DOCTOR OF PHILOSOPHY

‘An audible patient voice'

How can patients in hospital play a more active role in their safety?

Subbe, Chris

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Critical Analysis

Submitted by

Christian Peter Subbe

Student No 500256104

Executive Summary

Patients commonly suffer adverse events while in hospital. The fact that patients are often neither allowed to read documented warning signs in their own medical records nor able to record their wellbeing, symptoms and concerns in a way that is notable for health care professionals is a contributing factor. There is a significant body of literature on patient held medical records, but this relates near exclusively to patients in primary care and chronic disease management programs and knowledge about safety impact of patient held records is largely limited to medication safety. It is not known how patients in hospital could contribute to paper or electronic records and what effects this might have.

Scoping reviews of the literature showed little evidence for safety impact of electronic health records, personal health records or patient held mHealth applications. Focus groups and workshops with patients established understanding of the opportunities and barriers to patient participation in emergency care and resulted in a novel model for rapid co-design of prototype interventions.

Interventional studies showed feasibility and utility of an mHealth check-list for side-effects of treatments of cancer. Patients who documented their priorities for a hospital admission added insights into their ideas, concerns and expectations that were not covered elsewhere in clinical records.

Insights from the work discussed in this submission suggest that patient contribution might facilitate change in safety outcomes by creating capability and opportunity for desirable changes in behaviour of individuals and systems and encourage and support patients to be involved in their own safety.

Further development and testing of systems that enable broader participation of patients is needed and is likely to empower patients while making health care professionals more aware of risks, change their behaviour and lead to safer delivery of health care in hospitals.

Contents

List of tables & illustrations

None submitted. Tables and Illustrations are included in the submitted manuscripts.

List of accompanying material

None submitted. All accompanying materials are included in the manuscripts.

Acknowledgements

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I am most grateful for the support that I received from the Health Foundation, in particular I would like to thank Fiona Reed as my personal coach for all of her encouragement and generous time and to Oliver Smithson for his patients and thoughtful encouragement. The fellowship was granted in 2016 to a group of six candidates. Two of those (Helen Hogan and Yogini Jani) share my interest and focus on patient safety and have helped to shape this group of studies through conversations and guidance.

My work was generously supported by a group of mentors, and stakeholders who advised on the outline of the application, the design of the studies, the evaluation of data and the writing of the manuscripts. I would like to mention in particular

1. Patient representatives (from the Royal College of Physicians patient and carer network and local patient representatives)
2. Prof Paul Barach – International Patient Safety expert and mentor throughout my fellowship.
3. Prof John Ovretveit – International Patient Safety and Service Improvement expert and mentor for the first part of my fellowship.
4. Andy Goodman as a design and engineering expert from the Bangor University Innovation Centre.

The research was conducted in large parts with collaborators from two institutions: Betsi Cadwaladr University Health Board: Design is context dependent. This is the context in which I operate clinically. The hospitals of the health board are typical district general hospitals and therefore representative for a large proportion of UK hospital healthcare.

Patients from Betsi Cadwaladr University Health Board did support my work at every stage. I would like to particularly thank Dafydd Thomas, Betty Foster and Valerie Wakefield who stayed with me for the whole journey, encouraged, advised, co-created and validated the insights from the fellowship.

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Author’s declaration

‘Yr wyf drwy hyn yn datgan mai canlyniad fy ymchwil fy hun yw’r thesis hwn, ac eithrio lle nodir yn wahanol. Caiff ffynonellau eraill eu cydnabod gan droednodiadau yn rhoi cyfeiriadau eglur. Nid yw sylwedd y gwaith hwn wedi cael ei dderbyn o’r blaen ar gyfer unrhyw radd, ac nid yw’n cael ei gyflwyno ar yr un pryd mewn ymgeisiaeth am unrhyw radd oni bai ei fod, fel y cytunwyd gan y Brifysgol, am gymwysterau deuol cymeradwy.’

Rwy’n cadarnhau fy mod yn cyflwyno’r gwaith gyda chytundeb fy Ngrichwyliwr (Goruchwylwyr)’

‘I hereby declare that this thesis is the results of my own investigations, except where otherwise stated. All other sources are acknowledged by bibliographic references. This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree unless, as agreed by the University, for approved dual awards.’

I confirm that I am submitting the work with the agreement of my Supervisor(s)’.

Signature

Dr Christian P Subbe

I hereby confirm that the portfolio is my own work

Signature

Dr Christian P Subbe

I agree to deposit an electronic copy of my portfolio (the Work) in the Bangor University (BU) Institutional Digital Repository, the British Library ETHOS system, and/or in any other repository authorized for use by Bangor University and where necessary have gained the required permissions for the use of third-party material.

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Dr Christian P Subbe

Glossary

- BASE methodology – Business, Art, Science, Engineering are the disciplines required to the development of prototypes
- Electronic Health Record – EHR
- Epic Systems Corporation - EPIC
- National Health Service – NHS
- Personal Health Record - PHR
- System Engineering Initiative for Patient Safety - SEIPS

1. Outline

The main learning from my research is that patient safety might be significantly helped by a greater contribution of patients and those close to them to their process of care. This critical reflection draws on the original proposal for my fellowship as well as the final report that was submitted to the Health Foundation.

In chapter 2 I set the scene for the PhD submissions and describe the current challenges that patients face to understand their own safety and contribute to better care.

In chapter 3 I outline the design driven methodology of the fellowship programme. This has four distinct phases of discovery, definition of key challenges, development of solutions and deployment of prototypes into clinical practice.

In chapter 4 I present the publications that form the body of the submission.

In chapter 5summarise results from the submitted publications and highlight important context.

In chapter 6 I reflect on the insights gained in the light of theoretical frameworks of patient safety including Safety I and Safety II, human factors, and under-explored concepts of health literacy, and scope the potential clinical impact of the findings on care in a rapidly changing digital world.

In chapter 7 I summarise my key contributions and describe gaps in the current evidence that require further exploration.

2. Introduction

In this critical analysis I will review my contribution to the field of research into patient safety and a more active role of the patient in their own safety in particular. The analysis is based on an Improvement Science Fellowship with the Health Foundation and the resulting peer reviewed publications.

In this analysis I will outline the understanding that led to the Fellowship, summarize the key findings from the manuscripts and place them in a broader context of current understanding of safety in health care and behavioural psychology.

The research presented in this thesis was based on an understanding of available tools and methods to explore root causes for adverse events and methodologies to develop and test prototypes for interventions:

Behavioural psychology analyses and predicts behaviour of individuals and groups under specified circumstances. Behaviour change of patients and health care teams, requires the observation, analysis, and interpretation of behaviour. I was fortunate to have had the support and specialist skills of Professor John Parkinson and Dr Carl Hughes from this discipline as academic collaborators.

Information design is a subspecies of design that is occupied with the visual representation of information. Effectiveness of entry and output of any information system will be influenced by the quality of its information design. Pontio is Bangor University's new £49million Arts and Innovation Centre which hosts a Fabrication Laboratory (Fab lab) which conforms to international standards. Fab labs provide widespread access to modern means for invention. I had previously worked with the team of the Fab lab and was able to access expertise and facilities for the development of prototypes in co-production with patients.

I developed the research program by reviewing the potential drivers and influences that might affect the research question:

"What is the potential for active contribution of patients to health records to make health care safer in hospitals?"

2.1. Developing the Research Question

"Why did we not know what the score was?"

This was the question asked by a relative of one of our patients who had been admitted acutely ill and with a large burden of chronic diseases. The patient deteriorated and died within a week of being admitted to hospital. On admission the patient had some abnormal vital signs resulting in a moderately raised value of the National Early Warning Score that grades physiological instability and risk. The health care team expected his condition to improve, and the abnormal value was not discussed at the time with either patient or family.

What would the course of the disease have been if the patient and his family would have known the abnormality and its significance?

Failure to rescue is common despite documented deterioration but …

Adverse events to patients admitted to hospital are common (Kohn, Corrigan and Molla, 2000). In a significant proportion of patients who suffer adverse events there is clear documentation by health care staff of signs of deteriorating or concern from patients and their careers (Schein et al. 1990; McQuillan et al. 1998).

Avoidable harm leads to significant costs for health care organisations (Kohn, Corrigan and Molla, 2000; Hoonhout *et al.*, 2009), patients (Vincent, Neale and Woloshynowych, 2001; Hogan *et al.*, 2012) and carers with additional evidence that health care professionals suffer as 'second victims' after experiencing safety incidents (Seys *et al.*, 2012).

… patients are blinded to warning signs

Hospital records are accessible by health care professionals and in selected organizations by patients (Sathanandam, Rastall and Hoogewerf, 2016). In England the right of patients to access their own records is enshrined in the NHS constitutions (Department of Health, 2015). While some organizations allow relatives and patients to call Rapid Response Teams in case of a suspected catastrophic deterioration (Offner,

Heit and Roberts, 2007; Odell, Gerber and Gager, 2010), this is usually not based on an understanding of documented changes in vital signs or pathology results.

Patients are asked a lot of questions about their health and wellbeing, but the subsequent records of their answers are summaries generated by the health care team and as such often contain interpretations. Healthcare professionals are commonly not congruent with self-assessments of patients about the severity of their own symptoms, self-rated quality of life and preferences with regards to end of life decisions (Mansukhani, 2015).

The asymmetrical flow of information has to be interpreted in the context of system failure: “If an error is possible, someone will make it. The designer must assume that all possible errors will occur and design so as to minimize the chance of the error in the first place, or its effects once it gets made” (Norman, 2013).

Theoretical lenses I: Modular Redundancy and resilient systems

Safe systems in high reliability industries rely on independent modular organisation of safety critical steps (Pham and Galyean, 1992; Moehlenbrink, Wies and Jipp, 2011): No safety critical step relies on a single operator or technical part. This principle is applicable to deteriorating patients admitted to hospital (Bannard-Smith and Subbe, 2015) and can be used to dramatically reduce adverse events (VITAL II study – submitted for publication). Patients ability to observe and react to abnormality is only rarely used to increase the redundancy of systems but might improve medication safety (Sathanandam, Rastall and Hoogewerf, 2016). The limitations of an approach where patients become part of the redundancy that assures resilience might require further exploration.

Safety-I assumes that systems can be analysed successfully, the root causes of errors examined, identified, and subsequently eliminated. Safety-II observes that safety does not function in a bi-modal manner and that the reliability of human performance in healthcare is comparatively reliable and against all odds despite significant challenges (Hollnagel, Wears and Braithwaite, 2015). Resilience therefore stems from the fact that systems allow variation and interpretation by those working in them. Safety II therefore seeks to understand the real-world conditions in which systems function. Safety-II moves from an approach where ‘as few things as possible go

wrong' to ensuring that 'as many things as possible go right' (Elliott, 2016). Key to the thinking of Safety-II is that 'Work-as-Done' is different from 'Work-as-Imagined' (Hollnagel, Wears and Braithwaite 2015). Many systems function not because rules are being followed but precisely because some rules are being omitted, modified, or not being followed and thus adapting the work to the continuously changing environment in which it performed. This results in the insight that safety might be 'better measured by how often everyday work goes well' (Braithwaite, Wears and Hollnagel, 2015).

In line with Safety I there is a body of evidence from patients in chronic disease programmes and community care and on reporting of patient safety incidents in hospital (Ward and Armitage, 2012; Lawton *et al.*, 2015, 2017) with categories of safety incidents ranging from simple delays to prescription errors and complications of procedures. Through the lens of Safety II patients are experts in their own condition and therefore often manage to manoeuvre the challenging systems of health services. From this existing vantage position they have a unique ability to identify and circumnavigate errors (Unruh and Pratt, 2007): Missed clinical letter, wrong prescriptions and mix-ups in names have all be detected and corrected by patients. The resulting processes are a significant part of the 'invisible work of patients' (Unruh and Pratt, 2008) in any setting of healthcare, and specifically in the area that I used in one of my case studies (Subbe *et al.*, 2021), during the hand-off of information at interfaces between teams and at the transition between community and hospital (O'Hara, Baxter and Hardicre, 2020).

Theoretical lens II: Patient safety through the lens of human factors: The System Engineering Initiative for Patient Safety (SEIPS)

If patients are part of systems of care, then their experience can be examined using human factors methodologies. While there are several frameworks in use I would like to explore the System Engineering Initiative for Patient Safety (SEIPS) (Carayon *et al.*, 2006) and its variants for the purpose of this reflection. I will summarise my understanding of SEIPS. I will then identify insights from the human-factors literature related to specific patient groups and to digital health interventions.

SEIPS is a framework for human factors in healthcare describing work system, process, and outcomes. It has three principles: system orientation, patient centeredness

and design driven improvements. Systems are typically described by domains that interact around the person such as tools and technology, organization, internal environment, tasks, and external environment. The updated SEIPS 2.0 (Holden *et al.*, 2013) added configuration, engagement and adaptation to capture the work of patients and their carers.

Carayon (Carayon *et al.*, 2020) introduced SEIPS 3.0 as an expansion of the SEIPS framework applied to the 'journey of patients and caregivers over time' as a response to the increasingly complex models of care with the need to coordinate multiple providers. The adaptation of the model to the patient journey means that human centred design challenges have to be reviewed over time and through the lens of multiple professional and non-professional stakeholders. Tasks, organisational conditions, tools and technologies and physical environment are examined around the patients and their care team and repeatedly in a spatio-temporal context.

SEIPS 101 (Holden and Carayon, 2021) is a simplified system for practitioners. Is includes work systems, processes, and outcomes; outcomes are classified as desirable, undesirable, proximal or distal. For the analysis of 'systems' a simple mnemonic 'PETT' can be applied. 'PETT' stands for people, environment (physical, socio-organisational and external), tools and tasks.

The generic point has been made that many human factor tools have been developed for a lab or clinical setting and might need to be adapted for use outside these controlled environment (Valdez and Holden, 2016). Hazards in the patients' home environment were found to be different from those identified in institutional care (Keller *et al.*, 2019). Henriksen (Henriksen, Joseph and Zayas-Cabán, 2009) created a conceptual model to describe the factors affecting quality and safety in the delivery of home care with a specific emphasis on the care of elderly patients and their sensory, cognitive and behavioural capability.

SEIPS 2.0 has been adapted (Gorman, Wellbeloved-Stone and Valdez, 2018) to distinguish between visible work system/process/outcome and invisible work system/process/outcome. Invisible work was defined for the purpose as 'work systems […] that providers do not sufficiently understand through the vehicle of patient-provider communication'. By making some of the invisible process visible the patient might be able to reduce the difficulty in completing these processes. The invisible work of patients and their contributions to care are obviously subject to the same

challenge of safety systems and errors as the work of healthcare professionals (Allen, 2014).

There is some evidence for the application of SEIPS with a focus on an active role of the patient in their safety: SEIPS has been used to examine 'patient work' in patients with chronic conditions (Werner *et al.*, 2021). Holden et al (Holden, Cornet and Valdez, 2020) mapped 10 years' worth of conference proceedings on human factors and ergonomics. The proportion of patient centred papers was small: only 5%, a total of 212 out of 5257 papers and of these only 49 were experimental. Papers were mostly about elderly patients and those with chronic diseases and focused on care processes and technology or tools (such as safety of medical devices used by patients or non-professionals, mobile technology), medications, and error management.

In a study of 27 patients with heart failure, their increased difficulty to perform tasks of daily living and the challenge of 'getting to grips' with their condition was highlighted (Holden and Mickelson, 2013). Barriers related to 'physical limitations, mood or attitude, lack of knowledge or skills, motivation, or medical status' as well as to self-care tasks, health related tools and technology, social and physical barriers such as stairs or transportation. Safety implications were not explicitly mentioned.

SEIPS was applied to examine factors that influence family engagement in a paediatric hospital (Carayon *et al.*, 2011): The authors videoed ward rounds and then played those videos back to the clinical teams and families. Observations demonstrated feasibility of the work system model to describe the environment and its safety challenges but no interventions were tested.

Yardley (Yardley *et al.*, 2022) examined human factors affecting system performance in out-of-hours community palliative care using SEIPS to review context, mechanism and outcomes. Stakeholders including two informal carers identified themes from a national incident reporting system. Themes included timely access, quality of information transfer, safe medication provision and access to other treatments. At 'person' level mechanisms affecting care were isolation at night, feelings of safety and emotional labour, prioritisation and choice between response types.

SEIPS 2.0 has been applied to examine safety implications of mobile health (mHealth) applications and personal health records: For mHealth applications human

factors reported ‘involved patient characteristics, perceived social support, and (type of) interaction between patient and provider.’ Well-educated white females were the most commonly studied patient population. One of the studies reported that patients with COPD did not like using the application if they were unwell because it reminded them of the illness (MacNab *et al.*, 2015). Patients with hypertension relied less on their healthcare professional using the application (Ralston *et al.*, 2014). And parents who cared for children with Asthma felt that they had better insights resulting in less days lost at work and school respectively (Fiks *et al.*, 2015). The review highlighted insights about gender, socio-economic status, and educational background as important human factors for patient interaction. Despite the focus on chronic disease, insights were limited by the fact that only two studies included longitudinal data.

The inpatient portal ‘MyChart Bedside’ from market leader EPIC was the subject of a focus groups with four (!) patients and staff to describe relevant human factors in the use (Walker *et al.*, 2018). Patients ranked the following outcomes as most important: Satisfaction, shared decision making, patient engagement, ambulatory use and chart accuracy.

While these are worthwhile and obvious causes there are concerns that were voiced by the focus group that we undertook at the Royal College of Physicians (Subbe, Wyatt, *et al.*, 2019): Uptake of PHRs might reinforce the inverse care law and give additional support those who are more health literate. This is corroborated by a systematic review (Grossman *et al.*, 2019) examining evidence from over 100 studies that showed underutilisation of portals in vulnerable and underprivileged patients. The authors used the SEIPS system to examine interventional trials. Out of 18 studies, 13 intervened on the individual (person) component, 5 on the tool component (ie, patient portal), 1 on the task component (eg, prescribing portal component), 2 on the environment component, and 4 on the organisational component. Seven studies intervened on 2 components, but no study intervened on more than 2. 13 out of 26 interventions involved training or assisting patients with portal use, others involved increasing the volume of content, enabling mobile access, translation into other languages or improving usability. Few studies involved increased access to devices (environment component) or organisational policy (Organisation component). Safety outcomes were not reported in this paper, but the authors emphasise the challenge of educational interventions as ‘weak’ interventions to change behaviour and increase

safety. A focus on volume of usage left few studies measuring satisfaction or usability (and nonclinical outcomes).

The overall number of studies examining human factors implications of patients as active parts of safer systems is therefore small. Going forward the application of human factors systems need to therefore be reviewed in the light of bigger responsibility of patients, friends and families (Unruh and Pratt, 2008) using formal frameworks such as SEIPS.

Theoretical lens III: Self-preservation as a driver for safety

There are a number of reasons why the developments of safety culture in health care have not followed the lead of the historically hierarchical aviation industry or other high-risk industries that have become high reliability industries. One of them is the simple detail that a pilot flying a plane or a worker in a chemical plant will be interested in organizational safety for reasons of self-preservation. In health care this interest is much more indirect for nurses, doctors and other members of the caring team, on the other hand side the patient has rarely got access to safety critical information and relies on others to document significant symptoms, concerns or care preferences.

Modern health care is nominally putting the patients into the centre of its processes. Self-care programs and their measurements are seen as crucial to realize this (Ellins and Coulte, 2005; Coulter *et al.*, 2016). Patient-centred care has been defined as care that is respectful of, and responsive to, individual patient preferences, needs, and values and ensures that patient values guide all clinical decisions (Frampton, Guastello and Lepore, 2013). Patient consent procedures, patient-feedback, patient representation in colleges and healthcare trusts and co-design of services are all expressions of this philosophy. In hospital, patients are usually aware about 'the destination of travel' but most of them can't 'read the map' and are thus not able to determine course corrections. For patients to drive safety in health care, basic health literacy needs to be supported by better education, but much of the inability of patients to influence decision-making stems from a dialogue where only health care professionals are able to access information and document the outcome of the conversation. Systems are designed in a way where those who have the most interest in safety (the patients) have the least

access to safety critical information. Electronic systems might hold the key to changing this:

Outpatient and primary care clinics are increasingly using computer terminals for patients to check in for appointments. In paediatric medicine it is common practice for parents to document stool charts and urine output. Chronic disease management programs for patients with diabetes, asthma, hypertension, epilepsy and dialysis dependent chronic renal failure do commonly involve patient generated documentation either held by patients or in a central data depository (Ko *et al.*, 2010; Sathanandam, Rastall and Hoogewerf, 2016). These can improve error detection and patient-doctor relationships (Delbanco *et al.*, 2010; Leveille *et al.*, 2012; Bell *et al.*, 2015, 2016). At the same time more and more patients own Fitbit and other physiological monitoring devices and share their physiological data via Strava or Facebook. Technology is increasingly seen as a necessity for patient engagement (Coulter and Mearns, 2015).

My group has previously shown in a 'proof-of-concept' project that patients or careers are able to record their own social history into custom made software on commercially available tablet computers (not published). In a further project involving patients at risk of acute kidney injury 50% of participating patients were able to create detailed records of fluid intake and urine output of a comparable quality to those generated by health professionals.

The hypothesis

In this chapter I have summarised literature on adverse events: they are common and have profound impact on patients, clinicians, and organisations. They remain common despite the insights from more resilient approaches to patient safety and human factors analysis. The literature would suggest a gap in the evidence for a more prominent role of patients in a resilient health care system.

To drive down adverse incidents affecting hospitalized patients it would seem crucial to optimize communication systems in hospital to allow patients both meaningful access to safety critical information to identify errors of commission and omission and empower them to input safety concerns and monitor improvement of their illness or the absence of the same. I would therefore hypothesise: Greater control of patients of safety critical information will improve safety of care.

2.2. Aim and Outline of the Research Program

Aim

To examine the potential for active contribution of patients to documentation systems as a means of improving safety of patients at risk of catastrophic deterioration in hospital.

Objectives

Objectives map against the four phases of the double diamond methodology by the design council: discover, define, develop, deploy.

1. To discover (a) the impact of contemporary (electronic) documentation systems on predefined safety outcomes in hospital and (b) opportunities for patient contribution to documentation systems.
2. To define key safety challenges to prevent deterioration of patients in acute care with patients.
3. To use codesign to develop prototypes for these challenges.
4. To deploy those prototypes for feasibility testing in clinical settings.

In detail

Objective 1: I mapped existing knowledge and identified gaps in the literature through reviews of the literature examining safety aspects of electronic health records (Subbe, Tellier and Barach, 2021) (chapter 4.1), patient held and generated health records for hospitalized patients (not submitted for publication) and a critical appraisal of the impact of mHealth applications exemplified in the care of patients with a single disease group, i.e. patients undergoing treatment for cancer (Osborn *et al.*, 2020)(chapter 4.2).

Objective 2: I hosted a series of workshops and focus groups to explore ways for patients to contribute to their own safety in hospital. These involved patients, health care professionals, health managers and patient safety experts (Subbe *et al.*, 2019;

Subbe *et al.*, 2020) (chapter 4.3). This work was supported by an observational piece in a simulated environment (Subbe *et al.*, 2020) (chapter 4.4).

Objective 3: I developed a novel methodology for co-production in acute care with patients as part of an epistemological based model (Subbe, Goodman and Barach, 2022) (chapter 4.5). I used this methodology for a more detailed selection of safety challenges and development of linked prototypes.

Objective 4: I deployed two prototypes in representative health care environments and measured impact on behaviour of patients, carers and health care professionals using mixed methods. I explored the ability of the prototypes to affect safety in two interventional studies (Jones *et al.*, 2020; Subbe *et al.*, 2021) (chapter 4.6 and chapter 4.7).

I am now using learning for the development of grant proposals aiming for actionable improvement in the care of patients at risk of deterioration in hospital.

3. Approach to methodology

For the presented research I used a design methodology: The term design can be used colloquially to describe any process of creation and often implies improvements in aesthetics. ‘Design thinking’ is however a more strategic framework that links the three dimensions of desirability, feasibility and viability of a product or service (IDEO, 2020). Design thinking starts from a position of empathy and understanding of human need. Design thinking can be used by organisations to create value based on physical and emotional needs of users (Rapp and Stroup, 2016). In order to develop new processes or artefacts the Design Council proposes the ‘double diamond’ process to ‘discover, define, develop and deliver’ products (Davies and Wilson, 2015). This ‘double diamond’ formed the scaffold for the fellowship programme and this reflection.

Discovering the role of patients in hospital safety

Two scoping studies (O’Malley and Arksey, 2005) and a series of focus groups conducted during the first part of the project helped me to discover a broad range of published, unpublished, explicit and tacit knowledge about the dimensions of interactions between the actors in health care that can affect safety. I combined these with direct observation of healthcare processes in emergency departments, acute medical units, and general wards in order to ground learning in real life, focusing primarily on unscheduled and emergency care. While all areas used some electronic health records none was a ‘paper-less’ area with a complete electronic patient record.

Define key challenges for the design process

My prioritization of the key risks was underpinned by understanding of drivers and potential obstacles to development in a complex environment (Snowden, 2010): Snowden distinguishes between obvious, complicated, complex, and chaotic systems where scenarios from acute care would be classified as complicated or complex. Solutions depend highly on understanding the challenge of the situational context. They cannot be purely derived at by logical deduction but require ‘sensing’ or ‘probing’.

