Exploring opportunities for improving patient safety when GPs work in or alongside emergency departments: realist synthesis and evaluation

Alison Cooper

PhD (Medicine)
Cardiff University

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To Ian, Oli and Sophie

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Abbreviations

ACSC	Ambulatory Care Sensitive Conditions
ANP	Advanced Nurse Practitioner
CQC	Care Quality Commission
ED	Emergency Department
ENP	Emergency Nurse Practitioner
GP	General Practitioner
HS &DR	Health Services and Delivery Research
NHS	National Health Service
NIHR	National Institute for Health Research
NRLS	National Reporting and Learning System
OECD	Organisation for Economic Co-operation and Development
RCEM	Royal College of Emergency Medicine
RCGP	Royal College of General Practice
UCC	Urgent Care Centre
UK	United Kingdom
UTC	Urgent Treatment Centre
WHO	World Health Organization
WIC	Walk In Centre

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Plain English Summary

This thesis explores the nature of patient safety incidents when GPs work in or alongside emergency departments, how and why they may occur and the associated patient harm. It also explores how emergency department clinical leads and GPs working in these services, perceive they work together to deliver safe patient care and mitigate such patient safety outcomes. I used realist methods, appropriate for complex environments, to explore how contextual factors influence the mechanisms by which care is delivered to result in intended and unintended outcomes.

I start with a description of the evidence base for the different models of GP services in or alongside emergency departments and an overview of relevant patient safety concepts and approaches (Chapter 1). I then detail why I chose to use realist methodology, the philosophy and methods used for this work (Chapter 2). Next I describe the results from the rapid realist review (Chapter 3), national patient safety incident report analysis (Chapter 4), case site visits (Chapters 5&6), and stakeholder feedback (Chapter 7). In Chapter 8, I use the lens of formal theory to explain my findings and develop a proposed intervention to facilitate GP services delivering safe patient care in these settings. Chapter 9 discusses my overall findings in the context of current literature, the strengths and limitations of my work and implications for practice and policy. I designed this thesis and collected data before the Covid-19 pandemic. In Chapter 9 I discuss how the pandemic influences interpretation of my findings and further work.

Abstract

Background

Worldwide, increasing pressure on emergency services has led to the development of different models of care delivery including GPs working in or alongside emergency departments. However, evidence for the effectiveness of this initiative is weak, with a lack of evidence for patient safety outcomes. I aimed to explore the nature of patient safety incidents associated with these service models and how the risks may be mitigated.

Method

I used realist methodology to understand the relationship between context, mechanisms and outcomes to develop theories about how and why incidents occurred in different settings and how safe care was perceived to be delivered. Data sources included: a rapid realist literature review (synthesis); analysis of a sample of National Reporting and Learning System (NRLS) patient safety incident reports and Coroners' reports; and qualitative data ('datix' reports, observations and semi-structured audio-recorded interviews) from a purposive sample of 13 selected case study sites with different service models.

Results

There was little evidence in the literature about patient safety outcomes. I identified few incident reports describing diagnostic error associated with these service models: nine Coroners' reports (9/1347, 2013-2018) and 217 NRLS reports 217/13074550, 2005-2015). These were largely due to: inadequate streaming processes; errors in clinical decision-making or inadequate skillset;

and inadequate referral pathways and communication between services. Strategies perceived to facilitate the delivery of safe patient care at selected case sites included: an experienced streaming nurse using local guidance and early warning scores; support for GPs' clinical decision-making relevant to the intended role (a traditional GP approach or an emergency medicine approach); strong clinical leadership and clear governance processes. These findings have been used to develop a potential intervention to understand how local context influences service set-up, function and resultant outcomes, with associated potential measures and training resources, to facilitate GP services delivering safe patient care in emergency department settings.

Conclusion

There are few evidence-based interventions to improve patient safety for these service models. Priority areas to focus upon include: appropriate streaming processes; supporting GPs' clinical decision-making with clear governance processes; and improving communication between services.

Preface

My background

As a first-year medical student in 1993, ‘iatrogenic harm’ was a term I learnt as part of the ‘surgical sieve’ – an aide-memoire for one of many potential causes of a disease state or symptoms. It was accepted that healthcare and treatments can themselves at times cause harm to patients but further teaching on the extent of this and safer more efficient systems to mitigate risk was beyond the curriculum and research at the time.

Having completed my house officer year, I spent several years working in various junior doctor positions in Canterbury, New Zealand before returning to South Wales to complete vocational GP training. I worked in Ystrad Mynach Surgery for eleven years in total: initially as a GP registrar, then a salaried GP and six years as a GP partner. With the experience of working in a different healthcare system on a different continent, I became aware of inefficiencies in providing primary care services in the NHS, with associated potential patient safety risk. For example, GPs making clinical management decisions while second guessing results of investigations and diagnostic decisions made during inpatient admissions or outpatient visits because of a lack of, or delay in, communication. My additional role as a GP appraiser since 2013 made me aware of similar problems experienced in other practices and although these are addressed through practice level significant event analysis and personal reflection, I believe there is a need for improvements on a wider, system-level scale.

In 2014, I took up a GP Academic Fellow position at Cardiff University. This involved six-month GP placements in different GP surgeries to allow the practices time to complete quality improvement projects. I became involved in two national primary care patient safety studies during this time: analysis of patient safety incident reports;(1) and a case note review of medical records to establish the incidence of avoidable harm in primary care.(2) These studies generated a personal interest in patient safety research and I was fortunate enough to be given the opportunity to undertake this PhD, as part of the NIHR funded ‘GPs in EDs’ study, where I worked as a Clinical Research Fellow three-days a week, March 2017 - March 2020.(3) I have continued one clinical day a week as a salaried GP at Rumney Primary Care Centre, Cardiff and my GP appraiser role.

I look forward to applying the learning I have gained through this process to future studies. As the NHS evolves to manage increasing demand and the challenges of an ageing population, with primary and secondary care becoming more integrated, we must ensure that delivering safe patient care is always the priority.

The ‘GPs in EDs’ study

I am a co-applicant on the National Institute for Health Research (NIHR) Health Services and Delivery Research (HS&DR) GPs in EDs study 15/145/04: A realist evaluation of the effectiveness, safety, patient experience and system implications of different models of using GPs in or alongside Emergency Departments.(3) As a GP Academic Fellow, I led the drafting of the outline bid application with Professor Adrian Edwards, Chief Investigator, and 17 fellow co-applicants and then subsequently the full bid application. The planned study framework is illustrated in Figure i. It illustrates that this is a complex mixed methods study involving three phases over three years, each with multiple work packages.

Figure i: GPs in EDs study flow chart protocol(3)

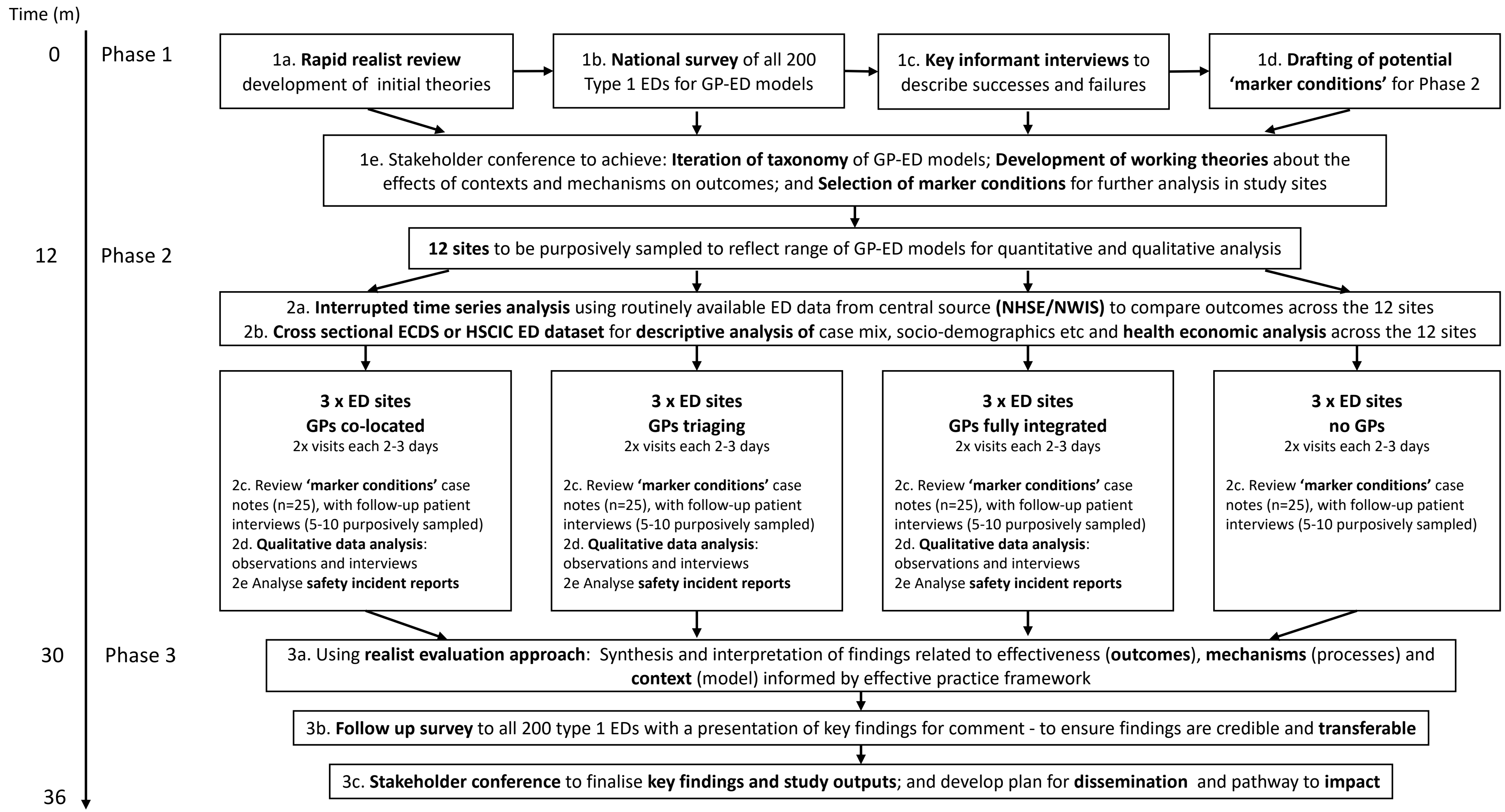


Table i: My work for the GPs in EDs project and this thesis

Phase	Work packages	My work
1	1a Rapid realist review	I led this work (see method in Chapter 2.3.1 and results in Chapter 3, publications in Appendix 1)(4,5)
	1b National Survey	This work was led by Dr Rebecca Sherlock. Case study sites were selected from survey respondents.
	1c Key informant follow-up interviews	This work was led by Dr Michelle Edwards. I interviewed 4 of the 21 clinical directors. All participants were asked about patient safety and I was able to analyse these data (see Chapter 6).
	1d Outlining of draft ‘marker conditions’	I supervised a medical student conducting a literature review of ambulatory care sensitive conditions. This work does not contribute towards this thesis.
	1e Stakeholder conference	I presented early findings and led a session which contributed towards study ‘marker condition selection’ and iteration of the GP-ED model taxonomy. (Publication in Appendix 1)(6)
2	2a Interrupted time series analysis	This work was led by the Swansea team, was not available at the time of write up and does not contribute towards this thesis.
	2b Health economic analysis	This work was led by the Swansea team, was not available at the time of write up and does not contribute towards this thesis.
	2c Case site visits for qualitative data collection	I personally visited all case study sites with a GP model and one control site (n=11/13) for qualitative data collection (see Chapter 5). Note the change in terminology for GP model from the original flow chart (Figure i) as described in Chapter 1.
3	3a Mixed methods data analysis	I analysed the qualitative data regarding GP role, safety and teamwork (see Chapter 6). I will be involved in triangulation of the data when the quantitative data becomes available, but this work will not contribute towards this thesis
	3b Follow up survey	This step was withdrawn, and another stakeholder event held in its place.
	3c Stakeholder conference	I presented qualitative findings about GP role and led a patient safety workshop (see Chapter 7). There is final stakeholder event also planned.

Table i details my work for the project, and which has contributed towards this thesis. Professor Jonathan Benger and the University of the West of England (UWE) GPED team were also commissioned by NIHR to conduct research in this area,(7). Both teams contributed towards the updated taxonomy publication.(6) The work described in Chapter 4 was additional to the original study protocol. I also supervised a BSc medical student analysing diagnostic errors in emergency departments, during this time (publication in Appendix 1).(8)

1 Introduction

I begin this thesis outlining the challenges faced by urgent and emergency care services. I describe the rationale for and the evidence base behind GP services in or alongside emergency departments and how different service models are characterised. I then outline what the concept of patient safety is, with key definitions, and the burden of patient harm. I describe concepts from the science of human factors, with the opportunity to learn from patient safety incidents and the theoretical basis for a systems approach to reduce the risk of patient harm. I then describe the approach in healthcare and why this is relevant to urgent and emergency care settings: policy approaches, research methods, and learning from the challenges of implementing quality improvement interventions. I conclude this chapter with my aim and objectives for this thesis.

1.1 Urgent and emergency healthcare services

The United Kingdom (UK) has a National Health Service (NHS) funded through taxation.(9) Urgent and emergency healthcare services are varied and often described using interchangeable terminology, with differences in care systems in the devolved nations. There are four different types of emergency departments: Type 1, 24-hour consultant-led units with full resuscitation facilities; Type 2: consultant-led mono-speciality services e.g. ophthalmology, dental; Type 3: nurse or doctor-led services without appointments, to treat minor injury or illness for example urgent care centres (UCC), urgent treatment centres (UTC) or minor injury units (MIU)); and Type 4: NHS walk-in centres (WIC).(10)

In primary care, general practice is led by general practitioners (GPs), community-based doctors with generalist training, supported by nurses, nurse practitioners and other allied health professionals usually through appointment-based services. GP-led out of hours services (OOH) are usually appointment-based systems, separate to emergency departments, receiving patients that self-refer or following consultation with an online or telephone service (e.g. NHS 111)(11)

As well as different set-ups, these services manage different patient demographics, in different geographic areas, with different healthcare professionals from different training backgrounds, reflecting the complexity of these services.

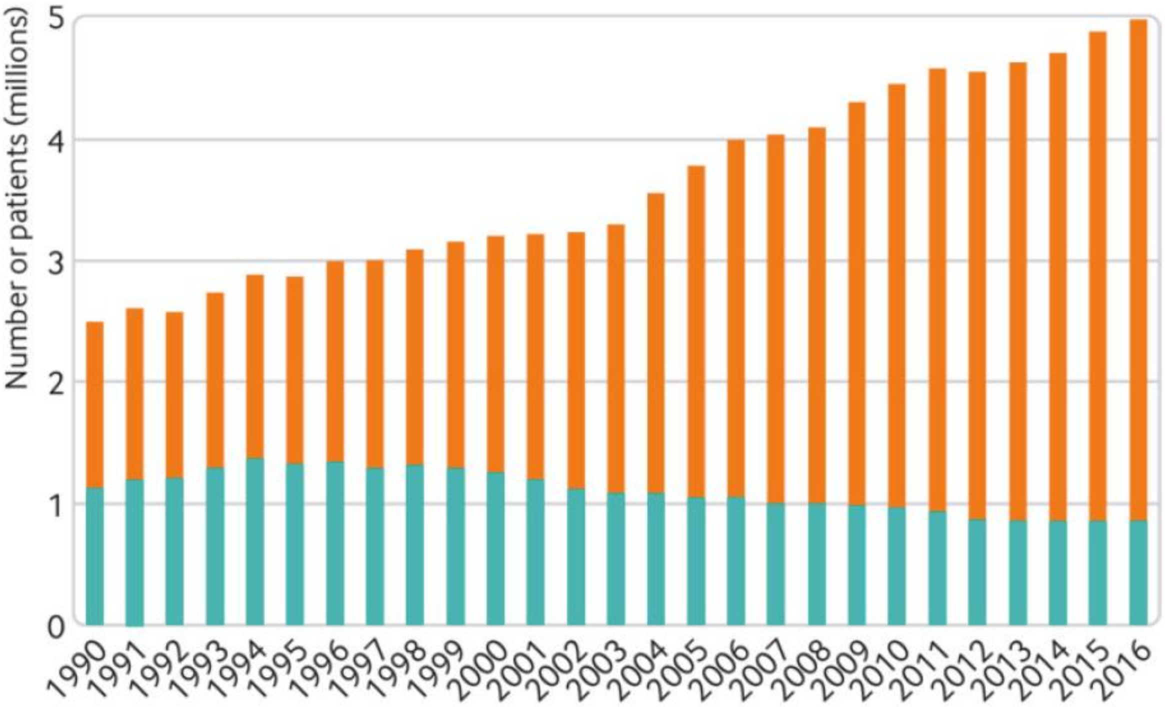
1.1.1 The challenges

Urgent and emergency healthcare services are struggling to cope due to increasing pressures within the system, with the NHS England national four-hour emergency department standard not being met for the last six years.(12) These pressures are multifactorial and include: increasing attendances; increasing demand on 999 services; an ageing population presenting with complex multimorbidity; and increasing hospital admissions.(4,12–16)

The UK population is growing (there were 63 million people in 2011 and 66 million in 2017),(17) however, emergency department attendances have risen faster than population growth, with an 8.8% increase from 2011-2016 (the equivalent of an extra 5100 attendances per day).(12) This increase in demand may partially be due to a cultural shift with increased patient expectation of 24-hour care in a consumerist society, as well as an ageing population.(17,18)

In 1997, one in six people (15.9%) were 65 years and older, this increased to one in five people (18.2%) in 2017, and is expected to increase to one in four people (24%), by 2037.(17) Co-existing chronic medical conditions (multimorbidity) and an associated increase in prescribed medications (polypharmacy) are associated with

Figure 1-1: UK NHS Hospital Episode Statistics (NHS Digital) showing hospital admissions from emergency departments (orange) and general practice (blue) (Reproduced with permission from The BMJ Cooper et al. 2020;368:m462)(11)



older age. These factors not only increase emergency department presentations and admissions but also complicate management for older adults, with potential risk of adverse reactions due to drug interactions or reduced physiological reserve. There are also diagnostic and management challenges for clinicians that may have undergone single system specialist training.(19–21)

Hospital admissions have increased at an even greater rate than attendances since 2011/12, see Figure 1-1.(4) With reduced hospital capacity to cope with this increasing demand, more patients wait in emergency departments on trolleys for over 12 hours following the decision to admit (123 patients in 2011/12; 3502 patients in 2016/17), placing additional pressure on emergency departments.(12) This is despite more investigations and diagnoses managed in the emergency department reflecting an increase in the complexity and acuity of presenting patients.(16)

Evidence is urgently needed to understand how best to manage this increasing volume and complexity of demand whilst safely achieving acceptable standards of care.(22)

1.1.2 The rationale for providing GP services in or alongside emergency departments

10-43% of patients presenting to emergency departments can be managed in primary care, according to observational studies.(23–27) Seminal UK studies by Dale et al. and Ward et al., also propose that GPs, as generalists and used to dealing with multimorbidity, may have a different management approach to ‘diagnostic driven’ emergency clinicians. They suggest that GPs are also less reliant on acute diagnostics and manage patients more quickly, which may improve flow in the department and reduce the number of hospital admissions.(23,28)

These factors have led to the development of new, more integrated, healthcare models including the *streaming* of patients presenting to emergency departments with non-urgent problems to onsite primary care services.(29) See Box 1 for definitions. Strategies like this seek to improve overall patient care and safety by reducing crowding in the emergency department and improving patient flow. Consequently in 2017, a £100 million capital bid investment (US$130million) was made by NHS England for all emergency departments to have a ‘co-located’ primary care facility, so they are, “free to care for the sickest patients”.(30,31)

Box 1: Key definitions(6)

Triage: a clinical activity to sort patients by acuity so that those with the greatest need are seen first Streaming: an operational activity to sort low acuity patients by clinician availability and suitability Redirection: patients are sent to a care provider at another geographical site

1.1.3 The evidence

However, the evidence base for this initiative is weak, (5,32–34) with healthcare policy and practice moving ahead of evidence of costs, effects and safety, not uncommon for healthcare services.(4)

Previous research studies have heterogeneous designs and there are few large-scale evaluations. Pooling of learning between emergency departments is hampered by different service models (including urgent care centres, walk-in centres or more integrated services) described in different contexts, using ambiguous terminology. For example, ‘co-located’ primary care services may treat patients in a separate unit to the emergency department without access to acute diagnostics, thus similar to normal general practice settings. Alternatively, for the same label, general practitioners may work within the emergency department, largely integrated with emergency service provision, with responsibilities beyond usual primary care. GPs have also been described screening patients at the front door of emergency departments, to *redirect* patients with primary care type problems to an alternative service off site (including pharmacists, opticians, or back to their own general practitioner).(35)

Four recent reviews are described in Table 1-1. A Cochrane review in 2018 included three single-site non-randomised studies, all conducted before 1999, with GPs seeing non-urgent patients (identified by different methods) in emergency departments, and one Australian randomised trial assessing the effectiveness of an emergency nurse practitioner service model. Results were inconsistent and assessed to be very low certainty evidence for effectiveness outcomes, with no data available on mortality or safety events.(32)

Table 1-1:Summary of evidence for effectiveness and safety of primary care services co-located with emergency departments

(Reproduced with permission from The BMJ Cooper et al. 2020;368:m462)(11)

Review	Published	Included studies	Intervention	Quality of evidence	Evidence of effectiveness	Evidence of safety
Goncalves et al. (32) (Updated Khangura 2012) Cochrane review(36)	2018	1 Non-randomised UK study (4641 patients) 2 Non-randomised Irish studies (1878 + 4684 patients)	GPs providing care for non-urgent patients in the ED	Very-low certainty evidence. High heterogeneity across studies precluded pooling data.	Uncertain if GPs reduce time to clinical assessment and ED length of stay, admission to hospital or referral to hospital-based specialists, use of diagnostic tests or costs.	No data were reported on adverse events (such as ED returns and mortality).
		1 Randomised Australian trial (258 patients)	Standard ED medical care vs emergency NP care			
NICE assessment(33)	2017	2 Non-randomised UK studies (4641 + 1996 patients)	GPs providing care for non-urgent patients in the ED	Very low quality due to risk of bias	GPs may provide benefit in reduced number of diagnostic investigations, with no effect on patient satisfaction. No relevant economic evaluations identified.	No evidence found for mortality, quality of life, time to admission/ discharge, avoidable adverse events, readmission.
Ramlakhan et al. (34) Narrative review	2016	20 primary studies from The Netherlands (n=8), England (n=4), others were from Australia, Ireland, Spain, Sweden and Switzerland.	Primary care professionals managing non-urgent ED patients	All evidence included to search for explanations loosely based on a realist approach. No formal individual study quality assessment	A paradoxical increase in attendances described, likely to be attributable to provider-induced demand. The evidence for improved throughput is poor. Marginal savings may be realised per patient, but this is likely to be overshadowed by the overall cost of introducing a new service.	No increase in patient reattendance described in two studies.
Cooper et al. (5) Rapid Realist Review	2019	96 articles, largely primary research studies, most from the UK (n=44), Netherlands (n=17), others were from Ireland, Belgium, Switzerland, Sweden, Italy, Finland, Australia, USA, Canada, Singapore and New Zealand.	Mostly GPs seeing non-urgent patients in the emergency department	Extracts included that offered explanatory power why and how the services worked. No formal individual study quality assessment.	The effectiveness of emergency department streaming to primary care services may be influenced by how staff interpret the streaming system and the roles GPs adopt. Little evidence that GPs directly or indirectly affected the care and throughput of the sickest patients.	Minimal data on the safety implications of GPs working in EDs. 5 studies showed no increase in reattendance rates and a Dutch study showed no increase in mortality rates.

Key: NICE, UK National Institute for Health & Clinical Excellence; GP, General Practitioner; NP, Nurse Practitioner; ED, Emergency Department

The UK National Institute for Health & Clinical Excellence (NICE) also assessed the available evidence for primary care services co-located with emergency departments and included two non-randomised UK studies conducted before 1996. Use of diagnostic tests and patient satisfaction were used as outcome measures which do not wholly address evidence for the effectiveness of the service. No evidence was found for safety indicators and no economic evaluations were identified. Given the limited clinical and cost-effectiveness evidence and concerns about the feasibility of staffing the workforce to support this initiative, NICE chose not to make a recommendation for general practitioners to work within or on the same site as emergency departments.(33)

Additionally, Ramlakhan et al undertook a narrative review of 20 studies in 2016 to search for explanations of why models worked or not. A paradoxical increase in attendances was described when primary care services were located at emergency departments, thought to be due to “provider-induced demand”. There was also poor evidence for emergency department throughput and minimal economic impact.(34)

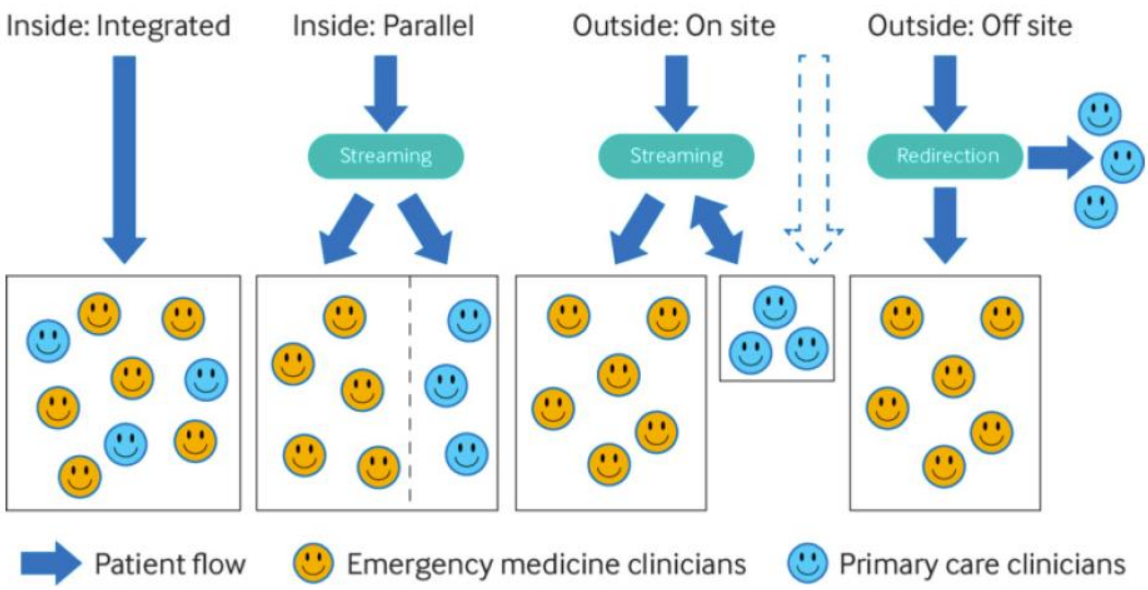
A rapid realist review was conducted by Cooper et al. in 2109 (myself as lead author, publication in Appendix 1) and found little evidence that general practitioner services in emergency departments influenced the care and throughput of the sickest patients, with other factors, including delayed patient transfers to wards and inadequate staffing, also contributing. Factors such as how staff interpret the streaming system and the roles adopted by general practitioners (whether they function in a traditional GP role or adopt an emergency medicine approach) could influence effectiveness of service models.(5)

The wide estimate (10-43%) for the proportion of patients with primary care type problems presenting to emergency departments highlights the difficulty in defining and identifying this target patient group, which may vary depending on local patient demographics and geographical location.(23–27) Various primary healthcare professionals, as well as GPs, work in these models, including nurses and advanced care practitioners. Specific training requirements, professional qualifications or governance arrangements to guide best practice are unclear.(37) The pre-test probability of serious disease in patients who present to emergency departments rather than primary care and need for acute investigation to exclude serious disease is not known. In this complex system, there is a lack of evidence for potential patient safety outcomes and how these can be mitigated to deliver safe patient care.

1.1.4 Updated taxonomy for primary care services in or alongside emergency departments

Phase one of the GPs in EDs study included a national survey, with follow-up key informant telephone interviews, (led by Drs Michelle Edwards and Rebecca Sherlock). This showed that the language used to describe the different primary care services associated with emergecny departments was inconsistent - with considerable ambiguity around the term ‘co-located’. Also, GPs rarely performed solely a screening role at the emergency department front door. The Cardiff team collaborated with the University of the West of England (UWE) team (led by Prof. Jonathan Benger, also conducting a NIHR funded study evaluating the effects of GPs working in or alongside emergency department) to propose an updated taxonomy that also incorporated the broader range of staff involved in primary care provision along with GPs (myself as lead author, publication in Appendix 1).(6) Both studies then used the same taxonomy.

Figure 1-2: The form of primary care services in or alongside emergency departments (Reproduced with permission from The BMJ Cooper et al. 2020;368:m462(11), adapted from Cooper et al (2019) Emerg Med J 2019;36:625-30(35))

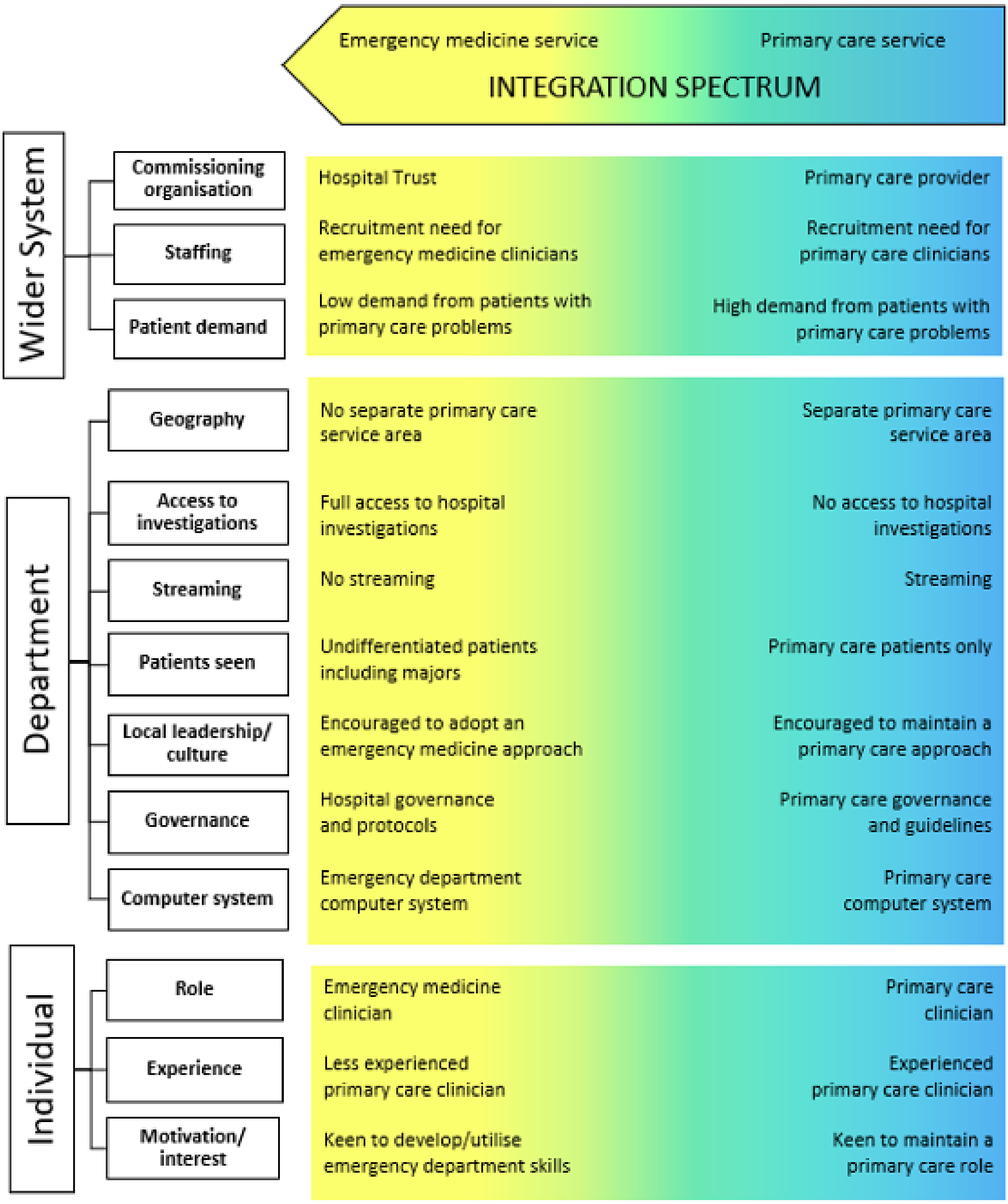


Location of the service, INSIDE or OUTSIDE the emergency department, was proposed as a useful classification for the form these services took - reflecting the patient's journey and experience, and often aligning with staff contractual arrangements, governance responsibility and accountability. The INSIDE models varied from those in which primary care clinicians are *integrated* with emergency medicine staff or in which they work in a separate *parallel* primary care service. An alternative primary care service OUTSIDE the emergency department could be on the same hospital site—which was termed *on site*—or elsewhere, which was termed *off site,* see Figure 1-2.

Constructs that influence how these services *function* were grouped at the wider system level, the department level and the individual clinician level. An integration spectrum was then developed to describe the function of services from being closer to an emergency medicine service or to usual primary care, see Figure 1-3.(6)

Figure 1-3: Conceptual model identifying constructs that influence the function of primary care services in or alongside emergency departments

(Reproduced from Cooper et al (2019) Emerg Med J 2019;36:625-30 CC BY licence)(6)



The updated taxonomy includes other healthcare practitioners that work within the primary care service. The original protocol for this thesis however focussed specifically on GPs and that focus has been maintained. The GPs in EDs study characterised the purposive sample of case study sites for in-depth qualitative analysis (selection method described in Chapter 2) using this taxonomy and included:

- 3 inside integrated models
- 4 inside parallel models (one was reclassified following the visit)
- 3 outside on site models
- 3 control sites (no GPs)

Off site models were not included because they were beyond the scope of the study.

1.2 Patient safety

In this section, I first discuss the concept of patient safety with key definitions. I describe how patient safety has been studied to date and the frequency and burden of patient harm in different healthcare settings, notably the risk of diagnostic error both in emergency departments and in primary care. I discuss human error, a systems approach and how understanding context can facilitate the effectiveness of patient safety interventions.

1.2.1 The concept and definitions

The landmark report by the Institute of Medicine in 1999, “To Err is Human”, introduced the concept of patient safety as a major threat to public health and a need for action. It highlighted that, at the time of writing, an estimated 98,000 people in the USA died each year from medical errors (patient safety incidents) in hospitals; more than from motor vehicle accidents, breast cancer or AIDS, causes that receive far more public attention. It proposed a movement to study and research the area, shifting focus from blaming individuals for past errors to focusing on designing safety into the system, taking learning from other high risk industries to prevent future harm.(38)

These aspirations were reflected in the Department of Health for England report at the same time, “An organisation with a memory”, quoting figures that 400 people a year died or were seriously injured from medical accidents in the NHS and 10,000 experienced serious adverse reactions to drugs.(39) Patient harm is now estimated to be the 14th leading cause of the global disease burden, comparable to diseases such as tuberculosis and malaria,(40) with 15% of hospital expenditure and activity in OECD (Organisation for Economic Co-operation and Development countries) attributed to treating safety failures.(40) Lower income countries have similar rates of patient safety incidents but an associated increased severity of outcome which contributes to the higher burden of mortality and morbidity. (40)

Twenty years on from 'An organisation with a memory', the NHS England/Improvement Patient Safety Strategy highlights that there is still much to do.(41) With improved understanding of safety and involving patients and staff to design and support programmes to improve care delivery, it predicts that 1000 extra lives and £100 million in care costs could be saved from 2023/24.(41)

1.2.1.1 Definitions

Definitions of safety, error and risk vary depending on the type of problem and the staff and patients involved. At the time of publication of "An organisation with a memory", there was no standardised definition of 'adverse event'.(39) Early patient safety researchers defined an adverse event as an injury that was caused by medical management rather than the underlying disease.(42) This concept is reflected in the later adopted World Health Organization definition of patient safety, "the prevention of errors and adverse effects to patients associated with healthcare."(21) This is the definition I will use for the purpose of this thesis but I acknowledge that defining safety by measuring the absence of negatives (Safety-I) is open to challenge and measuring safe working in expected and unexpected conditions (Safety-II) is an alternative approach gaining momentum.(43) Also, it may not be possible to prevent all adverse events, an acceptable minimum with given resources and the risk of no treatment may be more appropriate.(44)

Table 1-2: Definitions of key patient safety concepts(44)

Healthcare-associated harm	Harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury
Patient safety incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to a patient.
Incident type	A descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features
Contributing Factor	A circumstance, action or influence which is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.
Mitigating factor	An action or circumstance which prevents or moderates the progression of an incident towards harming a patient
Hazard	A circumstance, agent or action with potential to cause harm
Error	Failure to carry out a planned action as intended (error of omission) or application of an incorrect plan (error of commission)
Risk	The probability that an incident will occur
Violation	Deliberate deviation from an operating procedure, standard or rule
Patient outcome	The impact upon a patient which is wholly or partially attributable to an incident
Near miss	An incident which did not reach the patient
No harm incident	An incident which reached a patient, but no discernible harm resulted
Harmful incident (adverse event)	An incident which resulted in harm to a patient
Degree of harm	The severity and duration of harm, and any treatment implications, that result from an incident None: no patient harm Mild: mild symptoms, minimal intervention Moderate: permanent or long-term harm, requiring intervention Severe: major permanent long-term harm, lifesaving intervention Death: death was caused by or brought forward by the incident

1.2.2 How has patient safety been studied to date?

Understanding the frequency and burden of patient harm is limited by the data sources as well as the research methods used to study it, see Table 1-3. Case note reviews are useful to quantify the scale of the problem and for highlighting at-risk groups and priority areas. However, they are only able to report detected harm from documents such as the medical record. The process is reliant upon the expertise and capabilities of the reviewer as well as the honesty of the reporter and may therefore miss adverse events and near misses that may have been reported by patients or other sources.(45)

Analysis of patient safety incident reports is an alternative research approach that offers a different lens on the problem. Written through the eyes of the healthcare professional, contributing factors can be described which may have learning relevant to other healthcare settings. However this process again also relies on the honesty of the reporter. Studies of patient safety incident reports have been used to explore systemic causes of safety-related hospital deaths,(46) and to identify priority areas for practice improvement, such as in care for children.(47,48) However, often systems are not in place to investigate and learn from these incidents, many reports do not detail enough useful information to determine the cause, or the tool is used to blame other healthcare professionals rather than for what it was intended.(49,50)

Table 1-3: UK National level data sources used to study patient safety, with examples

Data source	Strengths and limitations	UK Examples	Reference
Case note reviews	Measurable outcomes quantifying the scale of the problem and highlighting at-risk groups. Limited by what is written in the medical record.	Two acute London hospitals including 1014 records from four specialities: acute medicine (including geriatrics); general surgery; orthopaedics; and obstetrics. An adverse event rate was reported at 10.8%, about half of the events were thought to be preventable and older adults were more at risk.	(51)
National patient safety incident reporting systems (NRLS)	Analysis can describe causation and highlight contributory factors that can be targeted for interventions. Subject to underreporting, sampling and reporter biases.	2,010 incidents involving patients aged 16 y and over in acute UK hospital settings. The most common incident types were failure to act on or recognise deterioration (23%), inpatient falls (10%), healthcare-associated infections (10%), unexpected per-operative death (6%), and poor or inadequate handover (5%).	(46)
Medical negligence claims	In-depth root cause analysis that may highlight contributory factors. Reports may bias with blame and sample may represent rare events with poor outcomes which are not generalisable.	A systematic review of 34 included studies regarding malpractice claims in primary care. Studies were from: USA(15), UK(9), Australia(7), Canada(2), France(1). Diagnostic error (26-63%) was the commonest misadventure followed by medication errors (5-20%).	(52)
External inquiry	Root cause analysis of high-profile cases. May be rare events.	External enquiry into the intrathecal rather than intravenous administration of vincristine identified over 40 weaknesses in the hospital system that led to the patient death.	(53)
Public inquiry	Highlights patient safety as a public issue with findings that may be generalisable.	Mid Staffordshire NHS Foundation Trust. Findings - an organisation that lacked insight and awareness of the reality of the care being provided to patients. Concluded a fundamental culture change was needed - 290 recommendations.	(54)
National databases to identify poor outcomes in specific healthcare fields	Monitors standard high-level outcomes e.g. maternal death/suicide that can prompt investigation if necessary.	The UK Confidential Enquiry into Maternal Deaths is the longest running system for maternal death review and the methodology is regarded as the global standard. The latest report categorises causes of death and highlights inequalities in maternal mortality due to age, ethnic group and living in deprived areas.	(55)
Medicines and Healthcare products Regulatory Agency	National level regulation of the safety of medicines and medicinal products. Relies on voluntary reporting.	Regulates medicines and medical devices through a voluntary reporting system (yellow card). Of note in the 2019 report, "We have also worked on re-designing the legislative frameworks for medicines, medical devices and clinical trials, to ensure the regulatory regimes are operational in the event of a no deal Brexit."	(56)
Patient stories / complaints	Patients have unique insight into the healthcare system and can give valuable information about how systems work and patient safety risks.	'Just a routine operation' highlighted from the patient story human factor errors (situation awareness, communication, teamwork, decision-making) that led to Elaine Bromiley's tragic death	(57)

Analysis of medical negligence claims is another data source for in-depth root cause analysis, but reports may bias with blame and the sample may represent rare events with poor outcomes which are not generalisable. External and public inquiries highlight patient safety as a public issue with findings that may be generalisable.

National level indicators can monitor specific health outcomes such as maternal deaths and suicide rates and if necessary, prompt confidential enquiry. The UK Confidential Enquiry into Maternal Deaths is the longest running system for maternal death review and the methodology is considered by the World Health Organization as the global standard.(58) The UK also has a national system for reporting and acting on adverse drug reactions and problems with medicinal products that it can act on and feedback to medical staff and will take the lead with medicinal regulatory processes as the UK leaves the European Union.

Patients may have different insights and can give valuable information about how healthcare systems work and patient safety risks. As Don Berwick reported following the Mid Staff Inquiry, “Place the quality and safety of patient care, above all other aims for the NHS. Engage, empower, and hear patients and carers throughout the entire system, and at all times.”(59)

1.2.3 The frequency and burden of patient harm in different healthcare settings

The nature and frequency of reported patient safety incidents, judged in hindsight to be preventable, vary in different healthcare settings. A recent systematic review and meta-analysis, of mainly hospital-based case note review studies (n=53/70, 73%), reported a pooled prevalence for preventable patient harm across different medical settings at 6% (95%CI 5-7%).(60) This varied from 2% (95%CI 2-4, 4 included studies) in obstetrics to 18% (95%CI 12-26, 6 included studies) in intensive care. The prevalence for preventable patient harm in hospitals was 5% (95%CI 4-6, 45 included studies), emergency departments 3% (95%CI 2-4, 6 included studies), and primary care 3% (95%CI 0-9, 3 included studies). Evidence gaps for primary care and limited studies for vulnerable groups such as children and older adults were highlighted.(60) The drivers for patient safety incidents including lack of communication, lack of skillset or knowledge, organisational culture or misaligned incentives are similar across different healthcare settings but depending on the context, result in different patient safety incidents.(60)

1.2.3.1 Patient safety incidents in hospitals and emergency departments

Patient harm occurring in acute hospital settings is well studied and commonly quoted as occurring in every 1 in 10 patients.(61) This figure is based on a series of case note review studies following the original US Harvard Medical Practice study of 30,000 randomly selected records in 51 randomly selected acute hospitals in New York in 1984.(42) Different data sources have been used to study patient harm in the UK hospital settings, with varying findings due to the research methods used, as shown in Table 1-3. Patient harm in hospitals is reported to be due to a small number of incidents: healthcare-associated infections, venous thromboembolism, medication error, pressure ulcers and surgical errors. The rate is higher in surgical and intensive care settings with older adults more at risk.(40) Incidents that should never happen, ‘never events’, include: wrong site surgery, wrong route administration of medication and incompatible blood transfusion.(62)

Emergency departments are high risk settings for patient safety incidents but these are more frequently due to diagnostic error or mis-management of conditions and often result in significant patient harm.(63–66) Diagnostic error also occurs more frequently in patients discharged from emergency departments than those who are admitted.(63) If GPs working in or alongside emergency departments are expected to discharge more patients than emergency medicine clinicians and utilise less acute investigations, then are they at more risk of diagnostic error?

1.2.3.2 Patient safety incidents in primary care

Until recently, there has not been the focus or urgency on patient safety research in primary care as there has been in hospital-based healthcare. There has been an assumption that due to the lower risk nature of patient encounters, harm will be less significant.(67) Estimates from a worldwide literature review (which noted high heterogeneity between the 100 primary studies and nine systematic reviews, and a lack of a standardised taxonomy to classify primary care incidents) suggest that patient safety incidents are a relatively frequent occurrence in primary care but most do not result in significant harm to patients (median of around 2–3 incidents per 100 consultations/patient records reviewed, with about 4% of these incidents associated with severe harm).(68) In primary care the patient safety incidents most likely to result in severe patient harm are medication and diagnostic errors.(52,60,68)

Marked diversity has been noted in the reported frequency and nature of errors,(69) suggesting multiple different methods are needed to learn about patient safety in primary care.(70) De Wet and Bowie used the *trigger review* method to establish previously undetected harm to identify unsafe care in primary care.(71) A proposed list of ‘never events’ for this setting includes not sending a suspected cancer referral, and prescribing a teratogenic drug to a pregnant patient.(72,73) However, issues have been raised with combining ‘preventable harm’ and zero tolerance ‘never events’ if there is a lack of evidence that such harm is totally preventable in the complex primary care setting and that managing risk into harm ‘as low as reasonable practicable’ may be more appropriate.(74)

Carson-Stevens et al. developed a primary care-specific classification system taxonomy with which to analyse 13,699 primary care patient safety reports from the NHS National Reporting and Learning System (NRLS).(75) Although infrequent, the incidents that led to most severe patient harm were diagnosis and assessment errors.(76) This classification system was then used to classify incident types in a retrospective case-note review study in 16 English GP practices using triggers such as a hospital admission or new diagnosis to identify avoidable patient harm.(2) The rate of significant harm considered at least ‘probably avoidable’ was between 35.6 (95%CI: 23.3-48.0) and 57.9 (95% CI: 42.2-73.7) per 100,000 patient-years. Diagnostic error accounted for 45 out of 74 (60.8%) primary incidents, followed by medication-related problems (n=19; 25.7%) and delayed referrals (n=8; 10.8%).(77) The study identified a mix of organisational, clinician and patient contributory factors associated with the avoidable incidents. The majority of these were patient factors (71.9% of the total contributory factors identified) including multimorbidity, old age and complexity arising from pathophysiological factors such as frailty.

Diagnostic error is a recognised patient safety incident that can lead to severe patient harm in both emergency departments and primary care settings. How and why these incidents occur and what interventions can be used for patients that present with undifferentiated symptoms to mitigate this risk, is poorly understood.

