Implementation of computerised clinical decision support (CCDS) in a prehospital setting: Processes of adoption and impact on paramedic role and practice.

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Abstract

Title

Implementation of computerised clinical decision support (CCDS) in a prehospital setting: processes of adoption and impact on paramedic role and practice

Aim

To examine the adoption of CCDS by paramedics, including the impact of CCDS on paramedic role and practice.

Methods

Systematic review of CCDS in emergency care followed by a cluster-randomised controlled trial (C-RCT) of CCDS with a qualitative component involving 42 paramedics at two study sites.

Results

19/20 studies identified for inclusion in the systematic review were from the Emergency Department setting, with no studies from prehospital care. The focus of the studies was on process of care (19/20) rather than patient outcomes (5/20). Positive impacts were reported in 15/19 (79%) process of care studies. Only two patient outcome studies were able to report findings (one positive, one negative). Results relating to CCDS implementation were reported as an ad hoc response to problems encountered. In this C-RCT paramedics used CCDS with 12% of eligible patients (site one: 2%; site two: 24%). Intervention paramedics were twice as likely to refer patients to a falls service as those in the control group (usual care) (relative risk = 2.0; 95% CI 1.1 to 3.7) although conveyance rates were unaltered (relative risk = 1.1; 95% CI 0.8 to 1.5) and episode of care was unchanged (-5.7 minutes; 95% CI -38.5 to 27.2). When CCDS was used patient referral to falls services was three times as likely (relative risk = 3.1; 95% CI 1.4 to 6.9), and non-conveyance was twice as likely (risk = 2.1; 95% CI 1.1 to 3.9) and overall episode of care fell by 114 minutes (95% CI from 77.2 to 150.3). Reasons given for not using CCDS included technical problems, lack of integration, it was not sophisticated enough to influence decision making. Paramedics adapted when and how they used CCDS to suit context and patient condition.

Conclusion

There is little existing evidence in relation to CCDS use in the emergency care setting, and the prehospital emergency care setting in particular. Studies of CCDS undertaken in emergency departments have shown benefit, particularly in relation to process of care. The C-RCT found that CCDS use by paramedics was low, particularly at site one, but use was associated with higher rates of patient referral and non-conveyance, and shorter episodes of care. There were encouraging signs that CCDS can support a new decision making role for paramedics. The study provides useful lessons for policy makers, practitioners and researchers about the potential benefits of CCDS and the challenges to adoption of new technology in emergency prehospital care.

Declaration and statements

DECLARATION

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed . ..... (candidate)

Date 24/09/13

STATEMENT 1

This thesis is the result of my own investigations, except where otherwise stated.

Other sources are acknowledged by footnotes giving explicit references. A bibliography is appended.

Signed ... . (candidate)

Date 24/09/13

STATEMENT 2

I hereby give consent for my thesis, if accepted, to be available for photocopying and for inter-library loan, and for the title and summary to be made available to outside organisations.

Signed .... (candidate)

Date 24/09/13

Contents

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Dedication

I dedicate this thesis to Rory and Humphrey

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Abbreviations

Acronym	Full version
A&E	Accident and Emergency
ALF	Anonymised Linkage Field
AMPDS	Advanced Medical Priority Dispatch System
CCDS	Computerised Clinical Decision Support
CCDSS	Computerised Clinical Decision Support Software
CDS	Clinical decision support
CDSS	Clinical Decision Support Software
CfH	Connecting for Health
CHIRAL	Centre for Health Information, Research And evaLuation
CONSORT	Consolidated Standards of Reporting Trials
C-RCT	Cluster Randomised Controlled Trial
DH	Department of Health
DMEC	Data Monitoring and Ethics Committee
EA	Emergency Ambulance
ED	Emergency Department
EEAS	East of England Ambulance Service
EPR	Electronic Patient Record
EPRF	Electronic Patient Report Form
HIRU	Health Informatics Research Unit
HTA	Health Technology Assessment
ICT	Information Communication Technology
LIT	Local Implementation Team
NHS	National Health Service
NISCHR	National Institute for Social Care and Health Research
NPfIT	NHS National Programme for IT
PC	Personal Computer
PCR	Patient Clinical Record
PECR	Prehospital Emergency Care Research
PI	Principal Investigator
QALY	Quality Adjusted Life Year
PRF	Patient Record Form
RCT	Randomised Controlled Trial
RRV	Rapid Response Vehicle
SAFER	Support and Assessment for Fall Emergency Referrals
SAIL	Secure Anonymised Information Linkage
SDO	Service Delivery and Organisation Programme
TMG	Trial Management Group
TRUST	Thematic Research network for emergency UnScheduled and Trauma care
TSC	Trial Steering Committee
WAST	Welsh Ambulance Services NHS Trust
WWORTH	West Wales Organisation for Rigorous Trials in Health

Definitions

Category A,B,C	Ambulance service system in place at the time of the trial for categorising the urgency of 999 calls
Category A	Immediately life-threatening 999 call
Category B	Serious but not immediately life-threatening 999 call
Category C	Not serious or life-threatening 999 call
CCDS	Any electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration.
CCDS adoption	Use of the CCDS by paramedics
CCDS implementation	Set-up of CCDS by the ambulance service for use by paramedics including: training, kit, software and ongoing support
Emergency care	The range of healthcare services available to people who need medical advice, diagnosis and/or treatment quickly and unexpectedly. It includes care delivered by emergency departments, minor injuries units, GP out-of-hours services and ambulance service care.
Episode of emergency care	Interval between 999 call and completion of care - including time at the emergency department
Job cycle time	The interval between 999 call and completion of call/ambulance free
On-scene time	The interval between the time of arrival of the ambulance at patient and leaving the scene of the call

Chapter 1: Introduction

Computers have become part of our daily lives. Computers are increasingly being used in the health service to support clinicians, but the transition to computerised ways of working is not necessarily simple. This thesis explores the introduction of computerised clinical decision support software (CCDS) for use on-scene by paramedics using tablet computers. The CCDS under investigation was designed for paramedics to use when assessing older people who have fallen, to support them in making decisions about when to convey patients and when to refer them to community based care. This study ties in with policies to develop the role of the paramedic as a healthcare practitioner and seeks to provide evidence as to how paramedics use CCDS in practice and whether it supports them to make autonomous decisions about patient care in a controlled and structured way.

The implementation and adoption of CCDS and its impact on practitioner role and practice has not previously been evaluated in the emergency prehospital care setting. This thesis provides some of the first insights into the issues related to the introduction of this innovation in the ambulance service setting, including the factors affecting implementation and adoption. It also provides evidence on how paramedics view and use CCDS in practice and its impact on their role, decision making and practice.

The original concept for this PhD evolved out of the SAFER 1 trial, a multi-centre cluster-randomised controlled trial (C-RCT) to evaluate the clinical and cost effectiveness of CCDS for emergency ambulance paramedics to use in the face-to-face assessment and care of older people who have suffered a fall. The author of this thesis first became involved in the SAFER 1 study in June 2005 as a researcher working with Professor Snooks and the study team to develop a full research proposal to apply for funding for the study. The study was funded by the Department of Health under its Information and Communication Technology Research Initiative. The author was named on the research proposal as the Trial Co-ordinator and took up the position once funding was in place.

While working as Trial Co-ordinator the author became interested in the issues surrounding implementation of the CCDS software and its adoption by paramedics. As this was not a main outcome of the SAFER 1 trial she applied to undertake this PhD to explore these issues in more detail alongside working on the trial. In this study 'implementation' refers to the introduction and set-up of CCDS by the ambulance service for use by paramedics including training, hardware, software and

ongoing support. Adoption refers to the use of CCDS by paramedics including how, when and why they did, or did not, use it.

While CCDS has the potential to assist paramedics in this setting, previous work relating to the diffusion of technology innovations in healthcare has shown that the use of such innovations in healthcare is not predictable. Whether or not a new innovation is adopted, how it is used and its impact on practice is not predetermined, but is a result of the interplay of many factors, including the innovation itself, the individual, the organisation and the evolution of processes over time.

Therefore, this study takes a mixed methods approach to explore issues relating to the implementation and adoption of CCDS by paramedics. Quantitative data are used to examine how often and when paramedics used CCDS and to assess the impact of CCDS availability and use on the pathway of care of patients, job-cycle times and the quality of clinical documentation produced. As a complementary strand, qualitative data were collected to explore paramedics' responses to CCDS, the factors that affected their use or non-use of the technology and how it impacted on their role and practice.

The analysis of the findings draws on both the quantitative data about how CCDS was used and the qualitative data on paramedics' response to the tool. The study assumes that adoption into practice of an innovation in healthcare – in this case, CCDS – does not necessarily follow in a direct, orderly and complete way from a decision made at management level to implement the innovation. Instead, that there is a much more complex story to be told, of imperfect conditions for change, pragmatism, resistance, and adaptation.

The study draws for its theoretical framework on Strong Structuration Theory, an approach that can be used to evaluate innovations in healthcare, taking into account the wider context, organisational factors, the technology and the individual.

The main focus of this PhD is on the adoption of CCDS by paramedics, including its impact on paramedic role, practice and decision making. However, the implementation of the technology at the two study sites provides an important contextual backdrop to the study of CCDS use. The implementation process is described in Chapter 6, and the way in which this process shaped and influenced CCDS use is considered in the analysis.

In Chapter 2 the author presents an overview of the policy context relevant to this study. Chapter 3 presents a systematic review of the literature on face-to-face CCDS studies in the emergency care setting. Chapter 4 reviews the literature

relating to the study of innovations in healthcare, and provides the theoretical context for the study. Chapter 5 describes the methodology employed for this study. Chapter 6 describes the research setting for this study, including how the CCDS was implemented at the two study sites. The focus in Chapters 7 and 8 is on the adoption of CCDS by paramedics. Chapter 9 presents the main findings from the study, drawing these together in the light of the theoretical framework, before presenting the implications of this research for future policy, practice and research.

Chapter 2: Policy background

2.1 Chapter overview

This chapter provides a background to the policy context at the time of the study. It presents the policies that are relevant to this study, initially across the NHS as a whole, and then with a focus on emergency prehospital care. Current technology policies and programmes are also reviewed, again with a focus on those most relevant to the ambulance service.

2.2 Search strategy

A search of websites and databases was carried out to identify current policy and guidance documents relevant to the PhD topic. The time period from January 2000 to January 2011 was chosen to cover the period from major NHS reform in 2000 to the time of this study. The search was conducted to identify policies, programmes and other key documents with relevance to England and Wales. Research papers are cited as appropriate in this chapter, with a systematic search and literature review undertaken for CCDS in emergency care presented in Chapter 3.

Relevant policy documents and guidelines were sourced from:

- Department of Health: http://www.dh.gov.uk/en/index.htm
- Health Management Information Consortium: National Health Intelligence Service: http://www.nhis.info/
- Health Management Information Consortium: HMIC: http://www.library.nhs.uk/help/resource/hmic
- Health Services Research Institute of Warwick University: Emergency care: http://www2.warwick.ac.uk/fac/med/research/hsri/emergencycare/emergencycare/
- Joint Royal Colleges Ambulance Liaison Committee (JRCALC): http://www.jrcalc.org.uk/
- National Institute for Health and Clinical Excellence (NICE): http://www.nice.org.uk/
- National and local ambulance service policy documents from Wales and England
- NHS library: http://www.library.nhs.uk/Default.asp
- NHS Library for Health Emergency Care Specialist Library: http://www.library.nhs.uk/emergency/

- References cited within policy documents obtained
- Welsh Assembly Government: http://wales.gov.uk/topics/health/?lang=en

2.3 Overall policy direction in the NHS in England and Wales

2.3.1 Structures and policy framework

The National Health Service (NHS) in the United Kingdom was established in 1948 with the founding principle that good healthcare should be available to all, regardless of wealth (NHS, 2012b). Since its inception the service has grown, along with its budget:

> *'When the NHS was launched in 1948 it had a budget of £437 million (roughly £9 billion at today's value). For 2011/12 it is around £106 billion.' (NHS, 2012b)*

Demand for NHS services in the UK is increasing and is expected to continue rising over the next couple of decades (Horton, 2005). This is partly due to life-expectancies having increased in the UK, resulting in an ageing population (NHS, 2012b, Horton, 2005). It is against this backdrop of increasing demand on finite resources and ongoing service development that policies have been introduced to improve the efficiency and effectiveness of patient care across the service.

Since 1999, the English and Welsh health services have operated independently and each has its own policy programmes. In England the health service is accountable to the UK Government, while in Wales it is accountable to the Welsh Government (known until May 2011 as the Welsh Assembly Government). In 2000 an ambitious 10-year reform plan was adopted in England, the 'NHS Plan' (Department of Health, 2000). This included commitment to additional investment in both facilities and staff, with a focus on up-skilling the workforce to enable nurses and other staff to extend their roles. It also pledged to modernise IT systems in hospitals and GP surgeries and committed to the development of national standards for patient care. The Welsh Government similarly committed to reform and improve its NHS service in the 2001 policy document 'Improving Health in Wales' (Welsh Assembly Government, 2001).

In the ensuing years many policy documents and reviews have been published, in both England and Wales, building on the commitments above and identifying ways in which appropriate care could be delivered more efficiently and effectively. In 2012 the Health and Social Care Act introduced major structural reforms to the NHS in England, and accelerated an already established trend towards the use of competition in health care; in Wales, meanwhile, the overall policy direction has

been the opposite one, towards greater integration of planning and provider functions within integrated NHS organisations (Department of Health, 2012).

Despite these differences in strategic direction, there are three areas of policy development which are highly relevant to this study and which are common to both the English and Welsh systems (though the detail specified in policy documents may differ). These relate to standardising patient care across the NHS; reducing unnecessary hospital attendances and admissions, and increasing the use of technology in the NHS. These are explored in more detail below, before consideration of how these broad policy themes have been implemented in terms of specific developments within ambulance services.

2.3.2 Standardising patient care

Both the English and Welsh Governments have taken steps over the last ten years to address inequities in the way that patients were treated based on where they lived, rather than on the medical evidence, following adverse media coverage that highlighted differences:

> *"Differences in access to NHS treatment have given rise to the notion of the postcode lottery - that where you live defines the quality and availability of NHS services you can expect." Society Guardian, 09.11.00*

A key policy aim in recent years has been to introduce evidence based standards of care and to ensure that care is delivered consistently across the country in a clinically safe and cost effective way. In Wales, policy documents such as 'Designed for Life' (Welsh Assembly Government, 2005a), 'Healthcare Standards for Wales' (Welsh Assembly Government, 2005b) and 'Doing Well, doing Better' (Welsh Assembly Government, 2010) have provided the under-pinning for this approach. In England, a commitment to evidence based care has been set out in 'Taking Healthcare to the Patient' (Department of Health, 2005), 'High Quality Care for All: NHS Next Stage Review' (Lord Darzi, 2008), and most recently in 'Equity and excellence: liberating the NHS' (Department of Health, 2010a), the White Paper which provided the basis of the 2012 Health and Social Care Act (Department of Health, 2012).

Measures to achieve more standardisation in service delivery included establishing service-wide evidence-based clinical guidelines and formalising care protocols for healthcare providers. In 1999 the National Institute for Clinical Excellence (now the National Institute for health and Clinical Excellence, still referred to in abbreviation as NICE) was established. One of the original objectives of NICE was to:

'Improve standards of patient care, and to reduce inequities in access to innovative treatment.' (NHS, 2012a)

NICE produces evidence-based standardised guidance for the NHS, local authorities, and all those with a remit for improving people's health in the public, private, community and voluntary sectors. A number of NICE guidelines are relevant to prehospital care, for example, those concerning head injury, self-harm, myocardial infarction and thrombolysis. NICE technology appraisals, clinical guidelines and interventional procedure guidance all apply in Wales as in England.

In the field of prehospital emergency care, the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) is a body that was set up in 1989 dedicated to developing and reviewing national clinical standards and practice guidelines for ambulance services based on the current evidence. Although the committee is not statutory, the JRCALC guidelines are the key guidelines used in prehospital emergency care. Despite the high incidence of emergency calls pertaining to older people who have fallen, there are currently no JRCALC guidelines for this.

Ambulance services also work to nationally agreed time-based performance targets that are linked to their funding. Prior to 2011 these included an 8 minute target for ambulance services to attend category A (immediately life threatening) calls and 14 minutes in urban areas and 19 minutes in rural areas for attending category B (serious but not immediately life threatening) calls. The pressure on ambulance services to meet these performance targets has resulted in ambulance services being driven to develop their services to meet targets based on response times rather than quality of patient care.

"The time taken to respond to calls has until recently been the be all and end all of measuring the performance of ambulance services. Illustrating the principle that what gets measured, gets done, the result has been a rapid response to urgent and emergency calls. However, this led to an increase in the number of multiple responses to incidents equating to millions of unnecessary ambulance journeys." (Morse A. head of the National Audit Office, 2011)

This resulted in ambulance services being driven to develop their services to meet targets based on response times rather than patient care. Following several key service reviews that drew attention to this problem, the Government announced in 2010 that these would be replaced in England by clinical quality indicators from 1st April 2011(Department of Health, 2011). Alongside the introduction of quality indicators, one of the key response time targets was removed (the 19 minute target for non-urgent calls). However, ambulance service performance in Wales remains measured against time-based targets alone. The introduction of quality indicators

and the removal of the 19 minute target for non-urgent patients is intended to allow English ambulance services to focus more on quality of care, including patient outcomes and clinical effectiveness, as well speed of care. During the period of this study both Welsh and English ambulance services were still operating to time-based performance targets (NHS, 2008). In Wales ambulance service performance remains measured against time-based targets alone.

2.3.3 Reducing unnecessary hospital attendances and admissions

Increasing demand on healthcare services, particularly in the acute sector was identified as being unsustainable in both England and Wales in two reviews by Derek Wanless (Wanless, 2002, Wanless, 2003). The reviews highlight the problem of increasing demand, and the fact that the UK has an ageing population, which will continue to fuel increasing demand for services. In order to address this, Wanless proposed service reconfiguration to shift the onus away from the acute sector and to make better use of community based care facilities.

In the emergency sector the demand for ambulance services is also increasing, by around 6-7% annually (Department of Health, 2005). Despite this, only 10% of callers have a life-threatening emergency, while many patients have a health need that could potentially be met by community based care:

> *"Many patients have an urgent primary (or social) care need. This includes large numbers of older people who have fallen in their homes (around 10% of incidents attended), some with no injury." (Department of Health, 2005) p8*

Internationally, a significant proportion of emergency ambulance calls are made for older people who have fallen (Bergeron et al., 2006, Sikron et al., 2004) and it is possible that early referral to a falls service by paramedics, so that patients can remain at home rather than attend the Emergency Department (ED), could be one way to improve care for this patient group.

'Taking Healthcare to the Patient' recognises the role of ambulance services in supporting the shift in provision towards community based primary and secondary care services (Department of Health, 2005)'. It proposes that potentially a third of 999 patients could be treated at, or closer to their home, rather than being taken to the ED unnecessarily. The document highlights the increased role of the paramedics in helping ambulance services achieve this aim, through improved education and supported decision making:

> *"With revised education and training of ambulance clinicians, the number of patients taken to A&E departments by ambulance can and should be significantly reduced.*

Ambulance clinicians need to be competent, trained and empowered to do this and supported in making decisions for themselves – rather than feeling that they have to get a second opinion. Appropriate education, guidelines, pathways and clinical support need to be in place locally to enable and support this decision making process." (Department of Health, 2005) p18

The policy context is helping to redefine the role of the paramedic. As the role evolves, paramedics are being expected to make important clinical decisions regarding patient care, including whether or not to convey vulnerable patients (e.g. non-injured older people who have fallen) to hospital. It is essential that mechanisms are in place to support paramedic decision making and to ensure standards of care and patient safety.

2.3.4 Increasing the use of Information Technology in the NHS

There has been a strong policy commitment in both England and Wales over the last decade to modernise services through the use of information technology. In England, both the NHS Plan (Department of Health, 2000) and the 2002 Wanless review (Wanless, 2002) proposed that IT would facilitate major improvements in service delivery. A ten-year National Programme for Information Technology (NPfIT) in England was launched in 2002 to put this in to practice (NHS, 2002). In 2003 Wales launched a parallel programme for IT development, broadly similar though with some important difference in detail, called Informing Healthcare (Welsh Assembly Government, 2003). This was reinforced by elements of the 'Healthcare Standards for Wales' (Welsh Assembly Government, 2005b) and again in 'Doing Well, Doing Better' (Welsh Assembly Government, 2010).

The National Programme for Information Technology (NPfIT) was established in England in 2002 with the remit of implementing new technologies to improve patient care and safety. In 2005 a new agency called Connecting for Health was formed to deliver the NPfIT programme. Elements of the programme included an electronic prescription service, an online 'choose and book' appointment service allowing doctors and patients to choose a hospital or clinic and book an appointment, and summary care records providing healthcare staff in the emergency and out-of-hours settings with fast access to key clinical information about patients. Of particular relevance to this study is the programme's introduction of electronic patient report forms (EPRF).

The Welsh Assembly Government's IT modernisation strategy, 'Informing Healthcare' (Welsh Assembly Government, 2003) set out to improve health services in Wales by introducing new ways of accessing, using and storing

information. In 2009 NHS Wales published its National Infrastructure Strategy (NHS Wales, 2009), outlining elements of the Informing Healthcare programme, including electronic Individual Health Record (IHR) to be accessed by out of hours doctors, nurses and pharmacists in the Medical Assessment Unit, Electronic Referral System to enable GPs to refer patients to a hospital via an electronic message, and a Welsh Clinical Portal, providing healthcare professionals with a secure web homepage to access data on patients and their care. However, unlike the situation in England, the Welsh IT programme did not include the introduction of EPRF to the ambulance service.

The NHS Plan and the 2002 Wanless review both envisaged that a broad range of IT developments would facilitate major improvements in service delivery (Department of Health, 2000, Wanless, 2002). However, in the 2007 progress report for the King's Fund, 'Our future health secured?' (Wanless, 2007), Wanless reported that these productivity improvements had not been achieved, concluding; "the continuing uncertainty and delays have the potential to undermine the productivity gains envisaged by the 2002 review" (p165). Following problems across the programme as a whole the Government announced that England's £12 billion national IT programme would no longer operate as a centralised national programme but that, in line with its broader reforms, decision making and responsibility for IT would be localised (Department of Health, 2010b). This highlights the need for better understanding of the way in which new innovations can be introduced effectively in the healthcare setting (Department of Health, 2010b, Greenhalgh, 2010).

2.4 Innovation in ambulance services in England and Wales

2.4.1 The changing role of paramedics

Traditionally ambulance services have responded to 999 calls by conveying patients to hospital. Originally ambulance service crew were drivers rather than care providers. Training was introduced for those that wanted to extend the level of care they provided, creating the role of paramedic alongside that of the more traditional ambulance service technician. Paramedic training was provided in-service, but now paramedic training and qualifications are degree based. Pressure on ambulance services has led to further development of the paramedic role with the aim of reducing unnecessary hospital attendances. Because not all patients who dial 999 clinically need to attend hospital, ambulance services have sought to develop new

models of care that meet patient need while avoiding unnecessary hospital attendances (Mason, 2010, Snooks, 2002).

One such initiative implemented in England was the introduction of the Emergency Care Practitioner role, as outlined in the 2004 report 'Right Skill, Right Time, Right Place' (Department of Health, 2004). This created a new role for paramedics who underwent additional training, enabling them to become emergency care practitioners (or ECPs). ECPs are able to assess and treat patients, with the aim of avoiding attendance at an ED or admission to hospital where possible (Halter, 2011).

In a similar vein the role of Advanced Paramedic Practitioner has also been developed in both Wales and England to provide paramedics with extended training to help reduce unnecessary hospital attendances (Mason et al., 2007, Woollard, 2006). Initial research on pilot schemes has suggested that, through provision of diagnosis, 'treat and leave' interventions and/or referrals to appropriate support services, paramedic practitioners are able to reduce the number of patients being inappropriately transported by approximately half (Woollard, 2006).

The ECP and paramedic practitioner roles add another level of professionalism to the expanding paramedic career path. The development of these roles represents another shift away from paramedics as transport providers and more towards that of autonomous practitioners.

2.4.2 New referral pathways

Another new model of care that ambulance services are adopting to help reduce unnecessary hospital attendance admissions involves establishing care pathways that enable paramedics to refer suitable patients directly to community based services. These include referrals to GPs and falls referral services.

One patient group for whom an alternative response has been identified as being potentially beneficial is older people who have suffered a fall and for whom a 999 call has been made (Snooks H et al., 2010). Falls account for in the region of 8% of calls to the ambulance service each year (Snooks H et al., 2010). However, many older patients who are attended by an ambulance crew after having had a fall do not have a clinical need to attend the emergency department and may receive more appropriate care if referred directly to community based services, such as local falls teams or the GP (Snooks H et al., 2010).

Although health policy in the UK encourages ambulance services to offer referrals to community based services for such callers, there is little evidence about the safety and effectiveness of these models of care, which rely on paramedics making clinically reliable decisions relating to onward patient care (Snooks et al., 2004a). Research relating to paramedic decision making highlights that it is very complex and influenced by a range of factors and variables (Porter et al., 2008). The context in which paramedics make decisions is different to that of most other clinical settings. Paramedics do not have the level of clinical training found in other healthcare settings, they generally work in clinically unsupported environments (i.e. without the benefit of clinical tests, specialists and documentation that would be available in hospitals), in the often chaotic setting of emergency care delivery and in the context of time-based performance pressures.

2.4.3 Paramedics as clinical decision-makers

Previous research on paramedic decision making has often focused on the issue of how paramedics decide when to convey a patient to hospital, and when to leave them at home. Non-conveyance decisions by paramedics have been of particular research interest because historically a) paramedics have not had formal training for making non-conveyance decisions and b) ambulance service protocols generally require patients to be conveyed to hospital (unless they refuse to travel). In the UK up to 30% of patients attended by an emergency ambulance are not conveyed to hospital (Department of Health, 1999, Marks et al., 2002), and this is a situation reflected elsewhere in the world (Selden, 1991, Zachariah, 1992).

Non-conveyance is particularly high among one group of patients, older people who have had a fall, with approximately 40% of patients not conveyed (Snooks et al., 2006, Snooks et al., 2004 , Marks et al., 2002). Worryingly, this group of non-conveyed patients has been identified as being at high risk of further falls (Snooks et al., 2006, Close et al., 2002). A 2011 study to examine paramedic decision making with regard to non-conveyance of this patient group summarised the existing evidence (Halter, 2011);

> "Decision making regarding conveyance in general has been found to be a complex and negotiated process (Porter et al., 2007) dependent on a number of factors including the experience and confidence of ambulance staff, time during a shift, location, the wishes of the patient, presence of carers, appearance of the person's accommodation, waiting times and the local ED and prior knowledge of the patient, (Snooks et al., 2004 , Snooks et al., 2004b) carried out in the context of anxiety about whether a non-conveyance decision will be supported within the ambulance service' (Snooks et al., 2004 , Porter et al., 2008)." p44

This qualitative study sought to understand the paramedic decision process with regard to older people who had fallen (the paramedics in this study had been given the use of a paper-based decision support tool). The authors reported that paramedics employed both formal and informal approaches to decision making, but predominantly relied on informal influences (such as instinct, intuition and experience) and they resisted using the decision support tool (Halter, 2011). Intuition and experience have been identified as being particularly present in decision making in situations where there is uncertainty, such as in assessments of emergency patients about whom there are many unknowns, and this is a potential source of error and bias (Tversky and Kahneman, 1974). Despite there being risks associated with informal decision making style, this study found that paramedics were reluctant to accept new methods of formal assessment to support their decision making. Adoption of the support tool was low and there was resistance to this change in practice (Halter, 2011).

2.4.4 Increasing use of IT in ambulance care

Although for some time ambulance services in the UK have used IT systems, such as Advanced Medical Priority Dispatch System (AMPDS) in their call centres in order to support triage of 999 calls and record keeping, the use of IT by paramedics and other ambulance members working in the field is much less developed.

In England, the National Programme for Information Technology (NPfIT), which ran from 2002 to 2010, began national roll-out of electronic patient report forms (EPRF) for use in ambulance services. The roll-out of EPRF at ambulance services was led centrally, with little flexibility for ambulance services in deciding implementation timetables. Ambulance services were, however, given some flexibility in being allowed to choose from several EPRF software packages that were available from commercial providers approved through the programme. The EPRF software enables ambulance crew to record patient information electronically, on-scene, via a hand-held computer, rather than on paper (Cross, 2006, Department of Health, 2005). It was envisaged that the benefits of using EPRF to record data would include; better data-linkage internally and with other services (e.g. A&E), better data for audit and patient outcome tracking (NHS, 2002). However, the implementation of the EPRF programme in England encountered many difficulties and delays (Hendy, 2005), leading to the roll-out being abandoned at a national level, and responsibility for it devolved to the local level (Department of Health, 2010b).

Policy makers have acknowledged the challenge that using IT represents in the mobile emergency care setting, specifically in relation to the on-scene connectivity

of ambulance crew (Department of Health, 2005). In contrast to the EPRF implementation policy in England, EPRF has not yet been introduced in Wales.

2.4.5 Computerised Clinical Decision Support Software (CCDS)

As technologies become more widely used in the healthcare setting generally, the opportunities for software to enhance service delivery expand also. One opportunity afforded by the use of hand-held computers on-scene by paramedics is the potential for using them for CCDS software to support paramedic assessments and decision making. Although there have been no specific policies to propose the use of CCDS, it could help achieve the aim outlined in 'Taking Healthcare to the Patient' of empowering and supporting paramedics to make clinical decisions regarding patient care (Department of Health, 2005).

CCDS is software designed for use by healthcare practitioners to help inform and support their decision making regarding patient care. Patient-related information is entered into a software package that then generates evidence based information and guidance related to the patient. The healthcare practitioner can then use this information to support their clinical decision making, for example with triage assessment or to reduce prescription errors (Dong et al., 2005, Terrell et al., 2009).

In other healthcare settings CCDS has been found to be effective in supporting clinical decision making (Souza et al., 2011, Roshanov et al., 2011a, Roshanov et al., 2011b, Sahota et al., 2011). A full systematic review of the research relating to CCDS in emergency care is presented in Chapter 3. It is possible that CCDS could also provide effective support for clinical decision making in the emergency care setting. CCDS offers paramedics a standardised assessment tool to assist them with identifying patients who might be suitable for referral to community based care, in line with policies to standardise care delivery and to reduce unnecessary hospital attendance. If CCDS can support paramedics to make clinically reliable decisions about when it is safe to leave patients at home with referral to community based care, patients may receive more appropriate care and unnecessary hospital attendances could be reduced.

2.5 Summary, critical analysis and conclusion

Current healthcare policy supports paramedics having increased autonomy and responsibility for clinical decision making. New models of care are being implemented to reflect this shift, including the introduction of alternative care

pathways for paramedics to refer suitable patients to, with the aim of reducing unnecessary hospital attendances.

Policies are also in place to increase the use of technology in the NHS, including the ambulance service, where implementation of hand-held computers and EPRF software to enable paramedics to record patient data electronically is underway. These hand-held computers also provide a suitable platform for the use of other software by paramedics, for example CCDS. CCDS software is used in other healthcare settings to support practitioner decision making in a standardised and auditable way. CCDS could be an effective decision support tool in this setting, assisting paramedics to identify which patients are suitable for referral to community based care, in line with policies to standardise care delivery and to reduce unnecessary hospital attendance.

Policy makers are keen to develop the role of paramedics so that they can make higher level clinical decisions and convey fewer patients to hospital unnecessarily. However, there are still two fundamental challenges to the development and support of new models of care and practitioner roles. The first is that ambulance services are required to meet stringent time based performance targets. This means that they are focusing their resources on vehicle deployment and sometimes inefficient initiatives which are only relevant to a small proportion of their workload (i.e. patients who are in a serious or life-threatening condition). This restricts senior management ability to give the necessary level of priority and support to change practice which may, at least in the short term, have a detrimental impact on operational performance. The second challenge is the lack of a theoretical basis or robust evidence for implementation and effects of new models of care. In the absence of a strong evidence base, localised, non standard initiatives, such as advanced level training for paramedics, are being introduced. This means that initiatives of uncertain effectiveness are being introduced in contexts which may or may not be receptive, leading to challenges to implementation, adoption and sustainability.

In conclusion, whilst the policy context appears to support the implementation of new models of care, including CCDS, the reality is that inherent contradictions within policy objectives mean that it is difficult for ambulance services to make changes that allow them to be successful across the range of objectives. Projects to evaluate new initiatives, such as CCDS, are necessary but face challenges in implementation.

Chapter 3: A systematic review of effects and implementation of face-to-face CCDS in emergency care

3.1 Chapter overview

A preliminary search of the literature was conducted to identify existing evidence in relation to face-to-face CCDS. A number of existing systematic reviews were identified, however none related specifically to the emergency care setting. A systematic review of face-to-face CCDS in the emergency care setting was then undertaken for this thesis, a full list of the search terms used can be found in Appendix 2. This chapter presents an overview of findings from the previous systematic reviews of CCDS identified, followed by the results of the systematic review of CCDS in emergency care that was conducted for this thesis.

3.2 Previous systematic reviews of CCDS

This section presents the findings from previous systematic reviews of CCDS in the healthcare setting, summarising the research and demonstrating how understanding of this developing field is growing, including what the limitations are and what future research is required to develop understanding further. A summary of the key CCDS systematic reviews and their findings can be found on Table 1 below.

3.2.1 Previous reviews of CCDS in the healthcare setting

Hunt et al (1998) conducted an early systematic review of controlled clinical trials to establish the 'Effects of Computer-Based CDSS on Physician Performance and Patient Outcomes' (Hunt, 1998). Effects on process of care were assessed by frequency of compliance with decision support guidelines. The review covered 1992 to 1998 and found that CCDS studies were increasing in number and quality during that period. Given the heterogeneity of studies a meta analysis was not conducted. Instead the effect on measures of process of care and clinical outcomes were evaluated on the basis of whether a statistically significant effect was reported. 68 studies were included, 65 of these assessed effects on physician performance and 43 (66%) of these found a benefit. Findings were broken down by intervention type or setting:

15 were on drug dosing systems – 9 (60%) found a benefit

5 were evaluating diagnostic aids – 1 (20%) found a benefit

19 were preventive care systems – 14 (74%) found a benefit

26 were CCDS for other medical care – 19 (73%) found a benefit

Of the 14 studies that assessed patient outcomes six (43%) found a benefit, 8 (57%) found no benefit (but five of these were inadequately powered to detect a clinically important improvement).

The review concluded that CCDS 'can enhance clinical performance for drug dosing, preventive care, and other aspects of medical care, but not convincingly for diagnosis.' It also highlights the lack of studies exploring the effects of CCDS on patient outcomes.

Garg et al (2005) updated the systematic review above, extending the inclusion period to 2004 and using better-defined inclusion criteria for a systematic review of the 'Effects of CCDS on Practitioner Performance and Patient Outcomes' (Garg et al., 2005). This review focuses on randomised and non-randomised controlled studies, exploring both the effects of CCDS and identifying the characteristics of CCDS that predicted benefit. Again the authors reported that the number and quality of CCDS studies was increasing over time. 100 studies were included, 97 of these assessed effects on practitioner performance and 62 (64%) of these found a benefit. Findings were reported by intervention type or setting:

- 10 were of diagnostic systems – 4 (40%) found a benefit
- 21 were of reminder systems - 16 (76%) found a benefit
- 37 were disease management systems – 23 (62%) found a benefit
- 29 were drug dosing or prescribing systems – 19 (66%) found a benefit

Studies were analysed to identify the factors of CCDS that were associated with improved practitioner performance. These included:

- CCDS automatically prompts users to use the system rather than requiring practitioners to activate the system (73% success with, 47% success without)
- Studies in which the authors also developed the software (74% success where authors developed software, 28% success otherwise)
- The authors report the importance of 'local champions' in facilitating implementation, however this is not quantified

Fifty two trials in this review assessed patient outcomes, however only 7 (13%) of these reported benefits. The authors found that patient outcomes were often

reported "in a limited capacity without adequate statistical power to detect clinically important differences" (Garg et al., 2005) p1231. The authors conclude that, while the CCDS shows benefits for practitioner performance, the effects on patient outcomes are not so well studied or clear. They highlight the ongoing need for studies to focus on factors that predict the success of CCDS, rather than to identify barriers to implementation (such as low CCDS usage levels, poor usability or integration into practitioner workflow or low adherence to CCDS recommendations) which are already documented (Reisman, 1996).

Kawamoto et al 2005 conducted a systematic review of clinical decision support (CDS), covering both electronic and non-electronic CDS use in randomised controlled clinical trials with a focus on identifying 'features critical to success' (Kawamoto, 2005). They identified 70 trials for inclusion and found that CDS significantly improved practice in 68% of these. Their quantitative meta-analysis (using multiple logistic regression) identified five system features associated with the interventions that were more likely to improve clinical practice. These were:

- Automatic provision of decision support as part of clinician workflow ($P < 0.00001$). 75% of the interventions succeeded when decision support was provided automatically, while none succeeded where the clinician had to seek out the advice of the CDS
- Provision of recommendations rather than just assessments ($P = 0.0187$)
- Provision of decision support at the time and location of decision making ($P = 0.0263$)
- Computer based decision support ($P = 0.0294$)
- Studies possessing all four features above. Of the 32 systems with all four features above, 30 (94%) significantly improved clinical practice

The authors also reported that CDS was more effective in trials where clinicians had to record their reasons for not following a CDS recommendation and also when clinicians were given periodic feedback about their compliance with CDS recommendations. Although this systematic review included both electronic and non-electronic CDS the features highlighted above are applicable across the board and demonstrate that when decision support is computerised there is a greater association with improved clinical practice. The authors identified too few studies in which patient outcome measures were evaluated to be able to conduct a subset analysis, again highlighting this gap in the current CDS evidence base.

Given the noted paucity of evidence related to patient outcomes, it is perhaps worth including the findings of Mollon et al (2009) who conducted a systematic review of

features related to the success of CCDS trials for prescribing (Mollon, 2009). This review included 41 studies; 23 of these reported patient outcomes, five of which reported improved patient outcomes (all five were published post 2005). The authors analysed the trials that measured patient outcomes and identified three features that were present in the studies with positive patient outcomes, and not in most of the unsuccessful ones. These were;

- Provision of a recommendation rather than just an assessment
- Justification of decision support via provision of research evidence (although what this entailed is not explained in the paper)
- The system uses data standards that support integration (again, what this means is not clarified)

However, the authors urge caution due to the small number of studies reported and the 'poor general reporting of features'. (P6) Mollon et al observe that patient outcomes in many of the papers included in their review were only secondary outcome measures, and studies were often not powered well enough to measure them.

In 2011 a related series of six further systematic reviews of CCDS were published to explore the impact of CCDS on process of care and patient outcomes for primary preventive care, drug monitoring and dosing, drug prescribing and management, chronic disease management, diagnostic test ordering and acute care management (Souza et al., 2011, Nieuwlaat et al., 2011, Hemens et al., 2011, Roshanov et al., 2011a, Roshanov et al., 2011b). These studies adopt and build on the methodological approach of the earlier reviews of Hunt et al. and Garg et al. The findings from these studies, and the two key reviews of CCDS on which they build, are summarised in Table 1 below.

In the findings from the six recently published systematic reviews, CCDS was found to improve process of care in 60% of studies, however CCDS only improved patient outcomes in 23% of studies. The authors, in line with previous studies, highlight the need for further evidence in relation to patient outcomes.

Table 1: Summary of findings from previous systematic reviews of CCDS

Systematic review	No of studies	Studies included	Measures of positive effect	Process of care outcomes	Patient outcomes	Conclusions
Hunt et al 1998 'Effects of computer-based CDSS on physician performance and patient outcomes'	68	Studies of CCDS used in a clinical setting by a healthcare practitioner where the effects of the system were assessed prospectively with a concurrent control	Measures of the process of care and clinical outcomes were simply characterised for each study according to whether a statistically significant effect was reported	CCDSs improved process of care in 43 of 65 (66%) studies	CCDSs improved patient outcomes in 6 of 14 (43%) studies	Published studies of CCDSs are increasing rapidly, and their quality is improving. CDSSs can enhance clinical performance for drug dosing, preventive care, and other aspects of medical care, but not convincingly for diagnosis. The effects of CDSSs on patient outcomes have been insufficiently studied.
Garg et al 2005 Effects of CCDSS on practitioner performance and patient outcomes	100	Randomised and nonrandomised controlled trials that evaluated the effect of a CCDS compared with care provided without a CDSS on practitioner performance or patient outcomes	For each study the authors defined the effects of CCDSs in terms of success, defined as an improvement in at least 50% of outcomes measured, each at a 2-sided significance level less than .05	CCDSs improved process of care in 62 of 97 (64%) studies	CCDSs improved patient outcomes in 7 of 52 (13%) studies	Many CCDSs improve practitioner performance. To date, the effects on patient outcomes remain understudied and, when studied, inconsistent.
Souza et al 2011 CCDSS for primary preventative care (PPC): A decision-maker-researcher partnership systematic review of effects on process of care and patient outcomes	41	RCTs that assessed the effect of a CCDS for primary preventative care on process of care and patient outcomes compared to care provided without a CCDS	A study was considered to have positive effect (i.e. CCDS showed improvement) if at least 50% of the relevant study outcomes were statistically significantly positive	CCDSs improved process of care in 25 of 40 (63%) RCTs	CCDSs improved patient outcomes in 4 of 14 (29%) RCTs	Evidence supports the effectiveness of CCDSs for screening and treatment of dyslipidaemia in primary care with less consistent evidence for CCDSs used in screening for cancer and mental health-related conditions, vaccinations, and other preventive care. CCDS effects on patient outcomes, safety, costs of care, and provider satisfaction remain poorly supported.

Systematic review	No of studies	Studies included	Measures of positive effect	Process of care	Patient outcomes	Conclusions
Nieuwlaat et al 2011 CCDSS for therapeutic drug monitoring and dosing: A decision-maker-researcher partnership systematic review	33	RCTs assessing the effect of a CCDS on process of care or patient outcomes for therapeutic drug monitoring and dosing	A study was considered to have positive effect (i.e. CCDS showed improvement) if at least 50% of the relevant study outcomes were statistically significantly positive	CCDSs improved process of care in 18 of 30 (60%) RCTs	CCDSs improved patient outcomes in 4 of 19 (21%) RCTs	CCDSs have potential for improving process of care for therapeutic drug monitoring and dosing, specifically insulin and vitamin K antagonist dosing. However, studies were small and generally of modest quality, and effects on patient outcomes were uncertain, with no convincing benefit in the largest studies.
Hemens et al 2011 CCDSS for drug prescribing and management: A decision-maker-researcher partnership systematic review	65	RCTs that evaluated the effect on process of care or patient outcomes of a CCDS for drug therapy management compared to care provided without a CCDS	A study was considered to have positive effect (i.e. CCDS showed improvement) if at least 50% of the relevant study outcomes were statistically significantly positive	CCDSs improved process of care in 37 of 59 (64%)* RCTs	CCDSs improved patient outcomes in 6 of 29 (21%) RCTs	CCDSs inconsistently improved process of care measures and seldom improved patient outcomes. Lack of clear patient benefit and lack of data on harms and costs preclude a recommendation to adopt CCDSs for drug therapy management.
Roshanov et al 2011 CCDSS for chronic disease management: A decision-maker-researcher partnership systematic review	55	RCTs that compared the use of CCDSs to usual practice or non-CCDS controls where at least one component of the CCDS was designed to support CCM	Studies were considered 'positive' if they showed a statistically significant improvement in at least 50% of relevant outcomes	CCDSs improved process of care in 25 of 48 (52%) RCTs	CCDSs improved patient outcomes in 11 of 36 (31%) RCTs	A small majority (just over half) of CCDSs improved process of care in chronic disease management and some improved patient health. Policy makers, healthcare administrators, and practitioners should be aware that the evidence of CCDS effectiveness is limited, especially with respect to the small number and size of studies measuring patient outcomes.

