer

diagnosis in the NHS depending on which group individuals belonged to.

HNSs consider that for the GPs there is a pressure to refer patients with even a low suspicion of cancer

because of the way the pathway is promoted and endorsed by the DoH.

The fact is the Department of Health want 97% of people not to have cancer, fine, but those 97% of people referred in probably never had a symptom that was indicative of cancer in the first place (HNS 1)

The aim of the NHSE targets and policy related to TWW are celebrated by some, for those with signs

and symptoms of cancer which are recognised in primary care and referred on the pathway it is an

excellent service.

I think it is probably one of the best things I have available to me ... If a patient comes through with cancer on a two week wait pathway, they get a phenomenally good service I think it's one of the best achievements of the NHS (HNS 2)

The idea of cancer understandably caused concern for patients

It is the emotive issue, I suspect. It's the big C. Most of us who don't understand are just frightened of it. And, you know, the numbers are alarming. You know, throughout your lifetime the chances of you coming across it are really quite high, it seems (HNCP-4)

I think everyone, as soon as they hear the word cancer, they tend to panic (PCPI-9)

And awareness of the early cancer diagnosis aspiration was evident in the comments made by several

of the patient participants

anything that helps somebody get to the right care or whatever - you know, the diagnosis quicker... You know, then it can only be a good thing, can't it? (HNCP-7)

Pressure to Refer

Several GPs commented on this perception that there is a pressure to refer which is hard to resist.

This comes out of the fear of missing cancer diagnoses or being responsible for a patients' late

diagnosis which by implication results in more difficult to treat cancers.

Your hands are tied, and I don't think there's much you can do about it ... unfortunately the guidance says "you have to refer" ... even though a GP thinks they probably don't ... just in case

... I know two people who have missed melanomas, as GPs, and they are very troubled about it. It's a mugs game, GP, isn't it? (GP 6)

For GPs there was also the additional pressure to refer determined by perceived peer pressure, a

resolve to comply with guidelines and not to be seen to be behaving in a clinically different way to

other GPs.

So, many are referred who haven't and while you know they haven't got cancer, you know you have to refer them because they meet the criteria and you are just scared you are going to miss somebody with a cancer. (GP 3)

There was acknowledgement that referral behaviours had adapted to changes in the national policy

threshold at which to refer patients with signs and symptoms suggestive of cancer.

The Department of Health and National Institute of Clinical Excellence cutting the threshold ... does reducing the threshold and altering the pathway increase that. If it's not, then they will have to look at that again, won't they? But it's some of the criteria you think, "really", but then I'm not the person that's done the research and who's making the policies, so ... It goes round in circles after years of practice (GP 10)

Not all GPs were convinced of the value of the TWW pathway and the early cancer diagnosis vanguard

and some GPs shared some of the concerns voiced by secondary care, describing an obligation to

refer.

I have never been convinced by the whole two week wait thing ... I am not so sure that it really has made any difference ... I think it might actually drive too many referrals. I guess the other side I'm not really sure that there has been the resources putting in ... they reduced their threshold from 5 to 3% that's something like a doubling or tripling of referrals (GP 9)

GPs commented that they consider primary care is encouraged to refer signs and symptoms with ever

lower thresholds of suspicion to secondary care.

I am happy to do that, if they are happy to accommodate all of the increased workload ... there is pressure, but maybe that's the right thing... they feel a pressure to refer when they don't feel it's appropriate to refer? (GP 7)

One GP commenting that he perceived a pressure to use the suspected cancer pathway because even

though he considered a patient low risk he would refer the patient because it would, he believed,

what other GPs would do.

There's this other lot, that I don't particularly want to refer but I feel as though I should, because it seems to be what everybody else does (GP 9)

Several specialists echoed these views that GP referral behaviour patterns had changed and that they

perceived a pressure from above influencing this change.

It's incredibly demanding on secondary care services to provide it, and I think that it was probably too much of an emphasis about 3 years ago from the Department of Health to put these patients on the pathways. To the point when now, I see a lot of GP letters which, make you feel that they are obliged to send them (HNS 1)

Despite the intention specialists felt that the TWW was not delivering the cancer yields from the

volumes referred despite the good intentions.

my understanding of NICE ... well that the government, is that they want earlier diagnosis, and they would rather flood the system with two week waits with a massively low pick-up rate, to try and overall reduce ...or improve early cancer detections (HNSC 5)

Confidence in Recognising Cancers in Primary Care

Several GP participants mentioned the belief that if they are not referring enough patients under the

suspected cancer criteria then they are bound to be underdiagnosing cancers.

Ultimately in my head, my understanding of it is, if you have over 50% of those being picked up as cancers at the far end you probably are under referring. Because of the lack of differentiation of symptoms at the early stage and of the lack of expertise of the generalist who's sifting through it all (GP 8)

GPs remarked on a sense of fear related to suspected cancer referrals and missing cancer diagnoses,

a pressure to refer patients via the TWW cancer pathway in general, and that the changes in

thresholds from NICE influence their referral practices.

I think that maybe this reflects my own slightly more cautious personality. But I think if everyone you refer is diagnosed with something, there are probably some people that are being missed (GP 7)

The Mandate for Change

Clinicians, both HNSs and GPs recognised that to introduce something akin to ORLHC into primary care

would be guaranteed successful implementation, only with a seal of approval from NICE and the DoH.

what you can't do is change national policy with your own local service (HNSC 3)

I think nationally advocated by NICE or some organisation like that ... You'd need some sort of national body ... recommending it. (GP 4)

Overarching health policy in England is a driver to suspected cancer referrals from primary care. There is an acceptance that over referral is preferable to under referral driven by the government policy which aims to diagnose cancer at an earlier stage. The lowering of signs and symptom thresholds for referral feed this.

Embedding and Adaptation Over Time

Domain 7 refers to the necessity of a technology to be flexible over time, to adapt to changes within the system. Consideration must be given to how future-proof ORLHC might be. The experience of those who used ORLHC during COVID-19 is likely to shape how it is used in the future and within which setting this might be.

Use of ORLHC Beyond the COVID-19

The use of ORLHC during COVID-19 was exclusively by ENT specialists who chose to use it to assist in the triage process when face-to-face appointments were rationed. In considering the future application of ORLHC for triage some specialists based this on their experience with it.

Prior to the pandemic questions about ORLHC being a patient utilised aid, some clinicians commented

on the patient narrative being more reliable than the referring clinician

if you make it in patient terms and the patient fills it in you are likely to get more I tend to trust the patient more than the referral or the clinicians input so I'd appreciate something the patient says than what the clinician said because the clinicians interpretation may be completely different the patient may have a said I've got a little bit of soreness at this particular point on my throat that's different from a sore throat (HNS 6)

Patient participants were dubious that ORLHC could be reliable in the hands of patients

I think if it's done with a professional ... you're just sitting at home, doing it. and you think, God, that could be... it would worry me a little bit ... It's like going into Google and, you know, putting something in – blood in your urine ... you get a whole list of things ... it's sort of self-diagnosis, isn't it? ... I don't think I would be that comfortable ... It depends on the person ... some people are born worriers ... I think used in conjunction with your GP or a health professional (PCPI 10)

Will the patient tell the truth, putting the information in? Or will their symptoms be suddenly overblown or understated, if they're scared? Or will they tell the truth? The truth to someone sitting in front of them? (PCPI 1)

ORLHC was not a perfect intervention for all types of HNC, as the specialists who used it during COVID-19 expressed in their interviews and explored in the condition domain earlier in the chapter, with areas identified requiring development, for some specialists their experience led them to retain enthusiasm for its use in the future.

Until someone says "stop using it" I think I will probably carry on using it actually ... especially if that neck lump thing can be tightened up, I think that would be helpful (HNSC 7)

This was not a consistent finding, and some ENT specialists were still using ORLHC at the time of the

interview, some chose to never use it, some had stopped using it once the service evaluation ended.

For those who had used it initially and abandoned its use, none felt that ORLHC had any role in their

future practice. They considered using ORLHC took too much effort in addition to normal working

practice and this meant that for them it was just not worth the extra work.

I think it has come to its end and the only reason is time ... It just takes a while to go through all of this and if you are going to see ... the vast majority of them anyway. It's a lot of effort to go through to wheedle out one or two patients ... if I am honest no (HNSC 5)

Several of the specialists latterly tired of this remote way of assessing patients and commented that as the lockdown period continued patients too became frustrated that they were not having a faceto-face assessment with a physical examination.

I had a few months when I was doing that and that was ok, but then you realise that ... patients ... are starting not to just want to be triaged (HNSC 12)

Others recognised that using their expert led telephone assessment was adequate and had never considered using it and several had abandoned their use of ORLHC completely at the time of the interview.

A couple of ENT specialists admitted that they would not continue to use it beyond the pandemic let alone expect it to be used by non-specialists. One specialist speculated about the use of ORLHC in the hands of non-specialists and questioned how well its use might transfer particularly when used by GPs and less experienced clinicians in general.

My main reservations are that these things work great when they are done by experienced people, who have the confidence to go "actually that's fine you don't need to be seen" or the confidence to go "you know what I am going to override the calculator on this and see you" ... if that's then ... farmed out to either less experienced people who don't have the expertise then it becomes more difficult. (HNSC 9)

The specialists had used ORLHC at the height of the pandemic during a period of unprecedented

change. A couple of the specialists were interested in exploring the continued use of ORLHC to manage

the volume of patients referred as suspected HNC. They considered retaining using it within

secondary care to triage referrals rather than considering its use in other settings like primary care.

I think this is a great thing...and post covid we're discussing that we keep doing this, not because we'll discharge people... what it means is that we'll see you, but you don't need to be seen as a USC [urgent suspected cancer] (HNCS 9)

Some of the interviewees intended to investigate how to adapt their work to use ORLHC for the future management of referrals.

You can triage as to where they are seen, and I think the tool does have a role there (HNSC 3) The COVID-19 experience gave ENT HNSs the opportunity to exert some control over how the large volume of patients were initially managed and this may give rise to permanent changes in how the patient pathway operates in the future.

The NASSS framework analysis of the data shows that there is complexity within all the domains. There has been no assessment of complexity prior to the development of ORLHC, some of the complexities have only been exposed because of its use during COVID-19. Firstly, and crucially ORLHC does not offer an adequate assessment of all the types of HNC even to the satisfaction of specialists. There is limited primary care support (at least from GPs, CCGs and GPs interested in cancer pathways) which would be essential to secure necessary resources to support a programme of implementation of ORLHC in primary care. The use of ORLHC in the HNC referral pathway is not considered a priority by those who would have to fund and plan its development, integration, and implementation in primary care. The fact that existing CCDTs are rarely used and poorly integrated into existing work primary care practices limits the possibility of a CCDT for HNC working in this setting even with NHSE support. Existing CCDTs which are incompatible with electronic patient records, existing local and national referral guidelines have demonstrably poor uptake despite the huge resources committed to develop and study them. The COVID-19 experience has provided secondary care specialists with greater confidence that they can successfully exert some control over the choice of assessment offered to patients referred as suspected HNC. In the post COVID-19 era this extension of secondary care control over how guickly suspected cancer referrals are seen still has to be compatible with TWW targets and DoH policy. The rapid uptake of existing and new technologies within primary and secondary care to communicate and share clinical management decisions about suspected cancer cases during COVID-19 has huge potential for the future of cancer referral pathway development. Given the complexities exposed that exist in all of the NASSS domains with regards to ORLHC, the analysis of the interview data suggests that there is little potential for implementation of ORLHC in the primary care setting now or in the future. ORLHC, at least in its current form, is not the solution to the problems associated with primary care recognition and referral of suspected HNCs. There is potential to use ORLHC in specialist secondary care triage for certain types of HNC and this remains an area requiring further investigation.

CHAPTER 10: DISCUSSION

Aims of the Study

This thesis identifies and explores complex challenges pertaining the proposed implementation of a primary care CCDT for patients with signs and symptoms suspicious of an undiagnosed HNC. The first part of the thesis provided context and synthesised the qualitative data about how existing CCDT for primary care have been received by those for whom their use is intended (GPs). This work establishes factors that shape the implementation of CCDT in primary care for exploration in the stakeholder interviews. The qualitative interviews aimed to explore views about the current HNC pathway and attitudes to potential changes in the way the pathway operates.

Summary of Results

This work speculated on implementation of a CCDT like ORLHC and what issues might affect future implementation in primary care and was supplemented by data collected following use of ORLHC by specialists during COVID-19. The work was designed to identify factors which might challenge and facilitate changes to the future referral pathway for suspected HNC from primary care. Embedding CCDTs into use in primary care to influence suspicious cancer referral behaviour face numerous challenges. These include successful integration into IT systems, compatibility with existing guidelines, collision with the reliance on clinical acumen and gut instinct and endorsement from a specialist or national body. The lack of engagement with existing CCDTs may preclude the development of another one for a clinical pathway which individual GPs use so rarely. The data suggests that there is little appetite from GPs or representatives from CCGs to adopt something like ORLHC into the referral pathway for suspected HNC. Specialist adoption of the ORLHC to triage suspected HNC referrals demonstrated its utility during a crisis in healthcare delivery but this does not mean it can automatically be transferred to primary care and be used with similar confidence.

There are opportunities to use simple, tried and tested technological interventions like telephone calls and electronic communication over a complex intervention such as ORLHC to improve communication between primary and secondary care about potential suspected HNC referrals. This improved

communication might ease some of the pressure on secondary care outpatient capacity, create relationships, improve patient management, and develop novel patient pathways.

Input from patients, primary and secondary care clinicians, commissioners, regional cancer networks and national health bodies will be required to successfully codesign, endorse, implement, and embed revisions of how the suspected HNC pathway functions. This is preferable to an intervention designed with no consideration of the wants and needs of the stakeholders or what is possible in the real world.

Interpretation of Results

Recognising the condition HNC in primary care is challenging for many reasons. The cancers arise in a diverse variety of anatomical sites, cause a variety of common symptoms and abnormalities sometimes in visibly inaccessible areas. For neck lumps, hoarseness, white and red patches there is usually an objective change or discernible clinical finding, which makes these referral criteria less prone to interpretation and reflects why they have been selected for the NG12 criteria. Some symptoms such as odynophagia, dysphagia and otalgia remain more difficult to evaluate in an objective manner in primary care because of the inability to access areas like the larynx and most of the pharynx to examination. There is likely a degree of misinterpretation of signs and symptoms, these might be motivated by a fear of missing an undiagnosed cancer. It is apparent that primary care clinicians' discomfort with confidently attributing signs and symptoms to benign processes creates some of the frustrations articulated by specialists. The ORLHC includes many signs and symptoms which are no longer on the NG12 criteria, but which are still part of some regional referral criteria (not the North East at the time of pre-pandemic interviews) and this muddies the water somewhat in applying the ORLHC across the country.

This study suggests that there is a lack of acknowledgement from specialists that GPs do not refer all the patients that they see in practice with head and neck symptoms. The data collected from specialists implies that there is little understanding of how GPs work and that HNC is such a tiny part of their clinical work. HNC is possibly too difficult a cancer group to apply a decision aid particularly

one like ORLHC which aims to include the whole spectrum of the disease from laryngeal to salivary gland cancers.

It is revealing that the data collected from those in secondary care who used ORLHC during COVID-19 suggests that using it was not as straightforward as suggested in pre-pandemic interviews when it had never been used to assess any patients clinically. There is a gap in understanding and interpretation of signs and symptoms between GPs and allied healthcare practitioners working in primary care and the head and neck specialists. This gap makes ORLHC more difficult to use by primary care practitioners compared to the way in which a specialist would use it. During COVID-19 when ORLHC was deployed to triage referrals for suspected HNC, specialists had reservations about specialty trainees and even other senior ENT consultants using it, considering it was best used by those with specialist interest in HNC or those in senior specialist training posts.

Overall, HNSs felt that ORLHC added little to their consultation, it was experience which drove decisions and they were confident that using this alone during a telephone consultation meant they were unlikely to miss a potential cancer case. Non-head and neck consultants, interestingly, were less comfortable triaging HNC referrals, and some consultants chose to not devolve responsibility to junior level trainees to using ORLHC for triage purposes as they felt they did not possess the relevant experience to do this well. If those within the specialty without the experience and interest in HNC were uneasy about deciding to defer a face-to-face assessment it therefore seems improbable that ORLHC would give clinicians in primary care the confidence to make similar decisions about suspected cancer referrals. This by implication means that use of ORLHC would be even more challenging for GPs and GDPs in primary care, not to mention those practitioners without a medical or dental degree like Advanced Nurse Practitioners who are likely to have even more limited experience and exposure to clinical cases of HNC.

Despite this there is some somewhat misplaced enthusiasm from specialists who used it during the pandemic that it could still be of use in the primary care setting particularly by those specialists who

mentioned issues with nurse practitioner referrals. The addition of a new decision aid for HNC will not address the apparent deficits in education, training, and experience because the problems of interpretation of signs and symptoms, which all specialists mentioned in pre-pandemic interviews, will persist.

There was no indication, at least from the interviews conducted with HNSs following the first lockdown period in the UK, that their OMFS colleagues adopted ORLHC for remote assessment for patients referred with suspected HNC during COVID-19. The interviews with a limited number of OMFS consultants prior to COVID-19 indicated that they were optimistic in terms of the potential use ORLHC in primary care. It is impossible without further interviews to comment on why OMFSs chose not to use it during COVID-19 but pre-COVID-19 data suggests that they felt ORLHC lacked any capacity for transfer of images of oral lesions. This appeared to be important to them to triage referrals and it may have become a more obvious omission when it came to using it for remote assessment. The ORLHC was developed by ENT surgeons and so may have failed to accommodate the requirements of this section of the HNC specialty and their needs in assessment of OMFS site HNCs so much so that they did not find ORLHC useful in the same way that ENT specialists did during COVID-19.

A collaborative approach to how the technology is presented and integrated is essential in its successful adoption. The framework synthesis suggests that collaborative work between primary and secondary care groups along with other stakeholder involvement in the development of CCDTs might lead to more successful attempts at developing decision aids within the primary care cancer field. There appears to be a gap in access and use of technology to bridge the interface between primary and secondary care when it comes to communication about these patients with suspicious signs and symptoms of HNC. Better use of existing simple technologies such as electronic images, telephone, and email to communicate about patients in whom primary care clinicians suspect a HNC could improve the risk assessment before a patient is referred on the TWW referral pathway. GPs appear reluctant (at least pre-COVID-19) to communicate via electronic means (A&G) about suspected HNCs

and GDPs do not seem to have access to these methods of communication in their practice at least according to the limited number of OMFS interviewed. The data from OMFS was limited but compared to ENT where there appears to be an established electronic system of referral from GPs, GDPs do not seem to conform to a standard method of patient referral for suspected HNC. It is unclear how to improve communication between OMFS and GDPs but this is an important referral route and there is potential to improve the interaction between primary and secondary care in this area which includes use of electronic advice and guidance to transfer images and aid decision making.

In addition, the framework synthesis shows that any CCDT made up of criteria which is both inconsistent and incompatible with those criteria used locally will inevitably be more difficult to integrate and implement into existing primary care referral pathways. If they are difficult to find, incompatible with IT systems and their use not a prerequisite to referral they are unlikely to be taken on in primary care clinical practice. The qualitative interviews suggests that GPs prefer to use the local referral criteria, namely that which is recognised and approved by the team to whom they are referring. GPs are motivated to use new decision tools if they are recommended and endorsed.

There is enthusiasm and support from the public and patients to back attempts to improve early diagnosis of cancer in the primary care setting. The views expressed in this research demonstrates that public and patient participants have implicit trust that clinicians utilise reliable sources and methods to support decision making, they are confident that primary care would be comfortable using soemthing endorsed by secondary care. More consideration needs to be given to how CCDTs are presented and discussed with the patients for whom they are used to make referral decisions as the calculation, understanding and concept of 'risk' is a tricky one for even clinicians to clearly comprehend and convey on an individual basis.

It is hard to justify the addition of another decision tool for cancer for primary care when the ones that currently exist do not appear to be widely used in clinical practice. A more successful approach

to the implementation of a symptom decision aid for cancer might be achieved with more robust evidence of effectiveness, better integration into the clinical system and ease of use. For a potential HNC specific decision aid such as ORLHC it would need to be compatible with existing referral criteria (be that local, regional, or national) and the lack of consensus on the definitions, terms, and shared language to reduce the risk of (mis)interpretation. The apparent poor take up and integration of existing CCDTs despite the national policy imperative for GPs to increase their suspected cancer referrals means that ambitions for the role of ORLHC in primary care should be reassessed.

The data from the GP perspective suggests that, for them, the current referral system works and are unlikely to adopt a new way of working without engagement and endorsement from secondary care. GPs are aware that their experience of HNC is limited but have confidence in the existing reliable route of referral to access specialist assessment for any patient about whom they have concerns. A willingness exists to use something like ORLHC if it were endorsed by secondary care, using ORLHC would be less unlikely without mandating it as part of the referral process. GPs so rarely use the HNC referral pathway that it would not be something they would remember to use each time. Although there are good routes for dissemination of information about changes to patient cancer pathways in place, this does not always guarantee that all clinicians are informed about the changes and engage with new processes.

The apparent pressure on primary care to increase suspected cancer referrals is matched by the expectation that secondary care will absorb this increase in demand, and it fuels mistrust. Participants from secondary care suggested that primary care referrals are unreliable, at times fudged and too frequently result in a non-cancerous diagnosis. Secondary care specialists seem to resent that the pressure on primary care to reduce unnecessary referrals is not applied to suspected cancer referrals and that the converse exists. Some specialists in the interviews give the impression that they resent that primary care can use the cancer referral pathway with apparent impunity. Secondary care clinicians frustrated with the changes in the thresholds used to justify referrals feel that the criteria

are open to interpretation, accessed too easily and lacks referral scrutiny or any triage (at least pre COVID-19 in the North East). This frustration appears to be that despite the changes in the two-week wait criteria over the last two decades it has failed to demonstrate, an appreciable increase in the numbers diagnosed earlier, an increase in cancer yield from the referrals or an improvement in HNC treatment outcomes. The HNC specialists are affected by the considerable demands on their service and their concern is that this impacts on ability to provide routine outpatient assessment, particularly when some of these waiting to be seen on routine basis will have an underlying cancer as the cause of their signs and symptoms. Unfortunately, the drive and the enthusiasm with which ENT adopted ORLHC during the first lockdown period of COVID-19 is not matched in the primary care setting despite positive feedback from patient participants about the utility of something like ORLHC.

In terms of the influence of institutions like NHSE and DoH, their policy and public health messages are crucial in determining primary care referral patterns and practice. The prospect of a cancer diagnosis which is late, delayed or which is accompanied by a complaint about a failure to recognise signs and symptoms along with public health messages and the NHS long term cancer plan all add to heightened awareness of suspected cancer referrals in primary care. It is acknowledged by GPs and specialists in this study, that because of NHSE policy, contractual agreements and local scrutiny of practice and numbers of practice cancer diagnoses (by type and volume compared to other local practices) GPs are encouraged to make more referrals via the two-week wait pathway. It is hardly surprising in this atmosphere that many GPs stated that they were aware of the dangers of too few referrals as opposed to too many.

Pre-COVID-19 data collected demonstrated high levels of complexity related to a potential implementation of a CCDT like ORLHC in the primary care setting.. Complexity exists in GPs understanding, experience of and exposure to HNC itself demonstrating that the technology development was done with little consideration to the differences between generalists' and specialists' understanding of the disease and the use of nomenclature to describe signs and

symptoms. There is a small volume of referrals from each GP practice for suspected HNC and therefore a lack of financial support forthcoming from CCG. CCG support would have to be available to fund the development of a decision aid for primary care, finance the work required to integrate it into the IT systems and disseminate the changes in the clinical pathway process to practices. The data suggests, at least from the point of view of the CCGs, that there would be considerable challenges to overcome in terms of financial justification for the work required to make ORLHC operational in primary care.

The role of the generalist is to use skill, experience and expertise when faced with undifferentiated pathology. A new decision aid for suspected HNC such as ORLHC does appear, at least from the GP perspective in this presented data, to be surplus to their need. There is little inclination from primary care to overturn how the suspected HNC pathway currently works so the impetus for change remains with secondary care. The lessons from the use of ORLHC in COVID-19 will influence the future development in the suspected HNC referral pathway process. It appears likely that the decisions about prioritising those patients most likely to require an assessment for suspected HNC may revert to secondary care as it was before the TWW pathway was established.

Future Use of ORLHC in Secondary Care

It is clear from interviews with head and neck surgeons (ENT) who used ORLHC during the first wave of COVID-19 that they can successfully utilise remote triage to appropriately delay assessment for patients with low suspicion of a cancer and to manage timely assessment or investigation for those in whom there is a higher level of suspicion. This may be a way to exert more control over the volume of patient referrals by triaging them into those that can go directly for investigation without an initial face-to-face assessment, those who can be deferred to a routine appointment and those who need to be seen within the two week cancer target. There is potential that it can be used in the future to identify those for whom an assessment with an allied healthcare professional such as a speech and language therapist is indicated as the first contact. COVID-19 experience in ENT meant that specialists were able to pick out those cases which are most likely to have a cancer as the reason for their signs

or symptoms. This means that the way the suspected cancer pathway operates at the hospital end may be changed forever. COVID-19 has given the UK healthcare sector the opportunity to rapidly adapt, both clinicians and managers have demonstrated ingenuity and innovation in the face of massive pressures. This upheaval is matched by an opportunity to emerge from the pandemic with new ways of working, new approaches to system pressures and it may lead to improvements in how healthcare is delivered and how patients are assessed.

The remote assessment of suspected HNC referrals during COVID-19 by secondary care means specialists were able to exploit their experience of the nuances in the clinical presentation of HNC to control access to resources at a time when safe and appropriate allocation of healthcare was paramount. HNSs were comfortable making these decisions and able to reliably base them on experience and expertise which cannot be said for the average clinician in primary care. It is not clear whether all the surgeons who took part in the service evaluation of ORLHC will continue to use it or not, many of them had stopped using it when the interviews took place. What the service evaluation and remote triage with the use of ORLHC demonstrates is that there are alternative ways of delivering healthcare compared to the traditional model where the patient is referred by the gatekeeper (primary care) and the specialist sees them in an outpatient clinic within two weeks of referral.

Future of Suspected HNC TWW Pathway

The NHS and DoH priorities of early cancer diagnosis have a marked impact on cancer pathways and patterns of referral. The role of the 3% positive predictive values of the signs and symptoms apply to all cancer types yet there is little evidence from primary care in terms of the predictive values of signs and symptoms of HNC apart from the larynx RAT (210). There are now calls to lower the positive predictive threshold to 2%, the inevitable increases in referrals will further add to the hospital pressures. Worryingly the impact of this is predicted to be felt more markedly by head and neck departments according to recent modelling (7). A redefinition of the criteria for suspected HNC, from
the perspective of the head and neck surgeons would have to be in line with or at the very least endorsed by the national cancer programme.

Scrutiny of TWW referrals

CCGs send reports to practices pointing out their underutilisation of the cancer pathways, practices are told they are outliers for their area if they use two-week wait pathways less often than other local practices. There is a contractual obligation to regularly review their use of two-week wait referrals and late cancer diagnoses to identify opportunities missed and compliance with referral criteria is the subject of academic publications, both from the perspective of primary (15) and secondary care (211), with, it must be noted, different political and clinical agendas. Despite this CCDTs are still not in widespread use in primary care to influence clinical decisions and determine referral route. There is encouragement within the GP contract to use risk decision tools for cancer referrals, it is apparent according to survey data (55) and from the interviews with GPs as part of this thesis that these are not currently in widespread use in primary care. The contract does not make use compulsory nor incentivise this financially which inevitably limits uptake. These problems of poor adoption and use exist despite the substantial research efforts and their endorsement and encouragement of use by NHSE. There is no convincing data that using these tools in primary care has led to any quantifiable improvement in earlier cancer diagnosis (77, 93). The same can be said for ORLHC since none of the work in this PhD nor from any other sources can provide any data that its introduction into primary care will make a difference to referrals for HNC. It is, yet, untested for referrals from primary care into secondary care.

Referral Criteria and Regional Variation

Regional variations in referral criteria mean that trainee and newly qualified clinicians might not be aware of the less common suspicious symptoms because they have disappeared from the referral criteria. Some specialists voiced concern that the referral criteria had become rather narrow compared to previous iterations. Some older GPs who had experience of previous versions of the twoweek wait criteria mentioned that some sinister clinical features no longer qualified to be referred under this pathway. For such a comparatively small cancer group it remains unclear why some regions have a vastly expanded set of signs and symptoms as part of their referral criteria compared to those who rely on the NICE NG12, particularly in light of the fact that concerns remain about the volume of patients referred on the suspected cancer pathway with persistent throat symptoms both pre and post COVID-19 (102, 212). Questions remain as to what extent the regional variation affects the route of cancer diagnoses (TWW pathway as opposed to routine, urgent or emergency). Another concern with variations in referral criteria is whether the differences exist because of recognised delays in diagnosis and assessment by the most appropriate clinical specialty which seems to be the case for odynophagia and dysphagia which in some regions follow the upper GI suspected cancer pathway and for others the head and neck one. For such a high referral low yield cancer referral pathway there should be consideration as to whether those who have adopted NG12 have seen a change to the pattern of referrals and whether deviating from this recommendation is justified.

Alternative Routes of Referral and Assessment for Suspected HNC

Not all patients referred with signs and symptoms which a GP recognises as suspicious of cancer need to see a head and neck surgeon particularly those with globus symptoms and hoarseness. What these patients need is a good explanation of their symptoms, simple self-management interventions and sometimes speech and language input is required. There are examples of low risk TWW clinics effectively run by speech and language therapists, some speech and language therapists deliver remote consultations addressing vocal hygiene and chronic cough, these have continued during COVID-19. The speech and language therapist role in the assessment of suspected cancer referrals continue to be developed to treat patients with genuine and distressing symptoms. Now that in more specialist centres, because of the COVID-19 experience, some mode of triage might be applied to twoweek wait referrals, there are opportunities to divert some of the referrals to healthcare professionals with expertise in functional voice and swallowing problems which are frequently referred to HNSs as suspected cancer.

The lauded ambition of early cancer diagnosis through a timely referral pathway is not in question. But half of HNCs are diagnosed in patients referred to routine outpatient clinics not via the suspected cancer referral route. HNSs have long claimed that a reconfiguration of the two-week wait could improve routine care waits and theoretically the outcome of those patients on routine pathways with seemingly innocuous symptoms caused by a cancer who might be seen earlier if more resources could be diverted from suspected cancer clinics to the routine work (96). ORLHC could be applied by specialists to routine referrals as well as the two-week wait ones. Patients who present with what is described as a delayed diagnosis (which can be for a variety of reasons) particularly those who present as emergencies might be helped with improved public health information about signs and symptoms of HNC and medical education to help primary healthcare professionals improve their recognition of suspicious signs and symptoms.

(Mis)Interpretation of Signs and Symptoms of HNC

Many patients with HNC (in primary care) present with symptoms that are common and nonspecific, which have very few objective visible signs and for which there are no laboratory-based tests that can be done to help differentiation.

This thesis does not aim to address this problem but acknowledges that these are major obstacles to the pursuit of earlier diagnosis of HNC. This is not a problem with the referral pathway, per se, it is a problem related to recognition, interpretation, patient perceptions and delayed presentation to healthcare services. The interest in exploring the sensitivities of certain signs and symptoms (176) alone and in combination to determine referrals does not address the gap that exists between specialist and generalist understanding and interpretation of these signs and symptoms which will determine the impact of this type of work.

Communication Between Primary and Secondary Care

This research has highlighted that there are untapped opportunities to improve the interface between primary and secondary care using more simple communication interventions like electronic images and advice and guidance to share concerns prior to making a two-week wait suspected cancer referral. The addition of some form of image transfer from primary to secondary care could arguably be helpful for some ENT as well as OMFS presentations such as abnormal tonsils, pharyngeal lesions and potentially neck lumps. There was certainly an appetite amongst these secondary care clinicians to work to support pursuing improved communication. Data collected prior to the pandemic illustrate that GPs did not see the same benefits in suspected cancer presentations. This may have shifted for primary care clinicians because of the changes which have come to the whole landscape of healthcare due to the pandemic. It may be that now is the time to look to embrace change to an established way of working by collaboratively developing a new approach to an old problem.

The Future of the Suspected Head and Neck Cancer Referral Pathway

Communication between primary and secondary care has improved through COVID-19, the electronic advice and guidance has expanded, access to primary care has changed in ways which many advocates have been promoting for decades (213, 214). The expansion in the use of remote consultation, access to electronic means of communication including text messaging of photographs and video consultations means that patients can access healthcare in a variety of ways and clinicians to clinician communication has improved (215). Hospital clinicians can now exert more control over the management of how quickly they see a variety of conditions and prioritise face-to-face appointments. This has benefits to the healthcare professional, the patient, and the NHS (215).

This rapid unprecedented adoption of remote consultation options has been in response to changes in the world because of COVID-19. In the case of ORLHC there was no pre-implementation work, it was adopted quickly at numerous ENT head and neck centres at the time of the first lockdown period in the UK. Those who employed ORLHC as well as those who did not now know that they can exert control over the volume of suspected HNC referrals, the lessons learnt will impact on how secondary care manage referrals for suspected cancer in the future.

The data presented suggest that secondary care feel they are overburdened with suspected cancer which can lead to the service failing to deal adequately with benign functional issues that present on this referral pathway. Cancer surgeons are not always the best healthcare professionals to address the concerns of these patients when they regard the function of the two-week wait clinic as primarily to rule out a cancer. Ruling out a cancer is important, but some patients will need a reason for, a way to rationalise and manage their swallowing or voice symptoms. Many patients will benefit from being offered options to relieve their symptoms or time to explore some strategies to learn to live with them. Such consultations could be with professionals with experience in voice and swallowing dysfunction such as speech and language therapists. Speech and language therapists can offer treatment and rehabilitation options for these patients. Because decisions about how quickly and by whom patients need to be seen is now within the purview of the receiving head and neck department there are more opportunities to develop low risk two-week wait speech and language clinics where appropriately triaged patients can be seen to make a personalised functional assessment and treatment plan.