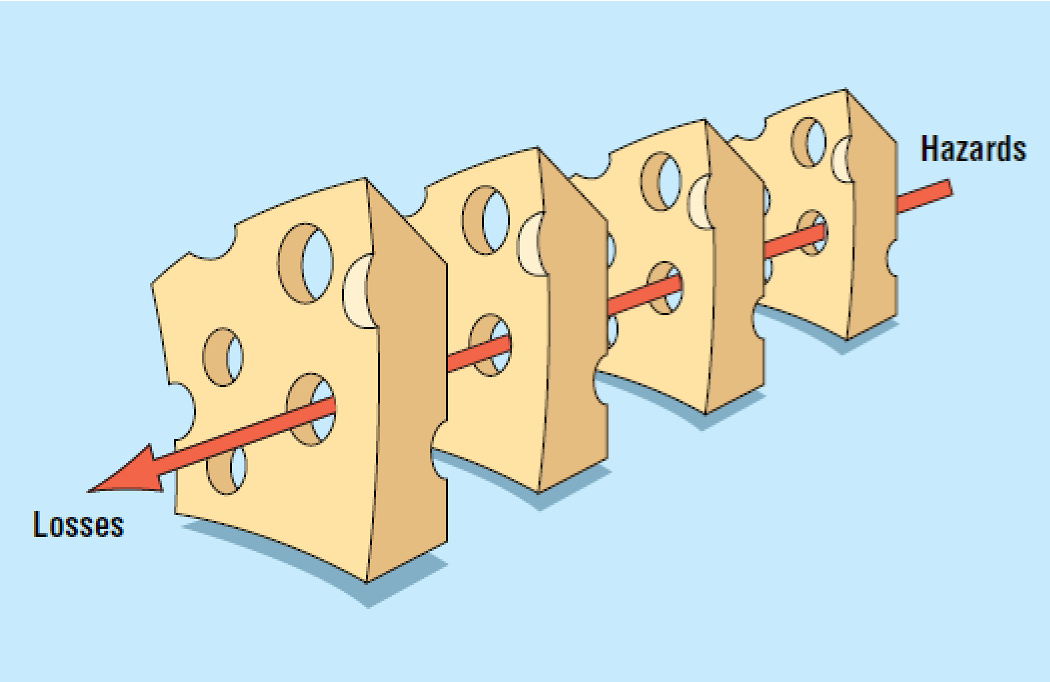
1.2.4 Human error

The concept of 'unsafe acts by humans', or 'human error', contributing to accidents was first highlighted in 1931 in Heinrich's industrial accident prevention work. He worked for an insurance company and studied over 75,000 accident reports. From this analysis, he suggested that that for every one major injury, there are 29 minor injuries and 300 near misses. The majority (88%) was due to human error.(78) He concluded that industries should focus on reducing the number of minor accidents to see a corresponding fall in the number of major accidents. However, his work has since been criticised: the data were not available for analysis by other researchers; the statistics were all reported by supervisors so may not have represented the true denominator; he worked for an insurance company so finding 'human error' as a cause may have been financially beneficial; and safety experts are now more appreciative of complex systems and that reducing high numbers of certain types of minor accidents may not reduce other major ones as causation may not be linear or function in a specific order.(79)

The understanding of human behaviour and why humans make errors, was expanded through Reason's research of cognitive processes. He described how human fallibility can be moderated but never eliminated. He described the difference between execution failures (slips, lapses, trips and fumbles) and planning or problem solving failures (rule-based or knowledge-based mistakes).(80) His swiss cheese model, see Figure 1-4, is well cited for highlighting how these unsafe acts by humans (active failures) are enabled by contributing conditions in the system (latent errors). He suggested the need to consider a systems approach, concentrating on the conditions and organisation under which individuals work to try to build defences in depth to avert errors or mitigate risks, rather than blaming the person.(80)

Figure 1-4: Swiss cheese model of how defences, barriers and safeguards may be penetrated by an accident trajectory

(Reproduced with permission from The BMJ Reason 2000;320(7237):768-70)(80)



Kahneman's work on cognitive function helps explain further why human errors may occur.(81) He described two distinct decision-making processes. 'System I' is fast, effortless, intuitive and automatic while 'System II' is slow, laborious and logical.(81) Croskerry applied this thinking to clinical medicine: if the initial presentation of illness is recognised by the clinician then System I processes engage but if it is not, then the slower analytical System II processes engage.(82,83) System I is considered typical of the diagnostic decision-making process of experienced clinicians who rely on pattern recognition. However, this process risks errors due to cognitive biases, for example by missing atypical presentations (the 'representativeness heuristic'), less common variants ('availability heuristic') or locking on to a diagnosis ('anchoring heuristic').(81–83)

'Human factor' was traditionally used as a term to frame the person as the source of trouble – the human error responsible for the accident or injury and a point to stop the investigation. Nowadays however, the term is used in different ways. It can be used to describe 'factors of humans' – abilities, limitations and other characteristics (including cognitive and physical) that need to be understood for effective design and management, as well as other internal and external 'factors' that affect human performance. 'Human factors' (ergonomics) is now used to describe the scientific discipline, including psychology and engineering, concerned with understanding the interactions among humans and other elements of a system to optimise human well-being and overall system performance.(84,85) In this view, 'human error' described by Dekker, is therefore a symptom of trouble deeper in the system and a point to start the investigation, not to end it – an opportunity to find out why the individual's actions made sense at the time and the circumstances that surrounded them.(86)

1.2.5 A systems approach

A system can be defined as a set of interdependent components (human and non-human) interacting to achieve a common aim.(38) The principles of scientific management to improve efficiency of systems originated in the early 20th century with Taylor, an American mechanical engineer, who suggested methods to improve the productivity of the manual workers in his steelworks.(87) Rather than encouraging the men to simply work harder, he proposed that by simplifying and optimising jobs, productivity would increase. He used scientific methods to study and measure work – using a stopwatch to record the time taken to accomplish a specific task and redesigning equipment accordingly. He introduced specialisation by matching workers to their jobs based on capability and motivation and trained them to work at maximum efficiency.

The Gilbreths replaced Taylor's stopwatch with a movie camera to analyse work processes and improve efficiency. Their human factor work in operating theatres, analysing surgeon movements to see if their work could be more efficient and less fatiguing, led to standardising processes in operating rooms. The process of surgical instruments being laid out in regular and consistent patterns, to reduce time looking for the tools and therefore operation times, is still used today.(88)

In the 1930's Shewhart, through statistics, introduced quality to the industrial manufacturing processes system. He worked at Western Electric Company in the United States with the aim of improving the quality of telephone hardware. He displayed outcomes as data on a special type of line graph called a control chart which could distinguish between what is now known as common-cause variation (random, natural, expected) and special-cause variation (attributable, unexpected, unusual), with the focus on reducing special-cause variation to maintain quality. He, with Deming, combined continuous learning and improvement with statistical analysis. The tests to improve processes were operationalised through a structured approach known as the plan-do-check-act cycle (PDCA) or plan-do-study-act (PDSA).(89) These quality improvement ideas were adopted by the Associates for Process Improvement and through the Institute for Healthcare Improvement have been introduced to the healthcare community.(90,91)

The concept of 'high reliability organisations' (HROs) was first introduced by the University of California Berkeley through studying safety in three high risk organisations: US naval aircraft carrier operations, air traffic control and nuclear power.(92) Weick and Sutcliffe took this work further, suggesting that reliable performance was maintained in HROs by embracing complexity and functioning as a learning organisation with ‘collective mindfulness’.(93) They described reliability as an invisible *dynamic non-event*: firstly because people do not know how many mistakes they could have made but did not, so only have a crude idea of how reliable they are; and secondly, since reliable outcomes are constant, there is nothing to which to pay attention.(94)

“Every system is perfectly designed to achieve the results it gets,”

Prof. Paul Batalden Institute of Healthcare Improvement

Batalden’s quote, co-founder of the Institute of Healthcare Improvement, highlights his thinking on system wide improvement strategies to improve healthcare services. He reflects on the complexity of healthcare and how it differs from manufacturing and ‘making a product’ since the core work comprises interactions and relationships between patients and professionals.(95) However, this view could be challenged because many healthcare systems have evolved rather being specifically designed.

Vincent and Amalberti reflect on the complexity of healthcare settings and describe how some can adopt an ‘ultra-safe’ approach with standardised interventions and automated processes to create high levels of safety, excluding the risk of human error, for example radiotherapy, blood transfusions. Others however, need to be ‘ultra-adaptive’, relying on professional expertise and experience to maintain safe outcomes because risk is inherent, for example, the treatment of rare cancers and trauma centres. They describe highly reliability systems as sitting midway. Here risk is inherent to the organisation but systems are in place to manage this risk.(96)

They describe how training and safety priorities differ for each of these models. In ultra-safe systems, risk of human error is excluded as much as possible by giving power to regulators and supervision of the system to avoid exposing the coal face workers to unnecessary risk. Prevention strategies are the priority with training in teams to apply procedures for routine and emergency tasks. Ultra-adaptive systems however embrace risk, it is the essence of the profession. Power is given to the experts who rely on personal resilience and expertise. Adaption and recovery strategies are the priority with training focused on the individual. High reliable systems accept and manage risk by giving power to the group to organise itself with training in teams to prepare and rehearse flexible routines for the management of hazards.(97)

However, this may be too simplistic. Healthcare services are complex adaptive socio-technical systems - they consist of large numbers of interacting dynamic human, technological and environmental components that are constantly reacting, learning and adapting to each other to influence behaviour and the system as a whole.(98) In these systems interactions are non-linear and small changes, often in response to local knowledge, can have large effects. Systems can be nested within larger systems – for example a hospital is a system in itself with patients, staff, equipment, suppliers and commissioners but it is also embedded within the local region health system and the wider NHS.(99) In these systems, individuals try to reconcile multiple goals in a complex dynamic setting with trade-offs between safety and productivity.(86) Reliability is a characteristic of system components while patient safety (along with other outcomes such as staff wellbeing) is an emergent outcome.(100,101) Order emerges rather than being predetermined, with the past helping shape present behaviour and the future unpredictable.(99)

Amalberti describes how in complex systems there can be an accepted migration from protocols and defences into an accepted ‘illegal normal’ way of working with increased risk of patient safety incidents.(97) However, Hollnagel introduces the concept of learning from when things go right and why everyday performance succeeds most of the time, through understanding ‘work as done’ rather than ‘work as intended’ (Safety-II). He describes the need to learn from how individual variation corrects the system from expected and unexpected events to display resilience.(43,102) Due to the non-linear complexity of healthcare systems there is therefore a new view to actively focus on why healthcare succeeds rather than why it fails.(103) For this approach, accident analysis models need to include systematic techniques that are designed to understand the structure and behaviour of any type of system rather than treating accidents as a sequence of cause-effect events.(104) These can give deeper understanding of how the behaviour of an entire system can contribute towards an accident (or patient safety incident) than previously used sequential and epidemiological techniques.(105,106)

In the unpredictable environment of the emergency department, with a wide variety of patients presenting with undifferentiated problems, seeing a range of healthcare professionals from different backgrounds and with different experience levels, risk is inherent. Being aware of these complexities within the system, I intend to explore how these risks are managed to deliver safe patient care.

1.2.6 Key approaches to improve safety in healthcare systems

Since the publication of “An organisation with a memory”,(39) there have been many UK patient safety initiatives aimed to improve the safety of care provision, see Table 1-4. For example, the surgical checklist introduced to reduce wrong site surgery, and programmes aimed to reduce central line-related bloodstream infections in intensive care patients.(107,108) However, implementing such safety interventions has been shown to give mixed results, described as an ‘implementation gap’ from policies, guidelines, checklists to improving patient safety outcomes due to local contextual factors.(109)

For example, Matching Michigan was a 2-year NHS National Patient Safety interventional programme 2009–2011. It aimed to replicate the reduction in central line-related bloodstream infections in intensive care patients, based on the Michigan Keystone programme in the USA. In Michigan, 103 intensive care units reported a major reduction in these infections using a complex intervention targeting specific technical practice, converted into a standardised checklist. Initially in England, results appeared successful, with a 60% reduction in reported infections. However, on closer inspection, the reduction in infection rates could be attributable as much to

Table 1-4: NHS England significant patient safety milestones(110)

Year	Event
2000	Publication of “An Organisation with a memory”
2001	Death of Wayne Jowett due to wrong route administration of the chemotherapy drug vincristine leading to police prosecution and a high-profile investigation
2001	National Patient Safety Agency (NPSA) and National Reporting and Learning System (NRLS) set up
2001	Dr Foster Good Hospital Guide (mortality rates and other healthcare indicators) published in national newspaper
2001	Mandatory reporting by hospitals of MRSA
2002	National patient and staff surveys start with questions about patient safety
2004	Safer Patients Initiative starts working with the Institute of Healthcare Improvement (USA)
2004	NHS Safety national standards introduced – basis for Healthcare Commission inspections
2004-7	Healthcare Commission conducted 14 investigations into hospital failures
2008	Lord Darzi’s review: high quality care for all with local quality indictors and financial incentives
2009	National ‘Patient Safety First’ campaign
2009	Department of Health issues list of ‘never events’ including wrong site surgery
2010	NHS Outcomes Framework published
2010	Summary hospital mortality indicator developed to measure deaths following admission to hospital including those within 30 days of discharge
2010	NHS Safety Thermometer set up to provide standard methods of measuring indicators in the Outcomes Framework such as falls with harm, pressure ulcers, venous thromboembolism risk assessment
2011	Hospital specific mortality indicator developed and published
2012	Public inquiry into deaths at Mid Staffordshire NHS Foundation Trust
2019	NHS Patient Safety Strategy NHS England and NHS Improvement(111)

concurrent and preceding improvement efforts than any specific component of the Matching Michigan programme itself.(107) It was noted that process measures, such as improving leadership and local safety culture, are more difficult to measure than compliance with a ‘simple’ checklist,(112) and suggested that future studies should investigate causal mechanisms and contextual factors influencing the impact of interventions directed at improving patient care.(107)

The World Health Organization (WHO) suggests four interventions to reduce patient harm:

1. Inspection of institutions for minimum safety standards that can be used as a mechanism to ensure there is a baseline capacity and resources to maintain a safe clinical environment;
2. Safety protocols, e.g. hand hygiene, that address many avoidable risks that threaten the well-being of patients;
3. Safety checklists, e.g. the WHO Surgical or Trauma Care Checklist – a simple tool that aims to improve teamwork and communication by emphasising key elements in the process; and
4. Adverse event reporting documents for an unwanted medical occurrence linked to a learning system.(111)

Performance measurements in NHS emergency departments however, may not be relevant to or routinely audited for GP services working in or alongside. Standard measures include: attendances, emergency admissions and the 4-hour wait (where at least 95% of patients should be admitted to hospital, transferred to another provider, or discharged within four hours).(113) More detailed measures also include: time to initial assessment, including a pain score and physiological early warning score; time to when the patient is seen by a ‘decision-making clinician’; aggregated patient delay over six hours (the number of hours waited over six hours aggregated across 100 patients to measure overcrowding); unplanned patient re-attendance at the emergency department within 7 days (differentiating between single re-attendances and frequent attenders); and the number of patients that leave without being seen.(114) The most recent NHS Digital Accident and Emergency

Quality indicators report (March 2020) acknowledges missing data from 54 organisations, largely lower acuity services, suggesting a lack of learning from the standard performance measures from GP services in these settings.(115)

Quality improvement emergency department clinical audits were initially introduced in 2010 as mandatory exercises. Although they are now voluntary they are still recommended by RCEM and checked by the Care Quality Commission and are therefore usually completed. These include: the success in managing certain conditions with ambulatory care rather than traditional inpatient admission, for example deep vein thrombosis and cellulitis: patient, carer and staff feedback on service experience; and consultant sign off for high risk conditions such as a febrile child under one year of age, non-traumatic chest pain in adults and unscheduled returns with 72 hours. (116,117) National reports are then published with findings against pre-determined standards. For example, the 2019 feverish child audit includes: initial assessment within 15 minutes including measurement of basic physiological observations; use of a sepsis screening tool; use of the NICE traffic light system; senior clinician sign off; and staff compliance with training requirements.(114) However, traditional GP services do not routinely use these emergency medicine quality clinical audits and many may not be relevant to a traditional GP consultation.

1.3 Evidence gaps and need for research

In response to challenges from increased patient demand and an ageing population, the NHS is changing. New healthcare service models are being developed with healthcare professionals taking on roles outside those for which they were originally trained, including GP services in or alongside emergency departments. These service models have been implemented with a lack of evidence for effectiveness and safety outcomes and a lack of standardised quality indicators.

Patient safety is a major public health concern. Patients attending emergency departments and primary care are both settings at risk of diagnostic error which can result in severe patient harm. Service models that encourage GPs to treat emergency department patients (with a higher pre-test probability of serious disease), as they would in the primary care setting without using acute investigations and avoiding acute hospital admission, may put patients at risk of diagnostic error. Also, expecting GPs to take on emergency medicine roles for which they may not have the training and skillset, also potentially puts patients at risk.

In complex socio-technical systems it is essential to understand how services work to identify potential risks and how systems can be adapted to minimise this risk. Interventions can then be targeted at priority areas relevant to local contextual factors. My research question is therefore, “What patient safety incidents are associated with GP services in or alongside emergency departments that cause most patient harm, how and why do they occur and how could they be mitigated?”

1.3.1 Aim

To explore the nature and causal mechanisms of patient safety incidents when GPs work in or alongside emergency departments to identify opportunities for improving patient safety and intervention development.

1.3.2 Objectives

1. To review patient safety outcomes when GPs work in or alongside emergency departments: initial theory development
2. To characterise and explore causal mechanisms of patient safety incidents regarding GP services in or alongside emergency departments: initial theory development
3. To explore factors that influence patient safety outcomes at case study sites: theory testing and refining
4. To explore areas of measurement that could be used to test the theories in practice: transition to quality improvement
5. To use formal theory to structure findings and inform intervention development

2 Methods

In this chapter I describe the principles of realist methodology and the strengths and limitations of using this approach for this work. I then present the study design and describe in detail the methods used to address my study objectives described in Chapter 1.

2.1 Realist paradigm

Pawson and Tilley describe scientific realist methodology, or realism, as a theory-driven approach to evaluation (primary analysis) and synthesis (secondary analysis).(118) It is often used in the assessment of complex evidence from the implementation of policy, programmes or interventions, for example, to evaluate how to make health services more efficient and patient centred,(119) or how a patient safety intervention is implemented.(120) The idea is to understand how people react or respond to the intervention, depending on local contextual factors, for the intervention to create change. These unseen causative factors are termed *mechanisms* and the influence of local context to activate them and then generate specific outcomes is described as a context-mechanism-outcome (CMO) configuration, or theory. The underpinning focus is not, “does it work?” but, “what works, for whom, in what circumstances and how?”(118)

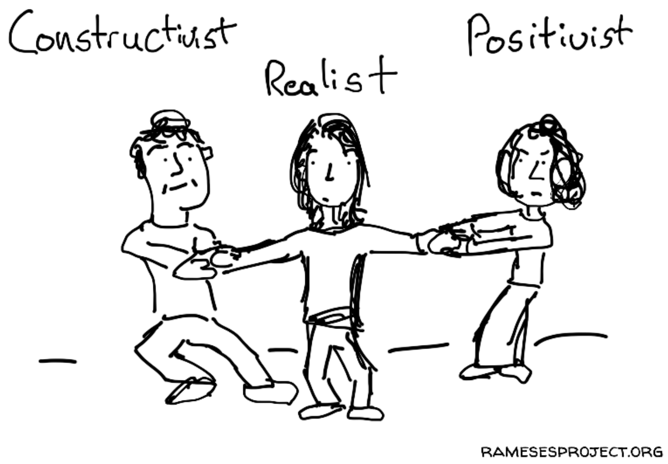
2.1.1 Complexity

How people react and respond to an intervention is complex; some will respond to rewards or regulations, while others to education. Therefore, the intervention may work in some settings but not in others. Pawson describes other key features that contribute towards this complexity.(121)

- The pre-existing conditions, or context, may vary at different levels: the individual characteristics of staff and patients (micro-level); interpersonal exchanges within the team (meso-level); and the geographical and organisational setting (macro-level).
- The power people have to make their own choices may also lead to violations and affect the aims of the intervention.
- The intervention itself may change and develop over time from how it was intended to be implemented or rival policies or programmes may compete against each other.
- Outcomes that are being measured may change irrespective of the intervention, for example staff behaviour if they are aware they are being monitored, and unintended outcomes may emerge as a result of the programme.(121)

Realist methodology accepts this complexity. The aim is to understand how, why, and for whom the intervention works to give insight into how the same intervention may work (or not) in different settings.(121)

Figure 2-1: The realist paradigm sits between constructivism and positivism (Reproduced with permission from Dr Geoff Wong)(122)



2.1.2 Methodological underpinning

Different schools of philosophy make different assumptions about the nature of the world (ontology) and the nature of knowledge (epistemology). Realism is said to sit somewhere in the middle between the positivist and constructivist paradigms, Figure 2-1.(123)

Positivism is the approach I have been more familiar with throughout my medical training. Through this philosophy, it is believed that understanding of the world can be achieved directly through observation. The focus is on deductive, theory-testing, quantitative methods, with experimental designs to exclude variation in the definition and delivery of the intervention (randomised controlled trials being the gold standard), to give reliable, valid and generalisable results. Data are numerical and analysed statistically. The power to determine causation depends on the variation across population (heterogeneity) and if the pre-planned target sample size is achieved, according to the effect size judged to be clinically meaningful, and therefore the minimum to be detected.

The philosophy of constructivism, however, is that we cannot know for sure what the nature of reality is because it has been interpreted by our senses and brain and we are all different. Inductive, theory building, qualitative methods are used to explore and interpret different perspectives in the search for the meaning of events and activities.(124)

The realist philosophy sits between both perspectives. Reality is described as being stratified in layers, with three realms of ontological depth: the empirical, the actual, and the real.(118,125) The empirical world is a realm that is observable and often measurable, described as flat ontology for example, measuring the number of people that present to emergency departments with a specific diagnosis. The actual world includes the empirical realm, along with activated but non-empirical mechanisms; for example, exploring how and why clinicians request investigations to diagnose this condition. While the *real* world includes the actual and the empirical worlds but also latent (not activated in this context) mechanisms for example, exploring why patients with symptoms of the diagnosis choose to present to healthcare services for investigation and subsequent diagnosis, to give ontological depth.(125,126)

Realism accepts that there is a *real* world but that our knowledge of it is processed through human senses, brains, language and culture and is therefore partial. Unknown unknowns are anticipated.(127) It recognises that some hidden mechanisms remain inactive, or latent, until they are triggered by a specific context. The realist aim is to understand what triggers these mechanisms to activate and therefore how causation works, to provide explanations within complex processes.(118,124,128) A logic of configuration (context-mechanism-outcome) is used to explain the process. The power is in determining how and why these critical pieces of evidence and causal mechanisms are arranged, rather than the effect size which may be more informative in directing implementation than simply observing the same thing happening multiple times.(123)

The idea of going behind or below observed patterns to discover what produces them, to unearth these hidden causal mechanisms, is known as *retroduction*. While *abduction* is the inventive thinking required to imagine the existence of such mechanisms, retroduction is the activity of inferring and theorising from the evidence.(124,126) Causation is not usually simple, linear or deterministic; there may be multiple mechanisms, triggered by different participants at different times, even at the same location. Retroduction is used to overcome the deficiencies of induction, theory-generation from the data, and deduction, theory-testing from the data, to offer context-specific causal explanation.

To make sense of complexity, realism therefore uses a mixed-philosophy approach with a combination of induction, deduction and retroduction. Quantitative and qualitative research methods can be used for theory development and testing. Semi-predictable patterns, or “demi-regularities”, may then become evident in the data to explain what works, for whom, in what circumstances and how. If may then be possible to transfer these findings and apply them to different settings.(124,126)

2.1.3 Terminology

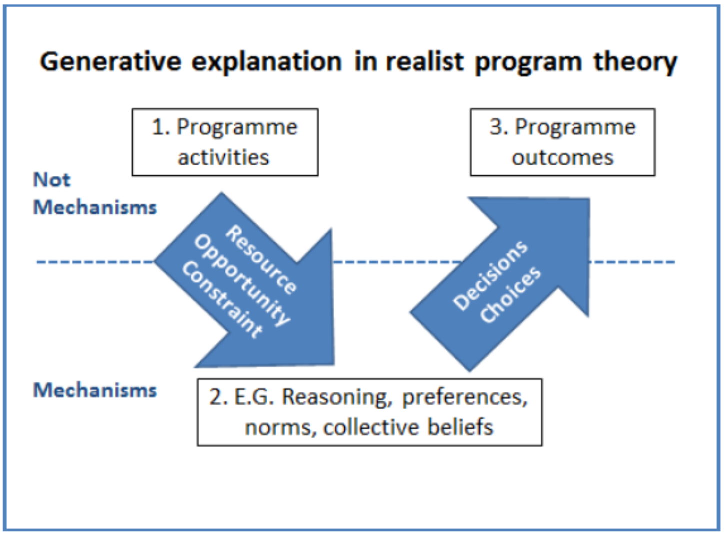
Realist methodology uses specific terminology to describe theory components and the level of supporting evidence, Table 2-1

Table 2-1: Definitions to be used in this thesis (1,7)

Context (C)	Pre-existing conditions which influence the success or failure of different interventions or programmes
Mechanism (M)	Characteristics of the intervention and people's reaction to it; how it influences their reasoning
Outcome (O)	Intended and unintended results of the intervention as a result of a mechanism operating within a context
Initial rough theory	An early theory, informed by available evidence, about how, why for whom, in what circumstances the intervention is thought to work described as a context-mechanism-outcome (CMO) configuration
Refined theory	An initial theory that has been refined using primary or secondary evidence
Programme theory	An overall high-level theory summarising how the intervention works, developed using the theories refined from the data
Formal theory	Existing social theories used as a lens through which to examine the data. Otherwise known as middle range theory or substantive theory

Context (C) has been defined as, 'Pre-existing conditions which influence the success or failure of different interventions or programmes'. These conditions are multiple and may include: cultural norms and values; history and geography; financial and economic considerations; political agendas and existing public policy; in fact, anything in the social and physical environment. Some factors may be modifiable, others may not. Following on from the discussion in Chapter 1 about systems thinking and human factors, it explores how the system influences outcomes. It addresses the questions, "For whom?" and, "In what circumstances?"(118)

Figure 2-2: Pictorial representation of mechanisms (Reproduced with permission from Dr Geoff Wong)(124)



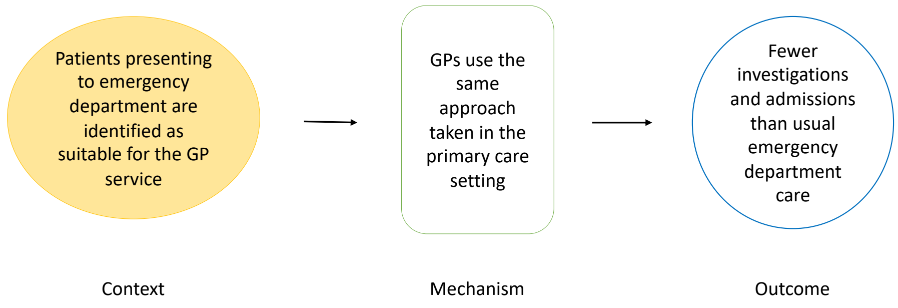
Mechanisms (M) are the invisible generative forces, for example human reasoning, preferences or beliefs that are triggered by contextual factors to influence decisions and therefore outcomes, see Figure 2-2. They can be disaggregated into constituent parts to help understand how the characteristics of the resource offered by the intervention (Mresource) influence the reasoning of participants (Mreasoning).(129) For example, as discussed in Chapter 1, mechanisms may explain why GPs working in emergency departments may treat patients differently (Mreasoning) than they would in usual primary care settings. Mechanisms may be latent until activated by a specific context and they may be triggered by different participants at different times, even at the same location. Since they are hidden they must be inferred from the observable data. Exploring mechanisms is to understand, “How?”

Outcomes (O) can be intended or unintended, expected or unexpected, beneficial or adverse. They can be measured with quantitative or qualitative data. Standard emergency department quality indicators are discussed in Chapter 1; for example, attendances, admissions and the four-hour wait but as discussed, these may not reflect the quality of care provided by GP services in or alongside emergency departments.(113) Unintended outcomes, such as patient safety incidents, may be rare so proxy measures may be considered; for example, unplanned patient reattendances at the emergency department within seven days (an outcome planned to be used for the GPs in EDs study).(119,130) Qualitative outcomes can also be considered, for example, GP reported safety experiences of working in or alongside emergency departments. Understanding outcomes explores, “What works?”

Initial rough theories are early theories described as context-mechanism-outcome (CMO) configurations, see example in Figure 2-3. They are often multiple and informed by available evidence (for example, background expertise or literature). These can then be tested with primary (realist evaluation) or secondary (realist synthesis) evidence and developed to become *refined* theories. A *programme* theory is a high-level theory summarising the evidence for how, why and in what circumstances the intervention works. It is not merely descriptive; it describes a causal pattern.

Formal theories (otherwise known as middle-range or substantive theories) are existing social, economic, psychology, educational or health theories that can be used in the early stages of evaluation to generate initial rough theories or later in the process, as a lens through which to examine the data and help refine theories.

Figure 2-3: Example of an initial rough theory



The cycle in which theories are generated, tested and refined, starting with theory and finishing with a (refined or programme) theory, is described as a *realistic evaluation cycle*.(131) Initially the theoretical constructs of context (C), mechanism (M) and outcome (O) are determined with initial rough theories developed about what might work, for whom and in what circumstances, which can be informed by formal theory. Mixed-method data are then collected to test the relationships between different contexts and outcomes to determine the underlying mechanisms to develop refined theories about what works for whom and in what circumstances. Refined theories may be further tested and refined by additional data collection or synthesised to develop high-level programme theory.

The outcome of a previous stage of the intervention (CMO) may also become the context of the next CMO configuration, with multiple linking CMOs over time referred to as the ripple effect.(132,133) For example, when a patient presents to the emergency department (C), how they are selected (M) for the GP service (O, C2), may influence the GP's reasoning processes (M) and treatment decisions (O).

2.1.4 Strengths and limitations of a realist approach for this work

My aim for this thesis is to explore the nature and causation of patient safety incidents when GPs work in or alongside emergency departments to identify priority areas for quality indicators and intervention development.

Donabedian's concept of evaluating the quality of healthcare through understanding structure (facilities, equipment, money), process (what is actually done in giving and receiving care) and outcomes (effects of care) is long established.(134) This can be applied to patient safety outcomes by evaluating how the structure of the organisation and local context, influences healthcare professionals to do what they are supposed to do. He introduced the concept of using the framework to establish "What goes on here?" rather than "What is wrong and how can it be made better?"(135) This is similar to Safety-II approaches, discussed in Chapter 1, which aim to understand "normal" day-to-day work practise and adaptions that contribute to successful system performance, rather than only focussing on system failures.(43)

The Systems Engineering Initiative for Patient Safety (SEIPS), a human factors model, incorporates the structure-process-outcome model but is largely a description of a socio-technical work system to illustrate how interactions between different system elements leads to outcomes including: the organisation, teamwork and communication; the working environment; technology and tools; education, skills and knowledge of the staff; and the tasks involved. It describes how care processes are related to this structure and result in patient and employee outcomes but mainly on work flow rather than how and why decisions are made.(136)

As discussed, realist methodology is a theory-based approach which aims to understand what works, for whom, why and in what circumstances using context-mechanism-outcome configurations to explain causation in complex settings. It aims to identify the non-visible context-specific causative mechanisms (for example, why clinical decisions are made) that generate outcomes to understand what works, for whom, why and in what circumstances. The understanding of these mechanisms gives greater ontological depth to Donabedian's concept and the SEIPS model of structure, process and outcome to develop programme theory that can then go on to inform subsequent quality improvement projects.

In Chapter 1, I have discussed the complexity of urgent and emergency care settings, the different models of GPs services in or alongside emergency departments and the lack of evidence for safety outcomes.(5,32–34) I have also discussed how emergency department quality indicators from routinely collected data are often missing from low acuity services and standard emergency department clinical audits may not be relevant to GP services, limiting learning from routine data sources and quantitative research methods.(115) It is known that emergency departments and primary care services are settings where there is a risk of diagnostic error with potential for significant patient harm but it is not known if this is a risk for GPs services in or alongside emergency departments.(52,60,63–66,68,76,77) How systems can be adapted, and teams trained accordingly with consideration of human factors, to minimise this risk is also unclear. Learning from previous patient safety campaigns has increased awareness of the need to understand how safety interventions are implemented by teams, depending on local context, to result in improved patient safety outcomes.(107,112).

A realist approach, which incorporates data from multiple data sources to identify the context-specific hidden mechanisms, can therefore improve understanding of causation and how and why patient safety outcomes may occur and how they are mitigated. The understanding of these local contextual factors, at clinician-patient level (microsystem), team and organisational level (mesosystem) or wider level (macrosystem), is becoming essential for quality improvement implementation and explaining outcomes.(137)

Quality improvement experts advise an idea or theory is developed, to understand how and why programmes work to achieve their outcomes, before quality improvement projects are implemented.(138) The ideas (or theory) for change, can then be incorporated into the plan, ‘P’, of the PDSA cycle (see Chapter 1 section 1.2.5). This approach is now reflected in quality improvement reporting excellence guidelines (SQUIRE 2.0) that advise authors to report the underlying theory and contextual elements considered important at the outset of the intervention.(139) Realist methods can be used to develop that theory (with evidence of context-specific causation) and therefore inform intervention development and quality indicators that can be used to test the theory and measure safe care.

Realist approaches are however limited by the data used to inform theory development. Quantitative findings from the interrupted time series analysis from the GPs in EDs study (for example investigation and admission rates by different GP service models and patient reattendance rates) were not available at the time of writing this thesis. For this study, qualitative data were used which is subject to bias. To minimise this bias, a purposive sample of case study sites was selected for a range of different settings and with different GP services in or alongside emergency departments. Findings were regularly discussed within the team to minimise researcher bias including an expert stakeholder group and formal theory was also used as a structure to review findings.

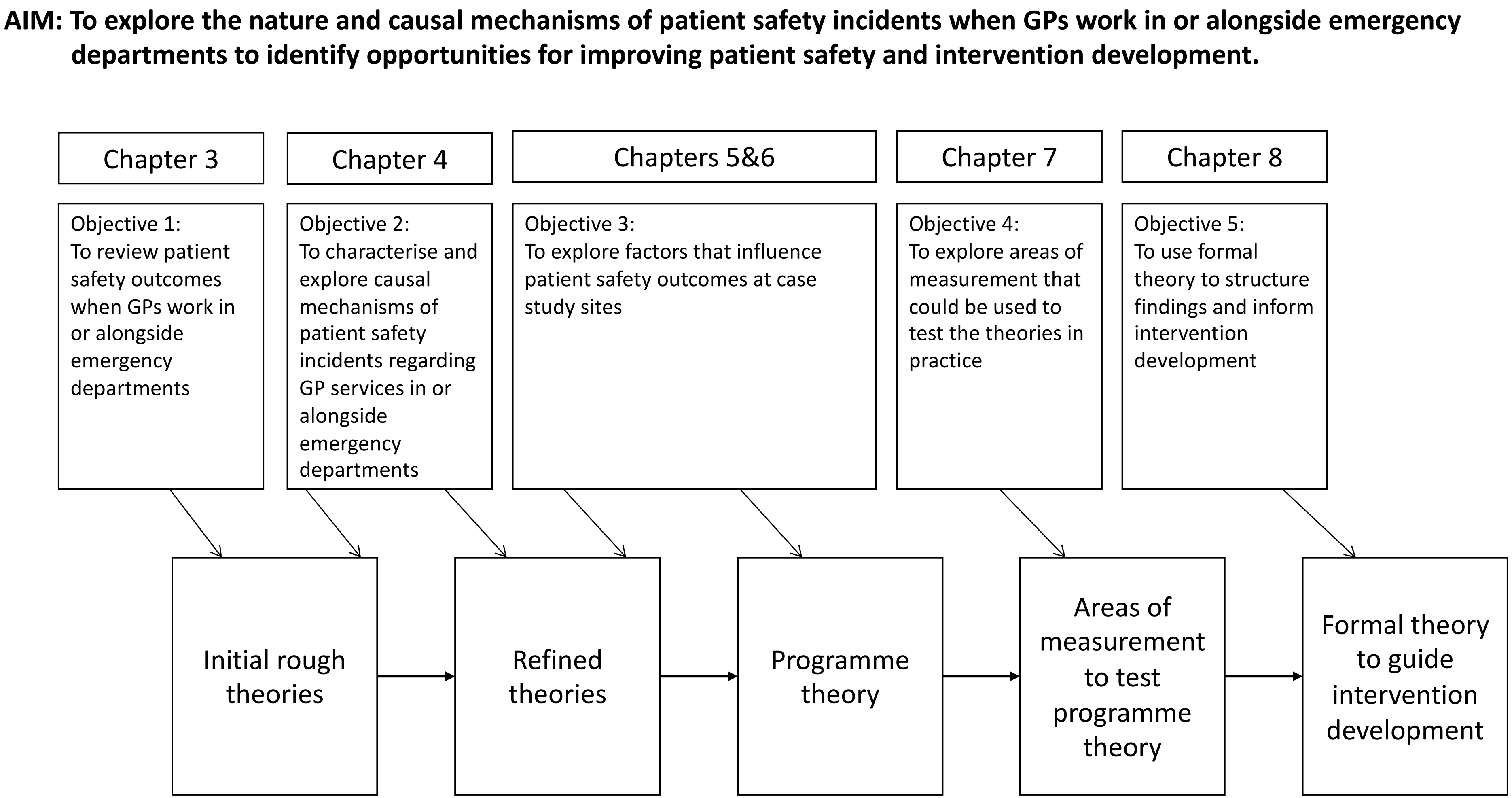
As a Clinical Research Fellow on the GPs in EDs study with commitments to the delivery of the project, in the interest of efficiency, it made sense to align thesis objectives with the planned study methods where possible. I deviated from the study protocol to explore potential safety issues by reading the publicly available CQC reports before case site visits and searching for relevant Coroners' reports. Patients were recruited for the GPs in EDs study to explore patient experience. However patient numbers were low and this work package was led by my colleague (Dr Michelle Edwards) and therefore I chose not to include this work in my thesis.(140) Exploring patient safety issues with patients may have added valuable learning to this work.(57)

I considered additional research methods outside the GPs in EDs study protocol: case note reviews and cognitive interviews. I dismissed reviewing case notes for patients seen by GPs and emergency care clinicians to identify patient safety incidents because of time restrictions. I considered cognitive interviews because cognitive biases in clinical decision-making, discussed in Chapter 1 section 1.2.4, are by definition due to unconscious thought processes, which realist methods are not fully able to explore. Clinicians may simply not be aware of any anchoring/tramlining biases influencing their clinical decision-making and deny them rather than them not being present. I developed some cognitive interview scenarios to discuss with GPs on site. However, on discussing this approach with academic GP colleagues (Dr Freya Davies, Professor Niro Siriwardena) we discussed that doctors, who are trained to give gold standard answers and pass tests, are likely to present their answers in this way. Also due to the time limitations and the busy workplace, discussions with the GPs was expected to be limited and not allow for more complex and time-consuming cognitive interviews, so I discounted this method and decided to continue with realist methods. I will now present the study design and research methods used.

2.2 Study design

This study includes a realist synthesis (secondary data analysis) followed by a realist evaluation (primary data analysis). The stages and data sources are outlined in Figure 2-4. Realist methodology focusses on 'nuggets of information' that explain how and why outcomes occur in an attempt to understand the *real* world (the domain in which mechanisms exist, whether or not they are observed and whether or not they are currently operating).(118,141–143) Throughout the process, I explored what mechanisms (M) could explain how or why contexts (C) related to outcomes (O), to generate *theories* described as context-mechanism-outcome configurations (CMOs).(144) The process was iterative and present throughout the cycle, guiding theory development and data collection to test the theories.(131) Rameses reporting and publication standards were followed for both the realist synthesis and evaluation (see Appendix 2 and Appendix 3).

Figure 2-4: Study design and data sources for theory development



I developed initial rough theories from the literature (Chapter 3) and patient safety incident reports (Chapter 4). These informed interview guides to further test and refine these theories with case study site qualitative data. I applied Pawson's reasoning processes to synthesise the theories to develop a programme theory about how safe care is delivered when GPs work in or alongside emergency departments (Chapter 6). This was presented to stakeholders and discussions held to identify potential areas of measurement that could be used to test the theory and measure safe care in practice (Chapter 7). I then used the lens of formal theory to structure my findings for potential intervention development (Chapter 8).

2.2.1 Quality considerations

A realist theory is considered high quality if it is plausible, coherent and based on trustworthy data.(141) To ensure my findings are reliable and valid, I have been transparent about the methods used – sample selection, data collection, data analyses and how the theories have been developed. I have used triangulation of multiple data sources to improve validity and regularly shared findings within the research team and with the wider co-applicant team and stakeholder groups. I have actively tried to develop rival theories from the data to challenge my initial assumptions and consider my own biases and how these can be addressed.

During the realist review, following realist methodology, I did not use a formal quality assessment tool because the researcher is looking for nuggets of information, often found within the discussion section of the paper, that explain findings rather than examining overall study quality. I did however review the methods for empirically driven data to see if they were clear and not simply fabricated.

To ensure my theories were coherent and the argument was logical and consistent with good explanation, I followed the ‘inference to the best explanation’ reasoning by Haig and Evers, to judge coherence with the following criteria:

- ‘consilience’, the theory explains as much as possible of the data;
- ‘simplicity’, the theory is simple, without special ad hoc assumptions;
- ‘analogy’, the theory fits with what we currently know and / or formal theory.(145)

I aim to describe patterns of causation which may then be relevant to different settings, therefore producing generalisable results.

2.2.2 Addressing my personal biases

My insider knowledge of the health system and what drives my own clinical decision-making helped inform my initial theorising. However, to ensure I did not prioritise theories which resonated with my own experience, I actively engaged with stakeholders in all stages of the process, as discussed above.

During the qualitative data collection phase at case site visits, I made my clinical role clearly visible, introducing myself as a GP. I believe this facilitated rapport building and encouraged GPs to engage in the research and participate in interviews despite the pressured emergency department setting. I was careful not to present my own opinions and biases during discussions and used the semi-structured interview guide. Patient safety can be a taboo subject and I was expecting some interviewees to become defensive, but this was not my experience. I found participants keen to honestly share their experiences.

My understanding of jargon and the way systems work often helped interviews to flow, but I recognise that at times I may have assumed I understood the

GPs' experiences and could have missed opportunities to probe further. I discussed the outcome of these interviews and my observations with my social scientist colleague (ME) daily on site as a process to manage my own biases. I did not observe clinical consultations – I recognise this may have proved challenging, as it may have been difficult not to focus on what I might have done in the same situation, raising possible ethical dilemmas.

During the analysis stage, I discussed findings and inferences regularly within the Cardiff team. I recognised that while my understanding of the context of clinical encounters may have informed the interpretive process of retroduction, I was at risk of going too far beyond the data and relying too heavily on my own perspectives. Validating the theories at the second stakeholder conference was an important step in this journey to ensure I was not focussing on those theories resonating with my own experience.

2.2.3 Addressing my learning needs

This entire process has been a massive learning curve. I had a ten-year break from academia from completing my MSc to commencing the Academic Fellow role. I have been supported all the way by my PhD supervisory team, the wider project local and co-applicant team and have also undertaken formal learning, Table 2-2.

Table 2-2: Formal training undertaken as a PhD student

Year of study	Training undertaken	Institution	Date
Year 1	Introduction to realist methods, 2-day course	Dr Justin Jagosh, Liverpool University	Jan 2017
	Qualitative interviewing, 1-day course	Prof Karen O'Reilly, London Social Research Association	June 2017
	Ethnography, 1-day course	Prof Karen O'Reilly, London Social Research Association	Sept 2017
Year 2	How to write a thesis, 2-hr session	Dr Amanda Tonks, Cardiff University	May 2018
	Working with long documents, 2-hr session	Dr Amanda Tonks, Cardiff University	June 2018
	Advanced realist methods training, 4-day course	Dr Justin Jagosh, Liverpool University (course held in London)	July 2018
	Qualitative methods further training, 2-hr session	Prof Annmarie Nelson, Cardiff University	Sept 2019
	Completed certificate in patient safety, online course	Institute of Healthcare Improvement	July 2019
	Realist methods workshop, 2-hr session	Sarah Brand, Cardiff University	July 2019
Year 3	Working with long documents	Dr Amanda Tonks, Cardiff University	Feb 2020
	Safety II, 1-day workshop	Prof Eric Hollengal, visiting Cardiff University	Feb 2020
	International Realist conference, 4-days *cancelled due to Covid-19 pandemic*	Dublin, Ireland	March 2020

I was new to qualitative methods and realist methodology so undertook specific training in this area. I was asked to run a workshop on realist methodology at the PRIME Centre Wales conference in Swansea in October 2017. Preparing for this event was helpful to consolidate my learning.

During the case site visits, I soon became aware of the difference between a clinical ‘interview’ in general practice, to a qualitative interview and a realist interview. I am very familiar with the clinical ‘interview’ - a process of moving from an undifferentiated problem to a provisional diagnosis and management plan with no written prompts, relying on non-verbal communication to probe certain areas more deeply. Following the first case visit and a quality assurance exercise within the Cardiff team where we read and discussed the transcribed interviews, I became aware of the need to use a semi-structured interview guide, based on the theories, for consistency and to avoid presenting my own biases. Since interviews were generally short due to the pressurised environment, I also learned it was better to explore fewer theories in more depth than to try to cover the full range of theories with each interviewee.

I found the advanced realist methods training in July 2018 very helpful. The session on realist interviews and the teacher-learner cycle helped improve my interview technique. I learned that the language used to present the theories to avoid leading the interviewee was important. For example, “there’s this idea…” may work better that “we think…” or “we have a theory…” so the interviewee is not intimated by the ‘expert’. The course gave me confidence to dig deeper for ontological depth. I was reassured that if I was comfortable challenging people to explain why they act in a certain way in different contexts as the teacher, then so would the learner be.(146) Reading transcripts from later interviews, more mechanisms are evident as a result.

I had a poster presentation accepted at the Dublin International Realist conference in March 2020. Here I was looking forward to further consolidating my realist thinking. Unfortunately, this event was postponed due to the Covid-19 pandemic. I have therefore instead used online resources to answer my queries and reinforce my reading. I look forward to attending this event in March 2021.

2.2.4 Ethical approval

My colleague (Dr Michelle Edwards, ME) led the ethics application for the wider GPs in EDs project, which this thesis is part of, and attended the committee meeting with the study Chief Investigator (Professor Adrian Edwards, AE). I assisted, detailing our planned methods on the application. Ethics review for the survey and follow-up interviews was carried out by Cardiff University School of Medicine Research Ethics Committee and permission was granted on 29/07/2017 (ref 17/45).

Aneurin Bevan (Gwent, Wales, UK) University Health Board's Research Risk Review Committee judged the study of anonymised national (NRLS) patient safety incident reports as for *service improvement* purposes and approved it on this basis (ABHB R&D Ref number: SA/410/13).

The fieldwork for case study site visits, local patient safety incident report analysis and staff and patient interviews were carried out after ethical review from Wales Research Ethics Committee on 23.07.2017 (ref 17/WA/0328).

2.3 Research methods

In this section, I describe the research methods used to address the study objectives outlined in Chapter 1.

2.3.1 Rapid Realist Literature Review

I undertook a rapid realist review (realist synthesis) to address objective one, “To review patient safety outcomes when GPs work in or alongside emergency departments.” As discussed in Chapter 1, I led this review for the GPs in EDs study and I am lead author on the BMJ Open publication (Appendix 1).(5)

A rapid realist review differs to a traditional realist review because it focuses on a specific context in contrast to a traditional review which would aim to produce theories about processes, incorporating formal theory, that could be transferable across different contexts and populations.(147) This is appropriate in the urgent and emergency care setting which has emerging service reconfigurations in response to the intense service demands and evidence of effectiveness is needed in a timely manner. A rapid review also utilises ‘expert stakeholders’ to discuss findings and help prioritise literature searches in view of time constraints - aiming to provide evidence and make explicit what is known on the given topic and articulating the current research gaps for policy makers.(147) For these reasons, I decided a rapid realist review approach, as described by Saul et al., would be more appropriate than a traditional realist review approach.(147)

The research question for the wider review was, “How and why do GPs working in or alongside emergency departments affect: patient experience and safety; demand and flow in the department; and the wider healthcare system?”(5) For the purpose of this thesis, I will present the findings and theories developed relating to patient safety outcomes. This includes more detail than in the BMJ Open publication.

As described in Chapter 2, I followed the realist methodology to identify mechanisms (M) that explain how or why contexts (C) relate to outcomes (O), to generate *theories* described as context-mechanism-outcome configurations (CMOs).(144) I developed a protocol based on the rapid realist review approach described by Saul et al.(147), following the RAMESES publication standards (see Appendix 2)(143) and registered the protocol on the Prospero database.(148) Pawson describes six stages of realist synthesis, all evident in this rapid realist review process: identifying the review question, searching for primary studies, quality appraisal, extracting the data, synthesising the data and disseminating the findings.(142) The review period was April – November 2017.

2.3.1.1 Scoping exercise

I started with a scoping exercise with two other reviewers: Freya Davies (FD), a GP Clinical Research Fellow with realist methods experience employed by PRIME Centre Wales and Michelle Edwards (ME) who is a qualitative researcher with a social science background, employed as a Research Assistant on the GPs in EDs study. The aim of the scoping exercise was to develop *initial rough theories* to present to an 'expert stakeholder group' for their input. We chose to include the four UK studies identified in the recently published review by the UK Sheffield team.(34)(23,28,149,150) These were the only UK papers identified in this review and despite three of these studies being published before the millennium, it was felt that starting with UK-based studies would be most relevant to modern NHS emergency services. I also identified two UK policy documents (2010 and 2015) outlining how these service models were expected to work, to include in the scoping exercise.(35,37) Realist reviews are much more about explaining phenomena than about calculating the size of their effects and can therefore include opinion articles, found in an editorial or discussion, as well as empirical data.(141)

We individually read the six articles and developed our own pilot data extraction forms. I used Microsoft Excel for Mac (version 16.35) and used realist principles to extract data regarding context, mechanisms and outcomes, to populate different columns, to develop the CMO configurations. We met to discuss the process and learn from each other. We discussed the need to search for evidence of causative factors related to context at the *micro-level* (the reasoning processes of general practitioners, emergency department staff and patients), the *meso-level* (staff interactions resulting in department level outcomes) and the *macro-level* (the impact on the wider system).(141)

2.3.1.2 Expert stakeholder group input

I collated the initial rough theories developed from the pilot exercise into a single spreadsheet grouping them at: practitioner level, department level, patient level and wider system level. Often the statements lacked contextual detail. The first face-to-face ‘GPs in EDs study’ co-applicant meeting was held on 9th May 2017. Attendees included the 17 study co-applicants including: emergency department clinicians, policy makers, GPs, public contributors and methodologists (listed in Appendix 4). Prof Dale, author of two of the UK studies included in the pilot exercise was a member of this group. Also present was the study Research Assistant Dr Michelle Edwards (ME), an Academic GP Fellow, Dr Rebecca Sherlock (RS) involved in the study survey, and the study project manager Nigel Pearson (NP).

We met in a conference centre and all sat around a single table. When theories from the pilot exercise were presented, the group took on the role of the 'expert stakeholder group' and were invited to contribute to the group discussion, chaired by the study principal investigator, Prof Adrian Edwards (AE). Discussions were rich, with all members contributing. It lasted an hour and was audio-recorded. I transcribed it at a later date and used these data to contribute to our list of initial theories.

Members from the group were also able to identify research papers in peer-reviewed journals and relevant reports in the grey literature for review.

2.3.1.3 Search strategy

I then reviewed the literature searching for evidence to support or refute these initial rough theories, for *theory refining*, or generate new initial theories. I used papers referenced in three previous systematic reviews as a starting point,(34,36,151) and to identify papers published since, I combined search terms from these three previous reviews (with the assistance of an information specialist).(34,151) I used a combination of free text and Medical Subject Headings (MeSH) terms (see Appendix 5 for Medline strategy which was adapted for other databases). I ran the searches on the following databases from 15th June – 4th July 2017: Medline via OVID, Embase, CINAHL, Cochrane DSR & CRCT, DARE, HTA Database, Business Source Complete, PsycINFO and SCOPUS and used Endnote X8 (Clarivate analytics) to export citations from the database searches and identify duplicates. I screened the titles and abstracts of all identified papers using a checklist to guide ranking, developed and tested in collaboration with FD.