Systematic review	No of studies	Studies included	Measures of positive effect	Process of care	Patient outcomes	Conclusions
Roshanov et al 2011 Can CCDSS improve practitioners' diagnostic test ordering behaviour? A decision-maker-researcher partnership systematic review	35	RCTs comparing the use of CCDSs to usual practice or non-CCDS controls in clinical care settings where at least one component of CCDS gave suggestions for ordering or performing a diagnostic procedure	Studies were considered 'positive' if they showed a statistically significant improvement in at least 50% of test ordering outcomes	CCDSs improved process of care in 18 of 33 (55%) RCTs	Not assessed	Some CCDSs can modify practitioner test-ordering behaviour. To better inform development and implementation efforts, studies should describe in more detail potentially important factors such as system design, user interface, local context, implementation strategy, and evaluate impact on user satisfaction and workflow, costs, and unintended consequences.
Sahota et al 2011 CCDSS for acute care management: A decision-maker-researcher-partnership systematic review of effects on process of care and patient outcomes	36	RCTs that evaluated the effect on process of care or patient outcomes of a CCDS used for acute medical care compared with care provided without a CCDS	A study was considered to have positive effect (i.e. CCDS showed improvement) if at least 50% of the relevant study outcomes were statistically significantly positive	CCDSs improved process of care in 22 of 35 (63%) RCTs	CCDSs improved patient outcomes in 3 of 20 (15%) RCTs	The majority of CCDSs demonstrated improvements in process of care, but patient outcomes were less likely to be evaluated and far less likely to show positive results.
* Figures provided as published						

3.2.2 *Previous reviews of CCDS in the emergency care setting*

Only one previous systematic review of CCDS in the emergency care setting was identified. A systematic review by Cooper et al, published in 2010 focuses on CCDS to improve the management of acute abdominal pain (Cooper, 2010). Of the 20 studies identified for inclusion, 10 were excluded due to inadequate baseline data, and a meta-analysis was conducted on the remaining 10. Eight of these 10 trials showed a clinically significant improvement due to CCDS, demonstrating an overall mean percentage improvement in clinical diagnostic accuracy of 17.25% with the use of CCDS systems.

The authors conclude that this supports the role of CCDS in the initial evaluation of acute abdominal pain, which very often takes place in the ED. None of the studies included were RCTs, so the authors urge caution in relation to the quality of the primary evidence. They also make the point that RCTs can be difficult to set up in the emergency care arena, and that because studies in this setting tend to have to be pragmatic, this can affect quality.

3.2.3 *Limitations of previous CCDS reviews*

A consistent finding from the systematic reviews is that CCDS has been found to have a positive effect on process of care in around 60% of studies. However, there was less evidence relating to patient outcomes and the evidence that did exist showed a positive impact in only 23% of the studies. All of the systematic reviews included here referred to the lack of studies that have successfully measured effect on patient outcomes.

One of the problems cited in the systematic reviews reported is the heterogeneity of CCDS tools and studies. These differed in various ways including the clinical problem, the clinician, the patients, the purpose of the CCDS, follow up and outcome measures. The result is that it has been difficult for systematic reviewers in this field to conduct meta-analyses. Other limitations reported by the reviewers in this field included that many studies lacked the power to detect clinically important effects (often due to problems with recruitment) and that negative or adverse effects and cost-effectiveness were often overlooked in the studies under review.

The quality of studies included in the reviews was variable, however a trend was reported of improving quality over time (Garg et al., 2005).

3.2.4 *Implications for future CCDS research*

There are a wide range of types of CCDSs, including diagnostic systems, automatic prompts and reminders etc. Their application is diverse, for use in a wide range of settings, for a wide range of conditions. While the heterogeneity of CCDS studies adds a layer of complexity with regard to comparison and analysis, the systematic reviews above were able to identify benefits associated with CCDS, particularly with regard to process of care. In some instances authors have also extrapolated the features of CCDS that make such benefits more likely. This provides useful building blocks for those developing CCDS software and research in this arena in terms of what features to incorporate into the software to make positive impact more likely, for example, CCDS recommendations that are automatically provided to the practitioner.

The next steps for research in this area are to continue identifying and honing what systems work in what settings and for use by whom. Clinical outcomes, risks and cost-effectiveness need also to be addressed in order to provide a full picture relating to the impact of CCDSs. Future research needs to address the limitations reported above, particularly with regard to measuring patient outcomes, and ensuring that studies have adequate power.

3.3 Systematic review of effects and implementation of CCDS in the emergency care setting

Computerised clinical decision support tools are increasingly being used by healthcare professionals. Previous systematic reviews have shown them to be of benefit with regard to improving process of care. However, a literature search only identified one existing review of CCDS in the emergency care setting, restricted to one clinical area. Therefore, this systematic review addresses this gap by identifying and describing the existing evidence in relation to face-to-face use of CCDS in the emergency care setting, focusing on effects on process of care and patient outcomes and the implementation and adoption of face-to-face CCDS by healthcare professionals.

The objective of this review is to answer the following research questions, 1) Does CCDS impact on process of care or patient outcomes in the emergency care setting? and 2) What implementation and adoption issues were reported?

3.3.1 *Systematic review methods*

All methods used in this review followed the Centre for Reviews and Dissemination and PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines (Centre for Reviews and Dissemination, 2009, Moher et al., 2009).

Eligibility criteria

This review includes published, peer-reviewed studies where CCDS is used to provide practitioners with patient specific guidance in the face-to-face emergency care setting. Both comparative and evaluative studies were included. The search was limited to studies relating to humans, published in English from Dec 2000 to the date of the last search, Jan 2011. Inclusion and exclusion criteria are summarised on Table 2 below.

For this review emergency care is defined as "the the range of healthcare services available to people who need medical advice, diagnosis and/or treatment quickly and unexpectedly" (Department of Health, Accessed 11.07.13). It includes care delivered by emergency departments, minor injuries units, GP out-of-hours services and ambulance service care. Telephone care was excluded as it is not delivered face to face.

CCDS is defined as "any electronic system designed to aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for consideration" in line with the definition used by Hunt et al (1998) (Hunt, 1998) p1339.

Table 2: Inclusion and exclusion criteria for study selection

	Inclusion	**Exclusion**
Population	Patients who receive face-to-face emergency care	- Intensive care patients - Tele-care patients
Intervention	CCDS that provides practitioners with patient specific advice for review prior to clinical action	Studies where: - CCDS used for learning, training or product development purposes - CCDS assessment does not provides patient specific recommendation - CCDS use was based on a simulated rather than real patient encounter - CCDS used for disaster management

	Inclusion	Exclusion
Comparison	Evaluation without comparator, or comparison of CCDS with usual care, care without CCDS, or with comparable CCDS	
Outcomes	Impact on process of care Impact on patient outcomes Reported implementation and adoption issues	
Study design	Evaluative or comparative (both qualitative and quantitative)	

Information sources

Searches for research literature were carried out in eight electronic databases (CINAHL, PubMed, HMIC, Cochrane, Web of Science, BNI, Intute, and NHS Evidence). The search term combinations were Medical Subject Heading (MeSH) terms, subject headings and keywords. The terms used included prehospital, paramedic, ambulance, unscheduled, unplanned, accident and emergency, emergency triage, 999, emergency medical services, and terms related to computerised decision support including computer-assisted decision making, computer* clinical decision support, computer assisted decision making, computer assisted diagnosis, computer* clinical decision support, computer* decision support system*, CCDS, CCDSS, CDSS, handheld device. Asterisks indicate where the truncated version of the word was used.

Additionally, the references of all studies identified for inclusion in the review, review articles, key policy documents and materials previously collated for the study were hand-searched in order to identify studies missed in the electronic search. An Endnote database was used to manage references.

Search

In line with the requirements of the PRISMA checklist the full electronic search strategy for the one of the databases (CINAHL) is presented below. A full list of the search terms used for each database can be found in Appendix 2.

CINAHL SEARCHES (Jan. 2011)

LIMITS – 2000-2011 Eng Lang Peer Rev.

(((MH "Decision Making, Computer Assisted") OR (MH "Diagnosis, Computer Assisted")) or ((("computer* clinical decision support" OR "computer assisted decision making" OR "computer assisted diagnosis" OR "computer* medical decision support" OR "computer assisted medical decision support" OR "computer* clinical decision support" OR "computer* decision support system*" OR "computer* clinical decision support system*" OR "decision analysis computer assisted" OR "medical decision making computer assisted" OR "computer-based decision support" OR electronic decision support)) or ((computer* OR electronic OR pda OR hand-held OR handheld) and (ccds OR ccdss OR cdss)))) or ((MH "Decision Support Systems, Clinical" OR MH "Decision Support Techniques" OR MH "Decision Trees") and (computer* OR electronic OR handheld device OR hand-held device OR pda or online or web-based))

AND

(prehospital OR pre-hospital OR paramedic* OR ambulance* OR unscheduled OR unplanned OR telemedicine OR emergency health personnel OR emergency services hospital OR emergicent* OR urgent care cent* OR first responder* OR "accident and emergency" OR emergency triage OR nhs direct OR telecare OR 999 OR rapid response vehicle OR mobile emergency unit* OR mobile emergency care) or ((MH "Prehospital Care") OR (MH "Emergency Medical Technicians") OR (MH "Ambulances") OR (MH "Telemedicine") OR (MH "Emergency Service") OR (MH "Emergency Medical Services") OR (MH "Triage") OR (MH "Emergencies"))

Study selection

A two-step process for selecting the studies was used to reduce selection bias. The author conducted an initial screening of titles and abstracts against the inclusion/exclusion criteria presented in the table above. All papers were independently screened by a second reviewer in order to reduce selection bias. Discrepancies were discussed and consensus achieved on papers to be acquired in full for second stage screening. The selected studies were obtained and the full papers analysed using the same two-step process.

Data collection process

The author extracted data from all studies meeting the eligibility criteria. All papers were data extracted independently by a second reviewer in order to validate findings and reduce bias. Discrepancies were discussed and resolved by consensus.

Data items

Data were extracted in relation to study and intervention characteristics, participants under evaluation, patient numbers, process of care outcome measures and results, patient outcome measures and results, implementation issues and adoption issues. Process of care outcomes were defined as measures related to the impact of CCDS on care delivery e.g. appropriate prescribing; while a patient outcome was defined as the impact of CCDS on measures related to the patient e.g. health measures, satisfaction.

Extracted data were entered onto a spreadsheet that was designed, and piloted, for this review. A copy of the data extraction spreadsheet can be found in Appendix 3.

Quality assessment of individual studies

A quality assessment was carried out to assess the risk of bias in individual studies. Papers were assessed to rate the quality of comparative studies using the 'Quality Checklist for Effectiveness Studies' developed by Lewis et al (Lewis, 2009) based on the earlier checklist by Downs and Black (Downs, 1998). This tool was used as it was designed for quality assessment of the methodological quality of both randomised and non-randomised studies of health care interventions. The checklist includes items that assess the risk of bias within individual studies, for example, blinded data analysis, patient recruitment, randomisation and follow-up across groups. On reflection the tool was primarily designed to assess quantitative studies and its application to qualitative methods was limited, although several criteria were relevant such as "1. Is the hypothesis/aim/objective clearly described?". In the future for the assessment of qualitative studies the author would select a checklist tailored to the methodological approach used. A copy of the quality checklist used and a table providing the full quality assessment scores for each study can be found in Appendix 4 and 5, respectively.

All papers were assessed by the author and second independent reviewer. In addition, a statistician provided validation of the scores obtained for the statistical quality of the eligible studies. Studies were scored against a 28 item checklist with a total possible score of 34. A score of 34 on the checklist indicated the highest study quality. Differences in overall scores for each study of three or less were considered acceptable. For studies where there was a difference of four or more the researchers met and discrepancies were discussed and resolved by consensus. Studies were not excluded on the basis of quality, but issues identified with quality are included in the discussion.

Summary measures

Summary measures for each study, where specified, are presented on the outcomes tables presented in the results section of this chapter.

Synthesis of results

The heterogeneity of the studies in terms of design, outcome measures, conditions, the CCDS intervention and variations in data reporting precluded a meta-analysis of the results. The author therefore conducted a preliminary synthesis by summarizing data from the eligible studies onto a table developed and piloted for this review (Appendix 3). The author then completed a narrative synthesis of the data, primarily in terms of type of intervention, process of care outcomes, patient outcomes, adoption and implementation. This allowed the author to explore factors explaining relationships in the data including differences in the data and reasons for different effects.

Risk of bias across studies

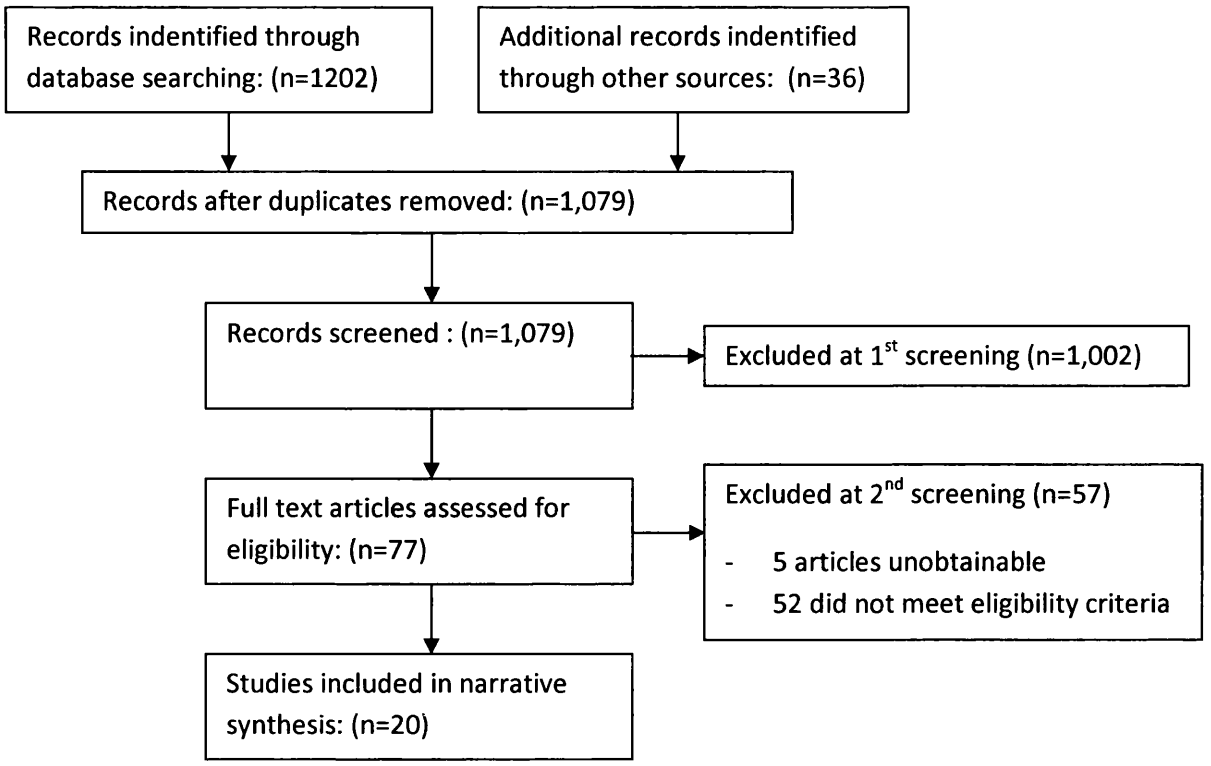
The studies reported on in this review were considered for risk of bias in terms of the study setting, patient population, practitioner population, clinical condition and outcome measures.

3.3.2 Systematic review results

Study selection

A total of 1202 citations were identified from the electronic searches and 36 citations through other sources. Following screening of the titles and abstracts using the two-step process a total of 77 full-text citations were identified as being potentially eligible on the basis of their title and abstract and retrieved in full for detailed evaluation. Five of these were unobtainable and therefore not considered further. Following critical appraisal of the 72 studies obtained in full, a total of 52 studies were excluded, based on the defined exclusion criteria. A total of 20 studies were identified for inclusion in this review.

Figure 1: Flowchart of papers identified and included/excluded at each stage



Study characteristics

The 20 studies which met the inclusion criteria were carried out in seven countries (eight from the US, six from Canada, two from Australia and one each from the UK, France, Italy and the Netherlands). They included more than 19,000 patients. Five of these were Randomised Controlled Trials (RCTs), one was a Cluster-RCT, one was described as a 'clinical trial' and another as a 'validation trial'. Five of the studies were cohort studies, five were observational studies and one was based on qualitative interviews. The remaining study was described as a comparison study.

The studies covered CCDS applications for a wide range of conditions including asthma, pneumonia, stroke, abdominal pain, chest pain, fever in children and pulmonary embolism. CCDS was used for a variety of purposes including: to support triage, for assessment or diagnosis, to improve prescribing practice, for drug dosing levels, or to improve the use of a clinical pathway.

The setting for all but one of the papers in this review was an emergency care department. The remaining study was set in an NHS walk-in centre (Dowding et al., 2009). The CCDS initiatives in this review were conducted on Personal Computers, hand-held computers, and laptops.

Ten of the CCDS systems in this review were completed by ED physicians, seven were completed by ED nurses, two were automated completion tools with follow-up from physicians. In the remaining study the parents of children presenting to the ED with asthma completed the CCDS on a multi-language, multi-media touch screen device and the output was made available to clinicians (physicians and nurse) for follow-up.

A summary of the papers included in this review and their characteristics is provided in Table 3 below.

Quality assessment of individual studies

Using the 'Quality Checklist for Effectiveness Studies' developed by Lewis et al (Lewis, 2009) the quality of the studies selected for this review was variable. Study quality ranged from poor (Brown 2007) to well-conducted (Terrell 2009). Scores ranged from 12 to 31 out of a possible 34. Nine of the studies scored under 20, ten scored in the twenties and only one study scored in the thirties.

Each study was scored against the quality checklist by the author and by a second independent assessor. Where scores differed by more than 3 points, assessors met to discuss and revise scores by consensus in order to increase inter-rater reliability and reduce bias. The two quality assessment scores attributed to each study are presented in Table 3. A table presenting the breakdown of quality assessment scores against the full quality checklist for each study, can be found in Appendix 5.

The scope of this review was not limited to randomised controlled trials and included both comparative and evaluative studies. This inclusive approach was adopted in order to ensure that the review provides a comprehensive account of the current CCDS research evidence in the emergency care setting.

Study and country	Quality score 1	Quality score 2	Study type	No of sites	No of patients	CCDS for use by	CCDS intervention & setting
Brown et al 2007 Implementation of an ED based transient ischemic attack clinical pathway: a pilot study (US) (Brown et al., 2007)	10	13	prospective cohort study (pilot)	1	75	ED residents and doctors	Feasibility study of CCDS to guide physicians through a Transient Ischemic Attack (TIA) clinical pathway for evaluating and managing patients who present with stroke symptoms to an ED. Community hospital ED
Buising et al 2008 Improving antibiotic prescribing for adults with community acquired pneumonia (Australia) (Buising et al., 2008)	23	22	pre and post cohort study	1	348	ED doctors	CCDS compared to educating physicians to improve antibiotic prescribing for patients diagnosed with pneumonia in the ED. Urban adult tertiary teaching hospital ED
Bullard et al 2004 Supporting clinical practice at the bedside using wireless technology (Canada) (Bullard, 2004)	21	21	Randomised, controlled trial	1	1500-2500	ED doctors	Physicians' use of a mobile computer (MC) with access to the ED information and CCDS systems for use at the bedside compared to use a desk computer (DC). Academic tertiary care ED
Dong et al 2005 Emergency triage: Comparing a novel computer triage program with standard triage (Canada) (Dong et al., 2005)	17	20	Prospective observational study	1	722	ED triage nurses	CCDS based triage (etriage) compared to triage from memory by ED nurses, as measured against triage by an expert panel. Urban tertiary care teaching hospital ED
Dong et al 2006 Reliability of computerised emergency triage 2006 (Canada) (Dong et al., 2006)	20	17	Prospective observational study	1	569	ED triage nurses and 2 study nurses	Inter-rater reliability of 2 CCDS triage scores as generated independently by 2 study nurses for ED patients. Urban tertiary care teaching hospital ED
Dong et al 2007 The effect of training on nurse agreement using an electronic triage system	14	14	Prospective cohort	1	1068	Triage nurses	Inter-rater reliability of CCDS triage scores between triage nurses with different levels of CCDS tool training. Urban tertiary care teaching

Study and country	Quality score 1	Quality score 2	Study type	No of sites	No of patients	CCDS for use by	CCDS intervention & setting
(Canada) (Dong et al., 2007)							hospital ED
Dowding et al 2009 Nurses' use of computerised clinical decision support systems: a case site analysis (UK) (Dowding et al., 2009)	14	14	multiple case site study - qualitative methods	4	115	Nurses	Interviewing nurses to explore how they use CCDS in clinical practice and the factors that influence this. Four case study sites were used; one of these was a walk-in centre using CCDS to support patient assessment.
Farion et al 2008 Prospective evaluation of the MET-AP system providing triage plans for acute pediatric abdominal pain (Canada) (Farion et al., 2008)	26	25	Prospective validation trial	1	574	ED doctors and residents	Comparing triage accuracy of ED physicians and residents with CCDS triage against a study generated gold-standard for children with acute abdominal pain in the ED. Tertiary care paediatric ED
Graber & VanScoy 2003 How well does decision support software perform in the ED? (USA) (Graber and VanScoy, 2003)	14	12	Prospective comparison	1	25	ED doctors	Comparing CCDS diagnosis (using Iliad and QMR software) with diagnosis by the ED attending. Tertiary care academic medical centre ED
Gravel et al 2008 Inter-rater agreement between nurses for the Pediatric Canadian Triage Acuity in a tertiary care centre (Canada) (Gravel et al., 2008)	16	15	Prospective cohort study	1	499	ED triage nurses	Inter-rater reliability of 2 CCDS triage scores (using Staturg/PedCTAS software) as generated independently by 2 study nurses for children in the ED. Tertiary care paediatric hospital ED
Kwok et al 2009 Improving adherence to asthma clinical guidelines and discharge documentation from EDs	23	21	Pre and post observational study	1	100	ED doctors	Impact of CCDS (using ACAFE software) for the management and documentation of asthma patients in the ED, a pre and post CCDS implementation comparison. Metropolitan

Study and country	Quality score 1	Quality score 2	Study type	No of sites	No of patients	CCDS for use by	CCDS intervention & setting
(Australia) (Kwok et al., 2009)							hospital ED
Lorenzoni et al 2006 A computer protocol to evaluate subjects with chest pain in the ED (Italy) (Lorenzoni et al., 2006)	19	18	Prospective observational study	7	472	Automated CCDS output for ED doctor	Assessment of a CCDS triage tool for evaluating patients presenting to an ED with chest pain of uncertain origin (to identify coronary and non coronary diagnosis). 13 hospitals in Tuscany with an ED and coronary care unit
Porter et al 2006 Impact of patient-centred decision support on quality of asthma care in the ED (US) (Porter et al., 2006)	23	21	Clinical trial	1	286	Parents of children with asthma in ED	Assessment of the impact of a CCDS tool for children presenting to ED with asthma. Parents complete the CCDS and clinicians receive a tailored plan of action from it. Tertiary care paediatric ED.
Roukema 2008 Randomised trial of a decision support system; impact on the management of children with fever without apparent source (Netherlands) (Roukema et al., 2008)	24	21	Randomised trial	1	164	ED nurses	Assessment of the impact of a CCDS tool for diagnostic management of children with fever without apparent source on time spent in ED and number of lab tests. Paediatric ED
Roy et al 2009 A computerised handheld decision-support system to improve pulmonary embolism diagnosis: a randomised trial (France) (Roy et al., 2009)	26	24	Cluster randomised controlled trial	20	1645	ED doctors	Assessment of impact of hand-held CCDS for diagnosing pulmonary embolism in ED on doctors' diagnostic decision making. 20 EDs

Study and country	Quality score 1	Quality score 2	Study type	No of sites	No of patients	CCDS for use by	CCDS intervention & setting
Sard et al 2008 Retrospective evaluation of a computerised physician order entry adaptation to prevent prescribing errors in a pediatric ED (US) (Sard et al., 2008)	26	26	Retrospective cohort study	1	840	ED doctors, fellows and residents	Impact of a CCDS medication 'quicklist' on prescribing errors as part of a computerised physician order entry system in a paediatric ED
Selker 2002 Use of the electrocardiograph-based thrombolytic predictive instrument to assist thrombolytic and reperfusion therapy for acute myocardial infarction (US) (Selker et al., 2002)	28	27	Multicentre randomised controlled trial	28	1197	Automated CCDS output with physician follow-up	To test whether an electrocardiograph-based CCDS tool (the Thrombolytic Predictive Instrument) improves use of thrombolytic and overall reperfusion therapy. 28 EDs in urban, suburban and rural hospitals in the US
Terrell et al 2009 Computerised decision support to reduce potentially inappropriate prescribing to older ED patients: a randomised controlled trial (US) (Terrell et al., 2009)	31	32	Randomised, controlled trial	1	5162	ED doctors	CCDS designed to reduce prescribing of medications that are potentially inappropriate for older adults. Academic hospital ED
Terrell et al 2010 Computerised decision support for medication dosing in renal insufficiency: a randomised controlled trial (US) (Terrell et al., 2010)	25	22	Randomised, controlled trial	1	2783	ED doctors and residents	CCDS to facilitate the appropriate dosing of medications for adult patients with renal insufficiency who were being discharged home from the ED. Academic hospital ED.

Study and country	Quality score 1	Quality score 2	Study type	No of sites	No of patients	CCDS for use by	CCDS intervention & setting
Venkat et al 2010 Feasibility of integrating a clinical decision support tool into an existing computerised physician order entry system to increase seasonal influenza vaccination in the ED (US) (Venkat et al., 2010)	17	17	prospective, observational trial	1	2270	ED nurses	Integrating a clinical decision support tool into an existing ED computerised physician order entry system in order to increase influenza vaccination uptake. Urban tertiary care centre ED

Results of individual studies and synthesis of results

The reported impact of CCDS on process of care and patient outcomes are presented on two summary tables below. Impact was determined based on whether authors reported that their findings were positive, negative or had no impact against the outcomes measured. Several authors did not indicate whether their findings were positive, negative or neutral. Descriptive studies were not categorised. Reported implementation and adoption issues are presented narratively.

Impact of CCDS on process of care outcomes

A summary table of process of care outcome measures and results for individual studies is presented below.

Nineteen of the 20 studies in this review evaluated process of care outcomes. In 15 of these studies a positive finding was reported against the outcome measures (Brown et al., 2007, Buising et al., 2008, Bullard, 2004, Dong et al., 2005, Dong et al., 2006, Dong et al., 2007, Farion et al., 2008, Kwok et al., 2009, Roukema et al., 2008, Roy et al., 2009, Sard et al., 2008, Selker et al., 2002, Terrell et al., 2009, Terrell et al., 2010, Venkat et al., 2010). One study reported that CCDS had no significant impact (Porter et al., 2006). One study reported a negative finding (Graber and VanScoy, 2003). One study did not indicate the impact of their findings (Gravel et al., 2008) and one study was descriptive (Dowding et al., 2009) The only study that did not include process of care outcomes was Lorenzoni 2006 (Lorenzoni et al., 2006). Three main types of process of care measures were identified:

- Adherence measures – these measure the extent to which practitioners adhere to (or comply with) the CCDS recommendations (i.e. adhere to, over-ride or ignore)
- Agreement measures - these measure the extent to which CCDS and practitioners' patient assessments agree with each other
- Usage measures – these explore whether (and sometimes how) CCDS is used

Four of the 19 studies included more than one process of care (Dong et al., 2007, Gravel et al., 2008, Roy et al., 2009, Roukema et al., 2008) with the result that twelve studies evaluated adherence (Brown et al., 2007, Buising et al., 2008, Dong et al., 2007, Gravel et al., 2008, Porter et al., 2006, Roukema et al., 2008, Roy et al., 2009, Sard et al., 2008, Selker et al., 2002, Terrell et al., 2009, Terrell et al., 2010, Venkat et al., 2010), six evaluated agreement (Dong et al., 2005, Dong et al., 2006, Dong et al., 2007, Farion et al., 2008, Graber and VanScoy, 2003, Gravel et al.,

2008) and five evaluated usage (Bullard, 2004, Dowding et al., 2009, Roy et al., 2009, Kwok et al., 2009, Roukema et al., 2008). In addition one study measured the impact of CCDS on time spent in the ED (Roukema et al., 2008).

Of the 12 studies that reported on adherence to CCDS, 10 reported a positive finding (Brown et al., 2007, Buising et al., 2008, Dong et al., 2007, Roukema et al., 2008, Roy et al., 2009, Sard et al., 2008, Selker et al., 2002, Terrell et al., 2009, Terrell et al., 2010, Venkat et al., 2010). One study reported no significant impact of CCDS (on treatment for children with asthma) (Porter et al., 2006) and one reported that CCDS recommendations were overridden by nurses 22.5% of the time but did not indicate the direction of this finding (Gravel et al., 2008). Adherence to CCDS was measured in relation to the following: patient evaluation and care management (Brown et al., 2007, Roukema et al., 2008, Selker et al., 2002), prescribing and dosing (Buising et al., 2008, Porter et al., 2006, Sard et al., 2008, Terrell et al., 2009, Terrell et al., 2010), triage (Dong et al., 2007, Gravel et al., 2008), test ordering (Roy et al., 2009) and for increasing the use of flu vaccine (Venkat et al., 2010).

Of the six studies that evaluated agreement between CCDS and practitioners' patient assessments, four reported a positive finding (Dong et al., 2005, Dong et al., 2006, Dong et al., 2007). One study reported that the diagnostic accuracy of CCDS (as measured against physician diagnosis) was not high enough to be relied on (Graber and VanScoy, 2003). One study identified 'moderate' inter-rater reliability between 2 CCDS etriage scores produced by nurses, but did not indicate the direction of this finding (Gravel et al., 2008). Agreement between CCDS and practitioners' assessments were measured in relation to triage/etriage in five studies (Dong et al., 2005, Dong et al., 2006, Dong et al., 2007, Farion et al., 2008, Gravel et al., 2008) and for diagnosis in one study (Graber and VanScoy, 2003) as follows:

- Between nurses using standard triage and nurses using CCDS (Dong et al., 2005)
- Between two groups of nurses both using CCDS triage (Dong et al., 2006, Dong et al., 2007, Gravel et al., 2008)
- Between Drs using CCDS and a gold-standard triage (Farion et al., 2008)
- Between CCDS and doctor diagnosis (Graber and VanScoy, 2003)

Of the five studies that evaluated usage, four reported a positive finding (Bullard, 2004, Kwok et al., 2009, Roy et al., 2009, Roukema et al., 2008) related to CCDS use and one was descriptive (Dowding et al., 2009). Use of CCDS was evaluated in

the following ways: to measure whether use of CCDS by physicians increased with the provision of mobile bedside computers (Bullard, 2004); to explore how nurses use CCDS (based on qualitative interviews) (Dowding et al., 2009); to assess use of CCDS and its impact on quality of clinical documentation for asthma patients (Kwok et al., 2009); to assess use of CCDS for children with fever without apparent source; and to assess use of CCDS for diagnosis of pulmonary embolism.

One study also explored the impact of CCDS on the time that children with fever without apparent source spent in the ED (Roukema et al., 2008). They found that the time patients spent in ED was not significantly different between the intervention and control groups.

Study	Intervention	Process of care outcome measures	Reported process of care results	Reported CCDS effect
Brown 2007 (Brown et al., 2007)	Feasibility study of CCDS to guide physicians through a Transient Ischemic Attack (TIA) clinical pathway for evaluating and managing patients who present with stroke symptoms to an ED.	Drs adherence to CCDS clinical pathway for patients with stroke symptoms. Simple proportions with 95% confidence intervals (CI) were presented.	Drs adhered to the CCDS clinical pathway 85.3% of the time, 95% CI 0.76 to 0.92.	Positive
Buising 2008 (Buising et al., 2008)	CCDS compared to educating physicians to improve antibiotic prescribing for patients diagnosed with pneumonia in the ED.	Impact of CCDS vs. training on improving prescribing for patients with pneumonia. A binary logistic model was used and odds ratios (OR) presented.	CCDS associated with greater improvement in prescribing than training alone. OR=1.99 [1.07, 3.69], p=0.02.	Positive
Bullard 2004 (Bullard, 2004)	Physicians' use of a mobile computer (MC) with access to the ED information and CCDS systems for use at the bedside compared to use a desk computer (DC).	Impact of MC on CCDS use. Repeated measures analysis of variance was used to examine the difference in use between shifts with and without CCDS.	CCDS used more frequently during MC shifts than DC shifts. CCDS use/shift, 3.6 with MC vs. 2.0 without (p=0.033).	Positive
Dong 2005 (Dong et al., 2005)	CCDS based triage (etriage) compared to triage from memory by ED nurses, as measured against triage by an expert panel.	Agreement between nurses using etriage and memory triage. Calculated using Kappa statistics.	Etriage scores were closer to that of the expert panel (K=0.426; 95% CI= 0.289 to 0.564)) than memory based triage (0.263, 95% CI=0.133 to 0.394).	Positive
Dong 2006 (Dong et al., 2006)	Inter-rater reliability of 2 CCDS triage scores as generated independently by 2 study nurses for ED patients.	Agreement between the 2 etriage scores. Calculated using both linear weighted and quadratic weighted Kappa statistics.	Inter-rater reliability of etriage was moderate if using linear (K=0.52, 95% CI=0.46 to 0.57) and good if using quadratic (K=0.66; 95% CI=0.60 to 0.71).	Positive
Dong 2007 (Dong et al., 2007)	Inter-rater reliability of CCDS triage scores between triage nurses with different levels of CCDS tool training. Phase 1 comprised 3 hour training, phase 2 comprised further training.	1) Agreement between 2 etriage scores 2) Adherence to CCDS pathway (overrides). Calculated using both linear weighted and quadratic weighted Kappa statistics.	Inter-rater reliability of etriage was moderate in phase 1 (K=0.55, 95% CI 0.49 to 0.62) and improved in phase 2 (K=0.65, 95% CI 0.60 to 0.70). CCDS overrides were infrequent	Positive

			results	CCDS effect
Dowding 2009 (Dowding et al., 2009)	Interviewing nurses to explore how they use CCDS in clinical practice and the factors that influence this. Four case study sites were used; one of these was a walk-in centre using CCDS to support patient assessment.	Nurses report how they use CCDS (4 settings). Qualitative data were analysed thematically.	Descriptive: various uses, up-skilling element, experience a factor.	Descriptive
Farion 2008 (Farion et al., 2008)	Comparing triage accuracy of ED physicians and residents with CCDS triage against a study generated gold-standard for children with acute abdominal pain in the ED.	Agreement between Dr triage and etriage scores against a gold standard. Percentages were presented with CI.	High level of accuracy of CCDS tool reported, 72% (95% CI, 67.9 to 76.1) for CCDS accuracy compared to 70% (95% CI, 65.9 to 74.2) for Drs.	Positive
Graber & VanScoy 2003 (Graber and VanScoy, 2003)	Comparing CCDS diagnosis (using Iliad and QMR software) with diagnosis by the ED attending.	Agreement between CCDS diagnosis and final ED diagnosis. Percentages were compared.	CCDS accuracy was not high enough to permit its use 'as an arbiter in any individual case'. 72% using Iliad and 52% using QMR.	Negative
Gravel 2008 (Gravel et al., 2008)	Inter-rater reliability of 2 CCDS triage scores (using Staturg/PedCTAS software) as generated independently by 2 study nurses for children in the ED.	1) Agreement between 2 etriage scores calculated using linear weighted and quadratic Kappa scores 2) adherence (overrides) were presented as a proportion.	Inter-rater agreement for etriage levels was moderate; Linear K= 0.55, 95% CI 0.48 to 0.61, quadratic K=0.61, 95% CI 0.42 to 0.80). Overrides were 23.2% for regular nurses and 21.8% for research nurses.	Not indicated
Kwok 2009 (Kwok et al., 2009)	Impact of CCDS (using ACAFE software) for the management and documentation of asthma patients in the ED, a pre and post CCDS implementation comparison.	Quality of clinical documentation. Chi^2, Mann Whitney U and T tests were used.	CCDS associated with improved clinical documentation (98% vs. 18%, $p<0.01$) and discharge plans (76% vs. 16%, $p<0.01$).	Positive
Porter 2006 (Porter et al., 2006)	Assessment of the impact of a CCDS tool for children presenting to ED with asthma. Parents complete the CCDS and clinicians receive a tailored plan of action from it.	Prescription of controller therapy by care provider. Wilcoxon and Fisher's exact tests were used.	CCDS had no significant impact on the prescription of inhaled corticosteroids (9/50 vs. 4/43). CCDS increased prescription on inhaled fluticasone (9/50 vs. 2/43) but not significantly.	No impact

			results	CCDS effect
Roukema 2008 (Roukema et al., 2008)	Assessment of the impact of a CCDS tool for diagnostic management of children with fever without apparent source on time spent in ED and number of lab tests.	1) CCDS use (registration of children to the study) expressed as a percentage 2) adherence (test ordering) using Chi^2 3) time spent in ED (Mann Whitney test).	1) CCDS use was 50% 2) adherence to test ordering advice was 82% vs. 44% ($p<0.01$) 3) No significant difference in time spent in ED.	1 & 2) Positive 3) No impact
Roy 2009 (Roy et al., 2009)	Assessment of impact of hand-held CCDS for diagnosing pulmonary embolism in ED on doctors' diagnostic decision making.	1) CCDS use for diagnosis 2) adherence to CCDS (test ordering). A logistic regression model was used and adjusted mean differences were reported.	1) CCDS improved diagnosis by 19.3% (95% CI 2.9 to 35.6). 2) CCDS reduced test ordering practice 1.76 SD 0.98 vs. 2.25 SD 1.04 $p<0.001$.	Positive
Sard 2008 (Sard et al., 2008)	Impact of a CCDS medication 'quicklist' on prescribing errors as part of a computerised physician order entry system in a pediatric ED	Prescribing errors were compared by incident rate ratios and were measured by Poisson regression analysis.	CCDS led to a significant reduction in medication prescribing errors. Error rate was 1.9/100 with CCDS and 18.3/100 without ($p=0.02$).	Positive
Selker 2002 (Selker et al., 2002)	To test whether an electrocardiograph-based CCDS tool (the Thrombolytic Predictive Instrument) improves use of thrombolytic and overall reperfusion therapy.	Thrombolytic therapy and reperfusion therapy rates were analysed using Chi^2.	CCDS increased the use of thrombolytic therapy for inferior acute myocardial infarction (61.1% vs. 67.6% $p=0.03$). Overall reperfusion therapy rate also increased (76.7% vs. 74.7% $p=0.03$).	Positive
Terrell 2009 (Terrell et al., 2009)	CCDS designed to reduce prescribing of medications that are potentially inappropriate for older adults.	Proportion of prescriptions for inappropriate medication. Logistic models with mixed effects were used to compare outcomes.	CCDS significantly reduced potentially inappropriate prescribing; 2.6% with CCDS vs. 3.9% without ($p=0.02$, OR=0.55, 95% CI 0.34 to 0.89).	Positive
Terrell 2010 (Terrell et al., 2010)	CCDS to facilitate the appropriate dosing of medications for adult patients with renal insufficiency who were being discharged home from the ED.	Percentage of targeted medications that were excessively dosed. Fisher's exact test was used with mixed effect models to compare dosing between usual care and intervention.	CCDS significantly reduced excessive dosing of targeted medicines; effect size = 31%, 95% CI 14% to 49% ($p=0.001$).	Positive

			results	CCDS effect
Venkat 2010 (Venkat et al., 2010)	Integrating a clinical decision support tool into an existing ED computerised physician order entry system in order to increase influenza vaccination uptake.	ED seasonal influenza vaccination levels in 2008 (no CCDS) were compared with levels in 2009 (with CCDS) using a two-sample Z test.	It was feasible to integrate CCDS into CPOE to increase ED influenza vaccine. ED influenza vaccine levels rose by 17.5%, 95% CI 16 to 19% ($p<0.001$).	Positive

Impact of CCDS on patient outcomes

A summary table of patient outcome measures and results for individual studies is presented below.

Five papers in this review measured patient related outcomes. One of these reported a positive finding (Lorenzoni et al., 2006), one reported a negative finding (Porter et al., 2006) and three of the studies were not powered to assess the impact of CCDS on patient outcomes (Brown et al., 2007, Roy et al., 2009, Selker et al., 2002). Patient outcome measures included uneventful hospitalisation (Brown et al., 2007), patient satisfaction with care for their children (Porter et al., 2006) and clinical outcomes at 3 months (Roy et al., 2009).

The positive finding was reported in a study of CCDS for evaluating the severity of chest pain in ED (Lorenzoni et al., 2006). Discharged patients were followed up and a low incidence of cardiovascular events was found, demonstrating that the CCDS had supported practitioners in appropriately triaging patients with chest pain, resulting in patients receiving appropriate care.

One study reported a negative finding (Porter et al., 2006). Porter et al 2006 tested an 'asthma kiosk', a CCDS tool that parents completed themselves in the ED for their asthmatic children. It produced a tailored plan of action for use by clinical providers. The patient outcome measure was satisfaction with care (investigated during follow-up telephone interviews with the parents). The output from the parent-completed CCDS was available to practitioners but was generally not used by them and this had a negative impact on parents' satisfaction. However, on the occasions when CCDS recommendations were used by the clinician the impact on parent satisfaction was positive.

Three studies measured patient outcomes but were not able to report on them (Brown et al., 2007, Roy et al., 2009, Selker et al., 2002). Brown et al 2007 set out to assess whether CCDS could be used to assess and discharge stroke patients from ED safely and efficiently (Brown et al., 2007). However, they were unable to report against their patient outcomes measures as a result of lower than anticipated patient recruitment levels. Roy et al 2009 reported on the use of CCDS to improve pulmonary embolism diagnosis (Roy et al., 2009). Despite measuring patient outcomes the authors identified that a study limitation was that the study had not been powered to detect a clinically significant difference in these. Selker et al 2002 monitored patient mortality and stroke rates, however, this trial was also not powered to detect significant differences in these (Selker et al., 2002).

A summary of the impact of CCDS on patient outcomes in emergency care is provided in Table 5 below.

Table 5: Summary of patient outcome measures and results for individual studies

Study	Intervention	Patient outcome measures	Reported patient outcome results	Reported CCDS effect
Brown 2007	Feasibility study of CCDS to guide physicians through a Transient Ischemic Attack (TIA) clinical pathway for evaluating and managing patients who present with stroke symptoms to an ED.	90-day risk of recurrent TIA, stroke, or death. Rate of uneventful hospitalization	Unable to report due to lower than anticipated patient recruitment levels	Not powered
Lorenzoni 2006	Assessment of a CCDS triage tool for evaluating patients presenting to an ED with chest pain of uncertain origin (to identify coronary and non coronary diagnosis).	Correct risk stratification by CCDS as measured by the incidence of coronary events at 1 month was reported as a percentage.	The predictive accuracy of the CCDS based on the incidence of patient events at one month was high (87.6%).	Positive
Porter 2006	Assessment of the impact of a CCDS tool for children presenting to ED with asthma. Parents complete the CCDS and clinicians receive a tailored plan of action from it.	Parent satisfaction with care for children for whom CCDS was used. The Wilcoxon test was used.	CCDS did not improve parents' satisfaction with ED care and worsened it when CCDS care plans weren't used by practitioners; mean number of problems: 1.5 (SD 1.9) at baseline to 1.9 (SD 1.4) for intervention.	Negative
Roy 2009	Assessment of impact of hand-held CCDS for diagnosing pulmonary embolism in ED on doctors' diagnostic decision making.	Clinical outcomes at 3 months	The study was not powered to detect a difference in patient clinical outcomes	Not powered
Selker 2002	To test whether an electrocardiograph-based CCDS tool (the Thrombolytic Predictive Instrument) improves use of thrombolytic and overall reperfusion therapy.	Patient mortality and stroke rates were monitored for safety reasons	This trial was not powered to detect significant differences in mortality and stroke rates	Not powered

Were any implementation or adoption issues reported?