The future of the suspected HNC referral pathway lies in building trust between primary and secondary care. There is scope to use the patient narrative to make decisions about urgency of assessment as opposed to the reliance on a primary clinician's interpretation of the patient's signs and symptoms, as planned in the National Institute of Health Research (NIHR) EVEREST-HN (Evolution of a patient-Reported symptom-based risk stratification system to redesign the suspected Head and Neck cancer referrals pathway). The specialist use of ORLHC during COVID-19 cannot be replicated in primary care and is unlikely to have the impact on the volumes referred that its originators hoped.

Any future pathway development should incorporate the use of advice and guidance schemes, improvements in communication channels, and the use of digital imaging. Carefully thought-out

provision for urgent as well as routine appointments with suitably qualified allied healthcare professionals as an alternative pathway to the two-week wait referral should be considered.

Literature Comparison

The ex-ante elements of this study were designed to anticipate potential complexities which might hinder future implementation of ORLHC. The approach offered the opportunity to explore possible solutions and engender a collaborative approach to future work. A recent feasibility study to examine an electronic clinical decision support tool for assessing stomach symptoms in primary care (ECASS) (216) came up against a variety of implementation and adoption issues which could have been anticipated. Despite good CCG and practice engagement, the technical practicalities, and changes in NICE guidance on management and referral of suspected cancer meant that uptake and use of the tool was poor. Even though screening identified more than 1,500 eligible patients and over 500 who consented to participate, the tool was used only eight times by five users. The feasibility study report called for suspension of any trials of eCDS that had not addressed similar potential constraints related to low adoption rates. Identification of these potential complexities prior and during the study period might have averted the poor uptake or even to abandon the effort at an earlier stage. Considering the factors that determine implementation and use of CCDTs in primary care identified in the qualitative framework synthesis in this thesis (186) (Chapter 7) the outcome of this feasibility study is no surprise. What is perhaps surprising is that this study was conducted by some of the authors involved in the studies included in the framework synthesis.

This ex-ante work exploring healthcare innovation particularly focused on future implementation, moves away from the assumptions of the enthusiastic innovator with a biased perspective towards a more collegiate, inclusive approach to how the real world can accommodate an innovation. NASSS can be used at any stage of the innovation-implementation continuum to provide a contextual lens through which to consider factors which may impede progress, question the validity of an innovation, give rise to creative solutions but additionally examine whether the investment in terms of time and resources is ultimately a good use money, expertise, and effort (217). Some anticipated research (218)

to co-develop and test a clinical decision support system for GPs to try and reduce inconsistencies in the identification, assessment, and management of suicide risk to generate a risk assessment plan, will provide relevant insights into work for the future implementation and use of clinical prediction models in primary care.

Much of the published work using NASSS has been ex-post analysis using case studies (219) much in the way the COVID-19 experience of the use of ORLHC has been considered in this study. The NASSS analysis of the Treatment of Cardiovascular Risk in Primary Care using Electronic Decision Support (TORPEDO) studies (implementation of a cardiovascular disease risk decision tool for primary care studied in Australian primary care setting) (220) praised the pre-implementation co-design work and commented on the presumptions made about systems technical infrastructure and capacity to accommodate the decision tool. The study highlighted the incompatibility of guidelines with informally held beliefs about best practice and the mismatch between the enthusiasm of those implementing the innovation and that of those who would have to use it in practice. There were issues of incentives in terms of professional, financial, and regulatory all of which have been identified in the current study and which need to be considered in any future work.

The role of the champions and their drive, passion and single-minded devotion should not be underplayed in the field of innovation and implementation. Individuals often drive change and serendipity often plays a part in the timing and uptake of an innovation as in the case of COVID-19 and ORLHC. Trust underpins successful implementation and permeates all the domains of NASSS where ORLHC is concerned. The application of NASSS framework does not intend to offer solutions to any of these issues but does assume that innovators are only motivated by clinical improvement. NASSS may expose issues of trust between individuals, organisations and institutions as this study has, the hope is that collaborative working and stakeholder involvement can overcome some of these issues (221). The devastating impact of COVID-19 on UK healthcare is current, it will continue to have an impact on future healthcare provision and therefore innovation and implementation for decades

to come. The data analysis from the pre-pandemic interviews presented in this PhD are difficult to apply to the current healthcare landscape. The study of implementation and complexity is not static, it must be considered as dynamic and in perpetual motion, it requires a pragmatic, creative and agile approach. The rapidity with which new technologies were adopted in healthcare during COVID-19 was admirable. Innovators need to reflect on the consequences of taking short cuts when pursuing the implementation of healthcare innovations, there will be inevitable deficits in user training, patchy uptake and differences in the response to the evolving role of the technology in clinical practice (222). There is already experience of using ORLHC and this should be harnessed for any of its future iterations.

This research has highlighted many areas requiring attention before any future use and application particularly in primary care of the statistical model underpinning ORLHC. Neglecting preimplementation stages which include the design, development and pilot use of web-based decision tools can lead to a failure to implement, embed, and sustain a well-intended technological innovation. The path to implementation is not as simple as launching a web-based calculator. Bonner et al (223) explain that attention must even be given to the how a web-based decision tool is presented to and therefore received by the target audience which can only be achieved with stakeholder involvement at the design stage.

There are opportunities to improve the interface between primary and secondary care in the suspected HNC pathway and in the triage of patients with non-suspicious symptoms into a more appropriate pathway than a suspected cancer one particularly when it comes to visible lesion which can be photographed. There are examples of successful adaption of existing communication methods to enable opticians to communicate with secondary care (ophthalmologists) about patients. This enables opticians to access specialist opinion of images (retinal), management plans and referrals. Opticians in London used a cloud based digital first referral process to send clinical and image information to consultant ophthalmologists based at Moorfields Ophthalmology hospital eye services

(224). The trial had a small number of patients (107) but showed that unnecessary referrals could be reduced by half. The cloud-based system allowed consultants to communicate decisions about outcome of referral with both patients and opticians.

More applicable to the gap in GDP and OMFS communication issues as identified in this thesis, a Malaysian iPhone application (Mobile Mouth Screening Anywhere (MeMoSA®) described as a "storeand- forward telemedicine tool allows the documentation of clinical data and images and facilitates communication between healthcare professionals". It was successfully used to make referral decisions and had comparable sensitivity and specificity to clinical examination outcomes for 280 oral lesions (225). The use of MeMoSA® was positively received by those dentists and OMFS interviewed in a qualitative study (226).

For some cancers, the largely symptom based suspected cancer referral pathway of the early 1990's has been supplemented with screening tests which can be accessed by primary care and add to the positive predictive risk of the referral. The use of ultrasound and tumour markers for suspected ovarian cancer and faecal immunohistochemical testing in suspected colorectal cancer mean some risk stratification can be applied to referrals. Unfortunately, there is no reliable, economically viable screening test for HNCs (ultrasound practice is inconsistent and use leads to delays in referrals). There is ongoing work in the NHS (227) to see whether a blood test, which was developed on samples from patients with and without a proven cancer (a variety of cancer types), can accurately identify signals in the blood of those without symptoms of cancer. The hope is that it can be used as a screening test eventually. There remains no reliable laboratory test for HNC but work on artificial intelligence, screening bloods tests are in development (228). It is hoped that a machine learning algorithm which combines the results of simple routine blood tests commonly performed in primary care with patient demographic information might have potential to accurately predict for symptomatic patients, those most likely to ultimately receive a cancer diagnosis. It is hoped that this will provide information from easily accessible blood tests in primary care to help inform decisions about referrals on a suspected

cancer pathway (229). Until such time as these are tested and reliable the problem remains that the HNC TWW pathway is one with a high referral low cancer yield, a problem to which a solution remains elusive. Whilst the research is underway to establish targeted primary care screening tests (228), improvements in the interface between primary and secondary care should be better exploited to manage the demands on HNC services.

Some issues with primary care clinicians' compliance with suspected cancer referral criteria (15) have been identified, there are occasions that despite a patients' signs or symptoms meeting the criteria for referral they are not referred. This contributes to concerns that opportunities for referral and subsequent earlier diagnosis are being missed. Until a time when risk stratification for HNC is easier in primary care these complex decisions will continue to be based on clinical signs, clinician gut instinct and the interpretation of symptoms. Risk prediction should be based on a combination of clinical acumen, gut instinct, and risk factors in discussion with a specialist. There have been huge changes in how healthcare is delivered, how primary and secondary care communicate and adaptations to the ongoing challenges from the changes made in response to COVID-19. The time is ripe with impetus (particularly from secondary care for whom the burden on resources is felt so keenly) to improve communication between primary and secondary care regarding decisions about individual patient risk of cancer. As it is evident from the thesis GPs are aware of the ever-present possibility of a missed diagnosis of cancer but admit a lack of familiarity with the details of the referral criteria for every type of cancer. There are a number of NHS organisational issues which influence how aware primary care clinicians are of updates in and access to the two-week wait referral pathway and how this influences referral behaviour some of which have been highlighted in the data presented in this thesis. Particular concerns identified in an editorial centre around organisational culture (230), which reflects some of the issues around the inconsistent application of NG12 and subsequent regional variations in HNC referral criteria. This has potential for healthcare inequity because of the unintended impact on primary care ability to respond to and make referral decisions about potential red flag signs and symptoms.

Contribution

This is the first study which synthesises the qualitative research exploring GPs experience of using CCDTs in primary care. This thesis comprehensively explores the factors that determine their implementation and use to shape the consideration of a new CCDT for HNC.

These are the first interviews with clinicians both GPs and HNSs about a symptom decision aid for individualised risk of HNC. This study combines ex ante and ex post exploration of the complexity of the context within which ORLHC was planned and then actually deployed for use by specialists during COVID-19. It is the first study which discusses whether there is a need for a decision aid as part of the suspected HNC pathway in the UK, where it would be best utilised, how it might be received by primary care clinicians and what contextual factors frame its future development and potential roll out.

Strengths

The qualitative interviews included several HNS who contributed interviews to both sets of interviews, one before the pandemic and another during the pandemic, three of these had used the ORLHC one had not. This study presents valuable data about the theoretical use of ORLHC in the year prior to COVID-19 and the realities of remote assessment with and without the use of ORLHC.

The use of the NASSS framework in this research allowed discussion of some of the competing factors and entrenched behaviours which could make a future implementation of the ORLHC into primary care untenable. The complexities revealed through analysis of the data may not be surprising but without thought to how they might be tackled make any moves to use a decision tool in this way and in this environment impossible. CCDTs developed from primary care in England have been poorly adopted across the primary care setting for which their use is intended. Another CCDT in this context will doubtless fail without addressing the challenges faced by previous activities to try and establish their use by GPs in the recognition and referral of suspected cancers.

The ORLHC was used during COVID-19, but not in the way it had originally been intended. It is difficult to directly extrapolate the findings to conclude that it could categorically not be used in primary care

but there were challenges to its use by specialists which would be difficult to overcome by nonspecialist users.

Triangulating and interpreting the data in a reflexive manner by an individual who can see the problems from both clinical perspectives involves the inherent biases of the researcher. I consider that I have experience working in a system which is incredibly demanding for secondary care and where I can recognise that a binary outcome (cancer present or not) is not particularly helpful for patients nor their GP to understand and manage their symptoms. From my experience working in primary care, I know that GPs find ENT and oral medicine challenging and that without access to fibreoptic nasendoscopy even my threshold to refer patients with symptoms which are suspicious for a cancer is lower than I would have expected given the experience I claim to have from seven years in ENT. I recollect my own vocal complaints as an ENT surgical trainee about the quality of the primary care referrals to the suspected cancer clinics and I now have a greater empathy and understanding of the challenges from both perspectives. Ultimately, though, there is a patient who needs a diagnosis, an explanation and sometimes a management plan whether a cancer is present or not.

The pre-COVID-19 data is limited to one English region within which all clinicians work with the referral criteria recommended by NICE NG12 from 2015. The data collected from HNS were all working in tertiary referral centres and includes only three OMFS therefore there is no data from any clinicians working in district general hospitals.

Limitations

The analysis would have benefitted from the inclusion of data from GDPs as they are an important stakeholder in the HNC TWW pathway. Recruitment of GDPs proved difficult and was made harder by the timing which was in the early pandemic period when dental practitioners were faced by huge challenges to their working practices. Any future work needs to include the views of this group and the obstacles they encounter using the TWW referral pathway and issues associated with communicating with hospital colleagues about their referrals to hospitals. GDPs have markedly different patient electronic records systems and seem to use rudimentary means of communication with secondary care as the limited data from OMFS surgeons interviewed suggests. Other groups with whom further researchers in this area should consult are advanced nurse practitioners and physician associates who are increasingly working alongside qualified doctors in clinical assessment and referral of patients to secondary care.

The patient participants were all white North Easterners, all of the HNC patient participants presented with neck lumps and do not represent the wide range of HNCs that are diagnosed in England and which informed the development of ORLHC. The PCPI participants, each with their own medical conditions, were drawn from a University active group involved in communication training for a wide range of healthcare undergraduate training and research activities. This group was used to talking to and about interactions with healthcare professionals and represents a distinct informed and motivated part of the local patient population.

Reflections

The PhD experience was filled with practical, logistical, and organisational challenges. I could not have predicted nor was I prepared for the parts of the PhD plan I would have to abandon, adapt, and then accommodate into the thesis. I now think all the aspects of the PhD plan that I had hoped to complete at the start were never realistically achievable in the time and with the resources available whether or not the pandemic had occurred.

As a mature student, I have well-developed skills which include organising independent work, determination, and tenacity. All these skills were essential at times during the PhD. Keeping the data collection and writing on track has been helped by having regular communication with Dr Gregory Maniatopoulos through the pandemic. He and I maintained remote supervision fortnightly with ongoing critique of my work, discussion of the philosophical standpoints underpinning research and particular emphasis on implementation science.

The PhD had its many challenges including, inevitably, the impact of COVID-19. I do not shy away from asking for help, this I had to do on several occasions and from several sources. Luckily, over the years, I have had input and encouragement from a variety of academic and clinical mentors. These connections mean that I have had opportunities to get support for the PhD work and do some research work alongside the PhD, which have provided opportunities for future work around the suspected HNC pathway (see *Appendix L*).

The most frustrating and disappointing part of the PhD was the guantitative element of the work that I had to abandon. The intention at the outset of the PhD was to do some predictive statistical modelling of the signs and symptoms of HNC using a database of electronic primary care records. After extensive exploration of the expensive options to access primary care data in England, I successfully negotiated to access data from The Health Improvement Network (THIN) database with assistance from academics at the University of Birmingham. I applied for and was granted money from BAHNO and Oracle Cancer to purchase the data and I found a local academic statistician with the relevant statistical multivariable predictive modelling expertise to support the work. Unfortunately, physical access to the data required a visit to Birmingham which was planned for late 2019 then postponed to early 2020. This was not possible firstly because I had knee surgery just before Christmas 2019 and then as the result of COVID-19 and subsequent March 2020 lockdown. Travel was delayed and though options for remote work was possible it became apparent that the work was not going to be feasible given the time restrictions for completion of the data collection. I returned both grants and explained to all involved that it was not possible to complete this aspect of the work. Fortunately, I was able to expand the scope of the qualitative work because of the work done by ENTUK in use of the ORLHC in telephone triage.

Data Collection, Participant Recruitment and Qualitative Interviews

My background made working with Head and Neck departments in the recruitment of surgeons for interviews and even recruitment of patients in two of the NHS recruitment centres relatively

straightforward. I recruited surgeons to interview with ease and all were keen and enthusiastic about the project (self-interest and a sympathetic, familiar interviewer were likely reasons). I had heard about frustrations in recruitment efforts and initially I was delighted in how easy it seemed to be. This was not the case in the recruitment of GPs, and it meant that I did have to interview clinicians with whom I had worked and trained because it was so challenging to recruit despite my best efforts. There was willingness to at least offer up an email address to contact for recruitment following some local training sessions about "dizziness" and 21 GPs supplied their details for contact to arrange an interview. I only managed to recruit one GP via this route. I think this reflects the low clinical priority this area of primary care practice for GPs (HNC), at least in terms of clinical priorities which I can understand and sympathise with given the minor place it has in the day-to-day operation of general practice.

The realities of the workload pressures and the fact that there were no financial incentives that I could offer for GP's time were likely factors in the difficultly recruiting from this group and should not be underestimated. Without primary care input, any efforts to improve healthcare delivery is likely to face obstacles and possibly even resistance and only including those with an interest in a particular field likely leads to bias driven by an unrealistically optimistic perspective.

Dental recruitment was challenging in a different way, it was a group which naturally refer to head and neck two-week wait clinics but in often a much more rudimentary manner, often writing letters or filling in forms in biro and faxing to the head and neck department. The recruitment effort was hampered by COVID-19 and the massive impact on dental surgeries and after one interview it was quite clear that the interviews could not proceed in quite the same way as the GP and head and neck surgeon ones. I decided early in the pandemic that pursuing this group was going to be difficult, the impact on their work and threat to their businesses was so large that I considered recruitment would fail. The adaption to the tool for use by head and neck departments to triage their two-week wait referrals appeared a more useful addition to the data that I had, and, in the end, the maxillofacial surgeons did not use the triage tool during the pandemic implying that its utility for dentists may be equally limited.

I found that a lot of the patient participants wanted to talk about their experience as a patient, it was not always easy to keep them focused on the questions that I had initially planned and wondered if the participant information had been digested before agreeing to interviews. This was challenging for me to negotiate but sometimes meant that an interview was more akin to a conversation about their cancer treatment journey which on reflection was probably more comfortable and familiar for me as well as the participants. Valuable insights came from these conversations though perhaps not in relation to the use of the ORLHC. I think if I did something like this in future work, focus group work prior to an individual interview would be a more fruitful exercise.

I wrongly assumed that patients would be able to talk about the use of decision aids by GPs in the management of their own healthcare but in fact they had little to no knowledge or experience of these. This demonstrated my own bias and my own clinical practice preferences. The PCPI participant group was small, but research savvy, all had chronic diseases and reasonably regular contact with GPs but there was still a lack of knowledge, understanding and experience with clinical decision tools. This was a surprise to me given my own perspective that clinical decision tools are ubiquitous and used frequently within my own clinical practice. I think that I use and share that I am doing so with patients on a regular basis. This apparent disconnect between my bias and the participant experience could reflect personal preference, training, education, or knowledge gaps within practice or just simply that patients are not aware or interested in certain aspects of their clinical consultation. There is certainly evidence from studies suggesting that even when a GP used a clinical cancer decision tool with a patient to make a referral decision about a skin lesion those patients interviewed following the consultation had no recollection that any aid had been used by the doctor to assist in the decision (196). Some of the questions that I had as a researcher were driven by my experience in primary care and ENT and were not always relevant or of interest to the patient participants.

I found that the patient interviews were the most difficult for me and this may have been my lack of experience in this area, poor choice of method, questions, and subject matter. Public patient involvement is crucial to research, and I do appreciate that but often those that volunteer to take part are "seasoned" contributors with their own agenda, be that promoting knowledge and understanding of a particular disease process, communication skills or because they a driven by altruism. There are important voices in HNC that are difficult to reach/hear, those who present late, those who have frequent consultations with their GPs before referral (a delayed diagnosis) and those who present as an emergency, in a project particularly small in scale like this one it is difficult to access these participants.

As a clinician I am used to having difficult conversations with people, the skills of a qualitative interviewer are different to these clinical communication skills. I found this when I was interviewed myself for a project about pharmacists. The experienced qualitative interviewer had what I considered quite a formal approach, I found that there was little affirmation of what I was saying, few non-verbal cues and I found it rather disconcerting despite this being in a face-to-face setting prior to the pandemic, this is subjective and related to an individuals' previous experience and skills. It made me realise that I had a very different approach in the interviews I was conducting. I found it very difficult to act in this seemingly detached formal manner with an interview participant. This may come from the hard-wired communication skills from my clinical experience or the personal interest and enthusiasm I have for the topic that I found it difficult to present a detached manner. It is possible to be objective up to a point, my experience informs my perspective but as a doctor my overriding principle is encouraging the patient narrative by a variety of means.

Impact of Covid 19 on PhD

I have already mentioned COVID-19 several times and its impact on my PhD journey. Covid-19 has reshaped, revolutionised and reconfigured how healthcare is delivered in the NHS in the most

dramatic way and working within this was challenging and exhausting whilst navigating my own personal response to the pandemic.

For my part, COVID-19 unfolded whilst on sick leave following an unanticipated three months off clinical work following a knee operation that left me on crutches from December 2019. I attempted to put my efforts into my PhD work whilst off but following the pandemic unfolding in China, Italy and rest of the world on the television, twitter and internet news channels predominated most of my waking semi-mobile hours. When I returned to work following recovery from the operation, I requested to return in a full-time capacity such was the need to contribute to the healthcare response. During this time, though difficult, I tried to keep things moving with the administration of the PhD, moving the NHS ethics process forward, editing a rejected manuscript and keeping my funders and university up to date.

In the early days of the pandemic there were tremendous moves within the NHS to transform delivery of healthcare and this was no different in how specialists approached the delivery of the suspected HNC pathway. The original referral decision tool (ORLHC) had already been updated with new patient data, further categories like smoking and alcohol and some of the sign and symptom questions had been further refined. With these amendments in place and in response to the pandemic, the Head and Neck division of ENT-UK launched a triage tool for clinicians to use remotely with patients referred from primary care under the two-week wait suspected HNC pathway. Forty-one centres which received suspected HNC referrals decided to use the triage tool to determine the next steps for their patients in the suspected cancer pathway. Clinicians committed to record and submit the data to a central repository about the patient outcomes at six months. This innovative work gave me the idea to interview specialists who had used ORLHC to supplement the qualitative work already undertaken for the PhD.

The recruitment of HNC patients was made more difficult, of course, given COVID-19 as all non-COVID-19 research within hospital Research and Development (R&D) was deprioritised, some of the R&D offices stopped responding to emails, fortunately two of the hospitals continued respond and assisted me to make contact and recruit patients who were keen to talk about their own HNC pathway experience.

The interviews that I had intended to complete face to face, like most everything else during COVID-19 had to move to a remote media platform. Telephone and video interviews were organised. As someone who regards communication as one of the essential and defining characteristics of a "good doctor", remote communication is a challenge, I missed non-verbal cues, even on video interpretation of body language is altered when compared to a face-to-face encounter. It was challenging to create a rapport with people over the telephone or via video, particularly with those who are essentially strangers with whom you are hoping to stimulate discussion about a sensitive subject like cancer diagnosis. Fortunately, I had to get used to using remote methods of communication within my clinical work earlier than for my research work so when it came to remote interviews, I had some points of reference from my experience having to apply total triage to the assessment of patients in primary care.

I think the most important lesson that I have learned from this experience is that engaging healthcare stakeholders in implementation design from the outset of a project seems the most productive approach to any improvement in healthcare delivery. A thoughtful approach to project prior to and during its design as well as the intention to study its implementation offers more opportunity to anticipate issues of complexity which might be crucial in determining the success or failure of a project (whatever success and failure means). A multidisciplinary co-productive approach which includes engagement from those with experience of the actual practicalities of delivery and receipt of the healthcare which is the subject of the change as well as those reliant on the work to drive their research/academic/political agenda is more likely to make demonstrable improvements to healthcare

delivery at a local and national level. The gulf between primary and secondary care clinicians both in clinical as well as academic pursuits is detrimental to the future of improving patient referral pathways particularly when it comes to suspected cancer. I believe there are opportunities to improve this, by building trust and mutual respect between the two groups for the benefit of patients. Because of the way healthcare delivery has had to adapt in response to COVID-19 means that in some areas there are opportunities to harness improvements in communication and build relationships.

My clinical position is now firmly in primary care but there is no doubt that my years of experience in secondary care ENT has been a huge influence on my perspective when it comes to the issues around the recognition and referral of suspected HNC.

Relationship with Participants

Having worked as both a doctor in ENT and General Practice I have knowledge of the pressures on both systems from the drive for early diagnosis of cancer. I have been the secondary care clinician in the suspected HNC two-week wait clinics receiving referrals and completing assessments of patients. I have worked in the primary care setting as a GP where clinicians, overall, have minimal training in HNC signs and symptoms, but must make timely and safe clinical assessment of patients.

I knew almost all of the head and neck specialist participants professionally because of my work as an ENT surgical trainee in the North East. One of the developers of the ORLHC was one of the PhD supervisors, had worked as a consultant head and neck surgeon in the region, had been one of my surgical trainers and with whom I had written and published academic work. Statistical modelling underpinning the predictive risk calculations of the tool used data from outpatient referrals to one of the regions hospitals so some of the participants will have been familiar with the online tool prior to the invitation to participate in an interview. These aspects may have made recruitment to this part of the qualitative study somewhat more straightforward, and this may have influenced the positive responses to invitations. This relationship between the interviewer and the participants may have subconsciously affected the manner of the questions were posed as well as the responses despite the

efforts to maintain a degree of neutrality. The use of ORLHC during COVID-19 was promoted and endorsed by the BAHNO and the supervisor who was involved in its development was a member of the council at the time. His role and reputation influenced the take up of ORLHC and the successful recruitment of specialists to talk about their experience, but he was not involved in any of the analysis of the interview data in this thesis.

Methods

In an ideal world, I would have preferred to carry out an ethnographic study of GP and GDP clinical consultations with patients with signs and symptoms of HNC to observe the interactions between doctors and patients. This type of study would allow an observation of any discussion with a patient about the individual risk of cancer, discussion about diagnosis, management, and referral decisions to a suspected cancer clinic. To conduct a study like this would be difficult given the rarity of episodes where a GP/GDP encounters a suspected HNC but would be fascinating, nonetheless.

Interestingly all the HNC patients that I interviewed presented to their GP with a neck lump and all had timely referrals in response to their consultation. In cases where there is not a physical finding a prompt referral is not always timely because the significance of the symptoms is not recognised or is misinterpreted. Some patients often have suspicious symptoms long before the appearance of a neck lump meaning that their disease has sometimes progressed beyond the early stages where it is more amenable to less toxic function altering treatment. These HNC patients however are notoriously more difficult to recruit for research purposes.

I think that focus groups with patient participants using vignettes or videoed actor role plays of clinical consultations using the ORLHC would have been one way of stimulating discussion about the potential role of a decision tool for HNC. This type of approach may also have been more appropriate for the general practitioners, who overall had limited experience of and with both HNC and CCDTs. It was perhaps naïve of me to discuss a theoretical prospect (the use of a CCDT) rather than something with which the participants had real life experience. Had the ethics process been less onerous I would have

considered interviewing some patients who had been involved in the remote assessment undertaken during the pandemic when HNS were using the ORLHC. I did consider this at the time and discuss it with my supervisory team, however, it unfortunately coincided with difficulties with the statistical data aspect, and I chose to concentrate on completing the work with the data I already had rather than take on further work which I now consider was the right thing to do.

It is beyond the scope of this thesis to unpick the regional differences in criteria, but this was quite eye opening for me. Before the start of the PhD, I was aware that NG12 criteria had not widely been adopted by HNC departments, but I had thought this was a lag time effect. Recommendations from NICE often take months to years to filter through to clinical practice but even by 2020 when the pandemic started there was wide variation around the country in terms of the criteria for referral for suspected HNC.

Implications for practice and policy

CCDTs have not been adopted in general practice despite work in this area over the past two decades, it is maybe time to stop persuing this as a solution to the problem of early recognition and referral of cancer. As a concept decision aids work in particular clinical contexts, ones which are much more common and clinically familiar than HNC like atrial fibrillation and deep vein thrombosis. Even for more common cancers like colorectal and upper gastrointestinal GPs use referral guidelines over using the RAT or QCancer so the likelihood of using one in a rarer clinical problem are at best optimistic. CCDTs appear to be regarded as a duplication of the TWW referral criteria rather than an adjunct to clinical decision making. The integration of CCDTs into primary care has not been predicated on any evidence that they work in this context and lack consultation with or acceptance from secondary care to whom the referrals are made. It may be time to cease researching this area, which appears to be fraught with integration and implementation issues. It is time to stop attempting to make them work in the context of primary care recognition and referral of suspected cancers. There is a gulf between primary and secondary care but communication options like A&G do not appear to be utilised enough in the arena of suspected cancer. This may be particularly pertinent for a high referral low yield cancers where the clinical context does not have a prereferral laboratory test to use in order to triage according to priority on the horizon.

Any intervention to influence referral patterns, communication options or to change clinical behaviour needs to be; designed with input from stakeholders (including patients, clinicians and those in management) from the ground upwards, integrated with consideration to working practices and trialled by those who will be expected to use it. An intervention which is viewed purely from the secondary care perspective but is expected to fit into alien working practices, clinical priorities, safety netting, balance of risk and clinical need is doomed to fail. Stakeholder consultation and collaborative work should be considered the only way to explore ways to change healthcare pathways in the future.

The inevitable outcome of lowering the tresholds for referral to achieve the early recognition and diagnosis of cancer targets has been that secondary care resources and allocation have become skewed towards providing this service. The target driven system, which under current pressures are not being met at the same levels as pre pandemic, has an impact on routine provision of hospital services. The fines and targets associated with providing two week wait out patient appointments should be reconsidered in the current climate. Investment in workforce and training including allied health professionals with the requisite skills to complement the medical workforce to meet the challenges of the volumes of suspected cancer referrals should not be pursued at the detriment of other services. More triage where the referrals are received might have to become the norm to enable better management of the flow of patients to the right clinician. If communication between primary and secondary care is not improved this will create difficulties in the clinician patient relationship in primary care where managing expectations and risk are different to the hospital setting. The current situation has potential to revert suspected cancer referrals to the pre TWW state where referrals were

downgraded, with the proposed reduction in thresholds hospital consultants may find it difficult to avoid some sort of triage in the face of increasing volumes of referrals.

Public health campaigns about cancer are predominantly related to recognising and seeking help for persistent symptoms and lifestyle factors which can increase likelihood of developing a cancer in the future. Opportunities exist to educate the public to increase understanding and communication about their personal risk.

Future research will inevitably assess the impact of NG12 guidelines on the early recognition and diagnosis of cancer and results will have implications for future policy, this needs to be interpreted with caution as there are regional differences in referral criteria and improvements or a deterioration cannot be solely attributed to the changes recommended in 2015.

Early cancer recognition and referral is subject to knowledge, understanding, interpretation, tumour types, site, population and local service issues and is far more complicated to implement and assess than a broad policy is able to capture and should good practice should ideally be analysed and shared for the benefit of the whole system.

Current and Future Research

I have been involved in several projects related to the suspected HNC pathway while completing this PhD. One project I have been part of was being involved in an NIHR programme grant which was submitted in April 2020. This grant for £3 million was successful and is called EVEREST-HN (Evolution of a patient-Reported symptom-based risk stratification system to redesign the suspected HNC referrals pathway). This project aims to develop and implement a patient questionnaire which will help secondary care clinicians manage patients referred from primary care as a suspected HNC. I will be a part of this six-year programme grant, initial work will involve leading a scoping review of signs and symptoms of HNC.

I have worked alongside a professor of speech and language therapy based in Liverpool University (Jo Patterson) to design, distribute, analyse, and publish a questionnaire to UK based speech and language

therapists working in head and neck. This questionnaire was designed to explore the potential development of speech and language therapist led low risk clinics to assess patients referred as suspected HNC. As a result of this work, a working group was formed; we aim to use qualitative interviews to understand perspectives of Head and Neck and Upper GI cancer specialists and members of the multi-disciplinary team, on developing a Speech and Language Therapy Low Risk Two-Week Wait Head and Neck Cancer Clinic (SLTLR-TWW). We were successful in securing a £3,000 grant from BAHNO and have started interviewing consultant HNS.

I have been awarded a grant from North of England Commissioning Support (NECS) to work on a codesign project bringing together clinicians and patients to design a prototype communication portal. The aim of this is to enable primary care clinicians to communicate with their secondary care colleagues to discuss and share information and images about possible suspected HNC patients prior to making a referral. This work will involve focus group work, followed by some co-design work to develop a communication platform which could be used as the basis for a future grant application. This will be a North East regional project, the application is supported by Professor of Cancer Epidemiology (Linda Sharp), Senior Lecturer and HNS (James O'Hara) and a Research Assistant (Jennifer Deane) all of whom share an interest in improving the suspected HNC pathway.

CHAPTER 11: CONCLUSIONS

The pre-implementation data presented in this thesis does not support a proposition that ORLHC is currently an option for use as a primary care CCDT for HNC. It does not appear that in its current form ORLHC can be easily or effectively implemented for use in primary care. The research experience of GP use of CCDTs for other types of cancer shows that at the practice level implementation is very challenging and there has been lack of engagement with CCDTs beyond the publication of the results of relevant research projects. To be successful a CCDT like ORLHC needs to be compatible with existing guidelines and benefit from approval for use from NHSE. ORLHC as it is currently presented is unlikely to alter how primary care recognise and, more importantly, interpret signs and symptoms suspicious of HNC particularly considering the experience of the specialists who used it during COVID-19. ORLHC, without a substantial improvement on how it is presented and is integrated into electronic health records, is unlikely to impact on the way GPs currently use the referral pathway. There is neither the clinical nor financial imperative from primary care (GPs, the CCGs) to invest in this work. A change to the suspected HNC pathway is not recognised as having any potential or discernible impact on primary care clinical or financial priorities. Assumptions about the ability of primary care to successfully use a clinical risk prediction (developed by specialists with their inherently different perspectives and clinical experience) were challenged by the specialist experience using ORLHC as part of their remote assessment.