2.3.1.4 Inclusion criteria

FD and I both participated in the full text screening stage, selecting articles to be included in the study if they included information to develop new initial theories or helped explain why the intervention worked or not to refine the initial theories. Following realist methodology, we did not use a formal quality assessment tool to assess the overall quality of included studies. The quality of individual data extracts or ‘nuggets of information’ were discussed and considered for relevance and rigour, more in light of trustworthiness and plausibility.(141–143) Papers that lacked relevance or were unavailable in English were excluded.

2.3.1.5 Data extraction

FD and I extracted quantitative, qualitative or contextual data from any part of a paper and imported it into NVivo 11 (QSR International), with a coding framework developed around the initial theories from the pilot work. The Excel spreadsheet was also updated weekly to summarise which theories had data to support or refute and which required further data to test. These findings were presented at weekly Cardiff team meetings (AC, FD, ME, AE) where FD and I also discussed how individual data extracts should be used to ensure appropriate inferences were made.(142) A quarter of all included articles was read by both FD and I, and we discussed the coding process in detail, to ensure consistency of approach.

2.3.1.6 Iterative process

Six members of the stakeholder expert group agreed to form an expert support group (A/Prof Alison Porter, A/Prof Pippa Anderson, Dr Bridie Evans, Ms Barbara Harrington, Prof Jeremy Dale, Dr Andrew Carson-Stevens, see Appendix 4 for disciplines and institutions) and met via teleconference every six weeks to discuss findings and guide priority search areas. I used snowballing techniques, such as searching companion papers and citation tracking, for all included articles. For this aspect, I was assisted by a summer medical student Faris Hussain (FH). He was working with the GPs in EDs study team on a different area (the marker conditions), under the Cardiff University Undergraduate Research Opportunities Programme (CUROP). I also searched to identify additional relevant grey literature (including policy documents and opinion pieces) from a variety of sources. The search process was iterative, overlapping with data extraction and analysis, and was directed towards the evidence gaps and finding explanatory information.

2.3.1.7 Synthesis

I applied Pawson's reasoning theory-building processes to synthesise the data.(152) *Juxtaposition* principles were used when process data from one method could be used to make sense of outcome data in another. *Reconciliation* could explain contextual differences that may have resulted in contradicting outcomes or *adjudication* to evaluate methodological differences. Data supporting the same outcome led to *consolidation* of theories into a multifaceted explanation or rival explanations that may be *situated* depending on which mechanisms are activated in which contexts.(152) I looked for *demi-regularities* – identifiable trends or patterns of outcomes that could be explained by people behaving in certain ways in certain situations, activating the same mechanisms. I then used retroduction to explain causation and why these demi-regularities may occur.

Refined theories were presented for discussion in the weekly team meetings (AC, FD, AE, ME) and I presented them to our 'expert stakeholder group' in

November 2017. At this stage, the group recognised that although the review had been useful for developing initial theories, there were limited opportunities for theory testing and refinement due to gaps in the evidence. Rather than continuing to search for additional secondary data, the group decided that gathering primary data from our evaluation case study sites in the next phase of the wider NIHR study, would give more meaningful testing to derive *refined theories*.(144) The theories developed from this work are presented in Chapter 3.

2.3.2 Analysis of national patient safety incident reports

I analysed a sample of Coroners’ reports to prevent future deaths (England and Wales) and National Reporting and Learning System (NRLS) patient safety incident reports to address objective two, “To characterise and explore causal mechanisms of patient safety incidents regarding GP services in or alongside emergency departments.” While I was undertaking this work, I co-supervised a BSc medical student, Faris Hussain (FH; 2017-18) who used similar methods to analyse a sample of NRLS patient safety incident reports from emergency departments involving diagnostic error, published in BMC Emergency Medicine (see Appendix 1).(8)

I have experience in analysing patient safety incident reports using the multi-axial Patient Safety Research Group (PISA) method based on the recursive model for incident analysis.(76,153) This process however, only allows coding for what is explicitly stated in the report. As a clinician, with a knowledge of NHS structures and processes, and an understanding of patient safety outcomes and factors of the human, I planned to incorporate the realist philosophy of ‘retroduction’ (described in section 2.1.2) into the thematic analysis stage of the PISA method. This can be used to infer why and how these incidents occurred and look for demi-regularities (patterns) to give greater understanding of possible causation that could then be tested in later qualitative work.

2.3.2.1 Data sources

Coroners' reports to prevent future deaths

According to the Coroners and Justice Act 2009, Coroners have a statutory duty to make reports to a person, organisation, local authority, government department or agency if they believe that action should be taken to prevent future deaths.(154) All reports and responses must be sent to the Chief Coroner; most cases are summarised and published on the publicly available Courts and Tribunals Judiciary website.(155) Reports are categorised into 14 categories, see Box 1.

Box 1: Categories of Coroners' reports to prevent future deaths(155)	
1	Accident at work and health and safety related deaths
2	Alcohol, drug and medication related deaths
3	Care home health related deaths
4	Child deaths
5	Community health care and emergency services related deaths
6	Hospital death (Clinical procedures and medical management related deaths)
7	Mental health related deaths
8	Other related deaths
9	Police related deaths
10	Product related deaths
11	Road (highways safety) related deaths
12	Railway related deaths
13	State custody related deaths
14	Suicide

National Reporting and Learning System patient safety incident reports

The NRLS is a database of over 18 million patient safety incident reports from healthcare organisations in England and Wales. A patient safety incident is defined as, "any unintended or unexpected incident that could have harmed or did harm a patient during healthcare delivery".(156) Reporting began voluntarily in 2003 but, since 2010, it has been mandatory to report any incident that resulted in severe patient harm or death. Since the inception of the NRLS, reporting arrangements have included batch returns via local risk management systems, and more recently in England, by direct notification to the Care Quality Commission (an independent regulator of all health and social care services in England). It is the responsibility of the local organisation to have learnt from and dealt with the incident locally but reports are aggregated at a national level to learn from rare events. Reports contain anonymised, structured information about location, patient demographics, and the reporter's perception of harm severity, complemented by unstructured free-text descriptions of the incident, potential contributory factors, and planned actions to prevent reoccurrence.

2.3.2.2 Pilot work

I conducted pilot work with NRLS patient safety incident reports in January 2017, with the support of an Academic GP registrar, Dr Joanna Hyam (JH). We aimed to analyse reports involving GPs working in or alongside emergency departments. We applied electronic filters to the 13,074,550 available reports (2005-2015) for those occurring in urgent and emergency care settings (PD05 filter, n=645,308) and then free text words to identify those involving GPs or primary care services. Consecutive reading of the most recent reports (n=200) however, only identified one relevant report regarding a GP working in the urgent or emergency care setting. In this report, the clinician was referred to as a 'GP streamer' and the report described a missed fracture. Only 1 in 5 reports documented the discipline of the clinician involved in the event (for example, consultant, nurse practitioner etc). In these reports, the 'GP' was generally referred to as part of the patient's journey; for example, 'sent in by GP', 'inappropriate GP referral' or 'GP to follow up'. I concluded at that stage that it would not be possible to obtain a relevant sample of NRLS patient safety incident reports for analysis and planned instead to use local patient safety incident reports collected during our case site visits.

However, early visits to the case sites offered very few local patient safety incident ‘datix’ reports related to the GP service in or alongside the emergency department. Then a tragic event made news headlines in 2017. A 44-year-old male patient presented with breathlessness to an emergency department and was streamed to the ‘alongside’ primary care centre. He did not undergo any acute investigations and his pulmonary embolism was not diagnosed and tragically he died two days later.(157) Events like this unfortunately do occur in healthcare but to understand if there was any learning from this event related to the service model, I looked at the Coroner’s report; this described a diagnostic error.

I then looked for other Coroners’ reports with learning relevant to primary care service models in or alongside emergency departments. The sample of nine relevant Coroners’ reports I identified all described diagnostic error. As described in Chapter 1, diagnostic error is an infrequent but recognised patient safety incident often associated with severe patient harm in emergency departments and primary care. I went back to the NRLS data aiming to filter again for diagnostic error as defined by the reporter, definitions Box 2, and identify a relevant sample of patient safety incident reports to analyse.

Box 2: Diagnostic error definitions(158)	
Diagnostic error	The failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient.
Wrong diagnosis	Occurs, for example, if a patient truly having a heart attack is told their pain is from gastro-oesophageal reflux.
Delayed diagnosis	The diagnosis should have been made earlier.
Missed diagnosis	Medical complaints never explained, or more specific complaints never accurately diagnosed.

2.3.2.3 Sampling strategy

Coroners' reports to prevent future deaths

I reviewed all available reports (2013-2018) in the 'Community health care and emergency services related deaths', 'Hospital Death' and 'Child Death' categories listed on the Courts and Tribunals Judiciary website, Box 1. Reports were included if there appeared to be learning relevant to GP services (including other healthcare professionals within those services) in or alongside emergency departments (inclusion and exclusion criteria shown in Box 3).

National Reporting and Learning System patient safety incident reports

I searched all available NRLS patient safety incident reports (03/01/05-30/11/15) with structured electronic variables (pre-specified by the reporter or their organisation prior to transfer to the NRLS) for emergency and urgent care settings (PD05); then the free-text with GP and primary care terms to identify reports regarding primary care services in these settings; then using structured variables for diagnostic error as defined by the reporter (IN05). After this three-stage filtering process, I read the reports to determine if they were relevant.

Box 3: Inclusion and exclusion criteria
Inclusion criteria • Reports describing diagnostic errors with learning relevant to GP services in or alongside emergency departments **Exclusion criteria** • Reports involving community 'in-hours' or 'out-of-hours' GP services not occurring at the same geographical location either within or alongside emergency departments • Diagnostic errors occurring during usual emergency department service provision

2.3.2.4 Data analysis

I based analysis on the three stages of work to generate learning from patient safety incidents, described in the multi-axial Primary Care Patient Safety (PISA) Classification System.(1) These include:

1. Familiarisation and data coding, based on the recursive model for incident analysis
2. Generation of data summaries, using descriptive statistical analysis, to describe the frequency and burden (harm) of incident types and key relationships with contributory factors, based on Tukey's exploratory data analysis approach.(159)
3. Interpretation of themes and learning, seeking to understand the most commonly identified patient safety themes and contexts within which they occur. At this stage I also applied the realist philosophy of inference (retroduction) for theory development and refinement.

1. Familiarisation and data coding

This involved reading the free text component of each report and coding information in relation to: the *primary* safety incident, the event that was reported to have directly affected patient care (e.g. delayed diagnosis); the *chain of incidents* leading up to the safety incident (e.g. delay in physician receiving test results because of error in communication between healthcare professionals); other independent patient, staff or system *contributory factors* or potential explanations (e.g. inadequate protocol for follow-up of test results); and reported patient *harm outcomes* with harm severity classified from the free text report according to WHO International Classification for Patient Safety definitions.(160) I classified diagnostic errors according to the Society to Improve Diagnosis in Medicine (Box 1),(158) see example Table 2-3. FH double coded 20% of reports to ensure a consistency of approach.

Example of a NRLS patient safety incident

> *"The patient had attended the* ***emergency department*** *with difficulty in breathing. After rapid assessment he had been* ***transferred to the UCC*** *(urgent care centre) as it was deemed that his condition had stabilised. While in rapid assessment* ***bloods had been taken but this had not been handed over to the UCC****. In UCC the patient had been assessed and it was determined he was well enough to be* ***discharged, without his blood results being looked*** *at as the staff in UCC were unaware bloods had been taken. A haematology doctor had looked at the results later and discovered that the patient had an* ***acute leukaemia and needed urgent admission****. By this time the* ***patient had been discharged****."*

Table 2-3: Multi-axial PISA classification of the above patient safety incident

	Primary incident type	Contributory incident	Contributory incident	Independent contributory factors	Patient harm as a result of the incident
Description	The patient safety incident that directly affected patient care	Other incidents that may have led to primary incident type	Other incidents that may have led to primary incident type	System, patient or staff factors that may put the patient more at risk of the incident occurring	Classified according to WHO definitions(160)
Example using the incident report above	Delayed diagnosis	Delay in physician receiving test results	Error in communication between healthcare professionals	Inadequate organisational protocol for follow up of blood tests taken in the emergency department	Unknown harm to patient

2. **Generation of data summaries**

I exported the codes into Microsoft Excel for mac (version 16.35) and used pivot tables to explore which contributory incidents, and the chain of incidents, were most frequently associated with each diagnostic error type. I also explored which presenting complaints resulted in the most severe patient harm and other contributing patient, staff or organisational factors.

3. **Interpretation of themes and learning**

I used thematic analysis to identify and describe recurring themes (not captured by the quantitative data) that could be targeted to mitigate future similar incidents,(1) incorporating realist methodology to infer why incidents may have occurred, to whom, in what circumstances and why.(118) I used the initial rough theories developed from the rapid realist review as a template for mapping supporting data on the Microsoft Excel spreadsheet. If the data gave additional information to explain how and why the event may have occurred, for example, how errors in communication may lead to patient safety incidents, I added this information to the CMO configuration to refine the theory.(118) I used new information, not included in my initial rough theories from the review, to develop new initial theories.

2.3.2.5 Stakeholder expert group feedback

To minimise my personal biases and, as per realist methodology, include expert advice and opinion, I regularly discussed findings within the local Cardiff team (ME, FD, AE), with my PhD supervisors (AE, ACS, NS, HS) and I formally presented the findings of this work to the ‘expert stakeholder group’ at a co-applicant study meeting in November 2018. This was the same group involved in the rapid realist review including patient safety experts (Mr Peter Hibbert, Dr Andrew Carson-Stevens), an emergency medicine consultant (Dr Thomas Hughes) patient representatives (Ms Bridie Evans, Ms Julie Hepburn), a GP with expertise in realist methodology (Dr Freya Davies) and other GPs in EDs team members. The theories developed from this work are presented in Chapter 4.

2.3.3 Qualitative methods at case study sites

I visited a purposive sample of case study sites to collect qualitative data and address objective three to, “Explore factors that influence patient safety at case study sites,” I will first describe how the purposive sample of case study sites was selected for the GPs in EDs study and then the qualitative methods used to address this objective.

2.3.3.1 Case site selection

Case sites for the GPs in EDs study (and this thesis) were recruited from a sample of Type 1 emergency departments in England and Wales,(6,10) that responded to the GPs in EDs national survey, followed up by a key informant telephone interview with the clinical lead.(161)

National survey

Rebecca Sherlock (RS), Academic GP Fellow, led the development and administration of an online survey assisted by the Cardiff GPs in EDs study team (AE, ME, FD, AC) and the University of the West of England (UWE) GPED team led by Jonathan Benger (JB) (funded by NIHR under the same HS&DR call) to send a joint survey. I contributed ideas for questions based on findings from the review.

The survey was administered through online surveys (www.onlinesurveys.co.uk), to capture data about what GPs services in or alongside emergency departments looked like and how they worked (published as supplementary information with the EMJ taxonomy concepts paper).(6) To design the survey we referred to study objectives and findings from recent systematic reviews from which we had started to develop initial theories about these services,(34,36,151) and a similar survey conducted by the Primary Care Foundation in 2010.(35) Topic areas included: the distance of the GP or primary care service related to the emergency department; disciplines of primary care staff providing the service (GPs, nurse practitioners etc); how and what type of patient groups were selected for the service; use of investigations; funding and governance arrangements; the aims of the service and whether these had been achieved; enablers and barriers to setting up the service; and changes made or planned for the future. We planned that it would take about ten minutes to complete and used multiple choice questions and additional space for free text comments. We ran a pilot with our co-applicants and local academic GPs and revisions were made.

Delyth Price (DP), study administrator, sent an invitation email to participate in the survey to the clinical directors of all Type 1 emergency departments in England (n=171) and Wales (n=13) from the principal investigators from the Cardiff and UWE teams (AE and JB). Clinical directors were first contacted on 13th September 2017 and a reminder email was sent on 27th September 2017. The study was advertised in the UK Royal College of Emergency Medicine (RCEM) monthly news bulletin. Co-applicants (Matthew Cooke and Tim Rainer) sent a further follow-up email in October 2017 to non-responders to encourage participation and the survey was kept open until 28th February 2018. Data from online survey responses were exported onto a secure database at Cardiff University.

We had 71 English and 6 Welsh survey responses (n=77/184, 42%), completed by medical directors, clinical directors or emergency department consultants.(6) The UWE GPED team also provided data for 41 English departments from additional data sources, totalling information on 62% (n=118/189) of Type 1 emergency departments in England and Wales. Of our 71 English survey responders, 82% (n=58/71) applied for capital bid funding, and of our 100 non-responders in England, 84% (n=84/100) applied for capital bid funding indicating no non-response bias.

The data demonstrated the complexity of models in use and inconsistency in the language being used to describe the different services. I was involved in screening the survey responses (with ME and RS) to identify a purposive sample of potential case sites, classified according to our taxonomy,(6) to visit for in-depth qualitative data collection. We developed an excel spreadsheet listing the variables in Box 4 to ensure we selected sites covering a range of contexts. For potential sites, we arranged a key informant telephone interview with the survey responder to clarify responses and request further information if needed to inform selection.

Box 4: Variables used to select a purposive sample of emergency departments

- GP service implemented in the emergency department since 2010 in order for the GPs in EDs study to carry out an interrupted time series analysis with intervention and control sites for comparison of outcomes associated with each model and overall GPs versus no GPs in EDs
- Different service models: Inside integrated; Inside parallel; Outside on site; and control sites with no GPs
- Spread of geographical location in England and Wales
- Variety of contexts – including hospitals in rural and urban locations/towns, small and large hospitals, higher vs lower attendances
- Variation in streaming method – who streams, streaming criteria and guidance
- Variation in the physical layout of the department
- Variation in relationship with the GP out-of-hours service

Follow-up telephone interviews with senior clinical managers

Dr Michelle Edwards led this work. I interviewed four of the 21 participants. Following the interview, 30 survey respondents were invited to participate in a telephone interview. Nine declined to take part or did not respond to invitations and 21 participated in an interview.(161) The interview period was from December 2017 to December 2018. Interview guides were semi-structured but also individualised to obtain more detail about survey responses and gain a better understanding of local context. The interviews aimed to explore what factors contributed or impeded the way the services worked and what the perceived outcomes were. All clinical directors were asked about patient safety concerns and I included these data in my qualitative analysis.

Included sample

Selecting a range of small and large hospital sites from urban and rural areas, with implementation dates from 2010 (for the quantitative interrupted time series analysis), and also communicating with the UWE team so that we did not both contact the same sites, limited the options for study site invitations. Co-applicant contacts were used to assist making contact with potential sites (Matthew Cooke and Tom Hughes).

If the site met recruitment criteria, the clinical director that had participated in the telephone interview was sent a formal invitation letter to be a case study site (Appendix 6). This also requested that the clinical director acted as a local collaborator for the project to help facilitate the visit and outlined what would be involved. The letter specifically requested access to local patient safety incident (datix) reports for analysis.

> *"A member of the research team with expertise in evaluating patient safety data, Dr Alison Cooper, will also review a sample of patient safety reports from e-Datix or your local reporting system. The analysis of these data from our 12 case study sites will improve understanding of how different GP-ED models can contribute to patient safety incidents and ways to mitigate such events."*

The included sample of case study sites in the 'GPs in EDs' (and this) study, classified by the updated taxonomy described in Chapter 1, section 1.1.4 (see Figure 1-2) were:

- 3 inside integrated models
- 4 inside parallel models (one was reclassified following the visit)
- 3 outside on site models
- 3 control sites (no GPs)

The nature and complexity of these services are described in Chapter 5. Off site models were not included because they were beyond the scope of the study.

2.3.3.2 Pre visit preparation

The clinical director acting as the local collaborator was sent an email a month before the three-day visit to clarify arrangements, as per the 'outline of research activities', (Appendix 7). Mindful of the pressurised environment, an introductory tour and access to the department was requested but then ME and I planned to work independently, spending time in different areas of the department including reception, streaming and clinical areas. Information leaflets and posters for staff were also attached, so they were aware of our forthcoming visit.

The email included a request for any relevant local patient safety incident (Datix) reports regarding the associated GP service. The request was for 'whatever they had' – incidents since the service had started, in the last year or whatever was available. During the visit, I took responsibility for collecting and analysing these.

Before each visit, ME and I met to discuss the forthcoming visit and prepare our researcher packs. As well as a password protected Dictaphone and a separate A5 hardback notebook for each visit, we took a folder of documents listed in Box 5.

Box 5: Researcher documents for case site visits
• the letter of access; • the transcribed clinical director telephone interview; • the most recent CQC* report for the emergency department; • the full list of theories developed from the rapid realist review the team had agreed to take forward to test at our case study sites; • interview guides for key staff members e.g. streaming nurse, GPs, (Appendix 8); • information leaflets and consent forms for staff members participating in audio-recorded interviews • patient recruitment packs including inclusion criteria, information leaflets and consent forms (led by ME)

*CQC is the Care Quality Commission, a UK Department of Health and Social Care public body to regulate and inspect health and social care service in England. This document was not available for the Welsh site.

We read the transcribed clinical director telephone interview and from these data discussed how we expected the GP service to function - as a traditional primary care service or more like an emergency medicine service.(6) We then studied the full list of wider study theories, developed from the rapid realist review, that the team had decided to take forward to phase 2 (the case study site visits) and which key theories the context of this site would be useful to test. For example, if the clinical director perceived that GPs admit a smaller proportion of patients than emergency department staff, then I needed to explore why that was the case, if there were any patient safety implications and update my interview guides accordingly. A structured approach was planned over the three days which was shared in advance with the local collaborator, as discussed above (Appendix 7).

2.3.3.3 Data collection

I used three methods of data collection: local patient safety incident 'Datix' reports; observations including informal interviews; and semi-structured audio-recorded realist interviews.

Local patient safety incident 'Datix' reports

These data were useful to understand safety *outcomes*. On arrival at the case study site, if reports had not already been obtained, I repeated the request to the local collaborator. At some sites the clinical director had already liaised with the patient safety unit personally, or delegated this role to a colleague, and reports were then available during the visit. If reports were not available during the visit, I sent follow up emails to the local collaborator requesting the reports were anonymised and sent via a secure password protected email. I sent reminders up to three times.

A total of four separate requests were therefore made to the local collaborator for any available reports:

1. In the invitation letter to become a case study site
2. The confirming email sent a month before the visit
3. In person on arrival at the department
4. Up to three email requests following the visit

These data were usually in the form of printed anonymised reports that were given to me in person by the local collaborator during the case site visit. On site, in a private area, I was able to remotely access a secure computer platform (PISA platform) at Cardiff University that I had used previously for similar projects, using my MacBook Pro laptop (version10.14.6).(2,75)

I copied the free text from relevant patient safety incident reports (including grammatical errors and spelling mistakes) directly onto this platform for analysis at a later date, making a note of any themes for new theory development that could then be explored on site. I gave the printed documents back to the local collaborator for disposal and did not take any printed copies of the reports off site. One case study site sent anonymised reports directly from the patient safety unit via a password protected zip file. These were then imported directly onto the PISA platform. Reports were included if there was evidence of a patient safety incident involving the GP service associated with the emergency department. Reports where there was no evidence of a patient safety incident and not involving the primary care service were excluded. No reports were therefore requested from control sites.

Observations

Observations were helpful to understand *context* for theory refining. Ethnography and observation research involves the researcher covertly or overtly immersing him/herself in the setting, watching and listening to patterns of social interactions not only to observe processes but also to elicit culture within the setting.(162) In the pressured emergency department setting, I anticipated that formal discussions with busy staff members would be limited so planned to collect data through observation, taking formal ethnographic training, including writing up field notes, as discussed in section 2.2.3.

The duration of visits was two to four days (mean three days). At all sites, the clinical director met us on arrival to give an introductory tour around the department (visits had been timed around his or her availability for this). The tour usually took 20-30 minutes and was a useful opportunity to follow up any queries from the telephone interview and survey data, gain understanding of how the primary care service worked in or alongside the emergency department and meet key staff members who could assist with our research during the visit. We were then left to work independently and split up so that each of us stayed in separate areas of the emergency department for 1-2 hours at a time for observations.

At all sites, I spent time in the reception and clinical areas (but did not have ethical approval to observe clinical consultations) and observed triage and streaming processes. I was mindful of the pressured environment with busy staff and tried not to obstruct any work. I opportunistically introduced myself to a wide range of staff including experienced and junior emergency department doctors and nurse practitioners, general practitioners, nursing staff, health care assistants and reception and admin staff. If time allowed, I would discuss how the system worked and depending on their role, ask questions to test various theories. For example, for the streaming nurse, I would ask what influenced his or her streaming decisions. At some sites, staff had time for longer discussions and a formal audio-recorded interview would have been more desirable to capture data but there was no quiet, private area to conduct a formal interview so handwritten notes were taken at the time. When it was not possible to talk with staff, I sat or stood in an inconspicuous place and observed interactions between staff and with patients.

I took handwritten notes in a notebook and included diagrams of the geography of the department and photographs of public areas (without identifiable staff or patients) to act as aide-memoires. ME and I met every couple of hours during the day to discuss findings, refer to our list of theories and identify evidence gaps for theory testing to explore. Eight visits were conducted midweek (usually Monday – Wednesday) with six including observations into the evening. Two visits were conducted over a weekend. Where possible an exit interview was held with the clinical director before leaving to validate findings and taken as an opportunity to ask any ongoing questions.

I wrote up my fieldnotes in the hotel room in the evenings of the site visits when events were still fresh in mind. I used the dictating function on my MacBook Pro laptop to create a word document and then read through the notes amending grammar and spelling corrections. Following each visit, I uploaded my fieldnote word documents onto the secure study file on the Cardiff University shared drive and ME did the same.

All case study sites that had an associated GP service (n=10) therefore had two sets of fieldnotes for analysis (AC and ME) and control sites (n=3) had one set of fieldnotes depending on which researcher had visited (AC or ME); total 23 sets of fieldnotes. My fieldnotes for sites with GP services were 10-17 pages long (mean 12 pages), often including anonymised photographs of public areas and diagrams, and ME’s notes were 4-11 pages long (mean 8 pages). Field notes for control sites were 3-5 pages long. Findings were shared with the study team, including the health economist, for feedback and whether any iterations were needed.

Staff semi-structured realist interviews

Staff were recruited during case site visits for realist interviews. The focus of these interviews was to identify *mechanisms*. Before these visits, I expected the focus to be on exploring how and why patient safety incidents occurred. However, the purposively selected case study sites that had chosen to be involved in this study had few patient safety incidents to report. The focus then shifted to how in the different contexts, with an understanding of how patient safety incidents may occur from the initial rough theories, GPs delivered safe patient care in or alongside emergency departments. For example, I explored how GPs perceived working in the emergency department affected their reasoning processes and subsequent outcomes. I focussed on recruiting GPs (introducing myself as a GP) and also interviewed nurses and nurse practitioners. I used an interview guide based on specific theories I wanted to test (Appendix 8). I used the recognised realist teacher-learner interview technique, where the initial theory is presented to the interviewee and explored whether this idea is correct or not.(146)

Where possible I analysed the local patient safety incident forms on day 1 of the visit so that I could discuss any safety outcomes identified with staff members on the site. I asked all staff I formally interviewed about patient safety concerns with the associated GP service. If a key informant was identified and consented to an interview but this was not possible at the time, I conducted a telephone interview following the visit, usually within a few weeks while the visit and local context was fresh in mind.

Audio-recorded interviews were downloaded from the password protected Dictaphones the next working day following the case site visit and saved as audio files on the secure Cardiff University shared drive. These were then transcribed verbatim inhouse (DP) or outsourced (Essential Secretary Ltd) and again stored on the same shared drive.

2.3.3.4 Data analysis

Local patient safety incident 'Datix' reports

I coded reports that described an incident involving the GP service in or alongside the emergency department using the same multiaxial PISA coding framework, described in section 2.3.2.4, that I applied when analysing the national patient safety incident reports (NRLS and Coroners' reports).(1) I identified the primary incident type closest to the patient, and any contributing incidents using the principles of recursive analysis. I also coded any other independent system, staff or patient factors and the resulting patient harm (WHO definitions).(160) Using the same approach described in section 2.3.2.4, I undertook exploratory descriptive analysis to assess the most frequent and most harmful primary incident types in the sample, the associated chain of incidents, and other contributory factors.(1) I then used realist principles, as described in section 2.3.2.4, to infer why incidents may have occurred in that context to refine my initial rough theories or develop new theories as context-mechanism-outcome configurations.

Observation and interview data

I created a separate NVivo 11 (QSR International) folder for each GP service model (inside integrated, inside parallel, outside onsite and control) which included all observation and interview data for each site. A separate folder was also created for the clinical director interview data for sites that had not been visited. I started by analysing the clinical director interviews (including those sites not visited) and the control sites, to create a coding framework. This was based on the themes from the initial rough theories and planned to be used for each service model folder. I then analysed the folders separately, one case site at a time, starting with the inside integrated models then the outside onsite models (models I expected to be at the extreme of the integration spectrum). I then moved onto the inside parallel sites, where I expected there to be some variation in the function of the services overlapping with the previously analysed models.

I coded the data using ‘if, then, because statements’. These are statements to explain the minutiae and nuances of different mechanisms in different contexts that produce outcomes, evident from the data.(163) The statements were grouped into positive and negative outcomes under the main theory theme headings in the coding framework – for example, ‘if then because’ statements describing why streaming statements were perceived to be appropriate or not were grouped under the theme ‘streaming’. Data that supported an ‘if then because’ statement already created were coded under the same statement but due to the detail of each statement, multiple ‘if then because’ statements were generated.

2.3.3.5 Data synthesis

There were too many ‘if then because’ statements generated to transfer the coding framework across to each NVivo file for each model as originally intended. Therefore, high level themes and positive and negative outcomes, grouped with mechanisms at the individual level, the department level and the wider system level, were used as a coding framework to categorise the statements across folders. As a study team (ME, FD, AC) we agreed to classify the level of qualitative evidence supporting these statements in a hierarchy based on meta-ethnography principles, Box 6.(164)

Box 6: Hierarchy for classifying qualitative evidence (164)
Level 1: Observations Level 2: How participants say they behave Level 3: How participants say others behave Level 4: My interpretation

There were multiple ‘if then because’ statements generated in each folder (inside integrated (n=145), inside parallel (two folders: n=166 and n=78), outside onsite (n=128). I exported these statements into a Microsoft Excel document (Mac version 16.35), one page for each model type, to develop into CMO configurations - the ‘if’ became the context, the ‘then’ became the outcome and the ‘because’ became the mechanism(s). I then consolidated the CMO configurations using the three questions, based on the conceptual platform by Person et al.,(163):

1. Is this account novel (and can therefore be imported directly into the CMO)?;
2. If the account was not novel, does this challenge the explanations made in related accounts?; or
3. does this account add important refinements to the understanding of contexts, mechanisms or outcomes?

Once I had developed CMOs for each service model, I created an excel page for each of the main patient safety themes to map and analyse CMOs between service models. I used a colour code for each service model type to act as an aide-memoire from which data they had been generated. The local patient safety incident ‘Datix’ report data were added in at this stage to support existing CMOs or generate new ones.

The CMOs were then synthesised using Pawson’s theory-building processes as discussed in section 2.3.1.7. *Juxtaposition* principles were used when outcome data reported in a Datix incident report (e.g. patient ‘lost’ from the computer system) could be explained by observation or interview data (e.g. observing reception staff managing three different computer systems to book patients onto). *Reconciliation* principles were used to explain contextual differences that may have resulted in contradicting outcomes (e.g. why a GP may use acute investigations in some service models but not in others even when they are available in both; or why GPs use investigations differently in the same service model). *Adjudication* principles were used to evaluate methodological differences, so as discussed, I used a hierarchy to classify different levels of qualitative evidence. Theories that resulted in the same outcome could be *consolidated* across service models into a multifaceted explanation (e.g. experienced nurse and guidance based on the local primary care service facilitated appropriate streaming decisions) and rival explanations could be *situated* depending on which mechanisms were activated in which contexts (e.g. inexperienced nurse, guidance not modified for the local primary care service.)

I then developed a master excel file to capture the whole process and populate the evidence (where available) for refined CMO development. I labelled the columns as:

- theme;
- initial CMO following pilot literature review and expert group input;
- refined CMO following rapid realist review;
- CMO following NRLS and coroners' reports analysis;
- refined CMO following qualitative data analysis (including 'Datix' reports);
- supporting 'if, then, because, statements' and the level of qualitative evidence;
- verbatim quotes to support the CMO.

The overall programme theory generated from this process of synthesising and integrating the CMOs into refined theories is presented in Chapter 6.

2.3.4 Stakeholder engagement to explore areas of measurement for theory testing

To address objective four and explore areas of measurement that could be used to test and therefore operationalise these theories in practice, I took my findings to the GPs in EDs stakeholder event. I prepared in advance potential areas of measurement that I could take to the group, structured around Vincent's framework,(110) which I presented in a morning workshop including an interactive online presentation (menti.com) and feedback from small group discussions.

2.3.4.1 Stakeholder recruitment

Stakeholder involvement is key in realist methodology – to provide expertise to help generate initial rough theories and validate refined theories.(118) The 'GPs in EDs' second stakeholder event was held in December 2019 in Bristol. All attendees from the first event were invited and participants from case study sites. Nurse practitioners were actively encouraged to attend due to low numbers of this healthcare professional group at the first stakeholder event. Representatives from the Royal College of Emergency Medicine and Royal College of General Practitioners and key members from the other NIHR funded study 'GPED' (UWE) were invited individually by email.

2.3.4.2 Pre-event preparation of potential measures

As described in Chapter 1, there are a number of safety theories, or conceptual approaches, that have been applied to healthcare to understand how patient safety outcomes are a product of the systems around them rather than seeking to blame individual fault. These include:

- James Reason's safety as defences in depth;(80)
- Charles Vincent and James Reason's systems safety in healthcare;(105)
- The Berkeley's High Reliability theory and safety;(165)
- Karl Weick and Kathleen Sutcliffe's safety as collective mindfulness;(93)
- Rene Amalberti's system dynamics and safety;(97) and
- Erik Hollnagel's safety as resilience.(43)

Vincent synthesised these theories to develop a framework to describe how to measure and monitor safety in health care settings.(110) The framework consists of five areas to consider:

1. Past harm: has patient care been safe in the past?
2. Reliability: are clinical systems and processes reliable?
3. Sensitivity to operations: is care safe today?
4. Anticipation and preparedness: will care be safe in the future?
5. Integration and learning: is the organisation responding and improving?(110)

Indicators, or measures, are also described. Some are *leading* (measures that predict whether an event will occur) and others *lagging* (measurements that are made after an event has occurred). I chose to apply this framework to identify potential areas for measurements because I did not want to be limited by measures I was familiar with or that are routinely used. Learning from these theories, often developed in industry, may improve understanding about how healthcare organisations can continuously adapt, in the face of dynamic risks to patient safety, to maintain failure-free performance most of the time and how potentially this can be measured and monitored.(110) I also took measures from the Royal College of Emergency Medicine (RCEM) 2019 Safety Scorecard.(166)

I used this framework to structure my findings to explore different areas of measurement to test these theories which I summarised in a driver diagram. This is a quality improvement tool used within the NHS to define ideas for change for an improvement project.(167) I chose this tool to present my findings at the stakeholder event because it is used within the NHS and therefore may be familiar to NHS staff and because it illustrates key messages from context-mechanism-outcome configurations which if presented in prose can be lengthy, wordy and difficult to follow.

2.3.4.3 Interactive online presentation

I imported a Microsoft PowerPoint presentation (Mac version 16.37) into an interactive online presentation (*menti.com*), accessible via smart phones and iPads. Attendees had been asked in advance to bring their portable electronic devices along to the session. There were also a number of iPads available if needed, and use of these was requested by some of the PPI contributors.

The session was largely a PowerPoint presentation to describe my findings but included several *menti.com* questions for live feedback, displayed as either bar graph of multi-choice options or free text comments. I started by asking attendees which multidisciplinary group they would put themselves in and whether they had an interest in patient safety outcomes. They were then asked to submit free text comments about any patient safety concerns they had about GPs working in or alongside emergency departments. My aim was to summarise and feedback comments to the audience and to identify if there were any patient safety concerns I had not covered that needed to be addressed.

I presented an overview of my findings from the rapid realist review (Chapter 3), the Coroners' and NRLS incident reports (Chapter 4) and the case study sites (Chapters 5&6) concluding with the three main safety theories of the programme theory: streaming, clinical decision-making and communication between services. Following the presentation of each theory, I used *menti.com* to ask stakeholders to vote on whether they felt three suggested measures to test each theory were: useful and measurable; useful but difficult to measure; or not useful. The purpose of this exercise was to encourage stakeholders to consider which measurements would be (and would not be) most useful, to later discuss in small groups.

Attendees were then asked to choose one theory and potential measures to discuss in more depth and, during a small break, to move to a table with the relevant label. Tables were labelled as follows: streaming (n=3 tables); clinical decision-making (n=2 tables); and communication (n=3 tables).

2.3.4.4 Small group facilitated discussions

A modified nominal group approach was taken. This process is a structured face-to-face meeting of experts, led by a moderator, that aims to provide an orderly procedure for obtaining qualitative information at the early stage of a consensus exercise.(168) Usual steps include:

- firstly, asking participates to individually list their ideas on a given topic;
- then in a round robin fashion, individuals present their ideas until the supply of ideas is exhausted;

- a highly structured session then follows where ideas are clarified and evaluated;
- finally individuals privately rank (in writing) their ideas.(168)

My aim of the session was to explore which areas of measurement stakeholders perceived were most useful and why (or why not). Also to suggest any other areas of measurement not included. Due to time constraints I had prepared a list of potential measures associated with each theory as a starting point for discussions (Appendix 9). I also used the *menti.com* electronic voting exercise to introduce the concept that a measure may or may not be useful and measurable, to help to prioritise indicators. This was similar to a study prioritising novel and existing ambulance performance measures.(169) I gave participants the option of discussing a theory about which they felt they could most contribute, to encourage them to voice their own ideas.

Each table (of planned 8-10 participants) was led by a facilitator, a member of the study team. Facilitator guidance was shared in advance of the event (Appendix 9) and I was available before the sessions to answer any queries. Each theory had a worksheet printed on A4 paper for each participant with the relevant section of the driver diagram and potential associated measures (Appendix 9). Facilitators handed out the worksheets to each participant on the table and collected them in at the end.

Participants were invited to introduce themselves and then work through the three questions on the worksheet as a group, with the facilitator encouraging equal participation and taking notes. They were encouraged to suggest other patient safety concerns not covered and any ideas for improvement and measures not listed. The three questions were similar for each theory:

1. Are the ideas for improvement and potential measurements useful (or not), Can you suggest others?
2. What are your top three most useful and practical measurements to evaluate safety in this area and why?
3. Can you share learning from good clinical practice?

At the end of the session, following group discussions, attendees were asked to individually indicate their three priority measures on their A4 sheet which were collected in by the facilitator. Facilitators at each table summarised discussions to plenary where notes were taken (DP and NP). Qualitative data were captured through facilitator notes and plenary feedback, participant handwritten comments on the A4 sheets and free text comments on menti.com in response to 'Any other comments?'(169,170) Menti.com results were exported into Microsoft Excel (Mac version 16.37). Results from this work are described in Chapter 7.

2.3.5 Using formal theory to explain findings and inform intervention development

To address objective five, I will explain how I used the lens of formal theory to structure findings and offer explanation for the causal relationships described in the programme theory (Chapter 6) and consider stakeholder feedback (Chapter 7) when informing intervention development. Firstly, I will describe my process for formal theory selection.

As part of a realist inquiry, Pawson and Tilley make use of Merton's concept of using *middle-range* (or formal) theories, to explain causation in programme theory.(118,171) Middle range theories are described as lying "between the minor but necessary working hypotheses that evolve in abundance during day-to-day research and the all-inclusive systematic efforts to develop a unified theory that will explain all the observed uniformities of social behavior, social organization, and social change."(171) Pawson argued that using this knowledge from social middle range theory, it was possible to develop a wide range of testable propositions (CMOs). Pawson gives examples of using education mechanisms and crime prevention mechanisms in his work, suggesting that the propositions, "do not have to be developed de novo on the basis of local wisdom in each investigation."(118)

GPs' clinical decision-making was identified in Chapter 6 as a major mechanism for delivering safe patient care and I have therefore focused on clinical decision-making whilst exploring formal theory. I was already aware of Croskerry's dual-process model of reasoning,(82,83) from my medical training, and following suggestion by the expert stakeholder group in the rapid realist review (Chapter 3). I did not know however, if other formal theories to describe GPs' clinical decision-making would offer alternative or further explanation. I therefore undertook a systematic approach to identify articles that used formal theories to explain GPs' clinical decision-making to explore which formal theory would be most appropriate to apply to my findings.

2.3.5.1 Search strategy

I applied the recognised BeHEMoTh framework, described by Booth (2015), to develop a database search strategy, Box 7.(172) I searched Medline, Embase and Psycinfo databases on 24th April 2020. I listed formal theories identified from title and abstract screening. I then used internet search engines (google and google scholar) to research definitions for these theories. I read the full text article for all articles that that described a clinical decision-making theory to gain understanding about the theory and how it had been applied. My aim was to identify a formal theory that would help explain my findings about GPs' clinical decision-making in emergency department settings.

Box 7: Database search strategy

1. 'Theory of Mind'/ or Social Perception/ or theor*.mp
2. Models, Theoretical/ or framework*.mp
3. Concept*.mp
4. Clinical decision-making.mp or Clinical Decision-Making/ or Decision Making/ or Primary Health Care/
5. General practitioner.mp or General Practitioners/
6. 1 or 2 or 3
7. 4 and 5 and 6
8. Limit 7 to (english language and humans)

The results of this search strategy and how I applied this formal theory to my findings and inform intervention development is described in Chapter 8.

3 Initial theories from the rapid realist review

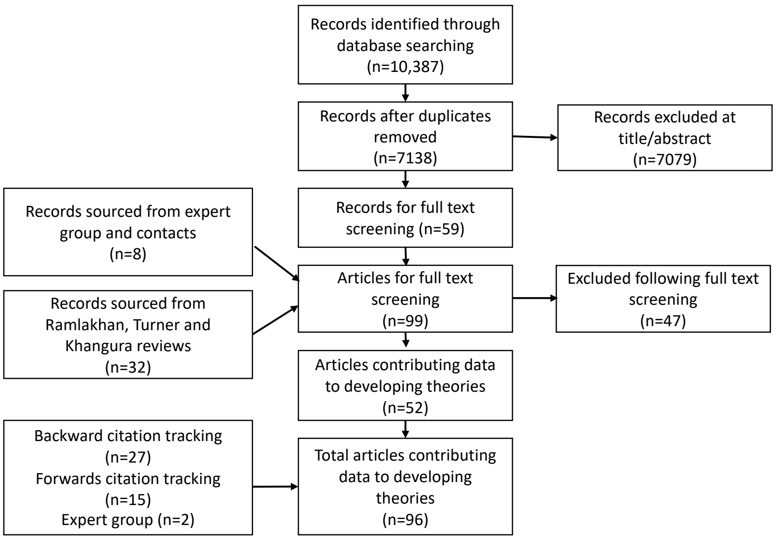
This chapter describes the results of the rapid result review presented as context-mechanism-outcome configurations, initial rough theories. This addresses objective one, to review patient safety outcomes when GPs work in or alongside emergency departments.

3.1 Overview of review results

Figure 3-1 shows the search strategy and results. An extensive review of the worldwide literature, supplemented by snowballing techniques from recent systematic reviews and 10,387 initial hits (7138 with duplicates removed) from updated database searches, resulted in a total of 96 included articles from 13 high-income countries. These were largely primary research studies involving patients with primary care problems directed to GPs for treatment. Most articles were from the UK (n= 44 articles), with a large contribution from The Netherlands (n=17). Others were from Ireland, Belgium, Switzerland, Sweden, Italy, Finland, Australia, United States of America (US), Canada, Singapore and New Zealand. Full details of all included articles are listed in Appendix 10.

The review highlighted an evidence gap in the literature for patient safety outcomes when GPs work in or alongside emergency departments. Several studies used reattendance as a marker of safety with no increase among patients seen by GPs, compared to usual emergency department staff.(149,150,173–175) Annual death rates were used as another crude marker in a Dutch study, with no significant increase following the introduction of an out-of-hours primary care physician cooperative.(176)

Figure 3-1: Search strategy and results
(reproduced from Cooper et al. BMJ Open 2019;9:e024501, CC BY license)(5)



Shared or separate governance systems between the GPs and the emergency department were rarely described in the primary studies, providing no evidence for best practice.

I developed theories as part of the wider review to explain how patients are streamed to GPs and help understand the role GPs may adopt in the emergency department setting: gatekeeper; traditional; extended; or emergency clinician.(5) In two London Case reports, GPs were described as adopting a ‘gatekeeper’ role, screening patients at the front door to redirect patients presenting with primary care problems out of the emergency department to alternative primary care services off site.(177,178) Most primary studies however, involved GPs using the same ‘traditional’ approach taken in the primary care setting, with a resultant reduction in the use of investigations and hospital admissions.(23,28,149,173,179–188) In other studies, these traditional GP skills were ‘extended’ towards a specific patient group, namely non-urgent paediatric patients, to reduce the use of hospital resources and admissions in this patient group.(37,182,189–191) There were limited data to support GPs adopting an ‘emergency clinician’ role – in these studies, the emergency department GPs were relatively inexperienced and also saw patients referred in from local primary care. (187,192)

These theories, published in the BMJ Open paper, add context to the way in which GPs may work in different service models.(5) This allows development of further theories to explain why and how patient safety outcomes may potentially occur in these different service models.

3.2 Initial rough safety theories

Despite focussed searches for evidence in the literature, minimal data were available from the included 96 articles to develop theories to explain why and how patient safety outcomes may occur. I therefore developed these theories from limited data sources with contributions from the stakeholder expert group and formal theory. These are described as context (C) – mechanism (M) - outcome (O) configurations and grouped into three sequential processes of care:

- streaming and redirection decisions;
- influence on GPs’ clinical decision-making; and,
- inadequate communication between services.

These initial rough theories were then used as a platform for theory development and refinement for remainder of this thesis.

3.2.1 Streaming and redirection decisions

If patients present to the emergency department with primary care problems (C)

the streaming nurse may use his/her personal experience and expectation to influence ***how streaming guidance is interpreted*** *(M)*

and inappropriate patients may be streamed to the GP service (O).

In the included studies, streaming was generally described to be combined with the triage assessment rather than as a separate process. A theory developed as part of the wider review described variable streaming rates (O) due to differences in guidelines (Mresource) and also how guidelines were interpreted by emergency department clinical and non-clinical staff with varying experience and expectation (Mreasoning).(5,187,192–195) For example, streaming decisions were described to be influenced by the nurse being more familiar with emergency medicine so favouring emergency department referral, even overruling the guidelines if he/she felt that the patient would require specific investigations or admission (Mreasoning).(35,183,187,195–197) GPs were also described overriding nurse decisions, to select patients that suited their own interests or perceived skills (Mreasoning).(198)

There was some evidence that streaming nurses may be unclear which patients are appropriate for the GP service (Mreasoning) (example below).(23,28,187,195,196,199,200) I therefore developed a theory that consequently, inappropriate patients may be streamed to the GP service (O). Since, increased streaming rates were reported when there was a good relationship between the GPs and emergency department nurses (C),(193) and when the GPs were directly involved in the streaming process (Mresource),(190,201) these factors may also facilitate appropriate streaming decisions.

> *“If you actually talk to the GPs, they’re actually saying the cohort of patients that they’re getting through are* ***not suitable*** *because they’re minor injuries and* ***we’re not trained in minor injuries****.” (Consultant)* (187)

If patients present to emergency departments with primary care problems (C)

*and are screened by GPs working in a ‘**gatekeeper**’ role on the front door, relying on their generalist skills rather than a comprehensive assessment including vital signs (M)*

*this may result in **inappropriate streaming/redirection decisions** and delayed patient assessment and treatment (O)*

There was limited evidence to support GPs using their generalist skills and knowledge of community resources (Mreasoning) to redirect patients with primary care problems back into the community for treatment (O). Two London case study reports identified in an “A&E avoidance” scheme document, described 228 patients in total.(178,202) There was evidence that GPs were more likely to redirect patients after an initial assessment than senior emergency department nurses, but only from a sample of 384 patients that self-presented to a London emergency department.(177)

Due to a lack of evidence for GPs performing a redirection role, following realist methodology, I also included studies involving redirection of patients from the emergency department by a senior emergency department clinician or nurse to gain understanding about how and why the system worked and safety implications. Many of these articles described reduced attendances because of the intervention (O).(203–209) Previous UK guidance has cautioned redirecting patients from emergency departments due to the risk of delayed assessment and treatment (O), especially in vulnerable patient groups including the homeless or those with mental health problems (C), but there were limited evidence of harm.(35,37)

Studies from Scotland, Sweden and the US that described a comprehensive assessment process involving measurement of vital signs and a focussed history (Mresource), reported that their redirection policies were safe and worked well to reduce attendances (O) (example below).(204,206,208–210) Other US studies, that did not describe a comprehensive assessment process as described above, reported adverse events when children were redirected without treatment (O).(211,212) The low sensitivity of triage criteria to identify those that needed urgent care,(213) especially infants,(214) and failure to validate a predictive model for refusal of care,(215) were highlighted in other studies.