The key information challenges to improve the management of patients' risk were a focus of the design process. They were derived from the analysis of story boards and process mapping. Prioritization was further supported by iterative discussions with stakeholders including patients and experts from the advisory group.

Develop solutions

I used the first two parts of the program to inform option generation. We tested a number of ideas with limited small-scale pilots using iterative 'Plan Do Study Act' cycles. These took place in a selected number of clinical areas and involved limited number of patients.

Development of proto-types involved mixed methods, including but not restricted to process mapping and co-production. This approach allowed us to maintain 'what-matters-to-you medicine' rather than 'what's-the-matter-with-you medicine' (Barry MJ, 2012). Co-production allowed patients to become 'prosumers' – linking production and consumption of services (Toffler A., 1980). Cooperation between health professionals and patients, by employing their expertise of service use, results in more choice and increasing responsiveness to user needs while reducing waste and cost (Loeffler E, Power G, Bovaird T, Hine-Hughes F, 2013). This part of the programme was based on the principle that "we do not improve healthcare services by adding coproduction. Rather […] we see new opportunities for innovation and improvement." (Batalden *et al.,* 2015). We used patient involvement to 'work smarter not harder' while reducing workload of already overworked healthcare teams (Hayes, Batalden and Goldmann, 2014).

Primary outcome measures were therefore related to feasibility in relevant patient groups and were context dependent (Phelps and Barach, 2014). The evaluation included observational measures of team interaction (Malec *et al.*, 2007; Schraagen *et al.*, 2010).

Deliver prototypes for large scale testing

In the last part of the project I tested prototypes from successful small-scale pilots in larger patient samples (50-100 patients) involving whole clinical teams (Jones *et al.*, 2020; Subbe *et al.*, 2021).

My evaluation included measurement of interactions of patients with health care professionals, knowledge of patients about key risks and formal patient feedback.

The theoretical frameworks

The overall epistemological position of the thesis is grounded in objectivism. I assumed that changes in safety relevant behaviours and their outcomes can be observed and measured quantitively. The scope of my work did not extend to an examination of the social meaning of either interventions or outcomes. Methodology was therefore predominantly positivist with a focus on quantitative methods in the experimental pieces with limited qualitative data collected or analysed. The rational for this choice of methodology was largely pragmatic: my work was funded through an Improvement Science Fellowship with no additional funding to include more qualitative methodologies.

My underlying 'grand theory' was the theory of complex adaptive systems (Hodges and Larrañaga, 2021): This theory assumes that complex systems will adapt to external challenges and that the behaviour of systems is therefore often not predictable but become only apparent during testing (Kurtz and Snowden, 2003).

My mid-level theory was based on behaviour change theory (Michie, van Stralen and West, 2011): behaviours change through alignment of capability, opportunity, and motivation of actors in a system. This system has been applied to a broad range of healthcare challenges (Steinmo *et al.*, 2016) but to a lesser extent to patient safety. I hypothesised that by changing capability and opportunity for patients (Subbe *et al.*, 2024) behaviours might change, and safety outcomes should improve.

Program theories and theories of change 'focus on the intervention and conceptualise it as a chain of events, often in a linear sequence, which leads through successive intermediate changes […] to final results (clinical or cost outcomes).' (Foy *et al.*, 2011). I used our previously published theory on patient deterioration (Subbe and Welch, 2013) as the underlying programme theory: Improvement of deterioration events in hospital require recording of safety critical data, recognition of abnormalities, reporting to those skilled and authorised to respond and a repetitive loop of this sequence.

Caveat: Challenges from changing information technology

At present most hospitals use some form of electronic support systems for pathology or radiology results, some are using interconnected Electronic Patient Records but only few are completely paperless. This is likely to change over the next few years. Despite this, it is common practice to test paper mock-ups for electronic documents prior to implementing them into an electronic environment. Themes identified in the 'discover' and 'define' part of the program were generic enough to continue and inform a variety of information systems including electronic systems.

I borrowed methodology from design science that is focused on creating robust solutions for ‘real world usage’ after acquiring a deep understanding of the design context. Patient participation was at the heart of each step of the process. Discovery of the problem was undertaken with a broad range of stake holders derived through an epistemological framework. Based on these inputs definition of problems was highly context specific. Development of solutions explored the broadest possible range of options before a prototype was finally deployed for testing in a clinical environment.

4. Included papers

4.1 Paper 1: Impact of Electronic Health Records on Pre-defined Safety Outcomes in Patients Admitted to Hospital: A Scoping Review

Running title: Impact of Electronic Records on Patient Safety

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Authors

Christian Peter Subbe, DM, MRCP; School of Medical Sciences, Bangor University, Penrallt Rd, Bangor LL57 2AS, UK; csubbe@hotmail.com
Genevieve Tellier; School of Medical Sciences, Bangor University, Penrallt Rd, Bangor LL57 2AS, UK; gnt18sxx@bangor.ac.uk
Paul Barach, B.Sc, MD, MPH; Children's Hospital of Michigan, Wayne State University School of Medicine, 3901 Beaubien Blvd, Detroit, MI 48201, USA; pbarach@gmail.com

Corresponding author:
Dr CP Subbe, 21 Menai Quays, Menai Bridge, LL59 5DB; csubbe@hotmail.com;
tel: +44-7771-922890

ABSTRACT

Objectives

Review available evidence for impact of electronic health records (EHR) on predefined patient safety outcomes in interventional studies to identify gaps in current knowledge and design interventions for future research.

Design

Scoping review to map existing evidence and identify gaps for future research.

Data sources

PubMed, the Cochrane Library, EMBASE, Trial registers

Study selection

Eligibility criteria: We conducted a scoping review of bibliographic databases and the gray literature of randomised and non-randomised trials describing interventions targeting a list of fourteen pre-defined areas of safety. The search was limited to manuscripts published between January 2008 and December 2018 of studies in adult inpatient-settings and complemented by a targeted search for studies using a sample of EHR vendors. Studies were categorized according to methodology, intervention characteristics and safety outcome. Results from identified studies were grouped around common themes of safety measures.

Results

The search yielded 583 articles of which 24 articles were included. The identified studies were largely from US academic medical centres, heterogeneous in study conduct, definitions, treatment protocols, and study outcome reporting. Of the 24 included studies effective safety themes included medication reconciliation, decision support for prescribing medications, communication between teams, infection prevention and measures of EHR specific harm. Heterogeneity of the interventions and study characteristics precluded a systematic meta-analysis. Most studies reported process measures and not patient level safety outcomes: We found no or limited evidence in 13 of 14 pre-defined safety areas, with good

evidence limited to medication safety.

Conclusions

Published evidence for EHR impact on safety outcomes from interventional studies is limited and does not permit firm conclusions regarding the full safety impact of EHRs or support recommendations about ideal design features. The review highlights the need for greater transparency in quality assurance of existing EHRs and further research into suitable metrics and study designs.

Strengths and limitations of this study

- Scoping review to identify the gaps in research on assessing the impact of Electronic Health Records (EHR) on patient safety.
- Only interventional clinical studies were included.
- Limitation of search to terms from a previously validated authoritative search strategy.
- Exclusion of observational and feasibility studies.

Key words: Electronic health records; patient safety; hospital; clinical trial; medication safety; Health information technology

INTRODUCTION

Caring for patients with complex conditions safely and competently mandates having access to the right information at the right time (1). Ineffective sharing of information between providers and patients seriously impedes the quality and safety of patient care and is a leading cause of adverse events in hospital (2). Harm from medical care is common, has a significant associated morbidity and mortality and affects the mental health of staff as well as the financial performance of institutions (3). A small number of categories of patient harm account for the bulk of adverse events (4). Most interventions aimed at reducing harm have included introducing a digital health record while restructuring the patient documentation and communication (5).

It is widely accepted wisdom that the introduction of comprehensive systems for documentation and communication such as Electronic Health Records (EHRs) should improve the safer delivery of care. Mortality improves after implementation of EHRs in smaller non-teaching hospitals (6). The number of reported adverse events changes after implementation of EHRs with 'meaningful usage' functionality (7) but it is unclear whether changes are due to improved practice or changed event reporting. There are technical standards for EHR implementation and metrics for meaningful usage have focused on technical and efficiency aspects but not safety outcomes (8). There is hence the need to review the existing evidence for this specific aspect of care at a time of increasing spread of EHRs.

The objective of this scoping review is to map key concepts as a basis for a deeper understanding on the effects of electronic record systems on commonly used clinical safety metrics while identifying gaps in our current knowledge to inform design of future research and the design of more effective EHRs.

METHODS

Scoping reviews are a traceable method of "mapping" areas of research and highlighting gaps in the literature for future research (9). Scoping reviews are a useful tool in the ever-increasing arsenal of evidence synthesis approaches and require rigorous and

transparent methods to ensure that the results are trustworthy (10). We used Arksey and OMalley's (11) framework for undertaking a scoping review. This methodology summarizes the evidence available on a topic in order to convey the breadth and depth of that topic by mapping the existing literature in a field of interest in terms of the volume, nature, and characteristics of the primary research and identify gaps in the existing literature. In line with the methodology of scoping reviews a formal evaluation of the quality of the studies was not undertaken.

The review included the following five key phases: (1) identifying the research question, (2) identifying relevant studies, (3) study selection, (4) charting the data, and (5) collating, summarizing, and reporting the results. A detailed review protocol can be obtained from the primary author upon request.

A checklist for the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) can be found in appendix 1.

Research question

This review was guided by the question: 'How do patients admitted to hospital (P) benefit from implementation of an EHR (I) compared to patients not exposed to this or exposed to a different technology (C) in relation to commonly used outcome measures of safe care(O).' Our PICO (12) search strategy for identifying and selection of studies is outlined below. The studies were divided into categories based on similarities in their main objectives/findings and the themes discussed.

Data Sources and Search Strategy

The initial search was undertaken in March 2019 on studies published between January 2008 and December 2018, in the following databases: PubMed (including MEDLINE) and Embase, the European Trials Register, the Australian New Zealand Clinical Trials Register, the International Standard Randomized Controlled Trial Register and the Cochrane Library with supplementary searches on Google. The databases were selected to be comprehensive and to cover a broad range of disciplines. No limits on language, subject or type were placed on the

database search. The initial search was conducted in March 2019 with the supplementary searches run in December 2019.

We used a validated algorithm from a literature review on search terms for studies on patient safety (13) that was subsequently used by an authoritative systematic review of interventions to reduce adverse events in hospital (14). Appendix 2 provides a sample listing of the search query terms tailored to the specific requirements of each database.

Fourteen topics of patient safety were identified in the review (14) including adverse drug events, infection, delirium, adverse event after hospital discharge or clinical handover, fall, adverse event in surgery, cardiopulmonary arrest, venous thromboembolism, staffing, pressure ulcer, mechanical complication and underfeeding, clinical pathway, safety culture, external inspection. Electronic health records were defined according to the National Centre for Biotechnological Information as Media that facilitate transportability of pertinent information concerning patients illness across varied providers and geographic locations (15).

Study Selection Process

The study initial selection for inclusion was based on the title and abstract of the studies that were reviewed to preclude waste of resources in procuring articles that did not meet the minimum inclusion criteria. Two of the authors (CBS, GT) reviewed titles, references and abstracts generated by the original search against the agreed inclusion and exclusion criteria. When the title and abstract provided insufficient information to determine the relevance, a full-text copy of the article was retrieved and reviewed. For the final selection, a full-text copy of each study was examined to determine if it fulfilled the inclusion criteria. The references of eligible studies were manually checked to identify additional relevant studies that were missed in the database searches (snowballing). The studies were reviewed for their research design and internal validity and the references of the selected studies were manually checked to identify additional relevant studies that were missed in the database search.

Eligibility criteria

Inclusion criteria: Record systems can be applied to in or out-patient settings as well

as to systems in community, primary or secondary care. This review focuses on medical record systems that are being used to support care of adult patients admitted to hospital wards. The review included publications identified in any language that reported experimental interventions in clinical trials that tested how records influenced patient safety. Only studies comparing two interventions or an intervention against usual or standard care were included. Studies excluded at this phase if they were found to not meet the eligibility criteria

Exclusion criteria: Study protocols**,** case series**,** technical descriptions, conference abstracts and studies limited to primary care records, outpatient care and highly specialised environments such as cardiac catheterisation laboratories, operating rooms or day-case units were excluded. Systematic reviews have been undertaken to document the safety impact of electronic prescribing systems. Studies examining the effects of interventions after hospital discharge were outside of the scope.

Supplemental searches

In order to validate the search strategy additional searches were undertaken against the name of commonly used electronic health record vendors from the USA and UK identified from a Google search of electronic health records companies. In order to assure the capture of important themes additional searches against the names of a sample of twelve major providers of electronic records was undertaken (Appendix 2). 451 studies were screened. Four clinical trials that fulfilled inclusion criteria were identified. One of these (16) reviewed safety alerts about gastro-intestinal prophylaxis in a population that included in- and out-patients. The study did not allow to differentiate between the two groups and the study was thus excluded. Supplementary searches identified one further trial (17).

Data Extraction

Each article that met the study eligibility criteria was abstracted by using a standardized form based on a template by the Cochrane Collaboration (18). The data was extracted from the studies using an extraction tool that included the following items: article

identifiers (authors, year of publication, objective); study identifiers (sample size, design, country, length of follow-up, inclusion and exclusion criteria); setting and population; outcome measures.

We organized the study characteristics in a tabular form. The identified studies were summarised according to key themes based on similarities of their main intervention and metrics and mapped against the 14 safety topics.

Ethics

This study did not involve human material or human data, so an ethics approval was not needed. Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of the research. The study was not formally registered.

Patients or the public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this literature review.

Role of the Funding Source

The Health Foundation provided funding for the study through an Improvement Science Fellowship (CPS). The funding agency did not participate in study conception, data collection, analyses, manuscript preparation, the decision to submit the manuscript for publication, or any other part of the study.

RESULTS

Search results

The initial searches identified 60 articles for full-text review in the scoping review and further analyses. 24 papers met the eligibility and inclusion criteria and underwent a full-text abstraction (Table 1). Because of heterogeneity of the study designs, participants, and outcome measures a meta-analysis was not feasible. The flow of articles through identification to final inclusion is represented in Figure 1.

Table 1: Synopsis of 24 identified studies

Author	Country	RCT	Intervention	Type of safety metric	Unit of measurement	Impact
Abramson EL	USA	No	Transition between EHRs	Medication Safety	Clinicians	n.s.
Adelman JS	USA	Yes	Change in version of EHR	System Safety: Wrong patient orders	Clinicians	Identification-re-entry function resulted in lower error rate ($p<0.001$)
Awdishu L	USA	Yes	Notification: AKI	Medication Safety: AKI	Clinicians	Adjusted prescriptions increased ($p<0.001$)
Barnett ML	USA	No	Transition between EHRs	Adverse event reporting: (PSI)-90, death & readmissions	Patients	n.s.
Boockvar KS	USA	Yes	Link to community EHR	Medication Safety: Reconciliation	Patients	n.s.
Cardozo S	USA	No	Notification: Trauma	Clinical pathway: Cervical-spine clearance protocol	Patients	Improved compliance rate with pathway
Cho HJ	USA	No	EHR generated lists	Alerts	Clinical unit	Reduction in catheter related infections ($p<0.05$)
Cho I	Korea	No	Notification: Falls risk assessment	Falls	Patients	Unchanged rate of falls
Colpaert K	Belgium	No	Transition to electronic system	Medication Safety	Patients	Reduction in prescription errors ($p<0.001$)
Cook P	USA	No	Transition to electronic system	Medication Safety: Antibiotic prescribing	Patients	Reduction in nosocomial infections ($p<0.07$)
Dowding DW	USA	No	Transition to electronic system	Hospital acquired pressure ulcers and falls	Patients	Increased documentation rates for hospital acquired pressure ulcers
Fahey OG	USA	No	Change in version of EHR	Medication safety: Wrong dosage of chemotherapy	Clinicians	Decrease in dosage error (n=0) compared to manual rounding (n=4)
Hess E	USA	No	Transition from paper to electronic	Medication Safety: Wrong dosage in chemotherapy	Clinicians	n.s.

			system			
Mishra V	USA	No	Notification: Medication dosage	Medication safety: Monitoring of Vancomycin dosage	Patients	Increase in frequency of trough levels (p<0.01)
Mohsen A	USA	No	Change in version of EHR	Venous thrombembolism Reduction in inappropriate alerts	Patients	Alert reduction (p<0.001), increase in alert effectiveness (p<0.001), but decrease in alert efficiency (p=0.007)
Muhlenkamp R	USA	Yes	Notification: Dosage alerts	Medication safety: Removal of inappropriate or unnecessary alerts	Patients	Decrease in dosage alerts by 3.6%
Nanchal R	USA	Yes	Change in version of EHR	ICU Handover: Occurrence of non-routine events	Clinicians	Structured sign-out process reduced the occurrence of non-routine events reported by residents (p=0.005)
Nendaz MR	Switzerland	Yes	Notification: VTE risk assessment	Medication Safety: Decision support for VTE prophylaxis	Patients	Less overprescribing with e-alerts (p<0.01)
Schnipper JL	USA	Yes	Medication Reconciliation	Medication Safety: Adverse drug events	Patients	Changes significant at discharge but not admission
Silbernagel G	Switzerland	Yes	Notification: Complications of Atrial fibrillation	Medication safety: Anticoagulation	Patients	Adequate prescription increased from 16 to 22% (P=0.021)
Spirk D	Switzerland	Yes	Notification: VTE prophylaxis	Medication safety: VTE prophylaxis	Patients	n.s.
Weiss CH	USA	Yes	Checklist in EHR	Medication Safety: Antibiotic prescribing	Patients	Increase in number of days with empirical antibiotics (p< 0.002)
Westbrook JI	Australia	No	Implementation of two EHRs	Medication Safety	Patients	44% reduction in serious errors, increase in system errors
Wilson FP	USA	Yes	Notification: AKI	Medication Safety: AKI	Patients	Increase in creatinine checks (p<0.05) & reduction in deaths & dialysis (p<0.01) only in surgical stratum

AKI – Acute Kidney injury; EHR – Electronic Health Record; VTE – Venous thromboembolism

General Characteristics of Included Studies

The studies originated from a number of countries: 18 from the USA, three from Switzerland and one each from Australia, Belgium and Korea. The studies involved general hospital wards areas, critical care (19,20) and laboratory settings (21). Studies almost exclusively originated from academic medical institutions.

Eleven studies were randomized controlled trials; 13 studies were observational before-and-after studies or parallel group studies comparing electronic records with paper records (20–25) and other electronic r(25)ecords (26) . The methodological quality of the studies was not formally assessed in line with the framework of scoping reviews.

The majority of studies involved only a single institution, some involved a group of hospitals and in one study, the authors reported from one geographical region (27). The small number of multi-centre studies involving between two (23,28) and 29 (29) hospitals. The study duration ranged from a single month to five years with most studies lasting 6 to 18 months.

The studies examined interventions created by installing new electronic systems, changes delivered within an existing system and changes between different electronic systems.

The unit of examination were patients, hospitals units, pathology specimens and categories of healthcare professionals: nurses, physicians, prescribers, etc.

Processes by which EHRs aimed to effect changes in Safety Outcomes

The majority of studies used interventions that created information aimed to influence the behavior of physicians or prescribers, one study was aimed at nurses and no study was aimed at patients. The interventions included randomisation that was delivered at hospital, clinical units, clinician or patient levels. The comparative studies reviewed changes in adverse event reporting in hospitals implementing EHRs to those that did not implement EHR or in clinical departments pre- and post-implementation. Alerts were created for a random sample of patients or for a random sample of clinicians. Most studies reported on compliance with processes

associated with safe care. Only a limited number of studies reported on actual adverse events or harm (24,25,27,29–32).

Metrics of Impact

Results were mapped against the 14 pre-defined topics of patient safety (Table 2): Significant evidence was identified for the topic of adverse drug events and limited evidence for the topics of clinical handover, venous thromboembolism, clinical pathways, pressure ulcers and falls. No evidence was identified for seven of the pre-defined topics.

Identified studies were linked to safety themes. The patient safety themes identified included a) the use of electronic notifications as reminders or alerts (22,25,31,33–39), b) electronic notifications specifically in relation to medication safety (19,20,34–36,40–43,22,23,26–28,31–33), c) communication between teams (27,28,44), d) prevention and treatment of infections (19,22,24), and e) harm caused by the architecture of the EHRs (29,45,46).

Theme a) Electronic Reminders: Automated notifications were used to alert prescribers to good practices in prescribing of antibiotics (19,22,24,43), prevention of falls and hospital acquired pressure ulcers(25), oral anti-coagulants (47), thrombosis prophylaxis, (31,38) and nephrotoxic medications (33,36).

Best practice alerts for prescribing of antibiotics on general wards (22) elicited only a response in 19% of prescribers in one study, with most of the responders following the advice that resulted in a reduction in the number of broad-spectrum antibiotics prescribed.

A study in a medical intensive care unit used checklists for antibiotics in the electronic health records (19). These checklists were more effective on their own when compared to additional face-to-face prompting by a dedicated resident in changing the antibiotics to empirical antibiotics. Adverse events were not reported. The length of stay in the Intensive Care Unit and standardised mortality rates were not different between the intervention and control groups.

The electronic reminders for clinicians to prescribe oral anti-coagulants in patients with stroke and atrial fibrillation (35) resulted in a relative improvement in the rates of appropriate prescribing from 16% to 22%, however, the adverse effects were not reported.

The computer generated alerts about rising creatinine levels that indicated acute kidney injuries resulted in a significantly higher rate of repeat creatinine laboratory checks (36). There was a small increase in the subgroup of surgical ward patients in the number of renal consults ordered and in subsequent dialysis sessions. The primary combined outcomes of maximum creatinine rise, dialysis or death at seven days, however, did not change.

Implementation of risk assessments for falls and hospital acquired pressure ulcers led to improved documentation rates(25): Falls rates did not change and the rate of hospital acquired pressure ulcers dropped continuously over the period of the investigation but no step-change after implementation of the EHR.

An electronic protocol for the clearance of the cervical spine after mechanical trauma resulted in improved documentation (37). A falls-prediction algorithm (48) created a notification tool for falls prevention – this was tested against a non-matched control group.

*Theme b) Medication safety***:** The studies included reconciliation of medications (27,28), anticoagulants (31,35), antibiotic prescribing (19,22,24), acute kidney injury (33,36), calculating and monitoring of correct dosage(32,42,43) and error-reporting (20,23,49). The effects on patient outcomes were either not reported or small and limited to subgroups of patients.

Theme c) Communication between teams: Medication reconciliation on admission to the hospital was the focus of two studies (27,28). The reconciliation on hospital admission led to no measurable impact on safety outcomes. The electronic handover was related to a reduction in clinician reported 'non-routine events'(44).

Theme d) Infection: The prescribing practice of antibiotics (19,22,24) was examined. Significant impact on patient outcomes was reported in one study with a fall in only one of several examined nosocomial infections (24). A list of indwelling devices generated by the EHR was used to inform multi-disciplinary rounds with some

evidence of lower exposure to risk (39). The evidence was lacking on surrogate metrics describing the clinical course of infections such as the patients' white cell count, level of C-reactive protein or vital signs.

Theme e*) Harm caused by the EHR*: The potential harm caused by introduction of the EHR was measured through a novel 'retract-and-reorder' tool (45,46) that captured when clinicians prescribed corrected prescriptions and were reordered again for other patients. The majority of these events were likely near-misses. A reduction of harm from 'wrong patient' orders were attempted through the repeat of identity checks/verification (45) and a reduction in the number of maximum opened patient records (46). A summary nationally reported measure of patient harm was used in another study to quantify the impact of transitions between medical records (29).

Table 2: Synthesis of evidence for impact of implementation of EHR on pre-defined patient safety areas (Zegers M, BMJ Open 2016)

Patient Safety Area	Evidence for impact	Limitations
Adverse drug events	Evidence identified	Evidence for effects on documentation of allergies, drug interactions (process measures) and rate and reporting of adverse events (outcomes measures) Additional evidence from literature on specialist systems
Infection	Limited evidence identified	Changes to antibiotic prescribing (process measure) and catheter related infections (outcome measure)
Delirium	None identified	
Adverse event after hospital discharge or clinical handover	Limited evidence identified	The review was limited to effects in hospital. There was limited evidence for impact on clinical handover with reduction of 'non-routine-events' (outcome measure).
Falls	Limited evidence identified	No change in falls rates (outcome measure)
Adverse event in surgery	None identified	
Cardiopulmonary arrests	Limited evidence identified	Evidence for reduced rate of cardio-pulmonary arrests (outcome measure) from literature on specialist systems only
Venous thromboembolism	Limited evidence identified	Changes in prescribing of prophylactic interventions (process measure)
Staffing	None identified	
Pressure ulcer	Limited evidence identified	Improved documentation (process measure)
Mechanical complication and underfeeding	None identified	
Clinical pathway	Limited evidence identified	Improved readability (process measure)
Safety culture	None identified	
External inspection	None identified	

Additional gaps in understanding of impact of EHRs on safety outcomes

Studies reported limited explanatory context required to fully understand the likelihood of an impactful implementation such as staff workload, patient satisfaction, staff satisfaction or health economic outcomes. Staff satisfaction was measured in a single study (44) and only one study reported a patient reported outcome measure: Adverse events collected through telephone interviews in the study on electronic discharge notifications were not specified and not affected by the intervention (30).