Despite the identified constraints related to using ORLHC for all types of HNC and by all types and seniority of ENT, several specialists remained optimistic about its application in primary care exposing their lack of appreciation about how well primary care clinicians use existing risk prediction tools and how comfortable they feel practicing in this field. Exploration of the context within which head and neck specialists anticipated the implementation of ORLHC demonstrates that this intervention is not the perfect solution to the problems specialists associate with the way the suspected HNC referral pathway works. The impetus for change comes from secondary care who must contend with the

cancer targets burden. Some form of triage at the point of referral acceptance in secondary care is likely to continue following the COVID-19 experience of using ORLHC. Opportunities remain to improve the communication between primary and secondary care about potential suspected cancer cases prior to sending a referral and to explore the contribution of a patients' own account of their symptoms in combination with the ORLHC data to aid clinical triage and therefore urgency of assessment.

REFERENCES

1. NHS Long Term Plan 2019 [Available from: <u>https://www.longtermplan.nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.pdf</u> last accessed 1st May 2022].

2. Hardman JC, Tikka T, Paleri V, Ent Uk B, Integrate. Remote triage incorporating symptom-based risk stratification for suspected head and neck cancer referrals: A prospective population-based study. Cancer. 2021;127(22):4177-89.

Jones R, Rubin G, Hungin P. Is the two week rule for cancer referrals working? BMJ. 2001;322(7302):1555 6.

4. Banks J, Hollinghurst S, Bigwood L, Peters TJ, Walter FM, Hamilton W. Preferences for cancer investigation: a vignette-based study of primary-care attendees. Lancet Oncol. 2014;15(2):232-40.

5. Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS 2011 [Available from: http://www.institute.nhs.uk/images//documents/Innovation/Innovation%20Health%20and%20Wealth%20-%20accelerating%20adoption%20and%20diffusion%20in%20the%20NHS.pdf last accessed 1st May 2022].

6. Barraclough K. New NICE guidance on referral for cancer. BMJ. 2015;351:h3640.

7. Moore SF, Price SJ, Chowienczyk S, Bostock J, Hamilton W. The impact of changing risk thresholds on the number of people in England eligible for urgent investigation for possible cancer: an observational cross-sectional study. Br J Cancer. 2021;125(11):1593-7.

8. Shephard EA, Parkinson MA, Hamilton WT. Recognising laryngeal cancer in primary care: a large case-control study using electronic records. Br J Gen Pract. 2019;69(679):e127-e33.

9. Ho KMA, Banerjee A, Lawler M, Rutter MD, Lovat LB. Predicting endoscopic activity recovery in England after COVID-19: a national analysis. Lancet Gastroenterol Hepatol. 2021;6(5):381-90.

10. Swann R, McPhail S, Witt J, Shand B, Abel GA, Hiom S, et al. Diagnosing cancer in primary care: results from the National Cancer Diagnosis Audit. British Journal of General Practice. 2018;68(666):E63-E72.

11. Moller H, Gildea C, Meechan D, Rubin G, Round T, Vedsted P. Use of the English urgent referral pathway for suspected cancer and mortality in patients with cancer: cohort study. BMJ. 2015;351:h5102.

12. Round T, Gildea C, Ashworth M, Moller H. Association between use of urgent suspected cancer referral and mortality and stage at diagnosis: a 5-year national cohort study. Br J Gen Pract. 2020;70(695):e389-e98.

13. Herbert A, Abel GA, Winters S, McPhail S, Elliss-Brookes L, Lyratzopoulos G. Cancer diagnoses after emergency GP referral or A&E attendance in England: determinants and time trends in Routes to Diagnosis data, 2006-2015. Br J Gen Pract. 2019;69(687):e724-e30.

14. Murchie P, Smith SM, Yule MS, Adam R, Turner ME, Lee AJ, et al. Does emergency presentation of cancer represent poor performance in primary care? Insights from a novel analysis of linked primary and secondary care data. Br J Cancer. 2017;116(9):1148-58.

15. Wiering B, Lyratzopoulos G, Hamilton W, Campbell J, Abel G. Concordance with urgent referral guidelines in patients presenting with any of six 'alarm' features of possible cancer: a retrospective cohort study using linked primary care records. BMJ Qual Saf. 2021.

16. Hardy V, Yue A, Archer S, Merriel SWD, Thompson M, Emery J, et al. Role of primary care physician factors on diagnostic testing and referral decisions for symptoms of possible cancer: a systematic review. BMJ Open. 2022;12(1):e053732.

17. Hamilton W. The CAPER studies: five case-control studies aimed at identifying and quantifying the risk of cancer in symptomatic primary care patients. Br J Cancer. 2009;101 Suppl 2:S80-6.

18. Rubin G, Walter F, Emery J, Neal R, Hamilton W, Wardle J. Research into practice: prompt diagnosis of cancer in primary care. Br J Gen Pract. 2014;64(625):428-30.

19. Dommett RM, Redaniel T, Stevens MC, Martin RM, Hamilton W. Risk of childhood cancer with symptoms in primary care: a population-based case-control study. Br J Gen Pract. 2013;63(606):e22-9.

20. Hamilton W, Kernick D. Clinical features of primary brain tumours: a case-control study using electronic primary care records. Br J Gen Pract. 2007;57(542):695-9.

21. Hamilton W, Peters TJ, Bankhead C, Sharp D. Risk of ovarian cancer in women with symptoms in primary care: population based case-control study. BMJ. 2009;339:b2998.

22. Hamilton W, Peters TJ, Round A, Sharp D. What are the clinical features of lung cancer before the diagnosis is made? A population based case-control study. Thorax. 2005;60(12):1059-65.

23. Hamilton W, Round A, Sharp D, Peters TJ. Clinical features of colorectal cancer before diagnosis: a population-based case-control study. Br J Cancer. 2005;93(4):399-405.

24. Hamilton W, Sharp DJ, Peters TJ, Round AP. Clinical features of prostate cancer before diagnosis: a population-based, case-control study. Br J Gen Pract. 2006;56(531):756-62.

25. Price SJ, Shephard EA, Stapley SA, Barraclough K, Hamilton WT. Non-visible versus visible haematuria and bladder cancer risk: a study of electronic records in primary care. Br J Gen Pract. 2014;64(626):e584-9.

26. Shephard EA, Neal R, Rose P, Walter F, Hamilton WT. Clinical features of kidney cancer in primary care: a case-control study using primary care records. British Journal of General Practice. 2013;63(609):E250-E5.

27. Shephard EA, Neal RD, Rose P, Walter FM, Litt EJ, Hamilton WT. Quantifying the risk of multiple myeloma from symptoms reported in primary care patients: a large case-control study using electronic records. British Journal of General Practice. 2015;65(631):E106-E13.

28. Shephard EA, Neal RD, Rose PW, Walter FM, Hamilton WT. Quantifying the risk of non-Hodgkin lymphoma in symptomatic primary care patients aged >= 40 years: a large case-control study using electronic records. British Journal of General Practice. 2015;65(634):E281-E8.

29. Shephard EA, Neal RD, Rose PW, Walter FM, Hamilton WT. Quantifying the risk of Hodgkin lymphoma in symptomatic primary care patients aged >= 40 years: a case-control study using electronic records. British Journal of General Practice. 2015;65(634):E289-E94.

30. Stapley S, Peters TJ, Neal RD, Rose PW, Walter FM, Hamilton W. The risk of pancreatic cancer in symptomatic patients in primary care: a large case-control study using electronic records. Br J Cancer. 2012;106(12):1940-4.

31. Stapley S, Peters TJ, Neal RD, Rose PW, Walter FM, Hamilton W. The risk of oesophago-gastric cancer in symptomatic patients in primary care: a large case-control study using electronic records. Br J Cancer. 2013;108(1):25-31.

32. Walker S, Hyde C, Hamilton W. Risk of uterine cancer in symptomatic women in primary care: case-control study using electronic records. British Journal of General Practice. 2013;63(614):E643-E8.

33. Walker S, Hyde C, Hamilton W. Risk of breast cancer in symptomatic women in primary care: a case-control study using electronic records. Br J Gen Pract. 2014;64(629):e788-93.

34. Bailey SER, Ukoumunne OC, Shephard E, Hamilton W. How useful is thrombocytosis in predicting an underlying cancer in primary care ? a systematic review. Family Practice. 2017;34(1):4-10.

35. Bailey SER, Ukoumunne OC, Shephard EA, Hamilton W. Clinical relevance of thrombocytosis in primary care: a prospective cohort study of cancer incidence using English electronic medical records and cancer registry data. British Journal of General Practice. 2017;67(659):E405-E13.

36. Hippisley-Cox J, Coupland C. Identifying women with suspected ovarian cancer in primary care: derivation and validation of algorithm. BMJ. 2011;344:d8009.

37. Hippisley-Cox J, Coupland C. Identifying patients with suspected lung cancer in primary care: derivation and validation of an algorithm. Br J Gen Pract. 2011;61(592):e715-23.

38. Hippisley-Cox J, Coupland C. Identifying patients with suspected gastro-oesophageal cancer in primary care: derivation and validation of an algorithm. Br J Gen Pract. 2011;61(592):e707-14.

39. Hippisley-Cox J, Coupland C. Identifying patients with suspected renal tract cancer in primary care: derivation and validation of an algorithm. Br J Gen Pract. 2012;62(597):e251-60.

40. Hippisley-Cox J, Coupland C. Identifying patients with suspected pancreatic cancer in primary care: derivation and validation of an algorithm. Br J Gen Pract. 2012;62(594):e38-45.

41. Hippisley-Cox J, Coupland C. Identifying patients with suspected colorectal cancer in primary care: derivation and validation of an algorithm. Br J Gen Pract. 2012;62(594):e29-37.

42. Hippisley-Cox J, Coupland C. Symptoms and risk factors to identify women with suspected cancer in primary care: derivation and validation of an algorithm. Br J Gen Pract. 2013;63(606):e11-21.

43. Hippisley-Cox J, Coupland C. Symptoms and risk factors to identify men with suspected cancer in primary care: derivation and validation of an algorithm. Br J Gen Pract. 2013;63(606):e1-10.

44. Hippisley-Cox J, Coupland C. Development and validation of risk prediction algorithms to estimate future risk of common cancers in men and women: prospective cohort study. BMJ Open. 2015;5(3):e007825.

45. Collins GS, Altman DG. Identifying patients with undetected colorectal cancer: an independent validation of QCancer (Colorectal). Br J Cancer. 2012;107(2):260-5.

46. Collins GS, Altman DG. Identifying patients with undetected pancreatic cancer in primary care: an independent and external validation of QCancer (R) (Pancreas). British Journal of General Practice. 2013;63(614):E636-E42.

47. Collins GS, Altman DG. Identifying patients with undetected renal tract cancer in primary care: an independent and external validation of QCancer(R) (Renal) prediction model. Cancer Epidemiol. 2013;37(2):115-20.

48. Collins GS, Altman DG. Identifying patients with undetected gastro-oesophageal cancer in primary care: External validation of QCancer(R) (Gastro-Oesophageal). Eur J Cancer. 2013;49(5):1040-8.

49. Collins GS, Altman DG. Identifying women with undetected ovarian cancer: independent and external validation of QCancer((R)) (Ovarian) prediction model. Eur J Cancer Care (Engl). 2013;22(4):423-9.

50. Nicholson BD, Oke J, Friedemann Smith C, Phillips JA, Lee J, Abel L, et al. The Suspected CANcer (SCAN) pathway: protocol for evaluating a new standard of care for patients with non-specific symptoms of cancer. BMJ Open. 2018;8(1):e018168.

51. Chapman D, Poirier V, Fitzgerald K, Nicholson BD, Hamilton W, Accelerate Coordinate Evaluate Multidisciplinary Diagnostic Centre p. Non-specific symptoms-based pathways for diagnosing less common cancers in primary care: a service evaluation. Br J Gen Pract. 2021;71(712):e846-e53.

52. Moffat JI, L. Green, T. . Clinical Decision Support Tool for Cancer (CDS) Project: Evaluation Report to the Department of Health [Available from: <u>https://34p2k13bwwzx12bgy13rwq8p-wpengine.netdna-ssl.com/wp-content/uploads/2014/11/CDS-evaluation-report-Executive-summary.pdf</u> last accessed 1st May 2022].

53. Dikomitis TG, T. Macleod, U. MacMillan Electronic Risk Assessment Tool Summary: Dealing with uncertainty: a qualitative evaluation of the usability and acceptability of an electronic risk assessment tool to aid cancer diagnosis in general practice: Supportive care, Early diagnosis and Advanced Disease (SEDA) research group. Centre for Health and Population Sciences (CHaPS); 2012 [Available from: https://www.macmillan.org.uk/documents/aboutus/health professionals/earlydiagnosis/summaryeratsreport (oct2012).pdf last accessed 1st May 2022].

54. Using Cancer Decision Support Tools to support the early diagnosis of cancer. Accelerate, Coordinate, Evaluate (ACE) Programme An early diagnosis of cancer initiative supported by:

NHS England, Cancer Research UK and Macmillan Cancer Support 2017 [Available from: <u>https://www.cancerresearchuk.org/sites/default/files/ace cancer decision support tools final report v1.1</u> 080517_0.pdf last accessed 1st May 2022].

55. Price S, Spencer A, Medina-Lara A, Hamilton W. Availability and use of cancer decision-support tools: a cross-sectional survey of UK primary care. Br J Gen Pract. 2019;69(684):e437-e43.

56. Electronic Risk Assessment for Cancer [Available from: <u>https://www.theericatrial.co.uk</u> last accessed 1st May 2022].

57. Medina-Lara A, Grigore B, Lewis R, Peters J, Price S, Landa P, et al. Cancer diagnostic tools to aid decisionmaking in primary care: mixed-methods systematic reviews and cost-effectiveness analysis. Health Technol Assess. 2020;24(66):1-332.

58. Green T, Atkin K, Macleod U. Cancer detection in primary care: insights from general practitioners. Br J Cancer. 2015;112 Suppl 1:S41-9.

59. Cook N, Thomson G, Dey P. Managing risk in cancer presentation, detection and referral: a qualitative study of primary care staff views. BMJ Open. 2014;4(6):e004820.

60. Smith CF, Drew S, Ziebland S, Nicholson BD. Understanding the role of GPs' gut feelings in diagnosing cancer in primary care: a systematic review and meta-analysis of existing evidence. Br J Gen Pract. 2020;70(698):e612-e21.

61. Smith CF, Kristensen BM, Andersen RS, Hobbs FR, Ziebland S, Nicholson BD. GPs' use of gut feelings when assessing cancer risk: a qualitative study in UK primary care. Br J Gen Pract. 2021;71(706):e356-e63.

62. Smith L, Sansom N, Hemphill S, Bradley SH, Shinkins B, Wheatstone P, et al. Trends and variation in urgent referrals for suspected cancer 2009/2010-2019/2020. Br J Gen Pract. 2022;72(714):34-7.

63. Grigore B, Lewis R, Peters J, Robinson S, Hyde CJ. Development, validation and effectiveness of diagnostic prediction tools for colorectal cancer in primary care: a systematic review. BMC Cancer. 2020;20(1):1084.

64. Thompson M, O'Leary D, Heath I, Wood LF, Ellis B, Flashman K, et al. Have large increases in fast track referrals improved bowel cancer outcomes in UK? BMJ. 2020;371:m3273.

65. Proctor V, Iftimie-Nastase I, Sinclair J, Sivakumar R, Shah S. Referrals for Suspected Colorectal Cancer before and after the Updated Nice Guidelines in June 2015. Gut. 2018;67:A199-A.

66. Mahase E. Covid-19: Urgent cancer referrals fall by 60%, showing "brutal" impact of pandemic. BMJ. 2020;369:m2386.

67. Sud A, Torr B, Jones ME, Broggio J, Scott S, Loveday C, et al. Effect of delays in the 2-week-wait cancer referral pathway during the COVID-19 pandemic on cancer survival in the UK: a modelling study. Lancet Oncol. 2020;21(8):1035-44.

68. Fox L, Monroy-Iglesias MJ, Aggarwal A, Haire K, Purushotham A, Spicer J, et al. Association between COVID-19 burden and delays to diagnosis and treatment of cancer patients in England. Journal of Cancer Policy. 2022;31:100316.

69. Helsper CW, Campbell C, Emery J, Neal RD, Li L, Rubin G, et al. Cancer has not gone away: A primary care perspective to support a balanced approach for timely cancer diagnosis during COVID-19. Eur J Cancer Care (Engl). 2020;29(5):e13290.

70. Gray R, Sanders C. A reflection on the impact of COVID-19 on primary care in the United Kingdom. J Interprof Care. 2020;34(5):672-8.

71. Cancer Research UK Head and Neck Cancer Statistics [Available from: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/head-and-neck-cancers accessed 1st May 2022].

72. Shaw R, Beasley N. Aetiology and risk factors for head and neck cancer: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016;130(S2):S9-S12.

73. McIlwain WR, Sood AJ, Nguyen SA, Day TA. Initial symptoms in patients with HPV-positive and HPVnegative oropharyngeal cancer. JAMA Otolaryngol Head Neck Surg. 2014;140(5):441-7.

74. National Institute for Health and Care Excellence: Clinical Guidelines. Cancer of the Upper Aerodigestive Tract: Assessment and Management in People Aged 16 and Over. London2016.

75. National Institute for Health and Care Excellence, Suspected Cancer: Recognition and Referral. London; 2015.

76. National Cancer Registration and Analysis Service National Cancer Research Institute [Available from: <u>http://www.ncin.org.uk/publications/routes to diagnosis</u> last accessed 1st May 2022].

77. Langton S, Siau D, Bankhead C. Two-week rule in head and neck cancer 2000-14: a systematic review. Br J Oral Maxillofac Surg. 2016;54(2):120-31.

78. Grafton-Clarke C, Chen KW, Wilcock J. Diagnosis and referral delays in primary care for oral squamous cell cancer: a systematic review. British Journal of General Practice. 2019;69(679):E112-E26.

79. Dimitrov L, Unadkat S, Khanna A, Rennie C, Saleh H. ENT training amongst general practitioners: results from a questionnaire. J Laryngol Otol. 2020:1-7.

80. Grimes D, Patel J, Avery C. New NICE referral guidance for oral cancer: does it risk delay in diagnosis? Br J Oral Maxillofac Surg. 2017;55(4):404-6.

81. Bradley P, Beasley N, Au-Yong I. Imaging of neck lumps. BMJ. 2014;349:g6136.

82. Nieminen M, Aro K, Makitie A, Harlin V, Kainulainen S, Jouhi L, et al. Challenges in diagnosing head and neck cancer in primary health care. Ann Med. 2020:1-8.

83. Scott S, McGurk M, Grunfeld E. Patient delay for potentially malignant oral symptoms. Eur J Oral Sci. 2008;116(2):141-7.

84. Scott SE, McGurk M, Grunfeld EA. The process of symptom appraisal: cognitive and emotional responses to detecting potentially malignant oral symptoms. J Psychosom Res. 2007;62(6):621-30.

85. Lim AE, Douglas CM, Montgomery J. An open structure questionnaire on reasons for delay in presentation: a study of patients attending clinic with red flag symptoms of head and neck cancer. Eur Arch Otorhinolaryngol. 2020;277(6):1801-6.

86. Allgar VL, Oliver SE, Chen H, Oviasu O, Johnson MJ, Macleod U. Time intervals from first symptom to diagnosis for head and neck cancers: An analysis of linked patient reports and medical records from the UK. Cancer Epidemiol. 2019;59:37-45.

87. Nieminen M, Aro K, Jouhi L, Back L, Makitie A, Atula T. Causes for delay before specialist consultation in head and neck cancer. Acta Oncol. 2018;57(12):1677-86.

88. Tromp DM, Brouha XD, Hordijk GJ, Winnubst JA, de Leeuw JR. Patient factors associated with delay in primary care among patients with head and neck carcinoma: a case-series analysis. Fam Pract. 2005;22(5):554-9.

89. Bethell GS, Leftwick P. Views of general practitioners and head and neck surgeons on the referral system for suspected cancer: a survey. J Laryngol Otol. 2015;129(9):893-7.

90. Recognising laryngeal cancer - hoarseness and neck lump 90% accurate 2019 [Available from: <u>https://bjgp.org/content/69/679/e127/tab-e-letters</u> last accessed 1st May 2022].

91. Koroulakis A, Agarwal M. Laryngeal Cancer. Treasure Island (FL)2022. Available from: <u>https://www.ncbi.nlm.nih.gov/books/NBK526076/</u> last accessed 1st May 2022.

92. National Disease Registration Service (NDRS) in Public Health England (PHE). National Cancer Registration and Analysis Service (NCRAS) [Available from: <u>https://www.cancerdata.nhs.uk</u> last accessed 1st May 2022].

93. Wong BY, Fischer S, Cruickshank HE. Clinical outcome of head and neck cancer patients: a comparison between ENT patients referred via the 2 weeks wait pathway and alternative routes in the UK health system. Eur Arch Otorhinolaryngol. 2017;274(1):415-20.

94. McKie C, Ahmad UA, Fellows S, Meikle D, Stafford FW, Thomson PJ, et al. The 2-week rule for suspected head and neck cancer in the United Kingdom: referral patterns, diagnostic efficacy of the guidelines and compliance. Oral Oncol. 2008;44(9):851-6.

95. Araghi AS, Harris Y, Kyzas P. An audit to analyse the two-week wait pathway at an oral cancer specialist district general hospital. Br Dent J. 2020;228(9):693-9.

96. Roy S, Anjum K. The two-week wait - a qualitative analysis of suspected head and neck cancer referrals. Br Dent J. 2018;225(2):159-63.

97. Miller CC, Hierons RJ. Two audits of the diagnosis of oral cancer and the two-week rule following referrals from primary care practitioners in Newcastle. Prim Dent Care. 2012;19(2):63-8.

98. Singh P, Warnakulasuriya S. The two-week wait cancer initiative on oral cancer; the predictive value of urgent referrals to an oral medicine unit. Br Dent J. 2006;201(11):717-20; discussion 4.

99. Hobson JC, Malla JV, Sinha J, Kay NJ, Ramamurthy L. Outcomes for patients referred urgently with suspected head and neck cancer. J Laryngol Otol. 2008;122(11):1241-4.

100. Tikka T, Pracy P, Paleri V. Refining the head and neck cancer referral guidelines: a two centre analysis of 4715 referrals. Br J Oral Maxillofac Surg. 2016;54(2):141-50.

101. Tikka T, Kavanagh K, Lowit A, Jiafeng P, Burns H, Nixon IJ, et al. Head and neck cancer risk calculator (HaNC-RC)-V.2. Adjustments and addition of symptoms and social history factors. Clin Otolaryngol. 2020;45(3):380-8.

102. Allam A, Nijim H. Persistent Unilateral Sore Throat: Should It Be Included in the 2-Week Wait Referral Criteria by NICE. Int J Otolaryngol. 2019;2019:4920514.

103. Gao C, Qin C, Freeman S, Oskooee N, Hughes J. Two week wait referral criteria - heading in the right direction? J Laryngol Otol. 2019;133(8):704-12.

104. Mettias B, Charlton A, Ashokkumar S. Outcome of two-week head and neck cancer pathway for the otolaryngology department in a tertiary centre. J Laryngol Otol. 2021;135(10):869-73.

105. Talwar C, McClune A, Kelly D, Lowe D, Rogers SN. Two-week rule: suspected head and neck cancer referrals from a general medical practice perspective. Br J Oral Maxillofac Surg. 2020.

106. Tikka T, Paleri V, MacKenzie K. External validation of a cancer risk prediction model for suspected head and neck cancer referrals. Clin Otolaryngol. 2018;43(2):714-7.

107. Lau K, Wilkinson J, Moorthy R. A web-based prediction score for head and neck cancer referrals. Clin Otolaryngol. 2018;43(4):1043-9.

108. Moor JW, Paleri V, Edwards J. Patient classification of two-week wait referrals for suspected head and neck cancer: a machine learning approach. J Laryngol Otol. 2019:1-4.

109. Sterne JAC, White IR, Carlin JB, Spratt M, Royston P, Kenward MG, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. BMJ. 2009;338:b2393.

110. Moons KG, Altman DG, Reitsma JB, Ioannidis JP, Macaskill P, Steyerberg EW, et al. Transparent Reporting of a multivariable prediction model for Individual Prognosis or Diagnosis (TRIPOD): explanation and elaboration. Ann Intern Med. 2015;162(1):W1-73.

111. Collins GS, Reitsma JB, Altman DG, Moons KG. Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD). Ann Intern Med. 2015;162(10):735-6.

112. Usher-Smith JA, Sharp SJ, Griffin SJ. The spectrum effect in tests for risk prediction, screening, and diagnosis. BMJ. 2016;353:i3139.

113. Banerjee S, Voliotidis D, Parvin L, Rama SPK. Telephone triage of suspected head and neck cancer patients during the coronavirus disease 2019 pandemic using the Head and Neck Cancer Risk Calculator version 2. The Journal of Laryngology & Otology. 2021;135(3):241-5.

114. Kaddour H, Jama GM, Stagnell S, Kaddour S, Guner K, Kumar G. Remote triaging of urgent suspected head and neck cancer referrals: our experience during the first wave of the COVID-19 pandemic. Eur Arch Otorhinolaryngol. 2022;279(2):1111-5.

115. International scoping report on aerosol generating medical procedure listings. [Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1000042 /Independent High Risk AGP Panel International Report.pdf last accessed 1st May 2022].

116. Paleri V, Hardman J, Tikka T, Bradley P, Pracy P, Kerawala C. Rapid implementation of an evidence-based remote triaging system for assessment of suspected referrals and patients with head and neck cancer on follow-up after treatment during the COVID-19 pandemic: Model for international collaboration. Head Neck. 2020;42(7):1674-80.

117. Eccles MP, Mittman BS. Welcome to Implementation Science. Implementation Science. 2006;1(1):1.

118. Greenhalgh T RG, Bate P, Kyriakidou O, Macfarlane F, Peacock R. How to Spread Good Ideas A systematic review of the literature on diffusion, dissemination and sustainability of innovations in health service delivery

and organisation. [Available from: <u>https://www.cs.kent.ac.uk/people/staff/saf/share/great-missenden/reference-papers/Overviews/NHS-lit-review.pdf</u> last accessed 1st May 2022].

119. Fitzgerald LF, E. Wood, M. Hawkins, C. Interlocking Interactions, the diffusion of innovations in health care. Human Relations. 2002;55(12):1429-49.

120. Rogers EM. Diffusion of Innovations: New York : The Free Press, 1962 (1969).

121. Bauer MS, Kirchner J. Implementation science: What is it and why should I care? Psychiatry Res. 2020;283:112376.

122. Checkland K, Harrison S, Marshall M. Is the metaphor of 'barriers to change' useful in understanding implementation? Evidence from general medical practice. J Health Serv Res Policy. 2007;12(2):95-100.

123. Garside R. Should we appraise the quality of qualitative research reports for systematic reviews, and if so, how? Innovation: The European Journal of Social Science Research. 2014;27(1):67-79.

124. Lau R, Stevenson F, Ong BN, Dziedzic K, Treweek S, Eldridge S, et al. Achieving change in primary care-causes of the evidence to practice gap: systematic reviews of reviews. Implement Sci. 2016;11:40.

125. Maniatopoulos G, Procter R, Llewellyn S, Harvey G, Boyd A. Moving beyond local practice: reconfiguring the adoption of a breast cancer diagnostic technology. Soc Sci Med. 2015;131:98-106.

126. Nilsen P. Making sense of implementation theories, models and frameworks. Implement Sci. 2015;10:53.

127. Titler MG, Kleiber C, Steelman VJ, Rakel BA, Budreau G, Everett LQ, et al. The Iowa Model of Evidence-Based Practice to Promote Quality Care. Crit Care Nurs Clin North Am. 2001;13(4):497-509.

128. Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a synthesis of critical steps in the implementation process. Am J Community Psychol. 2012;50(3-4):462-80.

129. Rogers EM. Diffusion of innovations. 5th ed. ed. New York, N.Y.: Simon & Schuster; 2003.

130. May CR, Mair F, Finch T, MacFarlane A, Dowrick C, Treweek S, et al. Development of a theory of implementation and integration: Normalization Process Theory. Implement Sci. 2009;4:29.

131. Moullin JC, Dickson KS, Stadnick NA, Albers B, Nilsen P, Broder-Fingert S, et al. Ten recommendations for using implementation frameworks in research and practice. Implement Sci Commun. 2020;1:42.

132. May C, Rapley, T., Mair, F.S., Treweek, S., Murray, E., Ballini, L., Macfarlane, A. Girling, M. and Finch, T.L. Normalization Process Theory On-line Users' Manual, Toolkit and NoMAD instrument. 2015 [Available from: Available from http://www.normalizationprocess.org last accessed 1st May 2022].

133. May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, et al. Understanding the implementation of complex interventions in health care: the normalization process model. BMC Health Serv Res. 2007;7:148.

134. May CR, Cummings A, Girling M, Bracher M, Mair FS, May CM, et al. Using Normalization Process Theory in feasibility studies and process evaluations of complex healthcare interventions: a systematic review. Implementation Science. 2018;13.

135. Kanagasundaram NS, Bevan MT, Sims AJ, Heed A, Price DA, Sheerin NS. Computerized clinical decision support for the early recognition and management of acute kidney injury: a qualitative evaluation of end-user experience. Clin Kidney J. 2016;9(1):57-62.

136. Speed C, Heaven B, Adamson A, Bond J, Corbett S, Lake AA, et al. LIFELAX - diet and LIFEstyle versus LAXatives in the management of chronic constipation in older people: randomised controlled trial. Health Technol Asses. 2010;14(52):1-+.

137. Murray E, Treweek S, Pope C, MacFarlane A, Ballini L, Dowrick C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. BMC Med. 2010;8:63.

138. Gupta AK, Tesluk PE, Taylor MS. Innovation at and across Multiple Levels of Analysis. Organization Science. 2007;18(6):885-97.

139. Rapport F, Braithwaite J. Are we on the cusp of a fourth research paradigm? Predicting the future for a new approach to methods-use in medical and health services research. Bmc Medical Research Methodology. 2018;18.

140. Pfadenhauer LM, Gerhardus A, Mozygemba K, Lysdahl KB, Booth A, Hofmann B, et al. Making sense of complexity in context and implementation: the Context and Implementation of Complex Interventions (CICI) framework. Implement Sci. 2017;12(1):21.

141. Rycroft-Malone J, Bucknall T. Models and frameworks for implementing evidence-based practice : linking evidence to action. Chichester: Wiley-Blackwell; 2010.

142. Sarkies M, Robinson S, Ludwick T, Braithwaite J, Nilsen P, Aarons G, et al. Understanding implementation science from the standpoint of health organisation and management: an interdisciplinary exploration of selected theories, models and frameworks. Journal of Health Organization and Management. 2021;35(7):782-801.

143. The Health Foundation. Evidence scan: Complex adaptive systems: The Health Foundation; 2010 [Available from: https://www.health.org.uk/sites/default/files/ComplexAdaptiveSystems.pdf last accessed 1st May 2022].

144. Braithwaite J, Churruca K, Long JC, Ellis LA, Herkes J. When complexity science meets implementation science: a theoretical and empirical analysis of systems change. BMC Med. 2018;16(1):63.

145. Long KM, McDermott F, Meadows GN. Being pragmatic about healthcare complexity: our experiences applying complexity theory and pragmatism to health services research. BMC Med. 2018;16(1):94.

146. Moullin JC, Dickson KS, Stadnick NA, Rabin B, Aarons GA. Systematic review of the Exploration, Preparation, Implementation, Sustainment (EPIS) framework. Implement Sci. 2019;14(1):1.

147. Greenhalgh T. Diffusion of innovations in health service organisations : a systematic literature review. Malden, Mass. ; London: Blackwell; 2005.

148. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581-629.

149. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O, Peacock R. Storylines of research in diffusion of innovation: a meta-narrative approach to systematic review. Soc Sci Med. 2005;61(2):417-30.

150. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res. 2017;19(11):e367.

151. Greenhalgh T, Abimbola S. The NASSS Framework - A Synthesis of Multiple Theories of Technology Implementation. Stud Health Technol Inform. 2019;263:193-204.

152. Greenhalgh T, Wherton J, Papoutsi C, Lynch J, Hughes G, A'Court C, et al. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. Journal of medical Internet research. 2017;19(11):e367-e.

153. Greenhalgh T, Maylor H, Shaw S, Wherton J, Papoutsi C, Betton V, et al. The NASSS-CAT Tools for Understanding, Guiding, Monitoring, and Researching Technology Implementation Projects in Health and Social Care: Protocol for an Evaluation Study in Real-World Settings. JMIR Res Protoc. 2020;9(5):e16861.

154. Kuhn TS. The structure of scientific revolutions. 3rd ed. ed. Chicago ; London: University of Chicago Press; 1996.

155. Garfinkel H. Ethnomethodological studies of work. London: Routledge & Kegan Paul; 1986.

156. Cicourel AV. Method and measurement in sociology: New York : Free Press, 1964 (1966).

157. Lincoln YS, Guba EG. Naturalistic inquiry. Beverly Hills, Calif. ; London: Sage; 1985.

158. Berger PL, Luckmann T. The social construction of reality : a treatise in the sociology of knowledge. New York, NY: Open Road Integrated Media; 1966.

159. Dewey J, Sidorsky D. John Dewey : the essential writings. 1st ed. ed. New York: Harper & Row; 1977.

160. Teddlie C, Tashakkori A. Foundations of mixed methods research : integrating quantitative and qualitative techniques in the social and behavioral sciences. London: SAGE; 2009.

161. Dillon DR, O'Brien DG, Heilman EE. Literacy research in the next millennium: From paradigms to pragmatism and practicality. Read Res Quart. 2000;35(1):10-26.

162. Braithwaite J, Churruca, K., Ellis, L. A., Long, J., Clay-Williams, R., Damen, N., Herkes, J., Pomare, , C. aL, K. Complexity Science in Healthcare – Aspirations, Approaches, Applications and Accomplishments: A White Paper. . 2017.

163. Hammersley M. Theory and Evidence in Qualitative Research. Qual Quant. 1995;29(1):55-66.

164. Shannon-Baker P. Making Paradigms Meaningful in Mixed Methods Research. J Mix Method Res. 2016;10(4):319-34.

165. Rapport FB, J. Transforming healthcare with qualitative research. England: Routledge; 2020.

166. Chew-Graham CA, May CR, Perry MS. Qualitative research and the problem of judgement: lessons from interviewing fellow professionals. Fam Pract. 2002;19(3):285-9.