"Our redirection policy provides a ***safe and effective*** *means of directing patients to more appropriate care."*(216)

3.2.2 Influence on GPs' clinical decision-making

In the emergency department setting where there is a higher pre-test probability of serious illness than in usual primary care (C)

GPs may be influenced by the prior decision-making of the streaming nurse and therefore be at risk of ***framing*** *or* ***anchoring*** *cognitive biases* (M)*

or may incorporate their usual community pre-test probability of serious illness into their diagnostic reasoning and be at risk of ***availability or representativeness*** *cognitive biases (M)*

and may therefore be more ***at risk of under-investigation*** *and* ***diagnostic error*** *than they would if working in their usual community setting (O)*

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*cognitive biases described later in this section

Studies showed a reduction in the use of acute investigations by GPs compared to emergency department staff (O), example extract below.(183–187) This was seen to be maintained in a variety of different settings despite full access to investigations: when GPs were allocated a separate consulting room mimicking usual general practice (Mresource);(23,28) and also when GPs worked in a more fully integrated model, alongside emergency department clinicians (Mresource).(173,185,186)

> *"Primary care consultations made by accident and emergency medical staff resulted in considerably* ***greater utilisation of hospital investigation and specialist resources*** *than those made by sessionally employed general practitioners."*(28)

There was no evidence in the included studies for the influence of working in an emergency department setting on GPs' cognition processes and risk management behaviour (Mreasoning), influence on the use of acute investigations (O), and the effect of this on patient safety outcomes (O). The stakeholder expert group however suggested specific cognitive biases (Mreasoning), which the GPs may be at risk of in these settings that could put them at risk of diagnostic error (O). The stakeholder group's expertise was informed by a knowledge of formal clinical decision-making theory which for clarity of explanation I will now address further.

Kahneman describes two distinct decision-making processes. 'System I' is fast, effortless, intuitive and automatic while 'System II' is slow, laborious and logical.(81) System I is considered typical of the diagnostic decision-making process of experienced clinicians who rely on pattern recognition or shortcuts (heuristics, rules of thumb), as opposed to the problem-solving, hypothesis testing System II approach of novices, described as a dual-process model of reasoning by Croskerry.(82,83) These processes may occur simultaneously, if the initial presentation of the illness is recognised then System I will engage. However if it is not recognised then the analytical processes of System II engage instead. (82,83) This model fits with the hypothetico-deductive model developed by Elstein and Schwarz where the clinician develops early hypotheses through pattern recognition (System I) then iteratively tests them (System II).(217,218)

However, the System I approach risks errors due to cognitive biases. The expert stakeholder group, identified specific biases of which GPs working in emergency departments may be at risk. These are: the ‘framing’ bias where clinicians are at risk of being swayed by the way in which the problem is presented (by another healthcare professional) and the ‘anchoring’ bias, where they may lock on the initial diagnosis (‘premature closure’), seek data to confirm this (‘confirmation bias’), sticking to a potentially incorrect diagnosis (‘tramlining’) rather than refuting this initial diagnosis. Therefore, GPs seeing patients already assessed as low risk by the streaming nurse or another healthcare professional, may have cognitive biases influencing their clinical decision-making rather than if they were working independently, as they would usually do.

Other biases raised by the stakeholder expert group to potentially affect GP clinical decision-making, were those that influence GPs’ perception of pre-test probability of disease, which now may be different in the higher risk setting of the emergency department. The ‘representativeness’ bias can lead to error by neglecting base rates (pre-test probability) and the ‘availability’ bias is an overestimation of the frequency of vivid or easily recalled events and underestimation the frequency of ordinary events or those that are difficult to recall, with over emphasis of rare conditions.(83,217,218) Realist methods encourage the use of formal theory when there are few empirical data, to develop initial rough theories for further theory testing. Therefore, this theory was developed to take forward in this thesis.(118)

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*If patients present to the emergency department with a **condition not usually dealt with in primary care** (C)*

*and are seen by a GP who may have **inadequate knowledge or skillset** for the condition (M)*

*the patient may be at **risk of a mis-management** (O)*

There was evidence that GPs working in or alongside EDs see a different cohort of patients to those seen in usual in-hours general practice with more acutely unwell patients,(187,219) and minor injuries (C). (23,24,187,195,196,200,220,221) Additional skillset requirements (Mresource) and learning needs were not described, with no data describing patient safety incidents as outcomes (O).

A paediatric study showed shorter durations of stay and fewer admissions for ‘GP appropriate’ patients seen by GPs compared to emergency department staff (O), although a higher use of antibiotics was prescribed (O) (extract below). The authors did not specify if this prescribing was appropriate or not but did discuss that the inclusion of a GP in the emergency department would require monitoring to avoid overprescribing or inappropriate prescriptions.(182)

> *“During a 6-month pilot scheme which co-located a primary care GP service in a busy paediatric ED, patients seen during the hours when the GP was available were **significantly less likely to be admitted, exceed the 4-hour waiting target or leave before being seen**, but more likely to receive antibiotics.”*(182)

3.2.3 Inadequate communication between services

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*If there is **poor communication** between the GP service and the emergency department service (C)*

with a lack of awareness about service capacity (M)

*then patients may be streamed to the GP service when the service does not have capacity and patient **assessment and treatment may be delayed** (O)*

This theory was generated from an English qualitative study where a lack of communication between the GP and emergency department services about capacity (Mreasoning) was described to delay patient assessment and treatment (O) (extract below).(187) Shared or separate governance systems between the GP service and the emergency department and the effect on teamwork and communication were rarely described with no evidence for best practice governance systems.

> *"There were times when the **overnight doctor who was on their own** had gone out to do 2 or 3 home visits and they'd come back to find that A&E had transferred over 3 or 4 patients to the sitting room waiting for them and **A&E had no idea how many visits that doctor had or how long they would be gone** … we felt that was inappropriate, so actually that was … a **definite lack of communication**." (GP)*(187)

Single entry (INSIDE) models, see Chapter 1 section 1.1.4, were reported to promote good communication and integration in some studies.(23,149,187,219) A UK study, where the urgent care centre provided a "see-and-treat" service for paediatric patients, described an 'excellent working relationship' between the emergency department and urgent care staff. This led to changes in governance systems to improve quality of care in medicine management, staff training and safeguarding of patients, but the article did not specify how this had been achieved.(191)

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*If there is poor **communication with usual primary care** about patient treatment in the urgent care setting (C)*

*the local GP may **not have adequate information** about the urgent care consultation and any follow up needed (M)*

*which may lead to **clinical decision-making** errors (O)*

There were limited data to support this theory and this was not a theory initially suggested by the stakeholder expert group. However, in a postal survey to GPs, following patient treatment at a walk-in centre, almost one quarter (23% 197/853) felt that communication received about treatment at the walk-in centre was poor (C) (extract below).(222) Poor communication and poor information transfer at the interface of primary and secondary care services (C) is recognised to contribute to patient safety incidents (O), and I therefore included this as another initial rough theory.(223)

*"The **letters are very confusing**, computer generated and make it difficult to unravel exactly what was the problem when the patient was seen."*
(GP)(222)

3.3 Discussion

Main findings

There is a lack of evidence for patient safety outcomes when GPs work in or alongside emergency departments. Initial rough theories about potential patient safety risks can be summarised into three care processes: streaming and redirection decisions; influences on GP clinical decision-making and skill set; and inadequate communication between services.

Strengths and limitations

Heterogeneous studies involving GPs working in or alongside emergency departments do not suit traditional systematic review methods. I, along with other named team members conducted the first realist review in this area, a method that is gaining prominence in healthcare research.(108,119) Specifically, we adopted the "rapid realist review" method, which includes an 'expert stakeholder group' of knowledge users and external experts to provide context specific evidence, quantification of existing knowledge and a summary of evidence gaps.(147) This approach is appropriate in relation to the rapidly evolving NHS policy on emergency department use of GPs,(29,30,224) showing where such policies may be reinforced or refuted by the evidence available.(147) I followed Rameses methodological quality standards to ensure an appropriate approach was taken and completed the publication standards checklist.

The study was limited by time constraints and only myself doing the initial screening of database searches, but the experience of the expert stakeholder group helped mitigate this, and enabled us to focus and direct our research.(147) Other weaknesses were that some studies did not describe the mechanisms behind the intervention or the nature of different healthcare and funding systems which limited international comparability.(144) Understanding the limitations of the primary data, even if more time and resources had been available, I do not expect I would have found significant new evidence to refine these theories further.

Comparison with other reviews

The recent Cochrane review of four studies published in 2018, as discussed in Chapter 1.1.3, highlights inconsistent results and a lack of evidence on safety.(32) The main standard-setting body in the National Health Service (NICE) currently makes no recommendation about GPs working in emergency department settings due to a lack of evidence about the safety implications.(33) Before this review, the largest review to date by Ramlakhan et al. included 20 papers.(34) I have reviewed this area with data from 96 articles and agree with a lack of evidence on the safety implications of GPs working in or alongside emergency departments. As part of this process however, this review has generated initial rough theories, explaining how potential patient safety outcomes may occur, which can now be tested from other data sources.

Conclusion

There is an evidence gap in the literature for patient safety outcomes when GPs work in or alongside emergency departments. Initial rough theories have been developed from limited literature sources, expert stakeholder input and Croskerry's dual process model of reasoning (formal theory) to explain why potential patient safety outcomes may occur, to take forward for theory testing and refining in the subsequent stages of this thesis.

4 Initial and refined theories from patient safety incident report analysis

In this chapter I explore causal mechanisms of patient safety incidents related to GPs working in or alongside emergency departments to address objective two. I describe the included sample of Coroners' reports to prevent future deaths and National Reporting and Learning System (NRLS). I then describe how these data developed and refined context-mechanism-outcome configurations to describe how and why patient safety incidents may occur when GPs work in or alongside emergency departments.

4.1 Overview of results

4.1.1 Coroners' reports to prevent future deaths

Table 4-1: Coroners' reports to prevent future deaths search strategy and results

Courts and Tribunals Judiciary Reports to Prevent Future Deaths Category	Date of published reports	Number of reports	Included in study
Community health care and emergency services related deaths	14/08/18 – 30/07/13	284	5
Hospital death (Clinical procedures and medical management related deaths)	14/08/18 - 30/07/13	1063	4

I screened 1347 Coroners' reports to prevent future deaths classified as "Community health care and emergency services" and "Hospital deaths" over the five-year period, see Table 4-1. From these I identified nine reports with learning relevant to GP services in or alongside emergency departments, summarised in

Table 4-2. These reports all involved diagnostic error. No new cases were identified in the “Child Death” category (with some duplication of cases found in the other sections) and therefore no other categories were searched.

Seven of these reports described a wrong diagnosis with a lack of referral for investigation on initial presentation. Three main groups of conditions were identified: veno-thrombotic events presenting with calf pain or shortness of breath (n=3); cardiac death with a presentation of chest pain (n=2); and intracranial haemorrhage following a head injury (n=2). Another report described a delayed initial assessment and diagnosis for a patient, which was felt to have contributed towards his death by sepsis. A further report described a missed diagnosis where a lack of communication about recurrent attendances from a walk-in centre was thought to have contributed to the death of a baby with pneumonia; the diagnosis was made post-mortem.

Root cause analysis and expert opinions were often detailed in the reports, giving understanding of the factors that may have contributed to the diagnostic errors. Patient characteristics included those presenting with rare conditions, for example Loeys-Dietz syndrome (thoracic aortic aneurysm), or others presenting with an atypical pattern of signs and symptoms, including no leg swelling in a patient presenting with a deep vein thrombosis or a young female with chest pain. The possibility of cognitive biases affecting the clinical reasoning of general practitioners, who may usually work in community settings with a lower probability of serious disease, was raised by an expert witness. Organisational factors that may have contributed towards diagnostic errors included: lack of clear streaming guidance for patients presenting with high risk conditions; unclear referral pathways for patients sent in for further investigation by their local GP; and communication barriers between primary and secondary care.

Table 4-2: Summary of Coroners' reports to prevent future deaths with learning relevant to GP services in or alongside emergency departments (9 reports identified from 1347 reports, 2013-2018)

Report number	Presenting symptom	Initial diagnosis	Actual diagnosis	Summary of report	Key learning quoted from reports
1. Wrong diagnosis	Calf pain	Muscular injury	Deep vein thrombosis (DVT)	A 47-year-old woman presented to the urgent care centre with calf pain. She had a strong family history of DVT (deep vein thrombosis) but this was not elicited in the history and she was diagnosed with muscular pain. She later died from a pulmonary embolism.	*"The A&E expert gave evidence that patients presenting to an urgent care centre, walk in centre or out of hours are a much higher risk group than those who present to their own GP surgery. As a consequence, there must be clinically agreed protocols that at the front end of any facility that receives undifferentiated patients that manage this higher risk population. Patients that present with certain high-risk conditions such as chest pain, shortness of breath or calf pain must be directed to a facility that can exclude serious illness and this is usually the nearest A&E."*
2. Wrong diagnosis	Calf pain	Muscular injury	Deep vein thrombosis (DVT)	A man presented to a walk-in centre with calf pain following a driving holiday in France. There was no calf swelling or tenderness and he was diagnosed with a musculoskeletal injury. He was then seen by his own GP a further 3 times but the walk-in centre records were not available. He later died of a pulmonary embolism.	*"Records of the August appointment (to the walk-in centre) were not available."*
3. Wrong diagnosis	Shortness of breath	Not documented	Pulmonary embolism (PE)	A 44-year-old man presented to A&E and was streamed to the GP. He died from a pulmonary embolism two days later.	*"Mr (), died of a pulmonary embolism having been diverted from accident and emergency assessment 2 days prior to his death. This meant that further tests, which could have led to an earlier diagnosis for his condition were not done. No 111 referral information was available to 'Front door' or the ED (emergency department)."*
4. Wrong diagnosis	Chest pain	Non-cardiac chest pain	Adult Cardiac Death Syndrome	A 30-year-old woman presented to the ambulance service with chest pain, normal examination and ECG. She chose to see her GP who thought the pain was non-cardiac; she died a few hours later at home.	*"Mrs (), aged 30 with a family history of heart disease, was seen by ambulance staff with chest pain, and examination and ECG were reported as normal. The GP had not considered the possibility of Sudden Adult Death Syndrome"*

5. Wrong diagnosis	Chest pain	Gastritis	Loeys-Dietz Syndrome (thoracic aneurysm)	A 42-year-old woman with chest pain was seen by an ambulance, had a normal ECG and chose to see her GP for review. She was seen by the local GP and referred to A&E for further investigation. She was streamed to the GP in A&E who referred her back to A&E where she was assessed, treated for gastritis and discharged with no further investigations. The patient's presenting history of the same pain as her previous aortic dissection and the initial GP referring letter was lost in transfer. She died a few days later.	*"Crucially, the only piece of the patient's presenting history which wasn't passed on (to the emergency department doctor from the local GP) was that the pain that she was feeling was the same pain which she had felt back in 2011 when she suffered her previous aortic dissection. Had he been aware of this piece of information, his evidence was that he would have ordered a CT scan."*
6. Wrong diagnosis	Head injury	Not documented	Intracranial haemorrhage	A man presented to an urgent care centre following a head injury and again the following day with headache and vomiting. No CT was done. He collapsed and died the next day.	*"Patients undergoing haemodialysis or significant uraemia are at risk of haemorrhage and this is not commonly known within the medical profession or referred to in relevant NICE guidelines."*
7. Wrong diagnosis	Head injury	Not documented	Extradural haematoma	A 10-year-old boy presented to A&E following a head injury and was streamed to the urgent GP clinic and discharged. He was seen at home by a paramedic the following day and not brought to hospital. He collapsed the next day whilst waiting to be seen in the GP surgery. He underwent neurosurgery but died a few days later.	*"The consultant from the department told me, during the course of his evidence, that it would be good practice for all suspected head injuries to be referred to the A&E team."*
8. Delayed diagnosis	Unclear	n/a	Sepsis	A patient presented to the emergency department and was booked into the urgent care centre. He was not triaged for over 45 minutes by which time his condition had deteriorated.	*"Staffing levels in the emergency department were not sufficient to be able to follow national or any local policy on treating suspected sepsis."*
9. Missed diagnosis	Cough	Chest infection	Pneumonia	A 9-month-old baby presented to a walk-in centre 3 times over 3 months with a cough. She was then seen twice by nurse practitioners at her own surgery with the same complaint who could not recall having access to information about the walk-in centre visits and did not refer the patient to the GP. She became unresponsive the following month and was declared deceased on arrival at the hospital. The inquest concluded she died from bronchopneumonia.	*"I am concerned that the systems for practice nurses checking an attending patient's past medical history, especially where the patient is a very young child or baby, may need review."*

4.1.2 National Reporting and Learning System reports

I identified and screened 1878 reports in the 10-year filtered sample. Irrelevant and duplicate reports were excluded, see inclusion criteria, Box 3 Chapter 2 section 2.3.2.3, resulting in an included sample of 217 reports describing diagnostic errors with learning relevant to GP services in or alongside emergency departments, see Figure 4-1. The reports were generally brief, with limited information about contributory events, and most did not describe the patient harm outcome resulting from the diagnostic errors (n=188). In those reports where harm could be ascertained, 11 reports described mild or moderate patient harm, 12 described severe harm and six described events leading to death. Three of the six reports describing a death involved patients presenting with headaches. From the nature of the serious diagnoses involved, see Table 4-3, for those reports without harm descriptions, patient harm appears likely.

Most reports described patients leaving the emergency department with a wrong diagnosis (n=144). These were largely due to errors in clinical decision-making: misinterpretation of x-rays later picked up by radiological reporting systems (n=87), or under-investigation of key symptoms (n=59). Other reports described a delayed diagnosis within the department or identified at a later date (n=71). Over half of these involved an inadequate triage or streaming process (n=42); others described inadequate specialist referral pathways from community or emergency department primary care services (n=21). In this sample there were no reports of missed diagnoses (Society to Improve Diagnosis in Medicine definition, Chapter 2, Box 2, section 2.3.2.2).(158)

Figure 4-1: National Reporting and Learning System reports search strategy and results

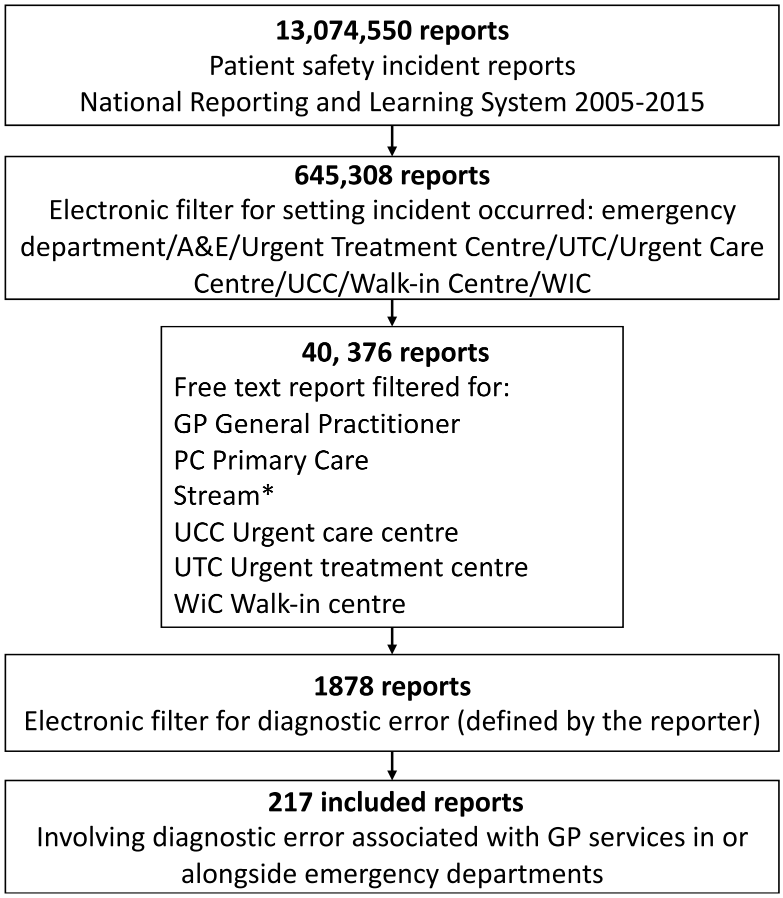

Table 4-3: Presenting conditions involved in included Coroners and NRLS reports

Presenting complaint	Number of Coroners' reports	Number of NRLS reports	Examples of conditions involved (not always stated in the report)
Musculoskeletal injury	0	114	114 fractures 7 Hip and 6 Spinal fractures
Chest pain	2	18	15 Acute Coronary Syndrome
Unwell child	1	15	7 sick infants requiring resuscitation level care
Headache	2	14	6 Head injury 5 Subarachnoid haemorrhage 2 Brain tumour
Abdominal pain	0	9	3 Appendicitis 1 Ischaemic bowel
Shortness of breath	1	6	1 Acute asthma 1 Pneumothorax 1 Respiratory failure 1 Stridor
Limb pain – no trauma	2	4	2 Deep vein thrombosis 1 Ischaemic foot
Collapse	0	4	1 Cardiac arrest
Back pain	0	4	1 Pulmonary embolism 1 Abdominal Aortic Aneurysm 1 Spinal cord compression
Limb weakness	0	2	2 Stroke
Eye injury	0	2	1 Missed foreign body in eye
Rash	0	2	1 Measles
Other	0	13	1 Testicular torsion 1 Ectopic pregnancy 1 Anaphylaxis
Not documented	1	10	1 Pneumothorax 1 Trauma case
Total	9	217	

4.2 Theories developed and refined from these data

Theories developed from these data grouped well under the same processes of care identified in the rapid realist review described in Chapter 3, section 3.2: streaming and redirection decisions; influence on GPs' clinical decision-making; and inadequate communication between services. Text in ***bold black*** in this section highlights refinements made to these theories (or new theories developed) following analyses of these data. Verbatim quotes have been added to illustrate the theories with minor grammatical changes, if necessary, to aid readability and additional information to explain medical jargon added in brackets, if indicated.

4.2.1 Streaming and redirection decisions

If patients presenting to the emergency department (C)

are assessed for streaming ***but the streaming nurse is unclear which patients are appropriate (due to unclear guidance or inexperience) (M)***

or the initial assessment is inadequate (limited history or lack of basic physiological observations) (M)

then higher risk patients may be streamed to the GP service (O)

From the literature, see Chapter 3 section 3.2, there was evidence that staff used their own experience when making streaming decisions (Mreasoning). One Coroner's report (Table 4-2, case 5) and 28 NRLS reports highlighted the difficulty in identifying which patients were appropriate for the GP service and how and why this may be the case. These included 10 patients presenting with chest pain (example below), seven unwell children and four patients presenting with a headache.

*"A (>50-year-old) Asian gentleman presents with **chest pain to GP streamer**. History of 1 week of left sided chest pain, left arm numb, nausea is recorded. **Streamed to UCC** (urgent care centre). ECG and further assessment in UCC - ischaemic ECG and cardiac sounding chest pain. **Delay in transfer to ED of over 1 hour from arrival**. On review describes central crushing chest pain from 0615, severe, radiating to left arm, sweaty and SOB."*

Inadequate assessment including a lack of basic observations (Mresource) was documented in several reports (n=13, example below), and a lack of understanding about which patients were appropriate for the primary care service could be inferred in others (Mreasoning) (n=7, example above).

*"A (>65-year-old man) presented at (time) with **dizziness** and feeling like he was going to collapse. **No vital signs recorded by GP streamer**. **Waited 1 hour** to be seen in urgent care centre - when assessed by nurse practitioner heart rate 24 and BP unrecordable. **Transferred to resus**."*

If undifferentiated patients present to emergency departments (C)

*and are screened by GPs working in a '**gatekeeper**' role on the front door, relying on their generalist skills rather than a comprehensive assessment including vital signs* **but are unfamiliar with emergency department protocols** *(M)*

*may result in **inappropriate streaming/redirection decisions** and delayed patient assessment and treatment (O)*

There was only one brief NRLS report regarding a GP working in a 'gatekeeper role' at the front door of an emergency department (report below), therefore opportunity to refine this theory was limited. This described the GP working in a triage role (Mresource), sending a child to the paediatric emergency department (O). The non-blanching spots to the body imply a suspected meningococcal infection and the reporter suggests the child should have been sent to the resuscitation area for assessment. The report does not describe the outcome of the incident on the child but inferences can be made that the GP is not aware of the emergency department protocol for this condition (Mreasoning).

> *"Seen by GP triage sent through to **kids cas** (paediatric emergency department) for further triage. Patient had **purple non blanching spots** to body - should have been sent through to **resus**."*

If patients presenting to the emergency department (C)

are streamed to a GP service that is not subject to the usual emergency department triage targets (M)

or understaffing means triage times cannot be met (M)

there may be a delay in assessment and treatment for patients streamed to this service (O)

This was a new theory developed from these data. One Coroner's report (Table 4-2, case 8) and six NRLS reports (example below) highlighted a delay in initial assessment for patients waiting to be assessed by the GP service (O) with inferences that if they had been triaged through a standard emergency department assessment (Mresource), then they would have been seen earlier (O). Under-staffing (C) was described to contribute towards the delayed assessment and diagnosis (O) in one Coroner's report (Table 4-2, case 8) and one NRLS report.

> *"Patient collapsed in minors moved to resus was in VF (cardiac) arrest. Patients relative complained that they had **been in the department for an hour** before he was called for triage. Patients relative stated that they had **waited in several queues with UCC** (urgent care centre), which **took approximately 30-40 minutes** before the patient was booked into A&E."*

4.2.2 Influence on GPs’ clinical decision-making

In the emergency department setting where there is a higher pre-test probability of serious illness than in usual primary care (C)

*GPs may be influenced by the prior decision-making of the streaming nurse and therefore be at risk of **framing** or **anchoring** cognitive biases (M)*

*or may incorporate their usual community pre-test probability of serious illness into their diagnostic reasoning and be at risk of **availability or representativeness** cognitive biases (M)*

*and may therefore be more **at risk of under-investigation** and **diagnostic error** than they would if working in their usual community setting (O)*

There was no evidence from these data to explain how and why these diagnostic errors occurred (Mreasoning) to further refine this theory (no black text). One Coroner’s report (Table 4-2, case 7) and seven NRLS reports (example below) described patients having previously been assessed to be low risk by another healthcare professional but with no description of how this may have influenced GPs’ decision-making. Three reports described patients seeing primary care clinicians who were unaware that acute investigations had already been requested in the emergency department (example Chapter 2, section 2.3.2.4) but again, no insights were reported on how this may affect GPs’ clinical decision-making.

*“Patient presented to ED with **headache in the middle of the night**. Patient streamed by ?nurse - no identification on record of who - **to urgent care centre** and presumably **discharged home**. Patient presented on the following day with headache - had a CT and was found to have a **subarachnoid haemorrhage** (bleed). Patient transferred to care of **Neurosurgeons**.”*

Six Coroners' reports (Table 4-2, cases 1-4, 6-7) and 59 NRLS reports described patients under-investigated by primary care clinicians (O) which was associated with diagnostic error (O). The conditions involved included: 27 fractures (four spinal and three hip fractures), 10 patients presenting with a headache (four following a head injury, four with confirmed subarachnoid haemorrhage, example below), five patients with a deep vein thrombosis, four patients with acute coronary syndrome and four unwell infants.

> *"Patient attended the ED (emergency department) following a fall. Landed onto right side. Patient sent to* ***Urgent Care Centre****. Seen by doctor and* ***discharged home****. Patient reattended the* ***same day*** *seen again and* ***diagnosed fractured Neck of Femur*** *(hip fracture)."*

Undifferentiated presentations such as these, for example musculoskeletal injury or headache, would be expected to present to usual primary care but these high-risk conditions would be more unusual (C). The impact of this on clinicians' cognitive biases (Mreasoning) and the effect of working in a potentially higher risk setting (Mreasoning) could not be elicited from these data. Qualitative data in the next phase of this thesis will be needed to further refine this theory.

If patients present to the emergency department with a ***condition not usually dealt with in primary care*** *(C)*

and are seen by a GP who may have inadequate knowledge or skillset for the condition (M)

the patient may be at ***risk of a mis-management*** *(O)*

There is cross-over between this theory and the one presented above but for now they are presented separately. The first describes how the emergency department setting may influence GPs' clinical decision-making (Mreasoning) on undifferentiated presentations, many of which may present also in primary care, for example musculoskeletal injury or headache. This theory describes how inadequate GP knowledge or skillset (Mresource) for patients that require emergency level care may put patients at risk of mismanagement (O). Again, there was no evidence to explain how and why these events occurred in these data (no black text) to further refine this theory.

Many NRLS reports described primary care clinicians managing patients not usually dealt with in primary care, some with evidence of inadequate skillset (example below). Most of these incidents were regarding fractures, (n=87).

*"Patient **attended the A&E department**, however **seen by the GP placed in the department** who examined the patient, ordered an x-ray and then **applied a plaster and discharged the patient** to fracture clinic. On reviewing the fracture, it was found to be a **comminuted fracture of the radial head**. This type of fracture would have **necessitated an orthopaedic review** as they benefit from early surgery. On reviewing the clinical notes **no mention of an orthopaedic review** was mentioned. It seems that the **practitioner concerned does not have the necessary experience to evaluate this type of injury** (this is not a primary care type of patient) and should not have managed the patient in the first place."*

There were five reports that highlighted a lack of knowledge of emergency department child safeguarding protocols (Mreasoning), in place to detect non-accidental injury (O) (example below).

*"An **8-month old baby** was seen at **Urgent Care Centre** with a **fracture of the right distal radius**. The ( ) **single fracture policy was not followed** in that the case should have been discussed with a paediatric registrar and the X-ray reviewed by a radiologist."*

4.2.3 Inadequate communication between services

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*If there is **poor communication** between the GP service and the emergency department service (C)*

because of a lack of awareness about capacity (M)

***a lack of awareness that investigations have already been requested** (M)*

***or inadequate referral pathways** (M)*

then patient assessment and treatment may be delayed (O)

Five NRLS reports described a lack of communication between services about capacity (Mreasoning) to support this theory originally generated from the rapid realist review. Inadequate communication about investigations already requested in the emergency department (Mresource) and inadequate referral pathways (Mresource) for patients to be referred back to the emergency department were also described to delay patient assessment (n=6, example below).

*"20-month-old child **seen by PC (primary care) doctor**, discharged from PC at 06:59 and **sent back to A&E**. Identified by PC doctor in letter as unwell, laboured breathing and requiring further assessment and treatment however **not referred to paediatricians or informed A&E**. As a result the child was not seen until 09:30 at which point was unwell **requiring admission to resus**."*

If patients use GPs in or alongside emergency departments as their first point of primary care access rather than their registered GP *(C) and there is poor communication with usual primary care about patient treatment in or alongside emergency departments (C)*

the local GP may ***not have adequate information*** *about the urgent care consultation and any follow up needed (M)*

and recurrent presentations or deteriorating conditions are not picked up which may result in delayed diagnosis and treatment *(O)*

There was one Coroner's report (Table 4-2, case 9) which highlighted a case where a lack of communication with community primary care regarding attendances to a walk-in centre possibly contributed towards the death of a baby. Here there were multiple attendances to an urgent care setting with inferences made that patients may choose these settings as a first point of call rather than their registered GP (C). No NRLS reports described an incident to support this theory but delayed patient assessment and treatment (O) due to inadequate referral processes from community GPs to specialist care assessment (Mresource) were also described in one Coroner's report (Table 4-2, case 5) and nine NRLS reports.

4.3 Discussion

Main findings

Extensive searching of two separate databases revealed few relevant patient safety incident reports suggesting that diagnostic errors associated with GP services in or alongside emergency departments are rare events. High-risk presenting complaints in this sample of reports included musculoskeletal injury, chest pain, headache, calf pain and sick children. Data from these reports supported and helped refine theories about how and why patient safety incidents occur under three care processes: streaming and redirection decisions; influence on GPs' clinical decision-making; and inadequate communication between services.

Strengths and limitations

There are recognised limitations in analysing these types of data. Coroners' reports to prevent future deaths only cover events involving the most severe of cases that have led to a patient death. They are therefore rare events and findings may not be generalisable. Analysis of NRLS patient safety incident reports is limited by under-reporting, selection bias and incomplete description of causation.(75) These data often did not describe the mechanisms which led to the outcomes (for example potential cognitive biases); however, these theories can now be tested with qualitative data in the next phase of this thesis.

I have not included reports describing diagnostic errors occurring in usual emergency department care and it may be that GPs make relatively fewer errors on the same patients compared with junior emergency department staff doctors. However, FH completed work separately in this area to give background context as discussed below.(8) I worked closely with FH when he started the coding process for his project and double coded 10% of the 2288 reports in his sample with a high Cohen's kappa (0.868).(8) We were satisfied with this high kappa and it was therefore not calculated for this sample. I worked with him to ensure he understood the recursive model approach, the nature of the codes and to discuss complex cases. This challenged me to think about my coding and was probably more useful than the kappa result itself. My work also included the additional realist approach and therefore I chose to validate my findings and address my biases through discussions with the Cardiff team and GP in EDs co-applicants expert group.

A strength of this work is that many of the Coroners' reports contained learning from in-depth root cause analysis, which could also be applied to near misses described in the (usually brief) NRLS reports. These two different lenses complemented each other for understanding unsafe care, in terms of what happened and generating perceived causes for both the most serious and other incidents with a range of severity outcomes. I also applied realist methodological approaches to patient safety incident analysis to infer why and how incidents occurred rather than basing conclusion explicitly on what was stated in the report. This was based on my clinical experience and patient safety knowledge and allowed development of theories that can be taken forward and tested with qualitative data at the case study sites with the aim of producing useful, insightful, actionable findings.

Context of current literature

Other studies support my findings that the causes of diagnostic errors in emergency departments are multifaceted and have potential to result in serious patient harm,(8,65,76,225–227) with staff cognitive factors highlighted as a major contributory factor.(227) The high-risk conditions identified in my work, are similar to those in other emergency department studies.(8,228) The Royal College of Emergency Medicine includes abdominal pain in the elderly, aortic dissection and cervical spine or hip fractures as the top three significant incident reports in emergency medicine following analysis of 61,449 incident reports in 2015.(228) The work done by FH, following analysis of 2288 NRLS reports over a two year period (2013-2015), describes fracture (notably cervical spine and hip fractures), myocardial infarction and intracranial bleed as the most common diagnostic errors.(8) In his work, contributory factors were also predominantly human factors, including staff mistakes, healthcare professionals' inadequate skillset or knowledge and not following protocols.(8) Applying an additional realist methodological approach to this work, I have been able to develop theories that explain why these mistakes may have occurred. High-risk conditions for diagnostic errors described in community primary care do not include musculoskeletal injuries, headaches or veno-thrombotic events, which may reflect the different cohort of patients seen in these settings.(229)

There is little national guidance on which emergency department patients should be streamed to GP services and this will depend on local service provision.(4,230) Initial NHS England guidance has adopted a model which advises against streaming patients with traumatic or head injuries and includes specific guidance for those presenting with chest pain, nosebleeds and feverish children.(31) There are however, established and internationally recognised triage systems which can help identify seriously ill patients who require urgent medical attention.(231,232) Early warning scores for unwell children are available,(233) with more recent tools incorporating clinician gut instinct and use by primary care clinicians.(234) The 'Gestalt' decision-making of senior nursing staff may also be better than algorithmic methods.(235) The findings from this work suggest that all patients who present to emergency departments should be subject to a prompt standardised initial assessment, including basic observations and gut reaction, before being streamed to GP services. Child safeguarding processes may vary and should also be standardised between services.(236)

The evidence for validated clinical decision-making tools in this setting is limited. Recognised tools to assess low risk chest pain for example, include ECG and biochemical investigation results that may not be available to primary care clinicians.(237,238) There are no validated risk assessment tools to assess patients presenting to the emergency department with headache, and the difficulty in identifying the few that do have a subarachnoid haemorrhage is acknowledged.(239,240) Diagnostic cognitive processes and the effects of simplifying rules, short cuts or heuristics to replace more complex procedures are well described,(218) but there is a lack of evidence for the implications of these when GPs work in urgent and emergency care settings.

Poor communication and inadequate referral pathways between primary and secondary care are known to contribute towards patient safety incidents and can be targeted on a local level. Integrated computer systems including timely mandatory forcing functions for key information can improve communication between services.(223,241)

The lack of patient safety research in this area should again be highlighted,(5,32,33) and teams should continue to learn from diagnostic errors, near misses and other patient safety incidents through local and national level reporting systems.(242,243)

Conclusion

The small number of reports describing diagnostic error when GPs work in or alongside emergency departments suggests that these are rare events, however they can lead to significant patient harm and death. Applying an additional realist methodological approach to patient safety incident report analysis improves understanding of how and why these events may have occurred. These theories can now be taken forward to the next stage and tested with qualitative data at the case study sites.

5 Case study site sample

In this chapter I present an overview of the case study site sample ahead of the qualitative results and programme theory presented in Chapter 6. There is a great deal of complexity, depending on local contextual influences, in how and why the GP service models function as they do. It is essential to understand this background context before it is possible to explore how and why patient safety incidents may be associated with these service models. I have therefore chosen to present this detail ahead of the qualitative results and programme theory described in Chapter 6.

5.1 Overview of case study site sample

As discussed in Chapter 2 section 2.3.3, the resultant sample of case study sites in England (n=12) and Wales (n=1) with good geographical spread, included:

- three inside integrated sites;
- four inside parallel sites (one site was reclassified following the visit);
- three outside onsite models; and
- three control sites (no GPs).

I visited all the sites with an associated GP service with Dr Michelle Edwards (ME) for a two-to-four day visit (mean three-days). Either ME or I (ME two visits, myself one visit) conducted one-day visits to the control sites. All visits occurred between January 2018 and April 2019.

Table 5-1: Case site study characteristics listed, where possible, according to the position on the integration spectrum (see Figure 1-3**)** from left (emergency medicine service) to right (usual primary care service)

Primary care model	Site reference	Hospital size and serving population*	Setting	ED attendances per year	Care Quality Commission (CQC) rating**	GP service commissioning organisation	GP streaming	GP access to acute investigations	Date GP model introduced	Hours of coverage per week in GP service	Staff mix in GP service
Control sites	GPED02 Wales	774 beds, population 600,000 people***	City	84,000	n\a Welsh site						
	GPED12 Central England	350 beds, (Trust serves 500,000 people in 4 hospitals)	Town	65,000	Outstanding (report 04.12.19)						
	GPED15 Central England	497 beds for the 2 hospitals in Trust, population 258,000 people	Town	55,000	Requires improvement (report 29.11.19)						
Inside integrated (II)	GPED14 South of England	430 beds, population 450,000 people	Small town	78,000	Outstanding (report 29.04.16)	NHS Trust	No	Yes	2009/10	10am-10pm, 7 days a week; 65 - 72 hours	GPs
	GPED08 North of England	160 beds, population 122,000 people	Rural area	20,000	Good (report 28.10.16)	NHS Trust	No	Yes	2017	8am-6pm, 3-4 days per week; 33 - 40 hours	GPs
	GPED03 South West of England	550 beds, population 340,000 people	Small town in rural area	65,000	Good (report 28.09.17)	NHS Trust	Yes, and GPs self-select	Yes	2017	8am-11pm, 7 days a week; >80 hours	GPs

Inside parallel (IP)	GPED09 South East of England	995 beds, population 1.3 million people	Large city	165,000	Requires improvement (report 19.07.18)	Primary care provider	Model 1: yes Model 2: no	Model 1: No Model 2: Yes	2012	8am-9pm, 5 days a week; 57 - 64 hours	GPs
	GPED04 North of England	379 beds, population 200,000 people	Rural area	56,000	Good (report 24.02.16)	Primary care provider	Yes	Yes, but encouraged not to use	2015	6am-11pm weekdays, 10am-10pm weekends; 49 - 56 hours	GPs and ANPs
	GPED06 North of England	580 beds, population 200,000 people	Large town	115,000	Good (report 24.02.16)	Primary care provider	Yes, plus 111 and walk in patients	Yes, but encouraged not to use	2015	10am – 10 pm 7 days a week; 80 hours	GPs and ANPs
	GPED07 South West of England	732 beds, population 500,000 people	City	84,000	Requires improvement (report 10.08.16)	Primary care provider until May 2018 then NHS trust	Yes, plus 111 and walk in patients	No	2014	10am – 10pm 7 days a week; 80 hours	GPs, ANPs, Paramedics
Outside onsite (OO)	GPED13 Central England	540 beds, population 250,000 people	City	70,000	Good (report 29.06.16)	NHS trust	Yes, plus 111 patients (no walk ins)	Yes	2017	10am - 10pm 5 days per week, 41 - 48 hours	GPs and ED ANPs
	GPED10 North of England	572 beds, population 400,000 people	Town	89,000	Good (report 14.03.18)	Local GP federation	Yes, plus 111 and walk in patients	No	2017	24 hours a day (includes OOH contract), 7 days a week; >80 hours	GPs and ANPs
	GPED11 Central England	763 beds, population 514,000 people	Large city hospital adults only	140,000	Requires improvement (report 13.06.16)	NHS trust and a Locum agency	Yes, plus 111 and walk in patients	No	2005	8am-10pm, 7 days per week; 73-80 hours	Locum GPs, mainly ANPs

Data taken from survey data unless stated otherwise *https://www.cqc.org.uk/sites, **for urgent and emergency care services, ***http://www.wales.nhs.uk/sitesplus/866/page/40419
(GPED01 omitted, pilot site; GPED05 omitted, streaming service staffed by emergency department staff not GPs)

The spectrum of integration was used to classify the function of the service models, from those where the GPs functioned more as emergency department clinicians (left of the spectrum) to those functioning more like community primary care services (to the right of the spectrum), as shown in Figure 1-3 Chapter 1, section 1.1.4.(6) Table 5-1 characterises the case sites listing them, where possible, according to the position on the integration spectrum from left to right. However, a great deal of complexity was evident. For example, we found that GPED09, although selected from survey responses as an inside parallel model, also had a GP working in an integrated model within the separate paediatric emergency department. The outside onsite model GPED13 is grouped with the other outside onsite models. However, the function was more integrated with the emergency department (further left on the spectrum), as the GPs utilised emergency department acute investigations and the unit was also staffed by emergency department Advanced Nurse Practitioners (ANPs) who were able to deal with minor injuries.

5.2 Constructs that influenced the function of service models

Different constructs were observed to influence the function of these service models. As described in the taxonomy, these could be grouped at the wider system level, the department level and the individual clinician level.(6)

5.2.1 Wider System level

A recruitment need for emergency medicine clinicians at GPED08 meant the GPs were employed by the NHS Trust and functioned more as emergency medicine clinicians (example below).

"I would see everything, ***I guess I'm employed as a middle grade really****. The reason I was interested in that is I wanted to get, not away, but* ***I wanted more acute management, experience or acute medicine management****, having done A&E in different places in the past I know I enjoy it, so I wanted more acute side of things****, to see every patient, majors, minors****, and get that side of things, alongside the sports and GP work." GP GPED08(II)*

Sites where the GPs were employed by the NHS Trust rather than a primary care provider, often functioned more like an emergency medicine service (GPED14, GPED08, GPED03), even when the service was geographically separate as with the outside onsite model (GPED13) described above. Sites where the GPs were employed by the NHS Trust but functioned more as traditional GP services were noted to have department level factors, for example, no access to acute investigations, that influenced the function of the service (example below) (GPED07, GPED11).

*"The **GP role** is facilitated by **department level factors** rather than individual level factors: **streaming** with clear guidance and experienced clinicians; **no access to investigations**; a **separate area** of the ED; a **different IT system**, GPs can only see those patients streamed to them."*
Fieldnotes GPED07(IP)

5.2.2 Department level

Multiple different department level constructs were noted to influence the function of the services. Services that were distanced from the emergency department, without access to acute investigations, functioned more as a traditional GP services (GPED11, GPED10, GPED07). Whereas, as described above, geographical distance was overcome at case site GPED13, by sending patients back to the emergency department for acute investigations. Strict streaming protocols and different computer systems meant the GPs at some sites were only able to see patients that had been assessed to be appropriate for GP management, facilitating a traditional GP approach (example below) (GPED11, GPED10, GPED07).

*"So obviously **cardiac sounding chest pain** we have got the **protocol in A&E** and **it should be seen by A&E**. Any musculoskeletal, we see that. Any **pleuritic type pain, any pulmonary embolism - A&E patients**, so we do take care, we don't want to miss it. Even if it's light suspicious, we will do d-dimer and everything, **they will come under the A&E**." GP GPED06(IP)*

At some sites clinical leadership allowed flexibility of the service depending on the skillset and interest of the individual GP (GPED03) while at other sites, leaders encouraged a traditional GP approach (example below) (GPED06, GPED10).

*"We're **trying not to be A&E,** we're **trying to be definite GPs** doing what we do. As GPs here **we don't do any tests at all,** we don't do x-rays and we don't do bloods for patient, unless we need those right now, then either **we've got the option to send them to A&E or they can be admitted** to the ward or the assessment unit and it happens there." Lead GP GPED10 (OO)*

Where governance responsibilities lay and whether GPs should follow emergency department protocols or treat the patient as they would in a community primary care setting was unclear at some sites (example below) (GPED04).

> *"As a GP I'm not going to follow A&E protocols and things which, there's always that pressure, I'm an autonomous practitioner, but then I'm working in A&E under another consultant effectively, so there are those problems there as well… It's just who's in charge isn't it, and how you work, whether you follow A&E protocol or you follow your GP hat." GP GPED04(IP)*

5.2.3 Individual clinician level

Individual GP interest and expectation was described to influence the function of services. At some integrated sites, GPs described how they had chosen to work there because of their interest in emergency medicine (example below) (GPED08).

> *"I wouldn't want to work seeing filtered GP patients in ED, I'd rather do another session at the military base. If this changes to an UTC (urgent treatment centre), I'll probably find work elsewhere in another emergency department." Fieldnotes GP comments GPED08(II)*

At another integrated site, the clinical director described how she had tried to set up a similar service in another hospital, but it did not work because the GP personalities willing to take it on weren't there (GPED14). Individual GP experience was perceived to facilitate a traditional GP role with one integrated site reporting that they actively recruited experienced GPs (GPED14). GPs described how they used their experience of careful history taking and examination skills to rule out serious disease as they did when working in the community.

> *"I think as soon as I start just kind of blanket testing everyone then I've lost a little bit of what I feel is my identity as a GP.* ***Because in general practice we rely an awful lot on the history and the examination findings and what we know, what we are looking for and wanting to rule out.*** *And I think* ***that experience*** *took a long time to get so I don't really want to lose it because it's easy to lean on other tools." GP GPED13(OO)*

5.3 Other contextual influences

A brief overview of how each service model functioned, depending on the local context, follows.

5.3.1 Control sites

GPED02

The hospital is based in a city and reports a high number of walk-in patients; there was no GP out-of-hours (OOH) service on site. The triage nurses can refer certain patients from the emergency department directly for specialist assessment e.g. early pregnancy assessment centre or redirect patients off site e.g. back to their own GP, if appropriate. GPs have worked within the service in the past but were reported to work as emergency department clinicians rather than provide a separate primary care service. There were concerns from the clinical director that emergency department patients are different to patients that present to their local GP and should be managed differently. Overcrowding in the department was also largely felt to be due to 'exit block', with a delay in patient transfer to hospital wards, rather than patients presenting with primary care type problems, therefore it was felt that a GP service in or alongside the emergency department would not be helpful.

GPED12

This is a district general hospital with a GP OOH service on site, but with limited capacity to accept emergency department patients. The triage nurses redirected appropriate patients back to their own GP, making an appointment for them first. The receptionists sent patients with minor injuries directly to the minors area rather than triage assessment first. Patients with primary care type problems were reported to attend mainly in the evenings. A GP has previously worked in the department but was employed by the same provider as the GP OOH and was described as being pulled into the GP OOH service rather than being based in the emergency department. Also, the nurses were described as being reluctant to stream patients to the GP. Many patients were noted to attend the emergency department having seen their own GP and being sent in with a referral letter.

GPED15

This hospital, based in a large seaside town, has an adult only emergency department. Previous pilots of GP services in the emergency department have not been successful because there were not enough appropriate patients for the GPs to manage (reported as approximately 2 patients per hour). Many patients with referral letters from their own GP were also noted to attend the emergency department.

5.3.2 Inside integrated sites

GPED14

The hospital is based in a small town. We were advised that there is a large population of nursing homes and elderly patients that often present to the emergency department via ambulance, having bypassed primary care. Therefore, the GPs actively focus on these patients during the day, in the majors area of the department. There was no alternative emergency department geriatric service. The GPs used acute investigations and were integrated with the emergency medicine clinicians but were encouraged to keep on a ‘GP hat’ and maintain a ‘GP approach’ where appropriate, to avoid hospital admissions in this population. Experienced GPs (>5 years post-licence) were actively recruited to provide this role which was led by a GP Consultant. There was no formal streaming; the GPs self-selected patients, or managed patients, identified as appropriate for their skillset by nursing staff.

The GPs also took patient referrals via telephone during the day from local GPs where acute investigations were deemed necessary to exclude serious disease, but it was felt unlikely that the patient would require hospital admission. The demand for patients with primary care problems peaked in the evening (usually children) so the GPs then moved to the minors area, focussing on these patients, and aiming to manage them with a GP approach, as they would in the community.

GPED08

This is a small rural hospital (not a teaching hospital) with a recruitment need for emergency clinicians and low demand for patients with primary care problems. The GPs that work in the department had a personal interest in emergency medicine and had approached the department themselves seeking employment. The GPs work as another member of the emergency medicine team, seeing undifferentiated patients with full access to acute investigations, supported by the emergency department consultants that, due to the quiet nature of the department, have time to train and support them.