We found limitations in measurement of attributable harm at the patient level: A study examining the effect of a Health Information Exchange on adverse drug events found only 37 adverse events in 381 patients (27): All reported adverse events were characterized by temporary symptoms (eg, pain) or temporary organ dysfunction (eg, a rise in creatinine), and none caused serious or permanent harm. A study using electronic alerts for acute kidney injury (36) examined events such as the administration of contrast in patients-at-risk without clinical validation of the preventability of these events.

There was some degree of innovative functionality specific to electronic systems in relation to safety outcomes: An EHR specific ‘retract-and-reorder’ measure (45,46) and a ‘patient safety composite measure’ for a selected validated summary indicator (PSI)-90 (29) were described. We were unable to identify a single trial using personal health records or patient portals in a hospital that reported on safety outcomes.

DISCUSSION

This is the first scoping review, to the authors’ knowledge, to systematically evaluate the impact of EHR interventions on patient safety metrics in hospital. We found little published evidence for positive effects of electronic health records on safety metrics that commonly feature in the literature such as hospital acquired infection, medication safety, allergies, falls, etc. The review identified some evidence for a meaningful impact of electronic health records in hospitals on surrogate outcomes that was largely restricted to changes in hospital prescribing practices. Limited follow-up periods might have been too short to capture the lasting effects beyond the immediate implementation period.

The review did not examine studies in primary care or paediatrics. Mortality was not included as a primary safety outcome as it depends on a large number of variables including the patient case-mix but there are indications that patient mortality improves in a sub-group of hospitals that have implemented EHRs(6).

Direct comparative clinical studies of EHRs by different vendors were missing. We were only able to identify two studies that directly compared EHRs. The first, a non-clinical study tested the safety processes in a simulated environment (50), and demonstrated large differences in the number of computer keyboard clicks and the time required to perform basic work tasks, and the second, an observational audit study that compared the prescription errors between two EHRs (51).

We found no evidence for EHR related patient engagement at any level. Patients have been called the first line of defence or the 'smoke alarm' to raise alerts about potential patient harm and are able if invited to do so, to play a key role in monitoring their safety across the health continuum (52,53). Personal health records (PHRs) held by patients might provide an obvious tool for enhanced patient safety but the evidence for a safety impact in primary care is limited to medication safety (54). The American Veterans Administration Healthcare system has undertaken a robust evaluation of their PHR that indicates a better adherence to treatment plans but little data on whether this adherence leads to safer or cost effective care (55) and patients' active contribution to documentation systems in hospital is likely to enhance care (56,57).

Our scooping review has several limitations. First the search strategy was limited to safety outcomes predefined by a group of experts (4) and we focused exclusively on EHRs. It is not clear whether other safety relevant outcomes could have been found in other studies of EHRs. Second, we focused on interventional studies to obtain a higher graded evidence and it is possible that safety outcomes are described in observational studies. Third, there is an understanding that monitoring systems for specific diseases that can be displayed through an EHR might be of benefit for safety outcomes such as measuring blood sugar levels in patients with diabetes (58) or the electro-cardiogram in patients with a coronary event (59). For unselected patient-groups there is evidence for the value of systems' monitoring of vital signs that might be linked to an EHR or have their own recording systems; these authors have illustrated an impact on relevant clinical and safety outcomes (60–62) albeit with some methodological challenges (63). Fourth, the studies identified in this review used exemplar

conditions and applications of electronic records. Frameworks to classify safety incidents in a broader, real world context (64,65) are missing. Fifth, the number of studies identified was small and despite using a robust, systematic search strategy we were unable to generate a hierarchy of effective or ineffective EHR interventions. The comparison between EHR systems is difficult given the lack of operational and interoperative standards (66), the lack of transparent data by the vendors, and even in a simulated environment straight comparisons are exceedingly rare (50). Sixth, the overwhelming number of studies originated in the USA which is highly influenced by the US healthcare regulatory and reimbursement schemes that are rather different from other healthcare systems. Finally, scoping reviews are not intended to assess the quality of the literature analysed. Nevertheless, this scoping review provides a comprehensive overview of the existing research and has clearly identified key themes and challenges for broader research which is needed.

EHRs can be used in many different ways in different hospitals. Linking the EHR intervention to a specific outcome might therefore be challenging even where process changes are the endpoints. Randomised trials might not be the most appropriate methodology for EHR evaluation and other generic service interventions because the effects at system level might be too diffuse. Carefully designed observational and adaptive interventional studies are needed to allow appropriate evaluation of service and policy interventions in this area(67).

The authoritative peer-reviewed search strategy deployed to identify publications reporting on patient safety topics uses a mix of process and outcome measures. Definition of these is subject to interpretation –. i.e. organisational culture could be used as an outcome measure as part of the quadruple aim or as a process that facilitates better quality of care for patients. Conceptually it would however be difficult to identify changes in outcomes without a model of change that does not involve some measure of change in process. Outcomes will of course depend on fidelity of implementation of processes but the absence of changes in safety critical processes is therefore likely to signify an absence in changes in safety outcomes.

The implementation of EHRs has got safety implications well beyond the scope of this review which range from the reliability of soft- and hard-ware, design or systems and user interfaces and risk of abuse and fraud(68). We have also not examined the broader context of implementations: evidence suggests that nurses

working in hospitals with no EHRs report poorer quality of care and patient safety(69) and cultural context and trust might modify impact(70–72).

Clinicians at the coal-face of care complain bitterly about poorly designed and supported EHR systems, which have unsuitable interfaces (73), add to workload, and fail to respond to change requests in a timely manner (74). EHR's are reported be the number one reason for clinician burnout and dissatisfaction (75). Given the enormous investment costs in the development and deployment of the technology and the emerging evidence of the negative effects of EHR on clinician burnout (76,77), the lack of reported benefits in sustainable and measurable safety outcomes is surprising and concerning. We share the concerns of others that there is largely 'anecdotal evidence of the fundamental expected benefits and risks relating to the organisational efficiency resulting from the storage and management facilities within the EHR and thus the potential for secondary uses'(78). Health information systems designed for and by a clinical teams using a technology that enables real-time adaptation might provide greater efficiency for the staff in decreasing the time to complete standard tasks (79).

Unstructured and fragmented information is at the core of countless serious adverse events and the link between fragmented information and patient harm is well established in the literature (80). Human factors and ergonomics design is part of the safety assurance of medical devices (81) but not the commonly used EHRs.

The EHRs are among the most expensive capital investments that health system leaders undertake with cost for an installation by a single organisation up to a billion dollars (82) despite the absence of evidence for cost-effectiveness (83), and routine complaints about the deleterious effects of implementation on clinicians and their workflow (84). EHRs have been introduced with an expectation workflow and safety improvements that have failed to materialize (85). An Australian study demonstrated that systematic errors in the usage of EHRs are common, and the audited files of 629 patients admitted to hospital were found to contain 493 errors related to the EHR and accounted for 42% of prescription errors (86),

Our review outlines a rich area for several key research questions, including the need to develop a clearer description of EHR interventions, using uniform and validated outcomes measures, and attending to care provider's needs, attitudes and training (87). Given the erosion of trust in the data safety of large projects,

smaller pilots in multiple locations might be needed to develop EHR systems that aid patients, professionals and policy makers (88). Enormous amounts of data relevant to patient safety are collated within EHRs. It is likely that hospitals and vendors are undertaking internal reviews of safety outcomes for purposes of audit, quality improvement, internal quality assurance or research. Given the size of the investment in EHRs and the adverse public health impact of patient safety it would seem that these type of datasets should be made public for research and quality assurance.

CONCLUSIONS

The clinical consequences of EHR use for patients might be considerable but the available studies suggest a limited understanding about the safety or potentially harmful outcomes following the implementation of EHRs. The literature contains inadequate evidence to guide policy or a digital strategy for healthcare jurisdictions in how best to select and implement EHRs.

Our review highlights an urgent need for greater transparency in quality assurance of existing EHRs and further research into suitable outcome metrics and appropriate study designs.

Contributorship statement

CPS and PB designed the study; CPS and GT screened the articles, CPS, GT and PB synthesized and interpreted the data; CPS, GT and PB drafted and revised the manuscript; all authors approved of the submitted version to be published; all authors agreed to be accountable for all aspects of the work.

Competing Interest

None of the authors have conflicts of interest in relation to the manuscript.

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Data sharing agreement

All data is contained in the manuscript.

REFERENCES

1. Nobili A, Garattini S, Mannucci PM. Multiple diseases and polypharmacy in the elderly: challenges for the internist of the third millennium. J comorbidity. 2011;1:28–44.

2. Lawton R, McEachan RRC, Giles SJ, Sirriyeh R, Watt IS, Wright J. Development of an evidence-based framework of factors contributing to patient safety incidents in hospital settings: a systematic review. BMJ Qual Saf. 2012;21(5):369–80.

3. Seys D, Wu AW, Van Gerven E, Vleugels A, Euwema M, Panella M, et al. Health Care Professionals as Second Victims After Adverse Events : A Systematic Review. Eval Health Prof. 2012;36(2):135–62.

4. Coleman AL, Staff A, Emptage NP, Mizuiri D, Kealey S, Lum FC. Secretary for Quality of Care. Vol. 7, BMJ Open. 2014.

5. Singh H, Naik AD, Rao R, Petersen LA. Reducing diagnostic errors through effective communication: harnessing the power of information technology. J Gen Intern Med. 2008 Apr 29;23(4):489–94.

6. Lin SC, Jha AK, Adler-Milstein J. Electronic health records associated with lower hospital mortality after systems have time to mature. Health Aff. 2018;37(7):1128–35.

7. Furukawa MF, Spector WD, Limcangco MR, Encinosa WE. Meaningful use of health information technology and declines in in-hospital adverse drug events. J Am Med Informatics Assoc. 2017;24(4):729–36.

8. Virginio LA, Ricarte ILM. Identification of Patient Safety Risks Associated with Electronic Health Records: A Software Quality Perspective. Stud Health Technol Inform. 2015;216:55–9.

9. Colquhoun HL, Levac D, O'Brien KK, Straus S, Tricco AC, Perrier L, et al. Scoping reviews: time for clarity in definition, methods, and reporting. J Clin Epidemiol. 2014 Dec;67(12):1291–4.

10. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. BMC Med Res Methodol. 2018 Dec 19;18(1):143.

11. O'Malley H, Arksey L. Scoping studies: towards a methodological framework. Int J Soc Res Methodol. 2005;8(1):19–32.

12. Richardson WS, Wilson MC, Nishikawa J, Hayward RS. The well-built clinical question: a key to evidence-based decisions. ACP J Club. 123(3):A12-3.

13. Tanon AA, Champagne F, Contandriopoulos AP, Pomey MP, Vadeboncoeur A, Nguyen H. Patient safety and systematic reviews: Finding papers indexed in MEDLINE, EMBASE and CINAHL. Qual Saf Heal Care. 2010;19(5):452–61.

14. Zegers M, Hesselink G, Geense W, Vincent C, Wollersheim H. Evidence-based interventions to reduce adverse events in hospitals: a systematic review of systematic reviews. BMJ Open. 2016 Sep 29;6(9):e012555.

15. U.S. national library for medicine [Internet]. [cited 2019 Sep 5]. Available from: https://meshb.nlm.nih.gov/record/ui?ui=D057286

16. Lilih S, Pereboom M, van der Hoeven RTM, Mantel-Teeuwisse AK, Becker ML. Improving the effectiveness of drug safety alerts to increase adherence to the guideline for gastrointestinal prophylaxis. Int J Med Inform. 2017 Jan;97:139–44.

17. Schnipper JL, Hamann C, Ndumele CD, Liang CL, Carty MG, Karson AS, et al. Effect of an Electronic Medication Reconciliation Application and Process Redesign on Potential Adverse Drug Events. Arch Intern Med. 2009 Apr 27;169(8):771.

18. Cochrane Effective Practice and Organisation of Care Review Group DATA COLLECTION CHECKLIST Cochrane Effective Practice and Organisation of Care Review Group (EPOC) Data Collection Checklist.

19. Weiss CH, DiBardino D, Rho J, Sung N, Collander B, Wunderink RG. A Clinical Trial Comparing Physician Prompting With an Unprompted Automated Electronic Checklist to Reduce Empirical Antibiotic Utilization. Crit Care Med. 2013 Nov;41(11):2563–9.

20. Colpaert K, Claus B, Somers A, Vandewoude K, Robays H, Decruyenaere J. Impact of computerized physician order entry on medication prescription errors in the intensive care unit: a controlled cross-sectional trial. Crit Care. 2006 Feb;10(1):R21.

21. Kinonen CL, Watkin WG, Gleason BC, Johnson CEJ, Thomas AB, Cibull TL, et al. Effects of computer reminders on complications of peripheral venous catheters and nurses' adherence to a guideline in paediatric care-a cluster randomised study. Puebla I, editor. J Gen Intern Med. 2017;39(1):868–74.

22. Schulz L, Osterby K, Fox B. The use of best practice alerts with the development of an antimicrobial stewardship navigator to promote antibiotic de-escalation in the electronic medical record. Infect Control Hosp Epidemiol. 2013 Dec 2;34(12):1259–65.

23. Westbrook JI, Reckmann M, Li L, Runciman WB, Burke R, Lo C, et al. Effects of Two Commercial Electronic Prescribing Systems on Prescribing Error Rates in Hospital In-Patients: A Before and After Study. Sheikh A, editor. PLoS Med. 2012 Jan 31;9(1):e1001164.

24. Cook PP, Rizzo S, Gooch M, Jordan M, Fang X, Hudson S. Sustained reduction in antimicrobial use and decrease in methicillin-resistant Staphylococcus aureus and Clostridium difficile infections following implementation of an electronic medical record at a tertiary-care teaching hospital. J Antimicrob Chemother. 2011 Jan;66(1):205–9.

25. Dowding DW, Turley M, Garrido T. The impact of an electronic health record on nurse sensitive patient outcomes: An interrupted time series analysis. J Am Med Informatics Assoc. 2012 Jul;19(4):615–20.

26. Abramson EL, Malhotra S, Fischer K, Edwards A, Pfoh ER, Osorio SN, et al. Transitioning between electronic health records: Effects on ambulatory prescribing safety. J Gen Intern Med. 2011;26(8):868–74.

27. Boockvar KS, Ho W, Pruskowski J, DiPalo KE, Wong JJ, Patel J, et al. Effect of health information exchange on recognition of medication discrepancies is interrupted when data charges are introduced: results of a cluster-randomized controlled trial. J Am Med Inform Assoc. 2017 Nov 1;24(6):1095–101.

28. Schnipper JL, Hamann C, Ndumele CD, Liang CL, Carty MG, Karson AS, et al. Effect of an electronic medication reconciliation application and process redesign on potential adverse drug events: a cluster-randomized trial. Arch Intern Med. 2009 Apr 27;169(8):771–80.

29. Barnett ML, Mehrotra A, Jena AB. Adverse inpatient outcomes during the transition to a new electronic health record system: observational study. BMJ. 2016 Jul 28;354:i3835.

30. Santana MJ, Holroyd-Leduc J, Southern DA, Flemons WW, O'Beirne M, Hill MD, et al. A randomised controlled trial assessing the efficacy of an electronic discharge communication tool for preventing death or hospital readmission. BMJ Qual Saf. 2017 Dec;26(12):993–1003.

31. Spirk D, Stuck AK, Hager A, Engelberger RP, Aujesky D, Kucher N. Electronic alert system for improving appropriate thromboprophylaxis in hospitalized medical patients: a randomized controlled trial. J Thromb Haemost. 2017 Nov 1;15(11):2138–46.

32. Hess E, Palmer SE, Stivers A, Amerine LB. Impact of an electronic health record transition on chemotherapy error reporting. J Oncol Pharm Pract. 2019;

33. Awdishu L, Coates CR, Lyddane A, Tran K, Daniels CE, Lee J, et al. The impact of real-time alerting on appropriate prescribing in kidney disease: a cluster randomized controlled trial. J Am Med Inform Assoc. 2016 May;23(3):609–16.

34. NENDAZ MR, CHOPARD P, LOVIS C, KUCHER N, ASMIS LM, DÖRFFLER J, et al. Adequacy of venous thromboprophylaxis in acutely ill medical patients (IMPART): multisite comparison of different clinical decision support systems. J Thromb Haemost. 2010 Jun;8(6):1230–4.

35. Silbernagel G, Spirk D, Hager A, Baumgartner I, Kucher N. Electronic Alert System for Improving Stroke Prevention Among Hospitalized Oral-Anticoagulation-Naïve Patients With Atrial Fibrillation: A Randomized Trial. J Am Heart Assoc. 2016;5(7).

36. Wilson FP, Shashaty M, Testani J, Aqeel I, Borovskiy Y, Ellenberg SS, et al. Automated, electronic alerts for acute kidney injury: a single-blind, parallel-group, randomised controlled trial. Lancet

(London, England). 2015 May 16;385(9981):1966–74.

37. Cardozo S, Angus LDG. Use of an electronic c-spine clearance strategy to ensure compliance with confrontational examinations. J Trauma Nurs. 2015;22(5):255–60.

38. Mohsen A, Kuperman E, McDanel J, Hacker S, Duffy M, Tunning K, et al. Using Electronic Clinical Quality Measures (eCQMs) to Perform a Venous Thromboembolism Prophylaxis Rapid Cycle Quality Improvement Initiative. Jt Comm J Qual Patient Saf. 2019;45(11):750–6.

39. Cho HJ, Khalil S, Poeran J, Mazumdar M, Bravo N, Wallach F, et al. "Lose the Tube": A Choosing Wisely initiative to reduce catheter-associated urinary tract infections in hospitalist-led inpatient units. Am J Infect Control. 2017 Mar 1;45(3):333–5.

40. Whalen K, Lynch E, Moawad I, John T, Lozowski D, Cummings BM. Transition to a new electronic health record and pediatric medication safety: lessons learned in pediatrics within a large academic health system. J Am Med Informatics Assoc. 2018 Jul 1;25(7):848–54.

41. Muhlenkamp R, Ash N, Ziegenbusch K, Rampe N, Bishop B, Adane E. Effect of modifying dose alerts in an electronic health record on frequency of alerts. Am J Heal Pharm. 2019;76:S1–8.

42. Fahey OG, Koth SM, Bergsbaken JJ, Jones HA, Trapskin PJ. Automated parenteral chemotherapy dose-banding to improve patient safety and decrease drug costs. J Oncol Pharm Pract. 2019;1–6.

43. Mishra V, Chouinard M, Keiser J, Wagner B, Yen MS, Banas C, et al. Automating Vancomycin Monitoring to Improve Patient Safety. Jt Comm J Qual Patient Saf. 2019;45(11):757–62.

44. Nanchal R, Aebly B, Graves G, Truwit J, Kumar G, Taneja A, et al. Controlled trial to improve resident sign-out in a medical intensive care unit. BMJ Qual Saf. 2017;26(12):987–92.

45. Adelman JS, Kalkut GE, Schechter CB, Weiss JM, Berger MA, Reissman SH, et al. Understanding and preventing wrong-patient electronic orders: a randomized controlled trial. J Am Med Inform Assoc. 2013 Mar;20(2):305–10.

46. Adelman JS, Applebaum JR, Schechter CB, Berger MA, Reissman SH, Thota R, et al. Effect of

Restriction of the Number of Concurrently Open Records in an Electronic Health Record on Wrong-Patient Order Errors. JAMA. 2019 May 14;321(18):1780.

47. Silbernagel G, Spirk D, Hager A, Baumgartner I, Kucher N. Electronic Alert System for Improving Stroke Prevention Among Hospitalized Oral-Anticoagulation-Naïve Patients With Atrial Fibrillation: A Randomized Trial. J Am Heart Assoc. 2016 Jul 6;5(7).

48. Cho I, Chung E. Effect of Automatic Inpatient Fall Prediction Using Routinely Captured EMR Data: Preliminary Results. Stud Health Technol Inform. 2016;225:828–9.

49. Liao TV, Rabinovich M, Abraham P, Perez S, DiPlotti C, Han JE, et al. Evaluation of medication errors with implementation of electronic health record technology in the medical intensive care unit. Open Access J Clin Trials. 2017;9:31–40.

50. Ratwani RM, Savage E, Will A, Arnold R, Khairat S, Miller K, et al. A usability and safety analysis of electronic health records: a multi-center study. J Am Med Informatics Assoc. 2018 Sep 1;25(9):1197–201.

51. Westbrook JI, Baysari MT, Li L, Burke R, Richardson KL, Day RO. The safety of electronic prescribing: manifestations, mechanisms, and rates of system-related errors associated with two commercial systems in hospitals. J Am Med Informatics Assoc. 2013 Nov;20(6):1159–67.

52. O'Hara J, Isden R. Identifying risks and monitoring safety: the role of patients and citizens. London; 2013.

53. Subbe CP, Øvretveit J, Quinn N, Wyatt JC. DIGITAL TECHNOLOGY: Opportunities and barriers for usage of personal health records in hospital – report from a -workshop of the Health Informatics Unit at the Royal -College of Physicians. Futur Hosp J. 2019 Feb 1;6(1):52–6.

54. Lusignan S De, Mold F, Sheikh A, Majeed A, Wyatt JC, Quinn T, et al. Patients ' online access to their electronic health records and linked online services : a systematic interpretative review. 2014;1–12.

55. Nazi KM, Hogan TP, Mcinnes DK, Woods SS, Graham G. Evaluating Patient Access to Electronic

Health Records Results From a Survey of Veterans. 2013;51(3):52–6.

56. Renggli JF, Eken C, Siegrist V, Ortega RN, Nickel C, Rosin C, et al. Usability of a Web-based Software Tool for History Taking in the Emergency Department. Acute Med. 2020;19(3):131–7.

57. Subbe C. Who is allowed to read and write? Acute Med J. 2020;19(3):116–7.

58. Levitt DL, Silver KD, Spanakis EK. Inpatient Continuous Glucose Monitoring and Glycemic Outcomes. J Diabetes Sci Technol. 2017 Sep 14;11(5):1028–35.

59. Ryan TJ, Anderson JL, Antman EM, Braniff BA, Brooks NH, Califf RM, et al. ACC/AHA Guidelines for the Management of Patients With Acute Myocardial Infarction:Executive Summary. Circulation. 1996 Nov 1;94(9):2341–50.

60. Jones S, Mullally M, Ingleby S, Buist M, Bailey M, Eddleston JM. Bedside electronic capture of clinical observations and automated clinical alerts to improve compliance with an Early Warning Score protocol. Crit Care Resusc. 2011 Jun;13(2):83–8.

61. Brown H, Terrence J, Vasquez P, Bates DW, Zimlichman E. Continuous Monitoring in an Inpatient Medical-Surgical Unit: A Controlled Clinical Trial. Am J Med. 2014 Mar;127(3):226–32.

62. Subbe CP, Duller B, Bellomo R. Effect of an automated notification system for deteriorating ward patients on clinical outcomes. Crit Care. 2017 Dec 14;21(1):52.

63. Smith GB, Prytherch DR, Schmidt PE, Featherstone PI, Meredith P. Bedside electronic capture - can it influence length of stay? Crit Care Resusc. 2011 Dec;13(4):281–2; author reply 283-4.

64. Scanlon MC, Karsh B-T, Saran KA. Risk-Based Patient Safety Metrics. Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment). 2008.

65. Sittig DF, Singh H. A red-flag-based approach to risk management of EHR-related safety concerns. J Healthc Risk Manag. 2013;33(2):21–6.

66. Ratwani RM, Hettinger AZ, Fairbanks RJ. Barriers to comparing the usability of electronic health records. J Am Med Informatics Assoc. 2016 Aug 29;24(e1):ocw117.

67. Lilford RJ, Chilton PJ, Hemming K, Girling AJ, Taylor CA, Barach P. Evaluating policy and service interventions: framework to guide selection and interpretation of study end points. BMJ. 2010 Aug 27;341(aug27 1):c4413–c4413.

68. Bowman S. Impact of electronic health record systems on information integrity: quality and safety implications. Vol. 10, Perspectives in health information management / AHIMA, American Health Information Management Association. American Health Information Management Association; 2013.

69. Kutney-Lee A, Kelly D. The effect of hospital electronic health record adoption on nurse-assessed quality of care and patient safety. J Nurs Adm. 2011 Nov;41(11):466–72.

70. Randell R, Abdulwahid M, Greenhalgh J, King N, Wright JM, Keen J. How and in what contexts does networked health it improve patient safety? Elicitation of theories from the literature. In: Studies in Health Technology and Informatics. IOS Press; 2019. p. 753–7.

71. Dixon-Woods M, Bosk CL, Aveling EL, Goeschel CA, Pronovost PJ. Explaining Michigan: Developing an Ex Post Theory of a Quality Improvement Program. Milbank Q. 2011 Jun;89(2):167–205.

72. Dixon-Woods M, Leslie M, Tarrant C, Bion J. Explaining Matching Michigan: an ethnographic study of a patient safety program. Implement Sci. 2013;8(1):70.