167. Richards H, Emslie C. The 'doctor' or the 'girl from the University'? Considering the influence of professional roles on qualitative interviewing. Fam Pract. 2000;17(1):71-5.

168. Ritchie J, Lewis J. Qualitative research practice : a guide for social science students and researchers. London: Sage Publications; 2003.

169. Riley R, Windt Dvd, Croft P, Moons KGM, Oxford Medicine Online. Prognosis research in health care : concepts, methods, and impact. 1 online resource p.

170. Steyerberg EW, Springer Mathematics and Statistics eBooks 2009 English/International. Clinical prediction models a practical approach to development, validation, and updating. New York, NY: Springer,; 2009. Available from: https://ezproxy.newcastle.edu.au/login?url=https://link.springer.com/10.1007/978-0-387-77244-8.

171. Harrell FEa. Regression modeling strategies : with applications to linear models, logistic and ordinal regression, and survival analysis2019.

172. Steyerberg EW. Clinical prediction models : a practical approach to development, validation, and updating. 2nd ed. ed2019.

173. National Collaborating Centre for C. National Institute for Health and Care Excellence: Clinical Guidelines. Cancer of the Upper Aerodigestive Tract: Assessment and Management in People Aged 16 and Over. London: National Institute for Health and Care Excellence (UK)

Copyright © National Collaborating Centre for Cancer.; 2016.

174. Alho OP, Teppo H, Mantyselka P, Kantola S. Head and neck cancer in primary care: presenting symptoms and the effect of delayed diagnosis of cancer cases. CMAJ. 2006;174(6):779-84.

175. Dhull AK, Atri R, Dhankhar R, Chauhan AK, Kaushal V. Major Risk Factors in Head and Neck Cancer: A Retrospective Analysis of 12-Year Experiences. World J Oncol. 2018;9(3):80-4.

176. Douglas CM, Ingarfield K, McMahon AD, Savage SA, Conway DI, MacKenzie K. Presenting symptoms and long-term survival in head and neck cancer. Clin Otolaryngol. 2018;43(3):795-804.

177. Flukes S, Garry S, Hinton-Bayre A, Lindsay A. Pre-treatment wait time for head and neck cancer patients in Western Australia: description of a new metric and examination of predictive factors. ANZ J Surg. 2019;89(7-8):858-62.

178. Grey R, Walsh S. A review of the electronic two-week rule referrals for head and neck cancer to Western Sussex Hospitals NHS Foundation Trust. Br Dent J. 2019;227(5):403-9.

179. Lee YA, Al-Temimi M, Ying J, Muscat J, Olshan AF, Zevallos JP, et al. Risk Prediction Models for Head and Neck Cancer in the US Population From the INHANCE Consortium. Am J Epidemiol. 2020;189(4):330-42.

180. Rasmussen ER, Schnack DT, Ravn AT. A prospective cohort study of 122 adult patients presenting to an otolaryngologist's office with globus pharyngeus. Clin Otolaryngol. 2018;43(3):854-60.

181. Roennegaard AB, Rosenberg T, Bjorndal K, Sorensen JA, Johansen J, Godballe C. The Danish Head and Neck Cancer fast-track program: a tertiary cancer centre experience. Eur J Cancer. 2018;90:133-9.

182. Williams C, Byrne R, Holden D, Sherman I, Srinivasan VR. Two-week referrals for suspected head and neck cancer: two cycles of audit, 10 years apart, in a district general hospital. J Laryngol Otol. 2014;128(8):720-4.
183. Hippisley-Cox J, Coupand C. Identifying patients with suspected lung cancer in primary care: derivation and validation of an algorithm. British Journal of General Practice. 2011;61(592).

184. Hippisley-Cox J, Coupland C. Symptoms and risk factors to identify people with suspected cancer in primary care. Br J Gen Pract. 2013;63(608):125-6.

185. Collins GS, Altman DG. Identifying patients with undetected pancreatic cancer in primary care: an independent and external validation of QCancer((R)) (Pancreas). Br J Gen Pract. 2013;63(614):e636-42.

186. Bradley PT, Hall N, Maniatopoulos G, Neal RD, Paleri V, Wilkes S. Factors shaping the implementation and use of Clinical Cancer Decision Tools by GPs in primary care: a qualitative framework synthesis. BMJ Open. 2021;11(2):e043338.

187. Barnett-Page E, Thomas J. Methods for the synthesis of qualitative research: a critical review. BMC Med Res Methodol. 2009;9:59.

188. Booth A, Sutton A, Papaioannou D. Systematic approaches to a successful literature review. Second edition. ed. 326 pages p.

189. Rohwer A, Booth, A., Pfadenhauer, L., Brereton, L., Gerhardus, A., Mozygemba, K., Oortwijn, W., Tummers, M., Van Der Wilt, G.J., Rehfuess, E. Guidance on the use of logic models in health technology assessments of complex interventions. 2016.

190. Booth A, Brice A. Evidence-based practice for information professionals : a handbook. London: Facet; 2004.

191. Akanuwe J. Exploring service user and practitioner perspectives of using cancer risk assessment tools In primary care consultations - PhD Thesis: University of Lincoln; 2018.

192. Chiang PP, Glance D, Walker J, Walter FM, Emery JD. Implementing a QCancer risk tool into general practice consultations: an exploratory study using simulated consultations with Australian general practitioners. Br J Cancer. 2015;112 Suppl 1:S77-83.

193. Dikomitis L, Green T, Macleod U. Embedding electronic decision-support tools for suspected cancer in primary care: a qualitative study of GPs' experiences. Primary Health Care Research and Development. 2015;16(6):548-55.

194. Green T, Martins T, Hamilton W, Rubin G, Elliott K, Macleod U. Exploring GPs' experiences of using diagnostic tools for cancer: a qualitative study in primary care. Fam Pract. 2015;32(1):101-5.

195. Hamilton W, Green T, Martins T, Elliott K, Rubin G, Macleod U. Evaluation of risk assessment tools for suspected cancer in general practice: a cohort study. Br J Gen Pract. 2013;63(606):e30-6.

196. Pannebakker MM, Mills K, Johnson M, Emery JD, Walter FM. Understanding implementation and usefulness of electronic clinical decision support (eCDS) for melanoma in English primary care: a qualitative investigation. BJGP Open. 2019;3(1):bjgpopen18X101635.

197. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.

198. Berger R. Now I see it, now I don't: researcher's position and reflexivity in qualitative research. Qual Res. 2015;15(2):219-34.

199. Critical Appraisal Skills Programme (2019). CASP (Qualitative Checklist) [Available from: <u>https://casp-uk.b-</u> <u>cdn.net/wp-content/uploads/2018/03/CASP-Qualitative-Checklist-2018 fillable form.pdf</u> last accessed 1st May 2022].

200. Hamilton AB, Finley EP. Qualitative methods in implementation research: An introduction. Psychiatry Res. 2019;280:112516.

201. Braun V, Clarke V. Using thematic analysis in psychology. Qualitative Research in Psychology. 2006;3(2):77-101.

202. Braun V, Clarke V. Successful qualitative research : a practical guide for beginners. London: SAGE; 2013.

203. Braun V, Clarke V. Reflecting on reflexive thematic analysis. Qual Res Sport Exerc. 2019;11(4):589-97.

204. Braun V, Clarke V. Can I use TA? Should I use TA? Should I not use TA? Comparing reflexive thematic analysis and other pattern-based qualitative analytic approaches. Counselling and Psychotherapy Research. 2021;21(1):37-47.

205. Ramanadhan S, Revette AC, Lee RM, Aveling EL. Pragmatic approaches to analyzing qualitative data for implementation science: an introduction. Implement Sci Commun. 2021;2(1):70.

206. Maniatopoulos G, Hunter DJ, Erskine J, Hudson B. Large-scale health system transformation in the United Kingdom. J Health Organ Manag. 2020;ahead-of-print(ahead-of-print).

207. O'Reilly M, Parker N. 'Unsatisfactory Saturation': a critical exploration of the notion of saturated sample sizes in qualitative research. Qual Res. 2013;13(2):190-7.

208. Braun V, Clarke V. To saturate or not to saturate? Questioning data saturation as a useful concept for thematic analysis and sample-size rationales. Qualitative Research in Sport, Exercise and Health. 2021;13(2):201-16.

209. Malterud K, Siersma VD, Guassora AD. Sample Size in Qualitative Interview Studies: Guided by Information Power. Qual Health Res. 2016;26(13):1753-60.

210. Shephard EA, Parkinson MAL, Hamilton WT. Recognising laryngeal cancer in primary care: a large casecontrol study using electronic records. British Journal of General Practice. 2019;69(679):e127-e33.

211. Khan KS GA, Denley S, Saldanha J, Mukherjee A. Two Week Rule Compliance: Assessing General Practice Use of the 'Two Week Rule' Referral Pathway for the Suspicion of Colorectal Cancer. Ann Public Health Reports. 2021;5(1):172-8.

212. Taylor R, Omakobia E, Sood S, Glore RJ. The impact of coronavirus disease 2019 on head and neck cancer services: a UK tertiary centre study. J Laryngol Otol. 2020;134(8):684-7.

213. Car J, Sheikh A. Email consultations in health care: 1--scope and effectiveness. BMJ. 2004;329(7463):435-8.

214. Car J, Sheikh A. Email consultations in health care: 2--acceptability and safe application. BMJ. 2004;329(7463):439-42.

215. Hutchings R. The impact of Covid-19 on the use of digital technology in the NHS: Nuffield Trust; 2020 [Available from: <u>https://www.nuffieldtrust.org.uk/files/2020-08/the-impact-of-covid-19-on-the-use-of-digital-technology-in-the-nhs-web-2.pdf</u> last accessed 1st May 2022].

216. Rubin G, Walter FM, Emery J, Hamilton W, Hoare Z, Howse J, et al. Electronic clinical decision support tool for assessing stomach symptoms in primary care (ECASS): a feasibility study. BMJ Open. 2021;11(3):e041795.

217. Samset K, Christensen T. Ex Ante Project Evaluation and the Complexity of Early Decision-Making. Public Organization Review. 2017;17(1):1-17.

218. Horrocks M, Michail M, Aubeeluck A, Wright N, Morriss R. An Electronic Clinical Decision Support System for the Assessment and Management of Suicidality in Primary Care: Protocol for a Mixed-Methods Study. JMIR Res Protoc. 2018;7(12):e11135.

219. Paparini S, Papoutsi C, Murdoch J, Green J, Petticrew M, Greenhalgh T, et al. Evaluating complex interventions in context: systematic, meta-narrative review of case study approaches. BMC Med Res Methodol. 2021;21(1):225.

220. Abimbola S, Patel B, Peiris D, Patel A, Harris M, Usherwood T, et al. The NASSS framework for ex post theorisation of technology-supported change in healthcare: worked example of the TORPEDO programme. BMC Med. 2019;17(1):233.

221. Adam MB, Minyenya-Njuguna J, Karuri Kamiru W, Mbugua S, Makobu NW, Donelson AJ. Implementation research and human-centred design: how theory driven human-centred design can sustain trust in complex health systems, support measurement and drive sustained community health volunteer engagement. Health Policy Plan. 2020;35(Supplement_2):ii150-ii62.

222. The Health Foundation. Securing a positive health care technology legacy from COVID-19 [Available from: https://www.health.org.uk/publications/long-reads/securing-a-positive-health-care-technology-legacy-from-covid-19 last accessed 1st May 2022].

223. Bonnett LJ, Snell KIE, Collins GS, Riley RD. Guide to presenting clinical prediction models for use in clinical settings. Bmj. 2019;365:1737.

224. Kern C, Fu DJ, Kortuem K, Huemer J, Barker D, Davis A, et al. Implementation of a cloud-based referral platform in ophthalmology: making telemedicine services a reality in eye care. Br J Ophthalmol. 2020;104(3):312-7.

225. Haron N, Rajendran S, Kallarakkal TG, Zain RB, Ramanathan A, Abraham MT, et al. High referral accuracy for oral cancers and oral potentially malignant disorders using telemedicine. Oral Dis. 2021.

226. Haron N, Zain RB, Ramanathan A, Abraham MT, Liew CS, Ng KG, et al. m-Health for Early Detection of Oral Cancer in Low- and Middle-Income Countries. Telemed J E Health. 2020;26(3):278-85.

227. The NHS Galleri Screening Trial [Available from: <u>https://www.cancerresearchuk.org/about-cancer/cancer-in-general/tests/blood-tests/Galleri-blood-test</u> last accessed 1st May 2022].

228. Liu MC, Oxnard GR, Klein EA, Swanton C, Seiden MV, Liu MC, et al. Sensitive and specific multi-cancer detection and localization using methylation signatures in cell-free DNA. Annals of Oncology. 2020;31(6):745-59.

229. Savage R, Messenger M, Neal RD, Ferguson R, Johnston C, Lloyd KL, et al. Development and validation of multivariable machine learning algorithms to predict risk of cancer in symptomatic patients referred urgently from primary care: a diagnostic accuracy study. BMJ Open. 2022;12(4):e053590.

230. Keenan R, Lawrenson R, Stokes T. Urgent referral to specialist services for patients with cancer symptoms: a cause for concern or oversimplifying a complex issue? BMJ Qual Saf. 2021.

Appendices

Appendix A: Tables

Yield of cancer diagnoses from TWW referrals with hoarseness

Study	Total referrals	Hoarseness	% of referrals	Cancer diagnosis from referral for hoarseness (no)	Cancer diagnosis as % of hoarseness referrals
McKie (94)	1079	271	25.1%	19	7%
Hobson(99)	177	50 intermittent 2 persistent 52 total	29%	4 (in total)	7.7% 2.3% of total referrals
Tikka (100)	4715	951 Persistent 364 intermittent 1315 total	28%	69 3 72	7.2% 0.8% 5.5% of total referrals
Allam (102)	1367	147 persistent 115 intermittent 262 total	25% 14.5% 19% total	10 0	6.8% 0 3.8% of total referrals
Gao (103)	1036	245	24%	6	2.4%
Tikka (101)	3531	374 persistent 668 intermittent 82 persistent explained 1124 total	32% 19% 2.3% 32%	75 13 3 91	20% 2% 3.7% 8%
Pooled	11,905	3269	27.4%	202	6.2%

Study	Total referrals	Dysphagia	% of referrals	Cancer diagnosed	Cancer Diagnosed % of total referrals for dysphagia
McKie (94)	1079	90	8.3%	7	7.7%
Hobson(99)	177	13 12 Globus 25 total	7.3% 6.8% 14%	1 oesophageal & 1 pharyngeal	8%
Tikka (100)	4715	235 70 Intermittent 32 Odynophagia 334 Globus 671 total	5% 1.5% 0.7% 7% 14.2%	32 3 6 5 46 total	13.6% 4.2% 18.75% 1.5% 6.9% total
Allam (102)	1367	33 181 Globus 214 Total	2.4% 13.2% 15.7%	2 0 2	6% 0 1%
Gao (103)	1036	83 31 Odynophagia 114 total	8% 3% 11%	2 1 3	2.4% 3.2% 2.6%
Tikka (101)	3531	246 persistent 257 intermittent 587 fossit 79 odynophagia 176 choking episodes/feeling 107 regurgitation 1452 total	7% 7.3% 16.6% 2.2% 5% 3% 41%	70 4 9 38 8 8 137	28.4% 1.6% 1.5% 48.1% 4.5% 7.5% 9.4%
Pooled Data	11905	2566	21.6%	197	7.7%

Yield of cancer diagnoses from TWW referrals with dysphagia - Dysphagia (includes intermittent, globus/FOSSIT (feeling of something stuck in throat) and odynophagia)

Study	Total referrals	Dysphagia	% of referrals	Cancer diagnosed	Cancer Diagnosed % of total referrals for dysphagia
McKie (94)	1079	90	8.3%	7	7.7%
Hobson(99)	177	13 12 Globus 25 total	7.3% 6.8% 14%	2	8%
Tikka (100)	4715	235 70 Intermittent 334 Globus 639 total	13.5% 1.5% 7% 13.5%	32 3 5 40 total	13.6% 4.3% 1.5% 6.3% total
Allam (102)	1367	33 181 Globus 214 Total	2.4% 13.2% 15.7%	2 0 2	6% 0 1%
Gao (103)	1036	83	8%	2	2.4%
Tikka (101)	3531	246 persistent 257 intermittent 587 fossit 176 choking episodes/feeling 107 regurgitation 1373 total	7% 7.3% 16.6% 5% 3% 38%	70 4 9 8 8 99	28.4% 1.6% 1.5% 4.5% 7.5% 7.2%
Pooled Data	11905	2424	20.4%	152	6.3%

Yield of cancer diagnoses from TWW referrals with dysphagia (with odynophagia cases removed)

Appendix B: Signs and Symptoms 22H3.00,O/E - thyroid swelling -bilat. 22H4.00,O/E - thyroid lump 22HZ.00,O/E - thyroid gland NOS 194..11, Dysphagia R072.00,[D]Dysphagia R072z00,[D]Dysphagia NOS 194..00,Swallowing symptoms 1942, Difficulty swallowing solids 1943, Difficulty swallowing liquids 1946, Chokes when swallowing 194Z.00, Swallowing symptom NOS ZV41612, [V] Problems with swallowing 25W1.00,O/E - swallowing abnormality 1952, Regurgitates food 1944.11,Odynophagia 1944, Painful swallowing 1CA2.11,Voice hoarseness R044.00,[D]Voice disturbance R044000,"[D]Voice disturbance, unspecified" R044200,[D]Loss of voice R044300,[D]Change in voice R044z00,[D]Other voice disturbance NOS Ryu6.00,[X]Symptoms and signs involving speech and voice Ryu6200,[X]Other and unspecified voice disturbances ZT15.00, Change in voice 1CA..00, Hoarseness symptom 1CA..11, Hoarseness - throat symptom 1CA2.00,Hoarse 1CA2.11, Voice hoarseness 1CAZ.00, Hoarseness symptom NOS 2DE4.00,O/E - hoarseness R044500,[D]Hoarseness F587.00,Otalgia F587000,Unspecified otalgia F587z00,Otalgia NOS F587.11,Ear pain F587200,Referred ear pain 1C32.00, Unilateral earache R042.00,"[D]Swelling, mass or lump in head and neck" R042.12,"[D]Swelling, mass or lump in neck" R042100,[D]Mass in head or neck

R042500,"[D]Localized swelling, mass and lump, neck"

R042z00,"[D]Swelling, mass or lump in head or neck NOS" 2C32.00,O/E -cervical lymphadenopathy R056100,[D]Swollen glands 1D21.00,Symptom: head/neck 1D21.12,C/O - a neck symptom 2I1A.00,Lump on neck 2I21.00,O/E - sign - head/neck 22G2.00,O/E - parotid swelling 22G5.00,Parotid lump 22G3.00,O/E - submandibular swelling R056z12,[D]Enlarged submandibular lymph gland 22G4.00,O/E - sublingual swelling R042B00,[D]Mandibular region swelling R042D00,[D]Swelling of mandibular region R056z12,[D]Enlarged submandibular lymph gland 1CB4.00, Feeling of lump in throat R042z11,[D]Lump throat E201612, Globus hystericus Eu45500,[X]Globus pharyngeus Eu45511,[X]Globus hystericus Eu45y12,[X]Globus hystericus 1C9..00,Sore throat symptom 1C9..11, Throat soreness 1C92.00, Has a sore throat 1C93.00, Persistent sore throat 1C9Z.00,Sore throat symptom NOS H02..11,Sore throat NOS H02..12, Viral sore throat NOS H121.11,Sore throat - chronic J096.12, Painful tongue R042700,[D]Tongue mass J096.00, Glossodynia 1922,Sore mouth 1922.11,Sore mouth - symptom 2567,O/E - ulcer on tongue 2568,O/E - leukoplakia on tongue J086.00,Leukoplakia of oral mucosa J086.11,Leucoplakia of oral mucosa J086z00, Oral mucosa leukoplakia NOS J087.00, Other oral epithelium disturbances J087000,Oral erythroplakia J086000,Leukoplakia of gingiva

1928, Bleeding gums

2556,O/E - bleeding gums 1923,Sore gums 1923.11,Sore gums - symptom 172..00,Blood in sputum - haemoptysis 172..12,Haemoptysis - symptom

1720, Massive haemoptysis

R063.00,[D]Haemoptysis

R063z00,[D]Haemoptysis NOS

172..00,Blood in sputum - haemoptysis

172..11,Blood in sputum - symptom

4E24.00,Sputum: contains blood

4E2G.00,Bloodstained sputum

4E35.00,Sputum: blood cells present

171B.00, Persistent cough

171E.00, Unexplained cough

171A.00, Chronic cough

173..13, Shortness of breath symptom

1739, Shortness of breath

R060800,[D]Shortness of breath

2DE2.00,O/E - stridor present

R061.00,[D]Stridor

2328,O/E - stertorous breathing

232C.00, Noisy breathing

232H.00,On examination - inspiratory wheeze

2D33.00,O/E - nasal polyp present

H11..00,Nasal polyps

H110.00,Polyp of nasal cavity

H110z00,Polyp of nasal cavity NOS

H11y.11,Nasal sinus polyps

H11z.00,Nasal polyp NOS

2D23.00,O/E-nasal discharge-foul smell

1C83.00, Nasal discharge present

2D2..00,O/E - nasal discharge

2D2Z.00,O/E - nasal discharge NOS

1C82.11,C/O nasal congestion

H1y1z12,Nasal congestion

1C82.00, Nasal obstruction present

H1y1600,Nasal obstruction

H1y1z11,Nasal obstruction

R04z400,[D]Nasal obstruction

1C86.00,Blocked nose

1CC..00,Blocked sinuses

14c..11, History of nose bleed

1C6..00,Nose bleed symptom 1C62.00, Has nose bleeds - epistaxis 1C6Z.00, Nose bleed symptom NOS 14c..00, History of epistaxis 1C6..11, Epistaxis symptom 1C62.00, Has nose bleeds - epistaxis 2D25.00,O/E - epistaxis R047.00,[D]Epistaxis R011.00,[D]Smell and taste disorder R011z00,[D]Smell or taste disorder NOS Ryu5200,[X]Other and unspecified disturbances of smell and taste ZV41500,[V]Problem with smell or taste ZV41511,[V]Problems with smell 1B45.00, Anosmia - loss of smell sense 1B45.12,C/O - loss of smell sense 2525,O/E - lip swelling J085412,Sore lip J085800,Lip ulcer J086100,Leukoplakia of lips 2BQ3.00,O/E - cranial nerve 3 - palsy 2BQ4.00,O/E -cranial nerve 3-paralysis 2BQ6.00,O/E - cranial nerve 4 - palsy 2BQ7.00,O/E -cranial nerve 4-paralysis 2BQ9.00,O/E - cranial nerve 6 - palsy 2BQA.00,O/E -cranial nerve 6-paralysis 2BR3.00,O/E - cranial nerve 5 - palsy 2BR4.00,O/E -cranial nerve 5-paralysis 2BR6.00,O/E -cranial nerve 7-palsy-LMN 2BS6.00,O/E - cranial nerve 11 - palsy 2BS7.00,O/E-cranial nerve 11 paralysis 2BS9.00,O/E - cranial nerve 12 - palsy 2BSA.00,O/E-cranial nerve 12 paralysis F32..00,Other cranial nerve disorders F326.00, Multiple cranial nerve palsies 1B32300, Facial weakness F31..00, Facial nerve disorders F31y.00,Other facial nerve disorders F31yz00,Other facial nerve disorder NOS F31z.00, Facial nerve disorder NOS F325.00, Hypoglossal nerve disorders F30y.00,Other trigeminal nerve disorder F30z.00, Trigeminal nerve disorder NOS F30..00, Trigeminal nerve disorders

F322.00, Other glossopharyngeal nerve disorder 1B72.00, Diplopia/double vision 1B72.11, Diplopia F482.00, Diplopia (double vision) 1B72.12, Double vision F4J5400, Abducens (sixth) nerve palsy F4J5111, Third nerve palsy - partial F4J5211, Third nerve palsy - total F4J5300,Trochlear (fourth) nerve palsy F323.00, Vagus nerve disorders 1371, Never smoked tobacco 1371.11,Non-smoker 137L.00,Current non-smoker 137..11, Smoker - amount smoked 1372, Trivial smoker - < 1 cig/day 1372.11,Occasional smoker 1373,Light smoker - 1-9 cigs/day 1374, Moderate smoker - 10-19 cigs/d 1375, Heavy smoker - 20-39 cigs/day 1376, Very heavy smoker - 40+cigs/d 137H.00,Pipe smoker 137J.00, Cigar smoker 137P.00, Cigarette smoker 137P.11,Smoker 137R.00, Current smoker 1377,Ex-trivial smoker (<1/day) 1378, Ex-light smoker (1-9/day) 1379, Ex-moderate smoker (10-19/day) 137A.00, Ex-heavy smoker (20-39/day) 137B.00, Ex-very heavy smoker (40+/day) 137F.00, Ex-smoker - amount unknown 137j.00,Ex-cigarette smoker 137I.00,Ex roll-up cigarette smoker 137N.00,Ex pipe smoker 1370.00,Ex cigar smoker 137S.00,Ex smoker 1625, Abnormal weight loss 1625.11, Abnormal weight loss - symptom 1627, Unintentional weight loss 1D1A.00,Complaining of weight loss 22A8.00, Weight loss from baseline weight R032.00,[D]Abnormal loss of weight R2y4.00,[D]Cachexia

R2y4z00,[D]Cachexia NOS

- 257..00,O/E breath smell
- 257..11,O/E smell of breath
- 2571,O/E breath smell normal
- 2572,O/E breath smell unpleasant
- 2577,O/E breath alcohol smell
- 257Z.00,O/E breath smell NOS
- 1752,Bad breath halitosis
- 1752.11,Bad breath
- 2573.11,0/E bad breath
- 136..00, Alcohol consumption
- 136L.00, Alcohol intake within recommended sensible limits
- 1368,Alcohol consumption unknown
- 1369, Suspect alcohol abuse denied
- 136e.00, Declines to state current alcohol consumption
- 136K.00, Alcohol intake above recommended sensible limits
- 136S.00, Hazardous alcohol use
- 136T.00, Harmful alcohol use
- 136V.00, Alcohol units per week
- 136W.00,Alcohol misuse
- 1462,H/O: alcoholism
- E23..00, Alcohol dependence syndrome
- E23..11, Alcoholism
- E23..12, Alcohol problem drinking
- E231.00, Chronic alcoholism
- E231000, Unspecified chronic alcoholism
- E231100,Continuous chronic alcoholism
- E231200,Episodic chronic alcoholism
- E231300, Chronic alcoholism in remission
- E231z00,Chronic alcoholism NOS
- E23z.00, Alcohol dependence syndrome NOS
- 1361.11,Non drinker alcohol
- 1361.12, Non-drinker alcohol
- 1367, Stopped drinking alcohol
- 4K3D.00,HPV Human papillomavirus test positive
- 685P.00, HPV Human papillomavirus test positive
- A541500, Anogenital herpesviral infection
- Ayu4G00,"[X]Anogenital herpes viral infection, unspecified"
- 4K2R.00,Cervical smear human papillomavirus positive
- A79B.00, Human papilloma virus infection
- 685Q.00, HPV Human papillomavirus test negative
- 4K3E.00,HPV Human papillomavirus test negative
- 4K2Q.00,Cervical smear human papillomavirus negative

Appendix C: List of Read Codes for multivariate regression modelling

Head and Neck Cancers

B0...00, "Malignant neoplasm of lip, oral cavity and pharynx" B00..00, Malignant neoplasm of lip B000.00,"Malignant neoplasm of upper lip, vermilion border" B000000,"Malignant neoplasm of upper lip, external" B000100, "Malignant neoplasm of upper lip, lipstick area" B000z00,"Malignant neoplasm of upper lip, vermilion border NOS" B001.00,"Malignant neoplasm of lower lip, vermilion border" B001000,"Malignant neoplasm of lower lip, external" B001100, "Malignant neoplasm of lower lip, lipstick area" B001z00,"Malignant neoplasm of lower lip, vermilion border NOS" B002.00,"Malignant neoplasm of upper lip, inner aspect" B002000, "Malignant neoplasm of upper lip, buccal aspect" B002100, "Malignant neoplasm of upper lip, frenulum" B002200,"Malignant neoplasm of upper lip, mucosa" B002300, "Malignant neoplasm of upper lip, oral aspect" B002z00,"Malignant neoplasm of upper lip, inner aspect NOS" B003.00,"Malignant neoplasm of lower lip, inner aspect" B003000,"Malignant neoplasm of lower lip, buccal aspect" B003100,"Malignant neoplasm of lower lip, frenulum" B003200,"Malignant neoplasm of lower lip, mucosa" B003300, "Malignant neoplasm of lower lip, oral aspect" B003z00,"Malignant neoplasm of lower lip, inner aspect NOS" B004.00,"Malignant neoplasm of lip unspecified, inner aspect" B004000,"Malignant neoplasm of lip unspecified, buccal aspect" B004100,"Malignant neoplasm of lip unspecified, frenulum" B004200, "Malignant neoplasm of lip unspecified, mucosa" B004300,"Malignant neoplasm of lip, oral aspect" B004z00,"Malignant neoplasm of lip, inner aspect NOS" B005.00, Malignant neoplasm of commissure of lip B006.00, Malignant neoplasm of overlapping lesion of lip B007.00,"Malignant neoplasm of lip, unspecified" B00y.00, Malignant neoplasm of other sites of lip B00z.00, Malignant neoplasm of vermilion border of lip unspecified B00z000,"Malignant neoplasm of lip, unspecified, external" B00z100,"Malignant neoplasm of lip, unspecified, lipstick area" B00zz00,"Malignant neoplasm of lip, vermilion border NOS" B01..00, Malignant neoplasm of tongue B010.00, Malignant neoplasm of base of tongue B010.11, Malignant neoplasm of posterior third of tongue B010000, Malignant neoplasm of base of tongue dorsal surface

B010z00, Malignant neoplasm of fixed part of tongue NOS B011.00, Malignant neoplasm of dorsal surface of tongue B011000, Malignant neoplasm of anterior 2/3 of tongue dorsal surface B011100, Malignant neoplasm of midline of tongue B011z00, Malignant neoplasm of dorsum of tongue NOS B012.00, "Malignant neoplasm of tongue, tip and lateral border" B013.00, Malignant neoplasm of ventral surface of tongue B013000, Malignant neoplasm of anterior 2/3 of tongue ventral surface B013100, Malignant neoplasm of frenulum linguae B013z00, Malignant neoplasm of ventral tongue surface NOS B014.00, Malignant neoplasm of anterior 2/3 of tongue unspecified B015.00,"Malignant neoplasm of tongue, junctional zone" B016.00, Malignant neoplasm of lingual tonsil B017.00, Malignant overlapping lesion of tongue B01y.00, Malignant neoplasm of other sites of tongue B01z.00, Malignant neoplasm of tongue NOS B02..00, Malignant neoplasm of major salivary glands B020.00, Malignant neoplasm of parotid gland B021.00, Malignant neoplasm of submandibular gland B022.00, Malignant neoplasm of sublingual gland B023.00,"Malignant neoplasm, overlapping lesion of major saliv gland" B02y.00, Malignant neoplasm of other major salivary glands B02z.00, Malignant neoplasm of major salivary gland NOS B03..00, Malignant neoplasm of gum B030.00, Malignant neoplasm of upper gum B031.00, Malignant neoplasm of lower gum B03y.00, Malignant neoplasm of other sites of gum B03z.00, Malignant neoplasm of gum NOS B04..00, Malignant neoplasm of floor of mouth B040.00, Malignant neoplasm of anterior portion of floor of mouth B041.00, Malignant neoplasm of lateral portion of floor of mouth B042.00,"Malignant neoplasm, overlapping lesion of floor of mouth" B04y.00, Malignant neoplasm of other sites of floor of mouth B04z.00, Malignant neoplasm of floor of mouth NOS B05..00, Malignant neoplasm of other and unspecified parts of mouth B050.00, Malignant neoplasm of cheek mucosa B050.11, Malignant neoplasm of buccal mucosa B051.00, Malignant neoplasm of vestibule of mouth B051000, Malignant neoplasm of upper buccal sulcus B051100, Malignant neoplasm of lower buccal sulcus B051200, Malignant neoplasm of upper labial sulcus B051300, Malignant neoplasm of lower labial sulcus B051z00, Malignant neoplasm of vestibule of mouth NOS

B052.00, Malignant neoplasm of hard palate B053.00, Malignant neoplasm of soft palate B054.00, Malignant neoplasm of uvula B055.00, Malignant neoplasm of palate unspecified B055000, Malignant neoplasm of junction of hard and soft palate B055100, Malignant neoplasm of roof of mouth B055z00, Malignant neoplasm of palate NOS B056.00, Malignant neoplasm of retromolar area B05y.00, Malignant neoplasm of other specified mouth parts B05z.00, Malignant neoplasm of mouth NOS B06..00, Malignant neoplasm of oropharynx B060.00, Malignant neoplasm of tonsil B060000, Malignant neoplasm of faucial tonsil B060100, Malignant neoplasm of palatine tonsil B060200, Malignant neoplasm of overlapping lesion of tonsil B060z00, Malignant neoplasm tonsil NOS B061.00, Malignant neoplasm of tonsillar fossa B062.00, Malignant neoplasm of tonsillar pillar B062000, Malignant neoplasm of faucial pillar B062100, Malignant neoplasm of glossopalatine fold B062200, Malignant neoplasm of palatoglossal arch B062300, Malignant neoplasm of palatopharyngeal arch B062z00, Malignant neoplasm of tonsillar fossa NOS B063.00, Malignant neoplasm of vallecula B064.00, Malignant neoplasm of anterior epiglottis B064000,"Malignant neoplasm of epiglottis, free border" B064100, Malignant neoplasm of glossoepiglottic fold B064z00, Malignant neoplasm of anterior epiglottis NOS B065.00, Malignant neoplasm of junctional region of epiglottis B066.00, Malignant neoplasm of lateral wall of oropharynx B067.00, Malignant neoplasm of posterior wall of oropharynx B06y.00,"Malignant neoplasm of oropharynx, other specified sites" B06y000, Malignant neoplasm of branchial cleft B06yz00, Malignant neoplasm of other specified site of oropharynx NOS B06z.00, Malignant neoplasm of oropharynx NOS B07..00, Malignant neoplasm of nasopharynx B070.00, Malignant neoplasm of roof of nasopharynx B071.00, Malignant neoplasm of posterior wall of nasopharynx B071000, Malignant neoplasm of adenoid B071100, Malignant neoplasm of pharyngeal tonsil B071z00, Malignant neoplasm of posterior wall of nasopharynx NOS B072.00, Malignant neoplasm of lateral wall of nasopharynx B072000, Malignant neoplasm of pharyngeal recess