GPED03

This is a hospital in a small town with a large rural surrounding area. Patient demand from patients with primary care type problems was reported as variable. There was a culture to ‘sort patients out’ rather than redirect patients with primary care type problems back into the community, which was not felt to be appropriate given the wide catchment area. There were adequate numbers of emergency clinicians and other multidisciplinary teams, including a ‘frailty service’ that focussed on older adults, also working in the emergency department. GPs worked in a flexible role, seeing both primary care patients using a ‘GP approach’ and also seeing patients that required emergency level care using acute investigations, depending on patient demand and their personal skillset and interests. Emergency department clinical leadership encouraged GPs to maintain a ‘GP approach’ but also to follow their personal interests, this was perceived to facilitate recruitment and retention of the GP workforce.

5.3.3 Inside parallel sites

GPED09

This is a busy inner-city hospital, with the emergency department described to have 400 attendances per day. GPs had initially been employed to prevent admissions in the frail elderly population, but the intervention was found to only prevent, on average, one admission a day and was therefore not felt to be a good use of the GP skillset. Two models are now in operation: two mornings a week, patients with primary care type problems are streamed to a GP to manage using a ‘GP approach’; and two evenings a week, a GP works in the paediatric department in a more integrated role using acute investigations if needed. There is also a process for redirecting patients back to their own GP in the community, with a ‘navigator’ (administrator) responsible for phoning the GP surgery to make the appointment under the guidance of the streaming nurse. The few numbers of patients seen by GPs in such a busy department are unlikely to have significant impact on high level data.

GPED04

This hospital is in a rural area. The GP service within the emergency department runs evenings and weekends only; GPs and primary care advanced nurse practitioners (ANPs) are employed. They work in the emergency department out of an emergency department cubicle. The clinical director had concerns about which patients they should be seeing and the skillset of the practitioners potentially seeing patients that require emergency level care. GPs had initially used the available acute investigations but due to safety concerns, were now encouraged not to see patients that require acute investigations; this subsequently meant they saw low numbers of patients. The clinical director felt that the service would work better if it was incorporated with the GP OOH service, when it would also be clearer to patients that they had been seen by a GP service.

GPED06

The local Walk-in Centre in this large town was incorporated into the new emergency department in 2015 with the aim of improving quality of patient care so the patient sees the ‘right practitioner at the right time in the right place’. The ethos is, ‘if you turn up, we will sort you out’. The GP service is led by GPs that work in a separate ‘pod’ (corridor) in the emergency department. Acute investigations are available, but the GPs are encouraged not to use them and maintain their ‘GP approach’. An emergency department consultant also works in this area and is available for advice if needed. The GPs provide support to nurse practitioners that also work in the pod, seeing minor injuries and illness. The service operates from 8am – 10pm, with all patients streamed through emergency department triage.

The service was felt to have generated its own demand and when it closed at 10pm, emergency department staff commented that patients presenting with primary care type problems were then directed to the emergency department, increasing overall demand. The GP OOH service is located in different rooms off the waiting room and uses a different computer system.

GPED 07

The urgent treatment centre (UTC) shares the front door, waiting room, and book-in desk with the emergency department. However, the UTC and emergency department use different computer systems (the OOH service that also operates out of the UTC has a different computer system again). Two streaming nurses, one based in the emergency department and one in the UTC, pick patients off the same list depending on the presenting complaint. The GPs and other clinicians (nurse practitioners, paramedics) can only see the patients that have been streamed to them on their computer system (with strict streaming guidelines), work in a separate area, and have no access to acute investigations so their role is dictated by department level factors rather than individual preference. The GP shifts are described as "quiet" and consequently, sessions are being cut back. They are expected to support the paramedics and nurse practitioners that also work in the UTC with advice and prescribing. There was an observed culture of aiming to redirect patients back to primary care for non-urgent investigations if needed rather than – 'if you turn up here we'll sort you out.'(The ethos of GPED06 described above.)

5.3.4 Outside onsite sites

GPED13

This service is based 100m from the emergency department front door with access within the hospital and outside. It was previously within the emergency department (and on many levels, appears to function in that way) but a 'frailty unit' has moved into the area of the emergency department that the service previously occupied. Staff are employed by the NHS Trust: GPs, emergency department doctors, and emergency department ANPs. GPs have access to the emergency department acute investigations and were reported to manage patients differently to the GP OOH doctors that work out of the same area. All patients are streamed from the emergency department or advised to attend by 111; they cannot "walk in". They are then assessed by a primary care streaming nurse (from the GP OOH service) using the Adastra algorithm system. The assessment appeared lengthy, with the streaming nurses not as experienced as at other sites, relying on the algorithm to make decisions rather than clinical judgement. There appeared to be a lack of primary care leadership and culture than we have seen elsewhere.

GPED10

This service is run by a local GP federation that also holds the GP OOH contract (so 24 hr service) on a city hospital site. There are strong links with community primary care, and they use the same computer system. The service has a separate front door, 50m from the emergency department entrance. Patients can present at either door, each of which has experienced streaming nurses. The primary care streaming nurse takes responsibility to direct patients to the practitioner with the most appropriate skillset - within the primary care unit using an appointment-based system (which included emergency nurse practitioners (ENPs) seeing minor injuries) or outside to another service (rapid assessment unit or redirecting patients back to their own GP). GPs maintain a traditional primary care role because of department level factors rather than individual preferences: there is strong GP leadership and links with community primary care; induction, governance and appraisal processes encourage GPs to act as they would in usual primary care; and acute investigations are not available to the GPs.

GPED11

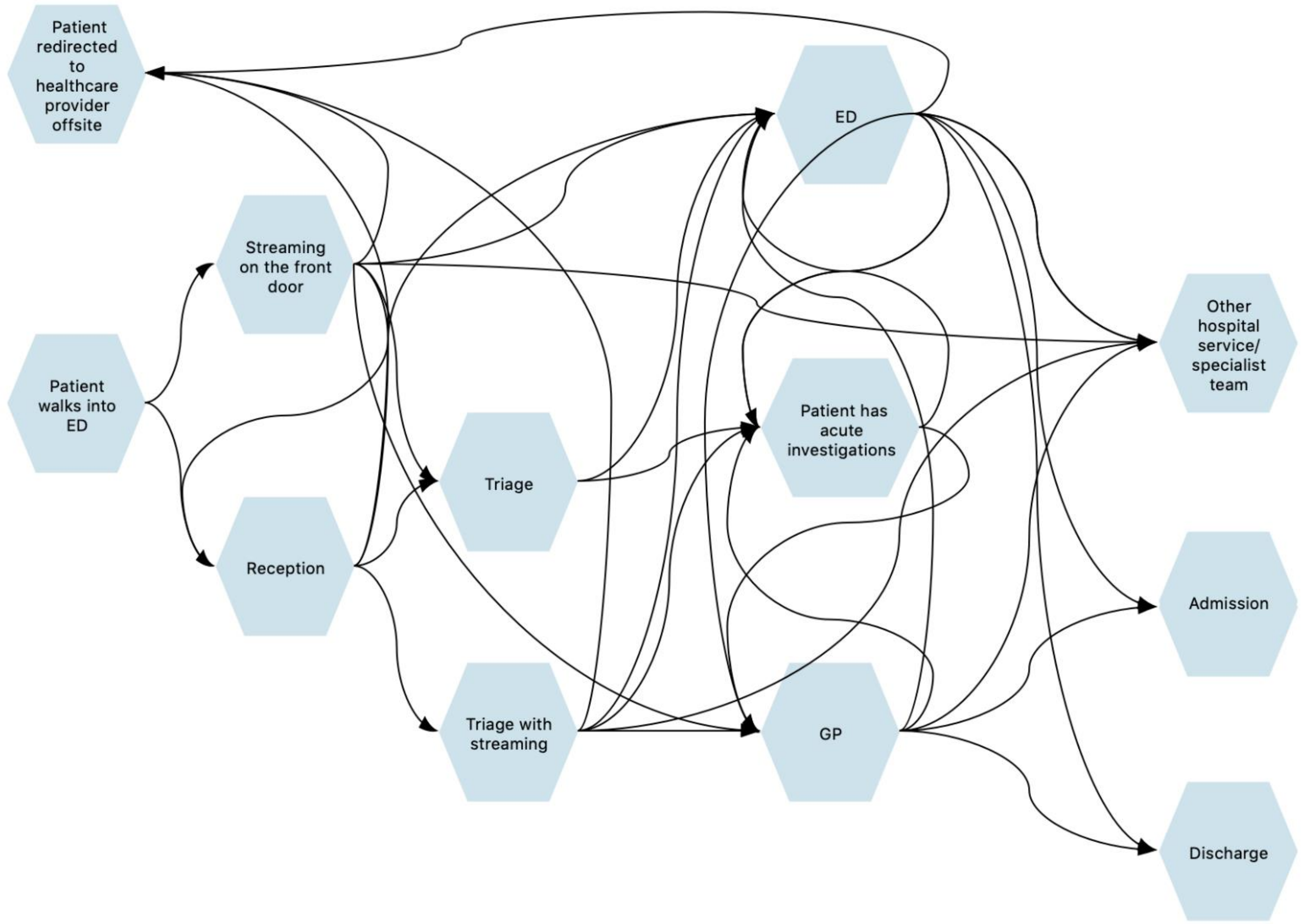
The walk-in centre is next door to the emergency department with a separate front door displaying a list of conditions that can be seen by the service. Patients can choose to present to either service or are streamed to the walk-in centre from the emergency department. There is no triage for walk-in patients (except for children <16 years and patients with mental health problems that are identified by the receptionist and triaged by the nurse practitioners within 15 minutes of arrival). The receptionist asks patients what the problem is and advises they go to the emergency department for triage if he/she feels this is appropriate. It is a large tertiary inner-city hospital with a high demand from patients with primary care problems. The service is nurse-led with one GP per shift employed as a locum, with no access to investigations. Some GPs reported that many patients that present expect investigations or specialist referral for their condition, neither of which the GPs are able to do, so the patient is advised to see their own GP, with some duplication of services.

5.4 More complexity

There is additional complexity, beyond the constructs described in the spectrum of integration, seen across these service models that influence the function of these services and the patient journey. Different methods of streaming were observed: at the front door, before reception book-in; inside the emergency department, after reception book-in; no streaming, where the GP self-selects their own patients; or a combination of models.

As illustrated in Figure 5-1, depending on the service model, a patient walking into the emergency department may first book in at the reception desk (with or without reliance on non-clinical receptionists to identify patients in need of immediate assistance) or have a brief assessment with the streaming nurse on the front door. The front door streaming nurse may be at the front door in a public area, e.g. behind the reception desk or in a small private room or ‘pod’, with or without access to equipment for basic observations. Alternatively, streaming may be combined with the triage assessment following reception book-in.

Figure 5-1: The complexity of a potential patient journey when GPs work in or alongside emergency departments



Key: ED emergency department; GP general practitioner

From streaming, the patient may be sent: for a ‘secondary triage’, further history and basic observations; straight into the emergency department service; to another hospital or specialist service; off site to another healthcare provider, usually the patient’s own GP; or directly to the onsite primary care service which may or may not also have its own streaming assessment, and direct patients back to their own GP or another acute hospital service if appropriate.

The GP (or other members of the primary care team, that may include nurse practitioners, paramedics, physician associates), may therefore see patients that have been assessed by streaming nurses of varying experience, with or without basic observations, or they may self-select their own patients. Acute investigations may have already been requested by the triage or streaming nurse and the patient may have initially been streamed to the emergency department and then sent to the GP service by a more experienced clinician. Following assessment, the patient may require further care and be: directed back to the emergency department; referred for assessment by another hospital service or specialist team; directly admitted as a hospital inpatient; or the GP may request investigations to aid decision-making whether the patient requires inpatient care or not. Alternatively, the patient may receive treatment and be discharged, with or without advice to attend their own GP for further care.

5.5 Summary of case study site sample

As described in Chapter 2, section 2.3.3, the sample of case study sites was selected from a national survey sent to the clinical directors of all Type 1 emergency departments in England and Wales with a response rate of 42%. Information from additional sources was also available for another 20% of hospitals but there may be different GP service models in or alongside emergency departments not included in our sample. Selecting service models by the form they take (inside integrated, inside parallel or outside on site) may also not have represented the various functions these service models take on. However, as described in this chapter, the sample included in this study represents a range of GP service models that function across the integration spectrum from services integrated with the emergency medicine service and services similar to usual primary care provision. I have also described how local contextual factors influence the complexity of these service models. This is therefore an appropriate sample to explore factors that influence patient safety outcomes at case study sites for theory testing and refining to address objective three.

6 Programme theory development from qualitative data analysis

In this chapter I describe how the case site qualitative data (local patient safety incident ‘Datix’ reports, observations and semi-structured interviews) were used to further refine and test the initial rough theories (described in Chapters 3&4) to develop a programme theory about how safe patient care is perceived to be delivered when GPs work in or alongside emergency departments. This is to address objective three, to explore factors that influence patient safety outcomes and case study sites.

6.1 Overview of data sources and samples

6.1.1 Local patient safety incident ‘Datix’ reports

Only 14 Datix reports in total were collected from the case sites which involved GP services in or alongside emergency departments. However at some sites, reports were not available to review (n=4) and at others, reports were available for only a limited time period, see Table 6-1. Three sites had reports available for a 12-month time period, other time periods varied from one to eight months. At two of the four sites where there were no Datix reports to review, the clinical directors reported that there were no relevant reports to the GP service. (At GPED08(II) the clinical director liaised with the hospital patient safety service and at GPED09(IP) the clinical director reported that all reports go through him and there were none relevant to the GP service.) At the other two sites, Datix reports were not available on site and the clinical director did not respond to three follow up email requests. An outline of the incidents reports from each site are listed in Table 6-1.

Table 6-1: Local patient safety incident (Datix) reports from case study sites regarding the GP service

Primary care model	Site reference	Incident reports available	No. of reports relevant to the GP service	Primary Incident type	Incident free text (key information extracted with minor edits for spelling and abbreviations only)	Patient harm (WHO definitions)(9)
Inside Integrated (II)	GPED014	Not available on site and no response to 3x follow up emails	n/a			
	GPED08	Not available on site. CD reported none involving GPs working in ED	n/a			
	GPED03	134 (3-month period Dec 2017 - March 2018, excluding pressure ulcers)	3	Triage/Streaming error	***"Patient triaged to (GP stream) and seen out of order due to lower position on computer (waited an hour longer than other patients with the same priority)***. Patient deteriorated and was transferred to majors."	Moderate
				Inadequate management	"ED protocol not followed, ***child with suspected NAI (non accidental injury) not admitted to paeds*** (paediatrics) and sent home for OPD (outpatient) follow up."	Unknown
				Inadequate management	"Patient sent to ED on advice of CAMHS (child and adolescent mental health service) as OOH (out of hours) and thought to be at risk of self-harm… ***GP unaware of policy should have been admitted for MH (mental health) assessment."***	Unknown
Inside Parallel (IP)	GPED09	Not available on site. CD reported none involving GPs working in ED	n/a			
	GPED04	1162 reports, 430 reports excluding pressure ulcers (from 1.4.17 - 31.3.18)	2	Diagnostic error	"Patient seen by agency (primary care) NP (nurse practitioner). Had fallen downstairs C/O (complaining of) neck pain ***Diagnosis muscular injury Returned today Multiple unstable fractures of C1 and C2 (neck fractures)."***	Unknown
				Inadequate management	"GP was gluing the wound on the patient's forehead ***the glue inadvertently dripped down into the patients right eye gluing his eyelids shut*** ."	Low
	GPED06	365 reports in 2017 (majors 254, minors 111)	1	Triage/Streaming error	"Patient triaged to UTC. As shift lead I allocated patient to see an OOH GP. ***This patient was later discharged from (OOH) (adastra system) and subsequently discharged from medway (ED computer system). However, the patient in question was still in the department."***	Unknown

	GPED07	7 reports only since change of provider 1 month ago	1	Inaccurate documentation	"Patient admitted to PAU (paediatric assessment unit) from UTC (urgent treatment centre). Nurse handed over that patient's ***DOB (date of birth) was wrong on their system*** which would make her 3 when she is 2."	Unknown
Outside on site (OO)	GPED13	Not available on site and no response to 3x follow up emails	n/a			
	GPED10	68 complaints, 150 incidents (April 2017 - first 2 quarters 2018)	1	Investigation follow up	***"Positive MSU (mid-stream urine) reports filed without action being taken*** - if action needed this is now highlighted to community GP."	Unknown
	GPED11	11 WIC reports (24.2.18 - 16.10.18)	6	Investigation follow up	"After waiting in accident and emergency department for over 2 hours, 2 patients were inappropriately referred to the WIC (walk-in centre) from A&E when the WIC opened at 8am. Both patients had blood tests performed by A&E. ***The WIC nurse practitioners and locum GP are unable to, and not here to review A&E investigations***... Having requested these investigations to not have them reviewed poses potential risk to patient safety."	Unknown
				Triage/Streaming error	"***One hour after triage the patient was transferred to WIC on symphony but the patient claims she was not directed to go to the WIC by any one from A&E.*** The WIC nurses discharged patient as called no reply as patient was not in walk in centre. ***After waiting 5 hours the patient asked A&E reception and she was directed to the WIC."***	Unknown
				Referral delay	"Patient seen at WIC ?torsion of testicle requiring urgent Urology review. ***Unable to contact Urology core-trainee***, middle or consultant through Vocera, just keep getting put through to switch who say nothing they can do to contact anyone from Urology."	Unknown
				Prescribing error	"Locum doctor prescribed Mirtazapine for a patient with depression. ***On the prescription he did not specify the quantity***."	Low
				Prescribing error	"Patient returned today with handwritten prescription. Patient said pharmacist said ***prescription was not legible*** so advised patient to return to the walk in centre to have prescription re written. Clinical notes checked and patient re-examined and further prescription was issued."	Low
				Prescribing error	"A patient was given a handwritten FP10 prescription for a community pharmacy with the ***wrong patient details."***	Unknown

Key: ED emergency department; CD Clinical Director; UTC urgent treatment centre, OOH out of hours; MSU mid-stream urine

The 14 Datix reports describing patient safety incidents relevant to the GP service were generally brief with limited information about contributing incidents or independent contributory factors. Due to the small number of reports, exploratory descriptive analysis to assess the most frequent and most harmful primary incident types was limited. Most reports (n=10) did not give adequate information to assess the harm outcome to the patient. Three reports described an incident that resulted in low patient harm and one report described an incident that resulted in moderate patient harm when a delay in assessment and treatment resulted in the patient deteriorating and requiring emergency level care.

The reports described the following primary incident types with contributory incidents and other factors outlined:

- three involving inadequate triage and streaming processes contributed by incompatible computer systems;
- three cases of inadequate patient management (two involving child safeguarding protocols not followed and one involving complications with wound management);
- three prescribing errors due to handwritten prescriptions;
- two cases of inadequate follow-up of investigation results (one where GPs could not access results requested at triage and one involving urine culture results available a few days after the visit);
- one diagnostic error (a delayed diagnosis of a cervical spine fracture)
- one delayed referral (where the walk-in centre clinician was unable to contact the specialist); and
- one documentation error (wrong patient date of birth).

While only few incident reports were available for analysis, learning from these reports was used to generate new theories on site that could be incorporated into interview guides and used to initiate conversations with staff and aid observations. These included, for example, how computer registration systems worked between services and how prescriptions were generated.

6.1.2 Observation and interview data

Fieldnotes

All case study sites with a GP service had two sets of fieldnotes for analysis (ME and I both wrote these up independently) and control sites had one set of fieldnotes depending on which researcher had visited (ME or myself). There was therefore a total of 23 sets of fieldnotes which described observations and informal staff interviews. My fieldnotes for sites with GP services were 10-17 pages long (mean 12 pages), often including anonymised photographs of public areas and diagrams to act as aide-memoires, and ME's fieldnotes were 4-11 pages long (mean 8 pages). Fieldnotes for control sites were 3-5 pages long. Findings were shared with the study team following the visit, including the health economist, for feedback and whether any iterations were needed.

Table 6-2: Case study site staff audio-recorded realist interviews

Model	Site	Staff interviews	Telephone	Face-to-face on site
Inside integrated (II)	GPED14	Medical director (n=1) GP (n=2) GP consultant (n=1)		*AC&ME (n=1) AC (n=2) AC&ME (n=1)
	GPED08	Clinical director (n=1) GP (n=2)	ME (n=1)	 AC (n=2)
	GPED03	Clinical director (n=1) ED Consultant (n=1) ED F1 doctor (n=1) ENP (n=2) ED staff nurse (n=2) GP (n=4)	 AC (n=1)	AC&ME (n=2) AC (n=1) AC (n=1) AC (n=1), ME (n=1) AC (n=2) AC (n=3)
Inside parallel (IP)	GPED09	Clinical director (n=1) ED consultant (n=1) GP (n=2)	AC (n=1) AC (n=1)	AC&ME (n=1) AC (n=1) AC (n=1)
	GPED04	Clinical director (n=1) ED consultant (n=2) ED middle grade (n=2) ED CT1 doctor (n=1) ENP (n=2) Healthcare SW (n=1) GP (n=2) Primary care ANP (n=1)	ME (n=1) AC (n=1)	AC&ME (n=1) AC (n=1) AC (n=2) AC (n=1) AC (n=2) AC (n=1) AC (n=2) ME (n=1)
	GPED06	Clinical director (n=1) ED consultant (n=2) ENP (n=1) GP (n=4)	ME (n=1) AC (n=1)	AC&ME (n=1) AC (n=1), AC&ME (n=1) AC (n=1) AC (n=3)
	GPED07	Clinical director (n=1) ED Consultant (n=1) UTC senior nurses (n=2) GP (n=1)	ME (n=1) AC (n=1)	 ME (n=2) AC (n=1)
Outside onsite (OO)	GPED13	Clinical director (n=1) Operations manager (n=1) GP (n=1) Primary care ANP (n=1)	ME (n=1)	 ME (n=1) AC (n=1) AC&ME (n=1)
	GPED10	Clinical director (n=1) ED Consultant (n=1) GP (n=4)	ME (n=1)	 AC (n=1) AC (n=4)
	GPED11	Clinical director (n=1) GP (n=3) Primary care ANP (n=1)	ME (n=1)	 AC (n=3) AC (n=1)
Control	GPED02	Clinical director (n=2)	ME (n=1)	AC&ME (n=1), AC (n=1)
	GPED12	Clinical director (n=1)	ME (n=1)	
	GPED15	Clinical director (n=1)	ME (n=1)	
Total		66 (5x clinical directors interviewed twice)	17 AC (n=6) ME (n=11)	54 AC (n=40), ME (n=5) AC&ME (n=9)

*Key: AC, Alison Cooper; ME Michelle Edwards

Audio-recorded realist interviews

A total of 66 interviews were completed; in 55 I was the single or joint interviewer, as indicated in Table 6-2. Where possible, ME interviewed the clinical director via telephone before visits as part of the selection process. This was not possible for our first visit (GPED03 (II)) and the interview was conducted onsite. For site GPED14(II), the telephone interview had been conducted with a clinical director at another hospital within the NHS Trust but it was felt that GPED14(II) would be a more appropriate site to visit and therefore an onsite interview was conducted with clinical director.

Post-visit telephone interviews were arranged for specific staff when an interview onsite had not been possible for example: GPED03(II), lead GP; GPED04(IP), emergency department consultant with an interest in governance; GPED06(IP), newly qualified GP recently started position, follow-up interview a month later to explore how he was finding the role; GPED07(IP), emergency department consultant involved in setting up streaming guidance; GPED09(IP), GP working in an integrated role in the children's hospital. Interview length ranges were as follows: initial clinical director interviews 22- 78 minutes (mean 46 minutes); GP interviews 8mins – 45 minutes (mean 21minutes); and other staff interviews 5 - 46 minutes (mean 20 minutes).

Twenty-six GPs (16 male, 10 female) were recruited across all service models for semi-structured interviews, which were audio-recorded and analysed. Most were experienced, as seen in Table 6-3. Of note, only one GP that participated in an audio-recorded interview from an integrated site also had a community GP role whilst most GPs in the other service models continued to work in the community.

Table 6-3: GP audio-recorded semi-structured interviews

Model	Number of GP interviews	GP gender	GP experience*	GPs with a current community role
Inside integrated (II)	9	4 male 5 female	Experienced including 2x GP leads (n=8) Newly qualified (n=1)	1
Inside parallel (IP)	9	6 male 3 female	Experienced including 1x GP lead (n=7) Newly qualified (n=2)	7
Outside onsite (OO)	8	6 male 2 female	Experienced including 1x GP lead (n=8)	6

*Experienced indicates over 5 years post certificate of completing training

6.2 Overall safety findings

The level of qualitative evidence from these data, as per the hierarchy of classification described in Chapter 2 section 2.3.3.5 (Box 1), was largely level 2 - participants sharing thoughts and perceptions from their own experience. Observational (level 1) data were useful to understand the context of how the service models worked but due to the short visits and not observing clinical encounters, observation of human factors was limited, and no patient safety outcomes were observed.

Clinical directors from 11 of the 13 case study sites, across all service models, had no patient safety concerns and did not describe any patient safety experiences related to the primary care service model. Two clinical directors from integrated case sites perceived that since GPs had been working in the department, overall patient safety had improved because the experienced, permanent GPs could also give advice to other staff members (example below) (GPED03(II), GPED08(II)).

*"We've **not had any significant safety issues whatsoever**, and a positive I suppose is the fact that **we've got someone with experience** that is **staffing** and supporting our rota, which makes it a **more safe department to work in**, because the staffing is good." Clinical Director GPED08(II)*

The clinical director from one of the control sites that no longer had GPs working in the department (GPED02) discussed a historical case of diagnostic error involving a child seen by a GP and expressed concerns that GPs treat patients differently to emergency department clinicians (example below). The clinical director of an inside parallel service model had concerns about which organisation held governance responsibilities and the skillset of primary care practitioners working in the emergency department following two local patient safety incidents, Table 6-1 (GPED04(IP)).

*"Well, **we got it wrong**, **we streamed the wrong patients** to them and **they got treated as GP patients and they weren't**. We had one… a litigation case… an under 1, unwell, horrible obs, went to the GP**. The GP didn't look at the obs**, looked at the child and went "they look okay", **went away, came back in and was really septic and almost died and they've got brain injuries and things like that**." Clinical Director GPED02 (no GPs)*

From the seven clinical directors' interviews from sites we did not visit: one clinical director felt safety had been improved by the intervention because there was now a senior nurse on the front door with oversight of the department, able to identify sick patients more quickly (GPED17(IP)); one described an event 10 years previously when a child had been streamed to the out-of-hours service, sent home and subsequently died from meningococcal septicaemia (GPED01 (no GPs)); and another clinical director described some 'missed small minor fractures' but felt reassured that they had safety netting in place to pick these up and he had no significant safety concerns overall (GPED21(II)).

6.3 Programme theory development

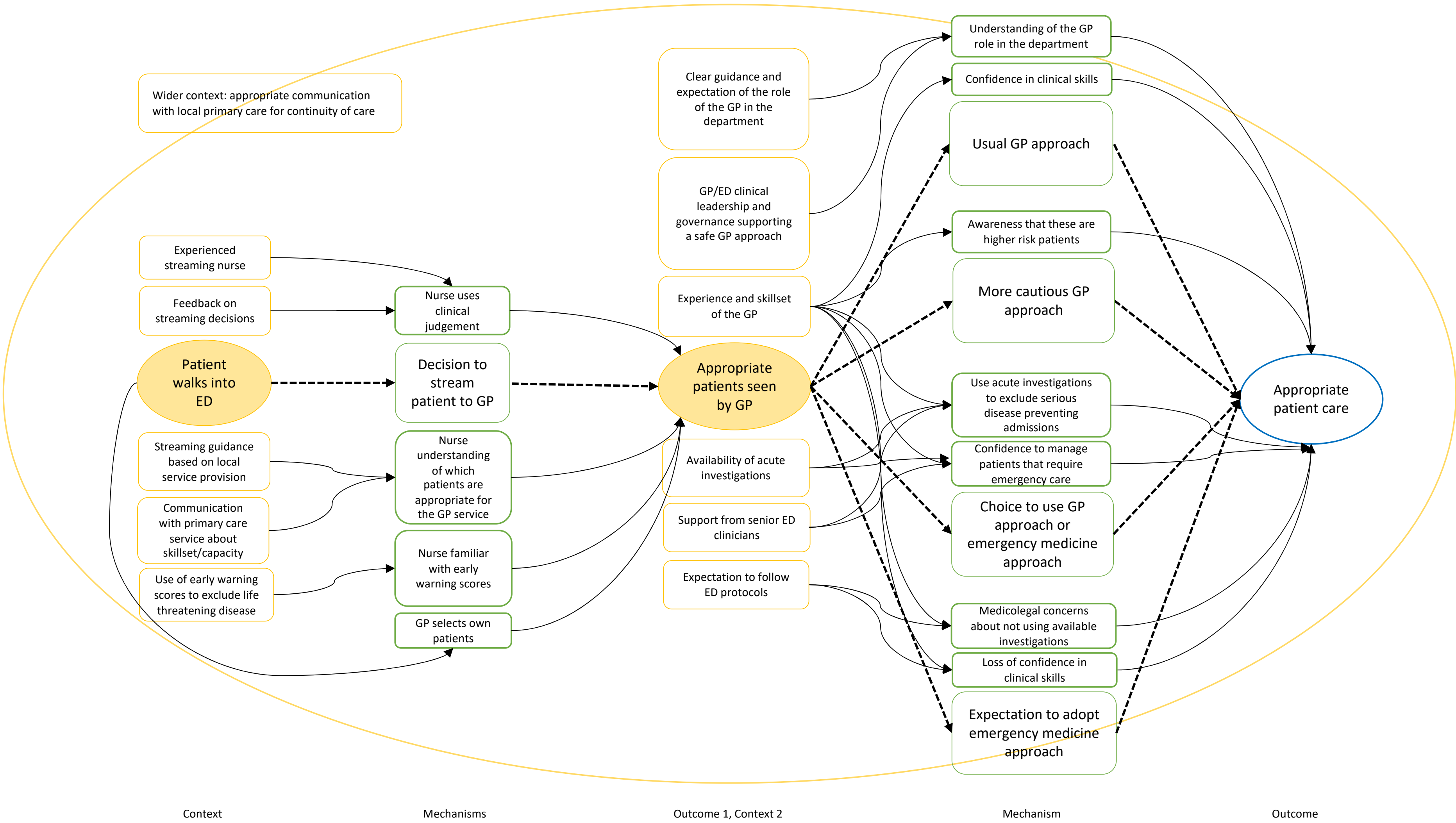
Initial theories developed through the literature review (Chapter 3) and patient safety incident report analysis (Chapter 4) were grouped under three care processes:

- Streaming and redirection decisions
- Influence on GPs' clinical decision-making
- Communication between services

Other new theories were developed from these data for example, prescribing incidents due to handwritten prescriptions. However, these were developed at later sites and required other data sources to test further for example, the pharmacies receiving prescriptions. Most data were regarding streaming, clinical decision-making (including follow up of investigations) and communication and therefore I chose to focus on these areas. The theories have been expanded, with a knowledge of how and why incidents may occur from Chapters 3 and 4, to learning from these data how such events are perceived to be mitigated. Findings are summarised as a *programme theory* to describe how safe patient care is perceived to be delivered when GPs work in or alongside emergency departments, Figure 6-1.

The programme theory comprises linking CMO configurations where the outcome of the first CMO (streaming appropriate patients the GP service) becomes the context for the second CMO configuration (GPs' decision-making). An overarching higher level theme contributing to the delivery of safe primary care in or alongside emergency departments is communication between the services - this is illustrated in Figure 6-1 by the circumferential yellow ring. The figure is complex and therefore sections have been enlarged in Figure 6-2, Figure 6-3 and Figure 6-4.

Figure 6-1: Programme theory for how GPs are perceived to deliver safe patient care in or alongside emergency departments (sections have been enlarged in Figure 6-2, Figure 6-3 and Figure 6-4)



6.3.1 Streaming and redirection decisions

At all the case study sites, triage and streaming processes were conducted by nurses or nurse practitioners. We did not observe or interview any GPs adopting a ‘gatekeeper’ role screening patient at the front door (and had not identified any sites with this model in the national survey), therefore this theory developed in Chapter 3 section 3.2.1, could not be refined any further. At integrated sites, GPs often self-selected their own patients.

Streaming nurses having difficulty identifying appropriate patients for the primary care service (Mreasoning) was a common theme reported by emergency department doctors, nurses and GPs across many sites (example below) (GPED04(IP), GPED06(IP), GPED09 (IP), GPED10(OO)). GPs reported that sometimes the nurse did not appear to be aware which patients were appropriate for the service, for example, patients requiring wound care when the GPs did not have the equipment to deal with such patients.

> *“It’s a **bit hit and miss**, it depends on what the **help of the triage nurse is**, there’s no set system so other hospitals have set triage systems like the Manchester system and things, they **haven’t got that in place here**, I think **that’s probably a hindrance** as sometimes patients you’re seeing are inappropriate**, I’ve seen epiglottis** which really I shouldn’t be seeing as a GP in A&E, but **there’s lots of things that I could be seeing** which I don’t end up seeing, because they’re deemed to be an A&E case." GP GPED04(IP)*

An experienced Advanced Nurse Practitioner (ANP) described junior triage nurses’ inexperience (C) negatively influencing streaming decision-making (GPED10(OO)). He gave the example of the nurse not exploring *why* patients had presented to the emergency department with what superficially appears to be a chronic condition and therefore missing red flag symptoms (Mreasoning); he gave the example of the possibility of cauda equina syndrome (a medical emergency) when a patient with chronic back pain presents with a history of incontinence.

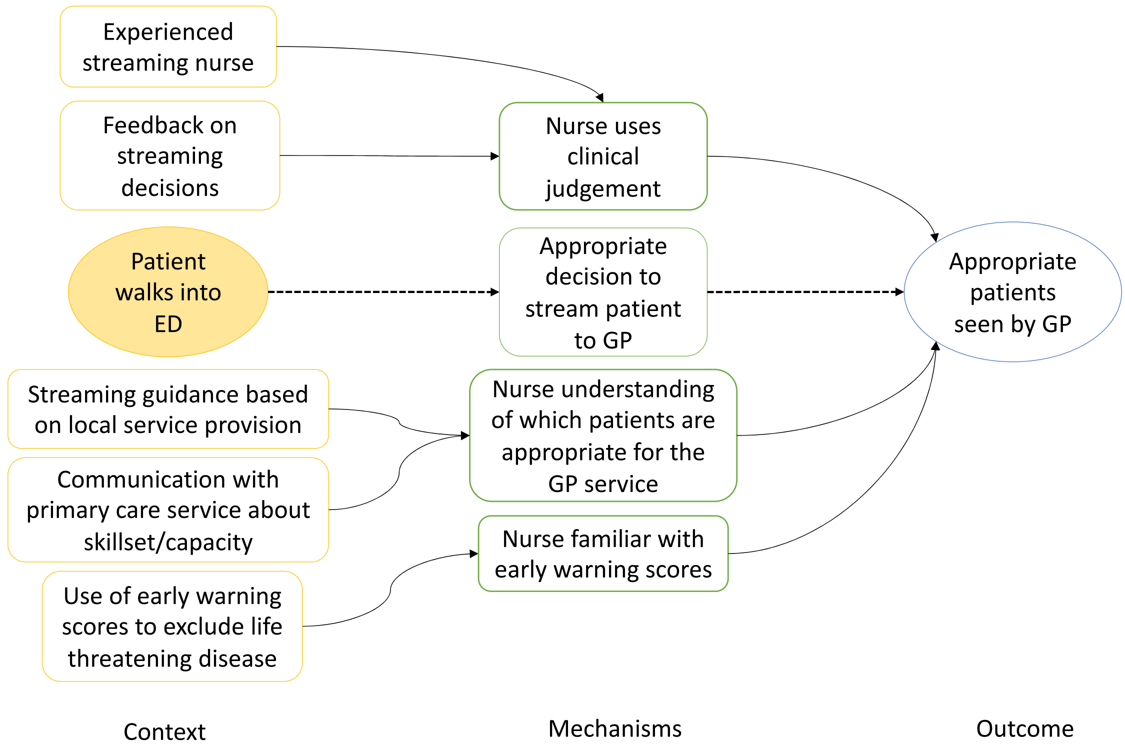
Understaffing in the department (C), and consequently the streaming nurse becoming involved in treating patients (O), was reported to delay triage and the streaming process at one site (O); consequently, receptionists who had no clinical training, had a list of conditions they were advised to call the triage nurse for to avoid delays (example below) (GPED07(IP)).

> *"A patient with epistaxis (nose bleed) had been* ***identified by the receptionist*** *and was taken to the red star cubicle. The triage nurse arranged for an ANP to see them immediately. She discussed that the target time to triage is 20 minutes – '****it's not going to happen' it's just me."*** *Field notes GPED07(IP)*

At another site, which had a walk-in service, there was no clinical triage (Mresource) (except for children and patients with mental health problems) so the receptionist directed patients to the emergency department next door for triage (O) if she felt this was appropriate (Mreasoning) (GPED11(OO)). Senior clinicians were also observed to override streaming nurses' decisions, based on the handwritten notes (Mreasoning), and to send patients, initially streamed to the emergency department, to the GP service (O) (example below) (GPED04(IP)).

> *"I witnessed the evening ED consultant* ***rearranging the notes*** *so that patients allocated to the ED stream were placed in the GP stream box along with the triage nurse who was an ENP. The ENP defended her decision on why the patient should be in the ED stream,* ***'I think that's an orbital cellulitis'".*** *Field notes GPED04(IP)*

Figure 6-2: Factors described to facilitate appropriate streaming decisions (enlarged section from Figure 6-1)



Many sites were happy to share learning about how and why the streaming process worked well in their experience and how it had been developed and modified to ensure appropriate patients were streamed to the GPs. This is summarised as a theory, CMO configuration, illustrated in Figure 6-2 (enlarged section from Figure 6-1). As in Chapter 4, key themes identified from these data are highlighted in ***bold black*** in the CMO configuration described below.

If there is ***adequate staffing*** *to meet* ***standard triage targets*** *and streaming is conducted by an* ***experienced nurse****, utilising* ***early warning scores****, with* ***guidance based on the local service provision*** *and there is* ***good communication*** *between services about* ***capacity and skillset*** *(C)*

then the nurse ***understands which patients are appropriate*** *for the service (M),*

uses ***clinical judgement*** *and* ***early warning scores*** *to identify sick patients (M),*

is aware of the ***flow and capacity*** *in different streams in the department (M)*

and the department ***modifies*** *the process based on* ***experience and learning*** *(M)*

then ***appropriate patients*** *will be streamed to the GP service (O)*

One site described how they felt the streaming guidance for young children was inadequate and after a near miss where a sick child was streamed to the GP (O), the process was modified to include paediatric-specific early warning scores (C) to assist decisions (Mreasoning) (example below) (GPED03 (II)).

"So to ***give you an example of how we've learned****… in the first week of implementing it (streaming) we had a* ***child seen in the triage room****, had the eyeball, went down it, went to Urgent Care, sat in the waiting room, got seen by a GP,* ***thankfully the GP picked up that this was a sick child****, got them to the resus room, ended up in* ***intensive care. So we had a very rapid learning and a very rapid PDSA cycle there."*** *Clinical Director GPED03(II)*

Senior nurses at the same site described being uncomfortable with basic observations not being measured on patients before they were streamed, so a health care assistant (HCA) now supported the streaming nurse to ensure these measurements could be taken (GPED03(II)). Guidance relevant to the local primary care service was felt important but an experienced streaming nurse who could use his/her clinical judgement (Mreasoning) was felt to be essential (example below) (GPED07 (IP), GPED09(IP), GPED10(OO)). Appropriate communication between services allowed the streaming nurse to understand the capacity of the different streams (C) (situation awareness) which again influenced streaming decisions (GPED10(OO)).

> *"In the end what it really boils down to is having **an experienced member of staff**, working within **fairly broad parameters** of what is appropriate and what is not… There's always a temptation amongst the nursing staff to put a less experienced person on streaming or triage simply to keep the most skilled people seeing the sickest patients, but that's definitely the wrong thing to do, we have to have **experience up front** 'because it's an **extremely important job getting them in the right place** I think."*
> *Emergency Consultant GPED10(OO)*

6.3.2 Influence on GPs' clinical decision-making

There were no qualitative data in the case study work describing patient safety outcomes that could be attributed to GPs' cognitive biases (e.g. framing, anchoring, representativeness, availability, discussed in Chapter 3, section 3.2.2). A couple of anecdotal incidents were discussed in clinical director interview data and the accepted risk of misdiagnosis for all clinicians seeing patients that present with undifferentiated symptoms at an emergency setting was also raised by two clinical directors (example below).

> *"If you look at it as a doctor, **we work on probabilities anyway,** which is never one, so **we all do misdiagnosis**… I suspect the legality part of it, obviously it feels bad if you miss something, but the legality part of it is practically what somebody at your level would have done... GMC looks that way, they get specialist opinion, court looks that way as well, you know, **we're expected to misdiagnose and other things**, and that, as long as it's not a huge proportion of that, it's probably fine, I would assume."*
> *Clinical Director GPED13(OO)*

There was some evidence however of GPs working in more integrated models having mismanaged patients with fractures (O) (GPED04(IP), GPED14(II)) and not following standard emergency department child safeguarding protocols (O) (example below) (GPED03(II), GPED04(IP)).

> *"A child was seen who was* ***known to have had input from social services****… and the* ***GP had seen them****, and they* ***really should have rung social services just to alert them*** *that the patient had been seen, and they probably didn't need to do any action other than that, but they just* ***seemed to maybe not have quite the right level of concern and appreciation of the need to keep social services involved****." Clinical Director GPED04(IP)*

I was able to explore the outcome for a patient described to have a delayed diagnosis of a cervical spinal fracture reported in a Datix report at one site (GPED04(IP)). Reassuringly, there had been no harm to the patient (O), but the clinical director reflected that he felt that the primary care nurse practitioner who had seen the patient was not familiar with NICE guidelines for this condition and when further imaging was indicated (Mreasoning). Unclear governance processes due to different commissioning organisations were felt by a senior consultant to contribute to confusion about which patients the primary care service should be managing at the same site (C) (example below).

> *"****I was concerned from the outset really****, about the* ***lack of clarity behind where was the governance****, what were they supposed to be seeing, was it within their normal scope of practice. We had a* ***couple of clinical incidents****, which I'm not saying would never have happened if they'd been seen by us, because I don't think you can ever say that, but we had an incident of a missed cervical spine fracture… So it just felt like we were in a bit of an unclear and not very satisfactory situation, really." Emergency Consultant GPED04(IP)*

GPs described how working in an emergency department setting influenced (or did not influence) their clinical decision-making to safely maintain their usual GP approach (Mreasoning), or safely adopt an emergency medicine approach (Mreasoning). As described in Chapter 5, section 5.2, in some service models, the role of the GP was dictated by the department level factors for example, the GPs did not have access to acute investigations (C) and patients had already been assessed to be low risk (C). In other service models, the GPs self-selected patients and individually took on that risk to choose whether to use a GP approach or to use acute investigations and adopt an emergency medicine approach (Mreasoning).

The way GPs described the emergency department setting influencing their clinical decision-making (or not) could be divided into four groups:

i) GPs reported they saw a *similar cohort* of patients to usual primary care, treated them with a *usual 'GP approach'*, as they would in primary care;

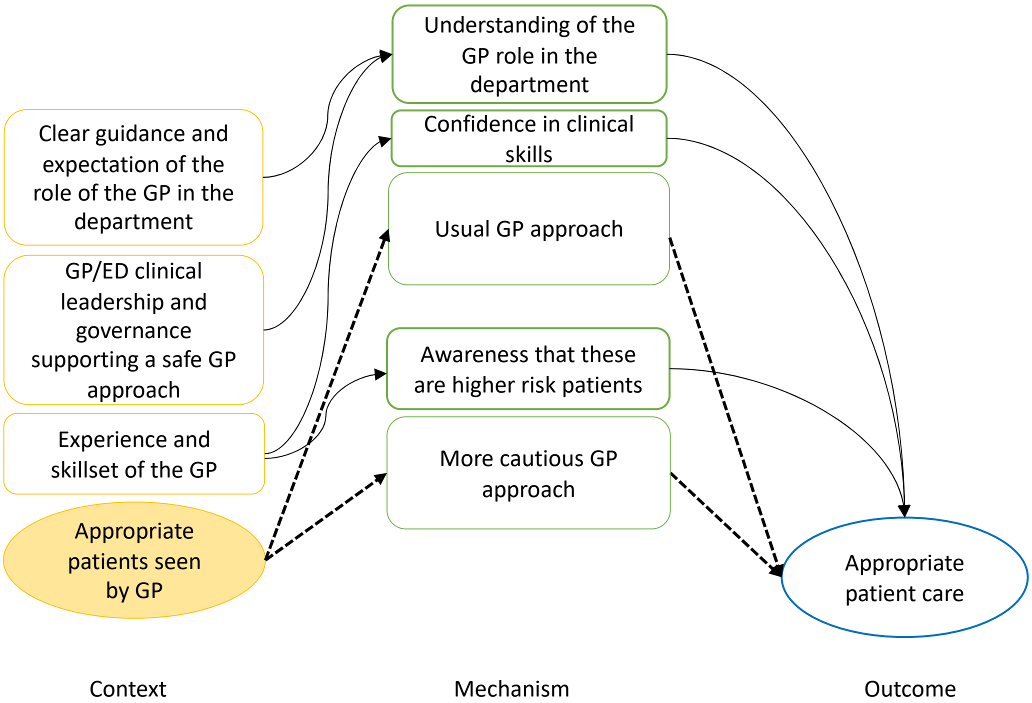
ii) GPs reported they saw a *wider cohort* of patients to usual primary care and therefore *took on a more cautious* GP approach;

iii) GPs with additional emergency medicine skills, working in a setting with access to acute investigations and seeing a *wider cohort* of patients than usual primary care, described *choosing* whether they treated patients with a 'GP approach' or whether they used acute investigations and adopted an emergency medicine approach; and

iv) GPs that felt they were *expected* to use investigations and adopt an *emergency medicine approach*.

CMO configurations are described below for these four different GP groups. CMOs i and ii describe how GPs described maintaining a usual GP approach or a more cautious GP approach, illustrated in Figure 6-3 (enlarged from Figure 6-1.)

Figure 6-3: Factors described to facilitate GPs maintaining a safe GP approach in the emergency department setting (enlarged section from Figure 6-1)



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i) If GPs that are ***experienced*** *(C) and* ***confident in their clinical skills*** *(C) work in or alongside emergency departments* ***without access to acute investigations*** *(C) seeing patients* ***identified as being appropriate*** *for the GP service (C) that* ***they perceive are a similar cohort to usual primary care*** *(C)*

they use their ***clinical skills to 'rule out worst case'*** *(M)*

are ***comfortable with uncertainty*** *(M)*

use ***'safety netting' techniques*** *(M)*

and ***admit patients*** *if they require acute investigation (M)*

to ***safely use a GP approach*** *(O)*

Some GPs who worked in a service where they had no access to acute investigations and often a strict streaming process (C), reported that the patient cohort that they managed was very similar to usual primary care (C) (where sick patients may also present) and they could therefore manage the patients with their usual GP approach (Mreasoning) (example below) (GPED04 (IP), GPED06 (IP), GPED09(IP), GPED10(OO), GPED11(OO)). GP skills that they reported to rely on included:

- having confidence in clinical skills,
- being comfortable with uncertainty,
- being able to admit patients for further investigation if necessary, and
- using recognised 'safety netting' techniques,(244) so that patients were aware when they should seek medical help again if symptoms persisted or deteriorated.

'Obviously patients that are self-selected to come into hospital, well it depends how they've got here really. ***If they've self-selected to come to hospital because they perceive that they're really ill*** *and in need of something urgent, I suppose they are at high risk but* ***quite a lot are re-directed here by NHS 111 or the practice receptionist*** *is most common now." GP GPED11(OO)*

Clear guidance and expectation of the role of the GP (C) was reported to facilitate this approach, supported by strong GP and emergency clinician leadership (C) (example below).

"The general theme we say to our GPs ***is we shouldn't work any differently here*** *than we would do if we sat in our practices, just because we're in a hospital, we don't do anything differently.* ***If we need to admit people we would obviously send them round as we normally would****, in a practice, we're not trying to be a mini A&E here and do anything differently." GP GPED10(OO)*

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ii) If GPs that are ***experienced and confident in their clinical skills*** *(C) work in or alongside emergency departments* ***with or without access to acute investigations*** *(C) seeing a* ***cohort of patients they perceive to be higher risk*** *(C)*

they incorporate this higher risk *into their clinical decision-making (M)*

consultations may be longer *for more thorough history taking (M)*

the ***threshold for admission*** *or using other acute services for investigation* ***may be lower*** *(M)*

but many patients can still be ***safely managed by using a GP approach*** *(O)*

Other GPs, some at the same hospitals as above, perceived that they saw a different cohort of higher risk patients than in usual primary care (C) and incorporated this into their clinical decision-making (Mreasoning) (example below)

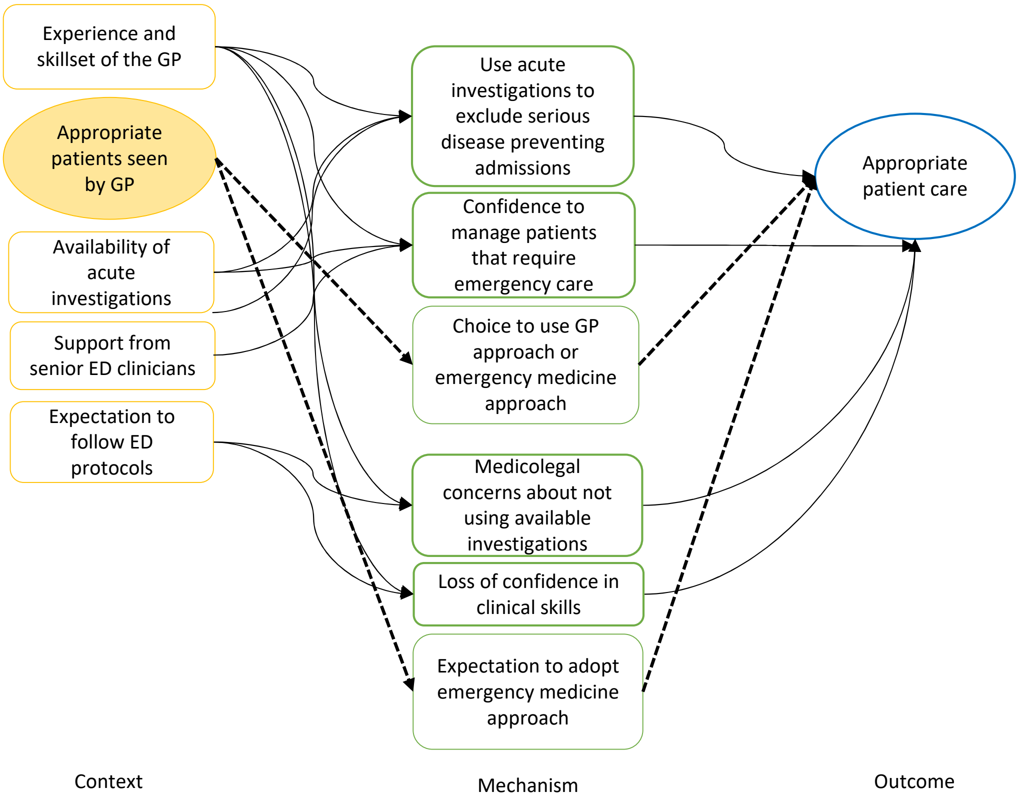
(GPED04 (IP), GPED06 (IP), GPED09(IP), GPED03(II), GPED14(II)). Additional clinical skills they described using to manage these patients included:

- longer consultations in order to take a more thorough clinical history to establish chronology of symptoms and events;
- being aware of their role and limitations;
- and having a lower threshold for admitting patients for further investigation.