73. Patrick JD, Ieraci S. Good HIT and bad HIT. Med J Aust. 2013 Mar 4;198(4):205.

74. Patrick JD. The Validity of Personal Experiences in Evaluating HIT. Appl Clin Inform. 2010 Dec 16;1(4):462–5.

75. Gardner RL, Cooper E, Haskell J, Harris DA, Poplau S, Kroth PJ, et al. Physician stress and burnout: the impact of health information technology. J Am Med Informatics Assoc. 2019 Feb 1;26(2):106–14.

76. Assis-Hassid S, Grosz BJ, Zimlichman E, Rozenblum R, Bates DW. Assessing EHR use during hospital morning rounds: A multi-faceted study. Laws MB, editor. PLoS One. 2019 Feb 25;14(2):e0212816.

77. Downing NL, Bates DW, Longhurst CA. Physician Burnout in the Electronic Health Record Era. Ann Intern Med. 2019 Feb 5;170(3):216.

78. Black AD, Car J, Pagliari C, Anandan C, Cresswell K, Bokun T, et al. The Impact of eHealth on the Quality and Safety of Health Care: A Systematic Overview. Djulbegovic B, editor. PLoS Med. 2011 Jan 18;8(1):e1000387.

79. Patrick J, Barach P, Besiso A. Information Technology Infrastructure, Management, and Implementation: The Rise of the Emergent Clinical Information System and the Chief Medical Information Officer. In: Sanchez J, Barach P, Johnson H, Jacobs J, editors. Perioperative Patient Safety and Quality: Principles and Practice. Springer US; 2017.

80. Coiera E. Technology, cognition and error. Vol. 24, BMJ Quality and Safety. BMJ Publishing Group; 2015. p. 417–22.

81. Carayon P, Xie A, Kianfar S. Human factors and ergonomics as a Patient safety practice. Vol. 23, BMJ Quality and Safety. BMJ Qual Saf; 2014. p. 196–205.

82. Monica K. Top 5 Most Expensive EHR Implementations of 2017 [Internet]. Ehrinelligence. 2017 [cited 2019 May 31]. Available from: https://ehrintelligence.com/news/top-5-most-expensive-ehr-implementations-of-2017

83. Reis ZSN, Maia TA, Marcolino MS, Becerra-Posada F, Novillo-Ortiz D, Ribeiro ALP. Is There Evidence of Cost Benefits of Electronic Medical Records, Standards, or Interoperability in Hospital Information Systems? Overview of Systematic Reviews. JMIR Med informatics. 2017 Aug 29;5(3):e26.

84. Fry E, Schulte F. Death by a Thousand Clicks: Where Electronic Health Records Went Wrong | Fortune [Internet]. Fortune . 2019 [cited 2019 May 31]. Available from: http://fortune.com/longform/medical-records/

85. Poissant L. The Impact of Electronic Health Records on Time Efficiency of Physicians and Nurses: A Systematic Review. J Am Med Informatics Assoc. 2005 May 19;12(5):505–16.

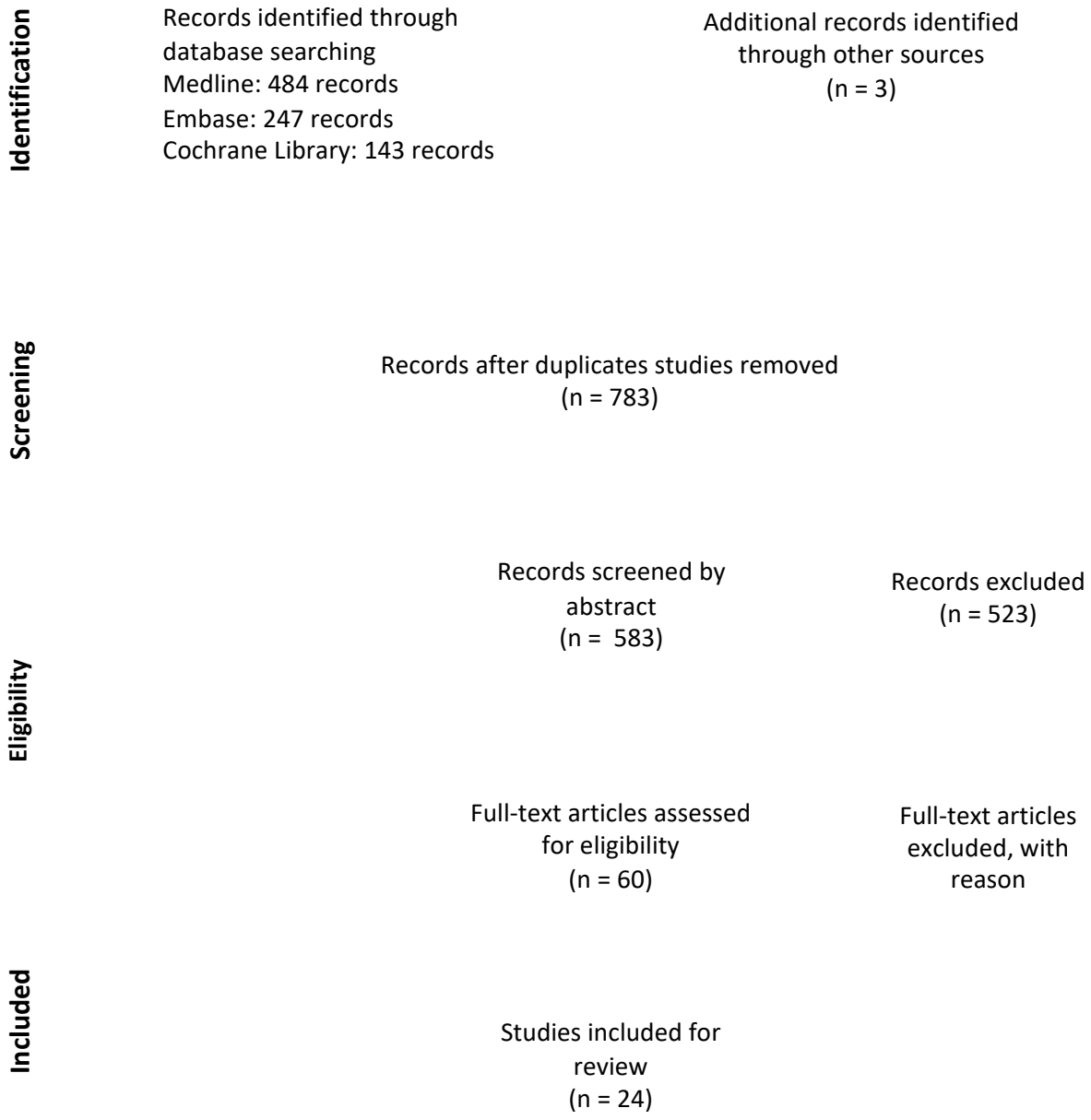
86. Westbrook JI, Baysari MT, Li L, Burke R, Richardson KL, Day RO. The safety of electronic prescribing: manifestations, mechanisms, and rates of system-related errors associated with two

commercial systems in hospitals. J Am Med Inf Assoc. 2013;20:1159–67.

87. Sittig DF, Wright A, Ash J, Singh H. New Unintended Adverse Consequences of Electronic Health Records. Yearb Med Inform. 2016 Nov 10;(1):7–12.

88. Frankel RM, Tilden VP, Suchman A. Physicians' Trust in One Another. JAMA. 2019 Apr 9;321(14):1345.

Figure: Flow Diagram of The Literature Search For Impact of Electronic Health Records



Appendix 2: Sample search Strategy

This is the search terms employed for pubmed:

((((((((((((((((((((Hospitals [Mesh]) OR Inpatients [Mesh]) OR Critical Care [Mesh]) OR Perioperative Care [Mesh]) OR Preoperative Care [Mesh]) OR hospital [tiab]) OR hospitals [tiab]) OR hospitalised [tiab]) OR hospitalized [tiab]) OR inpatient*[tiab]) OR critical care [tiab]) OR intensive care [tiab]) OR perioperative [tiab]) OR preoperative [tiab]) OR postoperative [tiab]) OR peri-operative [tiab]) OR pre-operative [tiab]) OR post-operative [tiab]))) AND ((Attitude of Health Personnel[mesh]) OR ((((((((((((((Patient Safety[mesh]) OR Patient Safety[tiab]) OR Risk Management [Mesh]) OR Risk Management [tiab]) OR Equipment Safety [Mesh]) OR Equipment Safety [tiab]) OR Harm Reduction [Mesh]) OR harm reduc*[tiab]) OR Safety Management[mesh]) OR Safety Management[tiab]) OR (((prevention and control [Subheading])))) OR prevent*[tiab]) OR safe*[tiab])) OR ((Hand Hygiene [Mesh]) OR Hospital Rapid Response Team [Mesh]) OR Hand Hygiene [tiab]) OR Rapid Response Team [tiab]) OR Medication Reconciliation [Mesh]) OR Medication Reconciliation [tiab]) OR Antibiotic Prophylaxis [Mesh]) OR Prophylaxis [tiab]) OR Infection Control [Mesh]) OR Infection Control [tiab]) OR Checklist[mesh]) OR Checklist[tiab]) OR Automatic Data Processing[mesh]) OR Automatic Data Processing[tiab]) OR Pain management[mesh]) OR Pain management[tiab]) OR Leadership[mesh]) OR Leadership[tiab]) OR Patient handoff[mesh]) OR Patient handoff[tiab]) OR Personnel staffing[Mesh term]) OR staff*[tiab]) OR Hospital nursing staff[mesh]) OR Hospital medical staff[mesh]) OR Nurse-Patient Ratio[tiab]) OR Education[mesh]) OR Education[tiab]) OR Patient simulation[mesh]) OR simulation[tiab]) OR Safety rounds[tiab]) OR fall prevent*[tiab]) OR pressure ulcer prevent*[tiab]) OR organizational culture[Mesh]) OR organizational culture[tiab]) OR safety culture[tiab]) OR Team training[tiab]) OR Case management [mesh]) OR Case management [tiab]) OR Continuity of Patient Care [mesh]) OR Quality indicators[mesh]) OR indicators[tiab]) OR Patient Participation[mesh]) OR Patient Participation[tiab])))) AND ((((((((((((((((mortality[mesh]) OR mortality[tiab]) OR adverse effects [Subheading]) OR adverse effect* [tiab]) OR Medical Errors [Mesh]) OR adverse event*[tiab]) OR harm*[tiab]) OR incident*[tiab]) OR Iatrogenic Disease[mesh]) OR complications [Subheading]) OR complication*[tiab]) OR adverse drug event*[tiab]) OR diagnostic err*[tiab]) OR medical

err*[tiab]) OR medication err*[tiab]) OR surgical err*[tiab]))) AND "Electronic Health Records"[Mesh] AND "Clinical Trial" [Publication Type]

Supplementary search for EHR providers

[Company name] AND ("Clinical Trial" [Publication Type]) OR "Safety"[Mesh])

List of companies searches: AdvancedMD, Agfa Healthcare, Allscripts, Athenahealth, CareCloud, Cerner, CureMD, Epic, GE centricity, NextGen, Eclinicalworks.

4.2 Paper 2: Do mHealth applications improve clinical outcomes of patients with cancer? A critical appraisal of the peer reviewed literature

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Authors:

Jemima Osborn[1], Anu Ajakaiye[1], Tim Cooksley[2], Christian P Subbe[1,3]

[1]Ysbyty Gwynedd, Penrhosgarnedd, Bangor, Gwynedd, LL57 2PW

[2]The Christie NHS Foundation Trust, Wilmslow Rd, Manchester M20 4BX

[3]School of Medical Sciences, Bangor University, Brigantia Building, Penrallt Road, Bangor, Gwynedd, LL57 2AS

Corresponding author: Dr CP Subbe; e-mail csubbe@hotmail.com; tel: +44-7771-922890

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Conflict of Interest Declaration

The authors have received no financial incentive for the work. None of the authors has any conflicts of interest in relation to the manuscript.

Ethics Declaration

The study did not involve patients. Ethics approval was not required.

ABSTRACT

Purpose: Patients undergoing systemic anti-cancer treatment experience distressing side-effects and these symptoms are often experienced outside the hospital setting. The impact of usage of cancer related mobile health (mHealth) applications on patient related outcomes requires investigation.

Methods: A critical appraisal of the literature was performed for the following question: 'In patients with cancer have mHealth applications been compared with usual care to examine impact on commonly used clinical outcomes.'

Literature searches were undertaken with the help of a research librarian and included Medline, Cochrane Collaboration, clinical trials data-bases and grey searches.

Results: 17 studies including between 12 and 2352 patients were identified and reviewed. Smartphone applications or internet-portals collected data on symptoms or patient activity. Several studies showed statistically significant differences in patient reported outcomes when symptom monitoring using mobile health application was compared to usual care. Change in mobility was the only outcome that was related directly to toxicity. Only limited data on mortality, cancer related morbidity including complications of care, health-economic outcomes or long-term outcomes were reported.

Conclusions: Studies of mHealth applications might improve aspects of symptom control in patients with cancer but there is currently little evidence for impact on other outcomes. This requires future research in interventional studies.

Keywords: Cancer, mHealth, Smartphone, internet, Health related quality of life

MANUSCRIPT

INTRODUCTION

Complications of cancer and its treatments are common (1). Many patients will experience side effects following chemotherapy, radiotherapy or targeted therapies. These lead to morbidity and mortality as well as increased resource utilisation in the community or hospital setting. Complications of cancer and its treatments are often predictable (fever, diarrhoea, skin reactions and drug specific effects). Education of patients might help to increase compliance with care pathways (2) especially if tailored to an individual's needs.. In the context of an increasingly digital healthcare system it is therefore worth considering the role of mobile health applications (mHealth) for clinical care, patient education and safety of treatment.

No standardized definition of mHealth exists but for the purpose of the Global Observatory for eHealth (GOe) mHealth or mobile health has been defined as 'medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices'(3). There are currently 97000 mobile health applications and in 2017 the number of global users for these was thought to be at 3.4 billion patients (4). The widespread use of smartphones (80% of patients (5), 95% of nurse and 99% of doctor (6)) in the United Kingdom means that mHealth applications are potentially accessible by most participants in healthcare: Healthcare professionals use smartphone applications to access risk assessment tools and scoring systems or to recap guidelines. Research on interventions based on mHealth applications suggests that they can be used to alter health related behaviours (7), such as medication adherence (8) but economic evidence for their usage is limited (9).

Patients use applications to get lifestyle advice, dietary information or practice mindfulness, yoga or other sports. Mobile health applications for patients with cancer might track deterioration (10) and support education and recovery (11–13) and have been suggested as a topic for research (14). It is not known how mHealth applications affect patient reported experience and patient reported outcome measures. The latter can be generic or cancer specific. Patient related outcomes measures are thought to be central for the understanding of effectiveness of treatments in cancer, improve patient-provider communication, patient satisfaction (15), everyday life (16) and survival (17).

In order to improve support of patients referred to the local oncology service that covers a large rural and remote area in North Wales the authors reviewed the literature to identify mHealth application with a peer reviewed evidence of impact on clinical outcomes that could be deployed in UK practice.

METHODS

Study design

The review of the literature used the format of a 'Critically appraised topic' (CAT). CATs are standardized summaries which draw together best available evidence to answer questions based on real clinical scenarios (18). CATs follow principles of evidence-based medicine in four steps: 1. The authors form a focused and answerable question based on a clinical encounter, 2. search for the best available evidence, 3. critically appraise the evidence for validity and clinical relevance and 4. examine the application of the results to clinical practice and future research.

Search strategy

The search question was created in a patient – intervention – comparison – outcomes (PICO) format: 'In patients with cancer (P) have mHealth applications (I) been compared with usual care (C) to examine impact on commonly used clinical outcomes (O).'

Outcomes that are commonly used in cancer trials include mortality, morbidity, quality of life, usage of hospital beds, number of outpatient appointments or appointments in primary care. In the context of care of patients with cancer morbidity related to treatments might be of particular interest.

A literature search was undertaken with the assistance of a research librarian. The following search string was used: (Mobile applications 'OR' Smartphone applications) 'AND' (Cancer 'OR' Neoplasms) followed by further searching using specific outcome measures: ('morbidity' OR 'mortality' OR 'quality of life' OR 'hospital beds' OR 'patient safety' OR 'outpatient appointments' OR 'GP appointments'). Additionally, a search for studies using patient portals was conducted: ("Patient Portals"[Mesh]) AND (cancer or neoplasm). Identified papers were searched for further applicable references ('snow balling').

Inclusion and exclusion criteria

Study criteria were agreed prior to undertaking the review: Publications up to April 2018 were included. No study pre-dating 2014 was identified. Randomized and non-randomised studies on all types of cancer including haematological malignancies were included. The review included dedicated mobile applications as well as programs that could be used on a smartphone such as web portals.

Non-patient facing applications, research protocols, studies that did not measure clinical outcomes and studies that reported purely application feasibility were excluded.

Studies were selected by one of the investigators (JO) and confirmed by the second investigator (AA). The papers identified in the search were analysed using the following questions: Does the study address the research

question, were the study methods valid in a generic oncology setting and are the results applicable to patients with cancer looked after in a clinical (vs research) setting.

Search terms were applied to Pubmed, Embase, Cochrane library and a national registry of trials (ClinicalTrials.gov).

No funding was received for the undertaking of the review.

RESULTS

Identified studies

The search found 139 abstracts, of which 17 fulfilled inclusion and exclusion criteria (Figure 1). Eighty-four studies initially identified did not meet the inclusion criteria as they did not measure a patient related outcome or were not for direct patient use.

The Cochrane Library identified a number of systematic reviews of mobile Health applications but none in the context of cancer care. The national database of clinical trials (ClinicalTrial.Gov) identified 72 trials, 20 of these were marked as 'completed' and two had published results in the peer reviewed literature (19,20).

17 studies met inclusion and exclusion criteria. Sample sizes varied from 12 to 2352 patients with a median of 130 patients. 11 of the studies had less than 100 participants. Ten of the studies were randomised controlled trials using usual care as their comparator. Patients with breast cancer were the patient group most commonly targeted (6 studies) (Table 1-3). Studies examined effects of custom built smart phone applications and internet portals as swell as existing messaging services (21) and patient portals (22).

Interventions delivered through mHealth applications

Interventions that were delivered in the studies fell into broad categories: 1. Delivery of information/education in a digital format (23–25), 2. provision of life style interventions such as mindfulness(19), exercise (26,27) or consumption of vegetables (28) and 3. symptom scores ranging from pain (23) to psychological symptoms of Post-traumatic Stress Disorder (PTSD) (24) and usually linked to a healthcare professional for escalation (29). One study looking at detection of lung cancer relapse, allowed patients to access follow-up and imaging sooner if concern was raised from reported symptoms (30).

Reported outcomes

As per our inclusion criteria, only apps which measured a patient related outcome were included (Table 2):

Patient symptoms: Outcomes were heterogenous, largely focusing on symptoms related to cancer and reporting severity, distress or quality of life impact related to specific symptoms. Quality of life measures included disease specific (27) or generic (31) tools.

The main positive clinical outcome from usage of mHealth applications was significant improvement in pain intensity, pain interference and consequentially quality of life (23), nausea, fatigue, urinary symptoms and emotional functioning (32), fewer days of moderate-severe neuropathic symptoms, distress and activity interference (23), reduction in Post-Traumatic Stress Disorder symptoms (24), reductions in distress (33) and less severe neuropathic pain compared to usual care (34) at scheduled outpatient visits. Physical activity improved in two studies (20,28). As a caveat: In several studies symptoms were more common in the intervention group (29,33,35).

Treatment toxicity: A Mexican study established a correlation between reduction in day to day mobility and chemotherapy toxicity in geriatric cancer patients (26). Symptom scores could be used to optimise treatments(31).

Mortality: One of the studies has subsequently published long-term follow-up data from using a symptom tracking application (31) about improved mortality in a research letter (36). The lack of detail makes evaluation of this publication challenging.

Health-economic outcomes: These were not explicitly evaluated but outpatient appointments and readmissions to hospital provide some surrogate outcomes for financial impact (22,29,31) with one study quoting higher (22)and one lower hospitalisation rates (31).

Adverse effects: Adverse effects from using the applications were reported in two studies: Higher readmission rates in a study of an existing provider portal (22) and increased anxiety and distress levels in an application with information about breast cancer (25).

Others: A single study focused on the detection of cancer relapse in lung cancer survivors (30): The study looking at detection of lung cancer relapse using sentinel questionnaires. On average relapses were found five weeks earlier than planned follow up visit, there was a high sensitivity for detection in relapse, but the intervention did not identify a single relapse that was not also detected by sentinel follow up.

Methodological considerations

Studies had clearly documented inclusion criteria and methodology. All applications using symptom reporting used validated and peer reviewed scales. While ten of the studies were randomised, for obvious reasons none of them were blinded. Education status and familiarity with internet/mobile technology improved outcomes (31) in one study but not in another (26).

Patients used the interventions in varying amounts but little data were available on the 'dosage' of application usage. Increase usage might perceivably lead to improved outcomes. A 'prescribed dose' of intervention would facilitate evaluation but would be unrealistic as patients will experience symptoms in varying amounts and will therefore need their intervention in varying amounts (23). Some measure of compliance was included in most studies whereas acceptability was only formally assessed in three studies (Table 3).

Applicability of results to patients undergoing routine oncology care

Studies identified covered a wide range of ages and demonstrated that both young people and the older generation were comfortable using apps. Some of the used measurement tools referred to a specific malignancy and extrapolation of results does therefore need to be with caution. Variation in sample size means that results from studies with smaller patient groups might be context sensitive and not be applicable without further testing in other clinical settings.

Whilst self-reported outcomes may be subject to some recall bias (28) many of the applications allowed for in the moment reporting (23,37) which is likely to have less recall bias than waiting to inform a medical practitioner in an out-patient or clinic setting.

Safety aspects

Several of the applications, described alert systems which informed a healthcare professional if further intervention was required, potentially improving patient safety and increasing communication between patient and healthcare providers. One application facilitated discussion between health care providers and patient by educating the patient on how best to communicate their concern prior to a clinic appointment (33). Response to new symptoms was at times delayed: In 'SIST-net' 74% percent of new symptoms reported by patients were addressed by a nurse practitioner in under three working days; this was below the pre-set target of 90% thus highlighting potential work-load implications and the need to put robust failsafe mechanism in place to follow up reported symptoms (29).

DISCUSSION

The authors have identified a small number of mHealth applications that have been examined in clinical studies with a randomized or non-randomized control group. Studies identified were aimed at a range of different cancers and age groups. Positive impact was largely limited to improved symptom control, but several studies reported increased symptoms. Data on other outcomes including health economic measures were limited.

Our search is limited by several factors: In patients with cancer changes in clinical status, morbidity and mortality can be expected within months but the sample size of most studies might have precluded significant numbers within the study duration. Only one of the studies examined impact on mortality (36), however since the longest study was only conducted for 12 months, there is at current lack of long-term data.

Friends, family and other carers are often able to identify deviation from a patient's normal status as a first step to facilitate calls for help. Only one study 'pain buddy' an avatar-based symptom dairy/pain management application invited a family member to also engage with the application, so this is a potentially a unique or underexplored feature (37).

The majority of studies identified were randomized controlled trial. Given the fast pace of innovation in digital technology this might not be the best methodology to evaluate impact (38), Smartphone applications are only one of the new digital ways to provide care with smart watches (39,40) and telehealth (41,42) offering alternatives to traditional models of care.

The reasons for the limited evidence for mHealth applications in cancer might be complex: mHealth applications are a relative new addition to the armamentarium of clinicians but safety implications are potentially considerable. The novelty means that principles of design and implementation are not as clear as those used for pharmacological interventions. Mobile applications for medical purposes require compliance with regulations and the obligation to updating information. A review of mHealth applications for patients with cancer in Spain found that only half had been developed by healthcare organisations (48). The potential lack of clinical input into the development might be one reasons for limited clinical impact despite the considerable promise of applications to monitor toxicity (26) or even adjust chemo-therapy drug dosing for safety impact (49).

The present search identified registered trials that might help to further insights into the impact of mHealth interventions in the near future: eRAPID is a system for patients to 'self-report and manage adverse events online during and after cancer treatment'. The platform has been developed with patients (43,44). Field testing has been completed (45) and the related randomized controlled trial is powered against symptom control but will include the number of hospital, primary care and community contacts.

The eSMART trial will study an application for symptom management in a European multi-centre study to assist patients receiving chemotherapy for breast, colorectal or haematological cancer (46). PRISMS will attempt a similar intervention in an Australian trial of patients with haematological malignancies(47).

Patients with cancer are in principle willing to embrace application assisted care (50): A survey of patients with prostate cancer found that out of 375 participants, about half were willing to use a cancer care assisted app and 72% of these said data protection/pseudonymisation were important. A third of the participants who were not willing to use an application cited that secure data transfer and data storage were a concern.

While mHealth application open the possibility of round a clock care where e-alerts generated from the app can be monitored and acted upon by a member of the cancer specialist team. In practice out of hours services might not be robust enough to accommodate round the clock monitoring in many areas. Whilst the ability for applications to facilitate improved communication and red flag alerting with health services, care needs to be made to ensure patients understand the app is not a replacement for usual care but an adjunct (51).

MHealth interventions work in part through changing communication patterns between patients and their care network. Randomized controlled trials might not be the most suitable way to test complex multi-faceted interventions that are difficult to blind. Studies using patient registries might provide alternative way to evaluate this type of intervention(52,53).