B072100, Malignant neoplasm of opening of auditory tube B072z00, Malignant neoplasm of lateral wall of nasopharynx NOS B073.00, Malignant neoplasm of anterior wall of nasopharynx B073000, Malignant neoplasm of floor of nasopharynx B073100, Malignant neoplasm of nasopharyngeal soft palate surface B073200, Malignant neoplasm posterior margin nasal septum and choanae B073z00, Malignant neoplasm of anterior wall of nasopharynx NOS B074.00,"Malignant neoplasm, overlapping lesion of nasopharynx" B07y.00, Malignant neoplasm of other specified site of nasopharynx B07z.00, Malignant neoplasm of nasopharynx NOS B08..00, Malignant neoplasm of hypopharynx B080.00, Malignant neoplasm of postcricoid region B081.00, Malignant neoplasm of pyriform sinus B082.00, "Malignant neoplasm aryepiglottic fold, hypopharyngeal aspect" B083.00, Malignant neoplasm of posterior pharynx B084.00,"Malignant neoplasm, overlapping lesion of hypopharynx" B08y.00, Malignant neoplasm of other specified hypopharyngeal site B08z.00, Malignant neoplasm of hypopharynx NOS B0z0.00, Malignant neoplasm of pharynx unspecified B0z1.00, Malignant neoplasm of Waldever's ring B0z2.00, Malignant neoplasm of laryngopharynx B0zy.00,"Malignant neoplasm of other sites lip, oral cavity, pharynx" B0zz.00,"Malignant neoplasm of lip, oral cavity and pharynx NOS" B200.00, Malignant neoplasm of nasal cavities B200000, Malignant neoplasm of cartilage of nose B200100, Malignant neoplasm of nasal conchae B200200, Malignant neoplasm of septum of nose B200300, Malignant neoplasm of vestibule of nose B200z00, Malignant neoplasm of nasal cavities NOS B201000, Malignant neoplasm of auditory (Eustachian) tube B201100, Malignant neoplasm of tympanic cavity B201200, Malignant neoplasm of tympanic antrum B201300, Malignant neoplasm of mastoid air cells B202.00, Malignant neoplasm of maxillary sinus B203.00, Malignant neoplasm of ethmoid sinus B204.00, Malignant neoplasm of frontal sinus B205.00, Malignant neoplasm of sphenoidal sinus B206.00, "Malignant neoplasm, overlapping lesion of accessory sinuses" B20z.00, Malignant neoplasm of accessory sinus NOS B21..00, Malignant neoplasm of larynx B210.00, Malignant neoplasm of glottis B211.00, Malignant neoplasm of supraglottis B212.00, Malignant neoplasm of subglottis

B213.00, Malignant neoplasm of laryngeal cartilage B213000, Malignant neoplasm of arytenoid cartilage B213100, Malignant neoplasm of cricoid cartilage B213200, Malignant neoplasm of cuneiform cartilage B213300, Malignant neoplasm of thyroid cartilage B213z00, Malignant neoplasm of laryngeal cartilage NOS B214.00, "Malignant neoplasm, overlapping lesion of larynx" B215.00, Malignant neoplasm of epiglottis NOS B21y.00,"Malignant neoplasm of larynx, other specified site" B21z.00, Malignant neoplasm of larynx NOS B300000, Malignant neoplasm of ethmoid bone B300100, Malignant neoplasm of frontal bone B300200, Malignant neoplasm of malar bone B300300, Malignant neoplasm of nasal bone B300400, Malignant neoplasm of occipital bone B300500, Malignant neoplasm of orbital bone B300600, Malignant neoplasm of parietal bone B300700, Malignant neoplasm of sphenoid bone B300800, Malignant neoplasm of temporal bone B300900, Malignant neoplasm of zygomatic bone B300A00, Malignant neoplasm of maxilla B300B00, Malignant neoplasm of turbinate B300C00, Malignant neoplasm of vomer B300z00, Malignant neoplasm of bones of skull and face NOS B301.00, Malignant neoplasm of mandible B53..00, Malignant neoplasm of thyroid gland B550.00,"Malignant neoplasm of head, neck and face" B550200, Malignant neoplasm of nose NOS B550300, Malignant neoplasm of jaw NOS B550400, Malignant neoplasm of neck NOS B550z00,"Malignant neoplasm of head, neck and face NOS" B213300, Malignant neoplasm of thyroid cartilage B53..00, Malignant neoplasm of thyroid gland

ByuB.00, [X] Malignant neoplasm of thyroid and other endocrine glands

PROSPERO

International prospective register of systematic reviews



UNIVERSITY of York Centre for Reviews and Dissemination

Systematic review

1. * Review title.

Give the title of the review in English

The factors influencing the implementation of clinical decision tools for suspected cancer within primary care:

a framework synthesis

2. Original language title.

For reviews in languages other than English, give the title in the original language. This will be displayed with the English language title.

3. * Anticipated or actual start date.

Give the date the systematic review started or is expected to start.

02/04/2018

4. * Anticipated completion date.

Give the date by which the review is expected to be completed.

31/08/2019

5. * Stage of review at time of this submission.

Tick the boxes to show which review tasks have been started and which have been completed. Update this field each time any amendments are made to a published record.

Reviews that have started data extraction (at the time of initial submission) are not eligible for inclusion in PROSPERO. If there is later evidence that incorrect status and/or completion date has been supplied, the published PROSPERO record will be marked as retracted.

This field uses answers to initial screening questions. It cannot be edited until after registration.

The review has not yet started: No

Page: 1 / 11

PROSPERO International prospective register of systematic reviews	National Institute for Health Research	
Review stage	Started	Completed
Preliminary searches	Yes	Yes
Piloting of the study selection process	Yes	Yes
Formal screening of search results against eligibility criteria	Yes	Yes
Data extraction	Yes	Yes
Risk of bias (quality) assessment	Yes	Yes
Data analysis	Yes	Yes
Provide any other relevant information about the stage of the review here. Being written up		

Being written up

6. * Named contact.

The named contact is the guarantor for the accuracy of the information in the register record. This may be any member of the review team.

Paula Bradley

Email salutation (e.g. "Dr Smith" or "Joanne") for correspondence:

Dr Bradley

7. * Named contact email.

Give the electronic email address of the named contact.

paula.bradley@sunderland.ac.uk

8. Named contact address

Give the full institutional/organisational postal address for the named contact.

Medical School

Science and Wellbeing

City Campus

Sunderland University

Sunderland

Page: 2 / 11

PROSPERO International prospective register of systematic reviews



SR1 3SD

9. Named contact phone number.

Give the telephone number for the named contact, including international dialling code.

+44 (0)191 515 3212

10. * Organisational affiliation of the review.

Full title of the organisational affiliations for this review and website address if available. This field may be completed as 'None' if the review is not affiliated to any organisation.

None

Organisation web address:

11. * Review team members and their organisational affiliations.

Give the personal details and the organisational affiliations of each member of the review team. Affiliation refers to groups or organisations to which review team members belong. **NOTE: email and country now MUST be entered for each person, unless you are amending a published record.**

Dr Paula Bradley. Sunderland University Dr Nichola Hall. University of Sunderland Dr Gregory Maniatopoulos. University of Newcastle

12. * Funding sources/sponsors.

Details of the individuals, organizations, groups, companies or other legal entities who have funded or sponsored the review.

PhD project, part time salary funded by Health Education England North East.

Grant number(s)

State the funder, grant or award number and the date of award

13. * Conflicts of interest.

List actual or perceived conflicts of interest (financial or academic).

None

14. Collaborators.

Give the name and affiliation of any individuals or organisations who are working on the review but who are not listed as review team members. **NOTE: email and country must be completed for each person**, **unless you are amending a published record.**

Professor Vinidh Paleri. The Institute of Cancer Research, London Professor Richard Neal. University of Leeds Professor Scott Wilkes. University of Sunderland

15. * Review question.

State the review question(s) clearly and precisely. It may be appropriate to break very broad questions down into a series of related more specific questions. Questions may be framed or refined using PI(E)COS or similar where relevant.

What are the factors influencing the implementation of General Practitioners using decision tools for

Page: 3 / 11

PROSPERO International prospective register of systematic reviews



Not applicable.

26. * Data extraction (selection and coding).

Describe how studies will be selected for inclusion. State what data will be extracted or obtained. State how this will be done and recorded.

Title, abstract and full paper screening for inclusion in the analysis will be carried out by PB along with a

Sætaræktrædeiwrerw(INDe) æatirigdrædetpæsinderætigomprehensive data extraction template which will be designed

based on the specific characteristics of the review. Extraction will be undertaken by PB and

checked="checked" value="1" by a second reviewer (NH).

27. * Risk of bias (quality) assessment.

State which characteristics of the studies will be assessed and/or any formal risk of bias/quality assessment tools that will be used.

DAS PeGezdidative voltheaktiistaviidh by used bird zesieszethie zgralityn of thraistudi be by alcheed v (PiB de pUH) dent

reviewers with arbitration from a third if necessary (PB & NH).

28. * Strategy for data synthesis.

Describe the methods you plan to use to synthesise data. This **must not be generic text** but should be **specific to your review** and describe how the proposed approach will be applied to your data. If metaanalysis is planned, describe the models to be used, methods to explore statistical heterogeneity, and software package to be used.

A description of the selected studies will be undertaken followed by a thematic analysis of the discussion

material from the identified studies using Normalisation Process Theory as the framework.

29. * Analysis of subgroups or subsets.

State any planned investigation of 'subgroups'. Be clear and specific about which type of study or participant will be included in each group or covariate investigated. State the planned analytic approach. Subgroup analysis may be possible according to types of clinical decision tool intervention.

30. * Type and method of review.

Select the type of review, review method and health area from the lists below.

Type of review Cost effectiveness No Diagnostic No Epidemiologic No Individual patient data (IPD) meta-analysis No Intervention

Page: 6 / 11

PROSPERO International prospective register of systematic reviews

National Institute for Health Research

https://bmjopen.bmj.com/content/11/2/e043338

Give the link to the published review or preprint.

https://bmjopen.bmj.com/content/11/2/e043338

Page: 11 / 11

PROSPERO

International prospective register of systematic reviews

34. Reference and/or URL for published protocol.

If the protocol for this review is published provide details (authors, title and journal details, preferably in Vancouver format)

Add web link to the published protocol.

Or, upload your published protocol here in pdf format. Note that the upload will be publicly accessible.

Yes I give permission for this file to be made publicly available

Please note that the information required in the PROSPERO registration form must be completed in full even if access to a protocol is given.

35. Dissemination plans.

Do you intend to publish the review on completion?

Yes

Give brief details of plans for communicating review findings.?

Dissemination will be to general practice audiences through oral presentations as well as submission to

appropriate journals.

36. Keywords.

Give words or phrases that best describe the review. Separate keywords with a semicolon or new line. Keywords help PROSPERO users find your review (keywords do not appear in the public record but are included in searches). Be as specific and precise as possible. Avoid acronyms and abbreviations unless these are in wide use.

Ganceal Practice

Risk Assessment Tools

Prediction

37. Details of any existing review of the same topic by the same authors.

If you are registering an update of an existing review give details of the earlier versions and include a full bibliographic reference, if available.

38. * Current review status.

Update review status when the review is completed and when it is published.New registrations must be ongoing so this field is not editable for initial submission. Please provide anticipated publication date

Review_Completed_published_being_updated

39. Any additional information.

Provide any other information relevant to the registration of this review.

40. Details of final report/publication(s) or preprints if available.

Leave empty until publication details are available OR you have a link to a preprint (NOTE: this field is not editable for initial submission). List authors, title and journal details preferably in Vancouver format.

Page: 10 / 11

NHS

National Institute for

Health Research

PROSPERO

International prospective register of systematic reviews

No

Physiotherapy No Pregnancy and childbirth No Public health (including social determinants of health) No Rehabilitation No Respiratory disorders No Service delivery No Skin disorders No Social care No Surgery No **Tropical Medicine** No Urological No Wounds, injuries and accidents No Violence and abuse No

31. Language.

Select each language individually to add it to the list below, use the bin icon to remove any added in error.

There is not an English language summary

32. * Country.

Select the country in which the review is being carried out. For multi-national collaborations select all the countries involved.

England

33. Other registration details.

Name any other organisation where the systematic review title or protocol is registered (e.g. Campbell, or The Joanna Briggs Institute) together with any unique identification number assigned by them. If extracted data will be stored and made available through a repository such as the Systematic Review Data Repository (SRDR), details and a link should be included here. If none, leave blank.

Page: 9 / 11

Appendix D: Database Searches

MEDLINE July 15th 2020

Results 1273

- 1. Neoplasms/
- 2. Oncology.mp.
- 3. Malignan*.mp.
- 4. Cancer.mp.
- 5. Tumo\$r.mp.
- 6. 1 or 2 or 3 or 4 or 5
- 7. General Practice/
- 8. general practice.mp.
- 9. Family Practice/
- 10. family practice.mp.
- 11. family medicine.mp.
- 12. Physicians, Family/
- 13. family physician*mp.
- 14. Primary Health Care/
- 15. primary health care.mp.
- 16. 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15
- 17. Risk Assessment/
- 18. risk assessment.mp.
- 19. risk assessment tool.mp.
- 20. Decision Support Systems, Clinical/
- 21. decision support system.mp.
- 22. Diagnosis, Computer Assisted/
- 23. Decision Making/
- 24. decision making.mp.
- 25. decision making aid.mp.
- 26. predictive modelling.mp.
- 27. prediction.mp.
- 28. model.mp.
- 29. Models. Statistical/
- 30. statistical model*.mp.
- 31. 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30
- 32. 6 and 16 and 31

- 1. malignant neoplasm/
- 2. cancer.mp.
- 3. oncology/
- 4. oncology.mp.
- 5. malignan*.mp.
- 6. neoplasm/
- 7. tumo\$r.mp.
- 8. 1 or 2 or 3 or 4 or 5 or 6 or 7
- 9. general practice/
- 10. general practice.mp.
- 11. family practice.mp.
- 12. family medicine/
- 13. family medicine.mp.
- 14. family physician.mp.
- 15. general practitioner/
- 16. general practitioner.mp.
- 17. primary health care/
- 18. primary health care.mp.
- 19. 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18
- 20. risk assessment/
- 21. risk assessment.mp.
- 22. risk assessment tool.mp.
- 23. decision support system/
- 24. decision support system.mp.
- 25. computer assisted diagnosis/
- 26. decision making/
- 27. decision making.mp.
- 28. medical decision making.mp.
- 29. prediction/
- 30. prediction.mp.
- 31. predictive modelling.mp.
- 32. model/
- 33. statistical modelling/
- 34. statistical modelling.mp.
- 35. 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
- 36. 8 and 19 and 35

CINAHL July 15th 2020– results 955

- S1 neoplasm OR malignancy OR cancer OR tumour OR tumor OR oncology
- S2 general practice OR family practice OR family medicine OR primary health care
- S3 risk assessment OR risk assessment tools OR decision support system OR decision support tool OR decision making models OR decision making aid OR prediction OR prediction model OR computer aided diagnosis OR model OR statistical modelling
- S4 S1 AND S2 AND S3

Web of Science July 15th 2020– results 1405

- 1. cancer
- 2. malignan*
- 3. neoplasm*
- 4. oncology
- 5. tumo\$r*
- 6. 5 OR 4 OR 3 OR 2 OR 1
- 7. general practice
- 8. family medicine
- 9. family practice
- 10. primary health care
- 11. 10 OR 9 OR 8 OR 7
- 12. risk assessment tool
- 13. decision support system
- 14. decision support tool
- 15. decision making
- 16. decision making tool
- 17. decision making aid
- 18. prediction
- 19. prediction model*
- 20. statistical model*
- 21. 21 OR 20 OR 19 OR 18 OR 17 OR 16 OR 15 OR 14 OR 13 OR 12 OR 11
- 22. 22 AND 11 AND 6
- 23. 22 AND 11 AND 6 refined by Web Of Science Categories (PRIMARY HEALTH CARE)

Grey literature search terms

Google searches

First 5 result pages screened

cancer decision tools primary care

cancer risk assessment tools primary care

cancer prediction decision primary care

risk assessment tool cancer primary care filetype:pdf



Appendix E: Examples of coding and theme development for Framework Synthesis

Rompts - Romet FATIGHE. ROF Arlord. Hamph Arlord. Hamph Arlord. Hammin http:// united. It the year is pandie. younged prestant response when to integrate Comme latienstrat. I ruitment in nearer show men truit drives acures. Andit Ovidence -Tral to make we kettertin an anoral mady dary. up pranie - Value > mile suthin womenent / entitimation etterment Software Internet water / boker. protene theacy deternat Church 1 phuntymen. alimnar Conhundens underschein Ashin top multic Jumile aceptibility duttient having to routirent lavela tules - S'Integration Intraduction out Objectutouse asport Amil. augrehere mig Kenera tol Recommentation of a surpression. Scapticism. Vietrenonnou Ign prevalence leards to Lew surprise. endurue ettemnese. taculante engançais Bethromanimust

Cartucturin NCE. Origination. Contracter. Contracter. Action Gleché Varader behreen CP. O'Care D. Provent - uncertul lead codip. allearning pereits, lledrongen dui col Jurdie anne 1247. Der wir Indre ATAU. hie hurehrie countrier. Gim her 12 why. Thacedy -? Jecquire Renauer higher - ogenerulynort. Energenergener. aver metersal. >Htonl=>curd. Smu au NHI Rechurch overseteral. Juris a lough the second When eine hertenant l'auttrachar duttorvigople Needwore avoiliget etco Varietye whereher Advidued. Collective Action

henonowalcharge. Une will near sharted have deneary putriel. Ortice non jundement 2° cove. Serpare mini Consulation. Corybure 1 Mi ferenth comments truesourp , to the month of the month have every home Repure A. A. evaluate effectuations Educaturel. (nonlycher A Re averetante (Amued deuner nowing 5 Rennance. points Shouppinhumperint Freddy Mulleren " 1xpleneter Reporting Naining and a laborat

charence.

Indertending ish And rather than instruction experience very protocol Import pred of or aprovid invertigates / reduce over investigates pringst- action Screen/ aroanty herromolowares assut avoveness / elemnic highlight / pringst. [Farmenets. Shoring inster firth partient.

Medicaley al overtetand

Cognitive Paricipation

Softwore integration ITT child systems. Obligation to use - Research — beingpaid Prompts - weeful hat. — hav use lutilic frequency ligse

Secondary care on boord.

Leud coding Inductual bespone traingloesponeto New unaoctien. Collective action Organisathereel aspects accessing gazing Integration bystern Possista totage

> Pa kulit snor hik Anaye kulin Time augusticher Calut Mr.


Easytome

Screenvy potnil

Enderce bared

F cencer sprystoms. " thruncener"

Pichupot carino /retensos Hat much to norchopyrud

Ses Andit

Increase referrals

Loro " Frangel. aunter s runtinet where represent Doatsbullie ICAL W JRW) " Third carcer Improve speed of diagnosis/investigations/reduce over investigation/prompt action -lature rection Read coding X Financial implications – resources, dichotomy of referral/over referral X Valiable interpretation of symptoms JONC · B. P. Hepman Backer wee Screening/modification of behaviour/awareness Je. Electronic highlights/prompt fatigue/constant awareness/electronic highlight frompt fatigue/overload X _ D Suckment Audit/endence X . Derinterverien made a bis cou seve Chayers Garaltaline reversion kased awareness of cancer symptoms of based awareness of cancer symptoms of bespore to new innovations/hools 🐝 Obligation to use - part of trial/being paid (Australian trial) Ass excertance datermining engagement (intrintion/mistruct Age experience determining engagement/intuition/mistrust Sharing with patient/or not at all - reassurance, any ethy to Organisational aspects - access, googling to Gecondary care on board * Proven efficacy does not guarantee acceptability. Software integration/IT/Glitches/clinical systems X Training/understanding/continuous interaction Evaluate effective referrals privilie an recourt Different to 2WW criteria/at odds with NICE 💥 Eutredderg work 5 super by fredon mynunt of oppresence on neor Raised awareness of cancer symptoms Adjunct to NICE ZWW - conflict Time saving/time consuming Implementation - make or break Easy to use * Aid rather than instruction ¥ Experience versus protocol Screening potential Understanding risk 🔆 Training Behaviour change drawment burntment + engerunt +) poticipats Buydow molestinolog + partie detres + againes a prudici as a cymer + Environment of survey of survey of helpin har provident first under the to a particular to Cardwillentradourg degraded an work much strift yorn aftered int. Armin coulons. Concorn thomand in frinkin Coulons. agoundare lugget Sar ucare. Col le drie universitatent i its Proprietor of succurrences of the astrony wards of the second of the sec White Montering of a char " + 1 a diff ad tup. dependent work hive machina throw effect. Haverauct it Cognitive participation いようしょう whether would be reguines collects Were

Coherence	Prompt to think cancer
How they make sense of the work of	Awareness
implementation and integration	Understanding risk
Enhanced by factors that promote or inhibit	Aid rather than instruction
	Experience versus protocol
	Improve speed of
	diagnosis/investigations/reduce over
	investigation/prompt action
	Screen modify behaviour/awareness
	Constant awareness/electronic
	highlight/prompt/increase awareness
	Medicolegal aspects
	Over-referral
Cognitive participation	Software integration/IT clinical systems
Commitment and participation by	Obligation to use - research/being paid
participants	Prompts - useful/not, frequency/type,
Factors that promote/inhibit participation	utilised
	Secondary care on
	board/involvement/legitimise
	Read coding
	Individual bespoke training/response to
	new innovations
Collective Action	Organisational aspects
How enact it	Accessing/googling/embedding into clinical
	systems
	Prompt fatigue
	Share risk with patient
	Time impact/time constraints/time to
	use/train/keep using
	Conflict with NICE guidelines
Reflexive Monitoring	Easy to use
Appraise effects	Screening potential
	Evidence based
	Increase in cancer pick up/referral because
	of tool
	"think cancer:
	Audit - increase in referrals/not

"Our own experience of NPT coding is that if data are based on planning and implementation of an intervention they are most likely to relate to coherence and cognitive participation and if they are based on actual experiences of enacting a new intervention they are most likely to relate to collective action and reflexive monitoring" (McEvoy 2014)

Appendix F: Topic Guides

Head and Neck Consultants

What are your thoughts about the Head and neck cancer two week wait criteria

How do you think it is working/not

How to you perceive GPs are finding it/using it

What changes do you think need to be made/How could it be improved/What changes to the system

do you think are needed

How do you think GPs would receive these changes

Are you aware of the risk assessment tools developed from head and neck departments

What do you think of these

If not aware can show the online tool at this point

What do you think of this

Where in the pathway do you think this could be used

What do you think GPs would think of this

What do you think would stop GPs using something like this

How could head and neck surgeons help acceptance/use/implementation of a tool like this in the cancer pathway for patients

GP Interview Topic Guide

Can you tell me about any risk assessment tools that you use (example Qrisk)

Tell me what makes you use this tool so frequently

What do you like about it/what makes it useful/easy to use

Are there any aspects of it that you dislike

What do you say to your patients when you use it/How do you explain what it is to your patient

How do you explain/quantify risk to your patient

How would you feel about communicating a risk of a cancer diagnosis with a patient, can you envisage any problems with this

Are you aware of any cancer risk assessment tools - show one of the RAT tables/qcancer if not

If so - tell me about them/your experience of them/your thoughts/reservations about using them

If you know any tell me about your experience of/with them/any thoughts on them

What would you think about a risk assessment tool for head and neck cancer

Show the ORLhealth website

How would you like it to be presented/what format would be most appealing for you to use it – examples – within EMIS/SystmOne/within the 2WW referral proforma/website

What would stop you using it

What would help you to use it/consider using it/use it more

What training/support/feedback (initial/ongoing) do you think would make it a workable addition to your current practice

How would secondary care support/recognition/endorsement of such an endeavour help or do you think this is even required

General Dental Practitioners Topic Guide

How often would you say that you refer a suspicious lesion into the hospital How do you facilitate that Do you use an electronic process or secretarial or physical letter to refer How do you think that process works for GDPs What are your thoughts about the Head and neck cancer two week wait criteria How do you think it is working/not How to you perceive other GDPs are finding it/using it What changes do you think need to be made/How could it be improved/What changes to the system do you think are needed How do you think GDPs would receive these changes Were you aware of the risk assessment tools developed from head and neck departments What did you think of the one that I sent to you If not aware can show the online tool at this point What do you think of this Where in the pathway do you think this could be used What do you think GDPs would think of this What do you think would stop GDPs using something like this What about the patients

What would you tell the patients – would using a tool like this change what you would say to the patient

How could head and neck surgeons help acceptance/use/implementation of a tool like this in the cancer pathway for patients

PCPI Interview Topic Guide

Introduction - do you have any questions about the interview

I want to find out about how patients feel about GPs using computer decision aids as part of a consultation, to do this I would like you to tell me about how you find your consultations with GPs then I will ask you some questions about whether they have used anything with you to talk about risk of having a disease or things that you can do to reduce risk to your health.

Tell me a bit about how you find your consultations with GPs in general

What are some of the good things that they do or that you do like

What are some of the bad things that they do or that you don't like

Can you remember any times when the GP has discussed risk with you

How did the GP explain it so that it made sense to you

Some GPs say that they use examples like.....what do you think of that

(can use examples here)

How do you find GPs using computers in the consultations

Do you have any experience of a doctor/GP using a decision aid to help them manage your medical problems?

(can use examples here)

If you have what did the doctor tell you about it?

What did you think about the doctor using the decision aid in the consultation?

How did it fit in the flow of the conversation

How would you feel about a decision aid that a GP could use to help predict the best way for your problem to be managed in terms of referral to hospital?

What would you think if a doctor used a decision aid that helped them to predict if your symptoms were because of cancer?

How would you feel about a GP using percentages, smiley sad faces, pictures to explain risk

Head and Neck Surgeons – Covid-19 Interview Topic Guide

What do you think of the tool

How have you found using it

What have been the difficulties?

What is good about it

Have there been any teething problems what have these been and how did you overcome them

Do you think you needed more information/support at the beginning/as you went along

How do you include it in the consultation, do you use it as a script, do you answer the questions as you go along or ask the specifics of the patient

How do you think the patients are finding it

Have they commented on any of the questions

Have you modified any of the questions or the language that you use with the patients

Are there any of the domains which take a bit more exploration with the patient than others, which ones are those

Do you have any access to photography from the patients, would that be a useful addition when triaging

Can you envisage GPs using it as a triage for 2ww in the future

What grades of doctors in your hospital have been using it

Can you imagine patients using it independently of a clinician

What do you think of this way of working

How long on average do you think your calls are when you are using the tool, do you think it saves time compared to a telephone consultation without the tool

How many of the patients would you say you still need to see face to face

Can you see it working being used beyond Covid-19

If yes why

If not why not

Who do you think is the best grade/person to be using this tool

Does it have to be a specialist

Has it been used by junior staff and how comfortable do you find this

Can you anticipate any problems with the tool being used by non head and neck cancer specialists

Are there other health care professionals who it might be suitable for

How do you explain what it is to the patient

How do you explain risk

Do you use the percentage/numbers with the patient

How often do you "override" the tool? And what are the reasons for this

How are you safety netting, what do you say to the patient about where to access help if they have ongoing/new symptoms

Are you documenting in the letter to the GP

How are you communicating it to them

How do you see the future of the 2ww pathway post covid-19

Do you think this experience will change the future iteration of the 2ww hnc pathway and in what way/s $% \left(\frac{1}{2}\right) =0$

What changes do you think need to be made

How do you think this will happen

How will this be received by the CCG/NICE/GPs/patients

If you don't use the tool what would persuade you to use it

Have you any thoughts about whether there are differences in how it is used or how useful it is for ENT/OMFS

Head and Neck Cancer Patients Topic Guide

Introduction

Thank you for agreeing to this interview, do you have any questions about the interview?

Before we start I want to let you know that you can stop the interview at any time, if you don't understand what I am asking please let me know and I will try and explain things more clearly.

If you want to stop the interview you can ask that I destroy any information that I have recorded if you do not want it to be used and I will do that. If following the interview you do not want the recording used you can contact me and let me know and I will deleted the recording and will not use it for any future work.

I want to find out about how patients feel about GPs using computer decision aids as part of a consultation, to do this I would like you to tell me about how you find your consultations with GPs then I will ask you some questions about whether they have used anything with you to talk about risk of having a disease or things that you can do to reduce risk to your health.

Questions

Do you want to tell me about how your cancer was diagnosed?

If you feel comfortable discussing it please tell me about your experience of your GP or dentist leading up to your appointment in the hospital.

Tell me a bit about how you find your consultations with GPs in general

What are some of the good things that they do or that you do like

What are some of the bad things that they do or that you don't like

Can you remember any times when the GP has discussed risk with you

How did the GP explain it so that it made sense to you

Some GPs say that they use examples like.....what do you think of that

(can use examples here)

How do you find GPs using computers in the consultations

Do you have any experience of a doctor/GP using a decision aid to help them manage your medical problems?

(can use examples here)

If you have what did the doctor tell you about it?

What did you think about the doctor using the decision aid in the consultation?

How did it fit in the flow of the conversation

How would you feel about a decision aid that a GP could use to help predict the best way for your problem to be managed in terms of referral to hospital?

What would you think if a doctor used a decision aid that helped them to predict if your symptoms were because of cancer?

How do you think a GP or a dentist can best explain what they are doing when they use a decision aid

What kind of things might you want to know about a tool that a GP or dentist accessed through a websit

Appendix G: Participant information Sheets





Specialist Participant Information Sheet – Head and Neck Risk Assessment Tool (HANRAT)

Why have I been invited to take part

We would like to invite you to take part in our study. Before deciding to take part we would like you to tell you why we are doing this study, why we are asking you to take part and what you will have to do if you agree to take part. We are happy to answer any questions you have about the study and your role in it.

What is the purpose of the study?

This study is looking at decision tools that can help general practice doctors decide whether a patient might be more likely to have an underlying head and neck cancer to explain their symptoms.

We are trying to establish what all the stakeholders think about the development of a tool. The answers to the questions will help us to plan a programme for the introduction of a symptom decision tool which could help general practice doctors decide if a patient needs to be referred to a specialist urgently or not.

Why have I been invited?

You have been invited because you specialise in the treatment of head and neck cancer. You have will have a personal point of view which we think will help our study.

Do I have to take part?

You do not have to take part. It is up to you to decide after you have read this information and had answers to any questions you want to ask. You can leave the study at any time and you do not have to explain why.

What will happen if I do take part?

If you decide that you want to take part, Paula Bradley (the researcher and a general practice trainee doctor) will arrange to meet with you to talk about the subject. The conversation between you and Paula will be recorded so that your answers can be typed and used along with other interviews to identify if there are any patterns in what specialists think.

What will I have to do?

You will meet with Paula and answer some questions about decision tools, you may have experience of your own doctor using and any awareness or opinion on those produced from head and neck units in the UK. You will also be asked some questions about how you think such a tool would be received by GPs, patients and head and neck cancer specialists.

What are the possible disadvantages of not taking part?

By not taking part you are not adding your point of view to the debate and if you have a strong opinion about the subject by not taking part you cannot express this to us.

What are the possible benefits of taking part?

This study may help in the future for patients with head and neck cancer symptoms who present to their general practice doctor. The answers you give may help patients, GPs as well as head and

Version 1.2 February 2019





Specialist Participant Information Sheet – Head and Neck Risk Assessment Tool (HANRAT)

neck cancer specialists in the future in terms of triaging patients to appropriate clinics and resource allocation.

What if there is a problem?

If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions (Dr Paula Bradley, Specialty Trainee in General Practice or Professor Scott Wilkes details below), if you remain unhappy and wish to complain formally, you can do this through the University of Sunderland complaints procedure by contacting Dr John Fulton (details below).

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. The transcripts will be anonymised and kept on password protected documents on a password protected computer in a locked office. If you choose to leave the study at any time, we will discuss with you whether you want any of the questions answered already to be used for our study or if you want the information destroyed. There will be no identifiable information in any published results.

What will happen to the results of the research study?

We intend to publish the results of this study in a scientific journal. We intend to provide participants with results from this study and will be happy to provide any answers you have when this is done.

Who is organising and funding the research?

The study is part of a PhD at The University of Sunderland and is part of Paula's Health Education England North East (HEENE) training in general practice.

Who has reviewed the study?

This study has been reviewed by the Ethics Committee of the University of Sunderland and by academics in primary care and head and neck cancer.

Who to approach if you have questions about the study or want to complain:

Dr Paula Bradley GP Specialty Registrar PhD Candidate 150, Pasteur Building Health Sciences & Wellbeing City Campus University of Sunderland Chester Road Sunderland SR1 3SD Tel: +44 (0) 191 515 3215 paula.bradley@sunderland.ac.uk Professor Scott Wilkes Head of School of Medicine Professor of Primary Care Room 112, Dale Building Health Sciences & Wellbeing City Campus University of Sunderland Chester Road Sunderland SR1 3SD Tel: +44 (0)191 515 2186 scott,wilkes@sunderland.ac.uk Dr John Fulton Director Post Graduate Research Health Sciences and Wellbeing City Campus University of Sunderland Chester Road Sunderland SR1 3SD Tel: +44 (0) 191515 2925 john.fulton@sunderland.ac.uk

Version 1.2 February 2019





GDP Participant Information Sheet - Head and Neck Risk Assessment Tool (HANRAT)

Why have I been invited to take part?