For the purpose of this review implementation relates to the set up of the intervention, including hardware, software, training and ongoing support. Adoption relates to the use of the CCDS by practitioners.

Although implementation issues were not the focus of the studies included in this review, three of the papers reported on implementation issues (Bullard, 2004, Graber and VanScoy, 2003, Venkat et al., 2010). In two instances these were related to hardware and software issues that had adversely affected the studies (Bullard, 2004, Graber and VanScoy, 2003). In the other instance the authors reported on implementation issues related to unanticipated situational circumstances that adversely affected the study (Venkat et al., 2010). These are described in more detail, below.

Bullard et al 2004 reported that there had been problems with the usability of the study hardware including: keeping the equipment charged, connection to the internet, the size of equipment and the effort required to manoeuvre it for an eight-hour shift (Bullard, 2004).

Graber et al 2003 reported implementation issues relating to the software not being sufficiently developed or sophisticated (Graber and VanScoy, 2003). Sometimes algorithms would produce a result that did not take into account the full information available, for example the ability to input the duration of signs and symptoms was limited and the CCDS programme was unable to account for the sequence of symptom development. It also did not allow data to be entered that was beyond its own limited vocabulary.

One author, Venkat 2010, reported implementation problems linked to extraneous variables that affected the supply of medication linked to their CCDS intervention (Venkat et al., 2010). In this study the implementation of CCDS to increase seasonal flu vaccinations was halted by a flu epidemic during the intervention period, which resulted in a shortage of flu vaccine. Despite these problems, Venkat also reported that they had achieved institutional buy-in at the implementation stage;

> *"One of our most important preparatory steps in implementing a protocolized ED influenza vaccination program at this center was the inclusion of representatives from the various stakeholders that were involved (emergency medicine, pharmacy and nursing)" (Venkat et al., 2010).*

Seven studies in this review reported on the adoption or use of CCDS (Brown et al., 2007, Bullard, 2004, Dowding et al., 2009, Farion et al., 2008, Porter et al., 2006,

Roukema et al., 2008, Sard et al., 2008). Two of these studies explored the use of CCDS through questionnaires and interviews with practitioners (Bullard, 2004, Dowding et al., 2009). Five studies reported on low CCDS usage levels by practitioners (Brown et al., 2007, Farion et al., 2008, Porter et al., 2006, Roukema et al., 2008, Sard et al., 2008). These are described in more details below.

Bullard (2004) and Dowding (2009) reported on CCDS use based on questionnaires and interviews with practitioners (Bullard, 2004, Dowding et al., 2009). Bullard recruited doctors to use CCDS with a wireless link to an ED information system. Doctors reported that problems with hardware set-up, outlined in the implementation section above, affected their usage levels (e.g. battery charging and carrying kit). Dowding (2009) interviewed nurses to find out how they used CCDS and found that they used it to record information, monitor patients' progress or confirm a decision that had already been made. They also found that nurses a) integrate the CCDS knowledge and b) rely on it less as they become more experienced (at job/with software). The nurses also reported learning how to use the software to get the outcome they felt was appropriate. Dowding also reported on issues that affected CCDS use including; familiarity with the patient, the patient's condition, the CCDS software itself (for example the appropriateness or flexibility of the algorithms).

In several studies authors reported low usage of the CCDS under investigation. The study by Brown (2007) was reduced from a trial to a pilot study because of low patient recruitment by practitioners to the CCDS pathway, which included referral to a stroke team (Brown et al., 2007). This was attributed to both flaws in the study set up and the additional demands of practitioners having to identify and register eligible patients to the trial in a busy ED (Brown et al., 2007). Farion (2008) did not achieve the study sample size required to study the impact of CCDS for paediatric abdominal pain due to 'difficulty maintaining physician engagement during a particularly busy viral season' (Farion et al., 2008). Porter (2006) reported that physicians and nurses rarely used the CCDS output (which was produced by parents of children with asthma using a CCDS kiosk) (Porter et al., 2006). Roukema (2008) reported lower than anticipated recruitment of eligible febrile children to the CCDS intervention (49%) (Roukema et al., 2008). Finally, Sard (2008) reported low usage levels of their CCDS 'quicklist' for preventing prescribing errors, with only half of the residents surveyed using the list 'sometimes or most of the time' (Sard et al., 2008).

The reasons given for low CCDS usage varied, but included; problems maintaining engagement, busy periods in the ED that detracted from using the software, the length of time CCDS took to use, software inadequacies (e.g. lack of appropriate algorithms, inflexibility of algorithms), and challenges with using the hardware (e.g. charging).

Risk of bias across studies

The studies included in this review were considered for risk of bias in terms of the study setting, patient population, clinical condition, intervention and practitioner population.

The studies were largely based in the ED setting (n=19/20), only one study was based in a walk-in centre, and no eligible studies were identified in the prehospital emergency care setting. It is therefore likely that the findings of this review are biased towards the impact of CCDS in the ED than in the emergency care setting more broadly.

The studies covered a broad range of patient ages, from children to older adults, with five of the studies conducted in paediatric EDs. The studies covered a broad range of patient conditions (only one condition, asthma, was represented twice). No particular bias with regard to patient age or clinical condition was identified.

The studies in this review covered a wide range of conditions (including pulmonary embolism, asthma, fever in children, renal insufficiency) and explored a variety of uses of CCDS as a tool (e.g. to improve clinical documentation, to increase uptake of flu vaccine, to improve prescribing and dosing, test ordering, triage and diagnosis). No bias with regard to CCDS intervention was identified.

Ten of the CCDSs were for completion by physicians, seven were completed by nurses, two were automated with follow-up from physicians, one was completed by parents with the output made available to clinicians (physicians and nurse). None of the CCDSs in this review were designed for use by paramedics.

3.3.3 Systematic review discussion

Summary of evidence

This review identified 20 eligible studies of face-to-face CCDS in the emergency care setting. Nineteen of these were based in the emergency department and one in an NHS walk-in-centre, highlighting that face-to-face CCDS research in the

emergency setting is largely confined to the emergency department setting to date, with no eligible studies identified in the field of prehospital emergency care.

The majority of studies focused on impact of CCDS on process of care (19/20 studies), with 15/19 (79%) of these reporting a positive finding. This is consistent with findings from previous reviews of CCDS which also found that a) more CCDS studies report on process of care than patient outcomes, and b) CCDS is associated with overall positive impact on process of care (Hunt, 1998, Garg et al., 2005, Sahota et al., 2011, Souza et al., 2011).

Five papers (5/20) in this review measured patient related outcomes, however only two of these were powered to assess the impact of CCDS. One of these reported a positive finding, one reported a negative finding and three weren't powered to assess the impact of CCDS on patient outcome measures. Again, this reflects findings from other reviews where gaps in the research on impacts of CCDS on patient outcomes, and problems with powering CCDS studies to measure these are highlighted.

Implementation issues were reported in three of the studies, highlighting the need for well developed CCDS, usable hardware, and the importance of engaging practitioners in the research. Adoption was reported on in seven studies, two of these explored usage issues with practitioners and five reported on low CCDS usage that impacted on their studies.

Impact on process of care

The main focus of CCDS research in this field is on process of care. The impact overall was reported as being positive. It could also be complex, for example Selker 2002 tested CCDS designed to assist thrombolytic and reperfusion therapy for acute myocardial infarction (Selker et al., 2002). The study found that although the intervention had minimal effect in patient groups with already-high rates of reperfusion, it increased and expedited use of thrombolytic and overall reperfusion therapy for patients typically treated less often or less quickly.

In general the studies could be categorised as exploring the impact of CCDS in terms of one or more of the following; compliance by practitioners to CCDS recommendations, agreement between CCDS tools and practitioners' assessments, and CCDS usage.

In studies assessing compliance (or adherence), authors frequently reported on practitioners' overrides of the CCDS recommendations. An override is where a

practitioner does not follow the CCDS recommendation. Overrides were reported in a variety of ways. In some studies overrides were viewed as compromising the delivery of the most appropriate care and introducing risk (Sard et al., 2008, Terrell et al., 2009, Terrell et al., 2010). In some studies overrides were reported neutrally (Dong et al., 2007, Gravel et al., 2008). In others overrides were reported as being a sign of practitioner experience and expertise, or a necessary response to inflexible software (Dowding et al., 2009). A similar situation exists in relation to test-ordering reporting. In one study increased test ordering was reported positively (Roy et al., 2009), and in another it was reported negatively (Roukema et al., 2008).

What was not always clear was the rationale behind why the impacts reported were assessed in the way they were. For example, when are CCDS overrides by practitioners acceptable and when are they not? Also, what constitutes a positive outcome in terms of CCDS impact on tests ordering? Outcome measures and how they are being evaluated needs to be clearly defined.

Among the studies that evaluated agreement between CCDS and clinician assessments and diagnosis, studies varied in terms of what was being measured and whether the clinician or the CCDS was deemed to be the most accurate. In some instances the CCDS was on test, its accuracy measured against the practitioner's diagnosis (Graber and VanScoy, 2003), and sometimes it was the other way round (Dong et al., 2005), raising the question; when does the CCDS recommendation carry more weight than that of the professional, and vice-versa? It is important that studies are clear about what is being measured, against what and why. One study overcame this issue by comparing agreement between Dr CCDS assessment and a gold standard (Farion et al., 2008).

Impact on patient outcomes

Of the five studies that measured patient outcomes only two were powered to assess the impact of CCDS. One of these demonstrated that CCDS had supported practitioners in appropriately triaging patients with chest pain, resulting in patients receiving appropriate care (Lorenzoni et al., 2006). The other found that, overall, CCDS actually led to reduced patient satisfaction when CCDS was used but the recommendations not adhered to (Porter et al., 2006). Two of the remaining studies were not powered to assess the impact of CCDS on patient outcomes due to problems with recruiting patients to the study because of low CCDS usage levels (Brown et al., 2007, Roy et al., 2009). The remaining study had included patient

outcomes in order to monitor them for safety reasons and had not been powered to report on these (Selker et al., 2002).

It is apparent from this review that there is very little evidence regarding the impact of face-to-face CCDS use on patient outcomes in emergency care. This reflects the situation in other areas of healthcare, where there is generally less evidence in relation to patient outcomes than process of care outcomes in CCDS research. Implicit in research that focuses on process of care is the assumption that by improving process of care, improved care outcomes should follow (Donabedian, 2005). However, evidence is also needed about the impact of these initiatives on patient outcomes. Where patient outcomes are to be assessed researchers need to take steps to ensure that studies are successfully powered.

Implementation and adoption issues

Three papers reported on implementation issues, mainly in response to having encountered serious implementation problems. It is possible that other studies in this review also encountered implementation issues, but did not report on them. Several authors alluded to the particular challenges associated with setting up and conducting research in the emergency care setting. Given the difficulties associated with undertaking research in the emergency care setting, it is possible that a better understanding of the factors associated with successful implementation could help researchers and service providers with implementing new technologies in the future.

While seven of the studies reported on adoption, only two of these set out to explore usage. These two studies were based on interviews and questionnaires with clinicians and provided useful insights into clinicians experience of CCDS. For example, practitioners were more likely to use CCDS if it was incorporated into standard practice rather than added-on. Also, for CCDS to be used by practitioners it had to work well and be acceptable to them.

The other five studies reported on adoption because they had encountered low CCDS usage levels that had affected the study. The reasons for low usage varied but included ease of use of the CCDS equipment, the time it took to complete CCDS, portability of equipment and practitioners that were disengaged or too busy.

The research in this review generally overlooked the opportunity to provide further evidence on the adoption element of CCDS initiatives. CCDS use is so fundamental to the success or failure of these interventions that it might be useful for usage to be measured more routinely in studies of this nature. This would ensure that both

positive as well as negative methods and findings related to adoption are reported. Only by identifying what the adoption issues are in CCDS research can researchers and practitioners begin to meet the challenges of addressing them.

Limitations

This review identified 20 studies that met the eligibility criteria for inclusion; however it must be noted that the search was limited to studies published in English between Dec 2000 and Jan 2011.

A wide range of study types were included in this review to provide a comprehensive overview of CCDS research in the emergency care setting. While this approach enables the author to provide a broad review of the range of CCDS uses and overall impacts in emergency care, it does not lend itself to meta-analysis. The heterogeneity between eligible studies in terms of study design, CCDS features and outcome measures precluded a meta-analysis to pool effect sizes. However, this review can be used as a basis for undertaking the next stage of research in this area; a meta-analysis of randomised controlled trials. The quality assessment scores indicate that the potential exists for a meta-analysis to be conducted on a selection of the papers in this review.

The quality of the studies included in this review was variable, ranging from poor to well-constructed. Studies with lower scores were more subject to internal bias. One study was particularly subject to external bias as there was a flu epidemic during the period of time that CCDS was introduced to increase the uptake of flu-vaccine (Venkat et al., 2010).

The vast majority of studies (19/20) were based in the ED, resulting in a bias in this review to CCDS in the ED setting. Finally, very few studies evaluated patient outcomes.

Conclusion

This review highlights that the emerging evidence on CCDS in emergency care is largely from the ED setting, with no studies included from prehospital care. The studies reported overwhelmingly on process of care. In contrast few set out to measure patient outcomes and those that did were not always able to achieve adequate study power. Positive impacts of CCDSs were reported in 15/19 (79%) of studies that evaluated CCDS in relation to process of care. Patient outcomes were only measured in 5/20 studies in the review, and only two of these reported its impact (one positive, one negative). Both CCDS implementation and usage were

often reported as an ad hoc response to problems encountered, rather than routinely, despite their importance in terms of successful studies of CCDS.

Chapter 4: Theoretical context for studying innovation in healthcare

4.1 Introduction

This chapter considers challenges associated with adopting and implementing innovative ways of working in healthcare, reviews literature, and presents a theoretical context and framework for the analysis of implementation and adoption of CCDS in this thesis.

4.2 Challenges associated with implementing and adopting innovation in healthcare

Getting practitioners to adopt and assimilate innovations is a challenge to healthcare providers. Recently a systematic review was commissioned by the Department of Health to increase our understanding in this area by exploring the issue of adoption and assimilation of technical innovations in healthcare (Robert et al., 2010). This review by Robert and colleagues 'explores the processes within healthcare organisations that influence not only the (often mandated) adoption and implementation of technological innovations but also their assimilation into routine practice' (p244). The study sought to identify which organisational factors and processes influenced whether or not, and the extent and rate to which such innovations were adopted in the NHS in England. The study also set out to identify what is known about the 'formal and informal processes internal to health care organisations that affect the speed and success with which beneficial technological innovations become part of the day-to-day clinical practice' (p 244).

The authors highlight that the majority of the empirical studies identified for inclusion followed a deterministic approach to this type of research, assuming simple causal relationships between variables. They claim that many of these studies overlook a) how different organisational settings influence individual behavior and decision making, and b) the importance of other contingent and contextual issues. They propose that there is more to be gleaned in relation to adoption and assimilation of new innovations from employing an approach that focuses more on technology in practice, for example through the application of Technology Structuration Theory (described later in this chapter).

Key findings from the study in relation to the process of adoption included the importance of the following:

- "the importance of the history, culture and quality of interprofessional relationships
- that there is often no single adoption decision
- the vital role of power and politics in determining the outcome of decision-making processes relating to innovation adoption and assimilation
- the impact of different types of decision-making processes (and that a short-term perspective predominates)
- that professionalism in healthcare can be a negative influence on adoption and assimilation". (p247)

Although the authors report that there is a gap in the current understanding related to the process of adoption and assimilation of technology innovations, they conclude that, 'In short, the adoption, implementation and assimilation of technological innovations comprise both social and organisational processes, and outcomes are largely determined by the dynamics within and between these.' (Robert et al., 2010) p249

4.3 Theoretical context for studies of the diffusion of innovations

This section presents the research and theory relating to the diffusion of innovations in healthcare, from the early influential work of Rogers in the 1960's to more recent publications including the systematic review of 'Diffusion of Innovations in health Service Organisations' (Rogers, 1995, Greenhalgh et al., 2005). It also provides an overview of the development of theoretical models for evaluating technology innovation in healthcare.

4.3.1 Rogers' Diffusion of Innovations Theory

Some of the most significant and influential early work in this field was developed by Rogers in his 1962 publication, 'The Diffusion of Innovations.' (Rogers, 1962). Rogers synthesised the research from over 500 studies and developed a theory for the way in which individuals and organisations adopt innovations. Ironically, Rogers cites as motivation for his work on this topic, the 'lack of diffusion in diffusion research', highlighting his frustration with the way in which the research community failed to learn from lessons across disciplines (Rogers, 1995).

Rogers defines an innovation as 'an idea, practice or object that is perceived as new by an individual or other unit of adoption. It matters little, so far as human behavior is concerned, whether or not an idea is objectively new as measured by the lapse of

time since its first use or discovery.' (p11) He defines diffusion as 'the process by which an innovation is communicated through certain channels over time among the members of a social system.' (p10)

The main thread of Rogers' findings is that the adoption of new ideas by people, and over time, follows a particular pattern. Rogers defines adoption as 'the decision to make full use of the innovation as the best course of action available'. (p37) This pattern of adoption can be divided up into four stages; the slow initial phase, an accelerated period (take-off), a deceleration, and a tail period where the last few people to adopt eventually do so. One way that diffusion researchers describe the people that fall into each of these adoption stages is as early adopters, early majorities, late majorities and laggards.

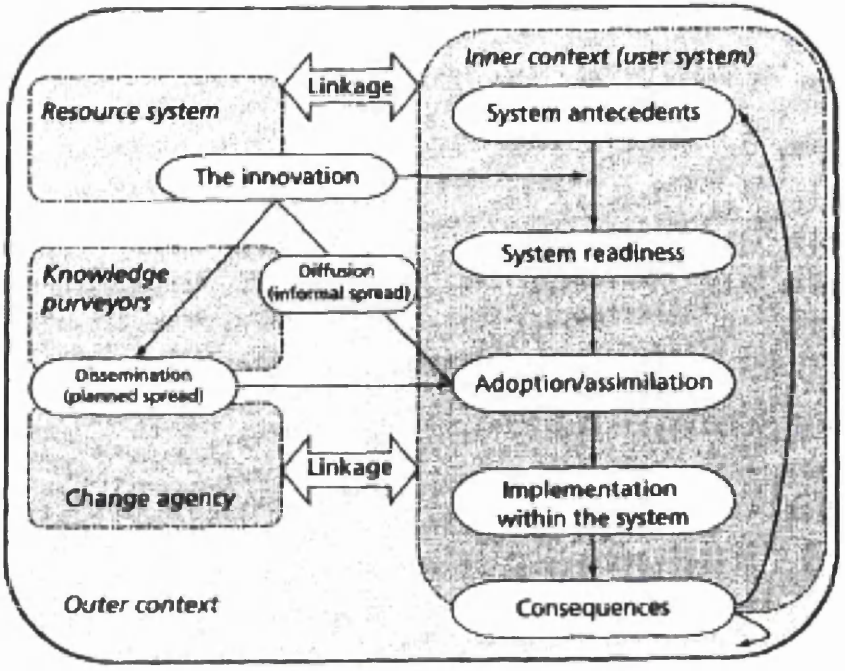
Rogers' work on diffusion has influenced much of the work in this arena, including the recent systematic review of the 'Diffusion of Innovations in Health Service Organisations', as commissioned by the Department of Health, and summarised below (Greenhalgh et al., 2005).

4.3.2 Diffusion of Innovations in Health Service Organisations: a systematic review

The systematic review by Greenhalgh et al identified 13 different research traditions that had produced evidence (largely independently of each other) relating to the diffusion, dissemination or sustainability of innovations in healthcare (Greenhalgh et al., 2005). The traditions included: rural sociology, evidence-based medicine and guideline implementation, narrative organisational studies and complexity studies, and they varied considerably in how they conceptualised innovation and its spread.

The authors highlight that there was no existing theoretical framework suitable for analysing their findings, so based on their synthesis of the evidence they developed the model below to serve as a 'unifying conceptual model' and an aid to those considering the elements of complex innovations and their many interactions.

Figure 2: A conceptual model for considering the determinants of diffusion of innovations in the organisation and delivery of health services



The key components of this model are summarised, along with some of the key findings, below.

- **Innovations:** while there are attributes of innovations that are more linked to success, these attributes in themselves, while key, are not predictors of success. 'Rather, it is the interaction between the innovation, the intended adopter(s) and a particular context that determines the adoption rate'. (Greenhalgh et al., 2005) p8 Attributes of innovations include: a clear relative advantage, compatibility with the intended adopters' values, norms and needs, simple to use etc.

- **Adoption by individuals:** Greenhalgh et al propose that people are more actively involved in the process than suggested by Rogers' model of early adopters and laggards. They identified 7 aspects of adopters and the adoption process that they used in their model. These include; general psychological antecedents, the meaning of the innovation for the intended adopter, the adoption decision (and to what extent that is contingent, collective or authoritative in nature), and how the concerns of the adopter are addressed at various stages during the adoption and assimilation process.

- **Assimilation by organisations:** adoption of an innovation at the organisational level is often called assimilation. Research in this area has tended to focus on individuals as the unit of adoption, however this overlooks the broader and more complex role of the organisation in the process of adoption. In main the evidence was of 'an organic and rather

messy model of assimilation in which the organization moved back and forth between initiation, development and implementation, variously punctuated by shocks, setbacks and surprises.' (Greenhalgh et al., 2005) p10

- **Diffusion and dissemination:** the authors describe the factors that influence the spread of an innovation as lying somewhere along the diffusion/dissemination continuum. They differentiate between the diffusion end of the spectrum, where innovation is spread passively (unplanned, informal, decentralised, and spread largely between peers) and dissemination, where innovation is spread actively (planned, formal, often centralised and via vertical hierarchies). The authors identified a number of elements that influence diffusion/dissemination. These include: the structure and quality of social networks, the influence of opinion leaders and champions, formal dissemination programmes etc.

- **The inner context: organisational antecedents for innovation:** some features of an organisation were found to influence the likelihood that an innovation was successfully assimilated (i.e. adopted by all relevant individuals and incorporated into 'business as usual'). Larger, mature organisations with specialised teams and resources for new projects, organisations that are systematically able to work effectively with (or absorb) new knowledge and organisations that provide a receptive context for change were all identified as being better able to assimilate innovations.

- **The inner context: organisational readiness for innovation:** the authors found that while an organisation may be amenable to an innovation in general, in reality they weren't ready or willing to assimilate it. Elements indicating organisational readiness include: a desire for change by staff, if the innovation is compatible with the organisation's goals and values, if the impact of the innovation has been fully assessed and anticipated, the number of supporters for the innovation, adequate and ongoing resources and capacity to evaluate the impact of the innovation.

- **The outer context: inter-organisational networks and collaboration:** a number of external influences were identified as influencing organisations' decisions to adopt, implement and sustain an innovation. These included whether other similar organisations had done so, or a policy 'push' coinciding with the implementation of an innovation.

- **Implementation and routinisation:** the evidence relating to implementation, defined as 'the early usage activities that often follow the adoption decision' (Meyers et al., 1999), was both complex and sparse. Routinisation (or sustainability), is defined as 'when new ways of working and improved outcomes become the norm' (NHS Modernisation Agency, 2003). In addition to system readiness, other elements associated with successful routinisation include: an adaptive organisational structure that supports devolved decision making, support at top and middle management levels, the motivation, capacity and competence of individual practitioners, early and widespread involvement of staff, dedicated and ongoing funding,

effective communication within organisations, timely feedback, and when an innovation is adapted to fit the local context.

- **Linkage between components of the model:** the authors identified evidence for building strong links between the components of their model. For example, linking the developers of an innovation with the potential users at an early stage of development, ensuring positive links, communication and compatibility between adopter organisations and change agencies.

This is a useful conceptual model for evaluation of innovation in the health service, highlighting the multiplicity of human and technological factors, context dependent variables and interactions between them that are part of the innovation process.

Other theoretical approaches for evaluating innovations in healthcare include Structuration Theory, Technology Structuration Theory, and Strong Structuration Theory. These are described in more detail below.

4.3.3 Theoretical approaches to evaluating innovations in healthcare

Greenhalgh and Swinglehurst (2011) argue that the philosophical assumptions (that is, positivistic and deterministic) underlying controlled experimental and quasi-experimental studies hugely oversimplify the social setting in which technologies are adopted. They make the case that researchers in this field need to study information and communication technologies (ICTs) as part of complex social systems.

> *"Studying how technologies are used in social practice moves us on from studying either people or technologies (just as the study of drumming moves us on from studying either the drummer or the drum)." (Greenhalgh and Swinglehurst, 2011) p3*

Structuration Theory

One theoretical approach that has been widely applied in relation to ICT research (Jones and Karsten, 2008) and that does not overlook the influence of context was developed by sociologist, Giddens (Giddens, 1984). Giddens' Theory of Structuration gives weight to both social structures and human agency in determining an individual's behaviour. Giddens proposes that human agency and social structure are in a relationship with each other and it is the repetition of the acts of individual agents which reproduces the structure. Therefore, the social structure (traditions, institutions, moral codes etc.) can be changed when people start to ignore them, replace them, or reproduce them differently. The Structuration Theory approach is described below by Greenhalgh as bringing together;

> *'objectivist social theories (which assume that a hard social reality exists independently of individual actors and is to a large extent deterministic of their actions) and subjectivist*

ones (which assume that no social reality exists except the one that individuals construct in their interpretations and perceptions). Social actors are knowledgeable, active agents who may either reproduce social structures faithfully or choose to change them by behaving differently.' (Greenhalgh, 2010). p1286

Technology Structuration Theory

Building on the work of Giddens', Barley applied Structuration Theory to underpin research into technological change in healthcare (Barley, 1986). Barley's study investigated the introduction of a CT scanner at two different hospitals. He found very different impacts at each site; at one there was a huge impact on the interactions and social order of the clinicians and technicians involved in the study, at the other site there was hardly any change. Barley was able to demonstrate that although new technology provides opportunities for change in the social order of the organisation, it did not in itself determine that change. Robert summarises Barley's approach, below:

'Technology Structuration Theory explores how in adopting (or choosing not to adopt, or finding that they are unable to adopt) a specific technology, human actors are influenced by a pre-existing organizational context ('meso') and by wider social structures ('macro') which include norms, symbolic meanings and the availability of resources, and their behaviours and actions in turn feed back on these external structures... A technology structuration perspective could help explore issues such as: how do teams collaborating around common tasks (e.g. multidisciplinary care of a patient) negotiate how their respective roles and practices will be shaped and aligned, and how do the material properties and constraints of the technologies impact on this in different settings?' (Robert et al., 2010) p248

Greenhalgh and Stones review the development of Technology Structuration Theory, providing the summary below based on the work of Orlikowski et al:

'Technology Structuration Theory considers how organisational actors, working collaboratively around common tasks, engage in a process of adapting the meaning, properties and applications of the technologies to a particular context, and a parallel process of adapting the context to the technology; this process in nested within the overarching duality between structure and agency'. (Greenhalgh, 2010) p1287

However they go on to highlight criticisms that the technical dimension in Technology Structuration Theory is under-theorised as "technical artefacts 'do' things that can't be attributed or reduced to social practice" (p1287) and also that time and evolution are not given enough analytical weight (Greenhalgh, 2010). Instead they propose Strong Structuration Theory (SST) with a technology dimension.

Strong Structuration Theory

Strong Structuration Theory (SST) builds on the more abstract work of Giddens to provide a methodological framework for empirical analysis (Stones, 2005). SST continues to recognise the importance of the recursive relationship between structure and agency, proposing four components of this relationship that can be studied empirically:

- external structures (conditions of action)
- internal structures within the agent (how and what individuals 'know')
- active agency (in which agents draw, routinely or strategically, on their internal structures)
- outcomes (in which both external and internal structures are either reproduced or changed)

Stones' framework for studying innovation involves identifying the key agent (in this study, the paramedic) and then identifying the internal and external agents and structures associated with that key agent (the political and organisational context) and then exploring the recursive relationship between these elements in order to understand how new processes (outcomes) are, or are not, adopted in practice. In order to address the issue of the role of the technology itself as having a recursive relationship with each of these, the approach was adapted to incorporate a technology dimension (i.e. technology itself also has agency in this relationship). SST provides a theoretical framework for addressing issues related to the implementation of technology based interventions in complex settings, such as healthcare, and will be used as the theoretical underpinning of this thesis.

4.4 Summary, critical analysis and conclusion

The literature on the way in which new technologies have been adopted has its origins in the 1960s, with the work of Rogers on 'Diffusion of Innovations Theory', which argues that the adoption of technology follows a predictable pattern of spread from individual to individual through a social system (Rogers, 1995). Subsequent work on innovation has incorporated ideas from Giddens' Structuration Theory, addressing the influence of context by giving weight to both social structures and human agency in determining an individual's behavior (Giddens, 1984).

This PhD is concerned with how innovation is shaped by organisational structures, individual decision making and technology and the relationship between the three.

Strong Structuration Theory was chosen as providing the most appropriate theoretical framework as it takes account of all three elements and, unlike Technology Structuration Theory, does not under-theorise the technology component. The author has followed the published advice of Greenhalgh et al, drawing on an extensive review of diffusion of innovations in healthcare, in selecting Strong Structuration Theory incorporating a technology dimension as a methodological framework for empirical analysis (Greenhalgh, 2010).

A potential weakness of this theoretical approach in relation to evaluation of the implementation of CCDS by paramedics is the emphasis on the technology itself as having agency. While it is critical that the technological dimension is incorporated into the evaluation, the proposition that technology has agency in the same way as individuals is questionable. This thesis will apply Strong Structuration Theory incorporating a technology dimension to the study of the implementation and adoption of CCDS in the prehospital setting.

Chapter 5: Methods

5.1 Introduction

This chapter sets out the aims and objectives, the study design and setting, and a detailed description of the methods. A mixed methods approach was adopted incorporating both a quantitative and qualitative component.

The methodology for the quantitative element of the study is presented in line with the CONSORT (Consolidated Standards of Reporting Trials) guidelines (Moher, 2010). The methodology for the qualitative strand of the study is presented in line with the COREQ (Consolidated Criteria for Reporting Qualitative Studies) checklist (Tong et al., 2007).

5.2 Study aim

The aim of this PhD is to examine the adoption of CCDS by paramedics, including the impact of CCDS on paramedic role and practice.

5.3 Objectives

1) To describe implementation of CCDS - to tell the story of how the technology was introduced and supported

2) To examine how paramedics used CCDS

- frequency of use
- patterns of use
- compliance

3) To assess the impact of the introduction of CCDS on practice through measures of processes of care

- patient dispositions (onward care)
- operational indicators (job-cycle times)
- clinical documentation

4) To explore paramedics' responses to the introduction of CCDS

- attitudes towards CCDS technology prior to and post implementation
- paramedics' experience of the CCDS implementation processes

- training/support
- ergonomic issues (ease of use/practicality)
- organisational factors
- cross-organisational working

- factors affecting paramedics' adoption of CCDS
- views on the impact of CCDS on paramedic practice and role
  - decision making processes
  - perceptions of autonomy and risk

5.4 Study design

A mixed methods approach was employed for this study. Qualitative and quantitative data were collected from two study sites between November 2009 and October 2010. Qualitative and quantitative data were collected simultaneously, the data were then analysed for each strand and the findings synthesised. This approach has been defined as a concurrent/triangulation mixed methods design with merged results. (Plano Clark, 2008)

A mixed methods approach was adopted in order that a variety of data could be collected, providing the opportunity for triangulation to enhance analysis and understanding of the findings. Qualitative approaches have been found to be particularly useful in understanding the processes of cultural and organisational change associated with complex interventions in health and social care that cannot be captured using quantitative methods alone (Pope and Mays, 1995, Lewis S et al., 2009). Data from the qualitative element of the study were used to explore, clarify and understand in more depth the CCDS usage data that was captured quantitatively.

For this thesis data were drawn from the SAFER 1 Cluster Randomised Controlled trial (C-RCT) for further analysis and detailed reporting of the data in relation to the aims and objectives of this PhD. Cluster randomisation has been recommended by the MRC as an appropriate approach where the intervention is targeted at health professionals with the aim of studying its impact on patient outcomes. (MRC, 2002) As the healthcare innovation under investigation was designed to be used by paramedics who could not turn their new skills on and off it was necessary to adopt a 'cluster' approach to randomisation with paramedics as the unit of cluster. For the trial paramedics were randomised into either the control (no CCDS) or intervention (CCDS) group.

Reporting of the quantitative aspects of the study is in line with the CONSORT guidelines (Moher, 2010). A table summarising SAFER 1 trial specific CONSORT information can be found in Appendix 6, for reference.

5.5 Important changes to methods after trial commencement

As a result of study site recruitment and retention problems the study was conducted at two study sites rather than three.

5.6 Study setting

Two ambulance service trusts participated in the trial, providing a study site in both Wales and England. The study was conducted in areas within these ambulance services where a falls referral pathway was available. For the purposes of anonymised reporting the ambulance services will simply be referred to as study site one and study site two. One of the study sites was an urban centre where paramedics were recruited from four ambulance stations; the other covered a wider mixed urban and rural area with paramedics recruited from nine stations.

There were some differences between the study sites, detailed below.

5.6.1 Study site one

At study site one the hardware (tablets, printers and chargers), EPRF software, CCDS software and falls referral pathways required for the study were implemented simultaneously. They were introduced purely for the purposes of the study and rolled out on a small scale, solely for use by study paramedics. The study site assigned an operational manager to support implementation and be the point of contact for paramedics involved in the study, but there was no dedicated person appointed to support implementation at this site.

5.6.2 Study site two

At study site two the hardware, EPRF software and falls referral pathways were already in place across the service. CCDS software for use by study paramedics was the only element of the intervention that was implemented at this site. At study site two the CCDS implementation was supported by a research paramedic who was deployed to support CCDS implementation at both the paramedic and the organisational level.

5.7 Participants

5.7.1 Paramedics

Paramedics from the two participating ambulance services, who were based in the catchment area of participating falls services and in locations where the study hardware was available, were eligible to participate. Paramedics were invited to volunteer via letters, flyers, posters and by direct invitation from ambulance service personnel involved in the trial. Participation was voluntary and no reward was offered. Twenty paramedic volunteers were required to participate at each site so we endeavoured to recruit 24 per site to allow for attrition. At the end of the recruitment period the paramedics were randomly allocated at each site to either the intervention group or the control group by the trial statistician.

5.7.2 Patients

Although the main participants for this thesis are the paramedics, data on CCDS use are reported in relation to patients in some instances, therefore the eligibility criteria for patients are also defined: 'Patients who were aged 65 and over, for whom a 999 call was made and who were categorised by the emergency call taker as having had a fall without priority symptoms, who were attended by a study paramedic during the recruitment period and who lived in the catchment area of participating falls services (excluding those living in residential care) were eligible for inclusion. No patients were excluded due to other conditions or competence, in order to maximise the generalisability of findings. Patients were recruited into the control or intervention arm of the study on the basis of their first contact with a study paramedic during the recruitment period, subsequent contacts were reported as outcomes.' (Snooks H et al., 2010)

5.8 The intervention

The intervention consisted of CCDS falls assessment software to be completed face-to-face by paramedics using a hand-held computer when attending eligible older patients who had fallen. The aim of the intervention was to support paramedics in their decision making regarding onward care for this vulnerable patient group. Elements of the intervention and its implementation across sites are described in more detail below.

5.8.1 CCDS software

The CCDS software (developed by Plain Healthcare) provided paramedics with an algorithm based assessment (including prompts) to aid their assessment and examination of older patients who had fallen. It covered injuries that may have been associated with the fall and co-morbidities that may have contributed to the fall (such as breathlessness or chest pain) and the patient's psycho-social needs (such as their mental state and their ability to undertake activities of daily living) plus an assessment of environmental risk. Based on these assessments, the CCDS suggested an appropriate care plan. For this study the appropriate care plan options were either to convey the patient to hospital or to refer them to their GP or a community based falls service, or both.

At study site one the CCDS was accessed through the EPRF software (i.e. the EPRF software had to be used before CCDS could be). At study site two the CCDS was accessed as a stand-alone piece of software. EPRF and CCDS were not integrated at either site, however they were linked at site one.

5.8.2 Paramedic training and practice

Paramedics assigned to the intervention group were trained to use the CCDS. At study site one, training was provided during a full day small-group training session, consisting of systematic demonstrations of the computer hardware, EPRF and CCDS software, followed by supervised practice. Following a delay between initial training and the study going live at study site one, paramedics were offered refresher training. At study site two the CCDS training was provided during half day training sessions. Paramedics at study site two were already trained to use the hardware and EPRF. Initial training at both sites was provided by the software company trainers. Subsequent training was provided by ambulance service staff that had themselves been trained to train their colleagues for this study. Paramedics were given a one month practice period to use the system with patients prior to data collection commencing.

5.8.3 Instructions to intervention and control group paramedics

Intervention group paramedics at both sites were instructed to use CCDS with all patients who had been categorised by the 999 call taker as having had a fall.

Control group paramedics at both sites were instructed to provide care as usual to the patient group. Although it was not possible to standardise practice in the control group across sites, several features of 'care as usual' were required for participation, including that control group paramedics were trained in assessment skills for leaving

patients at home, any decision support or protocols they used should be paper-based.

5.8.4 Paramedic links to falls referral pathways

Paramedics in both intervention and control groups had access to the community based falls referral pathways at both sites. At site one these links were put in place to coincide with the start of the study whereas at site two these links were already in place.

5.8.5 Differences in the intervention between study sites

As there were organisational and operational differences between ambulance services it was necessary to introduce the intervention in different ways at the study sites. At site one the CCDS software was accessed remotely via the internet by mobile phone connection, with data transferred wirelessly, at the time of use to a secure data storage facility. At site two the EPRF and CCDS software were stored and accessed locally on the tablet computers and patient data were saved securely on the computer until downloaded onto a database at the ambulance service. Different EPRF software providers were used at the two study sites reflecting the ambulance services' preferred providers of this software (Ortivus and Medusa). Differences between the implementation of the intervention at study sites are described in more detail in Chapter 6.

5.9 The quantitative study

This section provides methodological information related to the quantitative C-RCT element of this study in line with the CONSORT guidelines for reporting on trials .

5.9.1 Outcome measures

There were no changes to the PhD outcome measures after the study commenced.

1) CCDS usage
- frequency of CCDS use
- patterns of CCDS use
- compliance with treatment and referral protocols

2) Processes of care
- patient dispositions
    - proportion of patients taken to hospital

    - proportion of patients left at scene without onward referral
    - proportion of patients left at scene with onward referral
- operational indicators
    - on scene time
    - job cycle time
    - episode of care
- clinical documentation

CCDS usage data were obtained from the ambulance services and (at study site one) from the CCDS software provider. Patient dispositions were obtained from the ambulance service. On-scene time (the interval between the time of arrival of the ambulance at patient and leaving the scene of the call) and job cycle time (the interval between 999 call and completion of call/ambulance free) and episode of care (interval between 999 call and completion of care - including time at ED) were derived from routine ambulance and ED records for all calls meeting the study inclusion criteria. Completeness of clinical documentation relevant to the care of older people who fall was assessed from Patient Clinical Records and EPRFs completed by paramedics.

5.9.2 Paramedic sample size

The paramedic sample size was calculated to power the SAFER 1 trial in terms of patient recruitment. Initially the paramedic sample size was 60, but this was recalculated after the trial commenced to reflect a reduction in the number of trial sites and removal of the six month patient follow-up:

> *"In reducing to two sites, we planned to recruit 40 paramedics in all. In dropping the 6-month follow up, we estimated that the proportion of participants making a further emergency call for a fall within one month would be closer to 30%, and that a reduction to 20% would be clinically significant. Experience in designing SAFER 2 (a trial in a similar patient group and setting which began after SAFER 1) led us to reduce the estimated IPCC to 0.02. Hence, if each paramedic were to recruit 22 patients, making 880 in all, our power to detect a clinically significant difference when using a 5% significance level would remain at 80%." (Snooks et al., 2011) p59*

Based on this recalculation the paramedic sample size required was 40 (20 per site), with 24 paramedic volunteers sought at each service to allow for attrition.

5.9.3 Method of randomisation to study group

Paramedics were randomised to the control or intervention groups by the trial statistician using simple randomisation in line with advice from The West Wales Organisation for Rigorous Trials in Health (WWORTH). Randomisation took place post recruitment of paramedics and prior to implementation of the intervention. Random allocation of new paramedics to study groups to replace any who withdrew was weighted towards the depleted study arm. The trial statistician generated the random allocation sequence from random number tables and, still blinded, sent this to the trial co-coordinator who then informed the ambulance service and the paramedics who were in the control and intervention arms of the study. The trial statistician remained blinded to which paramedics were in the control and intervention arms of the study throughout the randomisation process.

5.9.4 Statistical methods

In order to analyse the quantitative data a combination of binary logistic regression models (using a staged analytic strategy), T-tests and two-way analysis of variance were applied, as appropriate. Equal variances were assumed.

In order to determine the impact of CCDS on process of care, intervention and control group data were analysed by treatment allocated. Further analysis was conducted to determine the impact of CCDS on process of care based on treatment received (i.e. when CCDS was used).

A formal sample size calculation was not required for this thesis as the main trial was powered to detect differences in patient outcomes. The sample size of the main trial was adequate to detect important differences between groups for the purposes of the thesis. Data analysis was carried out using SPSS version 19 (IBM Corp, 2010).

Results are presented with an appropriate number of decimal places for the analysis carried out. with usually at least three significant figures; this leads to a generally consistent presentation of summary values in tables, with occasional variation.

5.10 The qualitative study

For the qualitative element of the study data were collected from intervention group paramedics through focus groups and semi-structured interviews in order to explore their attitudes towards CCDS and its implementation, their views on and experience of using CCDS and how they felt it impacted on their role and practice. The data

were collected at three different time points during the study and analysed using the Framework approach (described below) in order to address objective 4.

5.10.1 Methodological approach

The methodological approach employed to analyse the qualitative data is the 'Framework' approach. (Ritchie J and Spencer L, 2002) The Framework approach was developed for applied policy research to enable researchers to handle and analyse data in a systematic and rigorous way with a view to providing timely outputs to influence policy and planning. It provides a method for researchers to systematically sort and analyse data in relation to key issues and themes. A key strength of this approach is that it is well suited to addressing specific research questions in the light of large quantities of data and finite timeframes.

Framework involves five stages of analysis: familiarization, identifying a thematic framework, indexing, charting, and mapping and interpretation. A summary of each of the stages is provided below.

- The familiarization stage involves the researcher becoming familiar with the data, immersing themselves in it as much as possible through reading and listening and beginning to form ideas and make notes about the emerging issues and themes.
- The second stage involves setting up a framework based on the key issues, concepts and themes. These are based on the original research aims and questions, issues raised by respondents and recurring themes emerging from the data. This stage requires ongoing revising and defining.
- The Indexing stage is where the framework is applied to the data, and the data is linked to the themes.
- Charting the data requires the analyst to review the data theme by theme. A chart of headings and sub-headings emerging for each theme is developed and the data from these is summarised in relation to the chart (with the original source text referenced).
- Mapping and interpretation is the key analytical stage in the Framework process and involves the researcher reviewing the original research questions in light of the data that has emerged; "the analyst reviews the charts and research notes; compares and contrasts the perceptions, accounts, or experiences; searches for patterns and connections and seeks explanations for these internally within the data. Piecing together the overall picture is not simply a question of aggregating patterns, but of weighing up the salience and dynamics of issues, and searching for a structure rather than a multiplicity of evidence." (Ritchie J and Spencer L, 2002)

As part of the last stage of the process, the researcher synthesises and interprets the data in order to define concepts, map the range and nature of phenomena, create typologies, provide explanations and develop strategies in relation to the research questions and objectives.

5.10.2 Data collection

Intervention group paramedics were invited to take part in focus groups or semi-structured interviews at three time points during the study. The time points were chosen to reflect key points of their involvement in the trial, i.e. pre, during and post the CCDS usage period. The mid-point data were collected and analysed in addition to the data collected for the SAFER 1 trial, solely for this thesis.

All intervention group paramedics were invited to participate in pre and post trial focus groups and/or semi-structured interviews. Where focus groups were not operationally feasible, a minimum of four interviews per site were conducted instead.