CONCLUSIONS

The CAT review was based on service consideration in the unit of the authors that provides care for patients in rural and remote areas in North Wales: This review found only a small number of studies measuring outcomes relevant to the PICO question despite a broad search string and multiple databases. Many of the screened studies looked exclusively at the design, feasibility and acceptance of mobile health applications but there was a significant lack of evidence for the efficacy of utilizing patient facing applications to improve clinically relevant outcomes. More in-depth studies are needed with larger cohorts to fully evaluate the impact of applications to improve patient outcomes.

Conflict of Interest Declaration

None of the authors has any conflicts of interest in relation to the manuscript.

Figure 1: PRISMA Flow Diagram of literature search

Identification

Records identified through database searching (n=145)

Additional records identified through other sources (n=7)

Records after duplicates removed (n=152 minus 13 duplicates)

Screening

Records screened (n=139)

Records excluded (n=98)

Assessed

Full-text articles assessed for eligibility (n=42)

Full-text articles excluded:
Purely a feasibility study (n=5)
Protocols (n=5)
Review article not study (n=1)
Irrelevant, not an application or not intended for cancer patient use (n=13)

Included

Studies included in qualitative/quantitative synthesis (n=17)

References

1. Cooksley T, Rice T. Emergency oncology: development, current position and future direction in the USA and UK. Support Care Cancer. 2017 Jan 4;25(1):3–7.
2. Hibbard J, Helen G. Supporting people to manage their health : an introduction to patient activation. King's Fund. 2014;(May):51.
3. World Health Organization. mHealth: new horizons for health through mobile technologies: second global survey on eHealth. Vol. 3, Global Observatory for eHealth series. 2011.
4. Jahns R-G, Houck P. Mobile Health Market - Trends and Figures 2013-2017. Berlin; 2013.
5. UK "has never been more addicted to smartphones" - BBC News [Internet]. 2016 [cited 2018 Jul 21]. Available from: https://www.bbc.co.uk/news/business-37468560
6. Mobasheri MH, King D, Johnston M, Gautama S, Purkayastha S, Darzi A. The ownership and clinical use of smartphones by doctors and nurses in the UK: a multicentre survey study. BMJ Innov. 2015 Oct 1;1(4):174–81.
7. McKay FH, Cheng C, Wright A, Shill J, Stephens H, Uccellini M. Evaluating mobile phone applications for health behaviour change: A systematic review. J Telemed Telecare. 2018 Jan 18;24(1):22–30.
8. Haase J, Farris KB, Dorsch MP. Mobile Applications to Improve Medication Adherence. Telemed e-Health. 2017 Feb;23(2):75–9.
9. Iribarren SJ, Cato K, Falzon L, Stone PW. What is the economic evidence for mHealth? A systematic review of economic evaluations of mHealth solutions. Mihalopoulos C, editor. PLoS One. 2017 Feb 2;12(2):e0170581.
10. Theile G, Klaas V, Tröster G, Guckenberger M. mHealth Technologies for Palliative Care Patients at the Interface of In-Patient to Outpatient Care: Protocol of Feasibility Study Aiming to Early Predict Deterioration of Patient's Health Status. JMIR Res Protoc. 2017 Aug 16;6(8):e142.
11. Nasi G, Cucciniello M, Guerrazzi C. The Role of Mobile Technologies in Health Care Processes: The Case of Cancer Supportive Care. J Med Internet Res. 2015 Feb 12;17(2):e26.
12. Davis SW, Oakley-Girvan I. mHealth Education Applications Along the Cancer Continuum. J Cancer Educ. 2015 Jun 9;30(2):388–94.
13. Geng Y, Myneni S. Patient Engagement in Cancer Survivorship Care through mHealth: A Consumer-centered Review of Existing Mobile Applications. AMIA . Annu Symp proceedings AMIA Symp. 2015;2015:580–8.

14. Nasi G, Cucciniello M, Guerrazzi C. The Performance of mHealth in Cancer Supportive Care: A Research Agenda. J Med Internet Res. 2015 Feb 13;17(1):e9.

15. Chen J, Ou L, Hollis SJ. A systematic review of the impact of routine collection of patient reported outcome measures on patients, providers and health organisations in an oncologic setting. BMC Health Serv Res. 2013 Jun 11;13(1):211.

16. Catt S, Starkings R, Shilling V, Fallowfield L. Patient-reported outcome measures of the impact of cancer on patients' everyday lives: a systematic review. J Cancer Surviv. 2017 Apr 10;11(2):211–32.

17. Gotay CC, Kawamoto CT, Bottomley A. The Prognostic Significance of Patient-Reported Outcomes in Cancer Clinical Trials. Artic J Clin Oncol. 2008;

18. Callander J, Anstey A V, Ingram JR, Limpens J, Flohr C, Spuls PI. How to write a Critically Appraised Topic: evidence to underpin routine clinical practice. Br J Dermatol. 2017 Oct;177(4):1007–13.

19. Rosen KD, Paniagua SM, Kazanis W, Jones S, Potter JS. Quality of life among women diagnosed with breast Cancer: A randomized waitlist controlled trial of commercially available mobile app-delivered mindfulness training. Psychooncology. 2018 Aug;27(8):2023–30.

20. Golsteijn RHJ, Bolman C, Volders E, Peels DA, de Vries H, Lechner L. Short-term efficacy of a computer-tailored physical activity intervention for prostate and colorectal cancer patients and survivors: a randomized controlled trial. Int J Behav Nutr Phys Act. 2018 Dec 30;15(1):106.

21. Zou Q, Zhang G, Liu Y. Health Education Using Telephone and WeChat in Treatment of Symptomatic Uterine Myoma with High-Intensity Focused Ultrasound. Med Sci Monit Basic Res. 2018 Sep 6;24:127–33.

22. Aljabri D, Dumitrascu A, Burton MC, White L, Khan M, Xirasagar S, et al. Patient portal adoption and use by hospitalized cancer patients: a retrospective study of its impact on adverse events, utilization, and patient satisfaction. BMC Med Inform Decis Mak. 2018 Dec 27;18(1):70.

23. Jibb LA, Stevens BJ, Nathan PC, Seto E, Cafazzo JA, Johnston DL, et al. Implementation and preliminary effectiveness of a real-time pain management smartphone app for adolescents with cancer: A multicenter pilot clinical study. Pediatr Blood Cancer. 2017;64(10):1–9.

24. Smith SK, Kuhn E, O'Donnell J, Koontz BF, Nelson N, Molloy K, et al. Cancer distress coach: Pilot study of a mobile app for managing posttraumatic stress. Psychooncology. 2018;27(1):350–3.

25. Foley N, O'Connell E, Lehane E, Livingstone V, Maher B, S K, et al. PATI: Patient accessed tailored information: A pilot study to evaluate the effect on preoperative breast cancer patients of information delivered via a mobile application. Breast. 2016;30:54–8.

26. Soto-Perez-De-Celis E, Kim H, Rojo-Castillo MP, Sun C-L, Chavarri-Guerra Y, Navarrete-Reyes AP, et al. A pilot study of an accelerometer-equipped smartphone to monitor older adults with cancer receiving chemotherapy in Mexico. J Geriatr Oncol. 2018 Mar;9(2):145–51.

27. Uhm KE, Yoo JS, Chung SH, Lee JD, Lee I, Kim J Il, et al. Effects of exercise intervention in breast cancer patients: is mobile health (mHealth) with pedometer more effective than conventional program using brochure? Breast Cancer Res Treat. 2017;161(3):443–52.

28. Kanera IM, Willems RA, Bolman CAW, Mesters I, Verboon P, Lechner L. Long-term effects of a web-based cancer aftercare intervention on moderate physical activity and vegetable consumption among early cancer survivors: a randomized controlled trial. Int J Behav Nutr Phys Act. 2017;14(1):19.

29. Wheelock AE, Bock MA, Martin EL, Hwang J, Ernest M Lou, Rugo HS, et al. SIS.NET: A randomized controlled trial evaluating a web-based system for symptom management after treatment of breast cancer. Cancer. 2015;121(6):893–9.

30. Denis F, Viger L, Charron A, Voog E, Dupuis O, Pointreau Y, et al. Detection of lung cancer relapse using self-reported symptoms transmitted via an Internet Web-application: Pilot study of the sentinel follow-up. Support Care Cancer. 2014;22(6):1467–73.

31. Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, et al. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. J Clin Oncol. 2016 Feb 20;34(6):557–65.

32. Sundberg K, Wengström Y, Blomberg K, Hälleberg-Nyman M, Frank C, Langius-Eklöf A. Early detection and management of symptoms using an interactive smartphone application (Interaktor) during radiotherapy for prostate cancer. Support Care Cancer. 2017;25(7):2195–204.

33. Berry DL, Hong F, Halpenny B, Partridge A, Fox E, Fann JR, et al. The electronic self report assessment and intervention for cancer: promoting patient verbal reporting of symptom and quality of life issues in a randomized controlled trial. BMC Cancer. 2014 Jul 12;14(1):513.

34. Kolb NA, Smith AG, Singleton JR, Beck SL, Howard D, Dittus K, et al. Chemotherapy-related neuropathic symptom management: a randomized trial of an automated symptom-monitoring system paired with nurse practitioner follow-up. Support Care Cancer. 2018 May 5;26(5):1607–15.

35. Foley NM, O'Connell EP, Lehane EA, Livingstone V, Maher B, Kaimkhani S, et al. PATI: Patient accessed tailored information: A pilot study to evaluate the effect on preoperative breast cancer patients of information delivered via a mobile application. Breast. 2016 Dec;30:54–8.

36. Basch E, Deal AM, Dueck AC, Scher HI, Kris MG, Hudis C, et al. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine Cancer Treatment.

JAMA. 2017 Jul 11;318(2):197.

37. Fortier MA, Chung WW, Martinez A, Gago-Masague S, Sender L. Pain buddy: A novel use of m-health in the management of children's cancer pain. Comput Biol Med. 2016;76(December):202–14.

38. Pham Q, Wiljer D, Cafazzo JA. Beyond the Randomized Controlled Trial: A Review of Alternatives in mHealth Clinical Trial Methods. JMIR mHealth uHealth. 2016 Sep 9;4(3):e107.

39. Hoilett OS, Twibell AM, Srivastava R, Linnes JC. Kick LL: A Smartwatch for Monitoring Respiration and Heart Rate using Photoplethysmography. In: 2018 40th Annual International Conference of the IEEE Engineering in Medicine and Biology Society (EMBC). IEEE; 2018. p. 3821–4.

40. Pope Z, Zeng N, Zhang R, Lee H, Gao Z. Effectiveness of Combined Smartwatch and Social Media Intervention on Breast Cancer Survivor Health Outcomes: A 10-Week Pilot Randomized Trial. J Clin Med. 2018 Jun 7;7(6):140.

41. Cox A, Lucas G, Marcu A, Piano M, Grosvenor W, Mold F, et al. Cancer Survivors' Experience With Telehealth: A Systematic Review and Thematic Synthesis. J Med Internet Res. 2017 Jan 9;19(1):e11.

42. Williams OE, Elghenzai S, Subbe C, Wyatt JC, Williams J. The use of telemedicine to enhance secondary care: some lessons from the front line. Futur Hosp J. 2017 Jun 1;4(2):109–14.

43. Avery KNL, Richards HS, Portal A, Reed T, Harding R, Carter R, et al. Developing a real-time electronic symptom monitoring system for patients after discharge following cancer-related surgery. BMC Cancer. 2019 May 17;19(1):463.

44. Holch P, Warrington L, Bamforth LCA, Keding A, Ziegler LE, Absolom K, et al. Development of an integrated electronic platform for patient self-report and management of adverse events during cancer treatment. Ann Oncol. 2017 Sep 1;28(9):2305–11.

45. Warrington L, Absolom K, Holch P, Gibson A, Clayton B, Velikova G. Online tool for monitoring adverse events in patients with cancer during treatment (eRAPID): field testing in a clinical setting. BMJ Open. 2019 Jan 1;9(1):e025185.

46. Maguire R, Fox PA, McCann L, Miaskowski C, Kotronoulas G, Miller M, et al. The eSMART study protocol: a randomised controlled trial to evaluate electronic symptom management using the advanced symptom management system (ASyMS) remote technology for patients with cancer. BMJ Open. 2017 May 6;7(5):e015016.

47. Breen S, Ritchie D, Schofield P, Hsueh Y, Gough K, Santamaria N, et al. The Patient Remote Intervention and Symptom Management System (PRISMS) – a Telehealth- mediated intervention enabling real-time monitoring of chemotherapy side-effects in patients with haematological

malignancies: study protocol for a randomised controlled trial. Trials. 2015 Dec 19;16(1):472.

48. Collado-Borrell R, Escudero-Vilaplana V, Ribed-Sánchez A, Ibáñez-García S, Herranz-Alonso A, Sanjurjo-Sáez M. Smartphone applications for cancer patients; what we know about them? Farm Hosp. 2016 Jan 1;40(1):25–35.

49. Weaver A, Love SB, Larsen M, Shanyinde M, Waters R, Grainger L, et al. A pilot study: dose adaptation of capecitabine using mobile phone toxicity monitoring — supporting patients in their homes. Support Care Cancer. 2014 Oct 26;22(10):2677–85.

50. Kessel KA, Vogel MM, Kessel C, Bier H, Biedermann T, Friess H, et al. Mobile Health in Oncology: A Patient Survey About App-Assisted Cancer Care. JMIR mHealth uHealth. 2017;5(6):e81.

51. Subbe CP, Øvretveit J, Quinn N, Wyatt JC. DIGITAL TECHNOLOGY: Opportunities and barriers for usage of personal health records in hospital – report from a -workshop of the Health Informatics Unit at the Royal -College of Physicians. Futur Hosp J. 2019 Feb 1;6(1):52–6.

52. Buccheri S, Sarno G, Fröbert O, Gudnason T, Lagerqvist B, Lindholm D, et al. Assessing the Nationwide Impact of a Registry-Based Randomized Clinical Trial on Cardiovascular Practice. Circ Cardiovasc Interv. 2019 Mar;12(3).

53. Sundh J, Bornefalk-Hermansson A, Ahmadi Z, Blomberg A, Janson C, Currow DC, et al. REgistry-based randomized controlled trial of treatment and Duration and mortality in long-term OXygen therapy (REDOX) study protocol

Table 1: Studies on mHealth applications for patients with cancer

Author (Year)	Country	Type of application	Number of patients	Study Design	Comparator group	Patient activity	Application function
Aljabri D (2018)	USA	Internet portal	2352 patients	Retrospective cohort study	Non-adopters	Not reported	Access to clinical records
Basch E (2015)	USA	Internet portal or kiosk in hospital	766 patients; 441 intervention, 325 control	Randomized	Usual Care	Symptom-checker: Chemotherapy related symptoms	Alert: e-mail to nurses for significant or worsening patient-reported symptoms
Berry D (2015)	USA	Internet portal	752 patients; 256 intervention group, 261 control group	Randomized	Usual care	Symptom-checker & quality of questionnaires	Education: Information about symptoms and reporting
Denis F (2014)	France	Mobile application	42 patients	Cohort study	Clinic appointment	Symptom-checker	Alert: of oncologist
Foley N (2016)	Ireland	Mobile application	39 patients; 13 intervention group; 26 control group	Randomized	Standard leaflets	None	Education: Information about breast cancer
Fortier M (2016)	USA	Mobile application	12 patients	Pilot study	n.a.	Symptom-checker: Avatar interaction on reporting of pain	Education: Link to information Alert
Golsteijn RHJ (2018)	Netherlands	Internet portal	478 patients; 249 intervention, 229 control	Randomized	Waiting list controlled	Life-style: Exercise data	Education: Exercise advice
Jibb LA (2017)	Canada	Mobile application	40 patients	Cohort study	n.a.	Symptom checker: Pain measured by questionnaire	Education: Link to information
Kanera I (2017)	Netherlands	Internet portal	462 patients; 231 intervention group, 231 control group	Randomized	Usual care	Life-style: Physical activity & vegetable intake measured by questionnaires	Education: Link to educational content
Kolb NA (2018)	USA	Automated telephone system	252 patients; 121 intervention	Randomized	Usual care	Symptom-checker	Education: Self-care strategies Alert: nurse practitioner

			group, 131 control group				review
Rosen KD (2018)	USA	Mobile application	112 patients; 57 intervention, 55 control	Randomized	Waiting list controlled	Education: 12-week mindfulness course	
Smith SK (2016)	USA	Mobile application	31 patients	Cohort study	Baseline	Symptom-checker: PTSD measured by questions	Education: Link to information
Soto-Pere-De-Celis E (2018)	Mexico	Mobile application	40 patients	Cohort study	Baseline	Life-style: Mobility measured by accelerometer	Alert: Phone call to smartphone for review of toxicity
Sundberg K (2017)	Sweden	Mobile application	130 patients; 66 intervention group, 64 control group	Non-randomized controlled study	Historic control group	Symptom-checker: Psychological distress measured by questionnaire	Alert: Oncology nurse
Uhm K (2017)	Korea	Mobile application	356 patients; 179 intervention group, 177 control group	Randomized	Exercise brochure	Life-style: Pedometer measuring activity	Education: Goal setting for physical activity
Wheelock A (2014)	USA	Internet portal	100 patients; 59 intervention group, 41 control group	Randomized	Usual care	Symptom-checker: Depression & quality of life measured by questionnaires	Alert: Review by oncology nurse
Zou Q (2018)	China	Telephone chat application	426 patients; 251 intervention, 175 control	Randomized	Usual care	Symptom-checker: Anxiety, pain & satisfaction measured by questionnaires	Contact with oncology team

Table 2: Functionality of applications, inclusion criteria, outcome measures and results of studies testing mHealth applications for patients with cancer

Author (Year)	**Name & function of application**	**Inclusion criteria**	**Outcome measures**	**Results**
Aljabri D (2018)	Existing patient portal	Adult patient admitted to hospital with cancer as a primary or secondary diagnosis	Provider-reported, in-hospital adverse event; post-discharge emergency department visits and unplanned readmissions within 30 days; satisfaction by Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.	Increased readmission rates amongst active adaptors of the patient portal. Self-management knowledge scores were higher among adopters vs nonadopters (univariate analyses only)
Basch E (2018)	**STAR** (Symptom Tracking and Reporting) Web-based interface for self-reporting of common symptoms associated with cancer treatment	Patients with metastatic breast, genitourinary, gynecologic, or lung cancers receiving chemotherapy stratified for experience with computers	Health related quality of life (HRQL measured by EQ-5D); emergency room visits, hospitalizations, survival.	Patient in the intervention group experienced less decline of HRQL less frequent admissions to the emergency room, less hospitalisation and remained on chemotherapy longer. Effects on HRQL limited to computer experienced subgroup.
Berry D (2015)	Self-reported online assessment of cancer symptoms: Application facilitated patient self - monitored symptoms, education and coaching on how to report worries to clinicians.	Adult patients, any type of cancer or stage, about to start a new treatment for cancer.	Symptom distress	Fatigue, pain and physical function issues were reported significantly more often by patients in the intervention group.
Denis F (2014)	Sentinel follow up questionnaire.	Lung cancer patients after undergone surgical	Compliance, easiness, anxiety and	Relapse detection was on average 5 weeks earlier using sentinel follow up.

	Email alert sent to oncologist if patient reports red flag symptoms.	excision, complete response or detectable but non-progressive lung cancer.	performances of web-application for detecting cancer relapse	Reported better relationship with oncologist and reduced anxiety about follow up.
Foley N (2016)	Application containing basic aetiology of breast cancer, treatment and surgical intervention information.	Female adult pre-operative patients with breast cancer	Anxiety and depression scores prior and post intervention	Higher anxiety levels in intervention groups.
Fortier M (2016)	**Pain-buddy** Avatar guided tablet application including a symptom diary, communication tool and coping strategies for symptom management. Triggers to health care providers for severe symptoms.	Paediatric patients aged 8-18, diagnosed with cancer, undergoing outpatient cancer treatment. One parent/guardian also invited to participate. No cognitive or developmental delay.	Feasibility, symptom frequency and compliance	Symptom were reported and recommended coping strategies utilised. Only 4% of symptoms would have triggered an alert to health care professionals, most of these for pain. Good compliance and user satisfaction.
Golsteijn RHJ (2018)	**OncoActive** Computer-tailored physicial activity program Providing personalised feedback with printed materials.	Patients and survivors with prostate and colorectal cancer from 17 hospitals throughout the Netherlands	Questionnaires for self-reported physical activity, fatigue, distress and quality of life. Actigraph for measurement of activity	Participants in the intervention group increased self-reported activity and improved physical functioning, fatigue and depression at six months.
Jibb LA (2017)	**Pain squad+** 22 item questionnaire to assess pain. Real time reporting. Patients were contacted if they reported frequent pain and information was available form the application on how best to manage the	Patients aged 12-28, undergoing cancer treatment, at least 2 months from diagnosis. Patients reported pain of 3/10 at least once in week prior to recruitment.	Primary: feasibility; Secondary: effectiveness: pain intensity, pain interference, health related quality of life, self-efficacy	Improvements in pain intensity and Health related quality of life. Satisfactory acceptability with good adherence by those who completed study.

	pain.			
Kanera I (2017)	Web-based self-reporting questionnaires and modules providing education about diet, smoking cessation, physical activity, anxiety, depression and fatigue.	Adult patients who had completed primary cancer treatment at least 4 weeks prior. Patients with recurrent cancer, severe medical, psychiatric or cognitive diseases excluded.	Physical activity, vegetable consumption	Sustained Increase in physical activity in intervention group. Increased vegetable consumption in intervention group, but results not sustained to 12 months.
Kolb NA (2018)	**SymptomCare @Home** Daily symptom monitoring by telephone. Intervention group with automated telephone delivered self-care strategies and alert of nurse practitioner for poor symptom control.	Patients beginning chemotherapy with taxane/platinum therapies as a part of a larger trial.	Severity, distress and impact on activity of neuropathic pain	Patients in the intervention group had significantly fewer days with moderate and severe symptoms, fewer days of symptom distress and a trend towards less activity interference.
Rosen KD (2018)	**Headspace** Commercially available mindfulness application	Women aged 25 or more within 5 years post breast cancer diagnosis	Functional Assessment of Cancer Therapy – Breast (FACT-B), mindfulness, and pain assessments at baseline, during 8 week intervention and at 12 weeks.	Participants in the intervention group reported higher quality of life with FACT-B and higher dispositional mindfulness.
Sundberg K (2017)	**Interaktor** Symptom questionnaire focusing on frequency and distress level, responses triggered red or yellow alerts to an oncology nurse.	Adults with localised prostate cancer, eligible for curative radiotherapy, considered physically, psychologically and cognitively fit enough to take part.	Symptoms and health related quality of life	No difference within groups in symptoms over time but improvements between intervention and control group. In control group after radiotherapy worse emotional functioning with more fatigue, nausea, insomnia and urinary symptoms.
Smith SK (2016)	**Cancer distress coach**	Lymphoma, breast or prostate cancer	PTSD symptoms,	The majority of patients found application helpful.

	PTSD symptom checker with advice on managing symptoms and information on reliable sources of support	patients, 19 years or older, active PTSD symptoms	distress, self-efficacy, feasibility, acceptability and perceived usefulness.	Statistically significant reduction is PCL-S score for PTSD symptoms after using the app. No change in self efficacy.
Soto-Pere-De-Celis E (2018)	**Accelerometer & application** Remote monitoring of daily steps, before and during chemotherapy, with a trigger of > 15% drop in baseline activity as an indicator of potential chemo toxicity.	Patients aged > 65 years, any solid cancer, chemotherapy as first line in either metastatic or recurrent cancer.	Primary: feasibility; Secondary: association of level of activity with grade of chemotherapy toxicity	High acceptability of application to patients despite limited interaction with mobile technology and low educational status. Association of low step counts with grade 3 toxicity.
Sundberg K (2017)	**Interaktor** Symptom questionnaire focusing on frequency and distress level, responses triggered red or yellow alerts to an oncology nurse.	Adults with localised prostate cancer, eligible for curative radiotherapy, considered physically, psychologically and cognitively fit enough to take part.	Symptoms and health related quality of life	No difference within groups in symptoms over time but improvements between intervention and control group. In control group after radiotherapy worse emotional functioning with more fatigue, nausea, insomnia and urinary symptoms.
Uhm K (2017)	Pedometer and smartphone app which monitored a prescribed 12-week exercise programme. Quality of life assess at baseline and 12 week.	Histologically confirmed breast cancer, age 20 to 70 years, completion of primary cancer treatment including surgery, chemotherapy, and/or radiotherapy.	Activity measurements, self-reported physical activity, quality of life	Physical function, physical activity, and Quality of Life scores were equally improved in both groups.
Wheelock A (2014)	**SIS - NET** Three-monthly web-based self-reported symptoms. Remote assessment by a nurse practitioner.	Patients with breast cancer after completion of acute treatment or any clinical trial adjuvant treatment (6 months post chemo, 3 months post hormonal therapy or surgery)	Time between symptom reporting and evaluation by healthcare professional, use of healthcare resources.	Only 74% of symptoms addressed within less than 3 days. Significantly more symptoms reported by patients in intervention group. No difference in oncology-related appointments, physician visits or medical tests.