We would like to invite you to take part in our study. Before deciding to take part we would like you to tell you why we are doing this study, why we are asking you to take part and what you will have to do if you agree to take part. We are happy to answer any questions you have about the study and your role in it.

You have been invited to consider an interview to answer these questions because you are a General Dental Practitioners (GDP) who refers patients with symptoms suspicious of cancer to hospital specialties. You may be aware of some of the tools developed to help referrals from primary care to two week wait clinics and have an opinion about their usefulness for triaging patients and managing risk.

Other things which you can help us to understand are the aspects that might make it more difficult for GDPs to use the tools and your answers might help us to make a decision tool that is acceptable to both patients and doctors (GPs GDPs and specialists).

What is the purpose of the study?

This research study is a qualitative study looking at decision tools that can help general dental practitioners decide whether a patient could have symptoms suspicious of head and neck cancer.

The answers to the questions will help us to plan a programme for the introduction of a symptom decision tool which could help general dental practitioners decide if a patient needs to be referred to a specialist urgently or not.

Do I have to take part?

It is up to you to decide after you have read this information and had answers to any questions you want to ask. You can leave the study at any time and you do not have to explain why.

What will happen if I do take part?

If you decide that you want to take part, Paula Bradley (the researcher and a general practice trainee doctor) will arrange to meet with you to talk about the subject, the conversation between you and Paula will be recorded so that your answers can be typed and used to compare with other so we can see if there are any patterns.

What are the possible disadvantages of not taking part?

There are no disadvantages identified.

What are the possible benefits of taking part?

The benefits of this study are that it may help future patients with head and neck cancer symptoms who present to their GDP, it may also help with GDP confidence in referring patients under two week wait or alternative route and it has potential to affect resource management within the hospital setting.

Will my taking part in the study be kept confidential?

We will follow ethical and legal practice and all information about you will be handled in confidence. If you choose to leave the study at any time, we will discuss with you whether you

Version 1 February 2020





GDP Participant Information Sheet - Head and Neck Risk Assessment Tool (HANRAT)

want any of the questions answered already to be used for our study or if you want the information destroyed. All information that is collected about you during the research will be kept strictly confidential. The transcripts will be anonymised and kept on password protected documents on a password protected computer in a locked office. There will be no identifiable information in any published results

What if there is a problem?

If you have a concern about any aspect of the study, you should ask to speak to the researchers who will do their best to answer your questions (Dr Paula Bradley, Specialty Trainee in General Practice or Professor Scott Wilkes details below), if you remain unhappy and wish to complain formally, you can do this through the University of Sunderland complaints procedure (Dr John Fulton - details below).

What will happen to the results of the research study?

We intend to publish the results of this study in a scientific journal. We intend to provide participants with results from this study and will be happy to provide any answers you have when this is done.

Who is organising and funding the research?

The study will be undertaken as part of a PhD study at The University of Sunderland as part of Paula Bradley's General Practice training through Health Education England North East (HEENE).

Who has reviewed the study?

This study has been reviewed by academics in the field of primary care and head and neck cancer.

Who to approach for any questions about the study or want to complain:

Dr Paula Bradley	Professor Scott Wilkes	Complaints can be addressed to
GP Specialty Registrar	Head of School of Medicine	
PhD Candidate	Professor of Primary Care	Dr John Fulton
150, Pasteur Building	Room 112, Dale Building	Director Post Graduate
Health Sciences & Wellbeing	Health Sciences & Wellbeing	Research
City Campus	City Campus	Health Sciences and Wellbeing
University of Sunderland	University of Sunderland	City Campus
Chester Road	Chester Road	University of Sunderland
Sunderland	Sunderland	Chester Road
SR1 3SD	SR1 3SD	Sunderland
		SR1 3SD
Tel: +44 (0) 191 515 3215	Tel: +44 (0)191 515 2186	

paula.bradley@sunderland.ac.uk scott.wilkes@sunderland.ac.uk

Tel: +44 (0) 191515 2925 john.fulton@sunderland.ac.uk

Version 1 February 2020





GP Participant Information Sheet - Head and Neck Risk Assessment Tool (HANRAT)

Why have I been invited to take part?

We would like to invite you to take part in our study. Before deciding to take part we would like you to tell you why we are doing this study, why we are asking you to take part and what you will have to do if you agree to take part. We are happy to answer any questions you have about the study and your role in it.

You have been invited to consider an interview to answer these questions because you are a GP who refers patients with symptoms suspicious of cancer to hospital specialties. You might have some experience using other kinds of tools, for example QRisk2[®]. You may be aware of some of the tools developed to help referrals from primary care to two week wait clinics and have an opinion about their usefulness for triaging patients and managing risk.

Other things which you can help us to understand are the aspects that might make it more difficult for general practice doctors to use the tools and your answers might help us to make a decision tool that is acceptable to both patients and doctors (GPs and specialists).

What is the purpose of the study?

This research study is a qualitative study looking at decision tools that can help general practice doctors decide whether a patient could have symptoms suspicious of head and neck cancer.

The answers to the questions will help us to plan a programme for the introduction of a symptom decision tool which could help general practice doctors decide if a patient needs to be referred to a specialist urgently or not.

Do I have to take part?

It is up to you to decide after you have read this information and had answers to any questions you want to ask. You can leave the study at any time and you do not have to explain why.

What will happen if I do take part?

If you decide that you want to take part, Paula Bradley (the researcher and a general practice trainee doctor) will arrange to meet with you to talk about the subject, the conversation between you and Paula will be recorded so that your answers can be typed and used to compare with other so we can see if there are any patterns.

What are the possible disadvantages of not taking part?

By not taking part you are not adding your point of view to the debate and if you have a strong opinion about the subject by not taking part you cannot express this to us.

What are the possible benefits of taking part?

The benefits of this study are that it may help future patients with head and neck cancer symptoms who present to their GP, it may also help with GP confidence in referring patients under two week wait or alternative route and it has potential to affect resource management within the hospital setting.

Will my taking part in the study be kept confidential?

Version 1.2 April 2019



Participant Information Sheet, Patient Group 2, GP Cancer Symptom Tool

Why have I been invited to take part?

You have been invited to take part in this study because you will be or have been a patient within the NHS system in the UK.

Please read the information and discuss it with other people, if you like, before deciding if you want to take part. We are happy to answer any questions you have about the study and your role in it.

What is the purpose of the study?

This study is looking at tools that can help general practice doctors decide whether a patient with certain signs and symptoms might have cancer.

We want to see if patients have any experience of their doctor using prediction tools during their appointments, what they think about them, how they are used and how they affect the consultation.

We are trying to find out if it would be acceptable to patients if their doctor used tools like this to help with urgent hospital referrals when cancer is suspected.

Do I have to take part?

No. It is up to you to decide after you have read this information and considered the answers to any questions that you might have about the project.

What will happen if I do take part?

If you decide to take part, Paula Bradley (the researcher and a general practice trainee doctor) will arrange to meet with you to talk about the subject, the conversation between you and Paula will last about 30-40 minutes, it will be audio- recorded so that your answers can be typed and used along with other patient interviews to see if there are any patterns in how the questions are answered.

What are the possible disadvantages of not taking part?

The discussion about this topic might bring back personal experience or memories about cancer, it may be an emotional thing to talk about. We can refer you to your GP if you need any ongoing support following the interview.

By not taking part you are not adding your point of view and if you have a strong opinion about the subject you would not have the opportunity to express this.

What are the possible benefits of taking part?

The benefits of this study are that it may help in the future for patients with cancer symptoms who present to their general practice doctor.

Version 1 July 2019 To be reviewed October 2019



Study identification number:

CONSENT FORM

GP Cancer Symptom Tool

	Initial in box
I confirm that I have read and understood the participant information sheet dated () for the study	
I have had the opportunity to consider the information and ask questions and have had these answered to my satisfaction	
I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research	
I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified	
I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason	
I agree to take part in the above study	

Name of participant

Date

Signature

Name of researcher

Date

Signature

Contact details for further information or questions:

Dr Paula Bradley, PhD Candidate 150 Pasteur Building, Health Sciences & Wellbeing City Campus, University of Sunderland Chester Road, Sunderland, SR1 3SD Tel: 0191 515 3215 Paula.bradley@sunderland.ac.uk





GP Cancer Symptom Tool – Consent Form

Study identification number:

Contact details for further information or questions:

Dr Paula Bradley, PhD Candidate 150 Pasteur Building, Health Sciences & Wellbeing City Campus, University of Sunderland Chester Road, Sunderland, SR1 3SD Tel: 0191 515 3215 Paula.bradley@sunderland.ac.uk

	Initial in box
I confirm that I have read and understood the participant information sheet dated (April 2019) for the study	
I have had the opportunity to consider the information and ask questions and have had these answered to my satisfaction	
I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research	
I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified	
I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason	
I agree to take part in the above study	

Name of participant	Date	Signature

Name of researcher

Date

Signature

Version 2 April 2019





GP Cancer Symptom Tool – Consent Form

Study identification number:

Contact details for further information or questions:

Dr Paula Bradley, PhD Candidate 150 Pasteur Building, Health Sciences & Wellbeing City Campus, University of Sunderland Chester Road, Sunderland, SR1 3SD Tel: 0191 515 3215 Paula.bradley@sunderland.ac.uk

	Initial in box
I confirm that I have read and understood the participant information sheet dated (February 2020) for the study	
I have had the opportunity to consider the information and ask questions and have had these answered to my satisfaction	
I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research	
I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified	
I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason	
I agree to take part in the above study	

Name of participant	Date	Signature	

Name of researcher

Date

Signature

Version 2 April 2019



Study identification number:

CONSENT FORM

Symptom Based Risk Calculator for Head And Neck Cancer Referrals v2 during Covid-19

	Initial in box
I confirm that I have read and understood the participant information sheet dated May 2020 for the study	
I have had the opportunity to consider the information and ask questions and have had these answered to my satisfaction	
I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research	
I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified	
I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason	
I agree to take part in the above study	

Name of participant

Date

Signature

Name of researcher

Date

Signature

Contact details for further information or questions:

Dr Paula Bradley, PhD Candidate Medical School City Campus, University of Sunderland Chester Road, Sunderland, SR1 3SD Tel: 0191 515 3215 Paula.bradley@sunderland.ac.uk







Study identification number:

CONSENT FORM

GP Cancer Symptom Aid

	Initial in box
I confirm that I have read and understood the participant information sheet dated (19 th May 2020) for the study	
I have had the opportunity to consider the information and ask questions and have had these answered to my satisfaction	
I agree that data gathered in this study may be stored anonymously and securely, and may be used for future research	
I understand that all personal information will remain confidential and that all efforts will be made to ensure I cannot be identified	
I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason. Taking part will not affect my treatment now or in the future.	
I agree to the researcher contacting my GP to inform them of my participation	
I agree to take part in the above study	

Namo	of.	nai	rtici	nani
Name	01	pai	LIC1	pan

Date

Signature

Name of researcher

Date

Signature

Contact details for further information or questions: Dr Paula Bradley, PhD Candidate Medical School City Campus, University of Sunderland Chester Road, Sunderland, SR1 3SD Tel: 0191 515 3215 Paula.bradley@sunderland.ac.uk

19th May 2020 Version 3 IRAS 278313



Dr Paula Bradley PhD Student Health Education England North East Pasteur Room 150 Health Sciences and Wellbeing City Campus Sunderland University, Sunderland SR1 3SD



Email: approvals@hra.nhs.uk HCRW.approvals@wales.nhs.uk

11 June 2020

Dear Dr Bradley,



Study title:Primary Care Risk Assessment Tool for Head and Neck
Cancer - a qualitative study of head and neck cancer
survivors' views on a decision aid to be used in primary
care.IRAS project ID:278313REC reference:20/NE/0098SponsorUniversity of Sunderland

I am pleased to confirm that <u>HRA and Health and Care Research Wales (HCRW) Approval</u> has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, <u>in</u> <u>line with the instructions provided in the "Information to support study set up" section towards</u> <u>the end of this letter</u>.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see <u>IRAS Help</u> for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to <u>obtain local agreement</u> in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "<u>After Ethical Review – guidance for sponsors and</u> <u>investigators</u>", 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 <u>HRA website</u> also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is 278313. Please quote this on all correspondence.

Yours sincerely, Steph Blacklock

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: Mr Martin Finlayson, Sponsor Contact

Appendix J: Examples of field notes, codes and theme development relates 6/3/19 JOM. + . More positive preven for · 2° cove adaptation of - 2 w W to exclude for most tolysping whatted . If then added & No again but the muldfustily deverding > resources. · Patients rovery regress hady to herpinowedu therea · UPs - time resignance, animut, montporcecher Need Por buyin. First-listen adapatiento reter under 2000. Education - What the physicons. Examination pr jymptoms.









HNS

lodes		
MACRO	11	75
Change in Primary Care Landscape	8	19
Investigations in primary care for cancer	2	2
Referral pressures	5	12
Time pressures	5	5
Workforce	0	0
Medical Training, Continuing Professional Development and Experience	A	12
Continuing Medical Education	2	2
Dental Training for Medically Trained	0	0
Exposure to Head and Neck Cancer in Working Life	8	30
Self Selecting	0	0
NHS	11	40
Early Diagnosis of Cancer Agenda	9	14
Aims of 2WW	2	2
Perception of Impact on	3	4

Referral behaviour		
Impact of 2015 guidelines	0	13
Internal Market, Targets & Service Provision	4	9
NICE Endorsed	3	4
Secondary Care	3	4
Impact of no triage	0	0
Resources services demand	3	4
MES/O	12	151
Art of Medicine	10	19
Differences between primary and secondary	3	3
Interpretation	3	6
Protocol	7	10
Communication	5	13
A&G	5	6
Difficulty in or the Change	2	3
Digital Communication (Images)	0	0
Enthusiasm for more communication	2	2
Issue of feedback to primary care	1	2
Position in the pathway	10	28
External to pathway	3	4
Part of the pathway 2WW	8	17
	9	2.00

The second s		States of the state of the states		A COLORINA
The state of the s				in the second
The Test			3	4
Adjunct to clinical recomment			12	90
(history examination)			U	-DOM
Ease of use and accessibility			9	17
Endorsement and Education			8	18
Evidence based			8	15
Existing tools			12	32
Obligation, incentive, part of the			4	5
referral process				
Salety Netting			4	4
CD Committee			12	76
dian America			11	51
Pasising making				13
Shared Decision Making			10	22
Vulnerability			4	0
Patient Consultation				10
In patients hands - the patient			2	2
namative, patient use				
Open the Conversation about			4	6
Cancer				and the
Webdate energies			0	0
Satoodany Ore Constant			1	11
Feb 26, 2022				3
Feb 26, 2022				3
Feb 26, 2022	Description			3
Feb 26, 2022	Description		That I	3
Feb 26, 2022	Description		That I	3
Feb 26, 2022	Description		Fraz 1 1 0	3
Feb 26, 2022 Note: Help with the conversation about canotr Role of the head and neck surgeon Workfaver	Description		1 0	3
Feb 26, 2022 Numer Help with the conversation abou concer Role of the head and neck surgeon Workload Bak	Description		1 0 3	3
Feb 26, 2022	Description		1 0 3 6	3 1 0 5 8
Feb 26, 2022 Norme Help with the conversation about cancer Role of the head and neck surgeon Workload Risk	Description		Fred 84	3 1 0 5 8
Feb 26, 2022 Note: Help with the conversation about canoer Role of Notekicad Risk	Description		First 84 1 0 3 6	3 1 5 8
Feb 26, 2022 National Help with the conversation about cancer Role of the head and neck surgeon Workload Risk	Description		Frag 24 1 0 3 6	3 1 5 8
Feb 26, 2022 Access Help with the conversation abou color of the head and neck surgion Workload Risk	Description		First 1 1 0 3 6	3
Feb 26, 2022 Autom Help with the conversation abou canoor Rokoad Workload Rok			1 1 3 6	3 1 0 5 8
Feb 26, 2022 Memory Help with the conversation about canoor Role of the head and neck surgion Workload Risk	Invertieller A		1 1 3 6	3 1 0 5 8
Feb 26, 2022 Access Help with the conversation abou concor Role of the head and neck surgion Workload Risk			1 0 3 6	3 1 0 5 8
Feb 26, 2022 Access Help with the conversation abou concor Role of the head and neck surgion Workload Risk			1 0 3 6	3 1 0 5 8
Feb 26, 2022 Manuel Manuel Mole of the head and neck surgeon Workload Risk				3
Feb 26, 2022 Nume A leip with the conversation about conce Role of the head and neck surgeon Workload Risk	Description			3
Feb 28, 2022 Nume Align with the conversation about oncor Roke of the head and neck surgeon Workload Rak	Description		Reat 8	3
Feb 28, 2022 Million Help with the conversation about Choiro Role of the head and neck surgeon Workload Risk	Description		Frost 1 1 0 3 6	3
Feb 28, 2022 Action Help with the conversation about concor Roci of the head and nock surgeon Workload Risk	Description		Frost 1 1 0 3 6	3
Feb 28, 2022 Mellow Help with the conversation abou color of the head and nock surgeon Workload Risk	Description		Frag 1 1 0 3 6	3
Feb 28, 2022 Access Help with the conversation abou concor Read Workload Read			1 1 3 6	3
Feb 28, 2022 Access Help with the conversation abou conor Rest Workload Rest			1 1 3 6	3 1 0 5 8
Feb 26, 2022 Action Alega with the conversation about concor Role of the head and neck surgion Workload Risk			1 0 3 6	3 1 0 5 8
Feb 28, 2022 Annual Anu			1 0 3 6	3
Feb 28, 2022 Autom Andree Refer of the head and neck surgeon Workload Refe			1 3	3

Untitled

Nodes					
	Bescription	Files	References		
Bespoke (Individualised contextualised)		10	15		
Computer use		10	26		
Generalist (GP)		5	7		
In patients hands		3	4		
Physical Examination		3	5		
Protocolisation		6	15		
Relationship		8	12		
Resources		8	16		
Risk .		9	21		
Safety Netting		4	4		
Think Cancer		6	14		
lool		11	33		
Trust		9	27		
Uncertainty					

Feb 28, 2022





presenvention friender crepture it where early inspect of partwoy dittertistic / divice an Rendony Core areinvelver nojderthorr Guer, najdeit NHS cumbelines local hreely Ous/2mi truppoorer to 12 none (cover. A K Now weber toto a star argeretter Cerentimer invity Cerentimer hour bound Bartins ODF Verne Flewer prid For during the How of performance trute where where the adverse Challheyes loppamentes at a polyevel - Horted ż (where Leduce muner 1 privation outer -unerunner -unerunner -unerunner Physical wes. Preminen Prinoyan Un econyarite us Referrent tho tow 1 Education Nedvical ark .

Caditain - much proceder - completo to ke Covered adaquetely by open every greeialiste - does not address these not recognitacaier - artige who doyot present Technology - designed y 2000ere for Lovere Morph 1'cere Not thanght about not grater of accels - upotate of stats Value - 2'and - not required by 1° care experimental for the cases per praotae. Adoptell -> Eneforcy -> latients - happy - in handing Need pare nort chapted
aferischiere -> due charge -> Two Entime. TOCCH DCarunetrok -Dirteme -- DAEG - muhave For suther any anope '- oid Systeria - Porical lionarie drage Catactnos completely Nice analyded Center provide paralerice pushipponnent imprish paralerice pushipponnent echaged hargare of NICE 200 reach core derivery (renote) + exposite distining in child legrand detternes is not the informisstant 7 - make to udequatelyaness. - deroper whit & pour francy

New pathing - I in cartier up exity MCE / Well Suidewes. Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Significant imput would be needed to estabuil in pact Noter contra - Pritord. Economic Regulatory Gri a laysupport. 12 - to much suthout Iniountie

Appendix K: Achievements Oral Presentations

September 2017	Primary Care Research Newcastle University	My story so far - a budding academic GP	
October 2017	Head and Neck Cancer Survivors Meeting Sunderland	Risk Assessment for head and neck cancer	
January 2018	Head and Neck Cancer research seminar University of Newcastle Upon Tyne	Primary Care Ear Nose and Throat symptoms risk assessment tool	
November 2018	Society of Academic Primary Care North, Kendal	Using risk assessment tools for suspected cancer within primary care - barriers and facilitators: preliminary results from a framework synthesis using the Normalization Process Theory	
February 2019	Cancer Research UK Early Diagnosis Conference, Birmingham	Predictive modelling of head and neck cancer from primary care electronic database records	
April 2019	CanTest Summer School, Oxford	A qualitative exploration of stakeholders perceived barriers and facilitators to a risk assessment tool for head and neck cancer	
October 2020	British Association of Head and Neck Oncologists (online)	webinar - utilising and expanding the broad range of roles of the MDT Bridging the gap - How we can assist each other in the management of the head and neck cancer patient	
April 2021	CanTest Summer School (online)	Qualitative evaluation of the use of the head and neck triage tool by head and neck surgeons in the UK during Covid-19	
May 2021	British Association of Head and Neck Oncologists Academic Conference (online)	NASSS framework evaluation of the use of the telephone triage tool by head and neck surgeons in the UK during Covid-19	
May 2022	The First Irish Head and Neck Society Annual Conference	A qualitative study of the potential implementation of a primary care clinical cancer decision tool for suspected head and neck cancer	
Posters			
November 2018	Society of Academic Primary Care North, Kendal	Using risk assessment tools for suspected cancer within primary care - barriers and facilitators: preliminary results from a framework synthesis using Normalisation Process Theory (NPT)	

February 2019	CRUK Early Diagnosis Conference Cancer Research UK, Birmingham	Predictive modelling of head and neck cancer from primary care electronic database records	
June 2020	Cancer and Primary Care Research International Network (CaPRI) Meeting Cancelled	Factors shaping the implementation and use of clinical cancer decision tools by GPs in primary care: a qualitative framework synthesis	
May 2020	British Association of Head and Neck Oncologists (online)	An exploration of a new approach to the Suspected Head and Neck Cancer Two Week Wait Referral Pathway in the North East; initial results of qualitative analysis of interviews with Head and Neck Surgeons	
November 2020	North of England Otolaryngology (online)	Qualitative Interviews with Head and Neck Surgeons about referral decision tool for suspected head and neck cancer	
May 2022	British Association of Head and Neck Oncologists Conference	ENTs' opinions of a SLT clinic model for low risk two week wait (2ww) patients with dysphonia and dysphagia	
Prizes			
May 2021 Best Presentation in Session	British Association of Head and Neck Oncologists Annual Scientific Conference	NASSS framework evaluation of the use of the telephone triage tool by head and neck surgeons in the UK during Covid-19	
Publications			
2020	Head Neck. 2020 Jul;42(7):1674-1680	Rapid implementation of an evidence-based remote triaging system for assessment of suspected referrals and patients with head and neck cancer on follow-up after treatment during the COVID-19 pandemic: Model for international collaboration Vinidh Paleri, John Hardman, Theofano Tikka, <u>Paula</u> <u>Bradley</u> , Paul Pracy, Cyrus Kerawala	
2021	BMJ Open 2021;11:e043338	Factors shaping the implementation and use of Clinical Cancer Decision Tools by GPs in primary care: a qualitative framework synthesis <u>Bradley PT</u> , Hall N, Maniatopoulos G, Neal R D, Paleri V, Wilkes S	
2021	Journal of Voice available online 24 th July 2021	Attitudes to the Implementation of Speech and Language Therapist Led Low Risk Two Week Wait Clinic in the UK: A Survey Exploration Using Normalization Process Theory <u>Paula T Bradley</u> , Joanne Patterson	

Grants

CRUK Early Diagnosis Conference		Early Researcher grant (conference fees, travel, and accommodation)
	Scientific Foundation Board Royal College of General Practitioners	£2,000
	Oracle Cancer Trust	£7,000 (returned as intended for statistics work package)
	British Association of Head and Neck Oncologists	£3,000 (returned as intended for statistics work package)
	British Association of Head and Neck Oncologists	£3,000 Grant to explore the views of ENT and GI Specialists on SLT-led clinics as a pathway for patients triaged as 'low risk' referred on the 2WW Head and Neck/ Upper GI cancer referral pathway
	North East Commissioning Support Unit	£33,016 Grant to explore the co-create improved means of communication between primary and secondary care when using the suspected head and neck cancer pathway
Courses		
January 2018	York University	Systematic Reviews and Meta-analysis
December 2018	Oxford University	Qualitative Research Methods
September 2019	University of Keele	Statistical Methods for risk prediction and prognostic models



Registered Charity No: 257199

BRITISH ASSOCIATION OF HEAD & NECK ONCOLOGISTS

BAHNO Annual Scientific Meeting 14th May 2021

Dr Paula Bradley

was awarded the

Best in Session

for her presentation

Qualitative evaluation of the use of the head and neck triage tool by head and neck surgeons in the UK during Covid-19

Gillerand.

Professor Cyrus Kerawala BAHNO President

BAHNO Secretariat, PO Box 9238, Sturminster Newton DT10 9BR 01730 813700 secretariat@bahno.org.uk www.bahno.org.uk

 Received:
 16 April 2020
 Accepted:
 20 April 2020

 DOI:
 10 1002/bed 26219

 10 002/bed 26219

 <

SPECIALISSUE



WILEY

Rapid implementation of an evidence-based remote triaging system for assessment of suspected referrals and patients with head and neck cancer on follow-up after treatment during the COVID-19 pandemic: Model for international collaboration

Vinidh Paleri MS, FRCS^{1,2,3,4} | John Hardman MRCS, MSc^{1,2} | Theofano Tikka MSc, MRCS⁵⁶ | Paula Bradley MClinRes, MBBS⁷ | Paul Pracy FRCS^{3,8} | Cyrus Kerawala FDSRCS, FRCS^{1,4}

¹Head and Neck Unit. The Roval Marsden NHSFoundation Trust, London, UK ²Institute of Cancer Research. London, UK ³ENT UK Head and Neck Society, London, UK ⁴British Association of Head and Neck Oncologists, London, UK ⁵Department of Otolaryngology—Head and Neck Surgery, Queen Elizabeth University Hospital, Glasgow, UK ⁶School of Psychological Sciences and Health, University of Strathdyde, Glasoow UK ⁷Northumbria GP Rotation, University of Sunderland, Sunderland, UK ⁸Department of Otolaryngology—Head

"Department of Ottofaryngology—Head and Neck Surgery, Queen Elizabeth Hospital, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

Correspondence Vinidh Paleri, Head and Neck Unit, The Royal Marsden Hospital, NHS Foundation Trust, London SW3 6.Ll, UK. Email: vinidh paleri@mh.nhs.uk Abstract

Background: Outpatient telemedicine consultations are being adopted to triage patients for head and neck cancer. However, there is currently no established structure to frame this consultation.

M ethods: For suspected referrals with cancer, we adapted the Head and Neck Cancer Risk Calculator (HaNC-RC)-V.2, generated from 10 244 referrals with the following diagnostic efficacy metrics: 85% sensitivity, 98.6% negative predictive value, and area under the curve of 0.89. For follow-up patients, a symptom inventory generated from 5123 follow-up consultations was used. A customized Excel Data Tool was created, trialed across professional groups and made freely available for download at www. entintegrate.co.uk/entuk2wwtt, alongside a user guide, protocol, and registration link for the project. Stakeholder support was obtained from national bodies

Results: No remote consultations were refused by patients. Preliminary data from 511 triaging episodes at 13 centers show that 77.1% of patients were discharged directly or have had their appointments deferred.

Discussion: Significant reduction in footfall can be achieved using a structured triaging system. Further refinement of HaNC-RC-V.2 is feasible and the authors welcome international collaboration.

KEYWORDS COVID-19, follow-up, new referrals, outpatient consultation, triaging

1 | INTRODUCTION

Travel has been identified as the single most important contributor to the spread of the coronavirus disease 2019

(COVID-19) pandemic. Reduction in the transmission of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has a direct link with the introduction of travel control measures.¹ The Wuhan shutdown delayed

Head & Neck. 2020;1-7.

wileyonlinelibrary.com/journal/hed

the occurrence of the first case of SARS-CoV-2 in other cities by 2.91 days (95% confidence interval: 2.54-3.29 days), an intervention that benefited >130 cities in mainland China, covering more than half its geographic area.²⁴ Social distancing measures are also a key component of the control strategies during pandemics and form one of the most effective techniques in reducing the number of infections. It is also vital that social distancing and travel restrictions are not lifted prematurely while there is a pool of susceptible hosts in the population, as this will lead to an increase in the number of infections.² When applied to the health care sector these measures should aim to reduce hospital attendance by triaging out low risk patients both to protect clinicians and hospitalized patients, while still allowing timely investigations on those deemed to be at higher risk.

Interventions, such as outpatient telemedicine consultations, can reduce footfall in hospitals, thereby promoting adherence to social distancing policies.³ These measures are especially relevant in the cohort of patients with head and neck diseases as the nose and nasopharynx have been shown to be reservoirs for high concentrations of the SARS-CoV-2.⁴ Reduction of upper aerodigestive tract interventions, including outpatient examinations, is important as many are considered to be aerosol generating procedures.⁵ In addition, SARS-CoV-2 remains viable in aerosols with a median half-life of 1.1 hours,⁶ potentially making the examination room a source of infection.

The National Health Service guidance for managing referrals with cancer during the COVID-19 pandemic recommends a telephone triage to minimize interactions and appointments with health services and stream patients for investigations where appropriate.⁷ In addition, a telephone appointment with a specialist clinician is accepted as a first appointment for the purposes of recording cancer waiting times for new referrals. As telephone triage is a relatively novel intervention for suspected head and neck cancer (HNC), there is currently no established structure to frame this consultation.

The aim of this study is to demonstrate a rapid implementation of an evidence-based, structured, remote triaging system for assessment of suspected referrals and patients with cancer who are on regular follow-up after treatment for HNC in the United Kingdom (UK).

2 | RATIONALE

2.1 | New referrals

A substantial part of outpatient care in head and neck surgical oncology work involves assessment of patients referred in with symptoms suspicious of HNC. Apart from a few malignancies (basal cell carcinomas, lowgrade salivary gland tumors and well-differentiated thyroid cancer in young patients), most HNCs progress within a matter of months, and a delay in management can have an adverse effect on the prognosis. In 2000, the Department of Health in the United Kingdom developed national guidelines for referral of suspected HNC from primary care, updated by the National Institute for Health and Care Excellence in 2005 and 2015. Systematic reviews have shown that the pooled detection rate of cancer in this population is between 8.8%⁸ and 11.1%.⁹ Thus, the vast majority of referrals may be safely triaged to a deferred assessment.

In 2016, our group used information from a cohort of 4715 patients referred in for suspected HNC to generate a 13-symptom inventory which, when combined with age, could generate a personalized risk of cancer with a high diagnostic efficacy (area under the curve [AUC] 0.77).¹⁰ Sensitivity analysis identified the 8% risk probability cutoff to offer optimal performance for the calculator. This risk calculator was subsequently validated in an external cohort of 1998 patients, where it performed well compared to the inception cohort, with an AUC of 0.81.¹¹

After further refinements using additional information to the symptom inventory in a new cohort (n = 3531), we published the Head and Neck Cancer Risk Calculator (HaNC-RC)-V.2, which demonstrated increased diagnostic efficacy with an AUC of 0.89, and a sensitivity of 85%.¹² The model performed optimally at a probability cut off of 7.1%, where the negative predictive value was 98.6%. Thus, when the symptom inventory is applied to a patient who has been referred for suspected cancer and the calculator indicates a <7.1% risk probability for cancer diagnosis, the chance of missing cancer if the patient is not seen by a face-toface conventional consultation is 1.4%. In all these instances, a logistic regression model was used to define personalized probability risk for each patient. When a variety of machine learning algorithms were used on a similar cohort of 5082 patients referred for suspected HNC, logistic regression, the technique used to create the calculator, offered one of the highest true negative rates, an essential characteristic of a test to triage patients out during resource constrained times.¹³

2.2 | Qualitative assessment of triaging from primary care practitioners and hospital specialists

SARS-CoV-2 has already changed the face of primary care in England; the need to reduce face-to-face

PALERI ET AL.

PALERI ET AL

interactions means clinicians are embracing new technology that allows remote assessment including SMS images and video consultations.

Our previous qualitative work (P. T. Bradley et al, unpublished data) to gauge the views of hospital specialists and primary care practitioners has been supportive of a risk calculator. This work used a normalization process theory (which evaluates implementation and complex interventions) to explore physicians' attitudes to the introduction and use of a head and neck clinical cancer decision tool (HaNC-RC-v.1) in both primary care and hospital practice.

The views of 11 head and neck surgeons from the North East of England were elicited via face-to-face interviews between March 6, 2019 and July 9, 2019. The interviewees welcomed an evidence-based symptom tool and opined that a robust tool offered additional confidence to decision making. Concerns about triaging in the hospital setting were expressed as adequate information may not be available in the referral form; however, a structured triaging system such as the one proposed in this work directly addresses this concern. Primary care practitioners' views (12 general practitioners in the North East were interviewed face to face between June 14, 2019 and December 5, 2019) discussing the head and neck cancer risk calculator (version 1) as a means to drive more confidence in the triage of patients to suspected cancer clinics was met with enthusiasm. With endorsement from secondary care and careful integration into the pathway, it was felt that this approach could be an asset to both primary and secondary care (P. T. Bradley et al, unpublished data).