Eight paramedics (four per site) were sought to participate in the mid-point interviews. Systematic sampling with a randomised starting point was used to select the sample (and order) of paramedics to be invited for interview.

Paramedics were invited to participate in focus groups and interviews by a combination of emails, telephone calls and face to face invitation from study researchers and ambulance personnel who were involved in the study.

Paramedics involved in the study either worked as lone responders in cars known as rapid response vehicles (RRVs) or as part of double-staffed crew on Emergency Ambulances (EAs).

5.10.3 Interviewers/facilitators

Data collection was carried out by four health and social care researchers (two male and two female, aged 30 to 45) with previous training and experience in facilitating focus groups or conducting interviews. All four interviewers were members of the SAFER 1 research team. None had a relationship with the participants prior to the commencement of the study. The researchers introduced themselves to the participants as researchers employed by Swansea University to work on the SAFER1 trial. It was also explained to them that the data would be used for both the trial and a PhD study linked to it.

The focus group facilitators and interviewers were part of the core SAFER 1 research team. It is possible that this lack of independence from the research might have introduced the potential for both interviewer bias (where the interviewer subconsciously influences the subject into giving answers that reflect their own opinions, prejudices and values) and response bias (where the interviewee consciously, or subconsciously, gives responses that they think that the interviewer wants to hear).

5.10.4 Sample size

In total, 20 of a possible 22 (17 male and 5 female) intervention group paramedics participated in at least one of the data collection exercises. 12/20 contributed to one period of data collection, 6/20 to two and 2/20 to three of the data collection periods.

Table 6: Intervention group paramedic participation in qualitative study

	Pre CCDS use focus group	Pre CCDS use interview	Mid CCDS use interview	Post CCDS use interview	Total no of participating paramedics
No of site 1 paramedics	9	0	4	4	13/14
No of site 2 paramedics	0	5	4	5	7/8

Five of the paramedics who participated in the pre CCDS use focus groups at site one withdrew from the trial prior to its going live. Two of these withdrew due to long-term sickness, two were moved out of the study area prior to its going live and one gave no reason. No other paramedics who were involved in the qualitative study withdrew.

5.10.5 Participant characteristics

The table below provides demographic and other study relevant information relating to the 20 paramedics involved in the qualitative element of the study.

Table 7: Age and experience of participating paramedics

	Site 1	**Site 2**
Mean age	35.5	43.8
Mean length of service	11.2	10
Mean years as a qualified paramedic	6.4	6.8

The average age of paramedics was higher at study site two; however the mean length of service and time spent as a qualified paramedic were comparable across

sites. The post-qualification experience as a paramedic in the two groups ranged from three to 20 years.

Table 8: Self-reported IT skills of participating paramedics

Intervention group IT skills	Site 1	Site 2
Good	1	5
Okay	5	2
Poor	2	0

Although not all paramedics responded to the question about their IT skills, the responses above suggest that paramedics at study site two were more confident in their IT skills than those at study site one.

5.10.1 Focus group topic guides and interview schedules

Semi-structured interview schedules and focus group topic guides were developed by the author with advice and feedback from the research team, Trial Steering Committee and local implementation teams. The author piloted these initially with members of the research team and then with either a paramedic or manager from the ambulance service. They were designed to address the objectives of both the SAFER 1 trial and the PhD.

The topic sheets and interview schedules included questions on the key themes, with a number of prompts for the interviewers to use. As there were only minor changes made post piloting (to question order and some wording improvements) pilot data were included in the analysis. A copy of the focus group and interview schedules can be found in Appendices 11 and 12.

The interview schedules and topic guides were designed to examine paramedics' attitudes towards new health technology in general as well as their experience of and views on the impact of CCDS on their role, practice and decision making. They were also used to explore sensitive topics such as organisational support for new practice and the role of peer pressure in influencing adoption of CCDS.

5.10.2 Focus groups and interviews

Focus groups were selected as the preferred data collection tool for the pre and post trial periods of data collection. This is because the dynamic setting of a small group has the potential to elicit data above and beyond what might be prompted through semi-structured interviews alone (Puchta, 2004). However, in practice it was difficult to arrange focus groups due to paramedic shift patterns and other operational

pressures. As a result only two focus groups were conducted (pre-trial at site one). These were carried out alongside paramedic CCDS training at site one in a small group meeting room at Swansea University. The author facilitated both focus groups, supported by a second researcher from the study team. A third member of the study team sat in on both focus groups. A member of the CCDS training team sat in on the first focus group. The focus groups took in the region of an hour each.

Semi-structured telephone interviews were conducted to collect the rest of the qualitative data. These interviews included a face-to-face small group interview with two paramedics, mid trial, at site one. Interviews were carried out over the telephone at a time convenient to the paramedics. The duration of the interviews ranged from 20 to 50 minutes with an average length of 34 minutes. The author conducted the majority of the qualitative interviews. The author also trained the other study researchers in use of the interview schedules in an endeavour to ensure a standardised approach to data collection.

Consent

Prior to interviews and focus groups participants were given or sent a copy of the study information sheet explaining what participation entailed to help inform their decision regarding participation and two consent forms. Paramedics who wished to consent were asked to sign one of the forms and return it to the research team and to keep the other one for their records. A copy of the letter sent to the paramedics, and the study information sheet and consent form can be found in Appendices 8 and 9.

Two interviewers discussed data saturation towards the end of the scheduled interviews and reached agreement that, as no new issues or themes were emerging, data saturation had been achieved.

All focus groups and telephone interviews were recorded using digital voice recorders. The data were then transcribed and entered into NVIVO (QSR International Pty Ltd., 2008), a software package designed to support qualitative data management and analysis. Transcripts were not returned to participants for comment or correction.

5.10.3 Data analysis

The qualitative data were analysed thematically according to the principles of Framework for applied policy research (Ritchie J and Spencer L, 2002). In total two focus groups, 20 interviews and one small group interview (with two paramedics)

were transcribed and analysed. Data were managed electronically using the NVIVO software package. The five stages of Framework along with a summary of how the author conducted the research at each of the stages is presented in the table below.

Table 9: The 5 stages of Framework

Familiarisation	The researcher listened to both focus groups and read through all the transcriptions.
Identifying a Thematic Framework	The researcher made notes and highlighted key sections of transcript in order to identify the key issues, concepts and themes arising from the data that were relevant to the aims and objectives. An overarching thematic framework was developed. The initial framework was applied to several transcripts and the categories (or index) refined to reflect more closely the emerging analytical themes to reflect the diversity of experiences, attitudes and patterns emerging from the data. A second researcher independently applied the framework to the same transcripts and a high level of overlap/agreement on the framework was found.
Indexing	The framework was then applied to the full data set by the researcher and emergent issues identified were categorised and placed appropriately within the framework for further analysis.
Charting	Headings and subheadings were developed according to core themes emerging.
Mapping and interpretation	Key characteristics of the data were pulled together and, to map and interpret the data set as a whole in the light of the research objectives, a model was developed (see Chapter 8) against which the findings are presented.

The data were coded using the Framework approach, building on the initial work in the SAFER 1 study (Ritchie J and Spencer L, 2002). A Framework was developed by the author according to the PhD objectives and cross-checked with a second researcher who had independently familiarised herself with a selection of transcripts and an overarching framework agreed. A second researcher was asked to contribute in this way in order to enhance objectivity in the process (Barry C et al., 1999, Barbour, 2001).

5.10.4 Thematic Framework

The recurring themes emerging from the interviews and focus groups divided broadly into five main categories: personal, organisational, technical, practical and consequential, with some overlap between the five. These are presented below.

Table 10: Emerging themes and sub-themes

Framework	Sub-themes
Personal (paramedic)	Views on paramedic role Attitudes to CCDS (pre and post) IT experience and skills Motivations and commitment Suitability of CCDS for paramedics, patients, emergency care setting Interpretation and ingenuity
Organisational (implementation)	Training Delays post training System functionality Organisational support (managerial, operational, technical, colleagues) Organisational/operational pressures and expectations Feedback for paramedics
Technical (CCDS)	Functionality and fitness for purpose Integration with ePRF Value of clinical documentation Paper versus computer Audit and data retrieval Security and confidentiality
Practical (adoption)	Situational considerations Practicalities of use Barriers and benefits to use

	How and when CCDS used Completion techniques Future use
Consequential (views of impact on practice and role)	Impact on decision making Impact on practice Impact on patient care Working with others Professionalism and skills Autonomy and risk Demands and responsibility Future directions

At the final mapping and interpretation stage of the process key characteristics of the data were pulled together and, in order to map and interpret the data set as a whole in the light of the research objectives, a model was developed against which the findings are reported in Chapter 8).

Quotation selection

Quotations were selected to illustrate the main messages and themes arising from the data. They were also chosen to reflect similarities and differences both over time and across study sites as well as from a wide range of the paramedics involved in the study. Where quotations are used to illustrate points that were not commonly made this is referred to in the accompanying text.

5.10.5 Limitations of the study design

This complex piece of research was carried out in the dynamic setting of the emergency services where the research agenda is not a priority; consequently, a pragmatic approach was required.

Quantitative study limitations

The main limitation relates to the implementation of the intervention at study site one where the CCDS software was introduced simultaneously with the hardware (tablet computers, printers and chargers) and the EPRF. At study site two the CCDS was introduced as an add-on piece of software to paramedics who were already trained

to use and familiar with the hardware and electronic PCR. The impact of this difference meant that CCDS usage levels at site one were potentially affected by issues related to implementation of the whole system, confusing the picture of CCDS use per se.

Connectivity issues at site one also potentially affected paramedics' ability to use CCDS and could also have resulted in some CCDS usage data being lost.

The paramedics who took part in this study were volunteers (a self-selected group) rather than a random selection, thereby limiting the generalisability of the results. Many who took part were very experienced practitioners, with long records of service, again raising concerns over representativeness and generalisability.

Qualitative study limitations

Although it was hoped that it would be possible to arrange focus groups at both sites at the pre and post-trial data collection points, this was not possible to achieve operationally and semi-structured interviews were conducted instead. As a result only two focus groups were achieved, both at site one pre-trial. It is possible that richer data relating to the paramedics experiences and attitudes towards the CCDS and using it would have been elicited by a focus group methodology, particularly at the post-trial time point.

Critical analysis of the methods

Although the intervention involved use of a software package that was not available to control group paramedics, contamination between study arms was still a possibility through intervention and control group paramedics working together. Control group paramedics could potentially adopt elements of the CCDS falls assessment from working with intervention group paramedics. One way to reduce the potential for such contamination in the future would be to randomise ambulance stations rather than paramedics as the unit of clustering, thereby reducing the opportunity for intervention and control group paramedics to work together. This approach has subsequently been adopted in the SAFER 2 trial (Snooks et al., 2012).

For pragmatic reasons we used cascade training, an approach that involves 'training the trainer' who then trains their colleagues and peers. For this study several paramedics and one operational manager were trained by the software specialists to train their colleagues in use of the study technology. This approach has the advantage of overcoming operational difficulties with arranging training for groups of

paramedics (e.g. shift patterns, pressure to keep paramedics on the road). A drawback to cascade training is that it is delivered by non professional trainers, who themselves are relative novices in use of the technology. This means that it can be difficult to ensure training standards. Competency testing for paramedics was planned at one month post training, but in reality was not delivered. Measures to help address these concerns in future studies include introducing quality monitoring for cascade trainers and thorough competency testing in use of the technology for trainees.

The author conducted the majority of the semi-structured interviews with paramedics and facilitated both focus groups, ensuring that she was fully familiar with the data and able to understand and conduct all data analysis. A potential drawback to this approach to data collection could be a lack of consistency between datasets. The author took steps to prevent this through thorough pre-interview training of all interviewers.

Chapter 6: Research setting and the intervention

6.1 Chapter overview

This chapter provides a background to the research undertaken for this thesis. It describes the development of the CCDS intervention, from original concept to the systems as they were implemented at two ambulance service study sites. It describes a range of challenges that were faced in recruiting and retaining study sites including; the implementation of a national technology programme in England, major ambulance service reorganisation, and legislation that increased the pressure on ambulance services to meet time-based operational targets (shifting the focus of ambulance service resources towards meeting operational targets, rather than research) and the introduction of new ethics and information governance procedures. This chapter also provides an account of the challenges encountered by the participating ambulance services in adopting and implementing the technology, and outlines some of the measures put in place to address these.

6.2 Factors affecting recruitment and retention of study sites

During the course of the set-up of the study several factors affected ambulance service recruitment and retention, for example the introduction of a National Programme for IT (NPfIT) in England (Department of Health, 2010b). The publication of 'Taking Healthcare to the Patient' also had a significant impact on ambulance services, requiring ambulance service reorganisation that reduced the number of ambulance services in England from 33 to 11 (Department of Health, 2005). This publication also revised the standardised reporting of ambulance service response time measures, increasing the pressure on ambulance services to meet existing time-based performance targets through an initiative called 'Call Connect' (Department of Health, 2005). Other pressures that adversely affected the ability of ambulance services to participate in the study included the introduction of new research and development and information governance procedures.

6.2.1 Ambulance service IT developments

During the early stages of study set-up it became apparent that the data collection period for the project was going to coincide with the roll-out of the Government's National Programme for IT in England. The programme set out to replace the paper-

based patient report forms used by paramedics with an electronic patient report form (EPRF) during the same time-frame as this project was to introduce CCDS. The EPRF programme required ambulance services in England to choose their preferred EPRF software from a small number of selected providers. In Wales the National Assembly also had plans to introduce electronic patient report forms through its 'Informing Healthcare' programme, although the timeframe for this was still under discussion (Welsh Assembly Government, 2003).

The implementation of EPRF in England provided both a challenge and an opportunity for the research team. The challenge was to find a way forward with the English (and potentially Welsh) ambulance services involved that did not conflict with their EPRF implementation timetables. The opportunity identified was to collaborate with the providers of the electronic patient report form software in order to develop an integrated piece of software, comprising both EPRF and CCDS, so that paramedics could access the CCDS seamlessly when required. The decision was made that the intervention would be rolled out as a combined ERPF/CCDS package across study sites.

The impact of this development on the study was that new negotiations with CCDS and EPRF providers were required, alongside further development and testing of the IT intervention. This impacted on the retention of study sites, where timeframes for EPRF implementation and the study timeframe were incompatible.

At the time of the study some ambulance services had already selected their EPRF provider, while others were still in negotiations. Both of the English ambulance services that had been recruited to the trial were working with a software provider that, after a feasibility study, concluded that it would not be possible to collaborate with the SAFER 1 in the given timeframe. This resulted in the loss of both these study sites.

A second EPRF provider that was being considered by several ambulance services was contacted, and agreed to participate in the study. Although the Welsh Ambulance Service Trust (WAST) was not planning to roll-out EPRF during the study timeframe it agreed to work with this EPRF software provider for the study. Additional time was required to allow for development and testing of the EPRF/CCDS package than had been anticipated in the original study proposal, delaying implementation.

6.2.2 Ambulance service reorganisation

Organisational change in both England and Wales also impacted on the recruitment and retention of study sites. Radical reorganisation of ambulance services in England saw the number of services reduced from 33 to 11 through mergers during the first year of the study, 2006. The two existing English study sites became part of new, larger services. A period of instability ensued while new staff and management arrangements were established. The study team pursued negotiations with key personnel in the newly formed services that now incorporated the existing study sites, however these were ultimately unsuccessful.

The ambulance service in Wales also underwent a period of major upheaval during the early stages of the study. In one year alone the Welsh Ambulance Service Trust (WAST) had five different Chief Executives, with associated changes in personnel throughout the organisation. Commitment to the study was maintained throughout this period of instability. However, as a result of the changes within WAST and the introduction of new internal procedures it became necessary for the research team to effectively renegotiate WAST's commitment to participation in the trial at managerial level through presentation of a new business case for approval by the Trust Board, which was time consuming but successful.

The impact of major ambulance service reorganisation and upheaval on the study was significant. Two of the recruited services ceased to exist and key personnel who had approved participation in the study changed. Loss of continuity and contacts hampered progress; new negotiations required additional work and time and were not always successful. Service reorganisation brought with it new processes for the management of research which often took additional time to adhere to. These factors contributed to the difficulties associated with recruiting and retaining study sites.

6.2.3 Call Connect

In 2008 the Department of Health introduced a revised definition of one of the key measures of ambulance services, the eight minute response time for high priority 999 calls. In the original definition ambulance service performance had been measured from the time when a patient's chief complaint had been confirmed. However this policy revision, entitled 'Call Connect', moved the starting point for measuring response times to the moment when the telephone call was received by the ambulance dispatch call centre (Department of Health, 2005). This effectively reduced the amount of time that ambulance services had to respond to the existing eight minute target by around 90 seconds. The premise for the revised Call Connect

target was based on the supposition that it would make '*a real difference to patients and the way we deliver patient care*' (Department of Health, 2005) p5, however the evidence base for this is lacking (Woollard et al., 2010). The impact of this policy revision during the study timeframe was to increase the operational pressure on ambulance services to meet time-based performance targets. Operational pressures contributed to the reasons why ambulance services withdrew from the study, demonstrating the adverse impact of such performance measures on ambulance service capacity for research activity.

6.2.4 New ethics, research and information governance procedures

Following the initial application for ethical approval for the study in April 2006, new systems for gaining research and development permissions and information governance processes were introduced at ambulance services. These required potential study sites to undertake more onerous administrative activities related to the study. These included conducting further risk and impact assessments related to participation and obtaining Trust approval. It was also necessary to agree data sharing protocols that required a higher level of administration by ambulance service staff than had previously been anticipated. Additional time was required to agree protocols for data sharing, to produce the relevant paperwork and obtain Trust approvals, adding to the work of the Trusts and delaying the progress of the study.

6.3 Study site recruitment and retention

At the time of the application to the DH for funding, three Ambulance Services (AS) were signed up to participate in the study (AS1, AS2 and AS3). These included the Welsh ambulance service and two English services. However when the study began in 2006 unanticipated clashes between the study timeframe and EPRF implementation, meant that both English study sites were unable to participate.

A new English ambulance service (AS4) was recruited to the study, however it withdrew after a year of study set-up due to operational pressure. In 2009 one of the ambulance services who had previously withdrawn due to clashes with the EPRF implementation programme (AS3) rejoined the study, but withdrew after another six months due to operational pressure, concerns over their IT capacity and concerns about the study's 'opt-out' approach to patient consent. In 2009 a further ambulance service was recruited, AS5.

The impact of the factors outlined above was that due to problems with recruitment and retention of ambulance services the study was eventually conducted at two rather than three study sites, AS1 and AS5, with a revised study timeframe. Although the study had funding approved in 2005, an agreed start date of August 2006, data collection planned for 2007 and a report date of January 2009, the impact of the factors that affected the study's progress resulted in these dates slipping. Extensions were applied for and agreed by the Department of Health (DH) on three occasions. Data collection eventually commenced in November 2009.

The table below illustrates the recruitment and retention of ambulance services over the course of the study.

Table 11: Key events by date in site recruitment and retention

	2006	2007	2008	2009	2010
AS1	Recruited	Recruited	Recruited	Recruited	Recruited
AS2	Recruited	Withdrew			
AS3	Recruited	Withdrew		Recruited & Withdrew	
AS4		Recruited	Withdrew		
AS5				Recruited	Recruited

Source: (Snooks et al., 2011)

6.4 The CCDS intervention

CCDS software has been developed for use in other settings to help support healthcare providers when making decisions about patient care, for example when prescribing medication (Terrell et al., 2009). The CCDS used in this study was a falls assessment software package designed to support paramedics in assessing when to convey a patient to hospital or to leave them at home with a referral to community based care. As part of the development process the CCDS was piloted with paramedics.

Funding for the SAFER1 trial was based on the proposal to trial a stand-alone software package that had been developed for use by paramedics as a decision support tool when assessing older fallers who might not require hospital treatment. It was envisaged that recruited paramedics would be trained to use CCDS on portable tablet computers that they could use with patients who had suffered a fall. The

intervention was to be implemented at three recruited ambulance service study sites.

The CCDS software was designed to be accessed and completed online by paramedics using a secure wireless internet connection over a mobile phone network. It was intended that patient data would be transferred and stored directly onto a secure server hosted by the CCDS software providers, rather than stored on the tablets. Vehicles used by participating paramedics were supplied with chargers and printers so that the tablet could be kept charged during shifts and so that CCDS output could be printed off for patients, the ambulance service and other service providers. Links were to be established with local falls services so that paramedics could refer non-conveyed patients to them to receive timely, community based care.

Due to differences between study sites and as a result of negotiations with each service to agree a model of the intervention that was operationally acceptable, two models of the intervention evolved.

6.4.1 The CCDS intervention as implemented at study site one

It was originally envisaged that intervention group paramedics at site one would be provided with a tablet computer and trained to use the CCDS software with older patients who had suffered a fall. The CCDS data would be transferred electronically to research team partners and a portable printer would enable them to leave a print out with the patient. However, the evolved CCDS intervention as it was implemented at study site one was much more complex than originally planned. At this site, which had no previous experience of computerised patient data collection, the scale of work required to implement the CCDS system was greater than envisaged by either the research team or the ambulance service.

Prior to the study, site one did not have in place the technology systems to support the use of portable computers by paramedics. At this site negotiations were required across the organisation to agree implementation of the infrastructure, support systems, training and data collection. The system that was implemented for the study at this site included hardware (docking stations, printers, chargers and tablet computers for both the cars and ambulances used by paramedics in the study) as well as the software (EPRF and CCDS).

The CCDS software at this site was accessed online via mobile phone technology (GPRS) and therefore required a mobile network signal for use. The EPRF and CCDS software was linked at this site, this meant that in order to access and use

the CCDS software paramedics first had to use the EPRF. Although it had been hoped that the two software packages could be seamlessly integrated for the study, the resources required to support this development were not available so the option of linking the two software packages was pursued instead.

In order to ensure that clinical audit and information governance standards of data storage, protection, retrieval and transfer were maintained at this site, electronic patient data from the study was transmitted via GPRS to a central NHS patient databank managed by Health Solutions Wales (HSW). The involvement of HSW meant that additional negotiation and collaboration between the study team, ambulance service, software providers, and HSW were required. Small group task and finish group meetings were set up to focus on the technical issues this raised. Time consuming and costly 'penetration' testing of the system was also necessary to ensure that it met technical security standards. This led to the study data collection 'go-live' date being postponed on several occasions at this site, contributing to an extended period between initial paramedic recruitment and training, and when they commenced using the technology with patients.

6.4.2 The CCDS intervention as implemented at study site two

When study site two agreed to participate in the study it had already implemented EPRF, so the hardware, EPRF software, technical support and electronic data storage systems were already in place at this site. Site two was working with a different software provider to the one collaborating on the study, so a decision was made to continue using the existing EPRF at this site and to simply download the CCDS software package onto the tablet computers to be used when required. This meant that paramedics did not have to use the EPRF in order to access the CCDS, nor did they require a mobile phone signal to use it. Secured patient data from the CCDS would be stored on the laptop for subsequent transfer to a database at the ambulance service.

6.4.3 Features of the CCDS intervention as implemented at study sites

The table below summarises the different features of the intervention as implemented at the study sites.

Table 12: Features of the CCDS intervention as implemented at the study sites

Feature	Study site one	Study site two
CCDS software	• Plain Healthcare CCDS software • Linked to and accessed via EPRF software • CCDS package accessed online	• Plain Healthcare CCDS software • Standalone software • CCDS package installed on tablet computers
EPRF software	• Ortivus EPRF • Installed on tablet computers	• Medusa Siren EPRF • Installed on tablet computers
Computers Printers Chargers	• Toughbook ruggedised tablet computers • In cars and ambulances • In car chargers and docking stations in ambulances	• Toughbook ruggedised tablet computers • In ambulances • In car chargers and docking stations in ambulances
Data Storage	• Data transmitted via GPRS to NHS servers managed by Health Solutions Wales	• CCDS output printed out by paramedics or stored as electronic files on tablets for downloading at ambulance station

Developed by the author for: (Snooks et al., 2011)

6.5 Organisational implementation of CCDS

Key personnel, including senior and middle managers, IT and operational staff from both sites worked with the study team to put in place processes to enable and support the implementation of CCDS at each study site. This included establishing managerial, technical and operational support at each site, identifying a lead person from each service to support the paramedics at an operational level, arranging training and ongoing technical support for paramedics and ensuring that internal data collection and management protocols were in place and effective.

6.5.1 Organisational implementation of CCDS at study site one

An operational manager was part-funded through the research to facilitate the implementation of the CCDS, to be the point of contact between the paramedics and the research team during the data collection period and to support the paramedics if they encountered problems with the system. However, in practice, competing priorities within the service meant that this arrangement proved ineffective. It became apparent from paramedic feedback received in the latter stages of the study that there were a number of implementation problems at this site, including one paramedic not being able to obtain a tablet to use, ongoing problems establishing

and maintaining internet connections, and a lack of printer paper. Direct communication between the research team and participating paramedics was not approved by managers at study site one and the alternative systems put in place were not effective. It is possible that poor communication channels were partly responsible for problems remaining unresolved throughout the trial. These are reported in more detail in the qualitative results chapter.

Small group training sessions were provided by the software providers. A member of the ambulance service training team was also taught how to use the system in order to provide training to those paramedics who were unable to attend these sessions. There were significant delays between initial paramedic training days and the study going live at this site, which could have affected paramedic retention and motivation at this site. Prior to the trial going live paramedics were provided with numbers to telephone for IT support from the ambulance service IT department and the software providers.

6.5.2 Organisational implementation of CCDS at study site two

A research paramedic was funded through the research and the study site's Comprehensive Local Research Network to facilitate CCDS implementation, to be the main point of contact for CCDS users and the research team during the data collection period and to help resolve any problems encountered. Paramedic feedback received in the latter stages of the study suggests that this approach to support implementation was effective at this study site and problems that arose were dealt with by the research paramedic, for example by getting a tablet fixed by the IT department and then returning it to the paramedic. Feedback on the implementation role played by the research paramedic is reported in more detail in the qualitative results chapter.

Paramedics at site two were trained to use CCDS either by trainers from the software provider or the research paramedic, who had also received training by the software training team. Paramedics at this site already had contact numbers for IT support as part of the already established EPRF programme.

6.6 Ambulance service research context

It is notoriously difficult to conduct RCTs in the prehospital emergency care setting (Brazier, 1999). It is also challenging to implement new IT programmes in health-care (Greenhalgh et al., 2005, Greenhalgh et al., 2008). This study proved no

exception. Some of the difficulties encountered related to the unanticipated major restructuring of the ambulance services at a national level. In addition there were policy amendments that refocused services on operational performance targets, and the implementation of a national IT programme that clashed with the study timeframe, and increased information governance and R&D requirements.

The challenge of recruiting and retaining ambulance services to the study illustrates one of the problems with conducting research in this environment. While the will is there in principle, in reality the demands of research can detract from or even undermine the ability of ambulance services to meet their operational pressures. Despite the challenges and barriers to participation associated with this study, the two services that did take part demonstrated both commitment and flexibility, working with the study team to adapt the intervention to the technological terrain, resulting in two bespoke solutions. Some of the lessons learnt from this process are summarised below:

- Time is required for ambulance services to undertake impact assessments, make informed choices about their ability to commit to participation and then obtain approvals
- Key stakeholders should be identified and involved at an early stage in the process, and communication lines and decision making processes agreed
- Commitment should be obtained from all levels of the organisation to participation, including senior managers, middle managers and operational staff
- Adequate IT resource and expertise should be available across research partners and time given to develop, test and implement IT systems
- Support should be provided at the operational level for paramedics, e.g. a research paramedic to facilitate and support their participation and a key point of inter and intra-organisational contact for the study
- Time is required to agree and obtain permissions for workable data collection, sharing and security processes

6.7 Conclusion

In presenting the research context for this thesis, this chapter also provides an insight into the challenges involved in both setting up an RCT and implementing a new healthcare technology at two ambulance service study sites in the UK. It highlights some of the challenges associated with conducting technology based research in a data sensitive environment, across multiple organisations and against

a backdrop of competing priorities (e.g. building the evidence base versus meeting operational performance targets).

As EPRF programmes are rolled out across the UK, now is the ideal time to embed technology research in the prehospital care setting. The research for this thesis takes the opportunity provided by the SAFER 1 RCT to explore data relating to the implementation and adoption of CCDS. To the author's knowledge this is the first example of an IT RCT using CCDS in face-to-face prehospital care and therefore this is the first time that these issues have been explored in detail in this setting.

Chapter 7: Quantitative results

7.1 Chapter overview

This chapter presents the quantitative results relating to CCDS use and its impact on process of care. Data drawn from the SAFER 1 cluster randomised controlled trial (C-RCT) are presented according to the CONSORT guidelines for reporting trials. The results include new and previously unused data that were collected or analysed for this PhD.

The participant flow of paramedic clusters and patients through the study are described and presented diagrammatically on flowcharts for both the trial as a whole and for each study site.

The characteristics of participating paramedics are presented and analysed to identify whether there were differences between these across study groups and sites. Patient characteristics are also presented and any differences between them across study groups and sites reported.

Data are then presented and analysed to identify whether there are any predictors of CCDS use, the impact of CCDS on process of care is also explored. Primary analyses are by treatment allocated (i.e. CCDS available for use by paramedics), with secondary analyses by treatment received (i.e. cases when CCDS was used by paramedics). CCDS usage data drawn from the wider study are also presented and described.

Although the focus of this thesis is on process of care rather than patient outcomes, the author has included a summary of the key information relating to patients.

7.2 Recruitment and participant flow

The CONSORT flowcharts on pages 112-114 show the flow of participants (both paramedics and patients) through the study. The term 'participant' is often used to refer to patients, however, there are both paramedic and patient participants in this study. For the purposes of clarity participants will be explicitly referred to as either paramedics or patients rather than as participants. The flowcharts show the number of paramedics who volunteered, were randomly assigned, withdrew or became unavailable; and the number of clusters analysed. Figure 3 presents recruitment across both sites, followed by Figures 4 for site one and 5 for site two. The CCDS

usage and patient recruitment period at site one was 17th November 2009 to 31st October 2010 and at site two it was 5th December 2009 to 31st October 2010.

The paramedic participant numbers on this CONSORT flowchart vary slightly from those used in the SAFER 1 final report (Snooks et al., 2011). This is because further analysis and exploration of the data for this thesis identified that there were seven additional paramedics across study sites who did not volunteer to participate, and one previously uncounted paramedic who withdrew from the intervention group at site one. At site two it was also identified that while there were seven paramedics in the control group, two of these paired up and worked together. For the purposes of the C-RCT analysis this pair was treated as a single cluster, therefore there were seven paramedics in the control group at site two, but six clusters. Two paramedics from the control group at site two withdrew from the trial post training but prior to data collection and were included in the original CONSORT, these remain on the revised version with the addition of an explanatory footnote.

In total 42 paramedics volunteered to take part in the study. The proportion of eligible paramedics who volunteered to participate in the SAFER 1 trial varied between sites [site one: 27/47 (57.4%); site two: 15/362 (4.2%)]. At the end of the recruitment period paramedics were randomly allocated to either the intervention group or the control group by the trial statistician. Paramedic allocation between intervention and control groups was almost equal (22:20).

One intervention group paramedic at site one did not receive training, hardware or software but remained in the intervention group for analysis, as per the trial protocol.

7.2.1 Paramedics who withdrew

Eight of the 42 randomised paramedics withdrew from the study before data collection commenced. Four withdrew for health reasons and four withdrew because they were no longer available for the study (e.g. had moved out of the study area) or no longer wished to participate. Six withdrew from site one (five intervention and one control) and two withdrew from site two (both control). Two further paramedics withdrew from the trial for health reasons after the patient recruitment period had commenced (one control group paramedic at each site). As these two paramedics had already contributed data they remained in the trial for the purposes of analysis and reporting.

Table 13 shows the number of paramedics allocated to each study group across study sites and those that withdrew before data collection commencing. In total data from 34 paramedics or 33 paramedic clusters were included in the analysis.

Table 13: Paramedic allocation to study groups and subsequent withdrawals

Group	Site	Withdrew	Remained	Total
Intervention	1	5	9	14
	2	0	8	8
	Total	5	17	22
Control	1	1	12	13
	2	2	5	7
	Total	3	17	20
Total	1	6	21	27
	2	2	13	15
	Total	8	34	42

In order to explore whether there were differences between groups and sites in relation to the paramedics who withdrew the data were analysed using a logistic regression model. Table 14 shows that there were no significant differences in withdrawals between study groups or across study sites.

Table 14: Logistic regression results for paramedics who withdrew across study sites and groups

	B	Sig.	Exp(B) (Odds ratio)	95% C.I. for Exp(B) Lower	Upper
Group	.53	.52	1.69	.34	8.30
Site	.63	.48	1.88	.33	10.85

Participating paramedics

Table 15 details the number of paramedics who participated during part or all of the data collection period (i.e. did not withdraw from the study prior to data collection) and whose data were analysed for the C-RCT by study site and group. Although there were a similar number of intervention and control group paramedics (ratio 17:17), control group paramedics were not evenly distributed across sites (ratio 12:5), however intervention group paramedics were (9:8). There were more paramedics included in the C-RCT analysis from site one than site two (21:13).

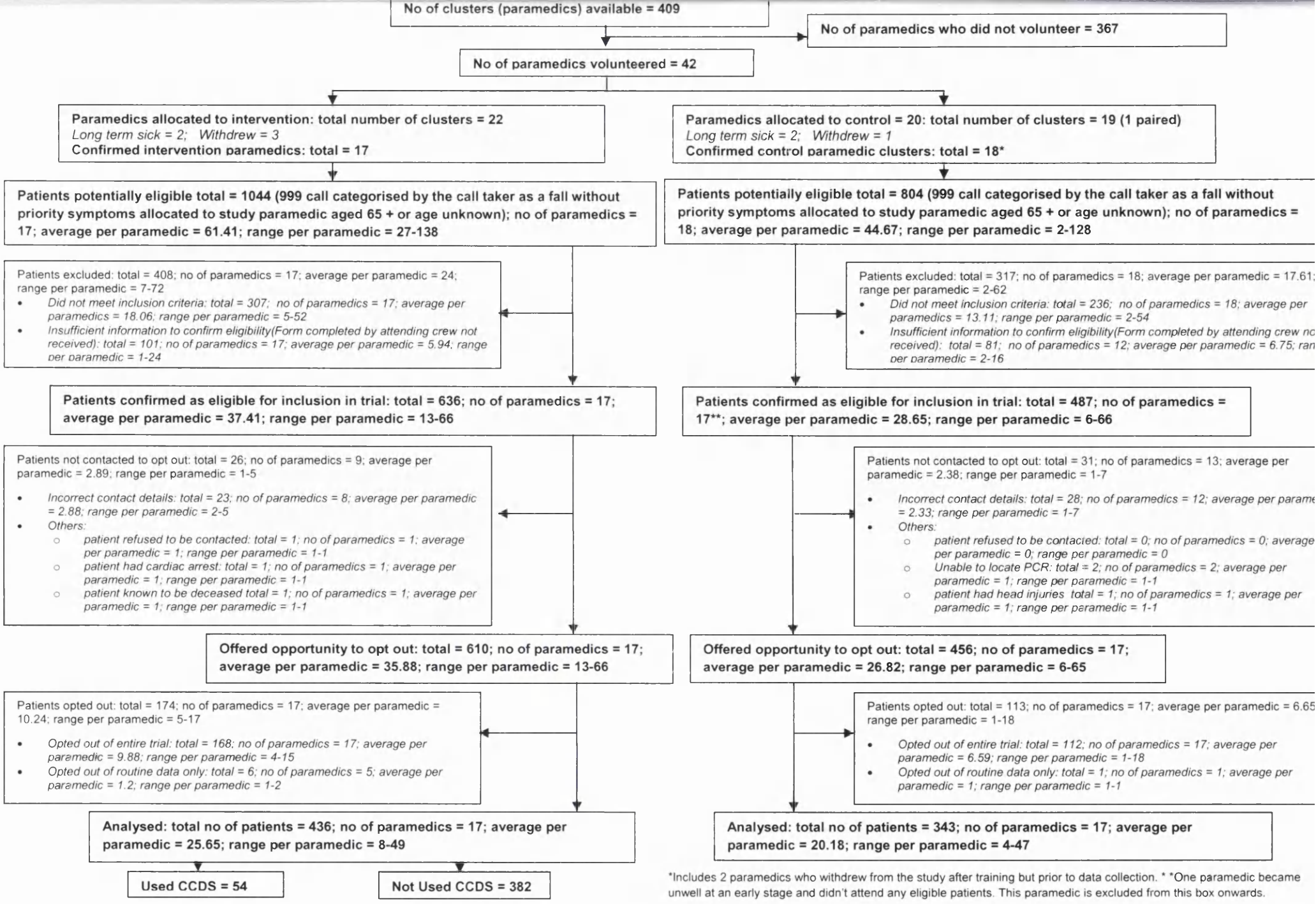
Table 15: Participating paramedics across sites and groups

Group	Site	Total
Intervention	1	9
	2	8
	Total	17
Control	1	12
	2	5
	Total	17
Total	1	21
	2	13
	Total	34

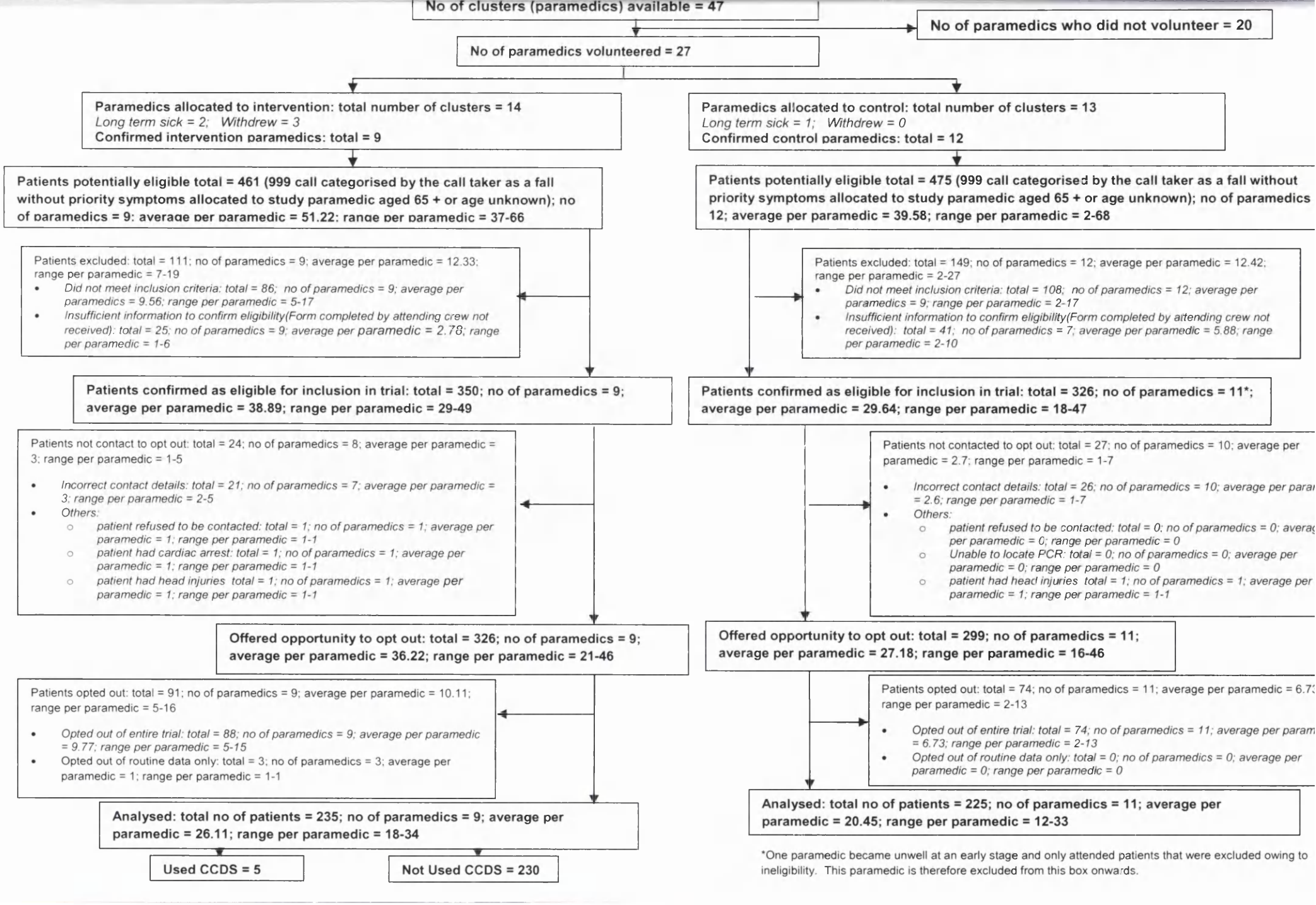
To explore whether there were differences in proportions of paramedics across study sites the data above were analysed using a logistic regression model. Table 16 shows the observed differences did not achieve statistical significance.

Table 16: Logistic regression results for paramedics included in the data analysis for the C-RCT

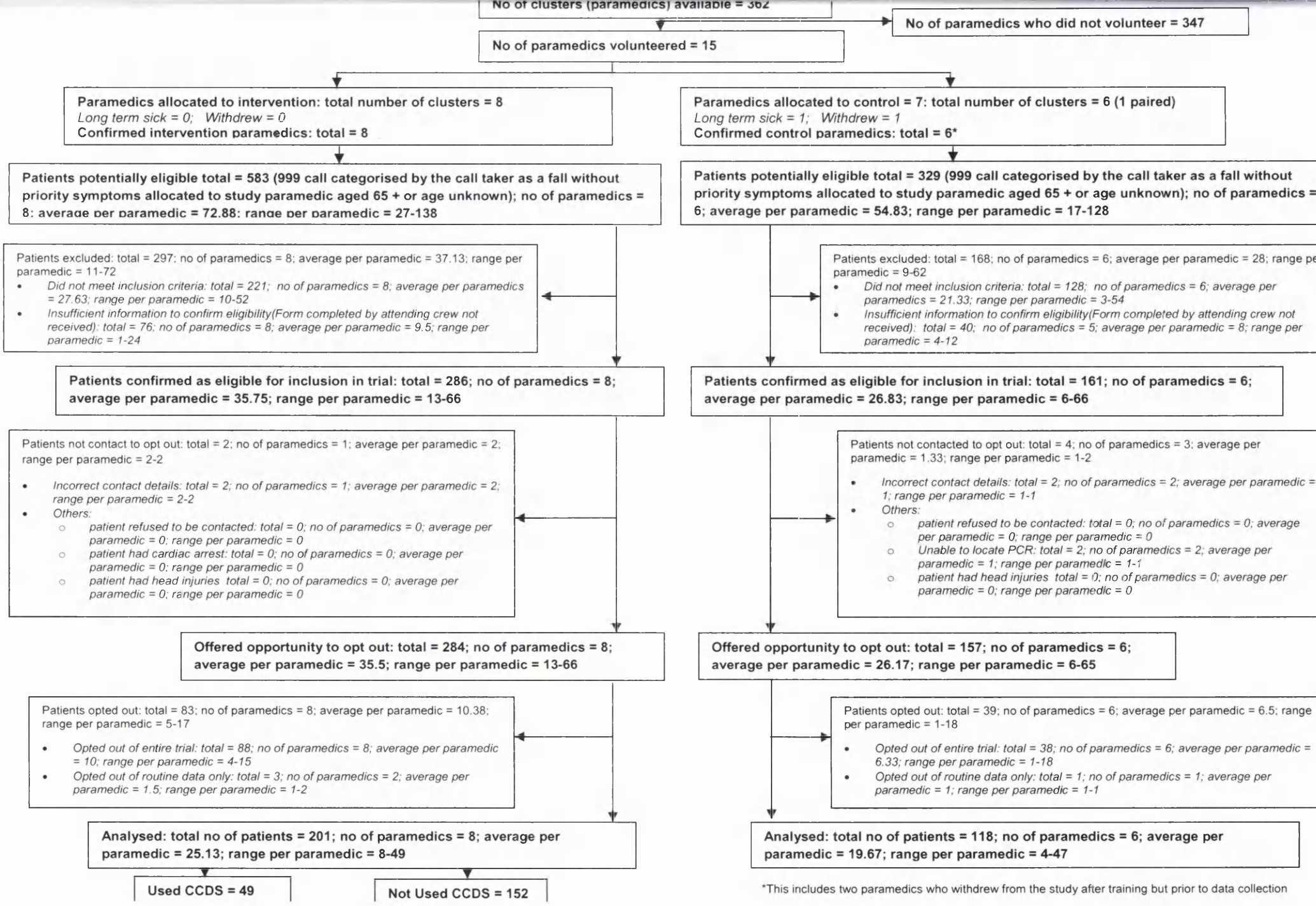
	B	Sig.	Exp(B)	95% C.I. for Exp(B)	
				Lower	Upper
Site	-.76	.29	.47	.11	1.93



*Includes 2 paramedics who withdrew from the study after training but prior to data collection. * *One paramedic became unwell at an early stage and didn't attend any eligible patients. This paramedic is excluded from this box onwards.