Zou Q (2018)	Telephone and WeChat application	Symptomatic adults with uterine myoma	Hamilton Anxiety Scale before and after treatment, Visual Analogue Scale for pain during first 24 hours after treatment.	Patients in the intervention group had less preoperative and postoperative anxiety, less postoperative pain, and higher treatment satisfaction.

4.3 Paper 3: Opportunities and barriers for usage of Personal Health Records in hospital – Report from a workshop of the Health Informatics Unit at the Royal College of Physicians

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Christian P Subbe, DM, MRCP; Consultant Physician, Honorary Senior Clinical Lecturer, School of Medical Sciences, Bangor University, Bangor; Improvement Science Fellow, The Health Foundation, London, UK; Tel: +44-7771-922890; csubbe@hotmail.com

John Øvretveit, B.Sc. (Hons), MPhil., PhD., CPsychol., AFBPsS, CSci.. Director of Research (MMC) and Professor of health care improvement implementation and evaluation; LIME/Medical Management Centre, Karolinska Institutet, Tomtebodavagen 18a, Stockholm, Sweden SE-171 77. Tel: +46 8 524 863 24; jovretbis@aol.com

Nicola Quinn, Health Informatics Unit, Royal College of Physicians, 11 St Andrews Place, Regent's Park, London NW1 4LE; Tel: 0203 075 1484; Nicola.Quinn@rcplondon.ac.uk

Jeremy Wyatt, Health Informatics Unit, Royal College of Physicians, 11 St Andrews Place, Regent's Park, London NW1 4LE Tel: 0203 075 1484; j.c.wyatt@soton.ac.uk

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The four authors planned the workshop together, chaired sessions, presented content and worked on the present.

We would like to acknowledgements the contributions of the participants who gave up their time and expertise for the workshop. We are especially grateful to the patient representatives for their input.

ABSTRACT

Personal health records (PHR) are thought to offer benefits and are promoted by health policy makers and some healthcare systems. Evidence for usage by patients in hospital is limited.

This article reports a one-day workshop hosted by the Royal College of Physicians (RCP) that considered the evidence of the value to patients and others, the challenges to adoption and use and of PHR and sought identify the practical and research questions that need to be answered.

The purpose of this article is to provide readers with an overview of the issues and possible future for hospital application of PHRs in the United Kingdom's National Health Service, especially for supporting self-care, family carers and advancing Person-Centred Care. It aims to share the experience and ideas of those taking part in the workshop and reference resources that we have found useful while highlighting areas for future research.

KEYWORDS

Personal health Record, hospital, person-centred care

INTRODUCTION

Patient health records (PHR) are "... a digital tool that helps people to maintain their health and manage their care. It may do this by enabling them to capture their own health and care data, to communicate with health and care services, and/or to have access to their care record" (1).

Additionally PHRs can be used for functions such as making appointments in primary care or specialty clinics, providing access to tests, collection of patient feedback such as patient related outcomes measures (PROMs), and reminders to patients and their care team.

It is National Health Service (NHS) policy to make available "personalized healthcare" by 2020 (2). Previous research by the Royal College of Physicians (RCP) on PHRs created a "landscape review" and a report about user insights(1,3). This brought together the available evidence from the United Kingdom on the use of Personal Health Records. Dissemination of PHR was almost exclusively in primary care and outpatient care. Results are often not reported widely but some implementation and benefits have been described in areas of primary care, in the care of patients with inflammatory bowel disease (4–6) and for patients with prostate cancer(7).

PHR can be a) part of an integrated health care systems such as Kaiser Permanente (8) or b) linked to single systems in primary care, outpatient care or single disease management or c) be a stand-alone depository of information of the patient. PHR serve a variety of purposes:

- They are used to empower patients by making information about their condition and materials in relation to that condition available to them.
- They allow patients to record and track symptoms over time, supporting their ability to identify triggers for symptoms and how they can be managed. This information can also be used by healthcare professionals to support the patient,
- They can serve as an online portal for health care specific services that supplement or displace physical encounters with healthcare professionals.
- They can be used as a marketing advantage in healthcare systems with competing healthcare providers.
- They can act as an additional source of data for healthcare providers to fine tune services, develop predictive algorithms and conduct health service research.

PHRs have been introduced in a number of healthcare systems: In Sweden patients have access to a patient portal containing a PHR in all regions since 2017(9). In the US Kaiser

(8,10) has also made a patient portal available to all its patients. In Europe Estonia (11) has probably the highest uptake with 95% of all health information digitalized and patients able to log into their own record. Sweden(12) has made some progress using regional patient portals and registries of patients with chronic health condition. Germany has seen attempts by insurance companies to introduce patient portals. France has an agreed standard for patient access but uptake has been low(13).

There is currently little published evidence on use or impact of PHRs by hospital patients or staff, before during or after a hospital encounter. This is despite the fact that a number of providers offer functionality in their electronic health records (HER).

UK context

In 2014 the UK Coalition government published 'Personalised Health & Care 2020' (14) with the 'ambition [..] for a health and care system that enables people to make healthier choices, to be more resilient, to deal more effectively with illness and disability when it arises, and to have happier, longer lives in old age.' The document makes proposals for better access to digital information for health care professionals, service transparency, innovation and industry growth, and to help patients to 'Enable me to make the right health and care choices". In the same year the Five Year Forward View (15) was published and gave a framework for action to use digital technology to "shift power to patients and citizens, strengthen communities, improve health and wellbeing and, as a by-product, help moderate rising demands on the NHS."

In the UK development of PHRs for patients admitted to hospitals has been limited. A few systems exist and are under development for certain patient groups in the community and in hospital:

PatientView (16) is a system for renal patients to manage and monitor their condition through access to laboratory tests, clinic letters and list of medications, diagnosis and other treatments. Patients can set up alerts, monitor symptoms, download their records, share their information with others and are given limited access to their hospital EHR.

A personal child health record(https://www.eredbook.org.uk/ (17)) is under development which could give primary and secondary care teams the ability to access and provide information on a child's health, growth and development. This record will accessible by the child's parent or guardian for children under a certain age.

Work is under way to develop an electronic smart prototype of current paper records: the "All Wales pregnancy Health record" in Powys (Personal Communication, Marie Lewis) that is intended to serve as a PHR for women in community and hospital.

Overall, developing local- or condition- specific PHRs could facilitate patient testing and provide a number of functions and services and be useful to both patients and clinicians. The disadvantage of local PHRs not linked to a wider NHS system and possibly not accessible outside of a locality is that it does not promote the "seamless care" advantages of PHRs. Local system are however much easier and faster to develop.

Little research or commentary has been published about PHR use by hospital patients and staff: The purpose of this paper is to provide a background and resources to those considering or developing PHRs in the context of admissions to hospital. It reports issues discussed and possible ways forward at a workshop hosted by the Royal College of Physicians.

METHODS

The workshop at the RCP was attended by four patient representatives, five health informatics specialists, four health service researchers and two practicing physicians and two health informatics specialists with clinical background.

The workshop was opened by Professor Ovretveit from the Karolinska Institute in Stockholm with an international overview of PHR experience, evidence and options for hospitals. Health service research experts then reported on existing knowledge from the United Kingdom. Participants examined use cases around typical patient journeys in four groups with each group having input from a patient representative, a person with a clinical background, a health informatics specialist and a health service researcher. After a final discussion Professor Jeremy Wyatt summarized learning from the workshop.

Definitions are summarised in Appendix A.

RESULTS

PHR USE BY HOSPITAL PATIENTS AND STAFF – GENERAL CONSIDERATIONS

The usage of PHRs can usefully be conceptualized in relation to planned and unplanned admissions over the three phases of pre-, during and post- admission.

Elective / planned admissions

Pre-admission: a significant proportion of hospital activity consists of planned procedures. Using a PHR, patients could access information and write notes that can contribute to a safe performance of the procedure. Ideally some help or support can be given to enable patients to become familiar with the system so that they do not later need to learn it during or post-admission.

During admission: with access to a PHR in hospital, a patient could use checklists (based on procedure standards and guidelines) to give their records and comments on performance and aftercare which could provide alerts to staff about possible complications and also provide a record for any retrospective assessments.

Post-admission: Aftercare could equally be documented in the PHR and shared with care teams in the community or the patients' home.

Unplanned / Emergency admissions

Prior to admission: For unplanned emergency admissions to hospital patients using PHRs could enter information that could speed up the admission-process and provide patients views' of what is important to them. Given that an increasing number of patients suffer with chronic health care conditions up to date information about these condition could be held in PHRs. 10-15% of admissions to UK hospital departments are readmissions. In these patients information in PHRs from the time after a previous discharge might inform care at the time of readmission and enable patients and their clinicians to learn about the prevention of future admissions.

During emergency admissions: PHRs could help to reconcile medication schedules, give information about newly diagnosed conditions and contain schedules for investigations or appointments with clinical teams. PHRs could facilitate monitoring or pain and other patient centered outcome measures. This could be shared with clinical teams to inform responsive care. In time, automated systems could identify discrepancies between patient-recorded information and EHR data such as medications or allergies.

After an emergency admission: PHR could facilitate transfers of care back to community teams.

Benefits for patients

Potential benefits of PHRs along the patient journey in and out of hospital are better information, efficiency and health literacy and activation of patients. This could free more time for clinicians to focus on complex issues that require detailed discussions with patients and their families (Table 1).

Benefits to staff

PHRs should ideally contain the type of information that is safety critical for the treatment of patients: medications, allergies, and co-existing healthcare conditions. This information is of great importance for hospital staff, but often already available through access to records from primary care. Feedback from patients through PHRs could guide treatment of symptoms (e.g. pain) or quality improvement of hospitals. However, research shows that staff often do not check existing data in EHRs and whether they would also consider the PHR data would depend in part on how user-friendly the system is. There may be a role for automated comparison of PHR and HER (Table 1).

Limitations: How much is too much?

The amount of data that patients might want to access might be different from the amount that they are able to use in a meaningful way for their own healthcare. PHR will face the challenge to find the balance between 'too much' and 'too little' data, which calls for co-design of the system with patients and then sensitivity to patients' particular needs at the time.

As PHRs spread, challenges will arise around those who are less able or less willing to use these systems. Challenges are comparable with the changes in the banking sector where fewer branches are now available to offer face to face service: This has posed particular difficulties for some elderly patients with limited IT and eHealth literacy. At the same time these challenges have led to better design and more usable formats of online banking as well as spread of usage from "digital natives" to the broader population.

Equitable access and the "digital divide"

If there are challenges for some patient groups to use PHRs this could lead to inequities if sufficient support is not provided and design is not user-friendly. Some patients might have significantly more opportunities to participate in their own healthcare and this could drive commissioning and funding decisions with more resources allocated to areas with high

engagement and visibility of need or less resources allocated as patients become more self-sufficient.

Integration of PHR to EPR

Hospitals throughout the UK are at current installing Electronic Patient Records (EPR) from a range of providers and with variable functionalities. Some systems are limited to bedside documentation whereas others provide the option of a 'paperless' hospital. Integration of NHS IT systems has previously been attempted but abandoned after an estimated bill of 10 billion pounds (22). Integration between multiple providers or PHRs and EPRs might therefore be challenging. Many EPR providers have also been reluctant to allow other programs to write into the EPR or access data from it for other applications. For easy access or presentation of key items in EPR standard definitions for data fields are needed and providers need to cooperate to allow devices to talk to each other. Otherwise duplication will lead to errors and inefficiencies. In the USA the main EHR vendors offer patient portals to add to the EHR system providing a PHR within this system, but the cost of adding and maintaining this can be high.

Safety

There are widespread concerns about data and system safety of information technology in healthcare with patients worried about confidentiality (3) and health care professionals worried about correctness of data (23). In order to allow patients secure access to their data a process of identity verification is needed to register and log-in. This requires a reliable verification procedure by healthcare staff and will affect ease of access for patients and the cost of implementation to hospitals. Biometrics (eg face recognition) may be one method that can be included in time to enable fast access.

Cost

The price of implementation of PHRs in hospital will depend the on the price of purchasing, implementing and maintaining the PHR as well as costs associated with training of staff and patients and any potential costs/savings arising from implementation. While a PHR might be a competitive advantage to attract customers to health service providers in the US this is less likely to be relevant to the UK market. It is possible that the control of the records by patients leads to a more focused pathway with earlier diagnosis, earlier treatment and earlier discharge. Equally better information for patients and health care professionals may lead to

more diagnostic procedures, treatments and cost which may or may not be appropriate. While there is some evidence about the impact of PHRs on patient activation in the community, there is no data to inform this debate for patients admitted to hospital.

Conditions for spread

Participants of the workshop felt that conditions for spread would include the following considerations:

Participants felt that patients would appreciate the ability to model on peers as demonstrated in the network 'PatientsLikeMe'(24): To witness patients or patient testimonies from patients with comparable conditions or pathways using a PHR could facilitate uptake and spread.

Participants were worried that PHR should augment and not replace human touch and capabilities: Information about a condition or patient questionnaires about concerns and pain can be made available prior a personal conversation and facilitate a focus on complex and difficult questions. Personal contact, the ability to examine a patient physically, or to hold a hand if a patient is sad or anxious are key to a trusting relationship between patients and healthcare professionals.

Participants suggested the need for a compelling value proposition that would convince patients and clinicians to start using PHRs: PHRs can be used for a large number of functions. Many of these functions can be undertaken without a PHR. Many PHRs don't have a function that is unique and at the centre of patient's and health care professionals' interests and thus so compelling that the usage would become a 'must'.

Participants were concerned about the need for special assistance/design for the less ehealth literate to avoid inequalities: While smart applications and programs often require little training (and therefore staffing cost) for those who are not computer literate Digital Inclusion Officers have been used to facilitate access (25). In many other industries online portals have replaced face to face interaction with customers. Energy telephone and insurance companies, banks and post-offices have all resolved to conduct much of their business transactions online. As this process has taken part applications have become easier to use and customer friendly. Nevertheless a significant number of users are unable to access online resources and have been marginalized in the process.

Review of use case scenarios

Participants discussed five use-cases of hypothetical patients admitted to hospital (table 2): One patient was admitted for elective prostate surgery, one had a semi-elective admission for a renal transplant, and three patients had emergency admissions for chest pain, diabetic ketoacidosis and pneumonia with delirium. It was assumed that an ideal PHR/EPR should be usable in a meaningful way by 80% of more patients of a given patient group.

Participants charted how an PHR/EPR could support a patient to

a) become more informed about their health condition (including their safety) and receive care in a way they would like to,

b) enable them to do more to care for themselves,

c) make a comment useful to care providers (e.g. incorrect information, most troubling symptoms)?

Participants considered the likelihood of these patients being able to interact with the PHR, factors which might hinder patient access to their PHR and impact of access on conversations between this patient and clinicians?

Key points from the discussions were about the need to use PHRs as an extension of human abilities and not a replacement:

- The establishment of relationships between clinicians and patients requires trust and this if often helped by personal conversations with the advantage of body language and eye-contact.
- In order to make PHR attractive for patients, clinicians and providers will need to add functionality that is ‘game changing’. Game changing functionalities might include the ability for patients to
    - support clinicians with entry of information into records and to sense check information about them. This could include most details of the past-medical history, etc. but also pain, stool or fluid charts.
    - guide patient led discharges based on pre-defined advisory criteria.
    - ‘dial-up’ follow-up appointments.

One of the themes of the discussion was the interaction with frail, elderly and possibly demented patients. The group felt that many might not be able to actively use a PHR. On the other hand side a PHR with a ‘share’ function that would allow patients to delegate some or all information to friends or family might be really useful for these patients. The function could allow insight into progress of the patient in hospital as well as reminders for follow-up clinics, allergies and medication lists.

A key concern of patients is to predict when they can go home and whether they will cope after an acute illness. The participants discussed whether a PHR could support patient centered care by asking ‘What would help get you home?’ and prompt sharing of concerns by patients early on in the course of their admission.

DISCUSSION

A key question is ‘Are the benefits worth the costs?’ to the different stakeholders and this in part depend which system is used, and how easy it is to learn, use and for the hospital to implement. What is clear is that digital health is not disappearing and more patients and staff expect the convenience and ease of use of such systems: a key strategic question for providers is hence whether to wait until better systems are develop or to start now.

The present workshop and research suggests that possible benefits of PHRs are better information flow supporting healthcare professionals and more ‘activated’ patients. Patients and their next of kin or carer rather than patients alone could be viewed as ‘the unit of intervention’ for PHRs. Data safety and patient’s variable preferences and ability to participate in care delivered with PHRs are significant concerns. Co-production of tools and services might alleviate some of these concerns and optimize the benefits of PHRs for patients in hospitals.

PHR have the potential to enhance and possibly transform the experience of patients prior, during and after hospitalization. There is limited evidence for clinical impact of PHRs usage in primary care and chronic disease management and virtually none for inpatient usage.

Patient held records in hospital are at best a complete change in the way that we deliver health care by enabling patients to become equal partner and control their own data. At worst patient held records may increase the amount of information for patients and clinicians without any added value or confusing matters, or may disadvantage less computer/internet literate patients. PHR ultimate could be a part of a ‘Learning Healthcare System’, defined by the Institute of Medicine (IoM) [9], as a system in which, “science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in

the delivery process and new knowledge captured as an integral byproduct of the delivery experience. “

The workshop raised a number of questions about the usage of PHRs. In order to learn from existing usage of PHRs is would be useful to examine

(1) What is the current spread of PHR in UK hospitals
(2) How many inpatients are already using what online information in PHRs that were set up for outpatient consultations or usage in primary care.

The participants from the workshop raised questions that will require further research:

(1) What are the conditions in relation to patients, services and infra-structure for a successful (‘meaningful’) implementation of PHRs in hospital?
(2) How much training / coaching/ digital liaison officers / navigators are needed to facilitate introduction in hospital practice?
(3) What are the measurable impacts of introduction of PHRs on patient experience, clinical outcomes and resource utilization?

Table 1 – Key projected benefits and costs of personal health records for use in hospital

	Benefits	Costs (time or money)
Patients	• Engaging with care • Ability to raise questions more directly • Information on what patients want to know about their health • Empowering to ask questions • Understanding more • Drug reconciliation • Prediction of future events	• Hardware costs • Time of training • Investment into inter-operability • Privacy, security • Utility of data collected • Anxiety about extra information, borderline abnormal tests
Clinicians	• Comprehensive overview of patients journey • Up-to-date allergies and medication lists • Catching errors early • Prediction of future events • Not needing to repeat message to relatives • Potential for gaining efficiencies	• Time to write things down in an understandable way • Time to explain to patients additional questions • Potential for loosing efficiencies
Others	• Community services: Physio-therapists, pharmacy: seamless information transfer	• Inequalities: not every patient can use / needs/ understands PHR • Upfront investment into infra-structure

Table 2: Use cases to examine opportunities and barriers for Personal Health Records in the context of hospital admissions

83-year-old retired lady admitted with a pneumonia complicated by delirium and acute kidney injury.	36-year-old patient admitted for a renal transplant and develops a haematoma neat the transplant.	68-year-old patient with surgery for benign prostate hypertrophy who develops uro-sepsis on day two after surgery.		
Emergency admission Osteo-arthrisis Obese Diabetes Hypertension Myocardial infarction Ex-smoker	Elective admission Chronic renal failure Vasculitis with immunosuppression	Elective admission with complication Hypertension ACE inhibitor		
Delirium Follow-up of abnormal chest X-ray Likely ability to use PHR functionality: Low on admission even if normally 7/10	Monitoring of chronic condition in acute care setting Management of complex medication Missed safety critical blood test Likely ability to use PHR functionality: 10/10 due to exposure to RenalView	Postoperative sepsis Risk of Acute Kidney Injury Likely ability to use PHR functionality: 8/10 on admission but declines during septic episode		
Follow-up plan for chest X-ray Ability to share data with carers Fluid in and output charting, maybe shared with next of kin Information to allow planning of transfer home	Usage of existing ‘ RenalView’ program that offers insights into laboratory data and similar functions. Patient held fluid balance chart Information about procedure, complications Symptom diary Scheduling for follow-up	Information about care team (‘ Who looks after me?’) Ability to enter most of medical history (1) Information about planned investigations and procedure Expected discharge date Checklists for anti-biotics, urine output and other complications Possibly safer care		
Delirium limits the ability to use device even if able to use skype when well		Personal preferences might preclude usage		
[1] Medical history could include: past medical history, medication history, known allergies social history, treatment preferences etc				

Patient	58-year-old patient with admitted with angina attack after a 999 call	19 year old student admitted diabetic ketoacidosis Likely usage 9/10
Type of admission	Emergency admission Hypertension Smoker	Emergency admission with life threatening emergency Diabetes
Themes	Inability to locate old electro-cardio-gram Weekend discharge with need for follow-up Likely ability to use PHR functionality: 8/10 with waiting time in Emergency Department representing a ‘ learning opportunity’	Admission to hospital away from usual place of residence Management of complex protocol with expert patient Follow-up planning Likely ability to use PHR functionality: 9/10 difficulty to use while poorly
Opportunities	Availability of old electro-cardio-gram Information about risk assessments Information about blood tests and possible interventions	Medication list with times of changes Log of blood sugar levels Log of food intake Patient led discharge Booking of follow-up appointments
Concerns	Information could be used for machine learning of safer algorithms. New European legislation might limit usage of ‘ donated data’ to inform future treatments.	Different systems in different geographical areas

APPENDIX 1: DEFINITONS

'Patient health record' is often used as a generic term referring to a range of different systems providing different functions offered by different providers and occasionally is used to refer to a specific system. In this paper we define these terms as follows:

Personal health record (PHR): is owned and controlled by the individual patient (or proxy), and may have information that is not contained in a medical record. It is used for managing health information, promoting health maintenance, and assisting with chronic disease management. Common e-health tools focus on health information, behavior change/prevention, and self-management.

Patient portal: a secure web site through which patients can access a PHR and often certain information from an EHR. Portals typically enable users to complete forms online, communicate with their providers, request prescription refills, pay bills, review lab results, or schedule medical appointments (18).

Electronic Patient Record (EPR): England's National Health Service (NHS) defines the EPR as "an electronic record of periodic health care of a single individual, provided mainly by one institution" (NHS:1998). The NHS notes that the EPR typically relates to the health care provided by acute care hospitals or specialist units. This definition of the EPR(19) has gained quite widespread currency outside of the UK but its usage is still often inconsistent in many places.

Electronic Health Record (EHR): The most common USA definition and adopted by many countries is "a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter - as well as supporting other care-related activities directly or indirectly via interface - including evidence-based decision support, quality management, and outcomes reporting" (20).

eHealth literacy: 'The ability to seek, find, understand and appraise health information from electronic sources and apply knowledge gained to addressing or solving a health problem'(21).

REFERNCES

1. Wyatt J, Sathanandam S, Rastall P, Hoogewerf J, Wooldridge D. Personal health record (PHR) - landscape review | RCP London [Internet]. 2016. Available from: https://www.rcplondon.ac.uk/projects/outputs/personal-health-record-phr-landscape-review
2. Bate P. Personalised Health and Care 2020. 2015;(May):1–18.
3. Royal College of Physicians. Personal health record (PHR) User insights Personal health record (PHR) User insights. London; 2017.
4. Johnson M, Lithgo K, Price T. Bowel Disease Patients Management Programme For Stable Inflammatory Ibd-sshamp; Uk's First Remote Web-based Self The First Years Outcome Data From PTH-051. 2017 [cited 2017 Nov 30]; Available from: http://gut.bmj.com/content/63/Suppl_1/A231.1
5. Price T, Lithgo K, Johnson M. PWE-062 The outcomes and benefits of moving stable inflammatory bowel disease patients from a paper based self management system to an supported, self help and management programme (ibd-sshamp) with specialist overview. Gut [Internet]. BMJ Publishing Group; 2015 Jun 22 [cited 2017 Nov 30];64(Suppl 1):A238.3-A239. Available from: http://gut.bmj.com/lookup/doi/10.1136/gutjnl-2015-309861.511
6. Carlsen K, Jakobsen C, Houen G, Kallemose T, Paerregaard A, Riis LB, et al. Self-managed eHealth Disease Monitoring in Children and Adolescents with Inflammatory Bowel Disease. Inflamm Bowel Dis [Internet]. 2017 Feb 13 [cited 2017 Sep 1];1. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28248735
7. Informatics H. Personal health record (PHR) Case study My medical record at University Hospital Southampton.
8. McCann E. Kaiser PHR sees 4 million sign on, most active portal to date | Healthcare IT News [Internet]. 2012 [cited 2017 Jul 11]. Available from: http://www.healthcareitnews.com/news/kaiser-phr-sees-4-million-sign-most-active-portal-date
9. Stephen Armstrong. Patient access to health records: striving for the Swedish ideal. BMJ. 2017;357:j2069.
10. Parker JP, McCombs JS, Graddy E a. Can pharmacy data improve prediction of hospital outcomes? Comparisons with a diagnosis-based comorbidity measure. Med Care [Internet]. 2003 Mar;41(3):407–19. Available from: http://www.ncbi.nlm.nih.gov/pubmed/12618644
11. e-Health Records — e-Estonia [Internet]. [cited 2017 Nov 16]. Available from: https://e-estonia.com/solutions/healthcare/e-health-record/
12. Levay, C (Lund University, Lund S. Policies to foster quality improvement registries: lessons

from the Swedish case. J Intern Med. 2016;279(2):160–72.