"I think as you alluded to earlier working in an urgent care A&E environment, ***you're going to see potentially a lot sicker patients****, you're going to see the sub-arachnoid bleeds,* ***potentially the subdurals after head injuries*** *and that sort of thing, so again, in my experience the sort of characters that tend to do, GP work in an A&E department are* ***quite au fait with these conditions****." GP GPED09(IP)*

CMOs iii and iv outline contexts that were described to influence GPs choosing to adopt an emergency medicine approach or feeling that they were expected to adopt this approach when working in emergency department settings (Mreasoning), illustrated in Figure 6-4 (enlarged from Figure 6-1).

Figure 6-4: Factors described to facilitate GPs safely adopting an emergency medicine approach (enlarged section from Figure 6-1)



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iii) If GPs with ***additional emergency medicine skills and experience*** *(C) work in emergency departments seeing a* ***wider range of patients*** *(C) with* ***access to acute investigations*** *(C)*

they can use their ***clinical skills*** *(described above) to manage risk (M)*

and choose which patients can be ***safely managed*** *by a* ***usual GP approach*** *and which patients require acute investigation and that they can manage using an* ***emergency medicine approach*** *(O)*

Some GPs working in these more integrated services, described how even if they did have access to acute investigations, then many patients could still be managed by a traditional GP approach using the clinical skills described above (Mreasoning).

Selecting the right patients and experience of the GP (C) were felt to facilitate this approach (example below).

> *"If you **select the right patients to see**, as a GP in the department, you **should be able to deal with them in a similar way** to you do in primary care, but always just having that **slight radar on** to think okay, is there something else going on, do we need to do that little bit more?" GP GPED14(II)*

Categorising patients into those that needed investigations (Mreasoning) and those that did not was also described (example below).

> *"I tend to **categorise patients** into 3 groups: ones that I can see and **treat and move on**; ones that I see and **need to admit** or whatever I decide to do investigation wise, the decision is made early on; and **then there's the group in the middle** where you're uncertain whether this patient needs urgent admission or not, and you **use the investigations as a tool to help in that decision-making**." GP GPED03(II)*

GPs described that they were able to use acute investigations for patients when clinically indicated because:

- they were confident in interpreting results;
- could advise patients about X ray reporting systems;
- were aware of protocols for high risk conditions;
- could prevent admissions if results were satisfactory; and
- had the support of emergency medicine staff to provide this level of service.

iv) If GPs work in emergency departments ***with access to investigations*** *(C) where there is* ***an expectation to follow emergency department protocols*** *(C)* ***or governance responsibility is unclear*** *(C) or* ***patients have already had investigations requested at triage*** *(C)*

GPs may feel that they are ***expected to use these investigations*** *in the emergency department setting (M)*

Or they may become ***less confident in their clinical skills*** *(M)*

or have ***medicolegal concerns*** *(M)*

then they ***may use investigations*** *for patients* ***that they would not have requested*** *if they had seen the patient in usual primary care (O)*

Some GPs however, described internal conflict about when it was appropriate or not to use acute investigations (Mreasoning). Sometimes the decision had been taken away because the patient had already had investigations requested at triage (C), which sometimes the GP might not be aware of (example below) (GPED03 (II), GPED04(IP)).

"It's very frustrating because then ***you've only found out because the patient's told you****, literally as they're going out the door "****oh, did my blood tests come back?"*** *and you're like 'oh for goodness sakes'" ANP GPED04(IP)*

Expectation of the department (C), loss of confidence in clinical skills (Mreasoning) and medicolegal concerns (Mreasoning) were all described to influence the GP's use of investigations when they felt they would not have done so in usual primary care (example below).

*"****Thinking about defence****,* ***if you don't do tests when they're right next to you****, and something were to happen, an adverse event, you would have to be able to stand up to that and* ***defend yourself*** *and say why you didn't do those tests." GP GPED14(II)*

A desire to help the patient along in their diagnostic journey, using acute investigations for non-urgent complaints (Mreasoning), was also described.

> *"If they're presenting with **hip pain**, or knee pain and they've already been seen and you examine them and think well actually **if I was their own GP the next step might be an x-ray** here. **So I'm here, the patient's here**, in this situation **I might do an x-ray** to help speed things along. It might not necessarily ... it won't lead to admission, but **it might just mean that the GP has got a bit more information** for what they might want to do next time they present in the community." GP GPED13(OO)*

6.3.3 Communication between services

Some sites were observed or reported to have limited communication between the emergency and primary care services. Contributing factors included:

- incompatible computer systems with patients becoming 'lost' between services;
- less opportunity for face-to-face communication to understand the capacity and skillset of the clinicians in the primary care service on the day; and
- an 'us and them culture' where communication between services was not encouraged by clinical leadership.

Incompatible computer systems between services (C) were linked directly to patient safety incidents in two Datix reports where patient assessment and treatment had been delayed (O), and one patient had become 'lost' in the system (O) (GPED03 (II), GPED06(IP)), Table 6-1. Receptionists at another case site described how they had three different computer systems to operate (for the emergency department (Mresource), the primary care service associated with the emergency department and the GP out-of-hours service) which led to duplicate patient entries on different systems and again increased the likelihood of patients becoming lost on or between the different systems (O) (GPED07(IP)).

Some GPs also complained that the emergency department computer system meant they were unable to see any patient information (C) (for example, significant medical problems or usual medications) as they would in primary care. Also, prescriptions needed to be handwritten (O) whereas in usual primary care they would be computer generated (example below). This had led to prescribing errors reported in Datix reports at one case site (GPED11(OO)), Table 6-1.

*"It's (the computer system) awful, it's **not designed for GPs**, it's A&E tracking software and they're trying to… sort it out on **paper, handwritten prescriptions**." GP GPED11(OO)*

The geography of the department (C), with distance between the services limiting face-to-face communication, was felt to contribute to a lack of communication between services at one site (example below) (GPED11(OO)). Another site however, with a separate GP service, reported good communication through the senior nursing team (C) - reviewing on the day capacity and skillset and moving staff between services to meet patient demand.

*"We're **not very integrated** with the ED and we don't, we don't feel very integrated, it still feels a bit us and them." GP GPED11(OO)*

An 'us and them' culture was observed at another site (where there was good opportunity for face-to-face communication since the GPs worked out of an emergency department cubicle). At this site juniors were not encouraged to ask the

GPs for advice (GPED04 (IP)). The personality of the GP was felt to contribute to this culture at another site (GPED06 (IP)).

Good teamwork and communication were reported within the separate GP service at some sites (O) (example below) (GPED10(OO), GPED11(OO)).

> *"I asked (the streaming nurse) why the GPs like working here. She says **they look after them**, **make sure they take breaks**, make them cups of tea and block off the last slot so they can catch up and handover. She says they are a good team." Field notes GPED10 (OO)*

While at another separate GP service, there did not appear to be the same team spirit (O). The GP looked as though he was lone working (my interpretation). I did not have the opportunity to discuss this further with the GP observed in the extract below.

> *"The department seems quiet and relaxed with the radio on in the background but **it does not look as though the GP stopped all day**… I was unable to interview him. I left him the study information leaflet, to contact me for a telephone interview at a later date but I've not had the opportunity to make any rapport and I think it is unlikely he will contact me. He was in his late 30s and all staff described him as lovely. **He looked tired** and **staff doubted he had stopped for a lunch break**." Field notes GPED13(OO)*

There was limited evidence in these qualitative data to explore patient safety outcomes from inadequate referral and communication pathways to and from local primary care. At several sites, we observed patients presenting to the emergency department having been referred by their local GP. Some staff reported they felt these patients should have been referred directly to the specialist (GPED09(IP), GPED11(OO)) but I was unable to explore from these data if there was any miscommunication due to duplicate assessments.

Inadequate discharge summary communication with community primary care was described in one Datix report (GPED10(OO), Table 6-1. Discussing this incident, the matron described how there had been a lack of a formal process (Mresource) for following up urine test results from the GP service, resulting in delayed treatment for some patients(O); there was now a new system in place for all positive results to be highlighted (Mresource) and sent to the local GP (O). A similar lack of formal follow-up system for urine test results was described at another case site where an emergency medicine consultant discussed how, due to the number of test results received each day (C), it was not possible to ensure all had been actioned appropriately (O) (GPED14(II)). A GP at this service discussed how she tried not to request such tests due to this issue. There was no evidence that this caused any adverse events.

A phone call was witnessed at one site from a community GP where inadequate information on the computer-generated discharge summary (O) meant she did not know which antibiotic had been prescribed for a pregnant patient.

*"A **potential safety event** was witnessed. The local GP had faxed a request for further information about a pregnant patient that had been treated for a UTI. The nurse explained that **on the discharge summaries the GP cannot see the treatment section or senior review section**. The GP could tell that she been seen for a query UTI but there was **no indication which antibiotics had been given**." Field notes GPED11(OO)*

An emergency medicine consultant expressed concern at one site that patients may choose to present to primary care services in or alongside emergency departments as their first point of call, perceiving easier access than community primary care (C). She felt this could result in less continuity of care and that chronic diseases, for example asthma, may not be managed as well as they could but it was not possible to explore this theory any further from these data.

From these data, with increased understanding of how poor communication can contribute to patient safety incidents in these settings and learning from good practice how communication could be improved, I developed a theory to describe how good communication and teamwork can be promoted between services to facilitate safe patient care.

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*Service models with **strong clinical leadership**, employing **experienced, permanent GPs** with opportunity **for face-to-face communication** between services and **compatible computer systems** (C)*

*with a **culture that encourages inter-professional communication and learning** (M)*

*and clinical leadership that promotes **mutual respect** (M)*

***encourages communication** between services and teamwork to facilitate safe patient care (O)*

The integrated case study sites reported good communication, which was perceived to promote interprofessional learning (O) (example below). At these sites the GPs were permanent staff members (C) and there was good opportunity for face-to-face communication (C). GPs were described not only to give clinical advice but also provide advice on primary care referral pathways which several emergency department staff reported as helpful. I observed a sense of multidisciplinary respect and teamwork (Mreasoning) with clear emergency department clinical leadership (C)(GPED03 (II), GPED08(II) and GPED14 (II)).

> *"One of the biggest thing we didn't expect is the **effect of education**, that there's a GP sitting in the department, so they're seeing a frail elderly patient, **the F2 is sitting next to them seeing a similar patient**, and the F2 is going "why are you sending your patient home and I'm admitting mine?", and **the amount of cross-fertilisation knowledge and support**… so **that was something that we didn't expect that we've really benefited from**." Clinical Director GPED14(II)*

Strong GP leadership (C) was seen at several case study sites which was reported to improve communication between the services (O) and perceived to improve patient safety (O) (GPED10(OO), GPED14(II), GPED03(II)). The lead GP at one site (GPED10(OO)) described good communication with local primary care (O) where both services used the same computer system and were able to access each other's consultation notes (Mresource). Additionally, she felt this assisted both services to unite antibiotic stewardship messages – if patients chose to present to a different service seeking antibiotics for a viral illness that the local GP had advised were not appropriate, this was clearly documented on the emergency department GP computer system and could be taken into consideration. She also gave an example of good practice describing clear induction and appraisal processes (C), including periodically auditing a sample of GPs' medical records for evidence of appropriate clinical decision-making (Mreasoning) and safety netting (GPED10 (OO)).

6.4 Discussion

Main findings

There were few patient safety incidents identified in these data from the 13 purposefully selected case study sites: 14 local patient safety incident (Datix) reports; some anecdotal reports from interview data; and no observed patient safety incidents. However, mechanisms were identified in the onsite in-depth interviews to explain how potential patient safety outcomes may occur and how, in different contexts, they could be mitigated. This understanding was used to develop a programme theory for how GPs are perceived to deliver safe patient care in or alongside emergency departments incorporating: safe streaming decisions; safe GPs' clinical decision-making; and promoting communication and teamwork between services.

Strengths and limitations

Thirteen case study sites were recruited for theory testing and refinement (including different service models in different sized hospitals, geographically spread across England and Wales). All sites were visited by myself or another researcher (ME) and we applied a consistent realist approach having developed initial rough theories from the literature and patient safety incident reports. ME and I have different skillsets (qualitative researcher vs GP) which complement each other and allowed us to challenge each other's thoughts and ideas on theory development during data collection and analysis to mitigate individual bias. Being a GP, I felt that professional courtesy helped recruit GPs to be interviewed. Analysing Datix forms early in the visits gave the opportunity to explore learning with staff during the visit. Data were collected from all sites within the planned time period. Despite the pressurised environment, staff appeared happy to discuss previous experiences and even if there was not the opportunity for a formal interview, short opportunistic interviews with handwritten notes were used to capture data.

Few patient safety incident (Datix) reports were collected across the sites; at four sites no reports were available to review (clinical directors at two of these sites reported that there were no relevant reports) and other sites' reports were available for a short time period only. An alternative strategy may have been to liaise directly with the hospital patient safety departments or recruit patients reporting problems from online forums. Staff however also reported few patient safety concerns. This could be due to selection bias - often case sites volunteered to take part in the study to showcase their collaboration with the GP service. However, transferable lessons could be learned from how these services had been modified to improve the safety of care delivery. I identified four typologies to describe GPs' clinical decision-making in these settings which is a helpful model to communicate methods of working but underlying reality is far more complex. GPs are not a homonymous group: individual experience, skillset and perceptions of risk may vary. Typologies may also vary for individuals on the day and other influences on clinical decision-making may not have been identified.

As discussed in Chapter 5 section 5.5, selecting sites from a national survey with a response rate of 42% limits sampling, although there was information on an additional 20% of hospitals. No sites were recruited where GPs screened patients at the front door, however there may be departments operating this service model that we were unaware of. The visits, at three days, were short. Longer visits may have given greater understanding of how processes worked and more opportunity to observe human factors - staff interactions with patients and within the team.

Observing clinical consultations may have identified mechanisms that GPs used to mitigate patient harm that they were unaware of and did not consider discussing in interviews even though I used the realist teacher-learner interview technique aiming to explore this ontological depth.(146) I was unable to test the theories about referral pathways and communication with community primary care with these data.

Context of current literature

GPs are recognised as low patient safety incident reporters, which may have contributed to the low number of Datix reports identified.(76) Communication failures, exacerbated by hierarchical differences and conflicting roles and role ambiguity, are known to be associated with patient safety incidents,(245,246) while interventions to improve communication between healthcare professionals such as briefings, or ‘huddles’, are associated with improved patient safety outcomes.(247,248) This may be due to many reasons including: efficiency of information sharing; accountability and the ability to verbalise concerns; and empowerment to speak up; but also to promote a culture of staff collaboration and collegiality.(249)

Informal methods of communication are also recognised to improve collaborative care.(250) Clinician involvement in leadership positions in hospitals is associated with improved quality of patient care.(251) Strong clinical leadership was observed at the sites with a sense of professional respect, teamworking and collaboration. Emergency department culture can be influenced by many elements but promoting staff feeling valued is recognised as essential for staff satisfaction and retention.(252)

Implications for practice and policy

As discussed in Chapter 1 section 1.2.5, the design of systems can range on a spectrum from ‘ultra-safe’, where risk from human error is excluded as far as possible, to ‘ultra-adaptive’ where humans taking risks is the essence of the profession. High reliability systems sit midway - here risk is inherent to the organisation but systems are in place to manage this risk.(96) Some service models had systems in place to minimise risk-taking by the individual GP – a structured streaming process and no access to acute investigations, therefore dictating a traditional GP role. In other service models, individual GPs took on the risk of choosing whether to manage patients by a GP approach or emergency medicine approach and training should focus on this area. The following mechanisms were perceived to contribute to safe patient care: formal (team huddles) and informal (peer Whatsapp groups) communication systems; clinical leadership; and a sense of professional respect, teamworking and collaboration.

Further work

These findings need to be validated. I plan to present findings to stakeholders and discuss which areas of measurement could be used to test these theories and measure safe care in practice (Chapter 7). I also plan to use the lens of formal theory to explain these findings for potential intervention development (Chapter 8).

Conclusion

Mechanisms have been identified in these data that contribute to GPs providing safe patient care in or alongside emergency departments: appropriate patients being streamed to the primary care service; appropriate GPs’ clinical decision-making; and promoting communication and teamwork between services.

7 Exploring areas of measurement with stakeholders to test these theories in practice

In this chapter I discuss how I developed a list of potential areas of measurement to test and operationalise these theories, structured around Vincent's framework.(110) I presented this list to stakeholders to initiate discussions and explore in small group discussions, which areas of measurement (and others) would be most useful to test these theories and measure safe care in practice. This chapter describes the findings from those discussions to address objective four.

7.1 Pre-event identification of potential areas of measurement

As discussed in Chapter section 2.3.4, I structured potential areas of measurement around Vincent's framework to measure and monitor safety in healthcare settings,(110) using additional measures from the Royal College of Emergency Medicine (RCEM) safety scorecard.(166) I presented findings to stakeholders in the form of a driver diagram (Figure 7-1).

7.1.1 Past harm

There is minimal evidence that GP services in emergency department settings are set up to be able to learn from past harm. Potential outcomes identified from the RCEM safety scorecard include routine data for mortality (death within 1-week of discharge or 24-hours of admission) and unplanned re-attendance rates (within seven days). Mortality statistics and re-attendance rates are not routinely reported separately for GP services working in or alongside emergency departments. Re-attendance within seven days has been selected as a marker of safety for the GPs in EDs study quantitative interrupted time series analysis, but results at the time of writing this thesis are not yet available.(130) Other methods of measurement to identify past harm include systematic or selective case note reviews,(51) reporting systems,(46) and patient feedback,(57). There are no published case note reviews and no specific safety indicators or 'never events' that have been identified for these services.

This thesis has identified learning from national and local patient safety incident analysis involving GPs working in or alongside emergency departments, described in Chapter 4. Report numbers are few and qualitative data support that these are rare events. However, learning from these incidents suggests that primary drivers for improvement (Figure 7-1) include: improving streaming processes; clinical decision-making support for GPs; and improving communication between emergency and primary care services.

7.1.2 Reliability

The term 'reliability' is used here to refer to measuring and monitoring the day-to-day running of basic healthcare, rather than 'high reliability organisations' discussed in Chapter 1, to ensure systems have not moved into the 'illegal normal' phase of operations.(97,110) As previously discussed, urgent and emergency healthcare services are complex. Clinical systems may be unreliable, and staff may develop 'workarounds' that may fall into the 'illegal normal' and not report or challenge problems that may increase the risk of unsafe care.(97) For example, if medical records are regularly not available, then the clinician may ask the patient for information which although this may not be as accurate, may become 'normal care'.

Vincent considers reliability under two main areas: reliability of clinical systems and reliability of human behaviour.(110) As discussed in Chapter 1, urgent and emergency care services rely more on the personal resilience and expertise of human behaviour to respond to the variable demands of urgent care, in an ultra-adaptive service model, than in other ultra-safe service models.(97) The clinical systems I have identified from this work that could be standardised to improve the reliability of care delivery are listed as secondary drivers in the driver diagram, see Figure 7-1. For example, to improve streaming processes, streaming guidance needs to be based on local service provision, early warning scores used to identify sick patients requiring emergency level care and standardised triage targets used by services to prevent delayed assessment.

How the streaming nurses use these resources however, may be due to individual human behaviour. I found that experienced nurses were perceived to be more reliable (and safe) than inexperienced nurses but they may rely more on their experience and intuition than following set guidance (which may be a strategy to improve reliability). The lead GP at one case site described that they measure the reliability of human behaviour by auditing documentation in GPs' records of clinical decision-making and safety netting which was discussed at their annual appraisal (GPED10).

Other potential measures I identified from the RCEM safety scorecard that could be used to measure the reliability of these clinical systems include the use of clinical pathways for high risk conditions, for example the feverish child audit described above.(114)

7.1.3 Sensitivity to operations

People working in high-risk environments need to be alert and safety aware, using effective communication to promote shared situational awareness to ensure they are sensitive to operations.(110) The streaming theory, chapter 6, identifies effective communication about GP skillsets and capacity as necessary to improve streaming processes so that appropriate patients are streamed to the GP service. Other contextual influences described in the communication theory in Chapter 6, include: compatible computer systems; strong clinical leadership in the emergency department and the GP service; employing GPs as permanent staff members to help build professional relationships; opportunity for face-to-face communication between staff members; and a culture that encourages an expectation of inter-professional communication and learning and mutual respect between different healthcare professionals.

However, measuring and monitoring effective communication and a culture which encourages inter-professional communication is difficult. Potential areas of measurement include the presence, frequency and quality of: safety huddles, (de)briefings, safety walk arounds and patient feedback but auditing their occurrence may become a tick box exercise rather than an effective intervention.(247,248) The ‘friends and family test’ is the established NHS England patient feedback tool but its uptake may vary between settings influencing results. Although it is not classified as ‘official statistics’, feedback may be helpful at department level.(253) Any feedback needs to be responded to in real time to have any impact on sensitivity to operation measures.(110)

7.1.4 Anticipation and preparedness

The case site qualitative data analysis highlighted the importance of a clear understanding of the role and expectation of the GP and the alignment with governance processes. This is an example of anticipating problems and preparing for them in advance. However, again these aspects can be difficult to measure. Potential measures include monitoring staffing levels and uptake of staff mandatory training, with a formal patient safety culture assessment tool used as a mechanism to identify priority areas. There was no evidence in the qualitative data of formal patient safety assessment tools routinely used by clinicians, but they may have been used by managers and clinical leaders. There was also no mandatory training for GPs working in emergency department settings. Findings from this work may be able to inform focussed training needs for GPs working in these service models.

7.1.5 Integration and learning

How services respond to safety data and how to measure and monitor learning at the individual and the wider organisation level is a challenge. Given the diversity of clinical settings, there are few standardised tools. I observed good practice with modifications made to a department's streaming process following a near miss patient safety incident and a healthcare assistant having the confidence to voice concerns in the wider team setting about how the sepsis pathway was being followed at the same site (GPED03). At another site, the lead GP explained how she circulated learning from any complaints to all GPs every three months (GPED10). There was no evidence in these data about how best to disseminate learning to the wider hospital, Trust or NHS.

7.1.6 Driver Diagram

Figure 7-1 presents a driver diagram of priority areas to focus improvement interventions to enhance the safety of care delivery when GPs work in or alongside emergency departments. The aim is to achieve the outcome of improving the safety of patient care when GPs work in or alongside emergency departments and the primary drivers are the three priority mechanisms identified from this work: ensuring appropriate patients are streamed to GPs; supporting appropriate clinical decision-making by GPs; and improving communication between services. Facilitating intervention factors are listed as secondary drivers; these are the basis of “actionable findings” that could be used for improvement projects. Examples of potential areas of measurement (identified from my findings, the RCEM scorecard and Vincent’s framework) associated with the primary and secondary drivers are also listed. Stakeholders engaged in small group discussions about one of the three primary drivers. They were presented with an enlarged section of the driver diagram relevant to the primary driver they had selected with more detailed potential areas of measurement from which to initiate discussions (Appendix 9).

Figure 7-1: Driver diagram to show priority areas to focus improvement interventions to improve the safety of care delivery when GPs work in or alongside emergency departments

Aim	Primary Drivers	Secondary drivers	Potential measures
To improve the safety of patient care when GPs work in or alongside emergency departments	To ensure appropriate patients are streamed to the GP	Local guidance on which patients are appropriate for the GP service	• Reattendance at ED within 7 days • Number of streamed patients sent back to ED • Patient feedback • Patient safety incident reports • Audit grades of streaming nurses • Audit staffing levels (sickness/unfilled shifts) • Audit recording of basic observations • Audit use of early warning scores • Audit triage times
		An experienced nurse assessment, including basic observations and use of early warning scores	
		Standard triage target times for both services	
	To support appropriate GP clinical decision-making	Well defined GP role and expectation considering GP experience, skillset and local patient demand	• Mortality rates • Reattendance at ED within 7 days • Clinical feedback systems (e.g. X ray) • Patient feedback • Patient safety incident reports • Auditing clinical documentation • Audit use of protocols for high risk conditions • Audit induction and appraisal processes • Mandatory staff training e.g. safeguarding
		Clear governance processes	
		GP education and learning including metacognition principles and cognitive forcing strategies	
	To improve communication between emergency and primary care services	Strong clinical (ED and GP) leadership to promote a culture of inter-professional learning	• GP(s) appointed in leadership role • GP representation at management meetings • Inter-professional educational activities • Frequency of GP/ED briefings/debriefings • Delivery of feedback from incidents/ complaints • Formal staff patient safety assessment tool • Audit patients lost in the system • Audit timely electronic discharge summary • Case management for frequent attenders • Audit investigations requested before patient streamed to GP • Audit action of urine and swab results
		GPs as permanent staff members	
		Face-to-face communication (informal and meetings)	
		Clear emergency or specialist referral pathways	
		Standardised computer systems for emergency and primary care services including discharge summaries and investigation follow up processes	

7.2 Overview of attendees

There was a wide range of English and Welsh-based attendees (n=56) at the December 2019 stakeholder event including policymakers or commissioners (n=4), managers (n=6), patient and public contributors (n=13), emergency department doctors (n=6), nurse practitioners (n=2), GPs (n=5), academics (n=17) and administrators (n=3). Not all attendees participated in the voluntary menti.com feedback but there was a good spread across the different groups that did engage, as seen in response to question 1. The majority of attendees expressed an interest in patient safety outcomes, question 2.

Question 1: Which of the following groups best describes you (please choose one)

Choices	Votes
Commissioners/policy makers	3
Managers	4
Patient and public contributors	10
Emergency department doctors	5
Nurses/Nurse practitioners	2
General practitioners	4
Academics	11
Other	2

Question 2: Are you interested in patient safety outcomes when primary care services co-locate with EDs?

Choices	Votes
Yes	41
No	1

7.3 Validation of theories

Stakeholders did not raise any new patient safety concerns. Examples from the 32 free text responses to the menti.com question 3 are listed below. This question was asked before the presentation of my findings.

Question 3: 'Do you have any patient safety concerns about primary care services co-locating with EDs?'
Examples of free text responses: *"IT systems not talking to each other if different systems used."* *"Unclear governance between 2 services."* *"Understanding the different patient cohort attending the ED vs GP."* *"Risk management re sending patients away to return."* *"No concerns. GP's are experienced and autonomous practitioners."*

The majority of responses were about communication, integration of services and continuity of care (n=13). Concerns about governance processes (n=5) and GPs' skillsets seeing a different cohort of patients (n=5) were also raised. There were two comments regarding concerns about the risk of streaming and redirection processes, while two comments expressed no concerns about primary care services co-locating with emergency departments.

The remainder of comments covered other patient safety areas including the management of prescriptions (n=1), mental health issues (n=1) and infection (n=1), or other concerns that may not have direct patient safety outcomes including NHS resource use (n=1) and addressing expectations (n=1). No other new patient safety concerns were raised following the small group discussions.

7.4 Priority areas of measurement

Stakeholders reported limitations for all areas of measurement depending on the type of GP model and the different roles GPs had. Some areas of measurement could fit with multiple categories in Vincent's framework, for example patient safety incident reports could include learning from past harm and responding to safety information. Participants were not encouraged to select from specific framework categories but explore which areas of measurements they perceived as most useful for the primary driver they were discussing.

Priority areas of measurement selected by stakeholders for all primary drivers covered a range of areas from Vincent's framework as listed below:

- unplanned re-attendance within 7 days (past harm);
- the number of patients streamed to the GP sent back to the emergency department or lost/delayed by the system (reliability of the service);
- use of early warning scores when streaming (reliability of the service);
- learning from clinical feedback systems, incident reporting systems and patient feedback (responding to safety information).

Measurements specific to 'sensitivity to operations' and 'anticipation of problems' were selected by the groups discussing areas of measurement to improve communication between services.

7.4.1 Streaming

Results of the menti.com questions suggesting possible measures to test safe streaming are listed below. The majority of stakeholders indicated that measuring the number of patients streamed back to the emergency department and whether basic physiological observations have been documented would be useful and measurable, while patient feedback may be more difficult to measure.

Question 4: Number of patients streamed to the primary care service and then sent back to the emergency department?

Choices	Votes
Useful and measurable	37
Useful but difficult to measure	10
Not useful	1

Question 5: Checking that basic physiological observations (e.g. pulse and BP) have been documented before the patient is streamed?

Choices	Votes
Useful and measurable	36
Useful but difficult to measure	7
Not useful	3

Question 6: Patient feedback on their streaming experience?

Choices	Votes
Useful and measurable	20
Useful but difficult to measure	24
Not useful	1

Table 7-1: Stakeholder priority areas of measurement for safe streaming processes

Framework category	Potential areas of measurement	Number of votes	Total votes per category
Past harm	Re-attendance at the ED within 7 days	16	
	Patient feedback	7	
	Patient safety incident reporting systems	9	
			32
Reliable service	Number of streamed patients sent back to the ED	12	
	Audit grades (experience) of streaming nurses	2	
	Audit recording of basic observations (pulse, BP etc)	2	
	Audit use of early warning scores	6	
	Audit clinical notes for triage times	1	
	Audit clinical notes for whether local streaming guidance was followed	1	
	Audit % of patients streamed to GP with NEWS 7+	1	
	Audit time of arrival to seen by clinician	5	
	Audit time with clinician	1	
	Audit number of patients seen by clinician	0	
			31
Sensitivity to operations	Frequency of staff formal or informal briefings/debriefings	2	
	Regular governance meetings	1	
			3
Anticipation of problems	Audit staffing levels (sickness/unfilled shifts)	1	
			1
Respond to safety information	Nil suggested	0	
			0
Total			67

*Key: black, shortlisted by me; red, suggested by stakeholders

There were three tables of small groups led by facilitators with a total of 19 participants that discussed these potential areas of measurement. Participants individually selected more than three "top priority" measures, with 67 measures selected in total (19 participants with three votes each would give an expected total of 57 votes). Selected measures were mostly measures of past harm and proxy measures for a reliable service as seen in Table 7-1. Additional measures for the reliability of service and anticipation of problems were also suggested by stakeholders, marked in red.

The most popular measures to be selected were unplanned re-attendances at the emergency department within 7-days and the number of patients streamed back the emergency department. The usefulness however was described to depend on local context. For example, re-attendance at the emergency department was reported to have limitations because patients may re-attend at other healthcare services or in a different area. Measuring the number of patients streamed to the GP service sent back to the emergency department was described as ‘not useful’ by a clinical director because in his department, patients seen by GPs that required acute care were referred by the GP directly to the appropriate speciality and not back to the emergency department. Patient feedback was reported to usually reflect patient satisfaction rather than safety outcomes.

Qualitative feedback supported using experienced streaming nurses (example below), early warning (NEWS) scores and monitoring whether local guidelines had been followed, all of which could be measured. Time from arrival to being seen by a clinician was suggested as a more useful proxy measure of safety than time in the department.

“Having a band 7 ENP streaming significantly contributes to patient safety despite it being a significant investment.”

7.4.2 GPs' clinical decision-making

Results of the menti.com questions suggesting possible areas of measurement to test safe GP clinical decision-making are listed below. They highlight that auditing medical records for evidence of clinical decision-making may be difficult to measure, monitoring unplanned re-attendance at the emergency department may be useful while mortality rates may not be useful.

Question 7: Checking clinical records for evidence of decision-making?

Choices	Votes
Useful and measurable	7
Useful but difficult to measure	38
Not useful	1

Question 8: Re-attendance at the emergency department within 7 days of being seen in the primary care service?

Choices	Votes
Useful and measurable	35
Useful but difficult to measure	9
Not useful	3

Question 9: Death rates within 1 week of discharge from the primary care service?

Choices	Votes
Useful and measurable	24
Useful but difficult to measure	8
Not useful	16

There were two tables of small groups led by facilitators with a total of 12 participants that discussed these potential areas of measurement. The majority were clinicians.

Table 7-2: Stakeholder priority measures for safe GP clinical decision-making

Framework category	Potential measures (No additional stakeholders' suggestions added)	Number of votes	Total votes per category
Past harm	Re-attendance at the ED within 7 days	7	
	Patient feedback	6	
	Patient safety incident reporting systems	7	
	Death rates (within 1-week of discharge or 24 hrs admission)	2	
	Clinical feedback systems for diagnostic error e.g. X-ray reporting, DVT clinic	6	
			28
Reliable service	Auditing clinical documentation (diagnostic decisions and safety netting)	4	
	Audit use of protocols for high risk conditions e.g. chest pain, headache	2	
			6
Sensitivity to operations	Frequency of staff formal or informal briefings/debriefings	2	
			2
Anticipation of problems	Auditing induction and appraisal processes	1	
	Compliance with mandatory training for staff taking on ED roles (investigations, safeguarding)	3	
			4
Respond to safety information	Feedback from complaints and adverse events delivered to clinical staff	5	
			5
Total			45

*Key: black, shortlisted by me; red, suggested by stakeholders (none)

Again, participants reported being restricted by only selecting the top three priority measures and selected multiple potential measures with 45 votes in total (12 participants with 3 votes would give an expected total of 36 votes). The majority of selected areas of measurement were to identify past harm, as seen in Table 7-2. No additional measures were suggested by stakeholders.

*"This is a **suite of governance measure that are all required** as basic measures of safety and clinical governance. **Don't choose 3 choose all**."*

Stakeholders described difficulty selecting appropriate quantitative outcomes and reported that qualitative data collection methods may be more appropriate, however acknowledging that these can be time consuming. GPs were described as having lower patient safety incident reporting rates than hospital doctors and that therefore this method of data capture may have more limited value in this setting, and this issue may need to be addressed. How clinical feedback is delivered in a timely manner back to individual clinicians was described as just as important as collecting the data, along with clear governance processes to support this.

> *"I have come away thinking the safest system needs to have the GP in ED employed by the ED. Sitting within the governance and organisational structures of that ED. Same principles apply. If your system is well organised it's mostly covered."*

7.4.3 Communication between services

Results from the menti.com questions suggested possible areas of measurement to test effective communication pathways between services are often difficult to measure including referral pathways and patients getting lost between computer systems. Learning from local patient safety incident reports was highlighted as a useful area of measurement.

Question 10: Checking if referral pathways could be simplified?

Choices	Votes
Useful and measurable	7
Useful but difficult to measure	36
Not useful	3

Question 11: Checking if patients could get lost between computer systems?

Choices	Votes
Useful and measurable	6
Useful but difficult to measure	39
Not useful	1

Question 12: Learning from local patient safety incident reports?

Choices	Votes
Useful and measurable	31
Useful but difficult to measure	12
Not useful	2

Table 7-3: Stakeholder priority areas of measurement to ensure effective communication between services

Framework category	Potential measures (stakeholders' suggestions in red)	Number of votes	Total votes per category
Past harm	Patient feedback (surveys / online)	3	
	Staff feedback systems	0	
	Patient safety incident reporting systems	4	
	Patients that do not stay	1	
			8
Reliable service	Audit number of patients lost in the system or delayed assessment	8	
	Audit timely adequate electronic discharge summary sent to local GP	7	
	Identification of frequent attenders for case management	4	
	Audit number of patients sent to GP with blood tests already taken	0	
	Audit action of urine and swab results	1	
			20
Sensitivity to operations	Frequency of staff formal or informal briefings/debriefings	5	
			5
Anticipation of problems	Staff completion of a formal patient safety assessment tool	5	
			5
Respond to safety information	GPs appointed in leadership role	3	
	Frequency of electronic updates/newsletters	1	
	Frequency of GP representation at ED managerial meetings	4	
	Delivery of feedback from complaints and adverse events to clinical staff	2	
	Relationship building between primary care team and ED	2	
			12
Total			50

*Key: black, shortlisted by me; red, suggested by stakeholders

There were three tables of small groups led by facilitators with a total of 16 participants that discussed areas of measurement to ensure effective communication processes. Most participants selected the three priorities as requested with a total of 50 votes recorded (16 participants with 3 votes would give a total of 48 votes).

Selected measures were split across the framework categories, as seen in Table 7-3. Additional measures were suggested to measure past harm and respond to safety information, highlighted in red.

Permanent staff members, compatible computer systems and adequate discharge records including test results were all described to improve communication between services. Another theme from the qualitative feedback was that communication between the GP and emergency department services was important but also communication with patients so that they understand what is going on.

"Patients need to have a consistent message / signpost no matter what part of the system they attend."

7.5 Discussion

Main findings

There were no new patient safety themes, different to those already covered in my work, raised by stakeholders about GPs working in or alongside emergency departments. This suggests I have included the priority patient safety risks in this area but further work is necessary to confirm this. Stakeholders selected multiple areas of measurement perceived necessary to ensure safe care was provided in these settings mainly involving learning from past harm and measures to indicate the reliability of the service.

Strengths and limitations

There was a wide range of stakeholder groups at the event, engaging in active participation, including online feedback. The availability of iPads for those that could not access the online site on their personal electronic devices helped this. Using a recognised framework enabled a wide range of measures to be considered and discussed by stakeholders.

Usually during a nominal group process, participants first express their own ideas before discussing ideas as a group.(168) The session was limited by time constraints so to facilitate this step, I included a list of potential measures associated with each theory to initiate discussions and used the menti.com electronic voting exercise during the presentation to encourage participants' own thoughts. This method may have introduced bias into responses and therefore findings should be interpreted with caution. Potential measures were a mix of outcome measures, proxy measures and methods of measurement, intended to explore what was most useful to stakeholders; however, this may have complicated discussions. Usually through the nominal group process, stakeholders rank all measures and are not limited to choosing three.(168) This approach was taken to simplify the process in view of time constraints. The results, however, show that many stakeholders chose more than three measures and traditional ranking may have been more informative.

Context of current literature

Standardised performance measures enable national data analysis and comparison between sites.(254) However stakeholder feedback suggests that the usefulness of certain measures depends on local context. Challenges are recognised in measuring and monitoring patient safety in (in hours) general practice, that may not have the organisational infrastructure to measure reliability of service and sensitivity to operations.(255) The RCGP patient safety toolkit suggests multiple methods to measure the safety of care provision including checklists, trigger tools, staff and patient questionnaires but these have not been designed for GPs working in emergency department settings and validation would be required to ensure these are appropriate.(256) Specific general practice ‘never events’, including not urgently referring a child with suspected non-accidental injury or not following up investigation results, are however relevant to GPs working in emergency department settings.(257)

Unplanned re-attendance at the emergency department within seven days is used as a national marker of quality, with the cut off capturing the majority of patients that return due to worsening or complications of the initial (index) condition.(130) It was selected by stakeholders as a priority measure but can be due to several factors including: the patient, the illness, the clinicians, organisations and systems.(258) Unexpected death following a visit to an emergency department was not selected by stakeholders as a useful measure because death may be evitable due to the presenting illness however, there is evidence that learning from these events can improve understanding about high-risk patients.(259) Clinical audits are routinely used in emergency medicine, for example a child presenting with a fever or febrile illness should have basic observations recorded within 15 minutes of arrival and should be assessed for their risk of sepsis.(114) Clinical audits could be developed to monitor the safety of care for high risk conditions that may be seen by GPs in emergency department settings such as patients presenting with headaches or non-traumatic chest pain.(260)

Further work

A quality indicator is defined as, “a measurable element of practice performance, for which there is evidence or consensus that it can be used to assess the quality, and hence the change in quality, of care provided.”(261) Dimensions of the quality of care are often based on the framework by the Institute of Medicine (IOM) including patient centredness, timeliness, equity, effectiveness, efficiency and safety.(262) A measure (or sets of measures) may be considered a good quality indicator of care if it: includes all patient groups; is comprehensive and addresses all the IOM dimensions of quality care; is co-ordinated with other indicators; and is parsimonious and avoids duplication.(263) Tools are available to inform appraisal of the validity and reliability of potential indicators and also ensure that they are important and simple to understand.(264) My work has identified that multiple areas of measurements are necessary to record and ensure safe patient care delivery in these services. Further consensus work is needed to explore the problems and identify important, valid and reliable measures. These would need to be evaluated for how and why they would work before a list of potential quality indicators could be developed.

Conclusion

Policy makers, managers and clinicians should acknowledge the lack of standardised measures to evaluate the safety of GP services in or alongside emergency departments and the need for further work in this area. To measure safe care locally, multiple areas of measurement should be selected with consideration of contextual factors. Feeding back learning to clinicians from adverse events and communication with the patients, as well as between services, were highlighted as important factors by stakeholders to maintain safe patient care.

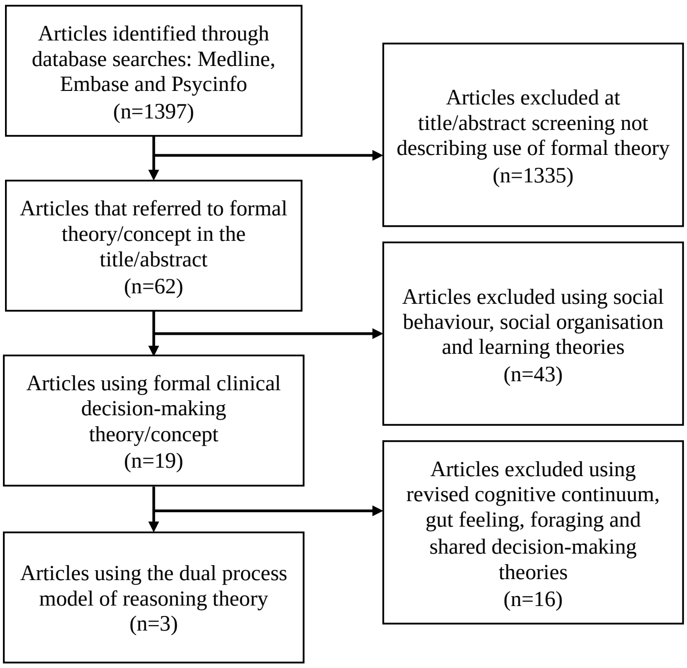
8 Applying formal theory to explain findings and guide intervention development

In this Chapter, I use the lens of formal theory to offer explanation for the causal relationships described in the programme theory (Chapter 6) and guide intervention development following stakeholder feedback that multiple areas of measurement are needed to measure safe care (Chapter 7). I chose a formal theory to apply to GPs' clinical decision-making because this is the mechanism closest to potential diagnostic errors and patient harm (inappropriate streaming decisions and inadequate communication may contribute towards inappropriate GP clinical decisions). I describe the results of the database searches and why I chose to use Croskerry's dual-process model of reasoning as the formal theory.(82,83,265,266) I then describe how this process guided the development of a potential intervention to facilitate delivery of safe patient care in these settings.

8.1 Overview of search strategy and results

There were 1397 hits from the database search and 62 articles identified from title/abstract screening that referred to 25 formal theories, concepts or frameworks as seen in Figure 8-1.

Figure 8-1:PRISMA diagram to show search criteria and selection of articles using formal clinical decision-making theories



These formal theories could be divided into four main groups, listed in Table 8-1: clinical decision-making; behaviour related; social organisation; and learning. Articles describing the use of five different clinical decision-making theories or concepts were identified through this process, these were:

- the dual-process model of reasoning,(82)
- the revised cognitive continuum theory,(267)
- the gut feeling concept,(268)
- inductive foraging,(269)
- shared decision-making.(270)

Table 8-1: Identified formal theories from database search

Category	Name	Definition	Reference
Clinical decision-making	Dual process model of reasoning	Dual-process theory includes two systems of decision making, System 1 (heuristic, intuitive) and System 2 (systematic, analytical).(82)	(271–273)
	Revised cognitive continuum theory	The revised cognitive continuum promotes awareness of the nature and variety of patient-centred judgement tasks and decisions including the fallibility of all forms of human judgement from intuitive/experiential to analytic/rational.(267)	(274)
	Gut feeling concept	The model integrates the two well-known diagnostic reasoning tracks of medical decision-making and medical problem-solving, and adds gut feelings as a third track.(268)	(275,276)
	Foraging theory	The patient is guiding the physician to relevant problem areas.(269)	(277)
	Shared decision making	An approach where clinicians and patients share the best available evidence when faced with the task of making decisions (choice talk), and where patients are supported to consider options (option talk), to achieve informed preferences (decision talk).(270)	(278–289)
Social behaviour	Behaviour change theory	Theories to explain why behaviour changes.(290)	(291–293)
	Social cognitive theory	Social diffusion of new styles of behaviour in terms of the psychosocial factors governing their acquisition and adoption and the social networks through which they spread and are supported.(294)	(295)
	Health belief model	Concepts that predict why people will take action to prevent, to screen for, or to control illness conditions.(296)	(297)
	Theory of planned behaviour	The prediction of intentions of behaviour.(298)	(299–306)
	Theoretical domains framework	An integrative *framework* developed from a synthesis of psychological *theories* as a vehicle to help apply *theoretical* approaches to interventions aimed at behaviour change.(307)	(279,292,308–312)
	Anderson behaviour model	To assist in understanding why families access healthcare and define and measure equitable healthcare.(313)	(314,315)
	Game theory	Analytical tools designed to help understand the phenomena observed in two person games.(294)	(316)
	Control theory	A model of self-regulation to analyse human behaviour.(294)	(317)

	Health behaviour theory	Includes Social Cognitive Theory, Health Belief Model and the Theory of Planned Behaviour as described above	(318)
Social organisation	Normalization Process theory	Normalization Process Theory is concerned with the social organisation of the work (implementation), of making practices routine elements of everyday life (embedding), and of sustaining embedded practices in their social contexts (integration).(319)	(278,320–327)
	Candidacy framework	Candidacy describes how people's eligibility for healthcare is determined between themselves and health services.(328)	(329)
	Complexity theory	Complex organizations exhibit surprising, nonlinear behaviour. Complex adaptive system models represent a way of simplifying the complexity.(330)	(331,332)
	Organizational learning theory	A lens for examining learning as organizational change.(333)	(334)
	Schein's theory	A model of organisational culture.(335)	(336)
	Burden of treatment theory	Burden of treatment theory suggests that interventions that will improve patient experience are those that acknowledge and attack dysfunctional structural elements of healthcare utilization.(337)	(338)
	Bourdieu's theory	Cultural reproduction: structural constraints and unequal access to institutional resources based on class, gender, and race.(339)	(340)
	Bordin's theoretical framework	A theory for understanding appropriateness for different occupations.(341)	(342)
	Framework of Stratification theory	A pattern of social stratification related to technology development.(343)	(344)
Learning	Knowledge translation theory	Application of research knowledge to clinical practice.(345)	(346)
	Diffusion of Innovation framework	Explains how, why and what rate new ideas and technology spread.(347)	(315,348,349)

8.1.1 Clinical decision-making theories identified through this process

I will now describe the theories or concepts identified through this search process in more detail.

Dual-process model of reasoning

As described in Chapter 3 section 3.2.2, the dual-process model of reasoning is based on two distinct decision-making processes: System I and System II, originally described by Kahneman.(81) 'System I' is fast, effortless, intuitive and automatic while 'System II' is slow, laborious and logical.(81) Croskerry applied this to clinical medicine and specifically to emergency department settings: if the initial presentation of illness is recognised by the clinician then System I processes engage but if it is not, then the slower analytical System II processes are engaged.(82,83,265,266) System I is considered typical in the diagnostic decision-making process of experienced clinicians who rely on pattern recognition or shortcuts (heuristics) but is subject to cognitive errors. The problem-solving, hypothesis testing, analytical System II approach is more typical of novices. This model fits with the hypothetico-deductive diagnosis model developed by Elstein and Schwarz where clinicians develop early hypotheses through pattern recognition (System I) then iteratively test them (System II).(217,218)

The three studies using the dual-process model of reasoning identified through this search process were relevant to my work. This theory had been applied to explain the clinical decision-making of junior doctors in emergency departments,(271) GPs in usual primary care settings,(272) and GPs working in the higher risk out-of-hours setting.(273) It is a well-known and accepted theory of clinical decision-making, evidenced by its reference in a recent BJGP editorial to explain the additional cognitive load on GPs conducting remote consultations due to the Covid-19 pandemic.(350)

Cognitive continuum theory

Hammond also bases his theory on Kahneman's concept of System I and System II thinking,(81) but suggests that instead of a discrete separation, there is a cognitive continuum with oscillation between the two, resulting in varying degrees of efficiency and accuracy in judgment.(351) I acknowledge this concept, however would prefer to apply my findings to the simpler explanation of two distinct systems.