*One paramedic became unwell at an early stage and only attended patients that were excluded owing to ineligibility. This paramedic is therefore excluded from this box onwards.



*This includes two paramedics who withdrew from the study after training but prior to data collection

7.3 Paramedic characteristics

Summary characteristics relating to paramedic gender, age, years of service and years as a paramedic are presented below, followed by analyses to explore whether there were any significant differences between paramedics across study sites or groups. The complete table of paramedic characteristics can be found in Appendix 13.

7.3.1 Gender

Table 17 provides a summary of the gender of paramedic volunteers across groups and sites.

Table 17: Summary of paramedic gender across groups and sites

Group	Site	Female	Male	Total
Intervention	1	4	10	14
	2	1	7	8
	Total	5	17	22
Control	1	3	10	13
	2	2	5	7
	Total	5	15	20
Total	1	7	20	27
	2	3	12	15
	Total	10	32	42

There was a high observed ratio of male (M) to female (F) paramedics (3:1) across the trial but no significant differences in gender proportions between sites or groups were identified. A logistic regression model was used to explore differences in gender proportions across study sites and groups. Table 18 demonstrates no significant differences in gender proportions between study sites or across study groups.

Table 18: Logistic regression results for paramedic gender across groups and sites

				95% C.I. for Exp (B)	
	B	Sig.	Exp(B)	Lower	Upper
Group	-.12	.87	.89	.21	3.68
Site	.34	.67	1.40	.30	6.46

7.3.2 Age

The age of paramedics who volunteered for this study ranged from 24 to 56 with a mean age of 41. Table 19 provides a summary of the mean age of paramedic volunteers across groups and sites.

Table 19: Summary of paramedic age across groups and sites

Group	Site	Mean	Std. Deviation	Nos. analysed
Intervention	1	35.5	7.4	14
	2	44.9	7.0	7
	Total	38.6	8.4	21
Control	1	45.0	8.1	5
	2	45.2	8.6	5
	Total	45.1	7.9	10
Total	1	38.0	8.5	19
	2	45.0	7.3	12
	Total	40.7	8.6	31

A two-way analysis of variance was carried out to explore age differences in paramedics across study sites and groups. Analysis using a 'full effects model' showed no significant interaction between site and group. Details for the full effects model are shown in Table 20.

Table 20: Analysis of variance for paramedic age across groups and sites (full effects model)

Source	Sum of Squares	df	Mean Square	F	Sig.
Group	157	1	157	2.74	.11
Site	149	1	149	2.59	.12
Group * Site	137	1	137	2.38	.14
Error	1551	27	57		

As the interaction between group and site was not significant, a more parsimonious two-way analysis of variance was conducted to estimate the main effects on age of study site and group (Table 21). There were no significant age differences between study groups. However there was a significant difference in age across study sites (mean = -6.2; 95% CI -12.10 to -0.22) with lower mean age at site one.

Table 21: Analysis of variance for paramedic age across groups and sites (main effects model)

Source	Sum of Squares	df	Mean Square	F	Sig.
Group	196	1	196	3.26	.082
Site	272	1	272	4.52	.043
Error	1688	28	60		

7.3.3 Years of Service

Years of service reported by paramedics who volunteered for the study ranged from five to 26 years with a mean length of service of 13.5 years. Table 22 provides a summary of the years of service of paramedic volunteers across sites and groups.

Table 22: Summary of paramedic years of service across groups and sites

Group	Site	Mean	Std. Deviation	Nos. analysed
Intervention	1	11.3	6.9	14
	2	15.6	6.2	7
	Total	12.7	6.8	21
Control	1	17.2	7.5	5
	2	13.2	9.6	5
	Total	15.2	8.4	10
Total	1	12.8	7.4	19
	2	14.6	7.5	12
	Total	13.5	7.3	31

A two-way analysis of variance was carried out to explore differences in paramedic years of service across study sites and groups. Analysis using the 'full effects model' showed no significant interaction between site and group. Details for the full effects model are shown in Table 23.

Table 23: Analysis of variance for paramedic years of service across groups and sites (full effects model)

Source	Sum of Squares	df	Mean Square	F	Sig.
Group	20.4	1	20.4	.38	.54
Site	0.1	1	0.1	.00	.96
Group * Site	112	1	111.8	2.09	.16
Error	1444	27	53.5		

As the interaction between group and site was not significant, a more parsimonious two-way analysis of variance was conducted to estimate the main effects on paramedic years of service of study group and site, presented in Table 24. The results demonstrated that there were no significant differences in paramedic years of service between study groups or across study sites.

Table 24: Analysis of variance for paramedic years of service across groups and sites (main effects model)

Source	Sum of Squares	df	Mean Square	F	Sig.
Group	33.5	1	33.5	.60	.44
Site	14.0	1	14.0	.25	.62
Error	1556	28	55.6		

7.3.4 Years as a qualified paramedic

In Table 25 Years as a qualified paramedic are presented. These ranged from 2 to 19 years with a mean of 6.6 years, spanning the range of experience from relatively newly qualified to very experienced.

Table 25: Summary of years as a qualified paramedic across groups and sites

Group	Site	Mean	Std. Deviation	Nos. analysed
Intervention	1	6.4	5.6	14
	2	7.7	5.4	6
	Total	6.8	5.4	20
Control	1	8.6	9.1	5
	2	5.4	6.7	5
	Total	7.0	7.7	10
Total	1	7.0	6.5	19
	20	6.6	5.9	11
	Total	6.9	6.1	30

A two-way analysis of variance was carried out to explore differences in years as a qualified paramedic across study sites and groups. Analysis using the 'full effects model' showed no significant interaction between site and group, as shown in table 26.

Table 26: Analysis of variance results for years as a qualified paramedic across groups and sites (full effects model)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Group	.01	1	.01	.00	.99
Site	6.03	1	6.03	.15	.70
Group * Site	30.87	1	30.87	.76	.39
Error	1061.16	26	40.81		

As the interaction between group and site was not significant, a more parsimonious two-way analysis of variance was conducted to estimate the main effects on years as a qualified paramedic of study site and group. The results, shown in Table 27, demonstrate that there were no significant differences in years as a qualified paramedic between study groups or across study sites.

Table 27: Analysis of variance results for years as a qualified paramedic across groups and sites (main effects model)

Source	Sum of Squares	df	Mean Square	F	Sig.
Group	0.5	1	0.5	.01	.91
Site	1.1	1	1.1	.03	.87
Error	1092	27	40.4		

7.3.5 Patient numbers attended by study paramedics

Table 28 shows the range of the number of patients attended by study paramedics across sites and groups. As reported in the SAFER 1 final report there was no significant difference in the number of patients seen by paramedics in the intervention and control groups (overall means 25.6 and 20.2, respectively).

Table 28: Characteristics of intervention and control clusters

Group	Site	Minimum	Maximum	Average
Intervention	1	18	34	26.1
	2	8	49	25.1
Control	1	12	33	20.4
	2	4	47	19.7

7.4 Patient characteristics

This section, reproduced from the SAFER 1 final report, provides details of the characteristics of participating patients as a background to the analysis of CCDS availability and use conducted for this thesis. (Snooks et al., 2011).

A high proportion of eligible patients were sent letters providing them with the opportunity to opt out of the trial [610/636 (96%) in intervention and 456/487 (94%) in control group]. The remaining 4% of intervention and 6% of control group patients were lost to follow-up as their records were not matched. The number of eligible patients who did not opt out of the study, and thus available for analysis, was 779, which was lower than the trial recruitment target of 880. Slightly more patients opted out of the intervention group 174 (29%) than the control group 113 (25%).

Table 29 shows that patient recruitment was higher in the intervention group than the control group but that there were no differences at baseline between patient groups except for the proportion of participants by site: more patients were recruited to the trial from site one than site two.

Table 29: Characteristics of patients recruited to intervention and control groups

Characteristics	Intervention (n=436)	Control (n=343)
Male (%): Female (%)	153 (35%): 283 (65%)	132 (39%): 211 (61%)
Median age in years (inter-quartile range)	83 (77-89)	82 (76-88)
Site 1 (%): Site 2 (%)	235 (54%): 201 (46%)	225 (66%): 118 (34%)
Made index call out of hours (%)	256 (59%)	189 (55%)
Type of incident	**(n = 379)**	**(n = 292)**
Fall (%)	197 (52%)	133 (46%)
Injury, presumed fall (%)	145 (38%)	131 (45%)
Total probable fall	342 (90%)	264 (91%)

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011.

7.5 CCDS usage results

This section presents data relating to the frequency and patterns of CCDS use. Frequency of CCDS use is presented by paramedics across sites. CCDS use is then analysed by both paramedic characteristics and patient and incident characteristics in order to identify predictors of CCDS use.

7.5.1 Frequency of CCDS use across sites

Frequency of CCDS use was low, with CCDS records created for only 12% of eligible patients across sites (54/436). This figure was especially low at site one where CCDS records were created for only 2% (5/235) of patients. At site two this figure was higher, with CCDS records created for 24% (49/201) of patients.

Table 30 shows how many CCDS records were created by intervention group paramedics for eligible patients during the trial. The number of records created ranged from zero to 22.

Table 30: CCDS records created for eligible patients

No of CCDS patient records created	Site 1 paramedics	Site 2 paramedics	Total paramedics
0	6	1	7
1	2	1	3
3	1	1	2
4	0	1	1
5	0	2	2
9	0	1	1
22	0	1	1
Total:	9	8	17

Table 31 shows how often the intervention group paramedics created a CCDS record for the eligible and consented patients they attended.

Table 31: Percentage of times paramedics used CCDS when attending eligible and consented patients

Percentage of patient participants for whom CCDS was used	Site 1 (n=9)		Site 2 (n=8)	
0	6	(67%)	1	(12.5%)
1% to 10%	3	(14%)	1	(12.5%)
11% to 20%	0		2	(25%)
21% to 30%	0		0	
31% to 40%	0		2	(25%)
41% or more*	0		2	(25%)

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011.

* The maximum was by a paramedic who used CCDS for 47% of his patients

7.5.2 CCDS use by paramedic characteristics

Table 32 provides an overview of the characteristics of paramedics who used CCDS (i.e. who generated at least one CCDS record) and those who did not.

Table 32: CCDS use by paramedic characteristics

	Used CCDS (n=10)	Did not use CCDS (n=7)	Mean	Std. Deviation
Male Female	8 2	6 1		
Mean age	44.8	33.1	40.7	8.6
Mean years of service	16.0	9.4	13.5	7.3
Mean years as a qualified paramedic	8.6	5.1	6.9	6.1

It was not appropriate to conduct a statistical analysis of CCDS use by gender as only three of the intervention paramedics were female. T-tests were conducted to test for differences in CCDS use by paramedic age, years of service and years as a qualified paramedic. Table 33 shows that older paramedics were significantly more likely to use the CCDS (difference in mean ages = -11.6 years; 95% CI -18.7 to -4.6). However the differences in CCDS use by length of service or qualification were not significant.

Table 33: Paramedic characteristics by CCDS use and non-use

	t	df	Sig. (2-tailed)	95% Confidence Interval of the Difference	
				Lower	Upper
Paramedic age	-3.53	14	.00	-18.7	-4.6
Years of service	-2.07	14	.06	-13.4	0.3
Years as a qualified paramedic	-1.30	13	.22	-9.3	2.3

7.5.3 CCDS use by incident and patient characteristics

Table 34 presents CCDS use by incident and patient characteristics.

Table 34: CCDS use by incident and patient characteristics

Characteristics	CCDS used	CCDS not used
Mean age	85.4	81.72
Men Women	18 (12%) 36(13%)	135 247
Distance to nearest ED (miles)	11.5	9.5
Site 1 Site 2	5 (2%) 49 (24%)	230 152

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011 (patient data were checked and amended by author, and validated by trial statistician).

A logistic regression model was applied to these data to test whether patient age, gender, distance to ED, or study site were predictors of CCDS use. Table 35 shows that: patient age was a significant positive predictor of CCDS use (estimated relative risk = 1.05; 95% CI 1.00 to 1.10) with paramedics more likely to use CCDS with older patients; paramedics at site two were significantly more likely to use CCDS than those at site one (estimated relative risk = 0.07; 95% CI 0.03 to 0.19); but neither patient gender nor distance to the ED were significantly related to CCDS use.

Table 35: Predictors of CCDS use (full effects model)

	B	Sig.	Exp(B)	95% C.I. for Exp(B)	
				Lower	Upper
Age	.05	.02	1.05	1.00	1.10
Gender	.20	.55	1.22	.63	2.34
Distance to ED	-.02	.46	.99	.95	1.03
Study site	-2.66	.00	.07	.03	.19

A more parsimonious logistic regression including only the two significant variables confirmed these findings (Table 36).

Table 36: Predictors of CCDS use (main effects model)

	B	Sig.	Exp(B)	95% C.I. for Exp(B)	
				Lower	Upper
Age	.05	.02	1.05	1.01	1.10
Study site	-2.62	.00	.07	.03	.19

7.6 Impact of CCDS availability ('treatment allocated') on process of care

This section explores the impact of CCDS availability (treatment allocated) on the process of care, comparing patient dispositions (rates of non-conveyance and referral to falls services), operational indicators (job cycle time and emergency care episode duration) and clinical documentation (documentation of key physiological indicators at scene) between groups.

7.6.1 Impact of CCDS availability on patient dispositions

Table 37 presents the frequencies of patients not conveyed and referred to a falls service by group. The right hand column shows that the observed referral rate to

falls services was twice as high in the intervention group as in the control group – in both sites, even though referral rates differed between them.

A parsimonious approach to data analysis was adopted. Initially a 'full statistical model' estimated the effects of group (intervention versus control), site, interaction between group and site, and all other significant covariates. Non-significant variables were then removed to base the final analysis on as few parameters as possible. The resulting reduced model showing only the significant effects of CCDS is the best summary of the impact of CCDS implementation on patient dispositions. Table 37 presents the observed frequencies followed by the results of the reduced model and then of the full model.

Table 37: Impact of CCDS availability on patient dispositions by treatment allocated

	Non-Conveyed		Referral to Fall Services	
	Intervention	Control	Intervention	Control
Observed frequencies				
Site 1	85 36%	64 28%	16 7%	9 4%
Site2	98 49%	62 53%	26 13%	8 7%
Combined	183 42%	126 37%	42 10%	17 5%
Reduced model with significant covariates:	Out of hours (P=0.018) Site (P<0.001)		Age (P=0.013) Recruitment interval (P<0.001)	
Site 1: frequencies adjusted by significant covariates	77 33%	67 30%	12 5%	6 3%
Site 2: frequencies adjusted by significant covariates	101 50%	55 47%	21 10%	6 5%
Combined frequencies adjusted by sig covariates	179 41%	131 38%	31 7%	13 4%
Relative risk for Group (95% CI); significance level	1.131 (0.839, 1.523) P=0.419		2.036 (1.115, 3.717) P=0.021	
Relative risk for Site (95% CI); significance level	0.482 (0.358, 0.648) P<0.001		0.462 (0.263, 0.810) P=0.007	
Full model incorporating group, site & group-site interaction & all significant covariates				
Relative risk for Group adjusted by Site & interaction (95% CI); significance level	0.836 (0.529, 1.321) P=0.442		2.643 (1.107, 6.266) P=0.028	
Relative risk for Site adjusted by Group & interaction (95% CI); significance level	0.353 (0.222, 0.563) P<0.001		0.660 (0.243, 1.792) P=0.415	
Relative risk for interaction between Group & Site (95% CI); significance level	1.693 (0.925, 3.097) P=0.088		0.589 (0.174, 2.000) P=0.396	

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011.

The full model demonstrates the interaction between site and group to be non-significant for both non-conveyance and referral to a falls service. The reduced model therefore shows the significant effects of group and site. It demonstrates that paramedics in the intervention group are significantly more likely to refer patients to a falls service than those in the control group (estimated relative risk = 2.04; 95% CI 1.12 to 3.71). This effect was found at both sites, although paramedics at site one were less likely to refer patients than those at site two (estimated relative risk = 0.46; 95% CI 0.26 to 0.81). However non-conveyance rates did not differ significantly between groups.

7.6.2 Impact of CCDS availability on operational indicators

Table 38 presents observed times and results from the reduced model followed by those from the full model, all by treatment allocated.

Table 38: Impact of CCDS availability on operational indicators

	Job cycle time (minutes) [n = 436 I & 343 C]		Emergency episode duration (minutes) [n = 436 I & 343 C]	
Observed times	Intervention	Control	Intervention	Control
Site 1				
Mean	90.0	84.6	279	290
SD	51.6	46.9	243	254
N	235	224	207	187
Site2				
Mean	92.2	73.0	155	152
SD	36.6	32.5	117	128
N	201	117	151	106
Combined				
Mean	91.0	80.6	227	240
SD	45.3	42.8	216	227
N	436	341	358	293
Reduced model: intervention effect	8.6 (2.2, 14.9); P=0.009		-5.7 (-38.5, 27.2); P=0.734	
Site effect	0 because not significant*I		130 (97, 164); P<0.001	
Significant covariates: Adjusted times	Out of hours (P=0.001) Distance to ED (P=0.01)		None	
Site 1				
Mean	91.0	86.5	As observed	As observed
SD	50.5	47.09		
N	227	216		
Site 2				
Mean	90.4	73.3	As observed	As observed
SD	36.9	31.7		
N	197	106		
Combined				
Mean	90.7	82.2	As observed	As observed
SD	44.7	43.0		
N	424	322		
*Full model: estimated effects (+ve: intervention higher), confidence intervals & significance levels				
Intervention effect	17.1 (6.7, 27.4) P=0.001		2.8 (-50.0, 55.6) P=0.917	
Site effect	13.2 (3.0, 23.5) P=0.011		137.9 (87.2, 188.5) P<0.001	
Interaction effect	-12.6 (-25.8, 0.6); P=0.062		-13.9 (-81.4, 53.6) P=0.686	

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011.

Thus the job cycle time was nine minutes longer for the intervention group than the control group (95% CI 2.2 to 14.9). However, there was no significant difference between groups in the duration of the emergency episode.

There was no significant difference between sites in the job cycle time. Nevertheless there was a significant difference between the sites in the emergency episode duration (mean difference = 130 minutes; 95% CI 97 to 164).

7.6.3 Impact of CCDS availability on completion of clinical documentation

Table 39 shows that the clinical documentation was completed to a consistently high standard and did not vary significantly between groups.

Table 39: Impact of CCDS on completion of clinical documentation

	Intervention group (n=436)	Control group (n=343)
Respiratory rate recorded	397 (91%)	323 (94%)
Pulse rate recorded	414 (95%)	329 (96%)
Consciousness recorded	405 (93%)	337 (98%)

7.7 Impact of CCDS use ('treatment received') on process of care

Analysis by treatment allocated (section 7.6) evaluates the impact of CCDS in practice; in particular intervention paramedics who fail to use their software for some or all of their patients cannot achieve any benefit. In contrast, analysis by treatment received focuses on patients for whom intervention paramedics used their CCDS; although this leads to bias in estimating general effectiveness, it has the merit of giving better insight into the true potential of CCDS when used to the full.

7.7.1 Impact of CCDS use on patient dispositions

By analogy with Table 37 'by treatment allocated', Table 40 presents observed frequencies 'by treatment received' of patients not conveyed and those referred to a falls service, followed by the resulting estimates of relative risk.

Table 40: Impact of CCDS on patient dispositions by treatment received

	Not conveyed		Referral to falls service	
Observed frequencies	Yes	No	Yes	No
Site 1	3/5 (60%)	146/455 (32%)	1/ 5 (20%)	24/455 (5%)
Site 2	32/49 (65%)	128/270 (47%)	11/49 (22%)	23/270 (9%)
Both sites	35/54 (65%)	274/725 (38%)	12/54 (22%)	47/725 (7%)
Relative risk for CCDS use (95% CI), significance level	2.088 (1.107, 3.940) P=0.023		3.109 (1.403, 6.888) P=0.005	
Relative risk for Site (95% CI), significance level	0.524 (0.385, 0.714) P<0.001		0.598 (0.331, 1.082) P=0.089	
Relative risk for interaction between CDSS and Site (95% CI), significance level	1.520 (0.225, 10.253) P=0.667		1.444 (0.135, 15.05) P=0.761	

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011.

Hence the actual use of CCDS led to significantly higher rates, both of non-conveyance (estimated relative risk = 2.09; 95% CI 1.11 to 3.94), and of referrals to

falls services (estimated relative risk = 3.11; 95% CI 1.40 to 6.89). In contrast analysis by treatment allocated showed little difference in non-conveyance rates, and a much lower relative risk of referral to falls services

7.7.2 Impact of CCDS use on operational indicators

Also to explore future potential rather than current performance, Table 41 presents analysis to estimate the impact of actual CCDS use on operational indicators.

Table 41: Impact of CCDS on operational indicators by treatment received

Operational indicators				
	Site 1	Site 1	Site 2	Site 2
CCDS	Used (n=5)	Not used (n=455)	Used (n=49)	Not used (n=270)
Mean job cycle time (minutes)	107.38	87.14	95.54	83.26
Mean episode of emergency care time (minutes)	150.55 (n=4)	287.71 (n=390)	124.15 (n = 39)	159.23 (n = 218)

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011.

Combining the findings from both sites shows that use of CCDS increased mean job cycle time by 10.9 minutes (95% CI from 0.5 to 21.4) – very similar to the estimate from analysis by treatment allocated. It also reduced the duration of the episode of emergency care (including ED attendance) by 113.8 minutes (95% CI from 77.2 to 150.3) – far greater than the non-significant difference in analysis by treatment allocated.

7.8 General CCDS usage

The CCDS usage results reported in this chapter so far are based on analysis of data relating to patients consented and eligible for inclusion in the SAFER 1. There were also some more general data available relating to CCDS use, which includes the number of CCDS records produced for patients who were not eligible for or who opted out of the study. At site one there were also data available relating to attempted CCDS usage that did not translate into CCDS records.

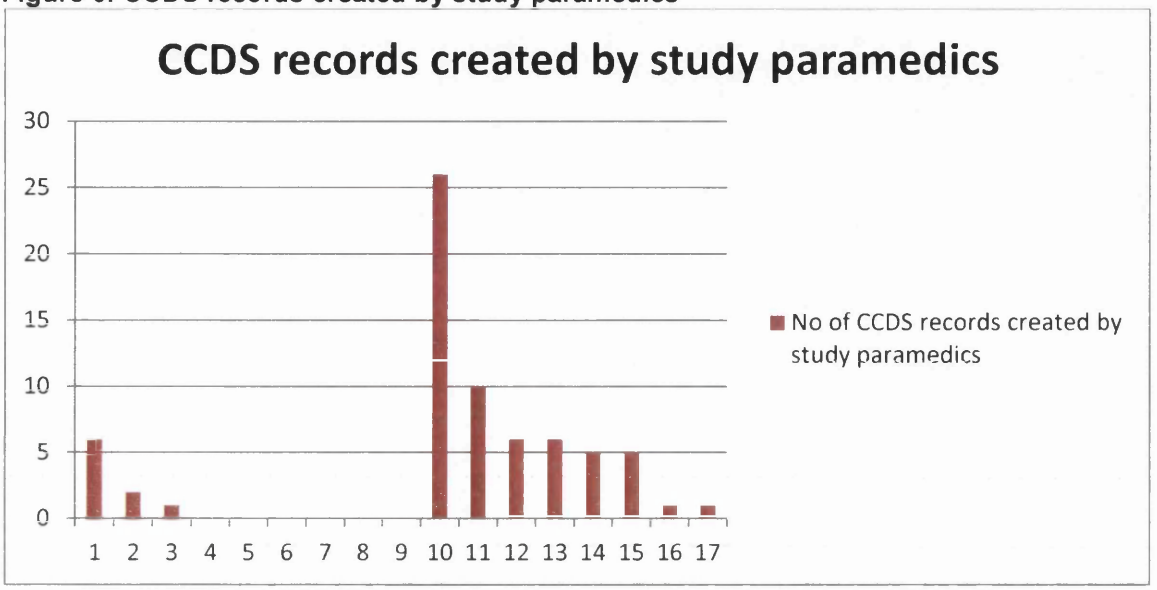
7.8.1 CCDS records created during the study

A total of 69 CCDS records were created for individual patients during this study. Only 9 CCDS records were created at site one, six of these by one paramedic. Sixty CCDS records were created at site two, 26 of these by one paramedic. The number

of patient related CCDS records created by individual paramedics ranged from zero to 26

Figure 6 shows how many CCDS records (vertical axis) were created for individual study patients, including those who were not eligible or opted out. On the horizontal axis the first nine columns represent paramedics from site one, and the last eight columns represent paramedics from site two.

Figure 6: CCDS records created by study paramedics



Thus 11 (65%) of the 17 intervention paramedics created at least one CCDS record. One clear difference between the sites is that all the intervention group paramedics at site two created at least one CCDS record, compared with only one third of paramedics at site one (Table 42).

Table 42: Intervention paramedics that created CCDS records by site

	Site 1	Site 2	Total %
Paramedics that created a CCDS record	3 (33%)	8 (100%)	11 (65%)
Paramedics that didn't create a CCDS record	6 (66%)	0 (0%)	6 (35%)

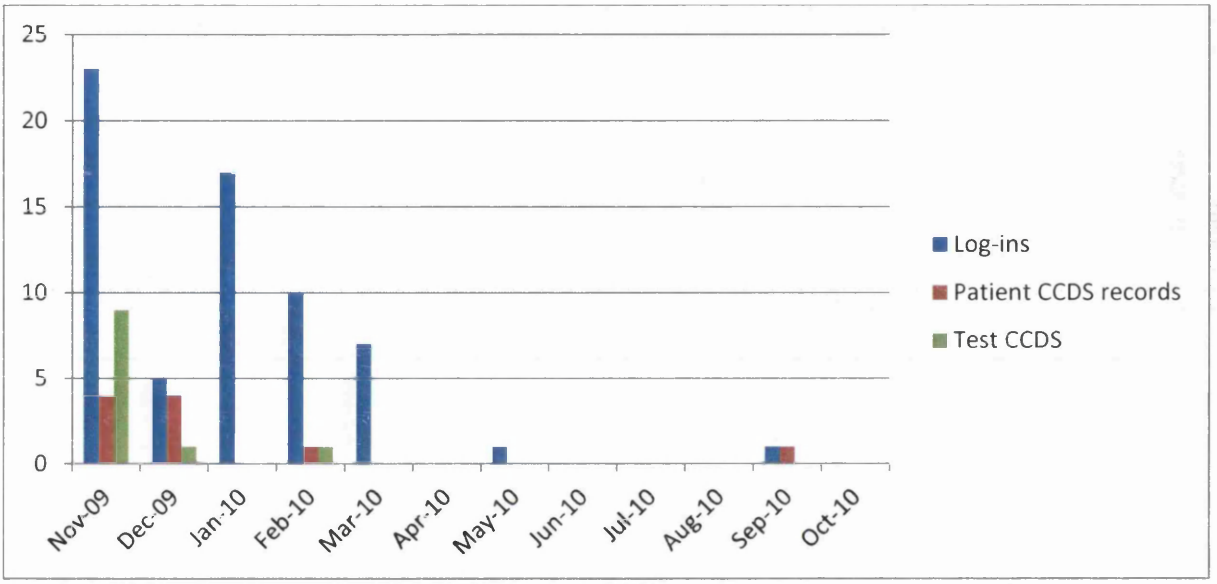
7.8.2 General CCDS usage at site one

At site one only three paramedics succeeded in creating CCDS records for patients. There were 64 successful log-ins to the CCDS system during the data collection period, creating a total of 27 CCDS records. Eleven of these records were for practice; six records held insufficient information to be usable. Of the ten records linked to patients, one was for an ineligible patient, three were for patients without consent and six related to eligible and consented patients. The six records for

eligible and consented patients contained one duplicate record, leaving a total of 5 eligible and consented patients for whom a CCDS record existed.

Log-in records indicate that paramedics frequently had to log in multiple times per patient. Figure 7 shows the incidence of paramedic log-ins to the CCDS system across the data collection period (Nov 09 to Oct 10). It also shows the number of test and patient-specific records created during this time. It reveals a sharply declining number of successful log-ins by paramedics during the first few months of the trial, followed by a period where attempts were very few, and virtually zero for several months.

Figure 7: Successful log-ins, test records and patient CCDS records created at site one

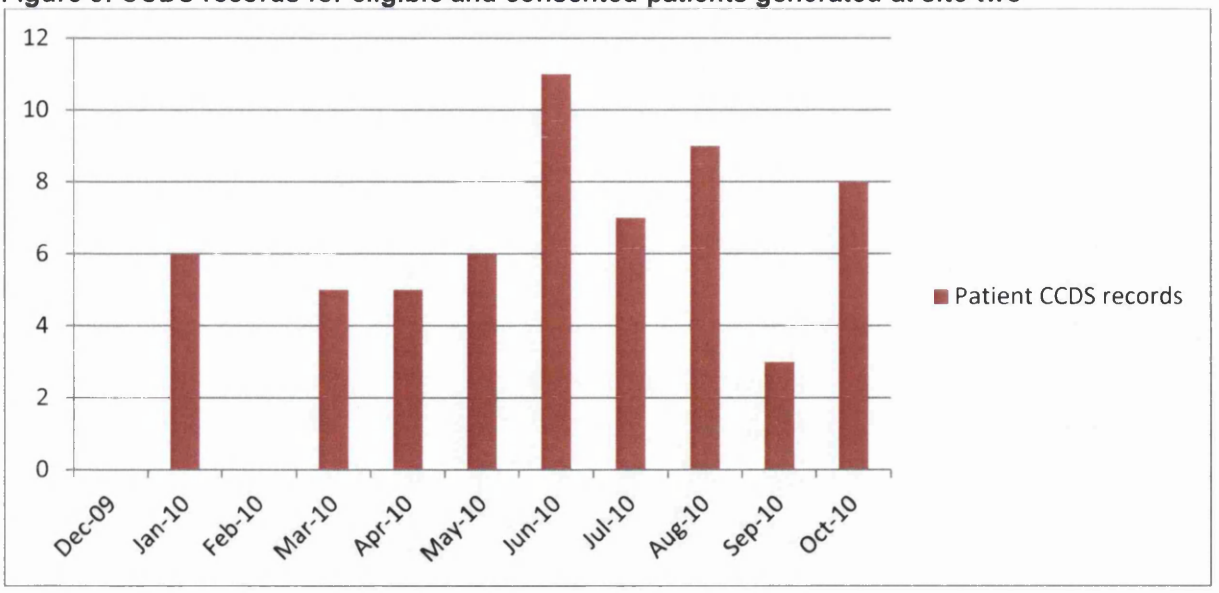


7.8.3 General CCDS usage at site two

A different technical approach to data capture at site two meant that CCDS records were created, stored and then downloaded to a research computer locally and without the need to log on to the internet or link up to a server. Therefore no log-in data existed at this site. Differences in the set-up and implementation of the intervention between the two study sites are described in detail in Chapter 6.

During the data collection period 60 CCDS records were created for eligible patients, 49 of these consented to participate and 11 opted out. Figure 8 shows when the 60 eligible CCDS records were created by intervention group paramedics at site two, reflecting a more consistent pattern of CCDS use over the study period than at site one.

Figure 8: CCDS records for eligible and consented patients generated at site two



7.9 Patient outcomes

In order to complement the analysis of CCDS usage, Table 43 displays the statistical analysis of the primary health outcome measure for SAFER 1 – the number of patients who remained free of four key events (viz. death, hospital admission, ED attendance and 999 call) at 30 days. In summary, there were no significant differences in the 'event free period' between intervention and control groups – at either site or combined. This confirms that the use of CCDS for this study was safe.

Table 43: Number of people who remained event free at 30 days by group & site

Event Site 1: Intervention n = 235 Control n = 225 Site2: Inter n = 201; Control n = 118	Any cause	Fall-specific	Adjusted by SF6D
Death (no significant covariate)			
Site 1: alive at 30 days	224I (95%):216C (95%)	Not available	Not applicable
Site 2: alive at 30 days	193I (96%): 116C (98%)	Not available	Not applicable
Both sites: alive at 30 days	417I (96%): 332C (97%)	Not available	Not applicable
Full model– key features			
Event hazard-ratio for Group (95% CI); significance level	0.454 (0.096,2.139) P=0.318		
Hazard-ratio for interaction between Group & Site (95% CI); sig level	1.887 (0.318,11.22) P=0.485		
Death or admission			
Site 1: observed event-free @ 30dys	200I (85%):191C (85%)	214I (91%): 203C (90%)	
Site 2: observed event-free @ 30 dys	183I (91%): 109C (92%)	192I (96%): 115C (98%)	
Both sites: observed event-free @30	383I (88%): 300C (88%)	406I (93%) :318C (93%)	383I (88%):300 C (88%)
Significant covariates:	Recruitment interval (P=0.009); out of hours (P=0.049)	Recruitment interval (P=0.014)	Questionnaire status (P=0.003); recruitment interval (P=0.028)
Both sites: adjusted event-free @ 30	389I (89%): 305C (89%)	426I (98%): 328 (96%)	406I (93%): 320C (93%)
Full model – key features			
Event hazard-ratio for Group (95% CI); significance level	0.846 (0.378,1.892) P=0.684	0.530 (0.143, 1.969) P=0.343	0.832 (0.371,1.865) P=0.656
Hazard-ratio for interaction between Group & Site (95% CI); sig level	1.274 (0.500,3.248) P=0.612	2.188 (0.143, 1.969) P=0.289	1.291 (0.506,3.296) P=0.593
Death or admission or Emergency Department attendance			
Site 1: observed event-free @ 30dys	176I (75%): 173C (77%)	210I (89%): 202C (90%)	
Site 2: observed event-free @ 30dys	166I (83%) :102C (86%)	183I (91%): 110C (93%)	
Both sites: observed event-free @30	342I (78%):275C (80%)	393I (90%): 312C (91%)	342I (78%):275C (80%)
Significant covariates:	Recruitment interval (P=0.005); out of hours (P=0.036)	None	Questionnaire status (P<0.001); recruitment interval (P=0.015); out of hours (P=0.024)
Both sites: adjusted event-free @ 30	361I (83%): 276C (80%)	As observed	370I (85%): 302C (88%)
Full model– key features			
Event hazard-ratio for Group (95% CI); significance level	0.678 (0.363,1.265) P=0.222	0.700 (0.292, 1.675) P=0.423	0.646 (0.345,1.207) P=0.170
Hazard-ratio for interaction between Group & Site (95% CI); sig level	1.396 (0.674,2.892) P=0.370	1.369 (0.484, 3.875) P=0.554	1.456 (0.702,3.019) P=0.313
Death or admission or Emergency Department attendance or 999 call			
Site 1: observed event-free @ 30dys	153I (65%): 150C (67%)	195I (83%): 184C (82%)	
Site 2: observed event-free @ 30dys	128I (64%): 82C (70%)	158I (79%): 96C (81%)	
Both sites: observed event-free @30	281I (64%): 232C (68%)	353I (81%): 280C (82%)	281I (64%):232C (68%)
Significant covariates:	Recruitment interval (P=0.007); out of hours (P=0.016)	Out of hours (P=0.021)	Questionnaire status (P=0.002) ; out of hours (P=0.019); recruitment interval (P=0.016)
Both sites: adjusted event-free @ 30	289I (66%): 217C (63%)	356I (81%):279 (81%)	292I :241 (67%:70%)
Full model– key features			
Event hazard-ratio for Group (95% CI), significance level	0.753 (0.494,1.146) P=0.185	0.888 (0.520, 1.516) P=0.664	0.738 (0.484,1.124) P=0.157
Hazard-ratio for interaction between Group & Site (95% CI), sig level	1.306 (0.771,2.213) P=0.320	1.272 (0.635, 2.548) P=0.498	1.357 (0.800,2.299) P=0.257

Source: Snooks HA et al. SAFER 1 Final Report. Swansea: College of Medicine; 2011.

7.10 Adverse events, harms or unintended events

The procedure for investigating a Suspected Unexpected Serious Adverse Reaction (SUSAR) was initiated only once during the trial – following the death of a patient left at home by the attending crew with a referral to the falls service. The research team remained blind to the details, including the random allocation. Following a report from the ambulance service Principal Investigator, the chairs of the trial's Data Monitoring and Ethics Committee and Steering Committee agreed no further action was required.

7.11 Discussion and interpretation of results

7.11.1 Principal findings

CCDS usage levels were low overall, with records created for only 12% of eligible patients. Usage varied between paramedics, ranging from 0% to 47% use with eligible patients. Older paramedics were more likely to use CCDS. It was more likely to be used at site two and for older patients.

Data were analysed to evaluate the impact of CCDS both by treatment allocated (i.e. CCDS available for use) and then by treatment received (i.e. CCDS used). In the analysis by treatment allocated, no account is taken of whether the CCDS was used or not. In contrast, analysis by treatment received focuses on patients for whom intervention paramedics used their CCDS; although this leads to bias in estimating general effectiveness, it has the merit of giving better insight into the true potential of CCDS when used to the full.

Analysis of the impact of CCDS by treatment allocated showed that the rate of referral to a falls service doubled across sites. The effect was significant at both sites but more pronounced at site two. There was no effect on the non-conveyance rate. Job cycle time increased by nine minutes but there was no significant difference in the emergency care episode.

Analysis of the impact of CCDS by treatment received (i.e. when the CCDS was used) showed that the falls referral rate trebled across sites when CCDS was used. The effect was significant at both sites but more pronounced at site two (although the numbers analysed were small). In contrast to the analysis by treatment allocated, CCDS use was associated with higher rates of non-conveyance, and the overall episode of emergency care duration was reduced by 114 minutes.

General CCDS usage data highlighted that there were many attempts to log on to the CCDS system at site one, particularly early on. At site two a more consistent pattern of CCDS use was observed across the study period. Overall only 69 CCDS records were created for patients during the CCDS usage period, with only nine CCDS records produced at site one.

7.11.2 Strengths and weaknesses

One of the major strengths of this study is that it was part of a successful C-RCT of a technology innovation in the prehospital emergency care setting. Many challenges were overcome to enable the research to go ahead. These included difficulties associated with site recruitment and retention, major ambulance service reorganisation, the coincidental timing of the roll-out of EPRF in England during the study timeframe and an increase in operational pressure placed on ambulance services to meet time-based performance targets.

New data were collected for this study, enabling the author to conduct analysis relating to the 42 paramedics who volunteered for the study. One limitation of this data set was that due to anonymised data processes it was not possible to link the paramedic demographic data to the individual patient for further analysis of CCDS usage as that would have potentially allowed for identification of individuals.

New analyses were also conducted to identify predictors of CCDS use. CCDS usage data from the wider trial (i.e. all use of CCDS, rather than CCDS use for eligible patients alone) was collected, demonstrating patterns of use across sites. A concern raised in the SAFER 1 report was that there was possibly incomplete or missing CCDS usage data at site one, potentially affecting the reliability of the findings. A strength of this study is that quantitative data from the wider study can be examined in combination with the qualitative data to identify what happened at this site when paramedics used, or attempted to use, CCDS.

There is a potential bias in this study relating to paramedic recruitment. The paramedics who participated were volunteers. Paramedics at site two had previous experience of using hand-held technology for electronic patient reporting. The proportion of paramedics who volunteered for the study at this site was much lower. It is possible that there was a bias between paramedics who volunteered at each site with a potential bias towards those who were more supportive of using IT in practice at site two.

Differences in the implementation of CCDS at study sites to reflect local differences in their technological infrastructure may also limit the applicability of findings to other settings.

7.11.3 Interpretation and implications

SAFER 1 was a pragmatic assessment of CCDS, designed to evaluate a complex intervention that the funders and sponsors had judged ready for field testing. Hence the problems that paramedics encountered in using the CCDS software, especially at site one (reported in more detail in Chapter 6), reflect a failure of that technology that is explored in detail in this study. Despite low CCDS usage overall, the analysis of CCDS data presented in this chapter identifies positive features and outcomes related to CCDS use that suggest future potential.

Analysis was undertaken to establish the impact of CCDS availability (analysis by treatment allocated) on falls referral rates, non-conveyance rates, job cycle time and overall episode of care time. It showed that patients in the intervention group were twice as likely to be referred to a falls service as those in the control group (estimated relative risk = 2.04; 95% CI 1.12 to 3.71), however, non-conveyance rates did not vary between groups. Job cycle time was 9 minutes longer in the intervention group (95% CI 2.2 to 14.9) but there were no significant differences in overall episode of care duration.

When the same analysis was conducted to determine the impact of CCDS use (analysis by treatment received) on these measures, The findings demonstrated that patients with whom CCDS was used were three times more likely to be referred to a falls service (estimated relative risk = 3.11; 95% CI 1.40 to 6.89). They were twice as likely not to be taken to hospital (estimated relative risk = 2.09; 95% CI 1.11 to 3.94). And although the mean job cycle time increased by 10.9 minutes (95% CI from 0.5 to 21.4) with CCDS use, the overall episode of care duration (including ED attendance) was reduced by 113.8 minutes (95% CI from 77.2 to 150.3).

These results demonstrate higher falls referral and non-conveyance rates and a shorter episode of care duration when CCDS was actually used with patients. Although this leads to bias in estimating general effectiveness, it has the merit of giving an insight into the true potential of CCDS when used to the full. While these results are promising with regard to the impact of CCDS use on falls referrals, conveyance rates and overall episode of care, it is possible that other factors are

responsible for this impact. These will be explored through analysis of the qualitative data in Chapter 9.

Chapter 8: Qualitative results

8.1 Chapter overview

This chapter presents the results of the qualitative research element of the thesis. The backdrop to this study was the SAFER 1 C-RCT, which was designed to assess the impact of CCDS use by paramedics with older people who had suffered a fall on patient outcomes. Qualitative data were collected at three time points, pre, mid and post CCDS usage in order to explore, in depth, factors relating to paramedics' use of CCDS and their views on its impact on their role and practice.

The results in this chapter are presented thematically, based on the Framework approach to data analysis of the data and then discussed in the light of Strong Structuration Theory (described in Chapter 4) which provides the theoretical underpinning for this thesis (Stones, 2005).