2.3 | Follow-up patients who have been treated for HNC

Change in patient symptoms during follow-up is the most frequent indication of recurrent disease and must be regarded seriously, even if clinical examination reveals no abnormalities.¹⁴

INTEGRATE, the UK Trainee Research Collaborative Network, performed a UK national audit of patients who underwent 5123 follow-up consultations after treatment for HNC in 89 hospitals across the UK.¹⁵ Residual or recurrent disease rates were 57% at 2 years, 32% between 2 and 5 years, and 11% post-5 years follow-up appointments expedited by either the patient or the clinician due to clinical concern correlated significantly with the presence of residual or recurrent disease, or a second primary tumor (P = .0001). The pick-up rate was 35% in expedited appointments compared to 5.2% in planned follow-ups. Of the expedited appointments, 63% were initiated by patients vs 37% by clinicians (Table 1).

TABLE 1 New symptoms and their positive predictive values (PPV)

New symptoms	PPV
Difficulty breathing	16.2
Tiredness	12.9
Pain in mouth/throat	10.4
Pain in neck/shoulder	9.2
Difficulty speaking	8.4
Difficulty swallowing	7.9
Bleeding	7.3
Dry mouth	3.4

Parallels exist in other cancer sites where remote follow-up is performed based on patent symptomatology and blood markers. Qaderi et al¹⁶ optimized an innovative electronic medical record application for patients with colorectal cancer. Patients can review their appointments and test results, symptoms are monitored using online questionnaires; the long-term results are awaited. However, in these resource constrained times, rapid innovation and dissemination of new care models are needed, which, with careful data collection and robust governance, can define new standards without causing patient harm.

3 | METHODS

A focus group of five senior clinicians agreed that structured remote assessment could be performed, for new referrals, using the latest iteration of the risk calculator. It was agreed that those who were at high risk should be triaged for further assessment and the low-risk referrals undergo a deferred assessment until later in the pandemic or when capacity became available. It was also considered appropriate for follow-up patients to be asked if they had developed any new and specific symptoms since their previous consultation, allowing data from the 2018 audit to risk stratify this group to inform decisions regarding future management.

The project looked to collect data on clinician choice and patient preference and did not mandate treatment according to set protocols. Accordingly, the project was deemed to be a service evaluation and did not constitute research (http://www.hra-decisiontools.org.uk/research/).

The project was developed in collaboration with INTEGRATE. Through lending its support, and using its network to promote the project, all UK head and neck cancer centers were approached to consider participation. Further advertising was delivered through emails from ENT UK and the Association of Otolaryngologists in Training (www.aotent.org).

4____WILEY_

Designing the project in this way presented a number of challenges with the data collection strategy.

- A need for immediate feedback to the clinician triaging the patient, and so the data must be entered directly into a computer interface.
- A need for a complete data set to give valid results, again mandating a computer interface for data validation.
- A need for follow-up data to be collected at 6 months to see if patients subsequently develop cancer, and so patient identifiable data must be used in some capacity.
- A need for rapid deployment of the project to ensure the newly implemented service to appropriately evaluated, and so formal applications for sponsorship or ethics may be too slow to achieve.
- However, to comply with data governance regulations, patient identifiable information should not leave the institution and, if these were to, it must be handled with appropriate standards and practices to maintain confidentiality. Furthermore, formal consent may be required from the patient for their data to be used in this way.

The solution developed was a customized Excel Data Tool (Microsoft Excel for Mac. Redmond, Washington:



Microsoft Corporation; 2018). This was made freely available for download at www.entintegrate.co.uk, alongside a user guide, protocol, and registration link for the project. Dates and hospital numbers may be entered into the Spreadsheet, which is stored on the hospital computer system, in line with local data governance regulations for handling patient identifiable data. Data entry is mostly limited to drop down lists and the decision aid only provides information if all required fields are completed. Clinician preference, patient choice and the immediate triage outcome can be recorded. Subsequently, the patient ID can be used to obtain the cancer status at 6 months follow-up to complete the data set.

At this point, the spreadsheet can be anonymized by removing the site, the date of triage (if recorded), and the patient ID. Anonymous data only are then submitted to the project management team who then apply sequential study IDs for further analysis. Using these methods, the data held by the project management team have high levels of data completeness but are not traceable back to any individual center or individual patient.

Figure 1 summarizes the remote triaging process in a flowchart for new referrals and follow-up patients, along with a recommended script to advise the patient on the outcome of the triaging process.

New patient: Low-risk outcon

The risk calculator suggests that people with your type of symptoms have a very low probability of a cancer in the nead and neck region. By not being seen in clinic, the chance of missing a cancer in people such as yourself is less than 9%.

Either:

e would therefore recommend bringing you in for a consultation once the pandemic issues have settle

Ve would therefore recommend discharging you

still have clinical concern and would recommend an urgent appointment/investigation is arranged for you

New patient: High-risk out

The risk calculator suggests that people with your type of symptoms might have a higher risk of a cancer in the head and neck region.

e would therefore recommend an urgent appointment/investigation is arranged for you.

Or. However, the clinical concern remains low and I would therefore recommend bringing you in for a consultation onc the pandemic issues have settled.

ollow-up patient: Recurrence rates and PPV of symptoms presented

Taking everything into acco

terrer. We will continue to follow you up and would recommend bringing you in for a consultation once the pandemic issues have settled.

Jr: Ne would therefore recommend discharging you from care

We think you would benefit from further assessment, so we would recommend an urgent appointment/ investigation is arranged for you.

n be viewed at wileyonlinelibrary.com]

PALERI ET AL

We intend for the service evaluation to continue for as long as telephone triage is being utilized in this patient group. It is anticipated that the period of disruption/telephone triage may last for at least 6 months. The outcome of presence/absence of cancer diagnosis at a minimum of 6 months will be treated as gold standard, and measures of diagnostic efficacy of the remote triaging system will be analyzed, including a descriptive analysis. This will allow external validation of the HaNC-RC-V.2 in a pan-UK or even a global suspected referral population with head and neck cancer. Moreover, a detailed assessment of the false negatives will be carried out to investigate the potential scope for further refinement of the calculator.

4 | RESULTS

None of the teleconsultations were refused by patients although some (<1%) expressed some dissatisfaction at the arrangements. The overwhelming majority understood the reasons for the remote consultation. Preliminary data were available from 511 triaging encounters from 13 centers; these show that 77.1% of patients were discharged directly or have had their appointments deferred until a later date; the remaining 22.9% were triaged to urgent investigations and/or face-to-face consultations. At time of submission, the project page at www.entintegrate.co.uk/entuk2wwtt had been accessed over 1800 times.

5 | DISCUSSION

The UK sees an average of 100 000 suspected referrals with HNC per year, with a cancer pickup rate of less than 10%. Our preliminary results indicate that >80% of referrals can be triaged out through teleconsultation.

Risk calculators are available for several solid malignancies: these include bladder, brain, breast, colorectal, kidney, lung, esophagus, ovary, pancreas, prostate, and uterus. Some have been externally validated. Unlike other cancers where risk calculators need blood tests and radiology to be performed, the HaNC-RC-V.2 for HNC was generated solely from patient symptomatology and demographics, rendering it suitable for the purpose of teleconsultation and remote triaging. The HaNC-RC-V.2 has a higher AUC than most of the risk calculators published for other cancers.¹⁷ As our model was based on recording of symptoms in the secondary care by specialist, it is feasible that the detailed recording of the symptoms during the consultation has helped to achieve higher predictive power than primary care derived models.

-WILEY

The use of telemedicine-directed patient care during public health emergencies is well described. However, the use of digital technology in the COVID-19 pandemic across the globe, especially in contact tracing and testing. has been unprecedented. Concurrently, the use of digital solutions for health care delivery has been accelerating since the pandemic began. In England, primary care has embraced telemedicine and deploys a new digital first pathway to manage and stream care, with over 90% of consultations being remote. Other examples include a central dashboard to manage bed availability within hospital settings and use of personalized online screening. A structured approach to remote triaging and generation of a personalized risk probability will allow clinical assessment with a consistency that otherwise cannot be delivered in this environment.

In the emergency setting, an important strategy for health care surge control during disaster management is forward triage. In the COVID-19 pandemic model, this involves remote assessment of patients before patients arrive to the emergency care services in the hospital, either in a location proximate to the hospital or via teleconsultation. Emergencies that are unrelated to COVID-19 are triaged to the emergency department while patients showing signs of the virus are separated to prevent transmission. The structured remote use of the risk calculator in the pandemic time is akin to the forward triage, where following appropriate assessment, to prevent a surge when health care is rationed, patients considered to be high risk are directed to the specialist for further assessment. Ideally the tool would be used in primary care but for expediency in the current medical crisis and given the fact it is a secondary care-derived model it was felt best placed there for triage.

Remote consultations will be a prominent part of the outpatient clinical practice for the near future. Telehealth services have been promoted actively during the COVID-19 pandemic setting for initial screening of symptomatic patients or those referred for medical care in other specialties and by more than 50 health systems in the United States.¹⁸ Structured remote assessment of sick patients has been described in the pandemic era.¹⁹ Research indicates that with appropriate structure and guidance, a teleconsultation model can be successful.²⁰

It is very likely that patients will be willing to engage with teleconsultation when face-to-face access to health care is restricted. Using internet search volume data from Google Trends, Hong et al²¹ showed that the U.S. population's interest in telehealth increased as the number of COVID-19 cases increased, with a strong correlation between population interest and COVID-19 cases reported (r = .948, P < .001).

≝____WILEY_

Medical decision making is cognitive, especially as experience accumulates. However, in the early phases of training, when conventional assessment cannot be performed and where there is less opportunity for supervision, a structured telemedical approach, backed up by robust algorithmic approach that has been generated and validated from the population at risk, will be of significant help in reducing anxiety among the clinical team and provider organization. As always, we would recommend experience and clinical judgment supersede the output on the screen. To the best of our knowledge, this is the first remotestructured assessment tool that has been robustly generated, validated, and rapidly implemented for use in the HNC setting.

5.1 | Stakeholder and international collaboration

This structured triaging system has been endorsed by ENT UK,²² the official body representing British Otolaryngologists—Head and Neck Surgeons and the British Association of Head and Neck Oncologists.²³ The authors would welcome international collaboration, and prospective centers are invited to visit the project page at www.entintegrate.co.uk/entuk2wwtt.

It is anticipated that the COVID-19 pandemic will influence clinical care for several years to come. The data generated from a real-world triaging such as this, when collected under robust data governance and oversight, analyzed and refined to reduce patient harm even further, can influence health care provision for years to come.

ORCID

Vinidh Paleri [©] https://orcid.org/0000-0002-7933-4585 John Hardman [©] https://orcid.org/0000-0002-6591-5119 Paula Bradley [©] https://orcid.org/0000-0002-1908-1053

REFERENCES

- Kucharski AJ, Russell TW, Diamond C, et al. Early dynamics of transmission and control of COVID-19: a mathematical modelling study. *Lancet Infect Dis.* 2020;20:553-558. https://doi. org/10.1016/S1473-3099(20)30144-4
- Prem K, Liu Y, Russell TW, et al. The effect of control strategies to reduce social mixing on outcomes of the COVID-19 epidemic in Wuhan, China: a modelling study. *Lancet Public Health.* 2020;5:e261–70. https://doi.org/10.1016/S2468-2667(20)30073-6
- Ebrahim SH, Ahmed QA, Gozzer E, Schlagenhauf P, Memish ZA. Covid-19 and community mitigation strategies in a pandemic. *BMJ*. 2020;368:m1066. https://doi.org/10.1136/bmj. m1066

- Zou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. *N Engl J Med.* 2020;382:1177-1179. https://doi.org/10.1056/NEJMc2001737
- 5. Public Health England. *COVID-19 Personal Protective Equipment (PPE)*. London: Public Health England; 2020.
- van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *New Engl J Med.* 2020;382:1564-1567. https://doi.org/10.1056/ NEJMc2004973
- NHS England and NHS Improvement. Cancer Alliance Information on Managing Cancer Referrals. London: NHS England and NHS Improvement; 2020.
- Langton S, Siau D, Bankhead C. Two-week rule in head and neck cancer 2000-14: a systematic review. Br J Oral Maxillofac Surg. 2016;54:120-131. https://doi.org/10.1016/j.bjoms.2015.09.041
- Kumar RDM, Mehanna H, Paleri V. Efficacy of the two week wait referral system for head and neck cancer: a systematic review. Ann R Coll Surg Engl (Supp). 2012;94:102-106.
- Tikka T, Pracy P, Paleri V. Refining the head and neck cancer referral guidelines: a two-centre analysis of 4715 referrals. *Clin Otolaryngol.* 2016;41:66-75. https://doi.org/10.1111/coa.12597
- Tikka T, Paleri V, MacKenzie K. External validation of a cancer risk prediction model for suspected head and neck cancer referrals. *Clin Otolaryngol.* 2018;43:714-717. https://doi.org/10.1111/ coa.13019
- Tikka T, Kavanagh K, Lowit A, et al. Head and neck cancer risk calculator (HaNC-RC)-V.2. Adjustments and addition of symptoms and social history factors. *Clin Otolaryngol.* 2020;45: 380-388. https://doi.org/10.1111/coa.13511
- Moor JW, Paleri V, Edwards J. Patient classification of twoweek wait referrals for suspected head and neck cancer: a machine learning approach. J Laryngol Otol. 2019;133:875-878. https://doi.org/10.1017/S0022215119001634:1-4
- Simo R, Homer J, Clarke P, et al. Follow-up after treatment for head and neck cancer: United Kingdom National Multidisciplinary Guidelines. J Laryngol Otol. 2016;130:S208-S211. https://doi.org/10.1017/S0022215116000645
- 15. Hardman J, Tikka T; on behalf of INTEGRATE (The National ENT Trainee Research Network). United Kingdom Head and Neck Cancer Surveillance study 2018. Paper presented at: British Association of Head and Neck Oncology 2019 Annual Scientific Meeting; London, England.
- Qaderi SM, Vromen H, Dekker HM, Stommel MWJ, Bremers AJA, de Wilt JHW. Development and implementation of a remote follow-up plan for colorectal cancer patients. *Eur J Surg Oncol.* 2020;46:429-432. https://doi.org/10.1016/j.ejso.2019.10.014
- Usher-Smith J, Emery J, Hamilton W, Griffin SJ, Walter FM. Risk prediction tools for cancer in primary care. Br J Cancer. 2015;113:1645-1650. https://doi.org/10.1038/bjc.2015.409
- Hollander JE, Carr BG. Virtually perfect? Telemedicine for Covid-19. N Engl J Med. 2020;382:1679-1681. https://doi.org/10. 1056/NEJMp2003539
- Greenhalgh T, Koh GCH, Car J. Covid-19: a remote assessment in primary care. *BMJ*. 2020;368:m1182. https://doi.org/10.1136/ bmj.m1182
- Seuren LM, Wherton J, Greenhalgh T, Cameron D, A'Court C, Shaw SE. Physical examinations via video for patients with heart failure: qualitative study using conversation analysis. *J Med Internet Res.* 2020;22:e16694. https://doi.org/10.2196/ 16694

PALERI ET AL.

- Hong YR, Lawrence J, Williams D Jr, Mainous IA. Populationlevel interest and telehealth capacity of US hospitals in response to COVID-19: cross-sectional analysis of Google Search and National Hospital Survey Data. JMIR Public Health Surveill. 2020;6:e18961. https://doi.org/10.2196/18961
- ENT UK. ENT UK Guidelines for changes in ENT during COVID-19 Pandemic. London: ENT UK; 2020.
- British Association of Head and Neck Oncologists. *ENTUK2WW Triage*. London: British Association of Head and Neck Oncologists; 2020.
- Tian H, Liu Y, Li Y, et al. An investigation of transmission control measures during the first 50 days of the COVID-19 epidemic in China. Science. 2020. https://doi.org/10.1126/science.abb6105

How to cite this article: Paleri V, Hardman J, Tikka T, Bradley P, Pracy P, Kerawala C. Rapid implementation of an evidence-based remote triaging system for assessment of suspected referrals and patients with head and neck cancer on follow-up after treatment during the COVID-19 pandemic: Model for international collaboration. *Head & Neck*. 2020;1–7. <u>https://doi.org/10.1002/</u> hed.26219

BMJ Open Factors shaping the implementation and use of Clinical Cancer Decision Tools by GPs in primary care: a qualitative framework synthesis

Paula Theresa Bradley ⁽⁹⁾, ¹ Nicola Hall,² Gregory Maniatopoulos,³ Richard D Neal ⁽⁹⁾, ⁴ Vinidh Paleri,⁵ Scott Wilkes¹

To cite: Bradley PT, Hall N, Maniatopoulos G, *et al.* Factors shaping the implementation and use of Clinical Cancer Decision Tools by GPs in primary care: a qualitative framework synthesis. *BMJ Open* 2021;11:e043338. doi:10.1136/ bmjopen-2020-043338

 Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (http://dx.doi. org/10.1136/bmjopen-2020-043338).

Received 04 August 2020 Revised 12 January 2021 Accepted 30 January 2021



¹Medical School, University of Sunderland, Sunderland, UK ²Faculty of Medical Sciences, University of Newcastle upon Tyne, Newcastle upon Tyne, UK ³Newcastle Business School, Northumbria University, Newcastle upon Tyne, UK ⁴Institute of Health Sciences, University of Leeds, Leeds, UK ⁵Head and Neck Unit, Royal Marsden Hospital NHS Trust, London, UK

Correspondence to Dr Paula Theresa Bradley; paula_bradley@me.com

BMJ

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

1

downloaded or activated one through their

clinical record systems. The survey responses suggest that 'levels of tool uptake are relatively low'.¹ A recent systematic review⁹ of CCDTs to investigate whether they improve diagnostic decision making for cancer in primary care demonstrates their potential but note that effective implementation is still elusive.

Drawing on normalisation process theory (NPT), this study explores factors shaping the implementation and use of CCDTs in primary care. NPT is a framework designed to contextualise, understand and evaluate 'the processes (implementation) by which new health technologies and other complex interventions are routinely operationalised in everyday work (embedding) and sustained in practice (integration)'.¹⁰ NPT provides a set of conceptual tools to aid understanding of this dynamic process. (2) cognitive participation, (3) collective action and (4) reflexive monitoring (4–6).

Aim

This study aims to synthesise qualitative research on GPs' attitudes to, and experiences of CCDTs. Drawing on a framework synthesis approach, it aims to provide a comprehensive analysis of factors shaping the implementation and use of CCDTs informed by NPT (6).

METHODS

Data sources and search strategy

A systematic electronic literature search from inception to July 2020 in MEDLINE, CINAHL, Web of Science and EMBASE databases was undertaken. A comprehensive predefined search strategy was developed by PTB using the SPICE (Setting Population Intervention Comparison Evaluation¹¹ box 1) approach. No publication type, language or date limits were applied to the searches. PTB carried out online searches via Google for grey literature using combinations of the terms from the electronic

Box 1 SPICE criteria

Setting

General practice/primary care in National Health Service /Western type public health carehealthcare system (primary care gatekeeper)

Population.

General practitioners/primary care doctors/family doctors.

Intervention

Cancer Clinical Decision Tools—paper, electronic, desktop, mousemap, electronic decision aid/system.

Comparison

Normal practice/no comparator. Other form of risk assessment.

Evaluation

2

Qualitative—face-to-face interviews, telephone interviews, questionnaires, focus groups, direct observation. SPICE, Setting Population Intervention Comparison Evaluation. database searches. Email contact was made with two authors to establish that multiple publications were from the same study and another author was contacted to obtain a copy of a PhD thesis. Manual searches were undertaken by reviewing the reference lists of relevant identified literature from the database search results.

An example of the search strategy for EMBASE can be found in online supplemental material.

Selection criteria

Studies were included if they reported qualitative analysis (including qualitative aspects of mixed-methods studies) of GP's participation and engagement with CCDTs. Studies which used face-to-face or telephone interviews, questionnaires, focus groups or direct observation were eligible. CCDTs were defined as any tool (digital, paper, electronic) used within a consultation which provided an outcome measure such as a percentage risk or a recommendation to the doctor to consider an underlying cancer diagnosis as the cause for a patient's signs or symptoms.

PTB and NH independently screened titles, abstracts and full articles using the inclusion criteria. Any differences in selections of full texts for inclusion were discussed until agreement on inclusion or exclusion was reached (full-text exclusions with reasons is available on request). An independent reviewer was available, this was not required.

Data extraction

For each article, all text from 'Results/Findings' and 'Discussion' were extracted and imported into NVivo V.11 software (NVivo Qualitative data analysis Software; QSR International, V.11, 2016). Study characteristics were extracted into a spreadsheet to explore potential associations between specific themes and studies.

Critical appraisal

All included studies were critically appraised by PTB and NH using the Critical Appraisal Skills Programme checklist (CASP) for qualitative research.¹² Any discrepancies were resolved through discussion, until consensus was reached. The studies were not excluded or weighted based on the quality of reporting or any hierarchy of qualitative evidence.¹³

Data synthesis

Following familiarisation with the selected studies, PTB and NH developed a thematic framework to apply to the studies. The data were coded and charted line by line by PTB and NH. Themes and interpretation were discussed and refined with GM and mapped onto the NPT framework.¹⁴ This work was aided by use of the adapted domain questions in table 1. The final analysis was discussed and validated by all authors.

Patient and public involvement

Patients and the public were not involved in the review.

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

Table 1 Domains of NPT in relation to CCDT				
NPT domains Questions				
Coherence (Meaning and sense making of participants) How they make sense of the work of implementation and integration in order to promote/inhibit routine embedding of a practice.	Is the CCDT easy to describe? Do GPs understand what the CCDT is? Do GPs understand how the CCDT should be implemented? Is the CCDT clearly distinct from other practices? Do GPs express understanding of how the CCDT is distinct from other practices? Does the CCDT have a clear purpose for GPs/patients? Do GPs report a shared understanding of the purpose/benefit/value of the CCDT? What benefits do GPS feel the CCDT will bring and to whom? (GPs/patients)? Are these benefits valued by GPs? Does the CCDT fit with the overall goals and activity of the organisation (practice/NHS) Do GPs feel the CCDT fits with their own responsibilities/ roles?			
Cognitive participation (Commitment and engagement by participants) Process and work go through to enrol individuals to engage with new practice	Do GPs think the CCDT a good idea—'buy in'? Do GPs see the point of the CCDT easily? Are GPs willing to drive implementation? Are GPs able to/willing to sustain involvement? Do GPs feel is it 'right'/legitimate they are involved? Do GPs feel using CCDTs is a legitimate part of their role?			
Collective action (The work participants (individuals and organisations) do to make the intervention function) How they enact it	What effect does the CCDT have on the work of GPs (how the CCDT affects the consultation)? Does the CCDT promote or impede GPs work? How compatible is the CCDT with existing work practices? Does it make work easier? How does it affect their roles/responsibilities/training needs? Do GPs require extensive training before they can use the CCDT? Is there organisational support for the CCDT? Is there confidence in the new practice when they are using/enacting it? What impact does the CCDT have on division of labour, resources, power and responsibility between professional groups? Is there confidence in the new practice when they are using/enacting it?			
Reflexive monitoring (Participants reflect on or appraise the intervention) How they appraise its effects — — informal and formal appraisal of new practice to assess its advantages and disadvantages	How do GPs perceive the CCDT once it has been in use for a while? Is the CCDT perceived as advantageous for patients or staff? Are effects on them and their work clear? How do they judge this? Is it clear what effects the CCDT has had? What are the effects on GPs and their work? How do GPs appraise/evaluate this? Can GPs contribute feedback about the CCDT once it is in use? How are benefits or problems identified or measured? Can the CCDT be adapted or improved on the basis of experience? Has its use been altered while in use?			

CCDT, Clinical Cancer Decision Tool; GPs, general practitioners; NHS, National Health Service; NPT, normalisation process theory.

RESULTS

പ്പ

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses diagram (figure 1) shows the results of the searches. Five published peer-reviewed articles, two reports and one PhD thesis were eligible for analysis. ^{4,8} ^{15–20} Two of the published papers came from the same study these have been considered as one dataset. ^{18,19} Another of the published articles and one of the reports were based on the same study data. ^{16,17} The studies were published between 2011 and 2019.

Characteristics of included studies

The studies were heterogeneous in design, CCDT used and analysis. One study was from Australia⁸ and the others were from the UK.^{415–20} Data from 107 GPs is included in the selected studies (table 2). The characteristics of the CCDTs assessed in the studies are summarised in table 3. These included RAT/eRAT,¹⁸¹⁹ QCancer⁸ two studies used both of these⁴¹⁵ and one used the 7PCL²⁰ (table 4). RAT/eRAT are CCDTs based on the results of population-based case-control studies, QCancer is based on statistically validated cohort studies, and the 7PCL is a check box CCDT intended to be used as a support to GP decision making about referral for melanoma.²⁰ 7PCL is part of National Institute for Health and Care Excellence (NICE) recommendations for the assessment of pigmented lesions in Primary Care.²¹ The CCDTs were presented to the clinician in different formats; including mouse mats, checklists and integrated computer prompts.

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

				Open ac
Research question	To explore GPs experiences of incorporating the Risk Assessment Tools (RAT) for lung and bowel cancer into their clinical practice and in so doing, identify constraints and facilitators to the wider dissemination of the tools in primary care.	Obtain views from general practitioners who piloted the electronic RATs (eRATs) for suspected lung or colorectal cancer. Whether GPs were able to integrate these tools into their everyday practice and identify practice and barriers to their more widespread use.	Explore the use of cancer risk tool (QCancer) in consultations and its potential impact on clinical decision making.	Are clinical decision support tools acceptable to GPs and what are the barriers and facilitators to their integration into routine practice?
Methodology	Framework	Framework	Framework	Framework
Data collection	Telephone interviews Topic guide	Telephone interviews Topic guide	Interview after simulated cases Semi-structured	Telephone interviews semistructured
ссрт	Risk Assessment 5 Tool	eRAT	QCancer	QCancer and Risk Assessment Tool
Setting	175 practices from seven cancer networks selected to include areas of affluence and practices with non-white praging from 2% to 50% UK	Diversity of practices located in deprived to affluent areas UK	Range of geographical location within Victoria Australia	A mix of rural, suburban and urban areas and a range of afluent/ populations UK
No of participant (male:female)	23 (not reported)	23 (13:10)	15 (10:5)	28 (19:9)
Country	ž	ž	Australia.	England, Scotland and Wales
Year of publication	2013 2015	2015 2015	2015	2014
Publication(s)	Green <i>et al</i> ¹⁶ Hamilton <i>et al</i> ¹⁹	Dikomatis et al ¹⁶	Chiang <i>et al</i> ⁸	Moffat and Green ⁴

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

BMJ Open: first published as 10.1136/bmjopen-2020-043338 on 19 February 2021. Downloaded from http://bmjopen.bmj.com/ on March 31, 2021 by guest. Protected by copyright.

1

for suspected cancer using the percentages generated by the CCDT would require some knowledge of the CCDT by secondary care. ^{415–17}

6

Participants in one study questioned the legitimacy of integration of a checklist in the clinical system which already existed within local pathways and on referral forms.¹⁶ Participants commented that using a CCDT to determine referral decisions potentially threatens the professional identity and clinical reputation of a GP possibly undermining their relationship to secondary care.

The 'one size fits all' approach to training

Use of the CCDT by GPs was determined by their involvement in a research study,^{15–17} the training they had prior to using the CCDT and the support that they received while using the CCDT.

Training is essential in determining coherence.⁴ It affects how GPs understand the CCDT, what makes the CCDT distinct from other practices and how it may benefit both the doctor and patient. Any training should aim to demonstrate how the CCDT fits with the responsibilities and role of the doctor as well as the overall goals of the NHS in terms of timely diagnosis of cancer.

Cognitive participation: elements determining GPs use of CCDT

Cognitive participation refers to the commitment and engagement with an intervention.¹⁸ Two influences on engagement with CCDTs were identified.

Clinical acumen vs protocol

Some participants commented on their discomfort using the CCDT to aid their decision making rather than it being an instruction that had to be obeyed. Other GPs made it clear that they did not want to have their clinical acumen challenged by a CCDT.^{48 15–17 19 20} Protocolisation was one of the most commonly discussed factors affecting implementation.^{48 15–17 19 20} GP responses suggest a reluctance to be protocol driven in their decision making. This questions the perceived legitimacy of the use of CCDTs when GPs do not feel it 'right' that they should be used.^{18 19} Some GPs did overrule the outcomes generated by the CCDT if these were not consistent with their clinical impression.^{48 15 20}

The CCDT was used to back up 'instinct' and ignored if it did not.^{4 20} Despite this theme being a dominant one, there was little exploration in the studies of whether the CCDT was used by GPs to justify not taking further action in those with a low risk of symptoms being caused by cancer and only one interviewee was quoted alluding to this.⁸ This could be because of assumptions about the underlying research agenda of early recognition and diagnosis rather than an appreciation that CCDTs might actually contribute to a reduction in over-investigation and improved selection of patients for 2-week wait referral pathways.⁸

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

Table 3 CCDTs used in studies				
Name	Cancer type	Format	Use and development	
Risk Assessment Tool (RAT)	Lung, colorectal	Desk based	Quantifies risk of cancer in symptomatic primary care patients. Consists of risk score for high-risk symptoms in isolation, for repeat presentation of the same symptom and in combination with one other symptom. Positive predictive Values for symptoms of cancer, developed through series of population-based case and control studies in primary care setting.	
Electronic RAT	Lung (non-smokers), lung (smokers), colorectal	Electronic	Electronic version of clinical decision Risk Assessment Tools described above.	
QCancer	Lung, colorectal, gastro- oesophageal, pancreatic, blood, renal, prostate and various others	Electronic	QCancer algorithms can be used to calculate the percentage probability of having an undiagnosed cancer. Developed using QResearch database in a series of prospective cohort studies, it incorporates a range of risk factors.	
Electronic clinical decision support 7 Point Check List	Melanoma	Electronic	Electronic Clinical Decision Support for assessment of pigmented lesions. Integrated into EMIS clinical system. A validated diagnostic checklist of 7 weighted features of a pigmented lesion. A score of 3 or more is suspicious of a diagnosis of melanoma.	

CCDT, Clinical Cancer Decision Tool.

The medicolegal implications of using a new CCDT

Medicolegal implications of using a CCDT to determine a referral were highlighted by two of the studies.^{16 17 20} Uptake could be impeded if GPs felt there was a medicolegal threat to their decision from patients who were later diagnosed with cancer after the CCDT had highlighted an increased risk, but a decision had been made not to investigate or refer.

Collective action: impact of the CCDT on the work of the GP

Collective action is the work individuals and organisations do to make an intervention work.²³ The implementation and use of CCDTs within primary care can impact on the work of a GP in a number of ways.

Increasing awareness

GPs found the use of CCDTs in clinical practice as beneficial. Using them increased their awareness of cancer symptoms. For some GPs, the CCDT acted as a reminder of suspicious signs and symptoms.^{4 8 15-19} This was considered important for trainees and GPs less experienced in dermatology in the case of the 7PCL.²⁰ There was appreciation that some patients may not otherwise have had such a prompt referral to cancer services. The use of the CCDT increased awareness, thus building confidence in NICE guidelines.^{4 16}

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

making work more difficult^{16 17} another commented on the usefulness of prompts for future consultations.²⁰

Impact of IT integration

Prompt fatigue

A major component of how easy it was for GPs to engage with the CCDT was software integration with existing clinical systems. GPs commented on clunky working and lack of support to operate the CCDT within the existing IT system.⁴ ¹⁵⁻¹⁷ One study highlighted that the explosion of decision aids in clinical systems means they are sometimes available, but the clinician is unaware of their existence.²⁰

Prompt fatigue because of CCDT generated reminders

was mentioned by several studies.416 17 The electronic

interruptions impacted on the flow of the consultation.

The prompts were regarded, in some studies, as a nuisance

Integration into clinical IT system was an issue which had the potential to 'make or break' implementation. When participants encountered problems with using the CCDT it was sometimes met with frustration, some GPs chose to abandon use.⁴ Time as a resource

Time and capacity issues was one of the most commonly discussed factors shaping implementation⁴ ¹⁵⁻²⁰ and a frequent response to questions involving any assessment of healthcare technology implementation. Recognition of the benefits of using a CCDT was essential to justify the additional time required for its use. This impacts on

6	

Table 4 Table of quotes to illustrate the themes				
Domain	Theme	Quote	Source	
Coherence				
	Communicating, sharing and understanding risk	'Sometimes I hide it, just in case I cause an alarm, but I will start to cover it during the consultation if there is any risk, yes. It depends because, you know, some patients, if they're anxious, when they see something like that, they become more anxious'	Male GP eRAT ⁴	
		'If someone was very worried and they scored zero then I might be able to say, 'Look, this is a scoring system that's been developed,' and it might just aid reassurance. Equally, if I was worriedI might just say, 'Look, this is the scoring system, you've got quite a lot of points on this. It doesn't mean it's anything serious but it does mean we need to look into it more closely"	Male GP 40 years old 7PCL ²⁰	
	Collaboration and involvement with secondary care and existing guidelines	'My concern is that the tools are not known to the secondary or hospital setup. So, I referred some patients, and I am concerned they may not recognise my QCancer referralSo, when I am thinking, if they see the patients I referred using QCancer, they will ask—who is this? Is this a new doctor, a new GP?'	GP, QCancer ¹⁵	
		'There are criterion boxes often and very occasionally a patient doesn't quite fit one of the boxes and you tend to worrybut I think if you can justify whether actually they've got 38% chance of colorectal cancer on this (tool) then I don't think they would argue with that'	Male GP, eRAT	
	One size fits all approach to training	'Finally, data certainly highlighted that GPs might decide to refer on the basis of a holistic approach and, as many respondents emphasized, the approach of the individual GP and his/her level of clinical experience also plays a crucial part in the decision making process'	Author analysis, eRAT ^{16 17}	
		'Although the tool itself doesn't look that bad on the training, in terms of the implementation and making it work in every single practice, I feel that the training was not bespoke'	Male GP, eRAT ⁴	
Cognitive Participation				
	Clinical acumen vs protocol	'I don't think you can ever protocolise,make a risk schedule that is better thanexperience'	GP, RAT 18 19	
		'Without the checklist I already know what to look for. I know that if it's changed in size, if it's irregular, that those are all seriousSo I would have already gone through it anyway, with or without the (list) in front of me, so does it really matter? Probably not. It's in my head like any other medical problem, I mean, I consult all day long'	Female GP 41–50 years old 7PCL ²⁰	
	The medicolegal implcations	'Quite a few partners were worried about any medical legal implications with thatwhat would be the implications? That was probably a point that put people off, really'	GP, eRAT ^{16 17}	
		'If that's the NICE guidance and that's in the CCG 2-week wait form, if you've got a score of 4 and you don't refer, I think the lawyers would say that you're not following guidance and they could sue you'	Female GP 41–50 years old, 7PCL ²⁰	
Collective Action				
			Continuec	

8

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

BMJ Open: first published as 10.1136/bmjopen-2020-043338 on 19 February 2021. Downloaded from http://bmjopen.bmj.com/ on March 31, 2021 by guest. Protected by copyright.