Gut instinct

Stolper again acknowledges the two well-known diagnostic reasoning tracks of medical decision-making (System I and System II), and adds "gut feelings" as a third track.(268) He describes intuitive gut feelings, that contribute to clinical decision-making when there is diagnostic uncertainty: a sense of alarm, where something is wrong; or a sense of reassurance, where everything fits in.(268) This theory, in my opinion, was not distinct enough from the dual-process model of reasoning that incorporated intuition into System I thinking.

Inductive foraging and shared decision-making concepts

Inductive foraging and shared decision-making describe patient-guided processes to initially search for information to generate differential diagnoses,(269) and facilitate outcome decisions.(270) These concepts centre on clinician focus rather than explaining the clinical decision-making and therefore could not be used as formal theories to explain my findings.

8.1.2 My reasoning for selecting the dual-process model of reasoning

I chose to use the dual-process model of reasoning theory because it had already been used at the initial rough theory stage of my work and I did not identify another theory that could better explain my findings. Two of the identified clinical decision-making theories (cognitive continuum and gut feeling) also used the same principles of System I and System II thinking as the dual-process model of reasoning.(82,267,268) I also identified articles that had applied this theory in settings relevant to my work to reflect on.(271–273)

Croskerry reflects on how the dual-process of reasoning aligns with the hypothetico-deductive model of clinical decision-making in the emergency department setting and risk of cognitive errors at each stage.(265,266) This approach is relevant to the setting of my research and I will therefore use this framework to present my findings, including: hypothesis generation (see 8.2.1.); hypothesis evaluation (see 8.2.2.); and hypothesis verification (see 8.2.3., below).

8.2 Applying the dual-process model of reasoning

The dual process of reasoning was applied at the initial rough theory stage of this thesis following suggestion by the expert stakeholder group (Chapter 3, section 3.2.2). This theory suggests that GPs working in the higher risk setting of emergency departments, if relying on their heuristics, may be at risk of cognitive System I errors, Box 1. These include: *framing or anchoring* biases, including being influenced by the prior decision-making of the streaming nurse; or *availability or representative* biases by incorporating their usual community pre-test probability of serious disease into their diagnostic reasoning, therefore being at risk of under-investigation and diagnostic error.

Box 1: Initial rough theory of GPs' clinical decision-making presented in Chapter 3

*GPs working in or alongside emergency departments, seeing **streamed patients assessed to be low risk**, and using a **traditional GP approach** as they would in usual primary care where there is a lower pre-test probability of serious illness (C)*

*may be influenced by the prior decision-making of the streaming nurse and therefore be at risk of **framing** or **anchoring** cognitive biases (M)*

*or may incorporate their usual community pre-test probability of serious illness into their diagnostic reasoning and be at risk of **availability or representativeness** cognitive biases (M)*

*and may therefore be more **at risk of under-investigation** and **diagnostic error** than they would if working in their usual community setting (O)*

The rapid realist review (Chapter 3) found evidence that GPs used fewer acute investigations than emergency department staff (O), (183–187) but a lack of evidence for the influence of working in an emergency department setting on GPs' cognition processes and risk management behaviour (Mreasoning), and the effect of this on patient safety outcomes (O).(5) Chapter 4 analysed national level patient safety incident reports (Coroners' reports and National Reporting and Learning System) and found small numbers of diagnostic errors due to under-investigation (O), suggesting that these incidents are rare events.

There were also few relevant patient safety incidents (O) identified from local patient safety incident reporting systems and reported by clinical leaders at the case study sites, as described in Chapter 6. Qualitative methods were used at case study sites to explore how GPs working in emergency departments perceive they manage their innate cognitive biases (Mreasoning) to deliver safe patient care (O). A programme theory to describe this phenomenon was presented in Chapter 6 comprised of linked Context-Mechanism-Outcome configurations: the first describing how appropriate patients are allocated to GPs (O); followed by how GPs appropriately decide whether to safely treat patients with a traditional GP approach (Mreasoning) (and manage their availability or representativeness biases) or adopt an emergency medicine approach (Mreasoning).

I now use Croskerry's framework to help explain the GPs' clinical decision-making theories (presented in Chapter 6, listed in Table 8-2) to infer how GPs may manage their potential cognitive biases at the different stages of clinical decision-making (Mreasoning) and perceive they deliver safe patient care in emergency department settings (O).

Table 8-2: Theories (CMOs) to describe how different GP groups perceive the emergency department setting influences their clinical decision-making (see Chapter 6, section 6.3.2 for more detailed descriptions and illustrations)

Theory number	Contextual factors (C)	Mechanisms (M)	Outcomes (O)
i) Usual GP approach	If GPs that are **experienced** and **confident in their clinical skills** work in or alongside emergency departments without access to acute investigations seeing patients **identified as being appropriate** for the GP service that **they perceive are a similar cohort to usual primary care**	they use their **clinical skills to 'rule out worst case'** are **comfortable with uncertainty** use **'safety netting'** techniques and **admit patients** if they require acute investigation	to **safely use a GP approach**
ii) More cautious GP approach	If GPs that are **experienced and confident in their clinical skills** work in or alongside emergency departments **with or without access** to acute investigations seeing a **cohort of patients that they perceive to be higher risk**	**they incorporate this higher risk** into their clinical decision-making **consultations may be longer** for more thorough history taking the **threshold for admission** or using other acute services for investigation **may be lower**	but many patients can still be safely managed by using a **GP approach**
iii) Chose when to use a GP approach or adopt an ED approach	If GPs with **additional emergency medicine skills and experience** work in emergency departments seeing a **wider range of patients** with **access to acute investigations**	they can use their **clinical skills** described above	to **choose** which patients can be safely managed by a usual **GP approach** and which patients require acute investigation that they **can manage** using an **emergency medicine approach**
iv) Adopt an ED clinician approach	If GPs work in emergency departments with **access to investigations**, where there is an **expectation to follow emergency department protocols**, or **governance responsibility is unclear,** or patients may have **already had investigations requested at triage**	GPs may feel that they are **expected to use these investigations** in the emergency department setting or they may **become less confident** in their clinical skills or have **medicolegal concerns**	and **may use investigations** for patients that they **would not have requested** if they had seen the patient in **usual primary care**

8.2.1 Hypothesis generation

Croskerry describes how generation of one or more diagnostic hypotheses begins early in the process, even before the clinical encounter with the patient has begun.(265) GPs described making early clinical decisions (O), before the patient had been seen, based on the written triage notes (Mreasoning). Despite the streaming nurse's assessment, if GPs felt that the patient was not suitable for a GP consultation (Mreasoning) then GPs described how they would send the patient back to the emergency department (example below) (O). I interpreted this as a mechanism to mitigate the risk of framing bias.

> *"**Send back - Yes, yes.** So patients get triaged in A&E, the triage nurse assesses whether it's a GP problem or an A&E problem, if it's a GP problem it goes into the GP slot and we have a look. **If we have a look and decide it isn't appropriate for us then we give it back to A&E**." GP GPED04(IP)*

Factors that are thought to be important in hypothesis generation include: the acuity (severity) of the patient's condition (C); disease prevalence (C) and heuristics (Mreasoning).(265) These are described in more detail below.

Acuity

Croskerry suggests that the *acuity* of the patient's condition is most relevant when emergency department doctors generate hypotheses.(265) This was also a common strategy described by GPs working in emergency department settings: categorising patients into those that required immediate medical attention or investigation and those that did not, rather than focussing on a specific diagnosis (example below) (Mreasoning).

*"It's a **different approach to working in the community** where there's usually nothing serious – **it's important not to miss a serious diagnosis.** My approach: **Are there red flags? If not – can I treat it? Can I redirect**?" Comments from GP Fieldnotes GPED09(IP)*

Prevalence

GPs' perception of the *prevalence* of serious disease and whether the cohort of patients was similar to usual primary care (C) or a higher risk (C) (Table 8-2) was described to impact their clinical decision-making (Mreasoning). Some GPs reported that sick patients with significant disease also present in usual primary care, therefore serious diagnoses would be considered in initial hypothesis generation with any patient as part of the usual 'GP approach' (example below). However, this finding in itself may be evidence of cognitive bias since patients presenting to emergency departments would be expected to have a higher pre-test probability of serious disease, for example patients presenting with a headache.(260)

*"GP practice in general is quite **challenging** and we have to be always **alert and open minded** to what, what the presentation could be… Most doctors feel that we only deal with viral illnesses which is not the truth **because we see all sorts of things**. We have to always **think about differential diagnosis, we have to be flexible not rigid**." GP GPED10(OO)*

GPs who perceived the cohort of patients was at higher risk in the emergency department (C), see Table 8-2 theory ii, described a different level of concern and managing risk (Mreasoning) than in usual primary care (example below).

*"I think that **the group of patients I see in A&E is very different to the patients that I see in general practice**, so my level of concern**, I'm quicker to be concerned** with an A&E patient than I would be with a general practice patient. The ability of the patients to self-select to come to A&E never ceases to amaze me. So, they can give what sounds like a **very innocuous history**, but statistically **the chances of it being something more significant are much higher in A&E** than it is in general practice." GP GPED03(II)*

Heuristics

GP experience and associated confidence in clinical skills (C) was a common theme across the case sites for why services were successful and patient care was safe (example below). *Heuristics*, or short cuts (also known as 'rules of thumb'), are used by experienced decision-makers to focus and be selective from their accumulated experience, knowledge and expertise (Mreasoning). Representative heuristics involve linking key features of a patient's presentation to a known clinical condition, while availability heuristics require experience of a clinical condition that is recalled when a striking feature or presentation is encountered clinically.

> *"**I like acute diagnostics**, so that's what attracts me to this post, is the acute diagnostics side, but **I don't do hospital diagnostics, I do GP diagnostics**... I think that we **use our clinical judgement** a great deal more than they do in A&E and I'm very comfortable with that, I'm very comfortable using clinical judgement, and **I think how much you might deviate from the general practice model of diagnostics will depend on how experienced you are**." GP GPED06(IP)*

Heuristics, while used in some situations as metacognitive forcing functions to reduce common errors, are however still at risk of cognitive biases, especially for rare conditions or atypical presentations, and do not typically incorporate prevalence.(265) Initial information-gathering from the patient (Mreasoning), to understand why they had presented to the emergency department that day and the background of the presenting complaint, was described by some experienced GPs as key to diagnostic decision-making (example below).

> *"You've got to **listen to that story**. Now **that story may take a few minutes**, it is essential that you get that because you document that and write down, and they tell you three weeks last Tuesday they were away somewhere, and it comes out, and it sometimes becomes very clear, and **what we do in primary care is we listen to patients.**" GP GPED06(IP)*

8.2.2 Hypothesis evaluation

Croskerry discusses how at this stage, clinicians create a framework to gather more information about context and either confirm or eliminate potential diagnoses (Mreasoning), with emergency physicians often focussing on eliminating potentially life-threatening diagnoses rather than confirming diagnosis.(265) This was reflected in the approach described by many GPs to exclude serious disease by ruling out 'worst case' as the priority (Mreasoning).(352) GPs working in more integrated services with access to acute investigations (C), described how many patients could still be managed by a traditional GP approach using the clinical skills described above to eliminate serious disease (Mreasoning) (example below) (O).

*"**Does it mean I investigate more?** No, I don't think it does, it just means **I listen very carefully to the history and examine very carefully**. That's my own perception." GP GPED03(II)*

However, some GPs described a lower threshold (Mreasoning) to admit patients for investigation to exclude serious disease than they would in the community setting because of the increased prevalence of serious illness in emergency department settings (example below) (C).

*"I'm **more cautious in what I see**, I'm **probably more likely to admit people**." GP GPED04(IP)*

Table 8-2 CMO iii, describes GPs that did have access to acute investigations (C) and used their clinical skills to manage risk and choose which patients to manage with a GP approach and which to investigate (Mreasoning). Croskerry discusses that the threshold for managing risk and when to request further investigation is influenced not only by experience but also personal traits of the individual (C). Contextual factors were also noted to influence this behaviour, including investigation availability and departmental expectation (C). Some GPs working in more integrated models expressed that time could be used as a risk-management tool (Mreasoning) in the emergency department, which was not possible in the usual primary care consultation (example below).

*"Sometimes we just give them a bit of time, I call it the **"cup of tea test".** Often they look better after a cup of tea **which helps the decision**." GP comment. Fieldnotes GPED14(II)*

Table 8-2 CMO iv, describes contextual factors such as departmental expectation and unclear governance processes that GPs described as encouraging them to use acute investigations when they would probably not have done so in usual primary care.

8.2.3 Hypothesis verification

Croskerry describes emergency physicians often stopping short of verification since confirmation and diagnostic closure are often not achieved or even sought.(265) This was also described by GPs with the priority being to exclude serious disease (Mreasoning) rather than making an actual diagnosis (O). There was also an acceptance of the limitation of the service (C) and that the diagnostic process may be incomplete if it was felt more appropriate to refer patients back to their own GP (O) (example below).

*"For me my sort of mental triage system is **'do I need to admit you, yes or no, and can I deal with your issue now'**, i.e. is it **long-term** in which case I probably can't do very much, because I **don't have access to all of your notes** and it's not very practical, I **can't organise blood tests**, I **can't organise scans**, I can't do any of that kind of stuff, in which case **I'll have to send you back to your GP**." GP GPED07(IP)*

Being comfortable with uncertainty (Mreasoning) has been suggested as a reason why GPs may be more comfortable not reaching a firm diagnosis than diagnostic-driven emergency medicine clinicians.(5) However, Croskerry reflects that this is also a common outcome for emergency physicians, for example the 'diagnosis' of 'non-specific abdominal pain' when serious causes have been excluded through acute investigation.(265) GPs did however describe the strategy of 'safety netting' (Mreasoning) as good practice to help manage diagnostic uncertainty – advising patients of potential worsening symptoms and when further medical advice should be sought (example below).(244)

*"**Safety netting is a bit more robust** and **documented a bit more robustly** because I suppose when you're working in a practice with patients that you know and they know you and they know how to get hold of you personally it's a bit easier for them to re-present and to follow up where you left off. Whereas here **we don't have that continuity**, so we've got to be quite **mindful that everything is documented carefully** and there's **good safety netting**." GP GPED13(OO)*

8.3 Refined programme theory

The framework was helpful to consider the diagnostic stages and to consolidate and refine the GPs' clinical decision-making theories. I then incorporated actionable findings from the refined streaming and communication theories (Chapter 6, sections 6.3.1, 6.3.3) to generate a refined programme theory to describe factors that facilitate GPs delivering safe patient care in or alongside emergency departments. This is outlined below with key elements in ***bold black text.*** It highlights actionable findings for services: ensuring the service is set up to take account of local contextual factors; and exploring with GPs how emergency department settings may influence their clinical decision-making, using metacognition principles and identify any learning needs.(83)

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*If GPs work in emergency departments where GPs and staff are **aware of the intended GP role** (traditional GP vs emergency medicine clinician) depending on the GPs' experience/skillset and patient demand, **with clear governance processes** to support that role; **experienced** streaming nurses use **local guidance** and **early warning scores** to assist decisions and have **good communication** with the GPs about **capacity and skillset** to stream an appropriate patient cohort; and there is **a culture that encourages interprofessional learning and mutual respect** (C)*

*GPs use their communication skills in the consultation **to gather patient information** for hypothesis generation (M)*

***actively consider the prevalence of more serious diseases** that may present to the emergency department setting (M)*

*use their **clinical skills to rule out** serious diagnoses (M)*

***refer to guidance** when acute investigation/referral may be necessary to exclude serious disease (M)*

*and use **safety netting** to help manage diagnostic uncertainty (M)*

*then this facilitates the delivery of **safe patient care** (O)*

8.3.1 Potential intervention development

This refined programme theory highlights key elements (of context – service set up; mechanisms - the consultation; and outcomes of the consultation) which could be targeted for a potential training intervention for GPs working in emergency department settings and highlight areas that may benefit from quality improvement.(353) This intervention could be a ‘work procedure’ - a human-centred framework, designed by the Chartered Institute of Ergonomics and Human Factors (CIEHF), to help standardise and simplify processes. It aims to understand how work is really done (including modifications to standard procedures or work arounds) to deliver safe, efficient person-centred care.(353) I have listed the key elements from the refined programme theory that could contribute towards this intervention in a template, with potential measures (identified from Chapter 7) mapped alongside, as shown in Table 8-3.

The work procedure could be designed as an interactive infographic, to be shared with users electronically, see Figure 8-2 for an example of what the static version may look like (infographic by Mrs Angela Watkins). Each numbered step would have an interactive ‘pop out’ (an information box that pops out as the mouse hovers over the numbered area) to provide the user with further information and electronic links to key resources and Royal College of Emergency Medicine (RCEM) guidelines. An example of the information to be included in these pop outs is detailed in Table 8-4.

Table 8-3: Template developed from refined programme theory for the proposed work procedure

Context (Service set-up)	**Potential measures**
• What is the intended role of the GPs (traditional GP approach or emergency medicine clinician)? • How are patients streamed (allocated) to the GPs? • Are governance processes in place to support the GPs' intended role? • How are communication pathways facilitated between services?	• Streamed patients sent back to the emergency department • Patients that do not stay • Time of patient arrival to being seen by clinician • Grade (experience) of streaming nurse • Use of early warning scores with streaming • Review of whether local streaming guidance was followed • GP representation at governance meetings • Frequency of formal and informal staff briefings/debriefings and relationship building
Mechanisms (The GP Consultation)	

• GP diagnostic thinking
  - What is the patient's condition acuity (severity)?
  - Do you need to consider the prevalence of more serious diagnoses in this setting?
  - How will you rule out serious diagnoses?
• How will the emergency department setting affect your clinical decision-making?
  - No change, usual GP approach
  - More cautious GP approach (lower threshold for investigation or admission)
  - Choose when to use GP approach or investigate as an emergency medicine clinician
  - Adopt an emergency medicine clinician approach
• Have you identified any learning needs?
  - How can they be addressed?
	• Patient unplanned reattendance within 7 days
	• Clinical feedback systems for diagnostic error e.g. X-Ray reporting, DVT clinic
	• Use of protocols for high risk conditions e.g. chest pain, headache
	• Induction (including mandatory training e.g. child safeguarding) and appraisal processes
	• Identified GP learning needs met/reviewed
	• Staff completion of formal patient safety assessment tool
	• Process for feedback to clinicians from complaints and adverse events

Outcomes from the consultation	
• How are patients referred or admitted to specialist services? • How do you prescribe urgent medication? • Is your safety netting advice clear? • How is follow up information clearly communicated to the patient's usual GP?	• Review referrals or admissions by GP service • Administered medication checked by another staff member • Review clinical notes for evidence of safety netting • Patient feedback • Patient safety incident reporting systems • Timely adequate electronic discharge summary sent to usual GP

Figure 8-2: Potential work procedure for GPs working in emergency department settings

Work procedure for GPs working in emergency department settings

Service set-up

Click the link for potential measures to monitor the safety of the service set-up

1. What is the intended role of the GPs (traditional GP or emergency medicine clinician)?
2. How are patients allocated to the GPs?
3. Do governance processes support the intended service and GP role?
4. How is effective communication facilitated between services?

The GP consultation

Click the link for potential measures to monitor the safety of the GP consultation

1. Diagnostic thinking
   - Does the patient need urgent medical attention?
   - Do you need to consider more serious diagnoses in this setting?
   - How will you rule out serious diagnoses?
2. Does this setting affect your clinical decision-making?
   - No change, usual GP approach
   - More cautious GP approach
   - Choose when to use GP approach or investigate as an emergency medicine clinician
   - Adopt an emergency medicine clinician approach
3. Have you identified any learning needs?
   - How can they be addressed?
   - How will this be reviewed?

Outcomes from the GP consultation

Click the link for potential measures to monitor the safety of the outcomes from the consultation

1. What are the specialist referral pathways?
2. How do you prescribe urgent medication?
3. Has your safety netting advice been understood?
4. How is follow up information clearly communicated to the patient's usual GP?

Table 8-4: Proposed further information to be included in ‘pop outs’ (over each numbered area) for the work procedure

Service set-up (Context)	
Click for potential measures	• Streamed patients sent back to the emergency department • Patients that do not stay • Time of patient arrival to being seen by clinician • Grade (experience) of streaming nurse • Use of early warning scores with streaming • Review of whether local streaming guidance was followed • GP representation at governance meetings • Frequency of formal and informal staff briefings/debriefings and relationship building
1	GPs may be encouraged to maintain a traditional GP role or adopt an emergency medicine approach depending on many factors including patient demand, the service set up and individual GP experience and interest. *Where does your GP service sit on this conceptual spectrum of integration? Can any factors be modified to meet the intended aim of the service? (interactive link to taxonomy paper below)* https://emj.bmj.com/content/emermed/36/10/625.full.pdf
2	Experienced nurses using guidance adapted to the local service and early warning scores to identify sick patients are associated with appropriate streaming decisions. High-risk presenting complaints include chest pain, headache, sick children and musculoskeletal injury. Streaming pathways may vary from a brief assessment on the front door, a complex assessment combined with triage or GPs may self-select their own patients. *Which steaming pathway does your service use? Could it be improved? (interactive link to paper which describes main UK streaming pathways below)* (Edwards, M., Cooper A. et.al. Typology of UK emergency department streaming pathways to primary care. BMC Emerg Med – under review)
3	Governance responsibility may lie with the Hospital Trust or the Primary Care Provider. Do processes support the intended GP role? *If GPs have an extended role, how do they keep up to date and how is this reviewed? (interactive link to RCGP guidance below)* https://www.rcgp.org.uk/-/media/Files/CIRC/GpwSI/RCGP-framework-to-support-the-governance-of-GpwERs-2018.ashx?la=en

4	Successful GP services in emergency departments were observed to have a culture of interprofessional learning and mutual respect. Poor communication between services is associated with adverse events. *Could communication pathways be improved between the services? (interactive link to RCP and RCEM guidance on improving team communication below)* https://www.rcem.ac.uk/docs/External%20Guidance/ITIH%20R3%20Final.pdf
The GP Consultation (Mechanisms)	
Click for potential measures	• Patient unplanned reattendance within 7 days • Clinical feedback systems for diagnostic error e.g. X-Ray reporting, DVT clinic • Use of protocols for high risk conditions e.g. chest pain, headache • Induction (including mandatory training e.g. child safeguarding) and appraisal processes • Identified GP learning needs met • Staff completion of formal patient safety assessment tool • Process for feedback to clinicians from complaints and adverse events
1	Clinicians often rely on their experience and cognitive heuristics to make quick decisions but heuristics do not allow for disease prevalence, which may be different in the higher-risk emergency department setting. *Which stages of the diagnostic process are at risk of cognitive errors in emergency departments? (interactive link to Croskerry paper below)* https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1553-2712.1999.tb01246.x
2	GPs described their clinical decision-making in emergency department settings as fitting into one of the four groups listed. *Which group do the GPs in your service fit into? Does this group fit the intended aim of the GP service and supporting governance processes? (interactive link to potential publication from this thesis below)* *What roles do GPs adopt in emergency department settings and how does this influence their clinical decision-making?*
3	Have these discussions identified any learning needs relevant to the intended role of the GP and local context? Are additional emergency medicine skills required? *Learn more about cognitive biases and de-biasing strategies (interactive link to Croskerry de-biasing strategies below)* https://onlinelibrary.wiley.com/doi/pdf/10.1197/aemj.9.11.1184

Outcomes from the consultation	
Click for potential measures	• Review referrals or admissions by the GP service • Administered medication checked by another staff member • Review clinical notes for evidence of safety netting • Patient feedback • Patient safety incident reporting systems • Timely adequate electronic discharge summary sent to usual GP
1	Specialist inpatient and ambulatory referral processes may vary depending on local context. *What are the local referral processes? Who has clinical responsibility when a patient has been referred? (interactive link to RCEM guidance below)* https://www.rcem.ac.uk/docs/College%20Guidelines/Clinical%20responsibility%20for%20patients%20within%20the%20emergency%20department%20-%20Nov%202016.pdf
2	Urgent medication may need to be dispensed from the emergency department or prescribed and dispensed from a community or hospital pharmacy. *What is the procedure to prescribe or dispense urgent medication in your service? (interactive link to RCEM guidance below)* https://www.rcem.ac.uk/docs/RCEM%20Guidance/RCEM_16-04-2019_Emergency%20Department%20Out%20of%20Hours%20Discharge%20Medications_Final.pdf
3	Safety netting is considered a core component of the GP consultation to help manage diagnostic uncertainty. *Does the patient understand what to look out for, how to seek further help and what to expect about time course? (interactive link to RCGP publication with guidance on communicating safety netting below)* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2765844/pdf/bjgp59-872.pdf
4	Poor communication at the interface of primary and secondary care is associated with adverse events. *Is it clear if any follow up or repeat investigations are required? (interactive link to RCEM guidance below)* https://www.rcem.ac.uk/docs/RCEM%20Guidance/RCEM_BPC_InvestigationResults_200520.pdf

The CIEHF have proposed 10 steps to consider during procedure development including: what it is, if it's needed, involving the whole team, identifying where things go wrong, capturing work as done, making it easy to follow, testing it, training people to use it, putting it into practice and keeping it under review. Their key messages about developing, simulating and testing the procedure may highlight if it (or aspects of it) work or not and how it could be improved.(353)

The work procedure could be used to standardise the process for the service set-up and initiate discussions between GPs, emergency department clinical leads and managers about how contextual factors may influence how the service works and influences individual GPs' clinical decision-making. These include: clarifying the intended GPs' role, how patients are streamed, supporting governance processes and factors that facilitate communication between services (C); how the emergency department setting may influence GPs' clinical decision-making and identify learning needs (M); and an opportunity to discuss outcomes from the consultation including specialist referrals, prescribing, safety netting and communication with usual primary care (O). The use of interactive pop outs provides further description to the user and electronic links to key resources are available if further information is required. Relevant measures (multiple as suggested by stakeholders) may then be selected from the list of potential measures to measure and monitor the safety of key areas of the service or to provide data for quality improvement activities, until standardised performance measures are available.

8.4 Discussion

Main findings

This chapter has consolidated the clinical decision-making theories through the lens of formal theory and incorporated actionable findings from the streaming and communication theories to develop a refined programme theory. This has been used to develop a potential training intervention to support the delivery of safe patient care when GPs work in or alongside emergency departments. It aims is to standardise the process of setting up GP services in emergency department settings and enable directors and staff members to understand how work is done in the local context, identify areas for improvement and consider how these could be measured and monitored.

Strengths and limitations

A systematic database search using a recognised BeHEMoTh framework was undertaken to identify the most appropriate formal clinical decision-making theory.(172) Limiting the search to ‘general practitioners’ ensured these were most relevant to the professional group being studied. However, this may have narrowed the results and other theories applied to other healthcare professionals may have been appropriate to consider. Other theories regarding ‘role’ or ‘risk’ may also have been relevant, but I felt it was better to explore one theory in depth rather than superficially consider multiple theories. My biases may have influenced this choice. Teaching and assessing the skill of clinical decision-making and the influence of expertise and acquiring knowledge is complex. The dual process model of reasoning may be too simplistic (Hammond argues that there is a cognitive continuum between the two)(81) but for this work, the structure was helpful to identify key elements that could be highlighted in the proposed intervention.(354,355) The dual process model of reasoning was used for initial rough theory development (Chapter 3) but using it additionally as a structure to inform interview questions as part of the research process may have further informed ontological depth in this area.

Data collection was limited by short case study visits at sites that volunteered to participate. However, as discussed in Chapter 5, section 5.5, the sample was purposive covering a range of models and complexity with wide geographical spread in England and Wales. Alternative research methods including analysing transcripts of consultations or 'think aloud' methods may have identified different cognitive strategies.(356,357) These findings and the proposed intervention are based on these qualitative data and therefore further validation and evaluation are required, which is discussed in more detail in Chapter 9.

Context of current literature

The dual process model of reasoning has previously been applied to GPs working in a similar high-risk setting, out-of-hours, where they would not know their patients.(273) Similar management approaches were described: dividing patients into those with serious (or potentially serious) conditions and patients with non-serious conditions; and using safety netting to manage diagnostic uncertainty.(273) Time pressure and 'firefighting' were however not reflected in my findings, with some GPs working in more integrated services describing time as less pressured than the traditional 10-minute consultation and using it as a decision-making tool similar to an emergency medicine approach.

An initial patient-guided search, or the 'golden minute' is described as key in the information gathering stage of the well-known Calgary-Cambridge clinical consultation.(356,358) My findings support GPs using their communication skills to gather information, and to exclude serious disease, which may explain the reduced use of acute investigations.(359)

As discussed in Chapter 1, in the complex environment of urgent and emergency care services, interventions designed to improve the safety of care delivery need to consider how local contextual factors influence how work is actually done (mechanisms) and therefore resultant outcomes.(43,107,108,120) Realist methods are well suited to this process, using a theory driven approach to develop statements that describe causal relationships as context-mechanism-outcome configurations to highlight why and how outcomes occur and therefore where an intervention should be targeted.(360) The CIEHF have produced guidance for work procedure development with an understanding of human capabilities and characteristics to design and adapt work systems to optimise individual and team performance while minimising patient safety risks and unintended consequences.(353) I have applied these principles to my realist findings to highlight the key elements of service set-up (context), the GP consultation (mechanisms) and outcomes of the consultation to develop a potential intervention to facilitate the delivery of safe patient care in these services.

Further work

Proposed complex interventions require piloting, feasibility testing and evaluating before implementation following Medical Research Council guidance. However, this can be a lengthy process. (361) Quality improvement principles use cycles of testing to learn how improvement occurs through continuously measuring the metric of interest with a series of interventions.(89,90)

If I were to take this work forward, I would initially request stakeholder feedback from the GPs in EDs co-applicant expert group and then explore testing and adapting the work procedure as a quality improvement tool with existing and new services. Research can inform quality improvement but quality improvement can also inform research and it would also be useful to explore how the intervention is used and by whom with ethical approval, to inform further research. Piloting and feasibility testing could include observations of how the work procedure is used and by whom. Qualitative feedback (interviews) with GPs and emergency department clinical leads could explore if it is perceived as helpful and where improvements could be made. Quantitative data on which areas were chosen to focus improvement efforts and what measures were chosen to monitor the safety of services may feed into further consensus work on which performance measures are appropriate to monitor the safety of these services. Focus groups with key informants may be helpful to adapt and refine the intervention and discuss which measures were most useful. Having adapted the work procedure with this feedback, a formal evaluation may be appropriate with consideration of recruitment and retention of busy healthcare professionals and appropriate short-term and longer-term outcome measures for testing and validation.

Since this work was conducted, urgent and emergency care services along with the majority of NHS service provision have changed due to the Covid-19 pandemic. As discussed in Chapter 9, these thesis results and any potential intervention developments, now need to be interpreted with consideration of this new normal way of working.

Conclusion

Realist methods, incorporating an understanding of how local contextual factors influence work-as-done and resultant outcomes, have been used to propose a potential training intervention, with associated potential measures, to facilitate the delivery of safe patient care when GPs work in or alongside emergency departments.

9 Discussion

In this chapter, I summarise the main findings from this work and the strengths and limitations of my methodology and research methods. I describe how these findings fit with the context of current literature and the changes in health service delivery due to the Covid-19 pandemic. I discuss consequent implications for practice and policy and where further research is indicated.

9.1 Main findings

There is a lack of evidence for patient safety outcomes, standardised performance measures and evidence-based interventions to monitor and improve patient safety when GPs work in or alongside emergency departments.

Few numbers of patient safety incident reports involving diagnostic error (NRLS, Coroners and local Datix reports) were found associated with GP services in or alongside emergency departments suggesting these are rare events. High-risk presenting complaints included musculoskeletal injury, chest pain, headache, calf pain and sick children. Priority areas to focus patient safety interventions from these reports included: streaming and redirection decisions; influences on GPs' clinical decision-making; and inadequate communication between services.

In-depth qualitative data analysis from a purposive sample of 13 case study sites visits explored how safe care was perceived to be delivered in these services and the incidents described above mitigated. These findings were used to develop a refined programme theory describing factors perceived to facilitate the delivery of safe patient care. A potential training intervention has been developed from these findings to explore contextual factors including: the intended aim of the GP service, how patients are allocated, supporting governance processes and factors that facilitate communication between services; how the emergency department setting may influence GPs' clinical decision-making to identify learning needs; and an opportunity to explore outcomes from the consultation including referral, prescribing, safety-netting and communication with the local GP. Stakeholders suggested that multiple areas of measurement were necessary to record and ensure safe care was provided in these settings and potential measures are included in this intervention to be considered.

9.2 Strengths and limitations

The strengths of this work include a consistent realist methodological approach with multiple data sources for theory development and refining. I developed initial rough theories from the literature and analysis of patient safety incident reports and had the opportunity to visit a purposive sample of 13 case study sites, including a range of GP service models and other complexities, to test and refine the theories to develop the programme theory. Throughout the process I have tried to challenge my own biases and discuss my findings. Stakeholders have given expertise throughout: the local GPs in EDs study team and the co-applicant expert stakeholder group including PPI members; two 'GPs in EDs' national stakeholder events (February 2018 and December 2019) and one University of the West of England (UWE) 'GPED' stakeholder event (November 2018); and academic peer review of my publications (rapid realist review and patient safety incident report analysis)(5,8) and national conference presentations.(362) I have undertaken formal realist methods training as discussed in Chapter 2, section 2.2.3, and benefitted from co-applicant realist methods experience (Dr Freya Davies, academic GP). I have also followed the Rameses methodological standards and completed comprehensive publication checklists (indicating a thorough study) for realist synthesis (Appendix 2) and evaluation (Appendix 3).

There are limitations to my work and therefore how my findings can be interpreted. Included data sources are all qualitative and therefore subject to reporter and researcher bias. The sample of case study sites largely included GP services where the service was perceived to work well, and clinical directors had chosen to be included in the study, and therefore may be subject to selection bias. Hospitals where the service was perceived not to work so well may have experienced patient safety incidents not included in this work. However, there was opportunity to learn from the included sites how and why the services did work well; what changes had been made to facilitate this and how safe care was perceived to be delivered.

Throughout the process, I have taken steps to ensure my results are valid and reliable. A realist theory is considered high quality if it is plausible, coherent and based on trustworthy data.(141) I have challenged my personal biases, documenting my reflections and inferences in fieldnotes, with meticulous record keeping, to discuss and challenge with peers. To ensure consistency, I have been transparent in my methods, analysis and reporting using semi-structured audio-recorded interviews for repeated revisiting of the data and included verbatim extracts to highlight themes. I have given a clear description of the context from which these data were collected so the reader can consider applicability to other settings.(363)

Other data sources could have been used which may have given a different lens and provided additional evidence to develop and refine theories. For example, in the ‘GPs in EDs’ national survey to clinical directors, the focus was on service provision, I could have included more specific questions on the safety of care provision. Also, patient postings on websites such as https://www.careopinion.org.uk/ relevant to the case study sites, may have generated patient safety theories from the patient voice that could then have been tested and refined during the visits. Quantitative data from the ‘GPs in EDs’ interrupted time series analysis were not available at the time of writing of this thesis but may indicate certain GP service models where there is an increase in the rate of unintended patient re-attendance within seven-days of attendance which could be explored. Quantitative data may also inform the interpretation and further refinement of my theories, discussed in the ‘further work’ section below.

9.3 Context of current literature

As discussed in Chapter 1 section 1.1.2, GP services in or alongside emergency departments have been implemented in England following a policy recommendation in 2017, with a lack of evidence for the effectiveness, costs and patient safety implications of these service models. There has been a subsequent increase in these service models associated with emergency departments in England from 81% - 95% (2017-2019). ‘Inside: parallel’ was the most common service model implemented, 30% (44/149) in 2017 rising to 49% (78/159) in 2019, while the number of ‘inside: integrated’ models dropped from 26% (38/149) to 9% (15/159).(364)

My work highlights the complexity of these services and that multiple factors may influence the clinical decision-making of GPs and whether they maintain a traditional GP approach or adopt an emergency medicine approach. The reduction in 'inside: integrated' models with an increase in 'inside: parallel' models may not reflect the function of these services, the roles GPs adopt and potential patient safety risks.

Interventions intended to improve patient safety outcomes in these service models need to take this complexity into consideration. I have developed a potential intervention which allows for local contextual influences when considering service set-up (context), impact on the consultation (mechanisms), outcomes from the consultation and how these processes can be measured and monitored. This could be used as a quality improvement tool or used to inform further research.

The results of two UK National Institute for Healthcare Research (NIHR) three-year mixed-methods studies are awaited in early 2021 ('GPs in EDs', led by Prof Adrian Edwards, Cardiff University; 'GPED', led by Prof Jonathan Benger, University of the West of England).(3,7) The results of these studies may influence further policy recommendations on whether GP services in or alongside emergency departments continue nationally, although the majority of English emergency departments now have associated GP services.(364) Optimising delivery of safe healthcare to meet the demand on urgent and emergency care services within NHS resources is a challenge. This thesis has focused on the emergency department setting but this demand is interlinked with other services: emergency ambulance services, NHS 111 (telephone or online advice), on the day (in hours) GP appointments and GP out-of-hours care provision. GP services in emergency departments have been associated with 'provider-induced demand',(187) and it is not known if providing GP services in emergency departments may contribute to lower staff recruitment and retention in the community and therefore contribute to unintended patient safety consequences. The NHS long term plan is for services to be more joined up and co-ordinated in their care.(365)

Since this work was conducted, urgent and emergency care services along with the majority of NHS service provision have changed due to the Covid-19 pandemic. Attendances at emergency departments initially dropped rapidly, 57% lower in April 2020 than in April 2019 with a greater reduction in minor emergency departments, which may include GP services (71%) than major emergency departments (48%).(366,367) The reasons for this are multifactorial and currently not fully understood but include the lifestyle changes of lockdown leading to reduced injuries and drug and alcohol related presentations, routine operations being cancelled and discharges expedited (thus enabling admissions when required), and patients with minor illness not attending emergency departments.(367) Concerns have been raised however that sick patients have also not attended to receive timely treatment for their condition with late presentations of childhood diabetes, sepsis and malignancy reported by paediatricians,(368) an increase in non-Covid deaths in England and Wales and concerns about the longer term impact of delayed cancer diagnoses.(369) The World Health Organisation has advised priorities for maintaining essential services during the pandemic which include the management of emergency health conditions and common acute presentations that require time-sensitive intervention.(370)

To meet the challenges of delivering health services during and following the pandemic, services have dramatically changed and are being set up ahead of evidence on effectiveness, costs and patient safety, as with previous health care services.(4) Emergency departments have been reconfigured to allow for social distancing and the doffing and donning of PPE. Community GPs have been advised to conduct consultations remotely where possible (via telephone or video) to avoid patients unknowingly bringing the virus into the surgery environment,(371) and pilot telephone triage services are being set up to screen emergency department walk-in attendances.(372) There are calls from the Royal College of Emergency Medicine that the system should learn from these changes and emergency departments should never be crowded again,(373,374) but concerns have been raised about potential patient safety risks.(375)

Findings from my work can however also be applied to these reactive new service designs and my proposed intervention used as a template to consider service set-up (context), impact on the consultation (mechanisms) and outcomes from the consultation and how these processes can be measured and monitored. For example, the set-up of GPs working in emergency departments may have changed and GPs may now be involved in telephone triage systems to screen walk-in attendances to the department. The work procedure first considers service set-up and what is the *intention of the service and role of the GP*? If conducting telephone triage, is the aim to redirect patients to another healthcare provider (for example to local GP services) or to conduct telephone consultations and advise patients over the phone? How will subsequent (re)attendance at the emergency department or other healthcare providers be measured and monitored? Will all patients be referred to the telephone triage service or will there be other *pathways to allocate patients* that may struggle with this service for example, patients with language barriers or learning difficulties. How will adverse events be captured? Where does the *governance responsibility* lie and who is the service provider? Do these processes fit with the intended aim of the service? *How can communication pathways be facilitated* between the GP service and the emergency department and other healthcare providers that may be involved?

Next the procedure would consider the consultation. How does the different setting (a telephone consultation with the absence of usual face-to-face cues) *influence clinical decision-making*? Do the GPs now take on more personal risk than they would in a face-to-face consultation to avoid attendances at the emergency department? Do they override guidance if they feel it is in the patient's interest? How is this risk communicated to patients and how would it be measured and monitored? How are the GPs *trained to manage this risk in this new setting*? Are they aware of cognitive biases and cognitive de-biasing strategies? Have any *learning needs been identified* and how can they be addressed?

Finally, outcomes from the consultation (subsequent processes of care) could be considered. *If a specialist referral is indicated what is the process?* Is the patient advised to attend the emergency department or are they referred directly to the specialist service (for example a patient with typical symptoms of an acute appendicitis referred directly to the surgical team on call)? How are these referrals, and those to other healthcare providers, measured and monitored? *Is it possible to prescribe medication* following the consultation and if so, what are the arrangements with the local pharmacy? Are prescriptions generated electronically and sent directly to the pharmacy or are they handwritten and collected in person? If so, what is the process for this? How can potential prescribing errors be reported so the system can be modified accordingly? Is there a *standardised format to capture safety-netting advice* and how can the consultation be *communicated to the local GP*?

Key elements in the work procedure could also be applied to other non-medical practitioners working within emergency departments taking on new roles for example, paramedics or nurse practitioners; also in other urgent and emergency care settings for example, paramedics treating patients at the scene rather than conveying to the emergency department. Applied in these different settings, the work procedure principles could be used to standardise the process of service set-up, understand how work is done in the local context, identify any areas for improvement and explore how these could be measured and monitored relevant to the local context.

9.4 Implications for practice and policy

To meet the challenges of delivering health services during and following the pandemic, services are being set up ahead of evidence on effectiveness, costs and patient safety, as with previous healthcare service changes.(4) It is vital that learning from these new service designs and good practice is captured to contribute towards organisational resilience and sustainable change. There is much to learn from why the process worked well, including trade-offs and adaptions, rather than focussing on adverse events.(376) My potential intervention, based on my refined programme theory, offers transferable findings with a tool to capture how services are set-up, how local context may influence consultations and how outcomes from the consultation are achieved. Potential measures are suggested to measure and monitor performance to contribute towards this learning.

9.5 Further research indicated

Next steps following this work involve triangulation of the quantitative interrupted time series analysis findings from the ‘GPs in EDs’ study. These data may further refine my theories or generate other new initial theories for testing. The main results from the ‘GPs in EDs’ and ‘GPED’ studies may also influence how the form and function of GP services in or alongside emergency departments are best adopted to achieve desired effectiveness. As discussed in Chapter 7, further consensus work, for example Delphi or RAND methods, would be indicated to identify which measures are considered valid and reliable to monitor the safety of these services.(377,378) Selected measures would need to be evaluated to establish how and why they work, before potential quality indicators could be developed to measure and monitor the safety of these service models. Piloting the work procedure may highlight measures that are perceived by stakeholders to be most useful in the emergency department context to represent safe and effective service delivery. I have experience of RAND consensus methods and this may be worth exploring as a further consensus exercise.(378)

As discussed in Chapter 8, section 8.4, my potential intervention could be used as a quality improvement tool or used to inform further research. It could also be adapted and piloted with other new service designs in emergency department settings, for example the telephone triage of emergency department walk-in patients discussed or to be used with other non-medical practitioners within the emergency department that take on new roles. In light of the changes to the provision of healthcare services following the Covid-19 pandemic, my further work may involve using the skills gained through this thesis to evaluate other new health service designs to explore opportunities for improving patient safety.

9.6 Conclusion

As urgent and emergency healthcare services are redesigned to meet the challenges of increasing patient demand in a post-Covid recovery phase and the future (including the possibility of additional waves of acute illness), it is essential that research designed to evaluate the effectiveness of these service models includes patient safety outcomes and opportunities to improve patient safety.

I have demonstrated that realist methods, with a strong evidence-based theory driven approach, are well suited for patient safety research in complex healthcare settings to explore what the problems are and how they may be mitigated. From my findings, I have developed a potential intervention to assist directors and staff members to understand how local context influences the service set-up (context), the GP consultation (mechanisms) and outcomes from the consultation, with associated potential measures and training resources. Priority areas to focus upon to facilitate GP services delivering safe patient care in emergency department settings include: appropriate streaming processes; supporting GPs' clinical decision-making with clear governance processes; and improving communication between services.

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Appendices

Appendix 1: My publications relevant to this work

thebmj

BMJ 2020;368:m462 doi: 10.1136/bmj.m462 (Published 25 February 2020) Page 1 of 4

PRACTICE

Check for updates

UNCERTAINTIES

Is streaming patients in emergency departments to primary care services effective and safe?

Alison Cooper *clinical research fellow*[1], Andrew Carson-Stevens *clinical reader in patient safety and quality improvement*[1], Thomas Hughes *emergency medicine consultant*[2], Adrian Edwards *professor of general practice*[1]

[1]Division of Population Medicine, School of Medicine, Cardiff University, UK; [2]John Radcliffe Hospital, Oxford, UK

What you need to know

- Co-located primary care services have been introduced in emergency departments in the UK to reduce crowding and improve patient care and safety
- There is limited, outdated evidence to show whether streaming emergency department patients to primary care services improves patient flow and reduces costs; and evidence is lacking for patient safety outcomes
- Commissioners and service providers should consider whether governance systems are clear and reflect whether general practitioners in emergency departments are encouraged to function more as primary care or emergency medicine clinicians to suit the local patient demographic profile, demand patterns, and staff recruitment needs

Between 10% and 43% of patients presenting to emergency departments can be managed in primary care, according to estimates from observational studies.[1-4] Increasing demands on emergency healthcare systems have led to the development of different healthcare models, including "streaming" patients presenting with non-urgent conditions to primary care services.[5] These strategies are intended to improve patient flow and reduce crowding in the emergency department. In 2017 NHS England made substantial investments for all emergency departments to have co-located primary care facilities so they are "free to care for the sickest patients."[6 7]

However, the evidence for this initiative is weak.[8-11] Different service models are described in different contexts using ambiguous terminology. A "co-located" primary care service may deliver patient care in a separate unit to the emergency department, without access to acute diagnostics, thus similar to normal general practice settings. Alternatively, general practitioners may work within the emergency department, with responsibilities beyond usual primary care.[13] It is uncertain if national implementation of streaming, considering the heterogenous nature of emergency medicine case mix and practice, improves patient care and safety.

What is the evidence of uncertainty?

There are few large scale evaluations of healthcare delivery models offering co-located primary care services. Studies have heterogeneous designs, making it difficult to draw conclusions on safety and effectiveness. Table 1 describes findings from reviews.[8-12] A Cochrane review found few studies on effects of general practitioners seeing non-urgent patients in hospital emergency departments. The results were inconsistent and highlighted a lack of evidence for effectiveness outcomes, with no data available for mortality or safety events.[8]

A narrative review described an increase in attendances at emergency departments with co-located primary care services that was attributed to the service creating its own demand—provider induced demand. There was little evidence on improved patient flow or costs to recommend this model.[11] A rapid realist review found little evidence that general practitioner services in emergency departments influenced the care and throughput of the sickest patients, with other factors, including delayed patient transfers to wards and inadequate staffing, also contributing.[12] Factors such as how staff interpret the streaming system and the roles adopted by general practitioners (whether they function in their traditional role or adopt an emergency medicine approach) could influence effectiveness of service models.

Given the limited, outdated clinical and cost-effectiveness evidence and concerns about the feasibility of staffing the workforce, the National Institute for Health and Care Excellence (NICE) chose not to make a recommendation for general

Correspondence to A Cooper CooperA8@cardiff.ac.uk

This is one of a series of occasional articles that highlight areas of practice where management lacks convincing supporting evidence. The series advisers are Sera Tort, clinical editor, Nai Ming Lai, clinical editor, and David Tovey, editor in chief, the Cochrane Library. You can read more about how to prepare and submit an Education article on our Instructions for Authors pages: https://www.bmj.com/about-bmj/resources-authors/article-types

Open access Research

BMJ Open

The impact of general practitioners working in or alongside emergency departments: a rapid realist review

Alison Cooper,[1] Freya Davies,[1] Michelle Edwards,[1] Pippa Anderson,[2] Andrew Carson-Stevens,[1] Matthew W Cooke,[3] Liam Donaldson,[4] Jeremy Dale,[3] Bridie Angela Evans,[5] Peter D Hibbert,[6,7] Thomas C Hughes,[8] Alison Porter,[5] Tim Rainer,[1] Aloysius Siriwardena,[9] Helen Snooks,[5] Adrian Edwards[1]

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For numbered affiliations see end of article.

Correspondence to
Dr Alison Cooper;
coopera8@cardiff.ac.uk

ABSTRACT

Objectives Worldwide, emergency healthcare systems are under intense pressure from ever-increasing demand and evidence is urgently needed to understand how this can be safely managed. An estimated 10%–43% of emergency department patients could be treated by primary care services. In England, this has led to a policy proposal and £100 million of funding (US$130 million), for emergency departments to stream appropriate patients to a co-located primary care facility so they are 'free to care for the sickest patients'. However, the research evidence to support this initiative is weak.

Design Rapid realist literature review.

Setting Emergency departments.

Inclusion criteria Articles describing general practitioners working in or alongside emergency departments.

Aim To develop context-specific theories that explain how and why general practitioners working in or alongside emergency departments affect: patient flow; patient experience; patient safety and the wider healthcare system.

Results Ninety-six articles contributed data to theory development sourced from earlier systematic reviews, updated database searches (Medline, Embase, CINAHL, Cochrane DSR & CRCT, DARE, HTA Database, BSC, PsycINFO and SCOPUS) and citation tracking. We developed theories to explain: how staff interpret the streaming system; different roles general practitioners adopt in the emergency department setting (traditional, extended, gatekeeper or emergency clinician) and how these factors influence patient (experience and safety) and organisational (demand and cost-effectiveness) outcomes.