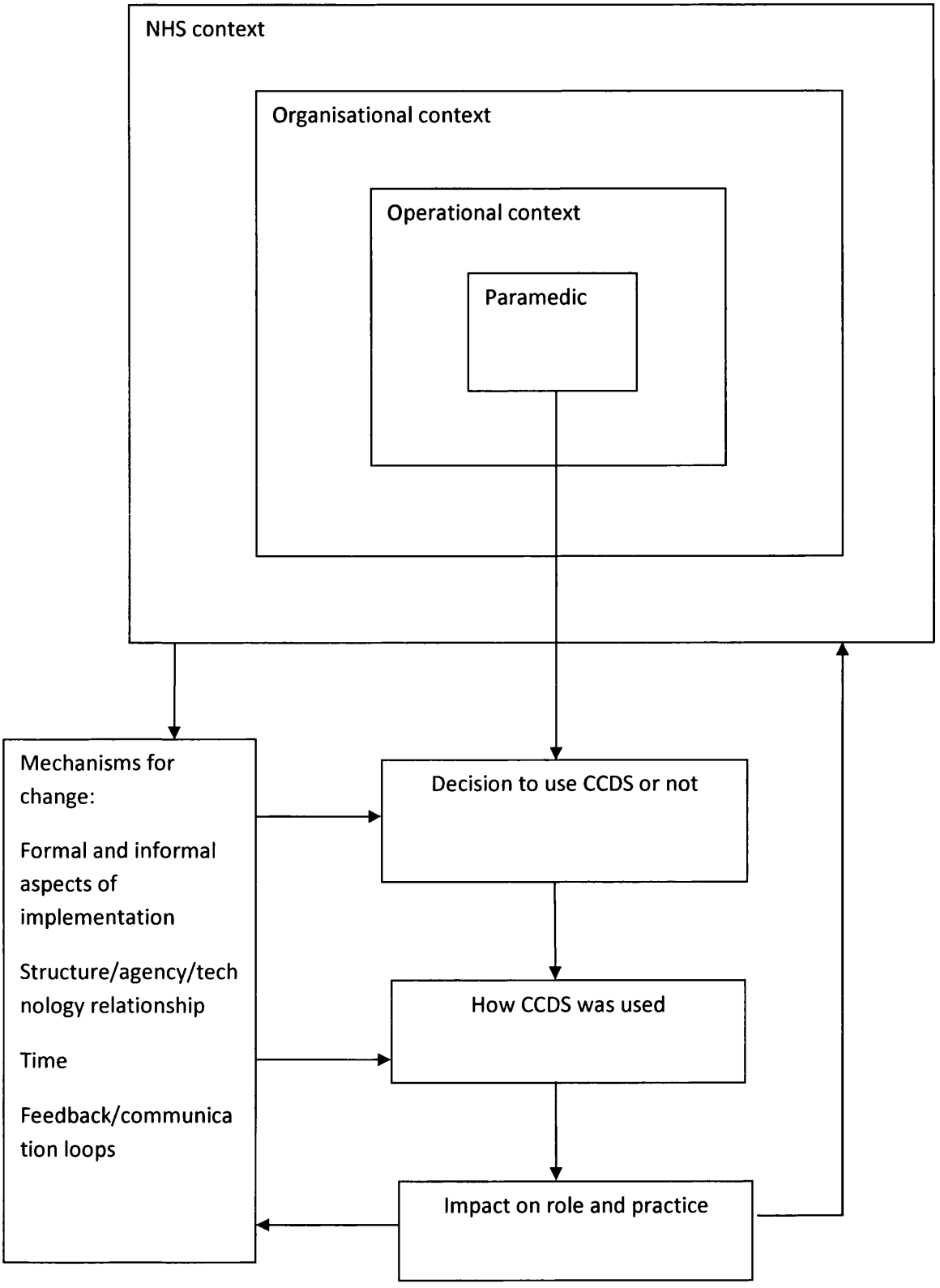
The qualitative study was conducted with intervention group paramedics who volunteered to participate in the SAFER 1 trial. These paramedics were trained to use CCDS with eligible patients during the SAFER 1 patient recruitment period (Nov 2009 to Oct 2010). As the study was based on a trial with a finite time span and a small number of paramedics adopting the technology in isolation, the focus of this chapter is not on the normalisation of practice over time but on the issues surrounding implementation and adoption of the new technology and the factors influencing this, such as organisational readiness.

In line with Strong Structuration Theory, the interrelationships between paramedics, the technology and the operational, organisational and policy contexts were explored. Analysis of the data included consideration of organisational and operational pressures in relation to CCDS use, factors influencing individuals' use of CCDS, paramedics' experiences of using CCDS, when and how they used it and their perceptions of its impact on their role.

8.2 Mapping and interpretation of the findings

The model in Figure 9, below was developed from the analysis and is used as the structure against which the results are presented.

Figure 9: CCDS implementation, adoption and impact model



The concentric squares at the top of the model represent aspects of the context within which the paramedic is working. 'NHS context' refers to the broad policy context, including moves towards increasing provision of community based care and reducing unnecessary hospital attendance and admissions, the shift to increasing use of technology in healthcare, and increasing the autonomy of paramedics. 'Organisational context' refers to the ambulance service within which the paramedic is working, and two aspects of this: firstly, the formal organisational structure, performance management processes and policies of the organisations; and secondly, the unwritten organisational culture and expectations. 'Operational context' refers to the day to day working environment of the paramedic, including working with colleagues and managers, and the technology itself. Finally, 'paramedic' refers to the paramedic as an individual practitioner and takes into account their attitudes, skills, motivations, expectations and adaptiveness.

The lower half of the model shows the flow of processes which took place when paramedics encountered eligible patients. They started by appraising the patient and their situation, and then decided whether or not to use the CCDS. If they did decide to use it, then they made a decision about how to use it, sometimes using their own ingenuity and interpretation. They then reflected on how it affected their role and practice in terms of decision making.

'Mechanisms for change' is about the factors involved in implementing new ways of working. It covers many of the organisational processes related to CCDS implementation. It also includes individual paramedics' attitudes towards and experience of the change process itself including: whether or not paramedics did change or adapt their practice, and also the mechanisms in place to support the transition. Elements of the mechanisms for change that are explored in more detail in this chapter include: the formal and informal aspects of implementation (including feedback loops); the relationship between the structure (the organisation across all levels of the hierarchy), the agent (the paramedic), and the technology, over time.

The findings below are presented against the structure of the CCDS implementation, adoption and impact model, developed for this thesis (Figure 9).

8.3 NHS context within which paramedics were working

Elements of the NHS context relevant to this study included the evolving role of the paramedic in the NHS, policy moves to reduce unnecessary hospital attendances, the role of IT in healthcare and the existence of time-based performance measures.

8.3.1 *Paramedic role development*

Paramedics reported that their role in the NHS had changed in recent years (reflecting policy initiatives to develop paramedics as healthcare practitioners) shifting from one of providing patient transport to having to make decisions relating to patient care.

> *"When I first started in the ambulance, which was 15 years ago now, it was kind of – we just took everybody to hospital and that was – you didn't have to make a decision." (Pre S2 03)*

> *"We're of the era of – chuck 'em on, and chuck 'em in [laughing together]. Get 'em up the hospital." (Pre S1 FG1)*

There were mixed attitudes towards the increased autonomy and responsibility that the shift brings, as this extract highlights:

> *"It is a difficult transition for some people isn't it. Going from being just being more or less a robot to making your own decisions." (Pre S1 FG2)*

Several paramedics referred to their sense of autonomy and how an increasing amount was expected of them in terms of the decision making, particularly with regard to making decisions about onward patient care. The theme of 'transition' from driver to autonomous healthcare practitioner is one which is explored in more detail later in this chapter.

8.3.2 *Reducing unnecessary hospital attendance and admissions*

Current NHS policy proposes to reduce the number of unnecessary hospital attendances and admissions through enabling paramedics to refer to alternative, community based care providers (such as GPs and falls prevention teams) (Department of Health, 2007, Department of Health, 2005, NHS, 2004). This increases the onus on paramedics to make decisions regarding whether or not a patient needs to attend hospital, or can be left at home with an onward referral.

In the pre-trial interviews, paramedics reported being frustrated by shortfalls in the existing community based service provision for older people who fall and dial 999, many of whom are 'repeat fallers'. Paramedics reported that there were gaps in the community based follow-up care for these patients.

> *"I think we're all – well, the majority of us are so frustrated with the system, that we just - want an alternative somewhere." (Pre S1 FG1)*

Paramedics reported being frustrated at having to convey some of these patients to hospital because they felt that the community based alternatives available to them could not be relied on to meet the patients' needs effectively and in a timely manner.

> *"If they're not injured and there's perhaps a social need surrounding it – sometimes we take them to hospital sort of – kind of unnecessarily. There's no medical reason to take them to hospital, if you like. We do have a Falls Referral System.... but it's not an immediate follow up. It – it's a little bit delayed." (Pre S2 01)*

This was seen as a particular problem when paramedics attended patients out of hours, for example on a Friday evening, when the services that they refer to may not be open again until a Monday morning. As a result, some paramedics reported taking non-injured patients to hospital in order to ensure that patients are seen and their needs assessed.

> *"I mean, they may not be significantly injured, but I know I have no other option. There are frustrations in that you are aware that a) it's night – and sort of Accident & Emergency is not the place for this person to be in. And they don't necessarily need this person to be there, but there was no – there's no other sort of – there's no other intermediate level." (Pre S2 01)*

Some paramedics reported that once a patient was referred to a GP or a falls pathway that they didn't hear any more about that patient, leaving them with concerns over whether the patient was actually seen by a follow-up service. Without feedback to confirm that patients left at home had been seen by community based healthcare practitioners, some paramedics were reluctant to leave patients at home.

> *"It is the only way you know safely that person is going to get assistance isn't it, by taking them in and getting them into the system* ***at the moment."*** *(Pre S1 FG2)*

Additional systems of feedback and communication between services working together to deliver patient care could have the potential to strengthen cross-organisational pathways:

> *"Because that's the big problem with the ambulance service as well, it's communication. Like we're constantly referring vulnerable adults and vulnerable children and things like that. Or just putting pen to paper for concerns about certain stuff, and we never get feedback. I mean, you know, people get very frustrated." (Mid S1 07)*

Paramedics reported seeing the same patients time and again and were frustrated that other services weren't in place to meet these patients' needs, contributing to repeat falls and repeat 999 calls.

"P2 So, they are left at home, they do not need to go to hospital you keep seeing them time and time again, so if there is no follow up just the same thing keeps happening to them all the time.

P3 It would be great for a backup or system like this to be able to come into place to take so that we are not going to these callers six or seven times a week or whatever, so that we have got some sort of service to help them out in whatever they require, rather than being, using the ambulance service which is their only option at the moment." (Pre S1 FG1)

So although paramedics were frustrated with taking some older fallers to hospital who they felt didn't needed to be conveyed, some reported that they weren't confident that community based alternative pathways could be relied on to meet their patients' needs.

8.3.3 Increasing the use of technology in healthcare

Given the technological nature of this study, and the policy backdrop of modernising the NHS through increasing the use of technology (including electronic patient reporting by ambulance services), paramedics were asked about their attitudes towards new technology.

Paramedic responses largely focused on the introduction of IT in the ambulance service. Some paramedics were keen for the ambulance service to incorporate more IT into its working practices, while others were less so. Concerns over the introduction of new technology were expressed across the board including: lack of paramedic IT skills; the time it takes to use it; whether it is of benefit to paramedics and patients; whether the ambulance service was capable of implementing new systems effectively, and whether the technology would be compatible with that of other healthcare providers.

"Well, like I say, if it works it's great. Paper's faster, but... If other places can accept it, because a lot of places, you'll have an electronic device and the other sort of healthcare areas that we go to, their systems aren't compatible." (End S1 07)

There seemed to be a general expectation among paramedics, regardless of whether or not they were keen to adopt new technology, that the ambulance service would inevitably become more IT based.

"At the end of the day, it's the 21st Century, innit, and if – if the way to go forward is electronic, obviously computers." (Mid S1 07)

"And computers are gonna become more and more – well, technology has become more – will become more and more advanced in the ambulance – in the ambulances, without a shadow of doubt." (Mid S1 02)

8.3.4 Time based performance measures

Ambulance service funding is linked to whether services meet national time-based performance targets as set by the Government. Paramedics reported that the pressure to meet these targets was an over-riding priority for the ambulance service at the organisational, operational and individual (paramedic) level.

"Everything is targets. Time and time alone – that's it." (Pre S2 FG1)

Paramedics reported that they spent longer with the patient when they completed the CCDS, and that this conflicted with the organisational pressure on them to get back on the road quickly.

"I think the actual idea is good, but obviously there are times when management are getting on my case 'cause obviously I take longer on scene than others would." (End S2 03)

The pressure on paramedics to meet national time-based performance targets is reported on in more detail in the operational context section of this chapter.

8.4 Organisational context within which paramedics were working

Some aspects of the organisational context were formal, for example procedures and processes, while others were more informal or implicit and related to the organisational culture. Themes that emerged from the data relating to the organisational context that impacted on paramedics' use of CCDS included organisational readiness, organisational support for the implementation process, and organisational support for paramedic conveyance decisions.

8.4.1 Organisational readiness for CCDS

As discussed in Chapter 6, differences between study sites prior to the trial meant that it could be argued that site two was more organisationally and technologically ready to adopt and implement CCDS as an add-on to its existing systems. At site two the hardware and software was already in place across the service to enable paramedics to produce patient report forms electronically, falls referral pathways also already existed. At site one the hardware, software and falls referral pathways were implemented simultaneously and only on a small-scale (for study paramedics

only). The impact of this difference between sites in terms of their organisational and technological readiness was reflected in the paramedics' reported experience of implementation which revealed that, overall, there were far fewer issues relating to the set up and implementation of CCDS at site two.

8.4.2 Organisational and operational support for CCDS implementation

Due to the overlap between organisational and operational support they are reported here together. In practice there was a big difference between the two study sites in terms of support provided during the implementation process. At site two the CCDS implementation was supported by a dedicated paramedic who was deployed to support system set-up, encourage CCDS use and to resolve any issues across the organisation. Paramedic feedback from site two suggests that the existence of a key person who provided ongoing support and addressed problems across the organisation on their behalf was an effective mechanism for supporting them during CCDS implementation.

> *"One thing I have noticed, there's – that there's always been good communication and good support's been offered." (Mid S2 08)*

> *"We had a lot of backup from the... the trial head if you like, or the trial lead, although they changed half way through. But she was always at the end of the phone, I could contact her by phone, text message if I needed to, or I could email her. And she'd get back quite quickly. So there was always good backup really." (End S2 02)*

This was not the case at site 1 where paramedics reported having problems that remained unresolved during the set-up and implementation of the CCDS system.

> *"Hmmm – neutral, bordering on non-supportive, because at the very beginning when we – when we had the – the tablets, I think... that wherever we had the screens and we didn't have the keyboards, or we had the keyboards and not the screens, and we didn't have new printing paper. And when I said – about that, oh, all you get is a shrug of the shoulders sort of thing, like, you know.... It took months and months and months to get the right paper. (End S1 04)*

In addition to their key person, paramedics at site two reported having direct access to a 24/7 IT department. This again perhaps reflects that site two was organisationally and technically more ready to support the implementation of CCDS, with systems and communication pathways already in place to enable paramedics to link directly to the support they needed across the organisation.

8.4.3 Organisational support for conveyance decisions

Organisational culture was one of the factors that paramedics raised in relation to CCDS use and compliance with its recommendations, specifically around whether there was a culture of conveyance or non-conveyance, and also whether there was a culture of blame or support for paramedic decision making.

> *"Because my last trust was pretty much a no blame culture. This trust is pretty much, hmmm, guilty until proven innocent. So, I think a lot people want to err on the side of caution, and not leave people at home and take them in regardless of what a computer is sort of suggesting." (End S1 07)*

Paramedics expressed concerns about taking the responsibility for making decisions to leave patients at home, especially in the absence of standardised protocols and explicit organisational support for non-conveyance decisions.

> *"I think we need a standard approach to the way we deal with people who are taken to hospital because currently it is different for every paramedic, as it is, everyone has got their own way of dealing with things and what one person may do another person may not, so we need a standard set approach and set pathways that we can follow." (Pre S1 FG1)*

8.5 Operational context within which paramedics were working

The operational context for this study refers to the day to day working environment of the intervention group paramedics including: operational support (reported on above), operational time pressures and working with the study technology (hardware, software and connectivity).

8.5.1 Operational time pressures

Paramedics consistently reported that using CCDS increased on-scene time, which was in conflict with the organisational and operational pressure on them not to spend longer than necessary on-scene.

> *"I mean, there's always Big Brother watching you, seeing how long, you know, you are on scene, or at hospital." (Pre S2 01)*

Paramedics reported that this pressure was exerted in a variety of ways, including via letters to their home addresses (prior to this study) and calls from managers and from ambulance control.

> *"So it's constantly, yeah. You know, we've got to just turn around, or they're calling, why haven't, you know--, why have we taken so long or what's the problem with this or why is that, so you've constantly got to watch how much time you're taking." (End S1 05)*

Overall paramedics were very concerned about the additional time it took on-scene to use the CCDS. However, the quantitative data demonstrate that although CCDS use was associated with a significant increase in on-scene time (time spent with the patient), it did not increase the overall episode of care (time until the crew were free to take their next call). One paramedic felt that the ambulance service was already aware that this was a possible benefit and were therefore tolerant towards the additional time paramedics were taking to use CCDS.

> *"Because at the end of it – I think they're now beginning to realise: Okay, if they are spending a little bit longer at scene, it's for a good reason, because they're not taking them into hospital." (Mid S1 SGI)*

It seems likely that the time pressures felt by paramedics served as a disincentive to use the CCDS as they reported that using it (as borne out by the quantitative data) significantly increased the time they spent with patients.

8.5.2 Working with the study technology (hardware, connectivity and software)

Paramedics were asked about their experience of the CCDS implementation in relation to system functionality and the CCDS software itself. The paramedics reported a variety of practical difficulties that they encountered during CCDS implementation, which are summarised below.

There were very few comments made by paramedics in relation to the tablet itself. A few points were raised, for example it was reported that older tablets tended to lose their charge quite quickly, and some paramedics found it inconvenient that the tablets didn't have a stand so had to be lain flat or propped up. Portability of the tablets was rarely mentioned as an issue, although additional journeys to fetch the kit from vehicles were cited as being a potential barrier to use.

Problems with keeping tablet computers charged during 12 hour shifts were frequently mentioned by paramedics as a challenge. Tablets could be charged via docking station in ambulances, vehicle chargers in cars, or by mains chargers. Several paramedics reported a lack of adequate means to keep the tablets charged;

> *"I've never used the charger. There – there was – there was only the lead in the back of the – the car. We had a problem with a couple them. I think the fuses were going on them or something." (End S1 04)*

> *"So we know roughly that the laptop won't quite last a full 12 hour shift if you're using it, even if it's, um, docked in the ambulance on charge because it's only a trickle charge, it doesn't really do a full charge." (End S2 02)*

There were a variety of practical problems reported in relation to printing. This posed a big challenge for paramedics as they had been instructed to leave a print-out of the CCDS assessment with patients. The problems included: that not all vehicles were equipped with working printers; not all printers were equipped with paper; printers were fixed to vehicles so paramedics had to go back to their vehicles to produce print-outs and then return to their patients to give them their copy (in all weathers, at all hours); slow printing speeds; quick fading print (therefore unreliable documentation); long, thin and unwieldy print-out paper.

> *"You have to walk back to the ambulance, print that off, and that – because it's – it burns it, it takes two or three minutes to actually print it off. And you end up with a sheet of paper that's about four foot long." (Mid S2 02)*

Paramedics reported a high level of frustration with printing issues (which for some became a barrier to CCDS use), as the quote below from a paramedic who was trying to print out a CCDS assessment demonstrates:

> *"I kept trying to try and get it working, try and get it working, and then when it was working there was no printer paper so like it was useless anyway, so I'd gone through it and then I couldn't print it out." (End S1 05)*

The printing set up in the rapid response vehicles (RRVs) at one site was problematic, especially as paramedics were exposed to the elements while using it:

> *"If it's pouring down with rain you've probably got it [the tablet] resting on the back – the back seat. Your backside's stuck out [laughs] in the – in the inclement weather, so from your waist down you're soaking – [laughs] you're soaking. And then you've got to open the hatchback to see the – to make sure the printer's working and that sort of business you know. .. You know, so that side of it – as far as the RRV was concerned was very difficult." (End S2 04)*

The way that the CCDS was set up at the two study sites differed greatly, resulting in quite different feedback from paramedics at each site. At site one paramedics needed an internet connection to complete CCDS assessments as they had an online version of the software. Patient data could not be stored on the tablets at site one (to meet local data security requirements) and had to be transferred at the end of CCDS completion via the internet to a secure NHS data storage facility.

This difference between ambulance services in the way that the CCDS was accessed and data transferred had a big impact on its usability, with paramedics at site one finding it difficult to use the software because of having to access it online without reliable connectivity. Problems with logging in and obtaining or maintaining an internet connection were commonly reported by site one paramedics.

"I was in one address at about two o'clock in the morning... she was referred and she accepted the referral and stuff. But when I went down to the car to – to send it, I didn't have a signal, which is frustrating after doing it all, you know.... Hmmm – there's one part of it when you have to connect to the server; that was slow. Oh – and I – in the end I'd – well, before the end, I said, "Oh, I'm not using that again." (End S1 04)

At site two the CCDS software was stored and completed on the tablet rather than online. Paramedics were able to store CCDS data on their tablets until it was convenient for them to download or email them to the ambulance station.

"The SAFER 1 package itself was fine, opened it up, started first time, and you could put the details in okay, so I didn't have problem with it. There was always--, it was always there when I wanted to use it." (End S2 02)

"If I have a problem actually I type it all up and save it to the actual Toughbook and then when I was able to get to somewhere I could actually send it or do it when I was at home, send it from home, so." (End S2 04)

Paramedics were generally positive about the ease of use of the CCDS software package itself.

"I'm of that generation where we didn't do it at school – it's all been through exploring and that kind of thing really. But I can – certainly I mean, the – the actual software isn't a challenge." (Mid S2 03)

However, many paramedics reported the lack of integration of the CCDS into the electronic patient report form as an issue. This meant that paramedics were not able to move seamlessly through the EPRF and CCDS but had to open and log into the CCDS separately, they also had to enter some of the same patient data onto both pieces of software, which was frustrating and time-consuming. Paramedics felt that the CCDS needed to be integrated into the electronic patient report forms in order to enable seamless, efficient working and to eliminate the need to enter the same data twice.

"If it [CCDS] could be somehow linked to the EPRF in a way, because I mean one of the things were obviously you do the tough book, and you write down all the observations that you found, you know, blood pressure, the pulse, and things like that, and you do it all for one, and then you'd have to go through all of those same reports again for the next one. So you was doing stuff twice." (End S2 02)

Paramedics felt that some of the CCDS questions needed to be refined. For example, one question in particular was highlighted by several paramedics as being inappropriate (and in fact self-defeating in relation to the purpose of the trial), with regard to whether the patient could get up:

"I mean the first question it asks was 'can the patient get up unassisted, or does it need assistance?' And basically the patient was calling you because they couldn't get up. You know, they've fallen and couldn't get up. So if you actually put down the patient needed assistance to get up, it automatically said, take the patient to hospital, which was... a silly question if you like.... But other than that the questions were, you know, they were quite thorough." (End S2 02)

In order to avoid an instant CCDS assessment that the patient should go to hospital, paramedics manipulated the answer to this question. In order for practitioners to have faith and confidence in CCDS, and for the CCDS to work effectively as a support tool, there need to be systems in place that provide the opportunity for problems such as these to be communicated back to the software providers and addressed.

8.6 The paramedic

This section explores the skills, knowledge, motivations, attitudes and other attributes of the paramedic that emerged from the data as salient to the use or non-use of CCDS by paramedics. A key theme emerging related to the individual differences between paramedics in terms of their attitudes to change and the degree to which they were resistant, receptive and adaptive (using interpretation and ingenuity) towards using CCDS.

8.6.1 Attitudes towards CCDS in principle

In general the paramedics involved in the study were positive about wanting to use the CCDS, although some reported concerns about their level of IT and keyboard skills and the practicalities of the system, including printing and charging. The paramedics in this study were volunteers and it is possible that this self-selecting group represented paramedics who were more open to change than those who did not volunteer.

"I think in general that paramedics, if it's going to be beneficial for both the public and for the paramedics, they are quite open to change and they are quite eager for anything that will improve our practice and as X stated in our conversation earlier, a standard approach is really needed rather than an individual approaches." (Pre S1 FG2)

The data revealed that paramedics saw the CCDS assessment, in conjunction with a timely response from a falls pathway service, as having the potential to a) address some of their concerns about non-conveyed patients receiving timely follow-up, and

b) provide paramedics with a standardised approach to assessment and care for this patient group.

> *"You know, the – I feel the trial is brilliant, where, you know, you can open doors for these elderly people. You know, I hope it becomes a thing that's – we'll be able to offer all the time within the health service, 'cause – 'cause I must've – I think I've referred more than ten people, at least. And, you know, obviously some of them are vulnerable adults as well, and to have something which is implemented within 48 hours then is superb, innit?" (Mid S1 07)*

Paramedics felt that the CCDS would provide them with backup, help and support and that it would make their decision-making easier, particularly in 'grey area' scenarios with patients i.e. where they weren't sure whether the best course of action was to convey or not. CCDS was seen as providing potentially useful information that the paramedic would take into account when making decisions and was not seen as being a threat to paramedic autonomy.

> *"It's a tool to aid decision-making, so my clinical judgement is assisted by it, if you like.... Just because the system says 'do this, do that', it doesn't necessarily mean that's correct for that particular patient... You know, there's certainly an element of overriding judgement, really. (Pre S2 01)*

> *"It's a system whereby you can type in all the relevant entries and it will give me an – not necessarily a definite answer, but an answer that I can use in conjunction with everything, including my experience, if you like. " (Pre S2 02)*

In general paramedics felt that the CCDS was suitable for this patient group, with several suggesting that it might also be adapted for use with other conditions (e.g. respiratory or abdominal problems, stroke pathways).

8.6.2 Paramedic approaches to CCDS use in practice

The data revealed that there were differences between individual paramedics with regard to how they approached using CCDS. While some paramedics responded to the challenges of using CCDS by discontinuing use, others exhibited a high degree of ingenuity and persistence in order to continue using the system. Some of the differences between paramedics that influenced their practice as individuals included:

- Attitudes towards change (receptiveness and resistance)

> *"I think we've got some crew members are very resistant to change and that's just a natural thing. They're just worried about anything new coming in. They think – they wouldn't bother with it." (Pre S1 FG1)*

- Approaches to the practical challenges encountered with the system

"I just gave up because it was just [sighs]--, too much hassle to be honest". (End S1 05)

- Previous IT skills and experience with using a computer and keyboard

"My IT skills will come into this every time. Do you know what I mean – or the lack of my IT skills. And I – you know, give me paper every time." (End S1 04)

- Attitudes towards organisational time pressure, additional workload and time spent on patient care
- Attitudes towards the risks associated with making non-conveyance decisions

While some paramedics reported losing motivation and momentum, others went to great lengths to overcome the problems they encountered with using the system and to adapt their practice to make it workable. As the study progressed, some paramedics evolved their own approach to when they would use CCDS. The rationales given for when they used CCDS included:

- Patients who they felt were potentially safe to be left at home with a referral
- Patients where they weren't sure whether to convey or not
- Patients they had already decided not to convey
- Only non-injured patients
- Not with patients requiring emergency care

"If they obviously need immediate attention – like they look on the point of collapse or they're about to die or something, then we obviously don't use it for that, because it's irrelevant to be honest with you, and it's gonna get I the way of patient care ." (Mid S2 03)

During the pre-trial focus groups paramedics discussed concerns that their practices were not standardised, and that practice and care delivery varied from paramedic to paramedic. The data from this study show that the paramedics involved did adopt the CCDS differently to each other. This is possibly partly due to the fact that although paramedics all received similar training and instruction, essentially they work in relative isolation to adopt new practices (especially in this instance as so few were using the new system), giving rise to a variety of approaches and interpretations of how and when to use CCDS in practice.

8.7 Factors influencing the decision to use CCDS

Paramedics in the study fell into three categories with regard to their reported use of CCDS; those who reported trying to use it with all eligible patients, those who only used it with patients who they thought were potentially safe to be left at home and those who didn't use it at all or discontinued use.

The two main reasons paramedics gave for not using CCDS were problems with the functionality of the system (see section 6.5, page 104) and that it took too long to use. At site one, where there were ongoing problems with the functionality of the system, it is possible that the unresolved problems effectively prevented paramedics from being able to use it.

> *"It was just like I was fighting all the time to get [printer] paper or get the password or get it working, I just gave up in the end." (End S1 05)*

In addition to it taking longer to use CCDS, paramedics reported that they couldn't predict in advance how long an assessment would take to complete as that depended on the patient's history. One paramedic reported that it could take anything from half an hour to one and three quarter hours.

> *"I used it a couple of times at the beginning and then towards the end, no. It's just too slow." (End S1 04)*

Some paramedics reported that their limited IT and typing skills slowed things down further:

> *"The more I started doing them in front of the patient, you'd have long pregnant pauses whilst I was trying to find the W and the E, do you know what I mean?... Hmmm – it – it did become a hindrance towards the end." (End S1 04)*

Other reasons paramedics gave for not using the CCDS included; that they didn't have the right equipment (paper, tablet, chargers), that they didn't have a signal or that they did not find CCDS to be of benefit. Several were not comfortable with taking the responsibility for making non-conveyance decisions and a few reported having lost motivation.

Several paramedics involved in the study reported that, as rapid response vehicle (RRV) drivers, they hadn't attended any eligible study patients. RRVs are vehicles used by ambulance services to reach a scene more quickly than a standard ambulance. Some of the rapid response paramedics involved in the study reported that they are only sent to urgent calls (Category A) in order to 'stop the clock' rather than to non-urgent calls, which included falls patients (Category C).

"I didn't use it because it only had – because of being in the car, out in this area, they were not sending us on the falls which are categorised as CAT Cs. They were keeping us for CAT A and CAT B responses at the time." (End S1 02)

Despite this, one paramedic suggested that RRV paramedics would be well placed to use CCDS with patients if the onus wasn't so much on their role being to 'stop the clock'.

"Right, there's a fall, up around. Can you go down? Just your normal road status, no need for.. for lights and sirens, it doesn't need that." ...That is when this system would, I think – would come into its fully glory. But then what they'd like to do then is not the car, because they want the car for the Category A calls." (Mid S1 SG)

In deciding whether or not to use CCDS, paramedics reported considering a number of factors relating to the patient and their situational context. These included the patient's condition, the location and time of the patient contact and, at site one, the availability of an internet connection to access the CCDS. For example, if a call was in the middle of the night some paramedics felt that completing CCDS could impact negatively on patients and their families:

"And – and it was in the early hours of the morning, and it's not a problem from our point of view because we were – we were working, [laughs] you know, but from – from – I mean the old – the – the person who had fallen had their son and his wife were there as well, and they were there because they'd been called and they were like, sort of, "Well, we want to go back home to bed, you know." (Mid S2 02)

Some paramedics felt that it was only beneficial to use the CCDS with patients who were possible candidates for referral to the falls service, and not for patients who needed to be conveyed. Others reported finding it useful with patients for whom it was unclear what represented best onward care option. Several paramedics in the study referred to this as the 'grey areas' where, having done all their assessments with a non-injured patient who has fallen, they can still be uncertain as to whether or not to convey a patient.

"It's the ones that are, "Well, do we need to take them to hospital or not?" That's where this package would be invaluable, because you can go through the questions and it would sort of back-up your thoughts, if you like." (Pre S2 02)

"I'd like – well, I'd like to think that with a thorough assessment, you wouldn't have to negotiate those grey areas quite so often, but they do crop up from time to time." (Pre S2 01)

In this situation, where paramedics are making key decisions about patient care in a context of ambiguity and uncertainty, the CCDS was also seen as a useful record of

the clinical assessment and decision making process. It was seen as being more robust than its paper counterpart, reducing the opportunity for variability in the way that information is recorded, and as providing evidence relating to the patient encounter.

8.8 How paramedics used CCDS in practice

As highlighted in section 6.6 on page 105, despite the low level of CCDS use across both sites, there were individuals who responded with persistence and ingenuity to overcome the challenges they encountered with using the system in order to be able to use it in practice.

> *"I managed to obtain a mains charger and a vehicle charger so I always made sure my laptop was fully charged whichever way I was doing it." (End S2 04)*

> *"Now, what I have managed to do is adapt it – the – the Toughbook in such a way, that I can now log it onto a printer at work. So I then have to print out the – the form, and sometimes go back to people's addresses and – and – and talk to them again. So, for me, it's a bit problematic, but I – I have found kind of ways round it. The – the system – the – the software itself is fine, it's just having the availability on all of our vehicles to have a printer that's functioning which – which has caused an issue." (Mid S2 08)*

As well as being keen to adopt the new technology, it could be argued that these particular paramedics are also 'front-line system innovators', identifying solutions to problems and evolving their practice in order to incorporate new ways of working. It would be interesting to find out to what extent these paramedics interact with their colleagues and managers and perhaps contribute to the development and evolution of new ways of working through sharing their ideas and practice.

There were some challenges for paramedics surrounding completing the software during the emergency care contact with patients, largely due to the time it took to complete. Some paramedics were inventive in coming up with ways that made using the system more feasible for them on-scene, including sharing the workload with colleagues. For example, some paramedics would work as a team to complete the patient record and CCDS. One would complete the CCDS on the tablet and the other would complete a paper patient form (as they only had one tablet between them). By completing the patient record and the CCDS simultaneously the amount of additional time on-scene was reduced.

> *"My crewmate would do a patient report form paper copy, and then that left me free to do the SAFER 1 laptop version... So – so we were both filling in records, and we was, sort of, working again as a little team." (Mid S2 02)*

Others reported completing the CCDS retrospectively.

The purpose of the software is to provide on-scene decision support to assist paramedics in their decision making regarding the onward care of patients. Retrospective completion of the software rather undermines its function as a decision support tool at the point when the decision is being made. It is possible that paramedics were using CCDS as a recording rather than an assessment tool in these instances.

> *"I tended to use it after the event to be honest. I said we'll pick them up off the floor, do all our checks, decide what we're going to do then--, and then kind of go through the software." (End S2-03)*

> *"And the last one I did last week, it was late in the evening and I know I'm supposed to do it, but I'd – I've – I filled it out retrospectively." (Mid S1 SGI)*

In some instances retrospective completion was undertaken because paramedics had already decided that the patient needed to be taken to hospital, and there was not enough time to complete the CCDS prior to the patient being conveyed.

8.9 Impact of CCDS on paramedic practice

This section presents the paramedics' view of the value and impact of CCDS on their practice with regard to patient care and clinical decision making.

8.9.1 Views on the impact of CCDS on patient care

While many paramedics cited time pressures as being a barrier to them being able to complete the CCDS with the patient, in a couple of instances paramedics reported finding value in the additional time they got to spend with the patient while they were using the software and saw it as having a beneficial impact on patient contact and care.

> *"See that way I gain consent and it gave me time to--, 'cause I like to also--, it gave me longer with the patient so I could keep an eye and see what they actually were like." (End S2 04)*

Several paramedics reported that spending additional time with patients to complete CCDS was not an issue for them as they were more focused on patient care than organisational time pressures.

> *"I don't have a problem with the time that it takes because, hmmm – if it means that I'm spending a little bit more time on-scene with my patient, then that's fine for me. I don't – I don't worry about the fact that I'm out of the system for a while." (Mid S2 08)*

"But it's more about duty of care to the patients so I haven't really got a problem with it, it just takes you longer." (End S2 04)

One concern mentioned by a few paramedics was the quality of their contact with the patient while they were looking at their keyboard and screen rather than being able to maintain eye-contact.

"But, that being said, I can still – I could put a lot of information into the care plan quickly, and still look at my patient. A lot of people said, "Well I have to look at the laptop, and because I look at the laptop, I can't look at my patient." (Mid S2 02)

One paramedic questioned the need for the decision support to be electronic at all, suggesting that paper-based decision support would be quicker, easier, more 'personal' and more reliable than CCDS.

"I would rather do the paper exercise. I think if you've got the paperwork trail and the clinical audit trail for that, that would be enough. As long as the [referral] pathways are there for you, they don't have to be electronically." (End S1 02)

8.9.2 Views on the impact of CCDS on paramedic practice

Despite the relatively low usage of the CCDS, many study paramedics reported that they felt it had some value in relation to their practice, as summarised below:

- As a useful support tool when a paramedic is unsure about whether it would be best to convey a patient or leave them at home with a referral (the 'grey areas')

"I see it as – it's an additional piece of equipment, or an additional package, that if you are unsure – I mean some patients that you go out that have fallen are quite clear cut. Yes, they can go to hospital, or no they don't. However, there are a percentage of them who fall into this bracket of, well, I'm not quite sure, and in that case – or in that instance, then they become – it's a good tool for that sort of – to assist you in your decision making if you like." (Mid S2 02)

- As confirmation that the course of action under consideration was appropriate:

"I found that it wasn't making the decision for me, it was just agreeing with the decision that I'd already come to.... It--, it aided my way once or twice, because there were one or two patients, as I said, that I was thinking well, does this patient need to go in, or doesn't it--, you know, or doesn't she. And it actually then confirmed that I was thinking... It sort of provided extra evidence for me to say, yes, I'm quite happy that that's the way we're going to take. So it did assist me in my decision making on a couple of occasions, yeah." (End S2 02)

- As a reminder and prompt to do all the necessary checks

"Yeah, just reminding you to do sort of--, the things you should do throughout the time but don't think about 'cause you think, well oh right blood pressure is okay I won't recheck it, and sometimes you find that when you did recheck it the blood pressure had dropped just for that short movement, so it's a primary cause why they fell then isn't it?" (End S2 04)

"It – it asks the question, you know, that: Is an EC- an ECG required? And it, again, you know, those sorts of things that maybe three or four o'clock in the morning, when – when you're – when you're not at your best is – it's always nice to receive that kind of prompt at times." (Mid S2 08)

- As a reminder to use the referral pathways available

"it's made me think more about making – about – about referring patients. I've always been an advocate of the – of – of referring people to Falls Prevention Teams and – and the suchlike. I think – I think that's one thing that it's highlighted to me, just to – a – a continual reminder that, you know, how important it is to make sure that you do do a referral." (Mid S2 08)

- As a legible and formal/standardised record of their patient assessment

"And I've now got something recorded and written, you know, legibly, that will back my decision. So if someone speaks to me tomorrow and says, "Why the hell did you leave that person at hos – at home?" you can say, you know – it's there's to, but – yeah, to back you up if you like, whereas before, it was just your word against whoever's, you know." (Mid S2 02)

"Well it's clearer isn't it because obviously I've written out--, under pressure my writing is atrocious and apparently I could beat a junior doctor with my writing." (End S2 04)

"I--, like I say I liked it because it--, one it gave you some form of documentation you had done a formal falls assessment, 'cause at the moment we've got no real formal assessment." (End S2 04)

- As a confidential and secure record of the patient assessment (as opposed to the paper forms, which they felt were vulnerable to being viewed, altered, stolen or misplaced either from vehicles or at ambulance stations)

"I work on a big site and the end of your shift you stick your forms in a tray in a corridor, so any Tom Dick or Harry could pick it up and look at it, or whatever can't they? Where an electronic one, once you've finished it, that's done isn't it? No-one can change the form in any way shape or form, it's done and dusted." (End S2 03)

- Honing paramedic skills with regard to assessing older patients who have fallen

"It – it's – it's almost as if it – as if my – my thoughts were more sort of focused towards falls – elderly falls, and – and the reason behind the falls. What we can do to stop the

falls – what you can do for the future? You know, that sort of business. Yeah, it's – it's opened – it's broadened my horizons as far as falls is concerned." (End S1 04)

"Hmmm, it got me thinking a little bit more of how we're treating falls." (End S1 07)

"No, as I say it's tweaked my skills a bit I think, like you say, that one about blood pressure with old people, I always will do it now, it's like second nature to me now to do a second--, after movement, and that sort of thing." (End S2 04)

Many paramedics held mixed views towards the CCDS, reporting benefits, but also questioning the value of its output, particularly with regard to its ability to assist with their decision making. Many of the paramedics in the study felt that the software was too simple or basic to assist them with their decision making.

"Sometimes we have a difference of opinion between myself and the software, and I'm going to every time default to my idea on that one. And just because it – it's quite basic software I think." (Mid S2 03)

"I just felt that, I don't know, some of the questions were... I don't know, just not as advanced or a bit below paramedic level on occasions." (End S1 05)

Some of the questions covered by the CCDS included whether the patient was able to get up or not, whether they were confused, bleeding or breathing normally. In these areas paramedics felt that their own clinical judgement skills and experience levels placed them in a better position than the CCDS to decide the most appropriate onward care.

The paramedics involved in this study were generally quite experienced paramedics, reflecting an imbalance in the recruitment of paramedics across a range of different levels of experience. The majority felt that the CCDS software would be better suited to paramedics with less clinical and decision making experience and skill than themselves:

"I think it would be more useful to those that are newly qualified, students, erm, people with less experience." (Mid S2 01)

"I've been in the job 20 years now and I found that it was just--, I could make the decisions quite quickly whether a patient needed to go to hospital or whether they didn't need to go to hospital myself. So as a tool, I think it has a place for a more inexperienced crew." (End S2 02)

"I had better clinical skills than the software. I think it would've been ideal if – if it was directed towards somebody who isn't medically trained, you know." (End S1 04)

While some paramedics reported that the CCDS was useful in support of their decision making, for example with 'grey area' patients, others reported that it didn't

influence them in the decisions they made about patient care as they relied on their own judgement rather than the CCDS output.

"I'll – I'll look at it – but, I won't actually – I won't let it influence me." (Mid S1 SG)

8.10 Impact of CCDS on paramedic role

Although several paramedics referred to how their role was changing and becoming more professional and skilled, in general using the CCDS was not considered fundamentally role-changing:

"Clinical decision making is still my primary role, like, so it's up to me." (End S2 04)

In some ways it was viewed as simply being another piece of kit in their toolbox and another skill they have learnt that is there to help them fulfil their role, rather than something in itself role-changing.

I don't think it's changed the role. No, no, it's – all the stuff we've had really has just been an extra tool in the – in the cupboard, if you know what I mean, whereas, yes, we still use all this fancy electronic stuff – we still use the bandages and the plasters and – and – and the drugs that we need, and – and – so – so it hasn't really changed – I suppose – the only way it's changed the role is if – it's – it's made us – hmmm – more skilled if you like. (Mid S2 02)

"I don't think it's changed my role, but it's certainly made parts of my role easier." (Mid S2 08)

Others felt that the CCDS, while not role-changing in the context of this study, had the potential for being used for a wider range of conditions and future use.

"I don't think it's changing my role, but this – I think it's definitely gotta be the way ahead. Hmmm – there's so much more that could be used with this, mind. You know, hmmm." (End S1 04)

Some paramedics felt that the CCDS impacted negatively on their ability to fulfill their role due to the additional demands it placed on them. One paramedic highlighted that if their role involved the use of technology that there needed to be additional time factored in to allow them to deal with the technological as well as the hands on elements of their work (time to use the computers and printers, access charging points, send and receive information etc.).

"We don't get downtime to access computers. So, hmmm, if you're sitting in an office all day that would be fine, but, hmmm, most of the time you're either on standby points or we're actually out working, so access to those computers are limited from the back of an

ambulance…. To book onto a computer after 14 hours of working is not ideal." (End S1 02)

Paramedics were asked whether they felt that having CCDS made a difference to the level of risk associated with their job. Although many didn't think that it made a difference, several paramedics reported feeling that having the CCDS assessment record provided them with additional backup and protection in relation to their decision making, particularly with regard to non-conveyance.

"The bottom line is I like this because I have got evidence to show that I have thought about what I am doing." (Pre S2 FG2)

When asked whether they felt that the CCDS undermined their autonomy or enhanced it paramedics generally reported that they felt it supported rather than undermined them as autonomous professionals.

"I mean I know they – they say that we're autonomous and stuff, but it's always nice to have somebody, you know, or something – Just you – what you believe – just to sort of back you up on it." (Mid S1 06)

"More empowered… especially because obviously I work as a lone worker, but it gives me some sort of… sections of authority and another guidance." (End S2 04)

8.11 Mechanisms for change

'Mechanisms for change' refer to both the formal measures put in place to support the implementation of CCDS such as training and ongoing organisational/operational support and the informal mechanisms such as feedback and communication pathways and the interaction of people and technology in effecting change.

8.11.1 Paramedic training

The majority of paramedics reported receiving between a half day and a full day's training to use the system (delivered either by the software company trainers, or by a trained member of the ambulance service). Several paramedics received a second, refresher training session which they reported finding beneficial. The feedback from most of the paramedics was that they felt they had received about the right amount of training. A few paramedics reported not feeling confident about using the CCDS following the training, and some felt that they would need to use it in order to get used to it.