13. Séroussi B, Bouaud J. Adoption of a Nationwide Shared Medical Record in France: Lessons Learnt after 5 Years of Deployment. AMIA . Annu Symp proceedings AMIA Symp [Internet]. American Medical Informatics Association; 2016 [cited 2017 Nov 16];2016:1100–9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28269907

14. Kelsey T, Cavendish W. Personalised health and care 2020: Using data and Technology to Transform Outcomes for Patients and Citizens. A framework for action. Natl Inf Board [Internet]. 2014;(November):1–66. Available from: https://www.gov.uk/government/publications/personalised-health-and-care-2020/using-data-and-technology-to-transform-outcomes-for-patients-and-citizens

15. Public Health England - Trust Development Authority. NHS England Care Quality Commission Health Education England Monitor. Five Year Forward View. 2014;

16. PatientView [Internet]. [cited 2017 Nov 16]. Available from: https://www.patientview.org/#/

17. eRedbook [Internet]. [cited 2017 Nov 16]. Available from: https://www.eredbook.org.uk/

18. Emont S. Measuring the Impact of Patient Portals: What the Literature Tells Us California HealtHCare foundation About the Author [Internet]. 2011 [cited 2018 Jun 3]. Available from: https://www.chcf.org/wp-content/uploads/2017/12/PDF-MeasuringImpactPatientPortals.pdf

19. International Organization for Standardization. ISO/TR 20514:2005 - Health informatics - Electronic health record -- Definition, scope and context [Internet]. 2005 [cited 2018 Jun 3]. Available from: https://www.iso.org/standard/39525.html

20. Healthcare Information and Management Systems Society. Electronic Health Records | HIMSS [Internet]. 2018 [cited 2018 Jun 3]. Available from: http://www.himss.org/library/ehr

21. Norman CD, Skinner HA. eHealth Literacy: Essential Skills for Consumer Health in a Networked World. J Med Internet Res [Internet]. JMIR Publications Inc.; 2006 Jun 16 [cited 2018 Jun 3];8(2):e9. Available from: http://www.ncbi.nlm.nih.gov/pubmed/16867972

22. Abandoned NHS IT system has cost £10bn so far | Society | The Guardian [Internet]. [cited 2017 Nov 30]. Available from: https://www.theguardian.com/society/2013/sep/18/nhs-records-system-10bn

23. Lerner JC, Solomon RP, Coates VH, Argentieri M, Bruley ME, Myers JL, et al. Top 10 Patient Safety Concerns for Healthcare Organizations [Internet]. 2015 [cited 2017 Nov 30]. Available from: www.ecri.org/PatientSafetyTop10.

24. PatientsLikeMe | Live better, together! | PatientsLikeMe [Internet]. [cited 2017 Nov 30]. Available from: https://www.patientslikeme.com/

25. Community Housing Cymru Group. Recommendation for Welsh Government Digital Inclusion & Adequate Affordable Broadband for Social Housing Tenants [Internet]. 2013 [cited 2017 Nov 30]. Available from: https://chcymru.org.uk/uploads/events_attachments/CHC_digital_inclusion_access_report.pdf

4.4 Paper 4: Scenario based design for a hospital setting: An exploratory study of opportunities and barriers for Personal Health Records usage

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Authors

Christian Peter Subbe, Consultant Physician & Senior Clinical Lecturer, Ysbyty Gwynedd, and School of Medical Sciences, Bangor University, Bangor LL57 2DG; Improvement Science Fellow, The Health Foundation, London, UK

Nick Pearson, Doctor in Training, Ysbyty Gwynedd, Penrhosgarnedd, Bangor, Gwynedd, LL57 2PW

Stephanie Wischhusen, Doctor in Training, Ysbyty Gwynedd, Penrhosgarnedd, Bangor, Gwynedd, LL57 2PW

Richard Hibbs, Patient Representative; Deganwy, 9SP O149

Sarah Wright, Programme Manager for Wales and Lead for Education, Patients Know Best; St John's Innovation Centre, Cowley Road Milton, Cambridge, CB4 0WS

Maria Xenou, Research and Innovation, Patients Know Best; St John's Innovation Centre, Cowley Road Milton, Cambridge, CB4 0WS

Corresponding Author

Christian Peter Subbe. Senior Clinical Lecturer, School of Medical Sciences, Bangor University, Bangor LL57 2DG; Tel 07771-922890 or 01248-384384, e-mail: csubbe@hotmail.com or c.subbe@bangor.ac.uk

Conflicts of Interest in relation to the study

Chris Subbe is an Improvement Science Fellow with The Health Foundation.

Patients Know Best (PKB) provided the personal health record test environment free of charge. Maria and Sarah are members of the PKB team and were involved in the development of the study protocol and training of participants in the usage of the software.

Authors Contributions

C Subbe, S Wright and M Xenau developed the concept for the study, drafted the protocol and wrote the research submission.

C Subbe, S Wright, N Peason and S Wischhusen undertook set-up and measurements of the study

C Subbe, N Peason and S Wischhusen performed the evaluation of the study data.

C Subbe, N Peason, S Wischhusen, R Hibbs wrote the first draft of the manuscript.

All authors contributed to the final version of the manuscript.

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ABSTRACT

Personal Health Records (PHRs) offer patients the opportunity to be more actively involved in their own care. There is limited research into the application during hospital admissions for elective or emergency presentations.

We used techniques from scenario-based-design to test the opportunities and boundaries of a commercially available PHR in a simulated environment. Scenarios included a patient in his 80s admitted for hip-surgery with his son and a younger patient admitted with pneumonia. A catastrophic deterioration was demonstrated with a mannequin in high-fidelity simulation. Workflows were summarized in swim-lane diagrams.

The PHR allowed patients to file information prior to the interaction with the clinical team. This led to shorter time requirements for acquisition of data. The elderly patient required assistance from a relative but this aided verification of history prior to the encounter with the clinical team. Ward rounds could be prepared by the patient with specific ‘what matters’ questions. Documentation in the PHR environment during a simulated life-threatening emergency did not result in information that was unintelligible or useful for the ‘patient’.

Usage of a commercially available PHR during hospital admission is feasible and might aid work-flow. Documentation of emergencies might require different documentation formats.

BACKGROUND

Hospital medicine is moving to paper light or paper free systems with the increasing use of electronic patient records. Patient care is moving away from the paternalistic approach to a shared decision-making model. Technological advances mean that patients are able to undertake increasing amounts of monitoring at home thus facilitating increased patient involvement by using patient held records (PHR). PHRs are not a new concept(1,2) but the methods of access are changing: Patients are tracking their blood sugar via near field communication and smart phone apps rather than by recording finger prick records in a paper diary. Children have their personal child healthcare record (known as the 'red book'), traditionally a hard copy but now available online(3). Through the usage of PHRs patients emphasised the importance of having ‘a record of one's condition’, being ‘empowered to ask questions’, and the potential for ‘unwanted responsibility’(4).

There is a significant body of literature on patient held medical records(5), but this relates near exclusively to patients in primary care and chronic disease management programs. Knowledge about safety impact of patient held records is largely limited to medication safety. There is only limited evidence for effects in hospital(6) and none for usage in emergency care.

Scenario-based design is a ‘family of techniques in which the use of a future system is concretely described at an early point in the development process’(7,8). It allows rapid interactive development of concepts and capture of possibilities and concerns.

We aimed to explore the opportunities for the usage of PHRs in hospital and explore the boundaries for patients to contribute to their own record through techniques of scenario-based design.

METHODS

Study format: Observational feasibility study in a simulation laboratory using scenarios and role-play to explore boundaries of usage for the PHR.

Setting: High Fidelity Simulation Lab at the Ysbyty Gwynedd Bangor. For the purpose of the study Patients Know Best (PKB) provided a PHR in a digital test environment.

Participants: Medical doctors (Foundation Year 1 and Foundation Year 2), one Physician Associate, two student nurses and three patient actors: a female actor in her 40s and a male actor in his 80s with his son.

Intervention: Use cases of common presentations for admission to hospital including elective and emergency admissions.

Evaluation: Participants of the workshop provided information on digital literacy and previous exposure to hospital admissions. The scenarios were recorded and analysed. Analysis included time and motion studies (i.e. time taken to perform documentation and related tasks) and semi-structured user feedback from patient actors, clinicians and students.

Mapping process: Graphic representation of processes using swim-lane diagrams to describe present work-flow in local clinical practice, and possible future states as observed during the simulated scenarios.

Patients Know Best properties: Patients-Know-Best (PKB) allows patients and healthcare professionals to access medical records anytime, anywhere, is controlled by patients who grant access to healthcare providers and hosted within the NHS N3 network. It is designed for use by individuals, NHS Trusts, Local Authorities, Charities, Social Enterprises and other organisations involved in the care of patients, particularly those with complex, long-term conditions necessitating multidisciplinary care from a plurality of providers(9). The platform connects health and care information from multiple primary and secondary care providers to create a single, unified copy of the data. Patients can then access their data via an online portal and use this to manage their health and wellbeing.

Patients can access and manage their appointments online, see test results with advice and explanations about what they mean, communicate directly with their healthcare professionals and seek medical advice in a timely way, share important information with nominated healthcare professionals, family members and/ or carers and link data from personal wearable devices to enhance monitoring.

PKB is the most deployed patient-held record system in the UK. As of October 2019 it has the records of 4 million patients in the UK and is used by researchers in eight European countries. PKB is the personal health record supported by NHS Wales(10).

Scenarios: Scenarios were repeated with variations to clinical course of the scenario and availability of digital resources (i.e. admission of a new patients with paper-based

documentation vs admission of a new patients with electronic documentation provided by PKB). Timings of processes were derived during the scenarios and verified with the recording where required.

Ethics & Governance: The study was approved by the Bangor Research Ethics Committee (REC reference: 19/WA/0170). The patient actors gave informed consent, all clinicians and actors gave informed consent for the recording of the procedures.

RESULTS

Four scenarios were examined: three used low fidelity simulation and one used high-fidelity simulation.

Scenario 1 – admission to hospital for elective hip replacement: Elderly patient in his 80s who presents with his son. Past medical history: Atrial fibrillation on Warfarin, constipation requiring regular laxatives: lactulose, occasional enemas. Allergic to Aspirin but had a stomach bleed after Brufen. The patient is concerned about pain in the hip. The pain has been present for four year, the patient hast lost weight for improved mobility without success and needs regular pain killers. The patient would like to stay in hospital for as short as possible.

Observations: Collating the history took a significant amount of time. The patient had significant problems with arthritics and poor eye-sight and was unable to operate the computer. His son was able to enter data for him and access information. There were clear discrepancies in the history documented by the son and details given by the patient. The presence of the son was felt to be essential to document reliable information.

During conventional history taking time requirements from the team were 48 minutes, 25 minutes for nursing and 23 minutes for medical history taking. During history taking using the PHR time requirements for the team were 36 minutes for the patient, 10 minutes for nursing and 12 minutes for medical history taking.

Scenario 2 – admission to hospital for an acute pneumonia: Female patient presenting with cough, fever and sputum and abnormal vital signs. Past-medical history: Diabetes mellitus, hypertension, surgery for hiatus hernia, ex-smoker (used to smoke 20 cigarettes per day). Allergic to co-trimoxazole. Home circumstances: independent and likes baking cakes, has got several rescued cats and likes horse riding. Medication: Bendroflumethiazide 2.5 mg once a day, Ramipril 10 mg od. The patient is worried to get back home and feed the cats. The

patient has low oxygen saturations. A value is agreed above which a transfer home would be usually safe.

Observations: The patient was able to enter all past-medical history, medication and allergies as well as features of her acute illness into the platform. This led subjectively to a faster admissions process.

Scenario 3 – next day ward round of the patient from scenario 2: The patient is feeling better. The patient is able to access her vital-signs and these have improved in line with the criteria from the previous encounter. The patient remains worried to get back home and feed the cats.

Observations: The patient decided to prepare the next day ward round online with questions to her care team about the diagnosis, the severity of her illness and the likely length of stay. This focused discussions during the acted ward round.

Scenario 4: peri-arrest post hip-replacement: High fidelity simulation with a dummy (METIman - Medical Education Technologies Inc) was used. The 'patient' was drowsy, had a low blood-pressure and low respiratory rate.

Observations: The clinical team undertook an emergency assessment of airway, breathing, circulation, disability and exposure. Clinical symptoms were correctly identified as related to intra-operative opioids with hypoventilation. Usage of the electronic record during the peri-arrest situation was challenging: electronic documentation was slow, fields were on different screens and a high proportion of the documentation was medical jargon. Patient actors found it subsequently difficult to understand the meaning of the documentation.

PARTICIPANT FEEDBACK

Scenarios were reviewed by the participants of the work-shop. Process-maps (Figures 1-3) were created to represent the present state from experience of the participants and compared to the process supported by the PHR.

Key-observations were summarized by participants during debriefing:

The elderly patient actor and his son could record and verify the past-medical history and medication history prior the arrival of the medical team. This reduced the requirements for the 'clinicians' to be present during the process of negotiating the agreed version of truth.

Using the electronic record resulted in prolonged periods of silence to find the correct data-entry field and typing with interruption of the flow of conversation.

For patients entry of a comprehensive medical history takes a significant amount of time. By pre-populating data fields this could be improved. A more focused system that captures only data pertinent to the current admission rather than comprehensive all system enquiries might hence reduce time requirements for documentation by health care professionals and improve work-flow.

The patient with the pneumonia was able to operate the system and complete large parts of her documentation without the assistance of a healthcare professional. The effects of this are captured in the process map. The patient actor felt empowered by seeing the same screen as the healthcare professional and having access to all information.

Preparing a ward round allowed the patient actor to assure that areas of her interest were covered. Participants of the workshop felt that it was of advantage to have time prior to a ward round to focus on issues that were of importance to her. This included interest in the severity of the illness triggered by knowledge of the clinical diagnosis from the PHR. This observation is contrasted with clinical experience of patients complaining of having questions after the ward round or struggling to retain information about clinical diagnosis, treatment plan or planning of transfers of care.

The clinical team was clearly overwhelmed by the usage of an unfamiliar electronic system to document clinical findings in real time during the simulated emergency. Due to the clinical requirements and under pressure clinicians reverted to usage of jargon both in spoken and written communication. Design of shared records for inpatient usage would need to take this into account.

Analysis of findings

Timings and work-flows were reviewed: in the system with the PHR patients and their carers, friends or family are able to perform some of the work that is traditionally part of the tasks undertaken by doctors or nurses. Access to records outside of the scheduled patient contacts of admission and ward round allows patients time to articulate questions based on accessed information or their own ideas, concerns and expectations. This was also reflected in the subsequent feedback by the relative of the elderly patient actor (Table).

DISCUSSION

In the present feasibility study we have shown that patients could in principle engage in partaking in their own documentation even in an acute or emergency care setting. PHR usage allowed the patients as well as the carer-actor to add real value to the clinical information and verify important safety critical clinical information such as allergies, medication and previous complications.

Elderly patients are not only less technologically experienced but might additionally struggle with arthritis or visual impairment that might preclude direct interaction with a digital platform. At the same time carers of family members might add measurable benefit if they are allowed to contribute their knowledge of the patient's condition.

On the other hand side the 'once for all' functionality of electronic records might reduce the strain not just on healthcare professionals but also on the patients who have to provide repeated answers to the same question in the current care system.

During a critical deterioration of a patient electronic health records might be significantly slower and less agile than paper-based systems and the reliance on jargon to summarise complex safety critical information makes the documentation by clinicians near un-useable for patients.

Personal Health Records (PHR) can demonstrate value by providing a single view of a patient's history - creating one source of the truth, bringing together potentially divergent documentation from different sources to ensure all healthcare professionals have the right information, at the right time to inform decision making, reducing duplication and enabling a more preventative approach. Benefits of PHRs are obvious for many patients in chronic disease management programs such as inflammatory bowel disease(11) even if implementation and evaluation in the UK has been sporadic(12). A literature review of usage of patient portals in hospitalized patients found little evidence for studies that have formally evaluated the impact on clinical outcomes(6). Current designs might be problematic even in the more sheltered environment of an outpatient clinic(13) and might require separate evaluation. Likes others we observed how electronic systems can aid to enhance communication between patients and healthcare professionals but might move focus from the patient to the screen and reduce eye contact(14).

Recording of urgent information was slowed down by the electronic system. This is consistent with the literature: clinicians perceive computer systems as slower than their

previous practice and have implemented extensive work-arounds including the usage of medical scribes(15). This has not changed over the last decade(16) despite the advent of more advanced systems.

To our knowledge this is the first study that has describes the opportunities and boundaries of usage of personal health records in emergency and hyper-acute care. The study was performed with a personal health record from a single provider. This limits the ability to extrapolate to functionalities of other PHRs. We only examined a small number of scenarios but were able to capture typical hospital interactions. We did not address training requirements to fully use functionalities. For all users this was the first time they used a PHR and training might enhance usage and impact(17).

We were unable to assess how patients would interact with the plethora of information generated by a modern hospital system and whether their attention would be drawn to mildly abnormal values rather than key clinical findings. We did not formally evaluate digital literacy(18) or the impact of PHRs on activation(19). Satisfaction of patients and impact of records on clinical care might relate to these(20).

PHRs have the potential to allow patients to feel more active and valued member of the team. PHRs might facilitate time savings as patients can preload clinical records prior to being seen by health care professionals and reduce duplication. Current systems might not be optimized for usage in acute and emergency care. Given the high proportion of time that doctors are already spending on documentation(21,22) design and evaluation need to focus on using patient inputs in an efficient manner.

Some of the benefits from usage of PHRs outside of hospital can be translated for inpatient usage. Development of tailored user-interfaces for the specific tasks in acute care will require prospective testing in multi-centre studies with capture of clinical outcomes, patient and staff satisfaction and cost-implications. Platforms that are targeted at the aging population might want to explore the usage of voice control or multi-user inputs that allows authorized friends and family members to support them.

CONCLUSION

PHRs have features that might usefully enhance care of patients admitted to hospital. Current systems might not allow to share documentation of catastrophic deterioration in a meaningful way.

Table – Observations by the relative

"Hospital admission and (emergency) triage represent a significant opportunity for the patient-carer diad to explore and agree a common version of history; specifically those events and associated timeline leading to the present clinical episode. Basic disagreements over dates, the relevance of symptoms, and the precision of recall must all be negotiated.

Data are generated within the diad from multiple standpoints, not simply the primary perspectives of patient and carer. but also those potentially arising from multiple roles played by the relative as carer, advocate and/or attorney, or indeed by the patient as both parent/child and sick person. The simulated elderly patient may wish to leave hospital as quickly as possible without too much attention being paid to their chronic constipation problem, whereas the simulated relative as carer may be more interested in a period of respite and a complete purge; whilst at the same time, as the patient's advocate or attorney, may consider that prolonged hospitalisation could result in further loss of independent living skills.

The PHR can facilitate the diad in completing this information-gathering task precisely because it obliges both members to focus on achieving unanimity. The logical design inherent in any associated data collection tool(s) and underlying database systems can also assist in imposing the use of a common jargon-busting language on all participants, both data contributors (patients, carers) and all subsequent users (patients, healthcare practitioners, hospital administrators). However some thought may need to be given to the fundamental unobservability of many variables of interest in the PHR (e.g. progress of disease) and that recording a single version of the truth may actually represent a loss of information, In particular the ability to assess degree of correlation between differing versions at the same timepoint.

Amongst the most important additional roles played by the carer when the PHR is computerised and the patient lacks dexterity, is visually impaired, or simply does not belong in the digital era, is that of 'touchscreen operator' (cf medical scribe) controlling data input. Whilst there may be few initial surprises (name, rank, serial number etc.), the general influence of the keyboard warrior grows as time passes and symptom/medication lists and

associated sub-menus become more interminable, which can result in an abbreviated approach to creating the record, whose ownership is then uncertain. The simulation was realistic in this respect."

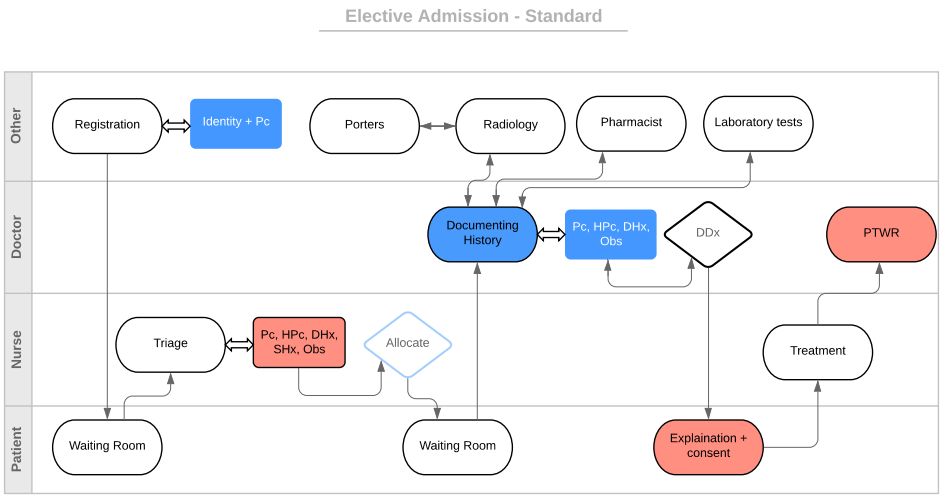
REFERENCES

1. Fischbach RL, Sionelo-Bayog A, Needle A, Delbanco TL. The patient and practitioner as co-authors of the medical record. Patient Couns Health Educ. 1980;2(1):1–5.
2. Giglio R, Spears B, Rumpf D, Eddy N. Encouraging behavior changes by use of client-held health records. Med Care. 1978 Sep;16(9):757–64.
3. eRedbook - electronic Personal Child Health Record [Internet]. [cited 2019 Nov 20]. Available from: https://www.eredbook.org.uk/
4. Sartain SA, Stressing S, Prieto J. Patients' views on the effectiveness of patient-held records: A systematic review and thematic synthesis of qualitative studies. Heal Expect. 2015 Dec 1;18(6):2666–77.
5. Sathanandam S, Rastall P, Hoogewerf J. Personal health record (PHR) landscape review Final report. 2016.
6. Kelly MM, Coller RJ, Hoonakker PLT. Inpatient Portals for Hospitalized Patients and Caregivers: A Systematic Review. J Hosp Med. 2017 Dec 20;13(6):405–12.
7. Carroll JM. Five reasons for scenario-based design. Interact Comput. 2000 Sep 1;13(1):43–60.
8. Rosson MB, Carroll JM, Tech V, Va B. Scenario-Based Design in: The Human-Computer Interaction Handbook: Fundamentals, Evolving Technologies and Emerging Applications. In Lawrence Erlbaum Associates; 2002. p. 1032–50.
9. Davies P, Basu A, Safi A. Sandwell and West Birmingham Hospitals NHS Trust - Patients Know Best [Internet]. [cited 2017 Sep 7]. Available from: https://www.patientsknowbest.com/sandwell-and-west-birmingham-hospitals-nhs-trust.html
10. Limb M. Patients in Wales to take control of medical records. BMJ. 2017 Jun 20;357:j2982.
11. Carlsen K, Jakobsen C, Houen G, Kallemose T, Paerregaard A, Riis LB, et al. Self-managed eHealth Disease Monitoring in Children and Adolescents with Inflammatory Bowel Disease. Inflamm Bowel Dis. 2017 Feb 13;1.
12. Wyatt J, Sathanandam S, Rastall P, Hoogewerf J, Wooldridge D. Personal health record (PHR) - landscape review | RCP London. 2016.
13. Yang Y, Asan O. Designing Patient-facing Health Information Technologies for the Outpatient Settings: A Literature Review. J Innov Heal informatics. 2016;23(1):185.