Figure 1 The PRISMA diagram. PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

One study asked GPs to participate in actor simulated cases using QCancer, followed by an interview exploring their experience.⁸ The other studies interviewed GPs after using the CCDTs in normal practice for a period of time. Two of these collected data via semistructured telephone interviews,^{4 16 17} one undertook face-to-face interviews,⁸ another convened a focus group¹⁵ and one gathered data via a mix of face-to-face and telephone interviews.²⁰ The interviews with GPs were conducted at variable time intervals after using the CCDTs ranged from immediately to months later.

All studies used the framework method to analyse data. Underpinning theoretical frameworks included The normalisation process model (an earlier version of NPT),¹⁶¹⁷ the Consolidated Framework for Implementation Research and Risk Communication Framework.^{15 20} The remaining studies developed their own inductive coding framework.^{48 18 19}

In the Australian study,⁸ there was a US\$300 incentive for participants. Practices were given some financial support via the Cancer Networks for participation in another study.^{18 19} These financial reward for participation were neither discussed in terms of its impact on the participants' engagement nor their responses to interview questions.

Quality assessment

4

Independent CASP assessment of all included studies, by PTB and NH demonstrated they were of high quality (available as online supplemental material). One omission from all studies was an exploration of the role of the interviewer in relation to the interviewee and any impact this could have on the data (reflexivity).²² This failure reflects on potential bias of the study and its conclusions.¹²

Synthesis

The synthesis focuses on; the CCDT, the role of the doctor, the consultation, the impact on cancer investigation and referrals, and the implications on and influence of secondary care cancer services.

Selected quotes from studies add richness to the framework synthesis. They illustrate the themes and how they map onto the NPT domains. Where available demographic information about the source of the quote and the CCDT that the participant discussed is provided (table 4).

Coherence: the impact of CCDT on the role of the GP

Coherence refers to how participants make sense of an intervention.¹⁸ The data suggest that how GPs understand and make sense of CCDTs is inextricably linked to the perceptions of their role as a GP and how this is impacted by their use.

Communicating, sharing and understanding risk

A key result was that GPs were expected to communicate the pros and cons of a course of action, investigation, treatment and the likelihood of signs and/or symptoms present because of an undiagnosed cancer. This was influenced by the potential reaction from patients. Different levels of comfort were experienced when using CCDTs within consultations^{8 15} because of the perceived impact of the information on the patient, how it was communicated and what reaction that might elicit.

Some GPs had concerns that using the CCDT would increase patient anxiety so did not share the cancer risk figures, even keeping risk figures hidden from the patient's view, or feeling that using the risk percentages in discussion with the patient would be challenging.^{4 8} Others were comfortable using the CCDT to reassure patients.^{15 20}

There was a lack of understanding about the intended role of the CCDT or how to use the results that it generated.^{4 15–17} This misunderstanding may reflect poor knowledge of how to interpret the results generated from a CCDT. Understanding how the CCDT fits within the current cancer pathway, how the cancer risk figures were calculated, might improve confidence in the validity of using a CCDT.^{8 15–17} Integration into the consultation might be encouraged by such knowledge.

Collaboration and involvement with secondary care and existing quidelines

A common theme across studies was the reported need for the CCDT to be integrated within existing referral pathways and endorsed by secondary care.⁴ ^{15–17} GPs worried that a change in referral patterns, as a result of its use, might not be well received by hospital specialty team with no knowledge of it. Some participants felt uneasy using the CCDT to make referral decisions as a consequence. Having secondary care doctors' endorsement of the CCDT appears to be an important aspect in promoting its routine use for GPs. Justification of referrals

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

Domain	Theme	Quote	Source
	Increasing awareness	'Normally I'd get a few investigations, get the results back and then based on that say do we need to do something, or I refer this on based on that. But I guess if I have a calculator saying it's higher risk, it might prompt me to make a referral to a specialist a bit earlier'	Female GP 31 years old, QCancer ⁸
		'It probably made us more aware than NICE guidanceit's probably made me more aware of symptoms which I may have not been as aware of in the past'	Male GP, eRAT ⁴
	Prompt fatigue	'we have all sorts of prompts coming atit gets a little bit distractingyou're trying to sort out and you've got all these messages flashing up at you'	Male GP, QCancer
	Impact of IT integration	'I suppose the prompt of a photo to be added would be helpful if they need to look through it'	Male GP 40 years old, 7PCL ²⁰
		'There was a problem of accessing the tools as they are not integrated in our IT system. It was not easy downloading or googling the tools during patient consultation'	GP, QCacner ¹⁵
		'so much hasslewe had to spend so much time trying to install it in every single desktop couldn't do it. I just gave up'	Male GP, eRAT ⁴
	Time as a resource	'if it's actually going to make life easieris it going to improve care for the patient? Or is ittime really spent in filling up proformas?'	GP, RAT 18 19
		'I thought it was going to be time consuming using the tool. Butthat will only be the case in the short termit will be time saving in the long term, as the consultation, the assessments, investigations and referral processes will be faster'	GP, QCancer ¹⁵
Reflexive Monitoring			
	Unintended consequences	'there is a potential for using the tools for screening They could also be modified for asymptomatic patients'	GP, QCancer ¹⁵
		'Your chest X-ray is perfectly normal, Your cough settlesI still have to try and convince you to stop smoking, to exercise, to lose weightit should be used as a relationship tool'	Female GP 50 years old, QCancer ⁸
	Investigation and referral patterns	'we were thinking that using the tools in consultation could result in unnecessaryover-referralsI don't think there will be over-referrals'	GP, QCancer
		'I think our referral thresholds for lower GI have definitely gone down'	Cancer Lead GP, RAT ¹
	Think Cancer	'Yes, I must admit ovarian didn't come so high up This really said hey, consider ovarian as well"	Male GP 46 QCancer ⁸
		'If I had a patient with a vague set of symptoms then finding and using the tool showed that it was an amberI might have followed up the patient in a different wayI'd like to see you again, just to see how these symptoms are, um, rather than leaving it to the patient to contact us"	Cancer Lead GP, RAT

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

a

consultation, time required to train users and the additional effort to continue using the CCDT. Time is at a premium in general practice in the UK: the pressures of the 10 min appointment,²⁴ to keep up to date and to attend training.

Participants reported that adjusting to new work practices and integrating new techniques could take additional time, attention and commitment. However, there was evidence of recognition that initial investment may deliver improved patient care.¹⁵

Reflexive monitoring: GPs reflections on using a new technique

Reflexive monitoring is the appraisal work that is carried out by individuals utilising the CCDT. 18

Unintended consequences

Despite not being an aim of CCDTs, it was recognised that they could be valuable to identify at risk patients or those suitable for screening.^{8 15 18 19} In terms of the NPT framework, this highlights how the use of a complex intervention is adapted, based on every day clinical practice and experience.

Another recognised unintended benefit of using the CCDT was in identifying patients' modifiable lifestyle factors.^{8 15} This information was used in consultations to try and encourage behavioural change in relation to smoking, weight or alcohol consumption to reduce cancer risk and for general health promotion.

Investigation and referral patterns

It was acknowledged that the CCDT could reduce overinvestigation and over-referral to secondary care.⁴ ^{15–20} Conversely, others raised concerns that CCDT would increase the referral rates, but accepted that this could be auditable.^{15 18 19} A reduction in referrals to secondary care would have a positive impact on stretched secondary care services.

'Think cancer'

All studies demonstrated that CCDTs prompted GPs to 'think cancer'^{4 8 15-20} and heightened awareness of relevant signs and symptoms. CCDTs improved the speed of diagnosis and prompted investigations, referrals and counselling of patients. The data revealed that some GPs felt the CCDT elicited earlier review for patients with vague symptoms possibly being caused by an underlying cancer.^{18 19}

DISCUSSION

This qualitative synthesis suggest that GPs recognise the need for awareness of the signs and symptoms of undiagnosed cancer and that the use of CDDTs can help to prompt early referral and diagnosis. As well as these intended benefits, GPs appreciate that CCDTs can be used in ways that benefit the patient doctor interaction. GPs used CCDTs to aid communication with patients about risks of cancer from suspicious as well as vague signs and symptoms and non-suspicious, to reassure anxious patients and to justify legitimate concerns. Using CCDTs in the context of worrying signs and symptoms provides GPs the opportunity to discuss preventative lifestyle changes like weight loss and cessation of smoking which can reduce future risk of developing a cancer.

IT integration issues, interruptions, training and prompts were important factors in how the CCDT functioned in practice and crucial to how participants felt about committing to, and using, the CCDT within consultations.

For CCDTs to be implemented in routine practice, it is important they are thoughtfully developed with collaboration and endorsement from secondary care to ensure compatibility with existing referral criteria. GPs need to be comfortable that the CCDT is another tool in their armamentarium and not seen as a replacement for their gut instinct, experience or factors related to relationships built up over time with patients.

In the field of CCDTs the understanding of risk and its communication needs to be tailored to GPs and patients in a simple, understandable way.^{25 26} particularly given the emotive and sensitive nature of suspected cancer and the emphasis on early diagnosis. The discussion of risk with patients and the emphasis on shared decision making (putting patients at the centre of any decisions 'no decision about me without me')²⁷ within GP consultations is a key component of universal personalised care.²

CCDTs need to be considered clinically valuable, as easy as possible to use and integrate with existing pathways and practices,²⁸ while causing minimal disruption to the consultation. Alert fatigue is a recognised consequence of prompts that are generated from the electronic patient record systems.²⁹ Clinicians find that electronic prompts interrupt the flow of a consultation, are annoying and are often dismissed without full attention to their contents. This means reminders and alerts that could have a critical clinical impact on a patient are ignored. This is a real concern when the reason is to alert a clinician to an undiagnosed cancer.

GPs acknowledged that any CCDT, and the evidence behind them, need to be acceptable to specialists to whom they refer. GP compliance with guidelines is variable,³⁰ so discordance between a CCDT and local or national pathways needs to be avoided. Endorsement of CCDT by secondary care would reassure GPs that decision making about referrals was acceptable to both groups. In this context, closer cross-organisational collaboration and trust between healthcare professionals in primary and secondary care could be key to the successful implementation of CCDT.³¹ The Cochrane Review of Interprofessional Collaboration³² concludes that to improve professional practice and healthcare outcomes, collaborative work is an area which deserves and is receiving increased academic interest.

The struggle between gut instinct (experience and knowledge of both the medicine and the patient with whom the doctor has a long term therapeutic relationship)

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

and protocol is a recognised phenomenon which taps into the GPs' professionalism (autonomy, accountability and responsibility).³³ No new system should undermine or overrule clinical intuition but should accept that medicine is an art, particularly in the emotively charged arena of cancer diagnosis. Mandating adherence to a particular set of protocols is fraught with barriers.³⁴ A recent systematic review and meta-analysis found that the GP's 'gut feeling' was an important predictor of a cancer diagnosis.³⁵

This is the first theoretically informed qualitative synthesis of the views and experiences of general practitioners in relation to the implementation of Clinical Cancer Decision Tools (CCDTs) used within the rimary are consultation. The systematic and theory informed approach to synthesis allowed the identification of some generic and transferable issues relevant across a range of different CCDTs and contexts.

The small number of studies and data available for inclusion in this review limited detailed comparative analysis between CCDTs and contexts, and further work in this area may be beneficial. The quality and depth of the findings are limited by the quality of the studies included, and any bias of the original authors. Unfortunately the he small number of studies and data available for inclusion in this review limited the ability to carry out a more detailed comparative analysis between CCDTs and contexts, and further work in this area may be beneficial.

The studies are recent (2011 onwards) reflecting modern primary care practice but predominantly within the English NHS. The CCDTs evaluated are different: in format, in how the individual patient's risk of cancer is calculated and their affinity with existing referral criteria. Nonetheless, this systematic and theory informed approach to synthesis identified some generic and transferable issues relevant across different CCDTs.

The ubiquitous electronic clinical decision aid takes many forms in primary care and this study reflects GPs' experience from just those designed to improve recognition of signs and symptoms that could be caused by an undiagnosed cancer. There are lessons to be learnt from the experience of successful implementation of electronic decision aids in other clinical domains such as cardiovascular disease.³⁶

More evidence is needed that suspected cancer referrals generated from the use of CCDTs lead to identification of cancers at an earlier stage with subsequent impact on treatment outcomes. This evidence would further legitimise the use of CCDTs along with endorsement of their use by national guidance bodies for cancer pathways such as NICE in England.

CONCLUSIONS

Comprehensive cooperative working between primary and secondary care in planning, designing and implementing CCDTs will benefit clinicians, patients, quality of healthcare and take account of scarce resources.

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmjopen-2020-043338

Stakeholder consultation and involvement should be regarded as essential aspects of healthcare innovation and implementation.

The value that clinicians place on their clinical acumen and their desire for this to be recognised makes them wary to rely solely on protocol driven decision making. There will always be clinicians who find decision aids reassuring, those who find them helpful as an aide-memoire and those that find them a nuisance and will not use them at all. An ideal CCDT is one that does not undermine clinical instincts but supports and enhances them.

CCDTs can be a helpful adjunct to clinical work in primary care, but without careful development legitimising their use as well as consideration of training and IT integration with secondary care and IT systems, they may remain to be perceived as superfluous to clinical acumen and experience. Stakeholder consultation and involvement should be regarded as essential aspects of healthcare innovation and implementation.

This theoretically informed synthesis of existing qualitative work has helped to identify key themes and issues that influence the use and implementation of CCDTs across cancers, tools and settings. These insights can help to inform future development and implementation of CCDTs and fuller integration within policy and referral guidelines.

Twitter Paula Theresa Bradley @drptbradley and Richard D Neal @richarddneal

Contributors PTB: protocol, literature search, data selection, data analysis, article. NH: protocol review, data selection, data analysis, manuscript editing. GM: data analysis, manuscript editing. RDN, VP and SW: supervision at all stages

Funding PTB is a PhD candidate and Extended Integrated Training Programme GP Trainee in a post funded by Health Education England North East as part of the Northumbria General Practice Training Programme.

Competing interests None declared.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed. Data availability statement There are no data in this work.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsibile for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: http://creativecommons.org/licenses/by-nc/4.0/.

ORCID iDs

Paula Theresa Bradley http://orcid.org/0000-0002-1908-1053 Richard D Neal http://orcid.org/0000-0002-3544-2744

REFERENCES

- Abdel-Rahman M, Stockton D, Rachet B, et al. What if cancer
- survival in Britain were the same as in Europe: how many deaths are avoidable? *Br J Cancer* 2009;101 Suppl 2:S115–24. NHS. Nhs long term plan, 2019. Available: https://www.longtermplan. 2 nhs.uk/wp-content/uploads/2019/01/nhs-long-term-plan-june-2019.
- England N. QOF quality improvement domain 2020/21 early 3 diagnosis of cancer, 2020. Available: https://www.england.nhs.uk/ wp-content/uploads/2020/02/20-21-qof-qi-cancer.pdf [Accessed 13 Dec 2020]
- Dec 2020). Moffat JI, Green TL, Clinical decision support tool for cancer (CDS) project: evaluation report to the Department of health, 2014. Available: https://www.macmillan.org.uk/_images/cds-executive-summary_tcm9-291978.pdf [Accessed 25 Feb 2020]. Walter FM, Morris HC, Humphrys E, *et al.* Effect of adding a diagnostic aid to best practice to manage suspicious pigmented parameter rendomized opertraNet tid. PMU Λ
- 5 lesions in primary care: randomised controlled trial. BMJ 2012;345:e4110. Walter FM, Prevost AT, Vasconcelos J, et al. Using the 7-point
- 6 checklist as a diagnostic aid for pigmented skin lesions in general practice: a diagnostic validation study. *Br J Gen Pract* 2013;63:e345–53.
- 7
- 2013,05.6345-55.
 Price S, Spencer A, Medina-Lara A, et al. Availability and use of cancer decision-support tools: a cross-sectional survey of UK primary care. Br J Gen Pract 2019;69:e437-43.
 Chiang PP-C, Glance D, Walker J, et al. Implementing a QCancer risk tool into general practice consultations: an exploratory study using simulated consultations with Australian general practitioners. Br J Concert 2102;11202; 8 Cancer 2015:112 Suppl 1:S77-83
- Cancer 2015;112 Suppl 1:S77–83. Chima S, Reece JC, Milley K, *et al.* Decision support tools to improve cancer diagnostic decision making in primary care: a systematic review. *Br J Gen Pract* 2019;69:e809–18. et alMay C, Rapley T, Mair FS, Normalization Process Theory On-line Users' Manual, Toolkit and NoMAD instrument, 2015. Available:
- 10
- Booth A, Brice A. Evidence-based practice for information professionals : a handbook. London: Facet, 2004. 11
- Critical Appraisal Skills Programme. Casp (qualitative checklist), 2019. Available: https://casp-uk.net/casp-tools-checklists/ [Accessed 31 Oct 2019]. 12
- Garside R. Should we appraise the quality of qualitative research reports for systematic reviews, and if so, how? *Innovation: The European Journal of Social Science Research* 2014;27:67–79. 13 14
- Brunton G, Oliver S, Thomas J, Innovations in framework synthesis as a systematic review method. *Res Synth Methods* 2020;11:316–30. Akanuwe J. *Exploring service user and practitioner perspectives of* 15
- using cancer risk assessment tools in primary care consultations. University of Lincoln, 2018. Dikomatis TG, Macleod, U T. MacMillan electronic risk assessment 16
- tool summary: dealing with uncertainty: a qualitative evaluation of the usability and acceptability of an electronic risk assessment tool to aid cancer diagnosis in general practice: supportive care, early diagnosis and advanced disease (SEDA) Research Group. centre for health and population sciences (CHAPS), 2012. Available: https:// www.macmillan.org.uk/documents/aboutus/health_professionals/
- earlydiagnosis/summaryeratsreport(cct2012).pdf Dikomitis L, Green T, Macleod U. Embedding electronic decision-support tools for suspected cancer in primary care: a 17

- qualitative study of GPs' experiences. Prim Health Care Res Dev 2015-16-548-55
- 18 Green T, Martins T, Hamilton W, et al. Exploring GPs' experiences of using diagnostic tools for cancer: a qualitative study in primary care. Fam Pract 2015:32:101-5
- Hamilton W, Green T, Martins T, *et al.* Evaluation of risk assessment tools for suspected cancer in general practice: a cohort study. *Br J Gen Pract* 2013;63:e30–6. 19
- Pannebakker MM, Mills K, Johnson M, et al. Understanding implementation and usefulness of electronic clinical decision 20 support (eCDS) for melanoma in English primary care: a qualitative investigation. *BJGP Open* 2019;3:bjgpopen18X101635. National Institute of Care and Health Excellence. Melanoma and pigmented lesions, 2017. Available: https://cks.nice.org.uk/topics/
- melanoma-pigmented-lesions/diagnosis/assessment/ [Accessed 20 Dec 2020]. Berger R. Now I see it, now I don't: researcher's position 22
- and reflexivity in qualitative research. *Qualitative Research* 2015:15:219–34.
- Murray E, Treweek S, Pope C, et al. Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med* 2010;8:63.
- Hobbs FDR, Bankhead C, Mukhtar T, et al. Clinical workload in UK primary care: a retrospective analysis of 100 million consultations in England, 2007-14. Lancet 2016;387:2323-30.
- med H, Naik G, Willoughby H, et al. Communicating risk. BMJ 25 2012:344:e3996.
- 26 Naik G, Ahmed H, Edwards AGK. Communicating risk to patients and the public. *Br J Gen Pract* 2012;62:213–6. Coulter A, Collins A. *Making shared decision-making a reality : no*
- 27 decision about me, without me, London; King's Fund, 2011.
- Maniatopoulos G, Procter R, Llewellyn S, et al. Moving beyond local practice: reconfiguring the adoption of a breast cancer diagnostic technology. Soc Sci Med 2015;131:98–106.
- Backman R, Bayliss S, Moore D, et al. Clinical reminder alert fatigue in healthcare: a systematic literature review protocol using qualitative evidence. Syst Rev 2017;6:255. 29
- Lugtenberg M, Burgers JS, Besters CF, et al. Perceived barriers to guideline adherence: a survey among general practitioners. *BMC Fam Pract* 2011;12:98. 30 Maniatopoulos G. Haining S. Allen J. et al. Negotiating 31
- commissioning pathways for the successful implementation of innovative health technology in primary care. BMC Health Serv rv Res 2019:19:648. Reeves S. Pelone F, Harrison R, et al. Interprofessional collaboration 32
- Database Syst Rev 2017;6:CD000072.
- Brancas Original Control Control
- on Clinical Pathway Support Systems. 2014 (eee International Conference on Healthcare Informatics, 2014:194–201. Smith CF, Drew S, Ziebland S, et al. Understanding the role of GPs⁴
- 35 gut feelings in diagnosing cancer in primary care: a systematic review and meta-analysis of existing evidence. *Br J Gen Pract* 2020;70:e612–21.
- 36 Ban J-W. Perera R. Stevens R. Gos familiarity with and use of Open 2020;4:bjgpopen20X101081.

Bradley PT, et al. BMJ Open 2021;11:e043338. doi:10.1136/bmiopen-2020-043338

12

BMJ

Open:

: first

Appendix N: Posters

Using risk assessment tools for suspected cancer within primary care barriers and facilitators: preliminary results from a framework synthesis using Normalisation Process Theory (NPT)



Paula Bradley¹, Nicola Hall¹, Vinidh Paleri², Richard Neal³, Scott Wilkes¹ University of Sunderland Ś ¹University of Sunderland, ²Institute of Cancer Research, ³University of Leeds

Introduction

Cancer symptoms are often non-specific and can be quite vague. Diagnosis of cancer at earlier disease stage determines the outcome. The 2 week wait referral pathways for suspected cancer have existed in the NHS since 1997. There are tools to help GPs "think cancer", these aim to heighten the suspicion of a cancer diagnosis and support early referral for suspected cancer. Some of these cancer prediction tools or decision aids have been developed and trialed in the UK and beyond, these include QCancer (as part of EMIS Web) and specific cancer Risk Assessment Tools (for example; colorectal, lung, pancreatic).

<u>Aim</u>

A Framework Synthesis, of the relevant literature using NPT to explore the barriers and facilitators to the use of cancer risk assessment tools by General Practitioners.

Normalisation Process Theory Method Results - Prisma Diagram NPT is used to study the 1. Electronic database literature development and implementation search of new processes, in other words 2. Title & abstract screening how a new process becomes 3. Study eligibility using the 'normalised' in practice inclusion criteria (Prisma Diagram) 4. Quality assessment of studies There are four domains: 5. Qualitative evaluation using NPT Coherence - 'making sense' work -tillity (Included publications - references 1-6 below) Cognitive participation relationship work ncluded Collective action - enacting work Coherence – making sense Reflexive monitoring - appraisal "You wouldn't really use it without work knowing what or how it was Cognitive Participation developed, why it was developed, relationship and what it was for" (6) "Many times we can calculate until we go Collective Action – enacting blue in the face, but if "And I thought, 'Wow! Patients coming **Reflexive Monitoring – appraisal** secondary care thinks, with these tummy pains,' even if I'm "I've been a GP for about 14, 15 actually, you know what, thinking, 'She's got a 10% chance,' to years now ... there aren't many this wasn't a two week actually think, 'Wow! Listen, you got a wait target referral at things that change your practice, 38% chance of cancer.' General public so it's good when you come all, then this [tool] is a are very—I would find that confronting across things that do." (4) load of rubbish." (5) and the general public have a shocking record at understanding risk." (3) Discussion Investment in development, education and training for GPs in the use of cancer risk assessment tools is essential to their

successful implementation or "normalisation".

GPs want tools that are endorsed by secondary care colleagues, can be used in shared decision making with patient and are evidence based.

GPs do not want to use tools which negate their clinical acumen.

idy. Br J Gen Pract. 2013;63(606):e30-6. im azes/pilot-study-ecds-tool-uk-gp-pra-

on support tool (cCDS) in UK General Practice [Available from: https://www.macm nplementing a QCancer risk tool into general practice consultations: an exploratory cleod U. Exploring GPS' experiences of using diagnostic tools for cancer: a qualitati popt tool for cancer project: evaluation reports to the Department of Health. 2014 millan.org.uk/_images/pilot-study-ecds-tool-uk-gp-practice-po ary study using simulated consultations with Australian general tive study in primary care. Family Practice. 2015;32(1):101–109 iar. Mont. 2015:112 Suppl 1:577-83

Predictive modelling of head and neck cancer from primary care electronic database records.

Paula Bradley¹, Emmanuel Ogundimu², Vinidh Paleri³, Richard Neal⁴, Scott Wilkes¹



¹University of Sunderland, ²Northumbria University Newcastle ³Institute of Cancer Research, ⁴University of Leeds



Background

The National Institute of Clinical Excellence (NICE) 2015 cancer referral guidelines¹ are grounded in the theory that symptoms with a Positive Predictive Value (PPV) of >3% for a diagnosis of cancer should be referred into secondary care.

The symptoms for Head and Neck Cancer (HNC) are derived from a pragmatic list based on clinical experience, without recourse to robust data. The lack of PPVs for the signs and symptoms of HNC is an area which requires development and there has been a call for evidence from symptomatic patients within primary care in more rare cancers; this study aims to answer this call.

Risk Assessment Tools (RAT) are designed to be used by General Practitioners (GP) to try and predict current or future disease².

As yet, no tool has been developed for HNC from primary care data, although a calculator has been generated using secondary care data³.

Aim

Develop a Head and Neck Risk Assessment Tool.

This project aims to assess if predictive values of signs and symptoms of suspected head and neck cancer can be calculated using patient information recorded by GPs in electronic patient records.

Method

A primary care electronic patient record database will be interrogated and useful data extracted to calculate predictive values for signs and symptoms of HNC.

The study primary outcome is dichotomous; a diagnosis of head and neck cancer.

Multivariable logistic regression model to describe the relationship between the binary outcome variable and a set of predictors

Based on the TRIPOD recommendations⁴.

Image from NHS website: https://www.nhs.uk/conditions/nasopha ryngeal-cancer/



Signs/Symptoms/Variables

- CTV3 coding will be used and examples of variables include;
- Dysphagia Odynophagia Neck Lump Unilateral otalgia Sore throat Hoarseness

Outcomes

Evidence-based RAT for use in primary care which may;

- Reduce the burden on 2WW clinics and free up staff to operate routine clinical work.
- Communicate clinical risk to
- patients and mitigate health anxiety.
- Change to NICE suspected HNC
 - referral guidelines

Discussion

Anticipated barriers include raising the funding to purchase the database, The Health Improvement Network database via The University of Birmingham have quoted a price of £10,000. Grant applications have been made to Head and Neck charities for this funding.

The quality of the data recorded and captured in GP electronic patient records may limit what modelling can be done.

Qualitative research which will be carried out during this PhD will contribute to the body of work supporting any future development of a primary care risk assessment tool for head and neck cancer.

References

1 National Institute for Health and Care Excellence: Clinical Guidelines. Suspected Cancer: Recognition and Referral. June 2015 2 MacMillan. A pilot study of an electronic cancer decision support tool (eCDS) in UK General Practice [Available from: https://www.macmillan.org.uk/_images/pilot-study-ecdstool-uk-gp-practice-poster_tcm9-292002.pdf. 3 TiKa T, Pravy Paleri V. Refining the head and neck cancer referral guidelines a two-centre analysis of 4715 referrals. Clinical Otolaryngology. 2016 Feb; 41(1): 66-75 4 Collins GS, Reitsma JB, Altman DG, Moons KG. Transparent reporting of a multivariable prediction mode I for individual prognosis or diagnosis (TRIPOD): the TRIPOD statement. BMJ. 2015 Jan 7;350: g7594

FACTORS SHAPING THE IMPLEMENTATION AND USE OF CLINICAL CANCER DECISION TOOLS BY GPS IN PRIMARY **CARE: A QUALITATIVE FRAMEWORK SYNTHESIS**

P Bradley, N Hall, G Maniatopoulos, R Neal, V Paleri, S Wilkes Paula.Bradlley@sunderland.ac.uk

AIMS & METHOD

Qualitative literature synthesis to explore reasons why the existing clinical cancer decision tools (CCDT) may not be in daily use by GPs despite their availability

Systematic Search - databases and grey literature

Narrative approach to synthesis using the Normalization Process Theory

synthesis

RESULTS

6,500

3

Titles from EMBASE, MEDLINE, CINAHL, Web of Science

Two reports & one thesis form grey literature search

CONCLUSIONS

Full texts included in

CCDT are a helpful adjunct for GPs but need careful development and implementation considering the following:

Collaboration with secondary care





Clinical acumen versus protocol



Opportunity for cancer prevention



Clinical acumen versus protocol and the medico-legal implications



Collective Action (impact on the work of the GP)

Increase awareness of signs and symptoms of cancer, poor integration into IT

Reflective Monitoring (reflection on use)

Unintended consequences – screening and behaviour modification

NORMALIZATION PROCESS THEORY SYNTHESIS Coherence (role of the GP) Communicating, sharing and understanding risk and consideration of

8

CanTest

A symptom-based risk calculator (ORLHEALTH) as part of the two week wait pathway: qualitative analysis of interviews with North East head and neck surgeons

University of Bradley, N Hall, G Maniatopoulos, R Neal, V Paleri, S Wilkes

3 OMFS

BACKGROUND

In an effort to improve the two week wait head and neck cancer referral pathway a decision tool has been developed.

This statistical modelling of patient characteristics, signs and symptoms, from information from referrals to the head and neck cancer clinics, has generated an online calculator which assesses an individual's risk that their symptoms are caused by cancer

<u>RESULTS</u>

11 interviews

<u>METHOD</u>

PB invited consultant head and neck surgeons from 4 units in the region to take part in recorded interviews about the two week wait pathway;

- whether there was scope to improve it
- their impression of the online tool
- whether they thought it could be integrated into the pathway



ANALYSIS

Participants felt that the calculator should be used in primary care and integrated into the electronic system as a gateway into the two week wait referral.



Surgeons agreed that secondary care endorsement would be important in the implementation of a new referral process and that a roll out would require coordination from the Northern Cancer Alliance and the CCGs to ensure consistent use across GP practices.

A pilot to evaluate would be valuable.

CONCLUSIONS

There is cautious enthusiasm from head and neck surgeons in the region to changes to the referral pathway.

8 ORL-HNS

There are many things to consider prior to using a calculator in a primary care population, more work is needed including speaking to GPs and statistical modelling using a primary care patient record database.



An exploration of a new approach to the Suspected Head and Neck Cancer Two Week Wait Referral Pathway in the North East; initial results of qualitative analysis of interviews with Head and Neck Surgeons



≽ SCAN ME

P Bradley, G Maniatopoulos, R Neal, V Paleri, S Wilkes

BACKGROUND

There is a disquiet amongst head and neck surgeons (HNS) that the two week wait referral pathway (TWW) for suspected head and neck cancer (HNC) is not a sensitive route by which cancers are diagnosed.

Stakeholder service evaluation which aims to explore the views of North East HNS on the future of the HNC TWW.

<u>METHOD</u>

Emails were sent to the chairperson of the four regional HNC multidisciplinary teams requesting dissemination of an invitation asking for HNS volunteers to be interviewed about orlhealth.com

The interviews were conducted, recorded and transcribed by PB.

The transcripts were coded to develop themes.

RESULTS 11 interviews

3 OMFS

ANALYSIS

HNS felt that the TWW could be improved. There was an appreciation that, particularly GPs, have to interpret symptoms with which they often have limited experience but thatthe guidelines were open to interpretation and heavily influenced by the agenda of early diagnosis of cancer.

If endorsed by HNS and placed as a gateway into the TWW referral form might be useful, help in the consultation with the patient and with endorsement from HNS, improve GPs confidence in managing a clinical area in which they lack experience.











There is an appetite for some redefinition of the suspected HNC TWW. A symptom based decision tool was regarded as being easy to use, could be integrated into the

pathway and may give primary care more confidence in choosing a route other than the TWW for patients with head and neck symptoms.

For a symptom decision tool for suspected HNC to be introduced into primary care further stakeholder involvement would be required to ensure any change to the current pathway are executed in a way that takes into account the way primary care (GPs and GDPs) works, the views of patients and potential impact on the consultation.

This has obviously been superseded by work during Covid19. Watch this space.....

8 ORL-HNS

CONCLUSIONS



ENTs' opinions of a SLT clinic model for low risk two week wait (2ww) patients with dysphonia and dysphagia

Occomore-Kent. L, Hardman. J, Roe, J. Bradley. P, Carding, P. & Patterson. J.M.

Aim

To explore ENT Surgeons' perspectives on SLT-led clinics for risk-stratified 2WW patients

Method

Participants: Consultant HNC/ENT Surgeons Semi-structured telephone interviews, transcribed Sampling: geographic location / service models Thematic analysis



Conclusion

A range of service models are emerging to address the 2WW problem. All participants were supportive of SLT-led 2ww clinics in principle. The model is running successfully at 2 participants' units.

Key considerations:

- •Adequate and sustainable workforce, resourcing and funding
- •Specified job role and training
- •Professional body recognition
- Appropriate governance to safeguard patients and staff

•Meets local need and agenda e.g. cost, patient experience, pathway challenges