At site one, paramedics reported that there had been a long delay between them receiving training and the start of the CCDS usage period (this was due to unforeseen technical problems) which had affected their enthusiasm for using the system. This could have contributed to lower CCDS usage levels at this site:

> *"I feel a bit disappointed that I was quite keen when it first started and it just never seemed to gather that momentum that I thought it would gather." (End S1 02)*

In contrast, at site two the paramedics started using CCDS as soon as they were trained:

> *"We went through the software with – with some practice cases to get used to using the software, and to familiarise ourselves with it, which was good – that was fine. I was happy with that, yes. I then went away and started to use the – the software straightaway." (Mid S2 08)*

Several paramedics reported that they discovered the existence of some elements of the CCDS from colleagues, post training (e.g. additional drop-down assessment menus). This suggests that the paramedics required some kind of post training follow-up to check competency levels and to provide additional training if required. If paramedics are to rely on CCDS software to support their decision making it is important that the tool is being used effectively, and that ambulance services support their practitioners during implementation to ensure that competence is achieved.

8.11.2 Ongoing support for the transition to new ways of working

Paramedics discussed the role of the ambulance service in supporting them through the 'transition' to new ways of working, not just through formal training but through providing ongoing support for paramedics as they adopt new ways of working. A support mechanism that paramedics proposed included having someone available to ask for advice. Paramedics also reported concerns over adopting new practice as sometimes they did not feel properly prepared or supported by their service to do this.

> *"P1 The thing is if there is a new policy X may read it, I may read it, Z may read, we will have a different interpretation of that and how it is worked I may have a different interpretation of how it and the way it is worked and that is where the discrepancy is if there is no training.*
>
> *P3 If there was full support and training and it was put in correctly and everybody knew on a broad scale that there was support and right ok this is, if you have got issues, this is the person to speak to whatever then obviously you would have a better response from*

those paramedics who are not prepared to make decisions, because they would have that back up and support - rather than there is that policy read it sign here and.." (Pre S1 FG2)

Examples were given by paramedics from one service where they felt that they had been asked to adopt new practices based on policies being introduced without formal training and ongoing support, for example in the assessment of mental capacity and in 'morphine implementation'. Paramedics reported that this approach to implementing new policies and practice in the ambulance service did not provide them with adequate training and ongoing support for the transition to autonomy, leading to resistance from some paramedics to new practices, and variability in practice and patient care (in part due to differing interpretations of how to implement new practice in the absence of formal training).

So, while many paramedics are prepared to adopt new ways of working and become more autonomous in their decision making, the transition requires adequate training and ongoing support for them to do so at both the operational and organisational level. It appeared from the differences between sites in terms of the organisational and ongoing operational support provided (reported in section 6.4) that the level of support required to facilitate implementation and enable paramedics to make this transition was in place at site two but not at site one.

8.11.3 The interaction of people, organisation and technology in changing practice

According to Strong Structuration Theory, the interplay between the individual, the organisation and the technology over time is key to the development and evolution of new ways of working. This section explores the interrelationship between the key elements involved in the implementation of CCDS i.e. the organisation (managers), the individual (paramedic) and the technology (CCDS). The role of feedback and communication across the tiers of the organisation in effecting change is also considered.

The two ambulance services involved in the study responded differently to the challenges of implementing this new technology. At an organisational level site two put a research paramedic in place to address problems encountered during implementation and to provide ongoing support to paramedics. The individual paramedics at that study site were able to communicate problems to this key person and have them addressed, resulting in the CCDS system being evolved and adapted to render it workable.

At study site one an operational manager was assigned to support the implementation of the study, to act as the key contact for the study and to help address issues raised by the paramedics. However, unlike at site two, this resource was not dedicated and other competing priorities existed. Paramedics at site one reported a very different experience in having their implementation problems addressed. One illustration of this was the lack of printer paper at the start of the trial, which prevented paramedics using the system because they had been instructed that they must leave a copy with the patient.

This gap in the support and communication pathway meant that problems were not communicated or addressed effectively across the organization at site one. One paramedic repeatedly went to pick up his tablet computer to take part in the study, but when it didn't materialise after several occasions he eventually decided to participate in the trial without the tablet (using paper-based falls assessment protocols instead of the CCDS). It was clear that the lack of organisational support at the operational level at site one was at least in part responsible for the abandonment of CCDS use by some of the paramedics involved in the study.

As the study progressed over time, paramedics began to adapt at an individual level how and when they used CCDS. Although paramedics were instructed to use the CCDS with all patients over 65 who had suffered a fall, in practice many paramedics reported that they came to the conclusion that there was no point in using it with patients who needed to be conveyed to hospital.

> *"If they obviously needed immediate medical attention – like they look, you know, they look on the point of collapse or they're about to die or something, then we obviously don't use it for that, because it's irrelevant, to be honest with you, and it's gonna get in the way of patient care." (Mid S2 03)*

This resulted in paramedics using CCDS with a more targeted patient group, i.e. those that they described as non-injured, who did not require immediate treatment at hospital and who they thought might be suitable for being left at home with onward referral. This illustrates how individuals can influence and shape the evolution of new ways of working over time.

> *"I mean, it's like I'm using it probably more now, the SAFER 1 system, when I'm not sure. You know, if I'm not sure that a patient immediately needs to go to hospital, or needs to see somebody, I will then introduce it as I'm going along." (Mid S2 02)*

Paramedics reported that time pressures were a disincentive to CCDS use in this study. If new working practices such as CCDS are adopted that require paramedics

to legitimately spend longer on scene with patients, then it will need to be communicated to paramedics additional on-scene time is acceptable. It could be argued that the organisational time pressures exerted an influence over paramedics that acted as a mechanism for maintaining the status quo, in conflict with supporting them in using CCDS.

With regard to working across the NHS, paramedics expressed that they had concerns prior to this study over non-conveyed patients as they weren't confident that they could rely on community based follow-up. While some paramedics reported that this study had given them confidence that the referral pathway in place would lead to non-conveyed patients receiving follow-up care through the falls referral pathway within 48 hours, others were still not comfortable with leaving patients at home with no confirmation that their patient had received follow-on care. In order for the policy objective of increasing referrals to community based care to be effective, the findings above suggest that paramedics need to have confidence in the referral pathways. These pathways need to respond to the needs of patients in a reliable, comprehensive and timely manner, with paramedics receiving some kind of feedback confirming that patients have been seen.

8.12 Study Limitations

The views and findings presented in this chapter are based on interviews and focus groups with 20 out of a possible 22 paramedics who volunteered to take part in the SAFER 1 trial and who were randomised to the intervention/CCDS use arm of the trial. There are a number of issues related to the study sample that could affect the broader applicability of the findings. Firstly, paramedics were invited to volunteer to participate in the SAFER1 trial and tended to have more experience as a group than would be expected among a randomly selected sample, so less experienced paramedics were under-represented. Also, as they were effectively a self-selecting group they may not represent the broader group from which they were drawn (it is possible that they over-represent paramedics who are keen to try something new). Finally, only 20 paramedics participated in this study as part of a pilot of CCDS, so limited study numbers also need to be considered when considering the applicability of the findings beyond the current setting.

There were implementation problems with the technology required to support the CCDS trial at site one that adversely affected the usability of the system at that site.

8.13 Conclusions and key messages

The findings from the qualitative element of this PhD highlight that there were many factors influencing the adoption of CCDS by paramedics. There were significant practical problems encountered with using the kit at both sites, including problems with charging, printing and data transfer. One site was able to address many of these issues (a dedicated member of staff was in place to support the trial and the IT systems were already set up to support the CCDS software), however at the other site problems persisted throughout the CCDS usage period.

In principle there was support and enthusiasm for computerised assessments and alternative pathways, where appropriate. However, some of the issues outlined in this chapter rendered if difficult for the paramedics to CCDS in practice. Despite the difficulties, which led to some paramedics giving up trying to use the software, other paramedics did use it, sometimes having to apply persistence and ingenuity to make it feasible to do so.

Paramedics gave an articulate and sophisticated analysis of what is wrong with the current system in relation to care for older patients who have fallen. However it is not clear from this study whether the structures are in place to allow this to be fed back and acted upon. The paramedics in this study saw CCDS in conjunction with a falls referral pathway offering a timely response to non-conveyed patients as a potential solution to some of the problems they feel they encounter when deciding the best course of onward care for this patient group.

Despite the low levels of CCDS use, many did highlight ways in which they found the tool useful, including:

- As confirmation that the course of action under consideration was appropriate:
- As a reminder and prompt to do all the necessary checks
- As documentary evidence of the assessment/decision making process
- For honing paramedic skills with regard to assessing older patients who have fallen
- As a useful support tool when a paramedic is unsure about whether it would be best to convey a patient or leave them at home with a referral

Many paramedics in this study were very experienced and reported feeling that the CCDS would be more suitable for newly qualified or less experienced paramedics. The paramedics that did use CCDS tended to adapt when they used it, who they

used it with and how they used it to suit the patient's situation and the operational context. In general paramedics did not feel that using CCDS changed their role, affected the risks associated with their job or undermined their autonomy.

Chapter 9: Discussion & conclusions

9.1 Overview

In this study the author examines the adoption of CCDS by paramedics. This chapter presents the findings from the research and is divided into sections, as follows. Firstly a brief summary of each of the main chapters is presented. The internal strengths and limitations of the study are then summarised and discussed. This is followed by a discussion of the strengths and limitations of this study in relation to other studies in this area, notably those presented in the systematic review conducted for this thesis. In the fourth section an interpretation of findings is presented in which the results from quantitative and qualitative elements of the study are synthesised and considered in the light of the theoretical framework. The chapter concludes with the implications of the study findings for future research, policy and practice.

9.2 Thesis summary

9.2.1 Policy context

In response to increasing demand on healthcare services, policies are being introduced to reduce the number of unnecessary hospital attendances and admissions. Policy makers are promoting a shift towards community based care, where appropriate. For example, community based referral pathways are being introduced for paramedics as alternatives to conveying patients to hospital. Initiatives have been introduced to enhance the autonomy of paramedics as clinical decision makers, to support them in making clinically appropriate decisions regarding onward patient care. There is currently a strong policy commitment to increasing the use of technology in healthcare. In the ambulance service electronic patient report forms are being introduced to enable paramedics to capture patient data electronically.

There is an underlying NHS policy principle that healthcare delivery should be standardised and evidence based. The evidence base needs to be developed alongside policy-driven service developments to establish impact on patient care and service delivery, and to inform future implementation.

9.2.2 Systematic review

A systematic review of CCDS in the emergency care setting identified that most of the emerging evidence was derived from studies carried out in the Emergency Departments of hospitals. None of the studies included were conducted in the prehospital emergency care setting. The majority of studies reported positive impacts associated with CCDS, largely related to improvements in process of care. However, consistent with studies of CCDS in other fields of healthcare, very few evaluated patient outcomes. The quality of the studies included in the systematic review was variable but did include several RCTs. Some authors reported that issues with study set up and implementation had adversely affected study quality. The findings from this review indicate that CCDS research in emergency care is in its infancy. Further high quality research is required to build on the evidence base and provide insight into the potential role for CCDS on process of care and patient outcomes, particularly in prehospital emergency care research.

9.2.3 Theoretical context

Theories relevant to the study of innovation in healthcare were reviewed. The theoretical approach used to underpin this study has evolved from the early work of Giddens (Giddens, 1984) on the diffusion of innovation. Giddens' work has been criticised from being too abstract for application by researchers (Greenhalgh, 2010). Strong Structuration Theory builds on the work of Giddens to provide a more concrete approach to the study of technology innovation in healthcare and provides the theoretical underpinning for this thesis (Stones, 2005).

9.2.4 Methods

This study brings together a systematic review of CCDS in prehospital care, data from a large scale cluster-randomised trial and data from qualitative research in order to examine the adoption of CCDS by paramedics at two ambulance service study sites, in England and Wales. This study builds on the work of the SAFER 1 trial and includes original data collected and analysed for this thesis in order to develop the evidence base relating to CCDS use in prehospital emergency care.

A concurrent/triangulation mixed methods design with merged results was used. This entailed collecting both quantitative data and qualitative data relating to paramedics use of CCDS over the same period of time. The data were then analysed and results presented for each strand of the study, before being synthesised and presented later in this chapter.

9.2.5 *Research setting*

Undertaking a cluster-randomised controlled trial in the ambulance service setting proved a challenge for both the research team and the participating ambulance services. Many of the challenges were related to the policy context, which led to a number of changes that resulted in some ambulance services withdrawing from the study. These included national ambulance service reorganisation, the roll-out of a national IT programme that clashed with the study timeframe, and the tightening of time-based performance targets leading to services focusing resources on operational targets rather than research activity.

The CCDS was implemented in a bespoke way at the participating study sites, due to differences in the existing technological set-up at these sites. At site two much of the technology infrastructure required to support the use of CCDS software was already in place prior to this study. Site two had previously implemented the hardware and software required for electronic patient reporting. Paramedics at this site were familiar with using a hand-held computer with patients, the IT department was already supporting paramedics to use computers with patients, and key ambulance service stakeholders already had experience of implementing new technology solutions. At this site the CCDS software was uploaded onto the service's existing computers and supported alongside existing systems.

As study site one the full range of hardware, software and support systems had to be put in place (tablets, printers, chargers, docking stations, training, IT systems, data transfer arrangements etc.) CCDS use at site one was also dependent on being able to maintain an internet connection. Despite endeavours to overcome the obstacles to successful implementation at this site, ongoing problems meant that the CCDS was very difficult to use at this site.

9.2.6 *Quantitative findings*

Patients in the intervention group were twice as likely to be referred to a falls service as those in the control group (estimated relative risk = 2.04; 95% CI 1.12 to 3.71). Non-conveyance rates did not vary between groups. Job cycle time was nine minutes longer in the intervention group (95% CI 2.2 to 14.9). There were no significant differences in overall duration of the episode of care.

Overall CCDS usage levels were low, particularly in site one (used with 2% of eligible patients at site one vs. 24% at site two). Usage varied between paramedics, ranging from 0% to 47% use with eligible patients. Older paramedics were more

likely to use CCDS and it was also more likely to be used for older patients. Study-wide CCDS usage data indicated that there were many attempts to log on to the CCDS system at site one, particularly early on, although very few CCDS records were produced. At site two a more consistent pattern of CCDS use was observed across the study period.

CCDS usage was also analysed, and patients with whom CCDS was used were three times more likely to be referred to a falls service (estimated relative risk = 3.11; 95% CI 1.40 to 6.89). They were twice as likely not to be taken to hospital (estimated relative risk = 2.09; 95% CI 1.11 to 3.94). While CCDS use increased mean job cycle time by 10.9 minutes (95% CI from 0.5 to 21.4), the overall episode of care (including ED attendance) was reduced by 113.8 minutes (95% CI from 77.2 to 150.3).

9.2.7 Qualitative findings

The findings from the qualitative element of this PhD highlight that there were many factors influencing the adoption of CCDS by paramedics. There were significant practical problems encountered with using the kit at both sites, including problems with charging, printing and data transfer. One site was able to address many of these issues (a dedicated member of staff was in place to support the trial and the IT systems were already set up to support the CCDS software), however at the other site problems persisted throughout the CCDS usage period. Despite the difficulties, which led to some paramedics giving up trying to use the software, other paramedics did use it, sometimes having to apply persistence and ingenuity to make it feasible to do so.

Many of the paramedics who used the CCDS reported adapting the way that they used it. For example they began selecting which older fallers to use it with (e.g. non-injured, or those where the paramedic was uncertain about the best course of action) and finding ways of using it effectively given the time-constraints on them (e.g. completing it retrospectively or by task-sharing with colleagues). The benefits of CCDS reported by paramedics included that it supported their decision making, provided documented evidence of the patient assessment, prompted them to do all the necessary checks and honed their skills with this patient group. Barriers to use included that the software was not integrated, it was time-consuming to complete and some paramedics did not find its output useful. In principle there was support for the potential of CCDS as another tool in their kit bag. However, further work is required to develop this potential.

9.3 Strengths and limitations of the study

9.3.1 Strengths and limitations of the systematic review

Twenty studies were identified for inclusion in the systematic review; however the search was limited to studies published in English between Dec 2000 and Jan 2011. Study selection and data extraction was strengthened by using a two-step process. All abstracts identified through the literature search were independently screened by a second reviewer in order to reduce selection bias. Full papers were then obtained and also screened using this two-step process. Data extraction was also conducted independently by a second reviewer in order to validate findings and reduce bias. At each stage discrepancies were discussed and resolved by consensus.

In order to present a comprehensive review of CCDS research activity in the emergency care setting, the author did not exclude studies on the basis of study design or quality. As a result the included studies vary greatly in their design, quality and outcomes measured. The heterogeneity between studies in terms of study design, CCDS features and outcome measures precluded a meta-analysis to pool effect sizes. A strength of this approach is that the systematic review chapter provides a broad picture of CCDS research activity in this setting, however a limitation is that the findings reported are of variable quality and CCDS effect is difficult to quantify. This narrative synthesis lays the foundation for meta-analysis. Preliminary analysis of the quality assessment scores indicate that there is scope for refining the inclusion criteria (e.g. to include RCTs only) and for a follow-on meta-analysis to be conducted.

9.3.2 Strengths and limitations of the quantitative research

New data were collected for this study, enabling the author to conduct analysis relating to the 42 paramedics who volunteered for the study. One limitation of this data set was that due to anonymised data processes it was not possible to link the paramedic demographic data to the individual patient for further analysis of CCDS usage as that would have potentially allowed for identification of individuals.

New analyses were also conducted to identify predictors of CCDS use. CCDS usage data from the wider trial (i.e. all use of CCDS, rather than CCDS use for eligible patients alone) was collected, demonstrating patterns of use across sites. A concern raised in the SAFER 1 report was that there was possibly incomplete or missing CCDS usage data at site one, potentially affecting the reliability of the findings. A strength of this study is that quantitative data from the wider study can be

examined in combination with the qualitative data to identify what happened at this site when paramedics used, or attempted to use, CCDS.

One limitation of this study was that the intervention was not implemented effectively at site one. The impact of this difference meant that CCDS usage levels at site one were potentially affected by issues related to implementation of the whole system, confusing the picture of CCDS use per se and the generalisability of the results to other settings.

9.3.1 Strengths and limitations of the qualitative research

The qualitative study was undertaken alongside the quantitative study in order to complement and supplement the quantitative findings. A strength of the data collection was that it was undertaken at three time points during the course of the study, pre-CCDS use, mid-CCDS use and at the end of the CCDS use period, allowing analysis of the paramedics' attitudes and experiences of CCDS as they evolved over time. All 22 intervention group paramedics were invited to participate in the qualitative element of the study, 20 of these agreed. Eight of these contributed data at two or more time points. The data collected are therefore representative of the intervention group paramedics across the study period.

Data were collected through a combination of focus groups, face to face interviews, telephone interviews and small group interviews with intervention group paramedics. It was not possible to conduct the majority of the focus groups scheduled for the beginning and end of the trial, as per the protocol, so semi-structured interviews were conducted instead. This was because it was not operationally feasible for ambulance services to release a large number of paramedics from ambulance duties, simultaneously, to attend focus groups. Shift patterns and leave patterns also made arranging focus group times very difficult. As a result only two focus groups were achieved, these were undertaken within the site one training day. Where focus groups were not practically achievable, a pragmatic approach prevailed and data were collected via semi-structured interviews instead.

9.4 Comparison with current literature

In Chapter 3, 20 studies of face-to-face CCDS in emergency care were reviewed. In this section the author compares the current CCDS study with those in the review. The comparison reviews the study settings, the CCDS interventions under

investigation, the methodologies used and the outcomes measured. Any similarities or differences observed are discussed.

9.4.1 Study setting

The studies in the systematic review were overwhelmingly conducted in the hospital ED setting, with no CCDS studies identified in the emergency prehospital setting. This is possibly a reflection of a difference between these two settings in terms of their organisational and technological readiness for conducting studies of CCDS. Front-line use of computers has only recently been introduced in the ambulance service, whereas computer technology is more established in the hospital setting, lending itself more readily to studies of CCDS at this time. As far as the author is aware this is the first time that CCDS has been implemented and its use studied in the prehospital emergency care setting.

9.4.2 CCDS intervention

Similar to the CCDS intervention under investigation in this study, 11 of the CCDS tools included in the review were designed to assist practitioners in the delivery of care, for example with diagnosis, prescribing or decision making (Brown et al., 2007, Kwok et al., 2009, Lorenzoni et al., 2006, Porter et al., 2006, Roukema et al., 2008, Roy et al., 2009, Sard et al., 2008, Selker et al., 2002, Terrell et al., 2009, Terrell et al., 2010). Ten of these reported positive impacts associated with CCDS, while one reported no overall impact (Porter et al., 2006).

Seven of the remaining studies were designed to compare CCDS outputs for patient triage or diagnosis, i.e. CCDS vs. CCDS, CCDS vs. practitioner or gold standard (Buising et al., 2008, Dong et al., 2005, Dong et al., 2006, Dong et al., 2007, Farion et al., 2008, Graber and VanScoy, 2003, Gravel et al., 2008). Five of these reported positive findings, one did not interpret the findings provided (Gravel et al., 2008) and one reported a negative finding, where the CCDS tool was found not to be accurate enough in its diagnosis to be relied upon (Graber and VanScoy, 2003). These studies were dissimilar to this trial of CCDS in that they set out to assess the reliability of the CCDS tool (or practitioner) rather than impact on delivery of care.

In common with this study, the two remaining studies focused on CCDS use. One of these compared CCDS use by clinicians when it was made available at the bedside on a mobile computer, compared to when it was only available on a desktop computer (Bullard, 2004). They found that CCDS was used more frequently when it was available at the bedside. The remaining study used a qualitative design to

explore CCDS use in several healthcare settings, containing similar elements to the qualitative study undertaken for this thesis (Dowding et al., 2009). Nurses were interviewed to explore how they used CCDS in clinical practice, and what factors influenced this. The reported findings were consistent with those from this study, including nurses reporting that CCDS had an up-skilling effect, that experience was a factor affecting use, and that nurses adapted their use of the tool to suit their needs.

Only one of the studies explicitly reported on the impact of CCDS on quality of clinical documentation (Kwok et al., 2009). A positive impact on the quality of clinical documentation and discharge plans was reported. The quality of clinical documentation was also assessed for the thesis and found to be consistently high both when CCDS was used and when it was not. The impact of CCDS on the duration of the clinical episode (time spent in ED) was also measured in one study, although no impact was reported (Roukema et al., 2008). This study, in contrast to Roukema's, did find a difference in times associated with CCDS use. It found that CCDS increased the job cycle time by 10.9 minutes, but reduced the overall episode of care duration by 113.8 minutes when CCDS was used. However, in the comparison between study groups (i.e. analysis by treatment allocated, rather than received) there was a similar increase in job cycle time, but no difference in overall episode of care time.

In common with this study, several of the studies in the review also reported issues with study set-up and implementation, low practitioner usage levels, and issues related to the unpredictability of the emergency care setting. For example, one prospective observational trial set out to measure the impact of CCDS on increasing the uptake of seasonal influenza vaccine (Venkat et al., 2010). The comparison was to be of vaccine uptake in year one (no CCDS) with vaccine uptake in year two (CCDS in place), however, the incidence of a national flu epidemic during the data collection period in year two resulted in a surge in the uptake of flu vaccine nationally, combined with the ED in the study running out of flu vaccine early on in the data collection period and having to halt data collection due to a national shortage of flu vaccine. The unfortunate timing of this flu epidemic for the research team resonates with the experience of this study in relation to the impact of the roll-out of a national EPRF programme during the study timeframe. It is arguable that the unpredictability of the emergency care setting is in itself a barrier to research, requiring high levels of perseverance and pragmatism from those involved in

research in this field, and understanding from study funders when unanticipated events impact on the research plan.

9.4.3 Study design

Seven of the 20 studies in the review were trials, five were cohort studies, five were observational studies, one a validation study, one a comparison study and only one of the 20 studies was qualitative. None of the studies in the review adopted a mixed methods approach to their CCDS study. However, in some instances authors provided descriptive accounts of events to provide a context for and explain some of the issues encountered in undertaking their research. These tended to be reported on in response to difficulties encountered, rather than routinely. It is a strength of this thesis that a mixed methods design was employed. This enables the author to synthesise both quantitative data collected as part of a cluster-randomised controlled trial, and qualitative data collected at three different time points in the study.

9.4.4 Outcome measures

Similar to this study, the majority of studies in the review (19/20) mainly reported on process of care outcome measures. The outcome measures related to process of care included whether the CCDS recommendations were adhered to, whether the CCDS and the practitioners' assessments agreed with each other and if or how the CCDS was used. Only two of the studies in the review reported patient outcome measures. One of these only did so as a validation measure of the predictive capability of the CCDS tool under investigation, rather than as a measure of the impact of CCDS use on patient health (Lorenzoni et al., 2006). The second study that reported patient outcomes found that CCDS had a negative impact on patient/parent satisfaction (Porter et al., 2006).

Studies that set out to measure patient outcomes were not always able to achieve the power required to report on them (for example, Brown, 2007). In a similar vein the SAFER 1 trial originally set out to measure patient outcomes at one and six months, however delays and difficulties with setting up the study and commencing data collection meant that it was not feasible to conduct the six month patient follow-up, affecting the ability of the research team to report the impact of CCDS on patient outcome measures, as per the original protocol;

> *"Whilst this meant that we were now unlikely to meet our target sample size, the Trial Steering Committee (TSC), research team and study funders agreed that worthwhile*

lessons could still be learned from the trial even if the effects were more likely to be found in the clinical and operational processes of care than the clinical or patient-reported outcomes of care." (Snooks et al., 2011) page 55

It is apparent from both the review and the SAFER 1 trial that studies of CCDS in the emergency care have been skewed towards reporting the impact of CCDS on process of care over patient outcomes. There are obviously challenges associated with powering studies to enable reporting against patient outcome measures. These need to consider and addressed, where possible, in future research in this area.

9.5 Interpretation of study findings

The study findings are synthesised and interpreted in the light of the theoretical framework, as described in Chapter 4, highlighting elements of Strong Structuration Theory: External structures; internal structures; action/active agency; outcomes (Stones, 2005). Stones' framework for studying innovation involves identifying the key agent (in this study, the paramedic) and then identifying the internal and external agents and structures associated with that key agent (the political and organisational context) and then exploring the recursive relationship between these elements in order to understand how new processes are, or are not, adopted in practice.

9.5.1 External structures

CCDS was implemented at two different study sites, enabling the author to compare the impact of the different conditions prevailing at these sites. At a macro level the political context was similar across sites in several ways. Both ambulance services at the time of the study were operating against a backdrop of policy pressure to meet tight response time targets that had been set by the Government. There was also political pressure on ambulance services to develop alternative care pathways for patients who did not need to attend hospital. Both services had recently been through a period of organisational change. The strategic vision for the CCDS at both sites was that it would support paramedics to become more autonomous decision makers in relation to the onward care of patients who had fallen.

The major difference between the two study sites (the external structures that provided the context for the CCDS implementation) was in their readiness for hosting a CCDS intervention. At site two, the ambulance service had already implemented electronic patient reporting and the infrastructure and support systems required to run the CCDS software were in place. It could be argued that this site

was technologically ready for the addition of CCDS software to its existing, stable IT network. In addition, key stakeholders throughout the organisation had previous experience of implementing new technology and addressing the challenges that this presents. It could be argued that the 'general disposition' of this organisation was more conducive to innovation. Indeed, this ambulance service was quick to realise the need for a dedicated person (a research paramedic) to support the implementation across the organisation, and to provide a key point of contact between paramedics and others involved in the study (e.g. service managers, the IT department and the research team). At this site paramedics reported receiving good support and having their problems addressed effectively by the research paramedic.

At site one, however, the technology infrastructure required to support CCDS was non-existent. It took a long time to identify and involve all the key players required to agree and implement the technology. The implementation required the establishment of IT processes and data sharing arrangements across several organisations (for a system solely for use by 10 paramedics for this study). The hardware had to be installed in vehicles, both electronic patient reporting software and the CCDS software were implemented simultaneously. Paramedics required training to use the hardware and both software packages. The person identified to support implementation operationally (an operational manager) had other, competing priorities. Paramedics at this site reported feeling that, despite problems being reported to the manager about not being able to use the system, they remained unresolved and led to many paramedics discontinuing attempts to use it.

It could be argued that at site one the CCDS implementation was not effective, the system as a whole did not function well and it never achieved stability. It is likely that some of the differences in CCDS use between sites reflected the differences between them in terms of their technological and organisational readiness to implement and support it effectively.

9.5.2 Internal structures (human and technological)

At the micro level the key human agents involved in this study were the paramedics. The paramedics who volunteered to take part in this study were motivated by a variety of reasons, including learning new skills and taking part in research, but largely in the hope of improving the care of the patient group. Many reported feeling that there was a gap in the provision of care for older patients who have fallen. Sometimes paramedics took these patients to hospital even though they didn't feel there was a clinical need because this was the only way they could be confident that

these patients' needs would be addressed, particularly out of hours. For them the CCDS and associated timely response from a falls referral pathway presented an opportunity to enable them to deliver potentially better care to this patient group.

Paramedics from site two came to the study with a previous technical knowledge and experience of using the tablet computer for electronic patient reporting. It is possible that the volunteers from this site represented those who, having experience of the technology were more comfortable using it. The degree of change in paramedic practice required to use CCDS at site one was greater than that required at site two as none of the paramedics had previous experience of the technology. Paramedics at site one therefore had to learn more and had to adapt their practice more to adopt the new system. It is possible that the incremental introduction of technological tools at site two (i.e. EPRF, followed by CCDS rather than introduced simultaneously) facilitated the increased likelihood of its adoption at this site.

Paramedics from both sites came to the study with a range of pre-determined socio-cultural norms related to their working environments. Some of these did not align with the requirements of the study, creating conflict for the paramedics about whether to use the CCDS or not. Two key examples of this relate to the conveyance culture at each site (i.e. level of perceived organisational support for non-conveyance decisions by paramedics) and the pressure to finish a job quickly in order to support organisational pressure to meet time-based performance targets. At site one paramedics reported that there was less of a conveyance culture, than those at site two, and fear of being disciplined by the ambulance service should a patient be left at home and then get sicker, was more of an issue for paramedics at this site. In addition, the time it took to complete the software was a barrier to many paramedics, as this was contrary to their established mindset and way of working. Only a couple of paramedics reported feeling that while it took longer to complete the CCDS on-scene the overall impact on resources might be viewed by the organisation as a benefit.

In order for tools such as CCDS to be effective, organisational expectations and ways of working need to be considered at the macro as well as the micro-level in order for conflicts between existing and new ways of working to be recognised and ameliorated.

9.5.3 Action/active agency (decision to use CCDS)

The findings from the qualitative element of this PhD highlight that there were many factors influencing the use of CCDS by paramedics. There were practical problems encountered with using the technology, particularly at site one where many paramedics abandoned trying to use it as a result. Other reasons given by paramedics for not using CCDS included that it that it took too long to complete, that it wasn't of benefit to them (e.g. the output was too basic), that it wasn't integrated and that they had to enter some data twice. A couple of barriers to CCDS use related to paramedics not being confident of the falls referral pathway end of the intervention, as they weren't comfortable not conveying patients, especially as they received no feedback about whether these patients had actually received the follow-up care intended and in the light of organisational support levels for non-conveyance decisions. This highlights the importance of the role of inter- and intra-organisational feedback mechanisms for supporting change in practice.

Paramedics in the intervention arm of the study were asked to use CCDS with all older fallers. However, many paramedics reported developing their own approach to when to use it or not. Several paramedics reported cherry-picking the patients with whom they used CCDS, reserving it for those who were non-injured, who they did not feel needed to go to hospital, or for patients where they were unsure whether or not to convey. Data showed that the CCDS was used more often with older patients, suggesting that this might be the group of patients for whom paramedics found CCDS support most beneficial. They also found ways of using it effectively given the time-constraints on them (e.g. completing it retrospectively or by task-sharing with colleagues).

Other factors that they reported taking into account included the location of the incident (more likely to use it when the patient was at home); the time of day (concerns over keeping people up in the middle of the night); time pressures and, at site one, whether or not there was a mobile network signal. It was apparent from the data that several paramedics adapted their ways of working to address and overcome some of the practical problems that they encountered with using the system. For example, finding ways to keep the tablet charged, to download information and to ensure that patients got a print out of the assessment. Paramedics, who work in relative isolation, adapted and evolved their practice at an individual level, to enable them to work with the technology in a way that suits them, their patients and the organisation as a whole.

It is possible that this evolving and adaptive practice is an inevitable and useful stage of the implementation process, offering insights to the implementing organisation with regard to how paramedics might be best placed to use new technology in practice. However, it may also reflect a propensity for practitioners in this field to develop a range of non-standard working practices with unknown impact on patient care.

9.5.4 Outcomes (effects on practice and patient care)

Overall CCDS usage levels were low, in fact it was only used with 12% of eligible patients. Across sites a very different picture of usage emerged, with CCDS used for only 2% of eligible patients at site one, and for 24% at site two. This possibly reflects the differences between these organisations in terms of their technical and organisational readiness to implement this intervention effectively.

General study data from site one suggest that there were many attempted uses of the system in the early months of the study at site (although these log-on attempts were not often translated into patient CCDS records), which diminished rapidly. Paramedics at this site reported being very frustrated at the start of the study as, despite feeding back the problems they were having using the kit to the person in place to support implementation, the problems remained unresolved, leading to many paramedics at this site abandoning the CCDS in the first few months of the study. This may reflect a critical period in implementation at this site, where feedback as a mechanism for supporting change in practice was not used effectively by the organisational systems in place, and the CCDS technology was rejected. CCDS use at site two was more consistent during the study period, with an average of five CCDS records produced per month at this site. It is clear that the technology in place and the systems to support CCDS practice were more stable and effective at this site.

There were also big differences in the number of times that paramedics used CCDS, with many using it only a few times or not at all, compared to one paramedic who used it 26 times. Those that used CCDS reported that it had been helpful in some respects in that it provided a back-up to their decision making and a documented record of their assessment. However, paramedics reported using their own professional judgement in preference to the recommendation of the CCDS when there was a difference of opinion between them.

The CCDS was found to have an impact on patient care. Analysis of the patient referral data showed that paramedics in the intervention group were twice as likely to refer patients to falls services as those in the control group. This was an effect that was seen regardless of whether the intervention group paramedic actually completed the CCDS or not. When the data were analysed to determine the impact of CCDS in those instances where it was used, it was found that CCDS use was associated with higher referral and non-conveyance rates as well as shorter episode of care times.

Given that the paramedics often reported selecting which patients to use CCDS with, there is a possibility that the higher referral and non-conveyance rates associated with CCDS use are due to paramedics selecting to use the tool with patients whom they would have left at home anyway.

Although the evidence shows that when paramedics used CCDS it made a significant difference to process of care outcomes, the fact remains that it was rarely used. In total only 69 CCDS records were produced for patients during the study, with site two accounting for 60 of these.

The outcomes of this study relate to the small-scale introduction of CCDS as part of a research project, to be used for a finite period (12 months). For that reason it is difficult to assess the ongoing impact of this intervention on paramedic practice, patient care or organisation and how these positions are reproduced or changed.

However, the results of the study demonstrate that even when implemented on a small scale, for a small time frame, amidst a host of competing priorities, the CCDS intervention had an impact on falls referral rates. When it was actually used with patients the referral rates were three times higher, non-conveyance rates were twice as high and the overall episode of emergency care was reduced by 113.8 minutes.

Despite low usage levels overall, the paramedics in the study were generally supportive of CCDS in principle, with many suggesting that it had potential for a range of conditions. Many saw the move towards more technology on the job as being inevitable. While some paramedics reported rejecting the technology, others incorporated it into their practice, seeing it as another tool in the kit bag.

From interviews conducted at the start of the study, some paramedics felt that the introduction of new technology would pose a problem for older members of the service. However, analysis of CCDS use by paramedic age identified that older paramedics were more likely to use CCDS.

9.6 Implications for the future

9.6.1 Implications for policy

Finding ways to meet the increasing demand on healthcare services is a challenge for policy makers in the UK and internationally. In emergency care, strategic ways of reducing unnecessary hospital and attendances are high on the political agenda. Policies that have been implemented to address this include introducing higher level training for paramedics (e.g. emergency care practitioner training) to enable them to make safe clinical decisions regarding patient care. Policies also exist to promote the use of alternative community-based care pathways for patients who do not need to attend hospital. In addition, the use of technology is being introduced at the front-line of emergency care delivery through the use of electronic patient reporting.

This study of CCDS demonstrates that it has the potential to support paramedic decision making regarding onward patient care. The implications of this for policy makers are:

- CCDS can provide paramedics with support to make higher level clinical decisions regarding onward care, without the need for extended training
- CCDS can be used in conjunction with alternative care pathways, providing support for paramedics to make decisions in the knowledge that if they leave a patient at home they will receive follow-on care
- CCDS in this study was targeted at older fallers, but has potential with a wider patient group
- CCDS is demonstrated in this study to have the potential to increase referral rates to alternative care pathways, to increase non-conveyance rates and to reduce the time of the overall episode of patient care
- CCDS is a technology that is compatible with national IT developments at the front-line of emergency care

In order to develop the potential and the evidence base for CCDS, research and development needs to be conducted at the service level. Current policies that result in ambulance services prioritising time-based performance targets over other activities detract from this aim. While CCDS has demonstrated the potential for supporting policy makers to meet some of their objectives relating to reducing unnecessary hospital attendance, more support for research and development activities at policy level is required.

9.6.2 Implications for practice

The role of the paramedic is evolving, from that of skilled ambulance driver to clinical professional. Degree level training is now required to become a paramedic. Alongside this shift is an increasing expectation on paramedics to make important clinical decisions regarding patient care, including decisions regarding non-conveyance. CCDS offers paramedics an evidence based clinical tool that they can use to help support and document their decision making in the field.

What we have learnt from this study is that in order for an innovation such as CCDS to be used by paramedics, it is vital that systems are in place that enable its use. Implementation of new technology requires support across the organisation and is not a one off event, but an ongoing process. Organisational and technological readiness for innovation is a factor that can impact on successful implementation of a new innovation. In this study the CCDS intervention proved difficult to use at one site due to unresolved problems with implementation.

While paramedics in the study were supportive of CCDS in principle and its potential for use with other conditions, in practice it was only used with 12% of eligible patients. Paramedics who did use CCDS reported choosing to use it with those patients who were 'suitable' rather than 'eligible'. For these paramedics it was not a case of adopting it or rejecting CCDS, but developing their own approach as to how and when they used it e.g. only with patients with whom they were uncertain about the best course of action.

Many paramedics reported that they felt the shift towards increasing use of technology at the front-line was inevitable. CCDS represents a major development in technological support for paramedics at the front line. In order for paramedics to adopt new technologies such as this, implementation needs to be supported effectively at the organisational level.

9.6.3 Implications for research

Technology innovation studies in prehospital emergency care are in their infancy. This thesis highlights that there are many interesting areas for exploration in this area. These include questions relating to organisational approaches to the implementation of innovation. This was a study of CCDS use as part of a piece of research. It is possible that if an ambulance service were to implement a technology such as this in real life, rather than in an artificial research setting that the findings might be different.

Prehospital emergency care is a challenging research setting. In order to facilitate CCDS research with ambulance services in the future, key service stakeholders should be identified and involved at an early stage, with commitment sought across all levels of the organisation. Communication channels and decision making processes need to be agreed. IT resources and expertise must be available to develop, test and implement new technology. Time is also required to agree and obtain permissions for workable data collection, sharing and security processes. The ability to establish a workable version of the intervention at each site is also critical, along with effective ongoing operational support.

The evidence from this study suggests that although usage CCDS usage levels in this study were low, when CCDS was used the impact on patient care was in line with policy objectives to increase referrals to community based care as well as reduce unnecessary hospital attendances. Many paramedics reported feeling that the CCDS could be used to cover a wider range of conditions. They also suggested that CCDS might be of benefit to less experienced paramedics.

Despite low usage levels, the early evidence is promising and the opportunity exists for researchers to develop this work to the next level, learning from the process of this first C-RCT to implement a second, integrated version of CCDS for a wider range of conditions. There are many lessons to be learnt from this study in relation to research set-up, implementation, organisational engagement, technological readiness, effective feedback mechanisms and the support required to support CCDS initiatives into practice.

The literature review demonstrates that there is little existing evidence in relation to CCDS use in the emergency care setting, and the prehospital emergency care setting in particular. The research that does exist tends to provide evidence in relation to process of care rather than patient outcomes. In order to address this imbalance and to build a quality evidence base related to CCDS in prehospital care, a further Swansea University study of CCDS in emergency prehospital care has been funded (a C-RCT with a qualitative component and a clinical safety panel) and is due to commence in 2013. The author of this study was involved in developing the proposal for funding of the above study, and is due to commence work on it in the New Year.

9.7 Conclusion

This thesis explored the introduction of CCDS to the emergency ambulance service, as a tool to support paramedics in decision-making about whether or not an older patient who had fallen could be safely left at home, with referral to a falls service. The overall aim was to explore how paramedics adopted CCDS, and what difference it made to their work. The study considered both processes of implementation (how CCDS was introduced at organisational level) and adoption (the decisions made by individual practitioners about use of CCDS). The topic was highly relevant to three themes of current policy in the health service: increasing the use of technology and in particular the use of computers in clinical practice; standardising and formalising procedures to achieve optimal care for all patients and minimise risk; and providing safe alternatives to hospital based care which offer a better experience for patients as well as being more efficient. The study built on the extensive empirical and theoretical literature about change and innovation within service delivery, making particular use of the theoretical framework set out in Strong Structuration Theory.

The quantitative phase of the study found that, in those cases where CCDS was used, it was associated with patients being more likely to be left at home and more likely to be referred to a falls service than were their peers. Although paramedics may have spent a little more time with them, the overall length of time that patients spent with the emergency services was on average substantially lower, because they were less likely to be spending time in the Emergency Department. All of this sounds extremely promising in terms of improving the quality of patient care and reducing demand on the Emergency Department.

However, CCDS was used only in a very small proportion of relevant cases – just 12% on average across the two study sites. All of those paramedics who had signed up to be in the study might be assumed to have some interest in adopting the technology, and yet some of them did not use it once. Others tried it out, then gave up, with only a few enthusiasts continuing to use it regularly through the trial period. Many of those who did use CCDS reported using it in a slightly different way from that which was intended – to confirm a decision already made, for example, rather than to support the making of a decision. Paramedics' adoption of CCDS – a process over the trial period rather than a one-off event – was shaped by both internal and external structures, and the relationship between the two played out in paramedics' own agency. Internal structures included their own skills with using technology, and their beliefs and attitudes about non-conveyance and risk. External structures included the kit itself – both hardware and software – and the training,

support and guidance provided by their employing organisations. A strong message emerged about the technical challenges of using the kit being, in some contexts, impossible to overcome. In other contexts, paramedics could perceive advantages of using CCDS, and chose to make use of it when appropriate.

A large scale cluster randomised control trial at Swansea University provided the context for the work reported in this thesis. The advantage of linking the PhD to the trial was that it provided access to extensive datasets on the impact of the new technology, in terms of changes to operational practice and patient outcomes. It also provided the author with an entrée to the two ambulance services being studied. Since the innovation took place in the context of a trial, it was time limited, paramedics had the opportunity to opt out, their motivations for using the CCDS may have had an extra element of complexity, and the guidance and support they were receiving from the hierarchy of their own employer organisations may have been ambivalent. Bearing this in mind, the processes of adoption studied in this thesis should be considered as an example of adoption of CCDS in a particular research context, rather than an example of implementation and adoption taking place solely within, and led by, a service delivery organisation.

Nevertheless, the study provides useful lessons for policy makers, practitioners and researchers about the challenges to getting a new technology adopted in practice in prehospital care. It is a context where, previously, there has been only limited use of technology, and the introduction of CCDS presented a major shift in working practice, especially in one of the study sites. Large scale research trials are also still a rarity in prehospital emergency care, and researchers face particular challenges in terms of trialling new approaches to healthcare - challenges which, as this study has shown, present a topic of interest in their own right.