Conclusions Multiple factors influence the effectiveness of emergency department streaming to general practitioners; caution is needed in embedding the policy until further research and evaluation are available. Service models that encourage the traditional general practitioner approach may have shorter process times for non-urgent patients; however, there is little evidence that this frees up emergency department staff to care for the sickest patients. Distinct primary care services offering increased patient choice may result in provider-induced demand. Economic evaluation and safety requires further research.

PROSPERO registration number CRD42017069741.

Strengths and limitations of this study

- A realist approach to evidence synthesis leads to theory development that explains how and why context links to outcome; contextual factors can then be incorporated into the evidence base to inform healthcare management and policy-making.
- We used experts and stakeholders to facilitate the process, help confirm findings and produce a context-specific document in response to emerging issues.
- Some studies did not describe how general practitioners worked in adequate depth to identify key mechanisms that led to the outcomes.
- We have focused on general practitioners treating patients in emergency department settings relevant to the UK healthcare system; patient demographics and other healthcare professionals working in primary care services may vary and influence the effectiveness of these services.

BACKGROUND

Worldwide, emergency healthcare systems are under intense pressure from ever-increasing demand.[1] Evidence is urgently needed to understand how best to manage this demand while safely achieving the highest standards of care.[2] An estimated 10%–43% of patients attending hospital emergency departments could be treated in primary care settings.[3–9] In England, this has led to a policy proposal, supported by £100 million of funding (US$130 million), that all emergency departments have a co-located primary care facility, so they are 'free to care for the sickest patients'.[10–12]

The UK has a universal healthcare system, the National Health Service (NHS), funded though taxation.[13] Primary care is led by general practitioners, community-based doctors with generalist training. General practitioners are described as working in or

OPEN ACCESS

Taxonomy of the form and function of primary care services in or alongside emergency departments: concepts paper

Alison Cooper,[1] Michelle Edwards,[1] Janet Brandling,[2] Andrew Carson-Stevens,[1] Matthew Cooke,[3] Freya Davies,[1] Thomas Hughes,[4] Katherine Morton,[2] Aloysius Siriwardena,[5] Sarah Voss,[2] Jonathan Benger,[2] Adrian Edwards[1]

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[1]Division of Population Medicine, School of Medicine, Cardiff University, UK
[2]Faculty of Health and Applied Sciences, The University of the West of England, Bristol, UK
[3]Warwick Medical School, University of Warwick, Coventry, West Midlands, UK
[4]Emergency Department, John Radcliffe Hospital, Oxford, Oxfordshire, UK
[5]Lincoln School of Health and Social Care, University of Lincoln, Lincoln, Lincolnshire, UK

Correspondence to
Dr Alison Cooper, Division of Population Medicine, School of Medicine, Cardiff University, Cardiff CF14 4YS, UK; CooperA8@cardiff.ac.uk

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ABSTRACT

Primary care services in or alongside emergency departments look and function differently and are described using inconsistent terminology. Research to determine effectiveness of these models is hampered by outdated classification systems, limiting the opportunity for data synthesis to draw conclusions and inform decision-making and policy. We used findings from a literature review, a national survey of Type 1 emergency departments in England and Wales, staff interviews, other routine data sources and discussions from two stakeholder events to inform the taxonomy. We categorised the forms inside or outside the emergency department: inside primary care services may be integrated with emergency department patient flow or may run parallel to that activity; outside services may be offered on site or off site. We then describe a conceptual spectrum of integration: identifying constructs that influence how the services function—from being closer to an emergency medicine service or to usual primary care. This taxonomy provides a basis for future evaluation of service models that will comprise the evidence base to inform policy-making in this domain. Commissioners and service providers can consider these constructs in characterising and designing services depending on local circumstances and context.

INTRODUCTION

Worldwide, increasing pressure on emergency departments from rising demand,[1] has led to much interest in different models of service delivery, including the use of primary care services in or alongside emergency departments.[2–4] However, the way these primary care services look and operate varies depending on local context and whether they are required to operate closer to an emergency medicine service or to usual primary care. Research to evaluate the effectiveness of different service models (including patient experience, service and cost-effectiveness outcomes) is hampered by inconsistent terminology, outdated taxonomies and heterogeneous, single-site study designs. This limits the opportunity for data synthesis to draw conclusions that will inform decision-making and policy.[5–7] Research is urgently needed to understand if the form these services take supports the intended function,[8] and requires an updated taxonomy to enable comparison of models and outcomes.

The UK has a universal healthcare system, the National Health Service (NHS), funded though taxation.[9] Primary care is led by general practitioners (GPs), community-based doctors with generalist training, supported by nurses, nurse practitioners and allied health professionals, often with additional diagnostic and prescribing skills working as independent clinicians. Urgent and emergency healthcare services are varied and described using interchangeable terminology (table 1). Three main GP roles are described for primary care services associated with emergency departments (table 1): treating patients identified as having primary care type problems in a unit alongside the emergency department including walk-in centres, urgent care centres or traditional out-of-hours services; screening patients at the front door of the emergency department to redirect those with primary care type problems to an alternative service off site; or fully integrated with the emergency department service, treating patients presenting with a wider range of conditions.[10] Identification of patients for these services is also varied, with triage (a clinical activity to sort patients by acuity so that those with the greatest need are seen first) and streaming (an operational activity to sort low acuity patients by clinician availability and suitability) sometimes combined or as separate activities. Embedded and co-located are further terms that have been used to describe primary care models, where clinicians receive patients streamed from the emergency department. (table 1)[11]

NHS England adopted a policy (2017) where emergency departments could apply for capital bid funding (one-off payments) to implement new or develop existing services to support GP streaming.[3] This has changed the nature of emergency department services and how they function, with evolving relationships with primary care services and the sorting of patients depending on patient acuity and clinician availability. Language to describe the different services is used inconsistently, with considerable ambiguity around the term 'co-located'. Also, GPs rarely perform a screening role at the emergency department front door. Agreed and consistent terminology is needed to describe the form these services now take, and if form supports the intended function, so that we can understand which service models are being implemented and how they work. The terminology also needs to

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BMC Emergency Medicine

RESEARCH ARTICLE Open Access

Diagnostic error in the emergency department: learning from national patient safety incident report analysis

Faris Hussain[1], Alison Cooper[1*], Andrew Carson-Stevens[1], Liam Donaldson[2], Peter Hibbert[3], Thomas Hughes[4] and Adrian Edwards[1]

Abstract

Background: Diagnostic error occurs more frequently in the emergency department than in regular in-patient hospital care. We sought to characterise the nature of reported diagnostic error in hospital emergency departments in England and Wales from 2013 to 2015 and to identify the priority areas for intervention to reduce their occurrence.

Methods: A cross-sectional mixed-methods design using an exploratory descriptive analysis and thematic analysis of patient safety incident reports. Primary data were extracted from a national database of patient safety incidents. Reports were filtered for emergency department settings, diagnostic error (as classified by the reporter), from 2013 to 2015. These were analysed for the chain of events, contributory factors and harm outcomes.

Results: There were 2288 cases of confirmed diagnostic error: 1973 (86%) delayed and 315 (14%) wrong diagnoses. One in seven incidents were reported to have severe harm or death. Fractures were the most common condition (44%), with cervical-spine and neck of femur the most frequent types. Other common conditions included myocardial infarctions (7%) and intracranial bleeds (6%). Incidents involving both delayed and wrong diagnoses were associated with insufficient assessment, misinterpretation of diagnostic investigations and failure to order investigations. Contributory factors were predominantly human factors, including staff mistakes, healthcare professionals' inadequate skillset or knowledge and not following protocols.

Conclusions: Systems modifications are needed that provide clinicians with better support in performing patient assessment and investigation interpretation. Interventions to reduce diagnostic error need to be evaluated in the emergency department setting, and could include standardised checklists, structured reporting and technological investigation improvements.

Keywords: Emergency department, Diagnostic error

Background

Diagnostic error occurs more frequently in emergency departments than in the recorded 10–15% of adverse medical events for routine hospital in-patient hospital care [1]. These errors often result in serious patient harm [2, 3], and in the United States of America (USA) these errors are associated with a significant number of deaths per year [4]. However, the reasons for this are not well established. There is growing concern over diagnostic error in United Kingdom (UK) emergency departments given the increase in patient demand in recent years [5–8]. Diagnostic errors have been largely unaddressed across most healthcare settings, including the emergency department [4, 9–11], despite current estimates suggesting one in ten diagnoses are likely to be incorrect [12–14].

Diagnostic error studies are mostly limited to single case sites [15, 16]. Methods include prospective identification of errors by emergency department clinicians [15], retrospective clinical review of closed malpractice claims [17], and review of cases where the diagnosis on admission differs to that on discharge [18]. There is an opportunity to study diagnostic error in patient safety incident reports in parts of the UK as they comprise

* Correspondence: Coopera8@cardiff.ac.uk
[1]Cardiff University, Cardiff, UK
Full list of author information is available at the end of the article

Appendix 2: RAMESES publication standards for realist syntheses(143)

TITLE			**Reported on page**
1		In the title, identify the document as a realist synthesis or review -	Chapter 2, section 2.3.1
ABSTRACT			
2		While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice.	Page ii-iii
INTRODUCTION			
3	Rationale for review	Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area.	Chapter 2, section 2.3.1
4	Objectives and focus of review	State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review.	Chapter 2, section 2.3.1
METHODS			
5	Changes in the review process	Any changes made to the review process that was initially planned should be briefly described and justified.	n/a
6	Rationale for using realist synthesis	Explain why realist synthesis was considered the most appropriate method to use.	Chapter 2, section 2.3.1

TITLE			**Reported on page**
7	Scoping the literature	Describe and justify the initial process of exploratory scoping of the literature.	Chapter 2, section 2.3.1.1
8	Searching processes	While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected.	Chapter 2, section 2.3.1.3
9	Selection and appraisal of documents	Explain how judgements were made about including and excluding data from documents, and justify these.	Chapter 2, section 2.3.1.4
10	Data extraction	Describe and explain which data or information were extracted from the included documents and justify this selection.	Chapter 2, section 2.3.1.5
11	Analysis and synthesis processes	Describe the analysis and synthesis processes in detail. This section should include information on the constructs analyzed and describe the analytic process.	Chapter 2, section 2.3.1.7
RESULTS			
12	Document flow diagram	Provide details on the number of documents assessed for eligibility and included in the review with reasons for exclusion at each stage as well as an indication of their source of origin (for example, from searching databases, reference lists and so on). You may consider using the example templates (which are likely to need modification to suit the data) that are provided.	Chapter 3, section 3.1

TITLE			Reported on page
13	Document characteristics	Provide information on the characteristics of the documents included in the review.	Chapter 3, section 3.1
14	Main findings	Present the key findings with a specific focus on theory building and testing.	Chapter 3, section 3.2
DISCUSSION			
15	Summary of findings	Summarize the main findings, taking into account the review's objective(s), research question(s), focus and intended audience(s).	Chapter 3, section 3.3
16	Strengths, limitations and future research directions	Discuss both the strengths of the review and its limitations. These should include (but need not be restricted to) (a) consideration of all the steps in the review process and (b) comment on the overall strength of evidence supporting the explanatory insights which emerged. The limitations identified may point to areas where further work is needed.	Chapter 3, section 3.3
17	Comparison with existing literature	Where applicable, compare and contrast the review's findings with the existing literature (for example, other reviews) on the same topic.	Chapter 3, section 3.3
18	Conclusion and recommendati ons	List the main implications of the findings and place these in the context of other relevant literature. If appropriate, offer recommendations for policy and practice.	Chapter 3, section 3.3
19	Funding	Provide details of funding source (if any) for the review, the role played by the funder (if any) and any conflicts of interests of the reviewers.	Page viii

Appendix 3:Rameses reporting standards for realist evaluation

Item to be included	Page number/Section
TITLE 1. In the title, identify the document as a realist evaluation.	Title page
SUMMARY OR ABSTRACT 2. Journal articles will usually require an abstract, while reports and other forms of publication will usually benefit from a short summary. The abstract or summary should include brief details on: the policy, programme or initiative under evaluation; programme setting; purpose of the evaluation; evaluation question(s) and/or objective(s); evaluation strategy; data collection, documentation and analysis methods; key findings and conclusions. Sufficient detail should be provided to identify that a realist approach was used and that realist programme theory was developed and/or refined .	Page ii and iii
INTRODUCTION 3. Rationale for evaluation. Explain the purpose of the evaluation and the implications for its focus and design. 4. Programme theory. Describe the initial programme theory (or theories) that underpin the programme, policy or initiative. 5. Evaluation questions, objectives and focus. State the evaluation question(s) and specify the objectives for the evaluation. Describe whether and how the programme theory was used to define the scope and focus of the evaluation. 6. Ethical approval. State whether the realist evaluation required and has gained ethical approval from the relevant authorities, providing details as appropriate. If ethical approval was deemed unnecessary, explain why.	Chapter 1, section 1.1 Chapter 1, section 1.1.2 Chapter 1, sections 1.3.1, 1.3.2 Chapter 2, section 2.2.4
METHODS 7. Rationale for using realist evaluation. Explain why a realist evaluation approach was chosen and (if relevant) adapted 8. Environment surrounding the evaluation. Describe the environment in which the evaluation took place 9. Describe the programme policy, initiative or product evaluated. Provide relevant details on the programme, policy or initiative evaluated 10. Describe and justify the evaluation design. A description and justification of the evaluation design (i.e. the account of what was planned, done and why) should be included, at least in summary form or as an appendix, in the document which presents the main findings. If this is not done, the omission should be justified and a reference or link to the evaluation design given. It may also be useful to publish or make freely available (e.g. online on a website) any original evaluation design document or protocol, where they exist 11. Data collection methods Describe and justify the data collection methods – which ones were used, why and how they fed into developing, supporting, refuting or refining programme theory. Provide details of the steps taken to enhance the trustworthiness of data collection and documentation.	Chapter 2, section 2.1.4 Chapter 1, section 1.1.1 Chapter 1, section 1.1.2 Chapter 2, section 2.2 Chapter 2, section 2.3

12. Recruitment process and sampling strategy. Describe how respondents to the evaluation were recruited or engaged and how the sample contributed to the development, support, refutation or refinement of programme theory 13. Data analysis. Describe in detail how data were analysed. This section should include information on the constructs that were identified, the process of analysis, how the programme theory was further developed, supported, refuted and refined, and (where relevant) how analysis changed as the evaluation unfolded	Chapter 2, section 2.3.3 Chapter 2, sections 2.3.3.4, 2.3.3.5
RESULTS 14. Details of participants. Report (if applicable) who took part in the evaluation, the details of the data they provided and how the data was used to develop, support, refute or refine programme theory. 15. Main findings. Present the key findings, linking them to contexts, mechanisms and outcome configurations. Show how they were used to further develop, test or refine the programme the	Chapter 6, section 6.1 Chapter 6, section 6.2
DISCUSSION 16. Summary of findings. Summarise the main findings with attention to the evaluation questions, purpose of the evaluation, programme theory and intended audience 17. Strengths, limitations and future directions. Discuss both the strengths of the evaluation and its limitations. These should include (but need not be limited to): (1) consideration of all the steps in the evaluation processes; and (2) comment on the adequacy, trustworthiness and value of the explanatory insights which emerged. In many evaluations, there will be an expectation to provide guidance on future directions for the programme, policy or initiative, its implementation and/or design. The particular implications arising from the realist nature of the findings should be reflected in these discussions 18. Comparison with existing literature. Where appropriate, compare and contrast the evaluation's findings with the existing literature on similar programmes, policies or initiatives 19. Conclusion and recommendations. List the main conclusions that are justified by the analyses of the data. If appropriate, offer recommendations consistent with a realist approach 20. Funding and conflict of interest. State the funding source (if any) for the evaluation, the role played by the funder (if any) and any conflicts of interests of the evaluators.	Chapter 9, section 9.1 Chapter 9, section 9.2 Chapter 9, section 9.3 Chapter 9, sections 9.4, 9.5. 9.6 Page viii

Appendix 4:'GPs in EDs' Stakeholder 'expert' group participants attending face-to-face meeting 9th May 2017

Name	Institution	Discipline
A/Prof Pippa Anderson	Swansea University	Health economist
The late Prof Damian Berridge	Swansea University	Statistician
Dr Andrew Carson-Stevens	Cardiff University	Academic GP – patient safety
Dr Alison Cooper	Cardiff University	Academic GP – PhD student
Prof Matthew Cooke	Warwick University	Emergency medicine clinician – policy expertise
Prof Jeremy Dale	Warwick University	Academic GP – conducted previous work on GPs in EDs
Dr Freya Davies	Cardiff University	Academic GP – Realist methods expertise
Prof Adrian Edwards	Cardiff University	Principal Investigator GPs in EDs project, Academic GP
Dr Michelle Edwards	Cardiff University	Research assistant
Dr Bridie Evans	Swansea University	PPI lead
Ms Barbara Harrington	Involving people	PPI
Mrs Julie Hepburn	Involving people	PPI
Mr Peter Hibbert	Macquarie University, Sydney	Patient safety expertise
Dr Thomas Hughes	John Radcliffe Hospital, Oxford	Emergency medicine clinician – ECDS expertise
Dr Alison Porter	Swansea University	Qualitative methods
Prof Tim Rainer	Cardiff University	Emergency medicine clinician
Dr Rebecca Sherlock	Cardiff University	Academic GP
Prof Niro Siriwardena	Lincoln University	Academic GP – urgent care services
Prof Helen Snooks	Swansea University	Health Services Research

Appendix 5: Rapid Realist Review Search Strategy

1. exp Primary Health Care/

2. primary care.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

3. exp Physicians, Family/

4. exp Physicians, Primary Care/

5. family physician*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

6. exp Family Practice/

7. family practic*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

8. GP.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

9. exp After-Hours Care/

10. (after-hours care or out of hours or out-of-hours or OOH).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

11. exp General Practitioners/

12. general practic*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12

14. exp Emergency Medical Services/

15. exp Emergency Service, Hospital/

16. emergency department*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

17. (accident and emergenc*).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

18. casualt*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

19. emergency room.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

20. A&E.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

21. urgent care centre*.mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

22. (walkin or walk in or walk-in).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

23. 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22

24. 13 and 23

25. limit 24 to yr="2015 -Current"

Appendix 6: Case study site invitation letter

Division of Population Medicine
Cardiff University
5th Floor Neuadd Meirionnydd
Heath Park
Cardiff
CF14 4YS
Telephone: 02920 870746
Email GP-EDStudy@cardiff.ac.uk

Invitation to take part a research project: realist eval safety, patient experience and system implications of different models of using GPs in or alongside Emergency Departments.

Dear Dr……………,

Thank you for completing our recent survey regarding GPs working in Emergency Departments. The findings, along with a literature review, have contributed to developing a taxonomy of how different GP-ED models function in England and Wales. Through the work, we have developed some understanding of the mechanisms by which these models operate in different contexts and are now moving into the next phase of our evaluation to test these working theories.

We would like to invite your emergency department at …………..Hospital to be one of our 12 case study sites.

We would like you to act as a local collaborator for our project and help us facilitate a visit to your Emergency Department by our research team over a three-day period between August and December 2018. We appreciate how extremely busy Emergency Departments are, but hope you will feel that it will be valuable to contribute to this research that will ultimately develop **national recommendations about use of GPs in EDs**.

If you agree to become one of our case study sites, our research team colleagues at Swansea University will request to extract NHS data on attendances, admissions, re-attendances, investigations, treatments and waiting times for statistical analysis via the Data Access Request Service run by NHS Digital. Our research team at Cardiff University will carry out the on-site qualitative research and will contact you to arrange a convenient time to visit your department for a period of three days. The team consists of a GP, Dr Alison Cooper, and a qualitative researcher, Dr Michelle Edwards. On some visits, we may also be joined by our health economics expert, Prof Pippa Anderson from Swansea University or another member of her team. During the visit, our researchers would like to see around the department and be introduced to members of staff. We aim to gather information on **how the GP-ED model operates and the experiences of the ED staff** through short informal (noted) conversations and audio recorded semi-structured interviews. (These can be done via telephone at a later date if more convenient. We are mindful of the busy ED environment and will do our utmost not to get in the way).

We have identified five **“marker conditions”** that are often seen by both GPs and ED doctors and perhaps managed differently. We will seek to interview between 5-

10 patients for each of the five marker conditions - also on site, over the three days, or again at a later date via telephone. A member of the research team with expertise in evaluating **patient safety** data, Dr Alison Cooper, will also review a sample of patient safety reports from e-Datix or your local reporting system. The analysis of these data from our 12 case study sites will improve understanding of how different GP-ED models can contribute to patient safety incidents and ways to mitigate such events.
Our study is funded by the National Institute of Health Research and has had a favourable ethical opinion on 23/11/18 by the Wales Research Ethics Committee 1 (Ref: 17/WA/03). We have obtained approval from the Health Research Authority on 5/2/2018, (Ref: 17/WA/0328). We will contact your local NHS Research and Development Department before commencing any work.

We have included a table of research activities for our case study visits to Emergency Departments and a flowchart diagram of our project protocol.
To indicate your interest in becoming a case study site please contact our research team at GP-EDStudy@cardiff.ac.uk or telephone 02920 870746. If you require any further information, our project officer, Mr Nigel Pearson, or research support, Miss Delyth Price, will be happy to answer any questions or be able to put you in touch with Michelle or Alison for more complex queries.
We look forward to hearing from you and thank you in advance for your contribution towards this important research that will go on to inform national guidelines on delivering safer, more efficient Emergency Department care.
Yours sincerely,

Professor Adrian Edwards
Professor of General Practice, Division of Population Medicine, Cardiff University

Appendix 7: Case study site outline research plan

One month before visit
The research team will send handouts and posters to the case study site to inform ED staff of the upcoming visit and the aims of the research.

Day 1

- Introduction to the department by the Clinical Director. Particular areas of interest include: the reception desk; the triage system; and how and where the GPs work
- Send out recruitment packs to patients for telephone interviews at a later date (identified from ECDS data to have marker conditions prior to the visit)
- Meet with the triage staff to explain eligibility criteria for selecting patients with marker conditions that could be invited for interviews on site.
- Conduct informal short interviews (conversations) with some ED Staff
- Invite some ED staff to take part in a 30 minute interview (in a private area) or a telephone interview at a later date.

Day 2

- One researcher to review the patient safety incident reports from e-datix or equivalent
- Informal short interviews with ED Staff (depending on availability)
- Triage staff hand out interview invitations to patients
- Research staff to take consent from patients (up to 10 over two days) and arrange post consultation interviews or follow-up telephone interviews with consenting patients
- Research staff invite some ED staff to take part in a 30 minute interview (in a private room) area) or a telephone interview.

Day 3

- One researcher to review the patient safety incident reports from e-datix or equivalent
- Informal short interviews with ED Staff (depending on availability)
- Triage staff hand out interview invitations to patients
- Research staff to take consent from patients and arrange post consultation interviews or follow-up telephone interviews with consenting patients
- Research Staff invite some ED staff to take part in a 30 minute interview (in a private area) or a telephone interview

Appendix 8: GP realist interview guide

Introduce the study to the participant

Thank you for taking part in the interview today. Our aim is to talk to you about you about your role and how the GP-ED model works. We are studying 12 hospitals in England and Wales as part of an NIHR funded project, 9 that have GPs and 3 that do not. We hope to explore what kind of models work in different contexts and what outcomes are achieved. Your interview will form part of our qualitative research evidence and then we will be extracting hospital episode data to look at outcomes such as admissions, use of resources and costs etc.

The interview can last for as long as you are available to speak to me today, please feel free to pause or stop the interview if there is something else you need to deal with. What we talk about during the interview will not be linked to your name as we use ID numbers for all hospitals and staff members that we interview. Please read the patient information and sign the consent form and we can begin the interview when you are ready.

Introductory questions

- I understand that you are a GP and work alongside other ED staff members and that you are not streamed patients but pick up the next one on the list – have I got that right?
- How do you feel the GP-ED service works here?

Role of the GP and diagnostic approach	• There's this idea that **GPs may manage patients differently to ED clinicians**, being more comfortable with uncertainty using less investigations and admitting less patients)? What is your experience of this? What influences this? Prompts – certain conditions (chest pain/child with fever/abdominal pain)? Different situations? Time of day? Type of patient? Experience of doctor? Because GPs diagnose differently? More comfortable with risk taking? Availability of investigations? Expectation of doing investigations? • Are there any specific conditions that you **feel GPs manage well or not so well**? (prompts why why why) • Do you have any **safety concerns**? (explore positive, negative, mitigating factors) • There's this idea that **GPs may manage patients differently when working in an ED setting utilising more investigations and admitting more patients than they would if they saw the same patient working in the community or OOH** What's your experience of this? (same prompts as above, also personal experience, less knowledge about the patient, expectation to investigate, awareness higher risk of serious illness)

	• There's this idea that **GPs decision making and request for further investigation and referral may be influenced by the decision making of other healthcare professionals** e.g. the triage nurse/streamer allocating patients not thought to require investigations (low risk chest pain, headache, musculoskeletal injuries) or paramedic with a patient with normal ECG and chest pain Have you any experience of this? (prompts seniority of certain healthcare professionals, certain conditions, any learning/change in management?)
Skillset knowledge	• There's some evidence in the literature that **GPs working in a more integrated role in emergency departments see sicker patients than they usually deal with in practice or conditions outside of their skillset requiring acute investigations.** Have you any experience of this? (patient allocation – no streaming, rural setting, small hospital) • How have you dealt with this? (prompts – personal reading, specific course/training, in house training, senior advice, cherry picking patients)
Team working/ learning/ integration	• There's this idea that GPs working alongside ED staff **learn from each other** about management pathways in the community and in emergency care which improves the quality care for the patient care Do you have any experience of this? And how does this happen? (Prompts – same meetings/protocols/governance/social events/informal conversation?)
Wider system	• There's this idea that GPs in ED may give GPs the opportunity for a portfolio career and retain GPs in the NHS or alternatively deplete community general practice of its workforce. Have you any thoughts/experience of this? (local primary care recruitment/retention issues? Personal interest?)

Thank you for taking the time to be interviewed today, your responses are valuable to us understanding how GPs work in the department here. Are there any questions that you have or any other comments that you would like to make?

Appendix 9: Stakeholder facilitator guide and worksheets

GPs in EDs patient safety group work - facilitator notes

Thank you for helping facilitate this group work as part of the patient safety workshop. Alison will first present patient safety findings from the GPs in EDs study. The presentation will include online feedback in real time using menti.com so please bring along an electronic device (phone/tablet) that can access to the internet. (If you do not have one please let us know so that this can be provided.) The group work will then explore which measures would be most useful to evaluate the safety in one of three areas:

- The streaming processes
- GP or primary care clinician clinical decision-making
- Communication and referral processes between the primary care and emergency services

Participant information is included for all three themes, each facilitator will have one theme (likely 3 tables of each). Participants will be invited to move to a table of their interest.

Format for the workshop (20 mins):

1. Please hand out the participant information sheets to delegates on your table and advise that the ideas for improvement and potential measures should be used as a guide; participants may have other ideas and suggest other measurements.
2. Please introduce yourself and ask the others to do the same.
3. Please work through the 3 questions on the participant information sheet, taking notes on the flip chart paper.
4. Please ensure that following the group discussion, participants have individually ticked the 3 measures they feel would be most useful AND easy/practical to measure. Additional measures can be handwritten on the sheet if necessary.
   PLEASE COLLECT THESE SHEETS FROM PARTICIPANTS AND HAND BACK TO ALISON AT THE END OF THE SESSION.
5. Please summarise key discussion points to plenary.

Many thanks again for your help with this session

GPs in EDs patient safety group work - STREAMING

The aim of this group work is to explore which measures would be most useful to evaluate the safety of the streaming process.

Ideas for improvement

Improve streaming processes

- Local guidance on which patients are appropriate for the primary care service including high risk conditions e.g. fractures, chest pains, headaches, unwell children
- Initial assessment by an experienced nurse including basic physiological observations and early warning scores
- Standard triage times for the emergency and primary care service

Potential measures: tick 3 most useful and measurable

Number of streamed patients sent back to the ED	
Re-attendance at the ED within 7 days	
Patient feedback	
Frequency of staff formal or informal briefings/debriefings	
Patient safety incident reporting systems	

Audit grades (experience) of streaming nurses	
Audit staffing levels (sickness/unfilled shifts)	
Audit recording of basic observations (pulse, BP etc)	
Audit use of early warning scores	

Audit clinical notes for triage times	

Group work

1. Do you think the ideas for improvement and potential measures would be useful as part of the toolkit?
   - Would you try any of the ideas for improvement or are you doing them already?
   - Are there any other ideas for improvement or essential measurements we need? (please add)
2. As a table what would be your top 3 most useful and easy/practical measures to evaluate the safety of streaming? Following the discussion, please INDIVIDUALLY tick your top 3 and hand the sheet back to the facilitator.
3. Can anyone on the table share learning from good practice?
   - How to develop appropriate local guidance?
   - Which patients should have basic observations and early warning scores?

GPs in EDs patient safety group work - CLINICAL DECISION-MAKING

The aim of this group work is to explore useful measures to evaluate the safety of primary care CLINICAL DESCISION-MAKING.

Ideas for improvement

Support clinical decision-making for primary care clinicians

- Understand where clinical decision-making support may be needed
- Evaluating why clinical decisions are made
- Education and learning for primary care staff

Potential measures: tick 3 most useful and measurable

Death rates (within 1-week of discharge or 24 hrs admission)	
Re-attendance rates to the ED within 7 days	
Clinical feedback systems for diagnostic error e.g. X-ray reporting, DVT clinic	
Patient feedback (surveys, online)	
Patient safety incident reporting systems	
Auditing clinical documentation (diagnostic decisions and safety netting)	
Audit use of protocols for high risk conditions e.g. chest pain, headache	
Auditing induction and appraisal processes	
Frequency of informal and formal briefing/debriefings (e.g. safety huddle)	
Feedback from complaints and adverse events delivered to clinical staff	
Mandatory training for staff taking on ED roles (investigations, safeguarding)	

Group work

1. Do you think the ideas for improvement and potential measures would be useful as part of the toolkit?
   - Would you try any of the ideas for improvement or are you doing them already?
   - Are there any other ideas for improvement or essential measurements we need? (please add)
2. As a table what would be your top 3 most useful and practical measures to evaluate the safety of clinical decision-making? Following the discussion, please INDIVIDUALLY tick your top 3 and hand the sheet back to the facilitator.
3. Can anyone on the table share learning from good practice?
   - Delayed diagnosis feedback systems e.g. from acute medical clinics, paediatrics? Effective feedback systems to clinical staff?

GPs in EDs patient safety group work - COMMUNICATION PROCESSES

The aim of this group work is to explore useful measures to evaluate COMMUNICATION between emergency and primary care services.

Ideas for improvement

Improve communication between emergency and primary care services

- GP leadership role in the primary care service to encourage formal and informal communication
- Clear referral pathways for emergency or specialist assessment
- Standardised computer systems for emergency and primary care services
- Improve investigation follow up processes

Potential measures: tick 3 most useful and measurable

GP(s) appointed in leadership role	
Frequency of informal and formal face to face briefing/debriefings	
Frequency of electronic updates/newsletters	
Frequency of GP representation at ED managerial meetings	
Delivery of feedback from complaints and adverse events to clinical staff	
Staff completion of a formal patient safety assessment tool	

Patient feedback (surveys, online)	
Staff feedback systems	
Patient safety incident reports	

Audit number of patients lost in the system or delayed assessment	
Audit timely adequate electronic discharge summary sent to local GP	
Identification of frequent attenders for case management	

Audit number of patients sent to GP with blood tests already taken	
Audit action of urine and swab results	

Group work

1. Do you think the ideas for improvement and potential measures would be useful as part of the toolkit?
   - Would you try any of the ideas for improvement or are you doing them already?
   - Are there any other ideas for improvement or essential measurements we need? (please add)
2. As a table what would be your top 3 most useful and practical measures to evaluate effective communication processes? Following the discussion, please INDIVIDUALLY tick your top 3 and hand the sheet back to the facilitator.
3. Can anyone on the table share learning from good practice about improving primary care and emergency communication processes?

Appendix 10: Included articles in rapid realist review listed by Country(32)

Lead author	Country	Title	Study Design
Ablard 2017	UK	Primary care services co-located with Emergency Departments across a UK region: early views on their development	Survey and semi-structured interviews
Bentley 2017	UK	Emergency Department redirection to primary care: a prospective evaluation of practice	Prospective evaluation of the subsequent management and outcome of redirected non-urgent patients from a Scottish ED over 2 months
Dale 2017	UK	Extended training to prepare GPs for future workforce needs: a qualitative investigation of a one-year fellowship in urgent care	Qualitative investigation of a one-year fellowship in urgent care
Tammes 2016	UK	Exploring the relationship between general practice characteristics, and attendance at walk-in centres, minor injuries units and EDs in England 2012/2013: a cross-sectional study	Cross-sectional observational large data analysed using multivariable regression models
Proctor 2016	UK	A&E Avoidance schemes across London: A rapid review of good practice examples	NHS report - 2 case studies involving redirection of non-urgent patients from the ED
Smith 2016	UK	To GP or not TO GP: Evaluation of children triaged to see a GP in a tertiary paediatric emergency department	Retrospective cohort study of children classified as 'GP appropriate' seen by a GP between 14:00 and 22:00 and seen by ED staff outside these hours
Gnani 2016	UK	Healthcare use among preschool children attending GP-led urgent care centres: a descriptive observational study	Retrospective observational study using routinely collected data
O'Cathain 2016	UK	Variation in avoidable emergency admissions: multiple case studies of emergency and urgent care systems	Ethnographic residual analysis. Interviews with members of emergency care teams at 6 case study sites

Begum 2016	UK	Solving the A&E crisis using GP lead triage and redirection	Poster - Patient questionnaire of 150 patients over 5 weeks redirected back to the GP for treatment with an appointment made on the same day
Gritz 2016	UK	More under fives now seen in urgent care centre than A&E should we shift our focus	Observational - retrospective analysis of routine operational data for attendances
Greenfield 2016	UK	Staff perceptions on patient motives for attending GP-led urgent care centres in London: a qualitative study	Semi-structured interviews
Cowling 2015	UK	Referral outcomes of attendances at general practitioner-led urgent care centres in London, England: retrospective analysis of hospital administrative data	Retrospective analysis of administrative data recorded at a London urgent care centre of 243042 attendances from October 2009 to December 2012
Morton 2016	UK	Describing team development within a novel GP-led urgent care centre model: a qualitative study	Staff semi-structured interviews at 2 GP-led urgent care centres in 2 London academic teaching hospitals
Arain 2015a	UK	Perceptions of healthcare professionals and managers regarding the effectiveness of GP-led walk-in centres in the UK	Qualitative using a phenomenological approach using semi structured interviews
Arain 2015b	UK	Impact of a GP-led walk-in centre on NHS emergency departments	Patient survey over a 3-week period and analysis of attendances at the local children's hospital and minor injuries unit a year before and after the WIC opened
Johnson 2015	UK	Evidence of primary care services at A&E	Letter (opinion piece) Provider of 4 UCC in London supporting co-located GPs services with emergency departments
NHS ECIST 2015	UK	Primary care in emergency departments: a guide to good practice	NHS policy document - Overview of factors to be considered when planning how best to use primary care clinicians in emergency departments, monitoring and refining the service

Harris 2014	UK	How do clinicians with different training backgrounds manage walk-in patients in the ED setting?	Retrospective case note review of a random sample of 384 patients that self-presented to the ED and were initially assessed by GPs or ED staff
Thompson 2013	UK	Suitability of emergency department attenders to be assessed in primary care: survey of general practitioner agreement in a random sample of triage records analysed in a service evaluation project	Four GPs independently used data extracted from 765 clinical notes to rate the appropriateness for management in primary care
Arain 2013	UK	Patients' experience and satisfaction with GP led walk-in centres in the UK; a cross sectional study.	Patient survey over 3 weeks in 2 GP-led WICs
Hunter 2013	UK	A qualitative study of patient choices in using emergency health care for long-term conditions: The importance of candidacy and recursivity.	Questionnaire and semi-structured interviews
Lengu 2012	UK	Application of simulation and modelling in managing unplanned healthcare demand	Conference paper - Simulation and modelling to assess the impact of primary care clinicians deflecting patients with non-urgent needs away from A&E
Carson 2010	UK	Primary care and emergency departments	Report based on results of a literature review, web-based survey and ED visits
Clancy 2009	UK	Launching a social enterprise see-and-treat service	Report outlining the service, number of patients seen and referred on in a 4-month period
Maheswaren 2009	UK	Repeat attenders at national health service walk in centres	Descriptive study using routine data from 4 walk-in centres in England
Sandhu 2009	UK	Emergency nurse practitioners and doctors consulting with patients in an emergency department: a comparison of communication skills and satisfaction	Observation study with a stratified sample of 296 video-taped consultations

Dale 2008	UK	The patient, the doctor and the emergency department: A cross-sectional study of patient-centeredness in 1990 and 2005	Observational study with a stratified sample of 430 video-taped consultations with data collection in May–July 1990 and May–July 2005.
Salisbury 2007	UK	The impact of co-located NHS walk-in centres on emergency departments	Controlled before and after study
Chalder 2007	UK	Comparing care at walk-in centres and at accident and emergency departments: an exploration of patient choice, preference and satisfaction	A controlled, mixed-method study comparing 8 EDs with co-located WICs with the same number of ‘‘traditional’’ EDs.
Pope 2005	UK	What do other local providers think of NHS walk-in centres? Results of a postal survey	Postal survey
Bickerton 2005	UK	Streaming A&E patients to walk-in centre services	Analysis of all patients attending a London hospital over 24 hours for suitability for WIC treatment
Chew-Graham 2004	UK	A new role for the general practitioners? Reframing inappropriate attenders to inappropriate services	Qualitative semi-structured staff interviews
Hsu 2003	UK	Effect of NHS walk-in centre on local primary healthcare services	Before and after observational study of consultation rate in 12 general practices after the implementation of a walk-in centre
Salisbury 2002	UK	What is the role of walk-in centres in the NHS?	Analysis of routinely collected data, questionnaire completed by managers followed by semi-structured interviews and site visits
Grant 2002	UK	An observational study comparing quality of care in walk-in centres with general practice and NHS Direct using standardised patients	Observational study involving assessment of clinicians by standardised patients at 20 walk in centres, 20 general practices ad 11 NHS direct sites
Coleman 2001	UK	Will alternative immediate care services reduce demands for non-urgent treatment at accident and emergency?	Questionnaire survey and notes review of non-urgent patients to assess the suitability of management by an alternative care service

McGugan 2000	UK	Primary care or A&E?	Prospective study over 2 months of a redirection policy
Rajpar 2000	UK	Study of choice between accident and emergency departments and general practice centres for out of hours primary care problems	Interview of patients attending A&E and GP out-of-hours
Freeman 1999	UK	Primary care units in A and E departments in North Thames in the 1990s: Initial experience and future implications	Postal questionnaire to ED staff and local GPs with follow up staff interviews
Dale 1998	UK	Primary care in accident and emergency departments: the cost effectiveness and applicability of a new model of care	PhD thesis – Includes data for included papers and additional analysis of 163 video-taped consultations
Ward 1996	UK	Primary care in London: an evaluation of general practitioners working in an inner-city accident and emergency department	Prospective survey over 6 weeks
Dale 1996	UK	Cost effectiveness of treating primary care patients in accident and emergency: a comparison between GPs, senior house officers and registrars	Prospective intervention study which was retrospectively costed
Dale 1995a	UK	Primary care in the accident and emergency department I: Prospective identification of patients	1 year prospective study at a London ED to compare patient characteristics and consultation activities for attenders assessed by nurse triage to have 'primary care' or 'accident and emergency' type problems
Dale 1995b	UK	Primary care in the accident and emergency department: II. Comparison of general practitioners and hospital doctors	1 year prospective study at a London ED to compare patient characteristics and consultation activities for attenders assessed by nurse triage to have 'primary care' or 'accident and emergency' type problems

O'Kelly 2010	Ireland	Impact of a GP cooperative on lower acuity emergency department attendances	A retrospective review of all attendances at the ‘Dubdoc’ service was compared with attendances at the ED for triage categories 4 and 5 of the same hospital over a 9-year period
Murphy 2000	Ireland	Effect of patients seeing a general practitioner in accident and emergency on their subsequent attendance: cohort study	Analysis of reattendance of non-urgent patients that had been allocated to general practitioners or usual accident and emergency staff depending on time of registration
Gibney 1999	Ireland	Randomized controlled trial of general practitioner versus usual medical care in a suburban accident and emergency department using an informal triage system	Patients 'randomised' at time of registration to either GP or ED care. Case note review
Murphy 1996	Ireland	Randomised controlled trial of general practitioner versus usual medical care in an urban accident and emergency department: process, outcome and comparative cost	Randomised controlled trial of care provided by general practitioners to non-emergency patients in an accident and emergency department differs significantly from care by usual emergency staff in terms of process, outcome ad cost
van Veelen 2016	Netherlands	Effects of a general practitioner cooperative co-located with an emergency department on patient throughput	Pre-post comparison before and after implementation of a GP cooperative at an ED
Schols 2016	Netherlands	Access to diagnostic tests during GP out-of - hours care: A cross sectional study of all GP out-hours services in the Netherlands	Cross-sectional survey of all 117 GP out of hours services in the Netherlands
Van-Gils-van Rooij 2016	Netherlands	Is patient flow more efficient in urgent care collaborations?	Observational study, compared usual care with UCCs (single point of access for ED and GP OOH)
van Gils-van Rooij 2015	Netherlands	Out-of-Hours Care Collaboration between General Practitioners and Hospital Emergency Departments in the Netherlands	Observational study - comparing attendance and patient characteristics between EDs with standard care and EDs with co-located primary care and single joint triage

Thijssen 2013	Netherlands	The impact on emergency department utilization and patient flows after integrating with a general practitioner cooperative: an observational study	Observational study - routinely collected data over 6 years
Huibers 2013	Netherlands	GP cooperative and emergency department: an exploration of patient flows	Retrospective record review of patients who had visited GPC or ED
Van der Straten 2012	Netherlands	Safety and efficiency of triaging low urgent self-referred patients to a general practitioner at an acute care post: an observational study	Prospective observational study
Bosmans 2012	Netherlands	Addition of a general practitioner to the accident and emergency department: a cost-effective innovation in emergency care	Observational study before and after implementation of new service
Van Veen 2012	Netherlands	Van Veen referral of non-urgent children from the emergency department to general practice: compliance and cost savings	Prospective observational before after study
Van Veen 2011	Netherlands	Safety of the Manchester Triage System to identify less urgent patients in paediatric emergency care: a prospective observational study	Analysis of the hospitalisation rate of self referred children triaged as non-urgent
Boeke 2010	Netherlands	Effectiveness of GPs in accident and emergency departments	Observational study before and after implementation of new service
Kool 2008	Netherlands	Towards integration of general practitioner posts and accident and emergency departments: a case study of two integrated emergency posts in the Netherlands	Observational study comparing contacts, patient satisfaction and staff satisfaction pre-and post set up of a 2 co-located GP OOHs and 2 control sites
Giesen 2006	Netherlands	Patients either contacting a general practice cooperative or accident and emergency department out of hours: a comparison	Retrospective record review

Van Uden 2006	Netherlands	Out-of-hours primary care. Implications of organisation on costs	Annual reports of 2 GP co-operatives (1 co-located, 1 separate) analysed together with ED costs
Van Uden 2005	Netherlands	The Impact of a Primary Care Physician Cooperative on the Caseload of an Emergency Department: The Maastricht Integrated Out-of-Hours Service	Observational study, patient characteristics collected for 3 weeks in Jan/Fen 1998 and March 2001 (co-operative set up in 2000)
Van Uden 2004	Netherlands	Does setting up out of hours primary care cooperatives outside a hospital reduce demand for emergency care?	Before and after observational study
Van Uden 2003	Netherlands	Use of out of hours services: a comparison between two organisations	Observational study of patient contacts at 2 different OOH centres and their associated EDs (1 co-located, 1 not)
Colliers 2017	Belgium	Implementation of a general practitioner cooperative adjacent to the emergency department of a hospital increases the caseload for the GPC but not for the emergency department	Quasi-experimental study analysing the implementation of 2 out of hours general practitioner co-operatives one adjacent to the ED, the other not and 2 control sites
Van den Heede 2016	Belgium	The 2016 proposal for the reorganisation of urgent care provision in Belgium: A political struggle to co-locate primary care providers and emergency departments	Outline of the 2016 political proposal for the reorganisation of urgent care provision toned down due to GP opposition
Ellbrant 2015	Sweden	Paediatric emergency department management benefits from appropriate early redirection of non-urgent visits	Prospective observational study using ED records and case notes
Krakau 1999	Sweden	Provision for clinic patients in the ED produces more nonemergency visits	Before and after observational study
Hansagi 1987	Sweden	Trial of a method of reducing inappropriate demands on a hospital emergency department.	Prospective observational study of 454 patients classified as non-urgent by the ED and redirected to alternative care over a 3-month period

Chmiel 2016	Switzerland	Implementation of a hospital-integrated general practice – a successful way to reduce the burden of inappropriate emergency-department use	Longitudinal observational study
Hess 2015	Switzerland	Satisfaction of health professionals after implementation of a primary care hospital emergency centre in Switzerland: A prospective before-after study	Questionnaire study of job satisfaction before and after a new emergency care model was implemented in Switzerland
Wang 2014	Switzerland	Hospital integrated general practice: a promising way to manage walk in patients	Pre and post comparison study before and after implementation of a new hospital-integrated general practice model
Chmiel 2011	Switzerland	Walk-ins seeking treatment at an emergency department or general practitioner out-of-hours service: a cross-sectional comparison	Analysis of routinely collected data of 2974 patient encounters attending a GPC or ED
Posocco 2017	Italy	Role of out of hours primary care service in limiting inappropriate access to emergency department	Retrospective analysis of 408 ED referrals from a local OOH service
Kork 2016	Finland	Improving access and managing healthcare demand with walk in clinic: convenient but at what cost?	Observational study over 48 months of the characteristics of 107 frequent attenders at a WIC from electronic patient records
Allen 2015	Australia	Low acuity and general practice type presentations to emergency departments: A rural perspective	Analysis of GP type presentations to 2 rural EDs over a 4-month period
Desborough 2013	Australia	Development and implementation of a nurse-led walk-in centre: evidence lost in translation?	Evaluation of the first 12 months of operation of the first Australian public nurse-led primary care walk-in centre compared to the English NHS model.
Nagree 2013	Australia	Quantifying the proportion of general practice and low-acuity patients in the emergency department	Four methods for calculating general practice-type patients were compared for 3 tertiary EDs in Perth, Australia in 2009-2011

Sharma 2011	Australia	Impact of co-located general practitioner (GP) clinics and patient choice on duration of wait in the emergency department	Mathematical modelling of wait times using routine ED data
Richardson 2009	Australia	Myths versus facts in emergency department overcrowding and hospital access block.	Report referencing previous work
Bolton 2001	Australia	The reasons for, and lessons learned from, the closure of the Canterbury GP After-Hours Service.	Report describing why a 12-month trial of GP staffed after hours service with an ED was not continued because the opportunity cost was greater than existing alternative services
Doran 2013	USA	An intervention connecting low acuity emergency department patients with primary care: Effect on future primary care linkage	Analysis of primary care follow up of patients presenting to ED assessed to have non-urgent problem and referred to an onsite primary care clinic
Williams 1996	USA	The costs of visits to emergency departments.	Analysis of emergency department charges and costs based on data from 6 community hospitals
Gadomski 1995	USA	Diverting managed care Medicaid patients from pediatric emergency department use.	6-month follow up of Medicaid children with non-emergent conditions not authorised to be seen in the Pediatric Emergency Department by their primary care provider
Derlet 1995	USA	Prospective identification and triage of nonemergency patients out of an emergency department - 5 year study	5 year study to analyse the outcome of adult patients refused care in the ED
Derlet 1992	USA	Triage of patients out of the emergency department: three year experience.	3 year study to analyse the outcome of adult patients refused care in the ED
Birnbaum 1994	USA	Failure to validate a predictive model for refusal of care to emergency-department patients.	Analysis of the outcome of 534 patients that met the pre-established criteria for refusal of care

Lowe 1994	USA	Refusing care to emergency department patients: evaluation of published triage guidelines.	Case note review of 106 patients who would have been refused care according to triage guidelines
Shaw 1990	USA	Indigent children who are denied care in the emergency department.	Six-month prospective study of 588 children denied care in the emergency department
Rivara 1986	USA	Pediatric nurse triage: its efficacy, safety and implications for care.	Evaluation of emergency room triage of 748 children over a 6-week period at a large urban children's hospital that routinely referred outside of the institution for care
Schull 2007	Canada	The Effect of Low-Complexity Patients on Emergency Department Waiting Times	Analysis of 4.1 million patient visits over a 1 year period (2002-3) and 110 EDs of the effect of low-complexity patients on time of physician contact of high complexity patients
Vertesi 2004	Canada	Does the Canadian Emergency Department Triage and Acuity Scale identify non-urgent patients who can be triaged away from the emergency department?	Retrospective database audit in an urban referral hospital ED.
Hutchison 2003	Canada	Patient satisfaction and quality of care in walk-in clinics, family practices and emergency departments: the Ontario Walk-In Clinic Study.	Prospective cohort study of the quality of care of 8 common acute conditions and patient satisfaction
Anantharaman 2008	Singapore	Impact of health care system interventions on emergency department utilisation and overcrowding in Singapore	Retrospective analysis of attendances at six main public EDs over 32 years
Wilson 2005	New Zealand	Co-locating primary care facilities within emergency departments: brilliant innovation or unwelcome intervention into clinical care?	Report reviewing a proposal to co-locate a primary care facility within the local emergency department