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Appendices

1. PRISMA checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	32
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	n/a
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	40
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	41
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	n/a
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	41
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	42
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	42
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	43
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	43

Section/topic	#	Checklist item	Reported on page #
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	44
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	45
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	44
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	45
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	45
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	45
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	47
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	213
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	56
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	n/a
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	213
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a

Section/topic	#	Checklist item	Reported on page #
DISCUSSION			
Summary of evidence	24	Summarise the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	64
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	68
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	68
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	n/a

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

2. Full details of database searches conducted for the systematic review

The search strategy for each database is presented below.

CINAHL

LIMITS – 2000-2011 Eng Lang Peer Rev.

(((MH "Decision Making, Computer Assisted") OR (MH "Diagnosis, Computer Assisted")) or ((("computer* clinical decision support" OR "computer assisted decision making" OR "computer assisted diagnosis" OR "computer* medical decision support" OR "computer assisted medical decision support" OR "computer* clinical decision support" OR "computer* decision support system*" OR "computer* clinical decision support system*" OR "decision analysis computer assisted" OR "medical decision making computer assisted" OR "computer-based decision support" OR electronic decision support)) or ((computer* OR electronic OR pda OR hand-held OR handheld) and (ccds OR ccdss OR cdss)))) or ((MH "Decision Support Systems, Clinical" OR MH "Decision Support Techniques" OR MH "Decision Trees") and (computer* OR electronic OR handheld device OR hand-held device OR pda or online or web-based))

AND

(prehospital OR pre-hospital OR paramedic* OR ambulance* OR unscheduled OR unplanned OR telemedicine OR emergency health personnel OR emergency services hospital OR emergicent* OR urgent care cent* OR first responder* OR "accident and emergency" OR emergency triage OR nhs direct OR telecare OR 999 OR rapid response vehicle OR mobile emergency unit* OR mobile emergency care) or ((MH "Prehospital Care") OR (MH "Emergency Medical Technicians") OR (MH "Ambulances") OR (MH "Telemedicine") OR (MH "Emergency Service") OR (MH "Emergency Medical Services") OR (MH "Triage") OR (MH "Emergencies"))

PubMed

Limits: Humans, English, Publication Date from 2000 to 2011

Search ((prehospital OR "pre-hospital" OR paramedic* OR ambulance* OR unscheduled* OR unplanned OR telemedicine OR "emergency health personnel" OR "emergency services hospital" OR emergicent* OR "urgent care cent*" OR "first responder*" OR "accident and emergency" OR "emergency triage" OR "nhs direct" OR telecare OR 999 OR "rapid response vehicle" OR "mobile emergency unit" OR "mobile emergency care") OR ("Emergency Medical Services"[Mesh]) AND ((((((((((("Emergency Service, Hospital"[Mesh] OR "Trauma Centers"[Mesh]) OR "Ambulances"[Mesh]) OR "Emergency Medical Services"[Mesh]) OR "Emergencies"[Mesh]) OR "Hotlines"[Mesh]) OR "Evidence-Based Emergency Medicine"[Mesh]) OR "Emergency Treatment"[Mesh]) OR "Emergency Nursing"[Mesh]) OR "Triage"[Mesh]) OR "Telemedicine"[Mesh]) OR "Remote Consultation"[Mesh])) AND (("Decision Making, Computer-Assisted"[Mesh] OR "Diagnosis, Computer-Assisted"[Mesh]) OR ("computer* clinical decision support" OR "computer assisted decision making" OR "computer assisted diagnosis" OR "computer* medical decision support" OR "computer assisted medical decision support" OR "computer* clinical decision support" OR "computer* decision support system*" OR "computer* clinical decision support system*" OR "decision analysis computer assisted" OR "medical decision

making computer assisted" OR "computer-based decision support" OR "electronic decision support") OR ((comput* OR electronic OR pda OR "hand-held" OR handheld) AND (ccds OR ccdss OR cdss)) OR ((("Decision Support Systems, Clinical"[Mesh] OR "Decision Support Techniques"[Mesh]) OR "Decision Trees"[Mesh]) AND (computer* OR electronic OR "handheld device" OR "hand-held device" OR pda OR online OR "web-based")))

HMIC

Paramedic

(prehospital or pre-hospital or paramedic* or ambulance* or unscheduled or unplanned or telemedicine or emergency health personnel or emergency services hospital or emergicent* or urgent care cent* or first responder* or "accident and emergency" or emergency triage or nhs direct or telecare or "999" or rapid response vehicle or mobile emergency unit* or mobile emergency care).mp. [mp=title, other title, abstract, heading words]

exp EMERGENCY TREATMENT/ or exp EMERGENCY HEALTH SERVICES/ or exp AMBULANCE SERVICES/ or exp AMBULANCE STAFF/ or exp EMERGENCY SERVICES/

exp TELEMEDICINE/

exp TRIAGE/

exp EMERGENCIES/

= 8912

Computerised clinical decision support

("computer* clinical decision support" OR "computer assisted decision making" OR "computer assisted diagnosis" OR "computer* medical decision support" OR "computer assisted medical decision support" OR "computer* clinical decision support" OR "computer* decision support system*" OR "computer* clinical decision support system*" OR "decision analysis computer assisted" OR "medical decision making computer assisted" OR "computer-based decision support" OR electronic decision support) - Including Limited Related Terms

ccds OR ccdss OR cdss - Including Limited Related Terms

(exp computer aided diagnosis/ OR decision making/ or computer aided decision making/

decision making/ or decision models/ or decision support systems/ OR exp DECISION ANALYSIS/) AND (computer* or electronic or handheld device or hand-held device or pda or online or web-based).mp. [mp=title, other title, abstract, heading words]

Cochrane

#1	MeSH descriptor **Decision Making** explode all trees	2315	edit	delete
#2	MeSH descriptor **Decision Support Techniques**, this term only	1380	edit	delete
#3	MeSH descriptor **Decision Support Systems, Clinical** explode all trees	206	edit	delete
#4	(computer* OR handheld device OR hand held device OR pda OR electronic OR online):ti,ab,kw	17332	edit	delete
#5	(((#1 AND oe AND #2) OR #3) AND #4)	138	edit	delete

#6	MeSH descriptor **Decision Making, Computer-Assisted**, this term only	134	edit	delete
#7	MeSH descriptor **Diagnosis, Computer-Assisted**, this term only	603	edit	delete
#8	(computer* OR electronic OR pda OR hand-held OR handheld) and (ccds OR ccdss OR cdss):ti,ab,kw	22	edit	delete
#9	(computer* clinical decision support OR computer assisted decision making OR computer assisted diagnosis OR computer* medical decision support OR computer assisted medical decision support OR computer* clinical decision support OR computer* decision suppo	1914	edit	delete
#10	(prehospital OR pre-hospital OR paramedic* OR ambulance* OR unscheduled OR unplanned OR telemedicine OR emergency health personnel OR emergency services hospital OR emergicent* OR urgent care cent* OR first responder* OR "accident and emergency" OR emerg	6888	edit	delete
#11	MeSH descriptor **Emergency Medical Services**, this term only	734	edit	delete
#12	MeSH descriptor **Emergency Service, Hospital**, this term only	1374	edit	delete
#13	MeSH descriptor **Trauma Centers** explode all trees	182	edit	delete
#14	MeSH descriptor **Ambulances** explode all trees	119	edit	delete
#15	MeSH descriptor **Emergencies** explode all trees	609	edit	delete
#16	MeSH descriptor **Hotlines** explode all trees	101	edit	delete
#17	MeSH descriptor **Evidence-Based Emergency Medicine** explode all trees	3	edit	delete
#18	MeSH descriptor **Emergency Treatment** explode all trees	3357	edit	delete
#19	MeSH descriptor **Emergency Nursing** explode all trees	51	edit	delete
#20	MeSH descriptor **Triage** explode all trees	191	edit	delete
#21	MeSH descriptor **Telemedicine**, this term only	639	edit	delete
#22	MeSH descriptor **Remote Consultation** explode all trees	312	edit	delete
#23	(computer* OR electronic OR pda OR hand-held OR handheld) and (ccds OR ccdss OR cdss) :ti,ab,kw	22	edit	delete
#24	(#10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22)	11161	edit	delete
#25	(#5 OR #6 OR #7 OR #8 OR #9)	1924	edit	delete
#26	(#25 OR #23)	1924	edit	delete

#27 (#24 AND #26), from 2000 to 2011 62 edit delete

Web of Science

Topic=(prehospital OR pre-hospital OR paramedic* OR ambulance* OR unscheduled OR unplanned OR telemedicine OR emergency health personnel OR emergency services hospital OR emergicent* OR urgent care cent* OR first responder* OR "accident and emergency" OR emergency triage OR nhs direct OR telecare OR 999 OR rapid response vehicle OR mobile emergency unit* OR mobile emergency care) AND Topic=(computer* clinical decision support OR computer assisted decision making OR computer assisted diagnosis OR computer* medical decision support OR computer assisted medical decision support OR computer* clinical decision support OR computer* decision support system* OR computer* clinical decision support system* OR decision analysis computer assisted OR medical decision making computer assisted OR computer-based decision support OR electronic decision support or ((computer* OR electronic OR pda OR hand-held OR handheld) and (ccds OR ccdss OR cdss)))

British Nursing Index (BNI)

Search modes - Boolean/Phrase

prehospital OR "pre-hospital" OR paramedic* OR ambulance* OR unscheduled OR unplanned OR telemedicine OR "emergency health personnel OR "emergency services hospital" OR emergicent* OR "urgent care cent*" OR "first responder*" OR "accident and emergency" OR "emergency triage" OR "nhs direct" OR telecare OR 999 OR "rapid response vehicle" OR "mobile emergency unit" OR "mobile emergency care"

and

("computer* clinical decision support" OR "computer assisted decision making" OR "computer assisted diagnosis" OR "computer* medical decision support" OR "computer assisted medical decision support" OR "computer* clinical decision support" OR "computer* decision support system*" OR "computer* clinical decision support system*" OR "decision analysis computer assisted" OR "medical decision making computer assisted" OR "computer-based decision support" OR "electronic decision support") or ((computer* OR electronic OR pda OR "hand-held" OR handheld) AND (ccds OR ccdss OR cdss))("computer* clinical decision support" OR "computer assisted decision making" OR "computer assisted diagnosis" OR "computer* medical decision support" OR "computer assisted medical decision support" OR "computer* clinical decision support" OR "computer* decision support system*" OR "computer* clinical decision support system*" OR "decision analysis computer assisted" OR "medical decision making computer assisted" OR "computer-based decision support" OR "electronic decision support") or ((comp showHistoryTerm('ct100_ct100_MainContentArea_HistoryControl_HistoryRepeater_ct102_showless',false)

NHS Evidence and Intute (keyword searches)

"computer* clinical decision support" OR "computer assisted decision making" OR "computer assisted diagnosis" OR "computer* medical decision support" OR "computer assisted medical decision support" OR "computer* clinical decision support" OR "computer* decision support system*" OR "computer* clinical decision support system*" OR "decision analysis computer assisted" OR "medical decision making computer assisted" OR "computer-based decision support" OR electronic decision support or ((computer* OR electronic OR pda OR hand-held OR handheld) and (ccds OR ccdss OR cdss))

AND

prehospital OR pre-hospital OR paramedic* OR ambulance* OR unscheduled OR unplanned OR telemedicine OR emergency health personnel OR emergency services hospital OR emergicent* OR urgent care cent* OR first responder* OR "accident and emergency" OR emergency triage OR nhs direct OR telecare OR 999 OR rapid response vehicle OR mobile emergency unit* OR mobile emergency care

3. Systematic review data extraction table

Study ID (from Endnote)										
Source										
Reviewer										
Study refs (+ country)										
Study type										
Quality score										
No of sites										
Participants (i.e. those under evaluation)										
No patients										
Intervention & setting										
Process of care outcome measures										
Patient outcome measures										
Process of care results										
Patient outcome results										
Implementati on issues reported										
Adoption issues reported										

4. Quality assessment checklist used for the systematic review

QUALITY CHECK LIST FOR EFFECTIVENESS STUDIES
developed by Lewis et al [1] based on the checklist by Downes and Black[2].

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

yes	1
no	0

2. *Are the main outcomes to be measured clearly described?*

yes	1
no	0

3. *Are the characteristics of the patients included in the study clearly described?*

In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. *Are the interventions of interest clearly described?*

Treatments and placebo (where relevant) or groups that are to be compared should be clearly described.

yes	1
no	0

5. *Are the distributions of principal confounders (including prognostic factors that are considered to be potential confounders) in each group of subjects to be compared clearly described?*

A list of potential confounders is provided; particular studies may have others.

yes	2
partially	1
no	0

6. *Are the main findings of the study clearly described?*

Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. Does the study provide enough information to allow the reader to calculate estimates of the variability in the data for the main outcomes?

In normally distributed data the standard error, standard deviation or confidence intervals should be reported. For non normally distributed data, confidence intervals if used should be bootstrapped or derived from transformed variables. Alternatively the inter-quartile range (larger samples) or minimum and maximum (small samples or subgroups) may be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes. For simple binary outcomes proportion and denominator are usually sufficient; these may need to be supplemented by confidence intervals for the odds ratio, relative risk or difference in proportions.

yes	1
no	0

8. *Have all important adverse effects that may be a consequence of the intervention been reported?*

This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. For studies in this review, some 'adverse events' may already be used as outcome measures. If so, the answer should be 'yes' unless other important adverse events have been ignored.

yes	1
no	0

9. *Have the characteristics of patients lost to follow-up been described?*

This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up (or does not report the number randomised/recruited, only the number analysed).

yes	1
no	0

10. *Have confidence intervals or exact significance levels (e.g. 0.035 rather than <0.05; although p<0.001 or p<0.0001 is acceptable) been reported for the main outcomes?*

Where a comparative study does not report any statistical analyses the answer should be no.

yes	1
no	0

External validity

All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*

The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant population exists. Where a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*

The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*

For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

Internal validity - bias

14. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

Blinded data analysis is often an adequate substitute, especially where outcomes (eg death) are unequivocal or when blinding is impracticable or even impossible. [NB *In effectiveness studies, blinding of patients or health care providers to the treatment received is usually unnecessary and often undesirable; but outcome measures may be obtained by a blinded researcher rather than the (unblinded) health care providers*]

yes	1
no	0
unable to determine	0

15. *If any of the results of the study were based on "data dredging", was this made clear?*

Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

yes	1
no	0
unable to determine	0

16. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls?*

Where follow-up was the same for all study patients the answer should be yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

yes	1
no	0
unable to determine	0

17. *Was the length of follow up adequate?*

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*

The statistical techniques used must be appropriate to the data. For example, where continuous responses have been unnecessarily reduced to a binary choice the answer should be no. Where a parametric test has been used to analyse markedly non-Normal data the answer should be no, unless the data has been transformed appropriately (e.g. log transformation); bootstrapped confidence intervals are also acceptable for such data. Examples of other questions that can be considered to examine appropriateness: Should a multilevel model have been used? How if at all were baseline values allowed for? If investigating screening or diagnosis, have appropriate measures been used?

yes	1
no	0
unable to determine	0

19. *Was non-compliance reported appropriately?*

In most studies of this type, non-compliance with the intervention by patients or NHS staff should be an outcome measure. Non-compliance with the study protocol by researchers should also be reported.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, the question should be answered yes (unless there appear to be problems with the validity and reliability of measuring the outcomes). For studies which refer to other work that demonstrates the outcome measures are accurate, the question should be answered as yes. For case-control studies where interventions and exposures are assessed in a different way, or studies where the disease state of cases has not been reliably assessed and validated, the question should be answered no.

yes	1
no	0
unable to determine	0

Internal validity - confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies), or the cases and controls (case-control studies), recruited from the same population?*

(I've deleted the first sentence) The question should be answered unable to determine for cohort and case control studies where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies), or the cases and controls (case-control studies), recruited over the same period of time?*

For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*

Examples of adequate randomisation include the use of computer generated random numbers r random number tables; these would score 'yes' (a). Examples of inadequate randomisation are alternate allocation, or the use of case record numbers, days of week or date of birth; because they are predictable. Studies using these methods would score 'yes (b)'. Studies that are reported to be randomised controlled trials (or to have patients randomised to intervention groups), but where the method of randomisation is not described, should be marked 'yes (c)'. For non-randomised studies

the answer should be 'yes (b)' if the way participants are allocated to intervention groups is clearly described; otherwise the answer should be 'no'.

yes (a) for adequate randomisation	2
yes (b) for clearly described but not adequately randomised	1
yes (c) reported as an RCT, but method not clearly described	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

For RCTs, examples of adequate allocation are centralised randomisation, the use of on-site computer-based systems where assignment is unreadable until after allocation. Examples of inadequate methods include the use of alternation, case record numbers, days of the week, open random number lists and serially numbered envelopes even if opaque. All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

yes	1
no	0
unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*

This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was neither described nor allowed for; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no. The question would also be answered no for case-control studies where over matching has occurred.

Yes, all adjusted for	2
Yes, some attempt made at adjustment	1
no	0
unable to determine	0

26. *Were losses of patients to follow-up taken into account?*

If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine (this includes studies that do not report the number of recruited participants, but only the number analysed). If the proportion lost to follow-up was too small *(<5%)* to affect the main findings, the question should be answered yes. For trials and cohort studies, where the drop out rates or the reasons for drop out differ between groups and have not been taken into account, the question should be answered no.

yes	1
no	0
unable to determine	0

Power

27. *Has an estimate of a clinically important difference been specified, and how has it (and an estimate of variability, if needed) been determined?*

This would usually appear in an explicit power calculation within the Methods section of the paper, but occasionally it is not mentioned until the Discussion. Estimates of variability are not usually needed for binary outcomes.

yes, from past studies or pilot study	2
yes, from clinical opinion	1
yes, unspecified	0
no	0

28. *Is the sample size adequate: what (standardised) effect size is detectable at 5% significance level with 80% power?*

In a simple two group comparison, the detectable effect size is the minimum *population* difference in outcome between intervention and control groups for which a study this size has 80% chance of giving a significant result, divided by the average standard deviation within a group. An explicit power calculation will often specify it; if not, it can sometimes be estimated from the observed means, standard deviations and sample sizes. Otherwise the score should be 0 unless information in the paper indicates otherwise (e.g. larger sample sizes than in other identified studies that have adequate power and similar design and outcomes), when the score should be 1.

sample size adequate: "small" effect size (<0.4) detectable	3
sample size probably adequate: "moderate" effect size (0.4 – 0.6) detectable	2
sample size probably adequate: pre-specified but large clinically important difference detectable	2
sample size possibly inadequate: only "large" effect sizes (>0.6) are detectable	1
If the detectable effect size cannot be determined from the paper, and no clinically important difference has been specified:	
sample size possibly adequate, with strong evidence from this or other studies	1
sample size too small, or unable to determine	0

References

1. Lewis R., N.R.D., Williams N.H., et al, *Nurse-led vs. conventional physician-led follow-up for patients with cancer: systematic review.* Journal of Advanced Nursing 2009. **65**(4): p. 706-723.
2. Downes S.H., B.N., *The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non randomised studies of health care interventions.* Journal of Epidemaeology and Community Health, 1998. **52**: p. 377-384

5. Table of the full quality assessment scores for each study

Each study was assessed in full by two reviewers. Scores for the statistical questions (numbers 7,10, 18, 23 and 28) were provided by a trial statistician.

No	Brown 2007		Buising 2008		Bullard 2004		Dong 2005		Dong 2006		Dong 2007		Dowding 2009		Farion 2008		Graber 2003		Gravel 2008		Kwok 2009		Lorenzoni 2006		Porter 2006		Roukema 2008		Roy 2009		Sard 2008		Selker 2002		Terrell 2009	
1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
4	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
5	0	2	0	1	0	0	1	1	1	1	0	0	1	1	1	0	1	1	1	1	1	1	1	1	0	0	1	0	1	0	2	1	1	0	2	2
6	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1
7	0	0	1	1	1	1	0	0	0	0	0	0	0	0	1	1	1	1	0	1	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1
8	0	1	0	0	0	0	0	1	1	1	1	1	1	1	1	1	1	1	0	0	1	0	1	1	1	1	1	0	1	1	1	0	1	1	1	1
9	0	0	0	1	1	1	0	1	0	1	0	0	1	1	1	1	1	0	1	0	0	1	1	1	1	1	0	0	1	0	1	1	1	1	1	1
10	0	0	1	1	1	1	0	0	0	0	0	0	0	0	1	1	0	0	0	0	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1
11	0	0	1	1	1	1	0	1	1	1	1	1	0	0	1	1	0	0	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
12	1	0	1	1	1	1	0	0	1	0	1	1	0	0	1	1	0	0	0	0	0	1	0	0	0	0	0	1	1	0	1	1	1	1	1	1
13	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1
14	0	0	1	0	0	0	1	1	1	1	0	0	0	0	1	1	0	0	0	1	1	1	0	0	0	0	1	1	0	1	1	0	1	1	1	1
15	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1
16	1	1	0	0	1	1	1	1	1	0	1	1	0	0	1	1	0	1	0	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1
17	1	1	0	0	1	1	1	1	1	0	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
18	0	0	1	1	1	1	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	1	0	0	1	1	1	1	1	1	1	1	1	1	1	1
19	0	0	0	0	0	0	1	1	1	1	0	0	0	0	0	0	0	0	1	0	0	0	1	0	1	1	1	0	0	0	0	1	0	0	1	1
20	0	1	1	1	0	0	1	1	1	1	0	0	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
21	0	0	1	0	1	1	1	1	1	1	1	1	0	0	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
22	1	0	1	0	1	1	1	1	1	1	0	0	1	1	1	1	1	1	0	0	0	0	1	1	1	0	1	1	1	1	1	1	1	1	0	1
23	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1	2	2	0	0	1	1	2	2
24	0	0	0	0	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1	0	0	0	1	1	1	1
25	0	0	2	2	0	0	1	1	0	0	0	0	2	2	0	0	0	0	0	0	1	1	2	1	1	1	1	0	0	1	1	1	1	1	2	2
26	0	1	1	1	1	1	1	1	1	1	0	0	0	0	1	1	0	0	0	0	0	1	1	0	1	0	1	1	0	0	0	1	1	1	1	1
27	0	0	2	1	0	0	0	0	0	0	0	0	0	0	2	2	0	0	2	1	2	0	0	1	0	0	0	0	0	0	0	1	0	0	0	0
28	0	0	3	3	1	1	0	0	1	1	1	1	0	0	3	3	0	0	1	1	1	1	1	1	2	2	1	1	3	3	3	3	3	3	3	3
Tot	10	13	23	22	21	21	17	20	20	17	14	14	14	14	26	25	14	12	16	15	23	21	19	18	23	21	24	21	26	24	26	26	28	27	31	32

6. Table summarising SAFER 1 trial specific CONSORT information

Section/Topic	Item No	Checklist item
Title		
	1a	***Identification as a randomised trial in the title***
		Support and Assessment for Fall Emergency Referrals (SAFER) 1: Randomised trial to evaluate the clinical and cost effectiveness of computerised decision support software for emergency ambulance paramedics to use in the care of older people who have suffered a fall
Introduction		
Background and objectives	*2a*	***Scientific background and explanation of rationale***
		Many people attended by emergency ambulances do not clinically need to attend an emergency department. Healthcare policy supports emergency services providing alternative models of care, but little evidence exists about their safety and effectiveness. Falls in older people account for around 8% of emergency service calls. Around 40% of these are not conveyed to hosiptal, despite the absence of formal triage training for paramedics or alternative referral routes for patients. A recent systematic review identified that 'Studies are needed that have the power to detect important effects on the number of fall-related injuries and quality of life, so as to resolve uncertainty about the clinical and cost effectiveness.' The SAFER 1 trial evaluates the costs and benefits of CCDS use by paramedics in planning appropriate onward care for older people who have suffered a fall.
	2b	***Specific objectives or hypotheses***
		The objectives of the trial were to estimate the effects of the intervention at one month on: 1. Pathway of care following attendance by an emergency ambulance paramedic for a fall - Referrals to falls service - Non-conveyance (ED avoidance) 2. Time to first subsequent emergency healthcare contact for a fall, or death 3. Time to first subsequent emergency healthcare contact for any reason, or death ('event-free period') 4. Event-free period adjusted by health-related quality of life 5. Quality of life of patients, including 'fear of falling', independence and satisfaction 6. Subsequent falls and fractures 7. Clinical and operational 'process' indicators: - Compliance with protocols including CCDS usage - Job cycle time – from 999 call to 'ambulance free' time - Length of emergency care episode – from 999 call to discharge of patient from ED or ambulance if not conveyed 8. NHS resource use and at each participating site, to explore: • implementation issues with service providers • patient experience and views of the intervention
Methods		
Outcomes	*6a*	***Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed***
		Principal outcomes: 1. Onward pathway of care: proportion of patients referred to falls services; patients left at scene by their attending crew without conveyance to ED 2. Interval to the first subsequent emergency healthcare contact for any reason or death ('event-free period') 3. Interval to the first subsequent emergency healthcare contact for a fall or death 4. 'Quality adjusted' event-free period, adjusted by health-related quality of life (SF12) scores Secondary outcomes: • Health-related quality of life (SF12)[29] • Patient satisfaction (Quality of Care Monitor) • Fall-related self-efficacy ('fear of falling') • Number of further falls and fractures • Quality of care: clinical documentation; compliance by paramedics with CCDS; and patterns of use of CCDS • Operational indicators: - length of ambulance service job cycle - length of episode of emergency care
	6b	***Any changes to trial outcomes after the trial commenced, with reasons***
		Implementation problems and delays led to dropping the six month patient follow-up. Results from the patient questionnaire pilot led to shortening it to improve response rates. These changes were approved by the TSC. These changes contributed to a shift in focus of the study so that the clinical process indicators became more important in determining the likelihood of the intervention being clincially and cost effective.

7. SAFER 1 trial registration, protocol and funding information

Trial registration number: ISRCTN10538608

Protocol: http://www.biomedcentral.com/1471-227X/10/2

Funding: Department of Health

8. Study information sheet and consent form for paramedics:

The SAFER 1 Study

Consent to record for research purposes

The SAFER 1 study is a research project being carried out by Swansea and Warwick Universities in collaboration with the Welsh and East of England Ambulance Services. It is funded by the Department of Health and the Welsh Assembly Government and will assess the impact of a new way of delivering emergency care to older people who fall.

We would like to record this meeting for the purposes of the research. The material gathered will be treated as confidential and stored securely. Recordings will be transcribed by the research team, or an independent transcriber who has signed a confidentiality agreement.

If you agree to this meeting being recorded for research purposes please tick the relevant boxes and sign below:

I confirm that I agree to this meeting being recorded for the purposes of research. I have been briefed on what this involves and I have understood the accompanying information provided overleaf. I understand that I can withdraw from the study at any time without having to give an explanation.	Yes ☐ No ☐
I agree to my words being quoted in research reports as long as they are anonymised.	Yes ☐ No ☐
I agree to this consent being extended to the recording of other SAFER 1 study meetings and interviews as long as my agreement is sought and confirmed prior to any such recording.	Yes ☐ No ☐

Name: _____ Signature: _____ Date:

If you have any queries or would like to find out more please contact Bridget Wells at Swansea University on [redacted] or [redacted]

Participant information for SAFER 1 Study

SAFER: **S**upport and **A**ssessment for **F**all **E**mergency **R**eferrals

This information sheet explains:

- the purpose of the research
- what we are asking you to do
- what will happen to the data
- who to contact if you would like more information

What is the purpose of the SAFER 1 study?

This research is designed to evaluate the costs and benefits of paramedics using computerised decision support software when assessing whether to convey an older faller to hospital or to leave them at home (with onward referral to a falls service). The main arm of the study is a randomised controlled trial with half of the paramedics who volunteer being randomly allocated to use the hand held computer (the intervention group) and half to deliver care as usual (the control group). This research will assess the impact (costs and benefits) of this new model of care on the patient. It will also explore issues relating to the implementation of the new technology including how using the technology affects the practice of paramedics.

What are we asking you to do?

We would like to record this meeting for the purposes of the research. We would use it to help us understand the process of implementing new models of care in the emergency care setting. The material gathered will be treated as confidential and stored securely. Recordings will be transcribed by the research team or an independent transcriber who has signed a confidentiality agreement. Before recording meetings we will ask you for your permission to record. If this is granted, we will ensure that you have been asked to complete and sign a consent form. A SAFER 1 study researcher will then record the meeting. Your participation is voluntary and consent can be withdrawn from the study at any time without having to give an explanation.

What will happen to the data?

The material gathered during fieldwork will be securely stored and analysed on computers based at Swansea University. Recordings will be transcribed by the research team, or an independent transcriber who has signed a confidentiality agreement. No-one else will see or hear the unprocessed information gathered during this fieldwork. There will be a report and journal publications following from this study but they will not identify any individual contributor.

Who do I contact if I would like more information about the study?

Bridget Wells, Swansea university [redacted] or [redacted]

9. Letter sent to paramedics with the consent and information form

(Date)

Dear (Paramedic name)

The SAFER Trial

Request for consent to record SAFER Trial fieldwork for research purposes

Thank you for volunteering to take part in the SAFER Trial, which is being carried out to assess the impact of a new model of delivering emergency care to older people who fall.

We are planning to assess the new model of care and its implementation, and to help us do this we would very much value your comments and feedback, during both the early and latter stages of the trial - either in group feedback sessions or through one-to-one interviews. We hope that by evaluating your feedback we can learn and share valuable information on implementing electronic clinical data capture systems and falls referral pathways in the future, in this setting and more widely.

We are planning on holding an initial feedback session over lunch on the SAFER Trial training day, and are writing to you to as we would like to record this feedback for the purposes of the research. I am enclosing two copies of the consent and information form for recording this and related elements of the study. One copy is for your own records and the other is for you to complete and return to us to indicate whether you consent to SAFER feedback sessions being recorded for research purposes.

We would be grateful if you could return the form in the enclosed FREEPOST envelope, or bring it with you to the training session. Please note, the material gathered will be treated as confidential and stored securely, and any data used will be anonymised. Your consent to record feedback is voluntary and can be withdrawn from the study at any time without having to give an explanation.

If you would like to speak to someone about this form before you complete it please don't hesitate to call me on [redacted] or email me on [redacted]

Yours sincerely,

Bridget Wells

(SAFER Trial Co-ordinator)

10. Paramedic demographic information request form

SAFER 1 Trial Paramedics

Demographic information

Name: _____

Gender: _____

Age: _____

Number of years in service: _____

Number of years as a qualified paramedic: _____

Level of IT skill prior to trial: _____

11. Pre-trial paramedic focus group topic guide

Focus group topic guide

Thank you for taking part today. This session is to find out a bit more about your current practice and to get your thoughts and views on the new model of care proposed for the SAFER Trial

Check that we have got the consent and demographic info forms completed.

What motivated you to get involved in the study?

Have there been any other 'new technologies' or new equipment introduced while you've been a paramedic?

- How are new practices introduced?
- Issues around changing practice – any pressures?
- Attitudes towards technological developments in the health service
- Differences between attitudes of paramedics and their managers
- Barriers and motivations to new technological developments?
- Issues around using new equipment/technology
- Support for using new equipment/technology
- Operational impacts

Do new technologies sometimes bring with them additional decision making for paramedics?

- Adapting to this
- Resistance?
- Time to adopt new processes?

How do you deal with calls from older fallers at the moment?

- options available to the paramedic
- links to other services to support older fallers
- explore issues around deciding to leave at home or convey
- any frustrations with the current system
- Risks with the current system – to patient
- Risks with the current system – to paramedic (confidence to leave patients at home)

Do you think that having access to a falls pathway will make a difference?

- To the patient
- To you
- Suitability of this patient group for the new care pathway

We're proposing that you use an electronic PCR to take down older fallers details, rather than a paper one. Does this raise any thoughts or concerns?

- Explore clinical documentation (purpose and value)

We asked at the beginning about your motivations for getting involved. We wondered what you thought your colleagues would make of you taking part in the study and using the new kit?

We've come to the end of this focus group, thank you all for your contributions.

Check that we have all the consent and demographic info forms

12. Pre-trial semi-structured paramedic interview schedule

Pre-trial interview schedule

What motivated you to get involved in the study?

Have there been any other 'new technologies' or new equipment introduced while you've been a paramedic?

- How are new practices introduced?
- Issues around changing practice – any pressures?
- Attitudes towards technological developments in the health service
- Differences between attitudes of paramedics and their managers
- Barriers and motivations to new technological developments?
- Issues around using new equipment/technology
- Support for using new equipment/technology
- Operational impacts

Do new technologies sometimes bring with them additional decision making for paramedics?

- Adapting to this
- Resistance?
- Time to adopt new processes?

How do you deal with calls from older fallers at the moment?

- options available to the paramedic
- links to other services to support older fallers
- explore issues around deciding to leave at home or convey
- any frustrations with the current system
- Risks with the current system – to patient
- Risks with the current system – to paramedic (confidence to leave patients at home)

Do you think that having access to a falls pathway will make a difference?

- To the patient
- To you
- Suitability of this patient group for the new care pathway

We're proposing that you use an electronic PCR to take down older fallers details, rather than a paper one. Does this raise any thoughts or concerns?

- Explore clinical documentation (purpose and value)

I asked at the beginning about your motivations for getting involved. I wondered what you thought your colleagues would make of you taking part in the study and using the new kit?

I've come to the end of this interview, thank you all for your contributions.

13. Mid-trial semi-structured paramedic interview schedule

Mid-trial interview schedule

Thank you for agreeing to be interviewed today. What I'd like to find out is your thoughts and observations on the CDS software being used for the SAFER study, how it's been introduced in your ambulance service, and how you're getting on using it.

Check consent and press record!

1) Can you tell me a bit about how you came to be involved in the study?
- Can you describe what taking part in the study has involved so far?
- How long have you had the CDS software and when did you start using it?
- How were you trained? Was this enough training – or too little/much?

2) What support was in place when you started using the equipment?
- Technical and clinical support?
- Was there support from your managers to use the CDS with older fallers?
- What about other ambulance service staff?
- What do your colleagues who aren't using the CDS make of it?
- Are they supportive of you using it? How does that affect you using it?
- Does using the CDS affect the way you work with other organisations at all? (E.g. falls services, hospitals, GPs)

3) On a practical level, how have you found using the different bits of kit involved? Pros and cons, ease of use, practicality of:
- The CDS software itself
- The computer, printer and charger
- Are there any time-related or other practical issues with using the system?

4) How do you decide when to use the CDS?
- How often do you use it with older fallers? For all calls or just some?
- Do you find it useful? Do you follow the CDS recommendations?
- So has it changed your practice at all?
- If it were entirely optional, are there occasions when you would choose to use it?

5) Has using the CDS made any difference to the way you work?
- Has it made any difference to your decision making on-scene?

- Does the CDS influence the way you decide appropriate care for patients?
- Do you think that CDS is suitable for the older fallers as a patient group?
- How has the CDS gone down with patients?

6) More generally, what do you think about the introduction of computerised technology in the health service?
- Do you feel it's changed your role or at all?
- How has it affected the way you work?
- How do you feel about the shift to electronic patient report forms?
- Do you feel there's a difference between having a paper or an electronic record? Which do you prefer and why?
- Do you feel that technology either enhances or undermines what you do as a professional?
- In terms of the risks associated with the work you do, do you feel new technology changes the level of risk you feel you're exposed to in any way?

7) Any recommendations for how the CDS and its implementation could be improved for paramedics in the future?

8) Is there anything else about the study that you think might be of interest, or anything you'd really like to get off your chest?!

Many, many thanks for taking the time to talk to me today!

14. Trial-end semi-structured paramedic interview schedule

Mid-trial interview schedule

1) To start off I'm interested in finding out a bit about how you got involved.
- Can you tell me how you found out about the study?
- What was it about the study that made you want to take part?
- What were you asked to do for the study that was different to what you were doing already?

2) Can you tell me about how you were trained and who by?
- Was this enough training – or too little/too much?
- Once you got the software how long was it before you started using it? (PROMPT: explore any delay or non-usage)

3) On a practical level, how have you found using the different bits of kit involved? (Explore pros and cons, ease of use, practicality of...)
- The computer, printer and charger
- The internet connection
- Any other ease of use or practical issues with using the system?

4) How do you find using the electronic patient report forms?
- How do you feel about the shift to electronic patient report forms?
- Do you think there are any advantages to recording patient information electronically?
- Disadvantages?
- Is it practical to use? Do/did you use it?
- Does it affect on-scene time?
- Do you feel there's a difference between having a paper or an electronic record? Which do you prefer and why?
- In practice when and where are ePCRs completed? (PROMPT: in EEAS find out who completed the ePCRs when falls assessments were undertaken)

5) How did you find using the falls assessment software?
- How did you decide when to use the falls assessment software?
- Did you use it with all older fallers or just some?
- Is it practical to use? Did you use it? Did you find it useful?
- How does it affect on-scene time?
- Has it made any difference to your decision making on-scene?
- Did you follow the recommendations that the software came up with?
- Did it help you decide whether to take a patient to hospital or refer them to the falls service?
- Has it made any difference to the way you work?
- Did it make you feel more, or less empowered professionally
- Did you feel it added to or reduced the risks associated with the job you do?

- If you could, would you choose to use the falls assessment software again?
- In practice when and where did you complete the falls assessment software?

6) Do you think that using the technology impacts on the quality of your interaction with the patient?
- How has it gone down with patients?
- Have any patients been concerned about data security and confidentiality?
- Do you have any concerns about this?
- Do you think that the falls assessment software was suitable for use with older fallers as a patient group?

7) I'd like to find out about any support that was available to you while you were taking part in the study.
- Was there any technical support available if you needed it?
- Was there any operational or clinical support available if you needed it?
- What did you feel the attitude of your managers was to you using the falls assessment software?
- Did that have an impact on you using it?
- What was the attitude of other paramedics towards you using the falls assessment software?
- Does using the falls assessment software affect the way you work with other organisations at all? (E.g. falls services, hospitals, GPs)

8) More generally, what do you think about the introduction of computerised technology in the health and ambulance service?
- Do you feel it's changed your role or at all?
- How has it affected the way you work?
- Do you feel that technology either improves or undermines what you do as a professional?

9) Any recommendations for how the falls assessment software and the way it's implemented could be improved for paramedics in the future?

10) Is there anything else about the study that you think might be of interest, or anything you'd like to tell me about, or ask me?

Demographic info

- Just to finish off, can I ask how long you've been in service?
- And how long you've been a qualified paramedic?
- How would you describe your level of IT skill before the trial?
- And now?
- And finally, how young are you?!

That's the last of the interview questions, but can I just ask if you've had a chance to sign your consent form and pop it in the post yet?

Many thanks for taking the time to talk to me today

15. Characteristics of participating paramedics at the individual level

Group	Site	Gender	Age	Years of service	Year as paramedic	Withdrew	IT skill
1	1	f	30	8	3		poor
1	1	f	33	7	3		okay
1	1	f	40	14	3	W	poor
1	1	f	45	22	17	W	okay
1	1	m	24	6	3		okay
1	1	m	29	5	2	W	good
1	1	m	30	5	2	W	okay
1	1	m	32	11	7	W	okay
1	1	m	33	7	4		okay
1	1	m	34	10	5		okay
1	1	m	36	10	6		good
1	1	m	45	21	15		okay
1	1	m	51	26	17		poor
1	1	m	35	6	3		
1	2	f	40	7	3		good
1	2	m	31	8	3		good
1	2	m	47	19	14		good
1	2	m	48	24	3		okay
1	2	m	49	16	14		okay
1	2	m	49	20			good
1	2	m	50	15	9		good
1	2	m					
2	1	f				W	
2	1	f				LW	
2	1	f					
2	1	m	46	23	18		
2	1	m	47	25	19		
2	1	m					
2	1	m	37	17	2		
2	1	m	38	6	3		
2	1	m					
2	1	m					
2	1	m					
2	1	m					
2	1	m					
2	2	f	41	6	3		
2	2	f				W	
2	2	m	34	6	2		
2	2	m	44	21	17		
2	2	m	51	26	na	W	

Group	Site	Gender	Age	Years of service	Year as paramedic	Withdrew
2	2	m	56	7	5	LW
2	2	m				

Group 1 = intervention and group 2 = control

W = Withdrew prior to patient data collection period

LW = Late withdrawal (i.e. withdrew after data collection had commenced and were therefore included in the C-RCT analysis)

IT skills: These data were only collected from the intervention group paramedics in order to assess CCDS use against self-reported IT skills

Blank cells indicate missing data. More demographic data were collected for intervention group paramedics, reflecting that there were more opportunities for pursuing data with this group e.g. during training and at focus groups or interviews.

16. Qualitative analysis framework

		Transcript 1	Transcript 2	Transcript 3	Transcript 4
Demographics/ personal descriptors	Age, gender, experience as a paramedic and IT skills				
Experience of use (+ and – within each subheading below)	Implementation and support				
	Training				
	Ease of use/practicality				
	Organisational factors (support etc)				
	Interorganisational working related to CCDS (handover/ transfer of info/working relationships)				
	Suitability to patient group				
Impact	Operational				
	Decision making				
	Autonomy/risk				
	General views re IT in NHS				
	Value and purpose of clinical documentation				
	Implication for practice/role (Looking to future)				
	Other issues				

17. Questions to guide a study of an unfolding technology project or programme from the perspective of Strong Structuration Theory

Macro Level Questions in Relation to an Unfolding Programme

Mapping the network-in-focus

1. What is the prevailing political, economic, technological and institutional context within which the technology is being introduced locally or nationally?
2. What is the socio-technical network of this project or programme? Which agents and technologies are represented, and what are their position-practices?
3. What are the key relationships (agent–agent, technology–technology, agent–technology) in the network and how are they changing over time?
4. To what extent has stability of the network been achieved – and why?

Micro Level Questions Focused on Specific Conjunctures within the Unfolding Process

Mapping the relevant part of the network ('network-in-focus')

1. Who are the key human agent(s) involved in this conjuncture?
2. What are the key technologies involved in this conjuncture?
3. What technological, financial and organisational infrastructure is needed to support the conjuncture?

Actant's internal structures relevant to the conjunctural situation

1. Human agent's general dispositions (e.g. socio-cultural schemas, hierarchies of values, virtues, cognitive capacity, embodied skills, past experience)
2. Relevant technology's material properties and inscribed socio-cultural structures (2c in Fig. 2)
3. Human agent's conjuncturally-specific knowledge (perhaps imperfect): of relevant external structures (the strategic terrain) – including socio-cultural knowledge of how other agents view the world (i.e. knowledge of domain of heading 1 in Fig. 2); of technology-in-focus's material properties and inscribed socio-cultural structures (i.e. of 2c in Fig. 2); and of technology-infocus's range of functionality relevant to the immediate situation (i.e. of 2d in Fig. 2).

Active agency

1. What does the human agent do – i.e. how does s/he reflexively relate to, and draw on, general dispositions, conjuncturallyspecific knowledge, and technological properties (actant's internal structures) in an unfolding sequence of action?
2. How do the social structures (e.g. norms, duties, physical and cognitive demands, rights, rewards/sanctions) inscribed, deliberately or inadvertently, in the technology-in-focus enable, influence, or constrain the active agency and strategic orientations of agents?

Outcomes

1. What are the immediate consequences of specific actions (intended and unintended)?

2. How do these consequences feed back on the position-practices in the network and wider external structures?
3. What significance – both positive and negative – do these consequences have for others in the network in terms of power,
legitimacy, and other factors?
4. What role has the technology-in-focus played in the production of these positive and negative consequences?

Policy/political implications
1. How modifiable are the inscribed technological features of 2c (in Fig. 2) that have contributed to negative consequences? By
whom are they modifiable, over what timescale and at what cost?
2. Addressing 1 ('how modifiable'?) should be linked to lessons learned from analysis of prior negotiations about standards,
codes, fields, access privileges, interoperability, and other 'technical' questions.
E.g., who were the players in these negotiations,
who 'won', and why?

Reproduced from Greenhalgh, T., Stones, R., 2010. Theorising big IT programmes in healthcare: strong structuration theory meets actor-network theory. Social Science and Medicine, 70, 1285-1294.