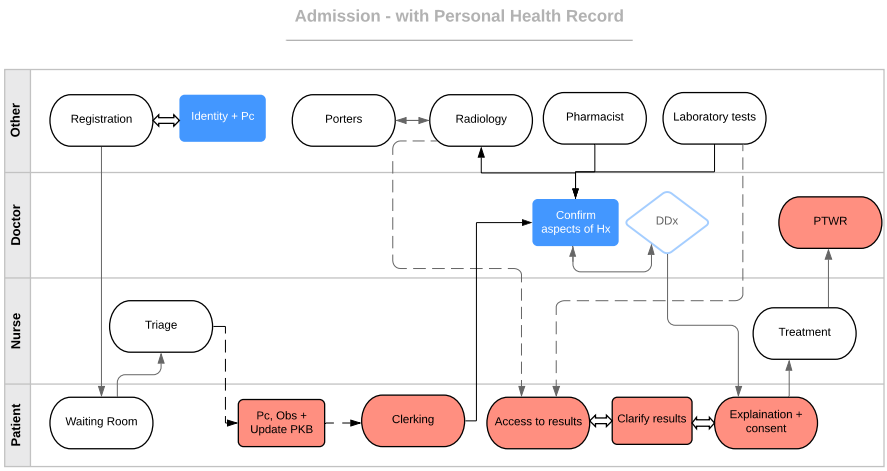
14. Khoong EC, Cherian R, Matta GY, Lyles CR, Schillinger D, Ratanawongsa N. Perspectives of English, Chinese, and Spanish-Speaking Safety-Net Patients on Clinician Computer Use: Qualitative Analysis. J Med Internet Res. 2019 May 22;21(5):e13131.
15. Shultz CG, Holmstrom HL. The Use of Medical Scribes in Health Care Settings: A Systematic Review and Future Directions. J Am Board Fam Med. 2015 May 1;28(3):371–81.
16. Kaipio J, Hyppönen H, Lääveri T. Physicians' Experiences on EHR Usability: A Time Series from 2010, 2014 and 2017. Stud Health Technol Inform. 2019;257:194–9.
17. McInnes DK, Solomon JL, Shimada SL, Petrakis BA, Bokhour BG, Asch SM, et al. Development and Evaluation of an Internet and Personal Health Record Training Program for Low-income Patients With HIV or Hepatitis C. Med Care. 2013 Mar;51(3 Suppl 1):S62–6.
18. Lobach DF, Hasselblad V, Wildemuth BM. Evaluation of a tool to categorize patients by reading literacy and computer skill to facilitate the computer-administered patient interview. AMIA Annu Symp Proc. 2003;391–5.
19. Hibbard J, Helen G. Supporting people to manage their health : an introduction to patient activation. King's Fund. 2014;(May):51.
20. Kelly MM, Coller RJ, Hoonakker PLT. Inpatient portals for hospitalized patients and caregivers: A systematic review. Vol. 13, Journal of Hospital Medicine. Society of hospital medicine; 2018. p. 405–12.
21. Sabin AJ, Subbe CP, Vaughan L, Dowdle R. Safety in numbers: lack of evidence to indicate the number of physicians needed to provide safe acute medical care. Clin Med (Northfield Il). 2014;14(5):462–7.
22. Sabin J, Khan W, Subbe CP, Franklin M, Abulela I, Khan A, et al. 'The time it takes... How doctors spend their time admitting a patient during the acute medical take. Clin Med (Northfield Il). 2016 Aug 1;16(4):320–4.

Fig 1. Swim-lane maps representing the experience of the participants currently compared with the process supported by the personal health record. a) Standard elective admission. b) Elective admission with personal health record. c) Ward round. DDx = differential diagnosis; DHx = drug history; HPc = history of present complaint; Obs = observations; Pc = present complaint; PKB = Patients Know Best personal health record; PTWR = post-take ward round; SHx = social history.

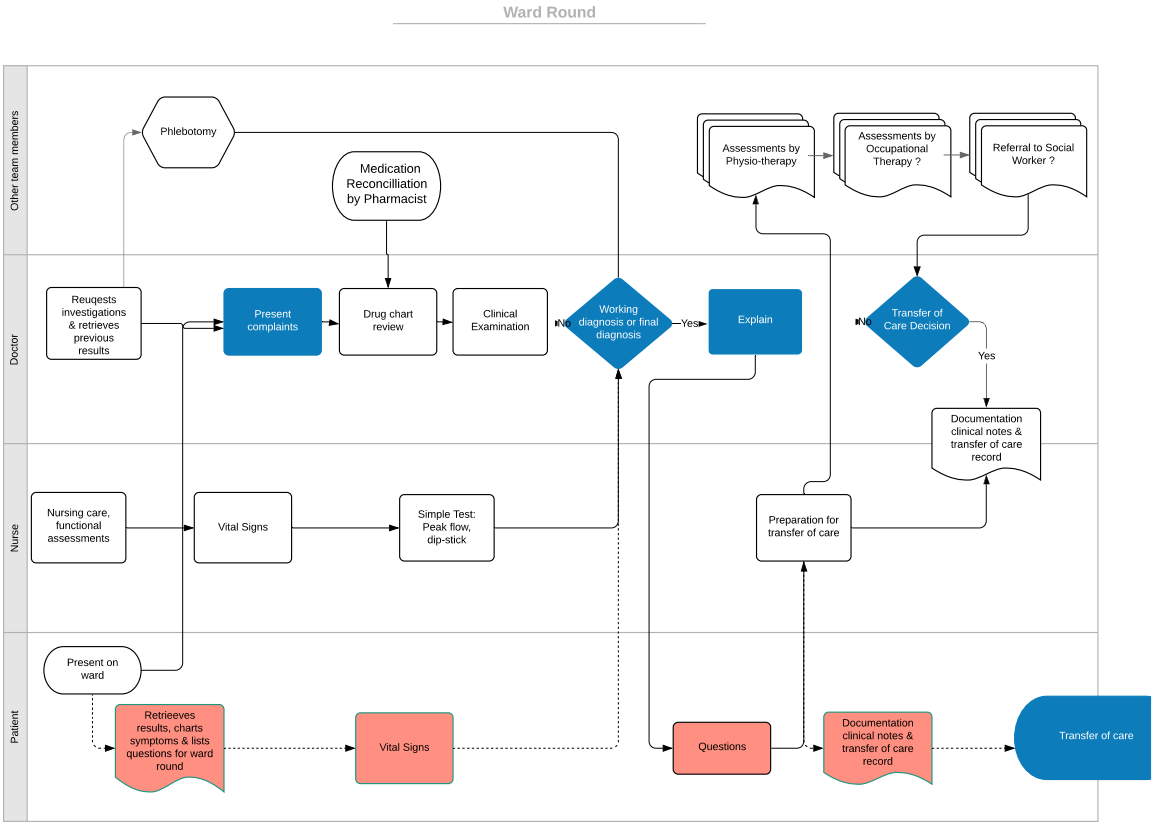
a)



b)



c)


Ward Round
Other team members
Doctor
Nurse
Patient
Phlebotomy
Medication Reconcilliation by Pharmacist
Assessments by Physio-therapy
Assessments by Occupational Therapy ?
Referral to Social Worker ?
Reuqests investigations & retrieves previous results
Present complaints
Drug chart review
Clinical Examination
Working diagnosis or final diagnosis
No
Yes
Explain
Transfer of Care Decision
No
Yes
Documentation clinical notes & transfer of care record
Nursing care, functional assessments
Vital Signs
Simple Test: Peak flow, dip-stick
Preparation for transfer of care
Present on ward
Retrieeves results, charts symptoms & lists questions for ward round
Vital Signs
Questions
Documentation clinical notes & transfer of care record
Transfer of care

4.5 Paper 5: Co-design of interventions to improve acute care in hospital: a rapid review of the literature and application of the BASE methodology, a novel system for the rapid development of prototypes with patients based on epistemology of stakeholders

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Christian P Subbe, DM, FRCP (corresponding author)

Ysbyty Gwynedd, Bangor and Senior Clinical Lecturer, School of Medical Sciences, Bangor University, Bangor LL57 2DG, UK; c.subbe@bangor.ac.uk

Telephone: +44-7771-922890

Andrew Goodman, Senior Lecturer in Design,

Bangor University, Bangor, Gwynedd, LL57 2DG; andy.goodman@bangor.ac.uk

Paul Barach, Clinical Professor,

Children's Hospital of Michigan, Wayne State University School of Medicine, 3901 Beaubien Blvd, Detroit, MI 48201, USA; pbarach@gmail.com

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subsequent product development and implementation studies of interventions prototyped during the process described in this manuscript.

Keywords: co-design, co-production, acute care, hospital, patient-centred

Key learning points

1. Co-design is underutilised in acute care
2. For the co-design of novel interventions stakeholder should be aligned according to epistemological criteria
3. In acute care co-design challenges include limitations of sick patients to act in a system with strong hierarchies and continuity and visibility of safety critical information across changing providers

ABSTRACT

Co-design in acute care is challenged by the inability of unwell patients to participate in the process and the often transient nature of acute care.

We undertook a rapid review of the literature on co-design, co-production and co-creation of solutions for acute care that were developed with patients. We found limited little evidence for co-design methods in acute care.

We adapted a novel design driven method (BASE methodology) that creates stakeholder groups through epistemological criteria for the rapid development of interventions for acute care. We demonstrated feasibility of the methodology in two case studies:

A mHealth application with checklists for patients undergoing treatment for cancer and a patient held record for self-clerking on admission to hospital.

BACKGROUND

During 2020 healthcare has changed beyond recognition: With COVID-19 pandemic we have seen an explosion in demand, constraints on delivery and a collapse in the economy with resulting challenges to funding that has created a 'burning platform' for healthcare[1]. In order to deliver against these time and financial constraints radically different methods of creating innovative solutions are needed. UK Innovation and Research has puts design methodology at the heart of its innovation strategy[2]. For innovation this report recommends three lenses: What do people desire? What is technically feasible? What is financially viable? The same lenses can be applied to innovation in healthcare.

There is little doubt that health services are under increasing political and public pressure, struggling to provide adequate and safe services. They are in dire need of redesign for improvement. At the same time there is a growing acknowledgement that services are best designed in close collaboration with those who are using them – both health care professionals and patients and their support network. This has resulted in a dramatic recent focus on the need to include patients and carers in the co-production of health services on both operational and health policy levels[3,4] with accumulating evidence that services that are co-produced deliver better outcomes for patients with higher satisfaction for healthcare professionals and patients at a lower cost to the taxpayer[5–8].

The terms co-production, co-creation, co-design are often used interchangeably[9] but co-design might be related mostly to the process of planning new services. Co-design focuses on the use of stories and storytelling by patients to gain a deep appreciative understanding of the strengths and weaknesses of a present service, co-production involves producing a product or service together and comes after the co-design phase, and co-creation usually refers to both co-design and co-production taken together[10].

Co-design in healthcare involves the equal partnership of individuals who work within the system (healthcare staff), individuals who have lived experience of using the system (patients and their families/carers) and the 'designers' of the new system (whether that be IT personnel in terms of electronic platforms to improve efficiency or researchers in terms of designing

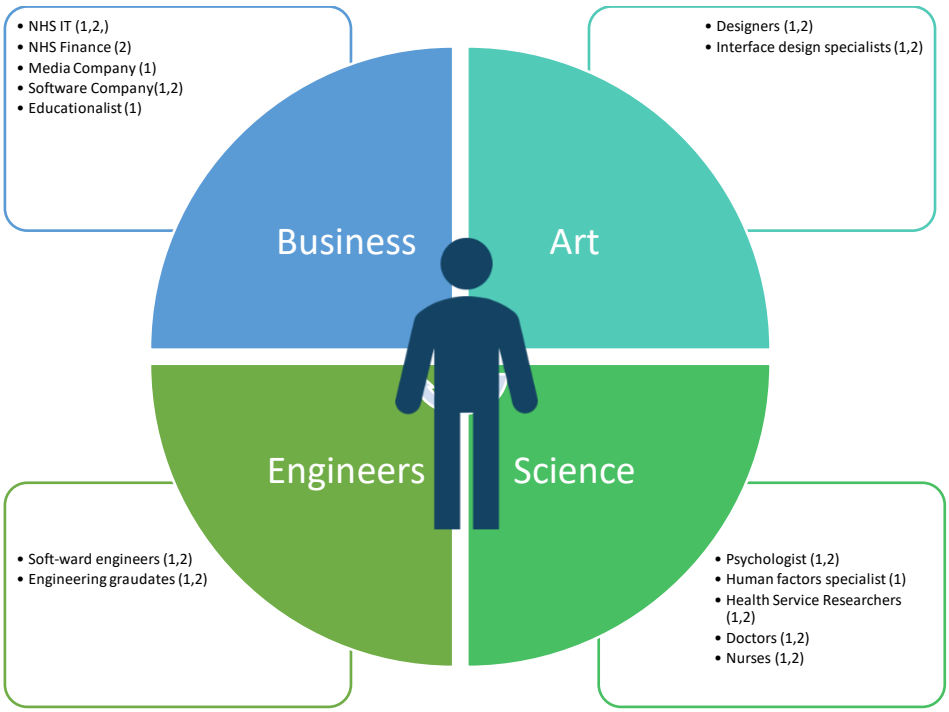
interventions to improve health systems)[11]. Co-design involves working together to achieve better outcomes or improved efficiency[12].

Despite the promotion of co-design/co-production and the focus on shared decision making[13] it is doubtful how robust these principles are embedded in healthcare with little evidence for their role in hyperacute and emergency care[14,15] and the current COVID pandemic.[16,17] The bulk of published experience of participatory design has been in programs for patients with defined long-term conditions such as in Cystic Fibrosis[18] or inflammatory bowel disease[19,20], or in primary care. However, co-production has lagged in the design of services dealing with life-threatening emergencies and unscheduled acute care[21,22]: On one hand side emergency care in and out of the hospital is costly but due to the acute nature of the relevant conditions associated with significant safety risks [23,24], on the other hand side the patient's ability to partake in shared decision making or exert agency is limited by the severity of their disease and their dependency on immediately life-saving interventions[25]. Curiously funders and patients are rarely part of the same service design process. In order to improve the impact of co-design a broader range of drivers might therefore warrant consideration.

Co-design is often focused on user-experience as a key driver. It is arguable that this is challenging to keep it front and centre as a key driver in systems providing emergency medical care that are under extreme clinical and financial pressures. This raises important questions on how the impact of co-design might change if end-users i.e. patient representatives and healthcare staff co-designed the intervention and if the process would result in interventions that differ from current care-models in relation to the 'ownership' and agency of patients of the final product?

The BASE prototypology [26] is a design led development method that ensures a holistic approach to collaboration through link of knowledge domains (epistemology) and participant characteristics (ontology). BASE prototypology emphasises that knowledge can be gained from different perspectives of a process B for business (viability, 'How is it paid for', financial implications), A for art (desirability, 'How does it look', understanding of the physical form of objects or processes), S for science (evidence, 'How does it work', subject matter experts), E for engineering (feasibility, 'How is it made') and user experience ('How does it feel') (Figure 1).

Figure: Workshop participants from case study 1 (1) and case study 2 (2) listed according to epistemological categories of the BASE methodology with the patient at the centre of all interactions: In addition to the categories listed four patient representatives participated in both workshops.



In this paper we (1) review the literature on co-design, co-production and co-creation in acute care, (2) describe in detail the processes employed in developing a novel template for co-design for healthcare teams in the challenging and complex environments of emergency care. Through two case-studies we illustrate the value, feasibility and explore the boundaries of the process for designing interventions in acute care.

METHODS

Rapid Review of the Literature

We undertook a rapid review of the literature[27]: we restricted the search to one database (PubMed), and articles were screened by only one reviewer.
Inclusion criteria were as follows:

- Population: Adult patients requiring urgent or emergency care in hospital but excluding intensive care or hospice settings
- Outcomes: Interventions created with patients
- Intervention: co-design of an artefact, process or service for patients
- Study types: observational and interventional studies.
- Source types: Published, peer-reviewed journal articles accessible through PubMed.

Studies describing interventions in children, editorials, discussion papers and studies that limited co-design to healthcare professional were excluded.
Search terms: Permutations of co-design, co-production, co-creation were linked to descriptors of emergency care (Appendix)
The following search string was entered into PubMed (coverage 1947–2014): ((emergency[Title/Abstract]) OR (deterioration[Title/Abstract])) AND ("co-design" OR "co-produce" OR "co-creation" OR "co-create" OR "co- production").

Validation of a novel intervention for co-design in acute care

Structure of the workshops:
We applied the BASE prototypology[26] in two two-day workshops with case-studies set in acute care with participants selected according to the principles outlined above. Patient representatives were volunteers from a Macmillan User Involvement Group. Participants received preparatory materials prior to the workshops. Each two-day workshop began with introductions of new members and icebreaker activities related to the topic of the workshop with a joint evening meal at the end of day. This might have contributed to the forming of bonds between participants and supported the emotional energy required to understand the impact of adverse events on patients and their loved ones.
Throughout the workshops interactive exercises were used to facilitate the co-design process including questions for small groups, discussion in pairs, personal reflections, discussion of case studies, mapping exercises of possible intervention components, mapping exercises of

desired behavioural changes, choosing and agreeing on evaluation measures. Workshops were broken into discrete activities, which provided a chance for all team members to share their experiences of various aspects of team working, co-design and patient safety.

Co-design by prototyping: Scenario based design

We used design scenarios[28–30] as useful tools for communicating ideas about user actions and a method that has been used for planning of healthcare emergencies[31] and with patients[32]. We mapped design scenarios to help formalize ideas and to take creative approaches to those ideas. This helped to root designs on terra firma taking a "what our users want/need" approach from the outset. User scenarios were designed to capture key tasks and interactions within a system rather than all possible interactions.

Choice of case studies

Emergencies are characterised by perceived or actual immediate risk to patients' life. Acute care settings are typified by complex interactions of multiple professional groups with variable level of ownership of location, process and outcomes[33]. Professional groups usually have strong hierarchical structures. There is limited patient agency as the patients is acutely unwell and unable to safely remove themselves from the setting. Two case studies were chosen to exemplify the design challenge of improving safety in acute care:

Case study 1: The acute threat of catastrophic deterioration of patients in hospital (often described as 'failure to rescue'[34]); this type of scenario is common and results in considerable preventable morbidity and mortality of patients[35], mental health issues in clinicians[36] and cost for healthcare providers.

Case study 2: The presentation with a potentially life-threatening illness at the hospital front door at the interface between primary and secondary care. Care processes at the interface between providers and teams are over-represented in reports on adverse events. Patients die as a result of failure to act on information that is available but not shared or communicated but lacking in salience[37,38].

Ethics and funding

No ethics application was required for the literature review and workshops with patients. Participants signed consent for the dissemination of evidence from the workshops to be disseminated.

The work was funded through an Improvement Science Fellowship by the Health Foundation for one of the authors (CPS).

RESULTS

Results of the rapid literature review co-design in acute care

References were verified last on the 11th of July 2022. The search of the literature resulted in 82 references. These were reviewed by hand. 73 references were excluded: 44 contained the wrong population, 17 used wrong outcomes, 5 a wrong study design, 5 were the wrong type of publication and a further 4 had no patient involvement. One further publication was identified from additional hand searches[39]. A recent systematic review of experience centred co-design in hospital was used to validate the search: no further studies in acute care were included in the systematic review[40].

The remaining 8 manuscripts were further investigated: 7 were from the UK and one from New Zealand (Table I), all were from the last 10 years.

Two themes were identified as published topics for co-design work: 1. processes to assist patients to call for help in hospital ('patient activated rapid response')[41,42], 2. service design guided by the experience of a patient group with a single specific condition such as asthma[43], epilepsy[44], palliative[45] or elderly patients[39] etc. Co-design resulted in new pathways in a small proportion of the studies. Design methods used for co-design were modifications of Plan-Do-Study-Act[44,46] cycles and Experienced Based Co-design[47,48] as well as a range of other less standardised

We found limited evaluation of clinical impact of the co-design process in acute or emergency care and no study that compared several design processes methods.

Table I: Summary of the identified studies using co-design with patients in acute care.

No	1st author	Population	Method of co-design	Stake holder recruitment	Intervention	Impact measure
1	Subbe CP[49] (2021, UK)	Hospitalised patients	PDSA cycle	Pragmatic, patients only	Patient held record	Feasibility
2	Noble A[44] (2020, UK)	Patients with epilepsy	PDSA cycle	Health care professionals and purposive sample of service user representatives	First aid training for epilepsy	Pilot randomised controlled trial showed no significant clinical impact
3	McKinney A[41] (2020, UK)	Hospitalised patients	Research protocol	Health care professionals, patients and relatives	Intervention to detect and refer patient deterioration	n.a.
4	Strickland W[42] (2019, New Zealand)	Hospitalised patients	Survey of patients	Purposeful sampling of patients and family members	Co-design limited to survey development	n.a.
5	Newell K[43] (2017, UK)	Patients with asthma	Not specified	Unclear	Asthma patient passport	Reduction of steps needed for patients to communicate their needs
6	Blackwell RW[45] (2017, UK)	Elderly patients with palliative care needs	Experienced Based Co-design	ED and paliative care clinicians (interviews with patients separately).	Prioritisation exercise and training materials	Not measured
7	Piper D[48] (2012, UK)	Patient accessing emergency departments	Experienced Based Co-design	Staff and patients	Changes to resources used in Emergency Departments	Patient & staff satisfaction
8	O'Donnel D[39] (2019, UK)	Frail patients in acute care	Structured consensus building workshops	Membership of non-governmental organisations, community-based patient & public advocacy organisations	Priorities for frailty pathways	n.a.

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Application of the BASE protoypology to co-design

Characteristics of workshop participants

Participants from all constituent groups of the BASE model were represented in the two workshops (Figure). Each workshop group was split into BASE 'families' for small-group activities. These did mirror the make-up of the whole group with at least one member of each constituent group represented in each of the 'families'. The authors and patient representatives took part in both workshops, all other members of the teams changed.

Development of case studies

Real-life scenarios of patient safety events, including events with fatal outcomes were used. We sourced published reports on sepsis[49], hospital care[50] and adverse events [51] rather than local events in order to maintain patient confidentiality and avoid the risks of litigation. Case scenarios were summarized in case-vignettes. Details of the sample cases were mapped against a timeline.

Both workshops followed the Double-Diamond methodology[52] (Table II). Weighting of the BASE groups in the 'families' varied between the workshops. Expert inputs were focused on different design-challenge specific topics. The Crazy-8 methodology[53] was used to ideate and develop solutions. Delivery in workshop 1 was only in the form of a prioritisation exercise with the expectation of continuous development of the prototype ideas outside of the workshop. In workshop 2, mock-ups were used in role-play to explore the functionalities of the proposed interventions.

Table II: Application of the Double-Diamond method to the workshops. The Double-Diamond distinguishes a research phase with divergent discovery of the research area of interest, and convergent definition of the key problem, and a design phase with divergent development of concepts and convergent deployment of the final solutions.

Double-Diamond phase	Case study 1	Case study 2
Discovery of subject	Graphic storyboards	Storyboards Board-game on patient flow In-situ-simulation of a catastrophic emergency
Definition of problem	Limitations of sick patients to act in a system with strong hierarchies	Continuity and visibility of safety critical information across changing providers
Development of prototypes	Crazy-8 method Scenario-based design	Crazy-8 method Short movie clips
Delivery of outputs	Shared-checklists for patients with cancer and families developed into a smart-phone application	Express-check-in: patient-held documentation-system for admission to hospital

Validation of case studies in clinical applications

Patient held checklists were a preferred intervention suggested by participants in Workshop 1: With funding from a separate grant a patient-held checklist was developed as part of a clinical trial to reduce adverse events from systemic cancer treatments (i.e., chemo- and radio-therapy). Check-lists for complications of cancer from the United Kingdom Oncology Nurses Society were adapted with patients into smart-phone application that linked patients to a 'safety buddy' and their clinician and has since been tested by the first 100 users as part of a clinical trial[54]. The application was used over 3000 times in the first 60 days of testing with high reliability of inputs and excellent feedback from users. A patient 'passport' with key information was proto-typed in Workshop 2. This was further developed as part of a feasibility study. An 'Express-Check-in' for patients admitted to hospital that allows patients to document their history and clinical priorities in hospital records has been tested in over 100 patients[55]. Well over 80% of patients approached filled the documentation. Resulting records contained a significant proportion of unique information not mirrored in clinical records.

Reflection on the design process

Donabedian conceptualised a chain linking structure, process, and outcome[56]. Many co-design methods use focus groups with patient representatives[32]. In contrast to other techniques,

we integrated patient representatives into the groups, prototype development was undertaken in three sub-groups that each had a member of each of the BASE constituents: The collaborative methodology was hence mirrored in the enabling structure of the works-shops. The enabling structure of our method means that healthcare professionals don't dominate the groups' conversation.

Emotional experience of the safety challenges of acute care were reflected in both workshops. In the first workshop we used witness reports of harmed patients and the empathic video of the mother of a patient who died as the result of a safety error. In the second workshop we complemented the secondary experience of reports from the literature with the primary emotional experience of shared immersive enactment of a medical emergency and subsequent prototyping of interventions with joint role play.

We found the input of our patient representatives throughout the workshops to be invaluable. The patient representatives brought the rich experience of their perception of how healthcare teams worked and their impressions of relationships among healthcare team members. We observed little hesitancy and hierarchical behaviour with patients participating, leading the

narrative and development of the case-studies as much as other participants. This might be specific to the participants but might be an effect of a design methodology where structure facilitated the democratic group interactions.

DISCUSSION

What we have shown

In the present study we have shown the co-design of interventions in acute care is feasible. We demonstrated the functionality of the BASE methodology as a model to define the constitution of a co-designing team. The link of scenario-based design with the BASE prototypology allowed the generation of viable prototypes for complex healthcare problems within a very short time frame.

We believe that the heterogeneity of the groups helped to establish flat hierarchies. We started out workshops with clinical care studies that were observed and interpreted by all participants – including the non-clinicians. We believe that this approach assisted the patient focus and helped to avoid dominance of the discussion by clinicians.

Outputs from the two workshops have since been developed further and tested in clinical studies.

What others have shown

At current no authoritative guidelines on the balanced perspective of a stakeholder group that results in change exists: The BASE prototypology gives some guidance on the epistemology that might usefully guide the make-up.

Focus groups are a common way to involve users in the design of services or interventions in clinical trials[57]. In quality improvement patients can act in distinct roles[58] as 'knowledge brokers' who 'who facilitate knowledge exchange and adoption', a 'technology of persuasion' of clinicians about the importance of a problem. This resulting patient-centred interventions might however not always lead to real-world impact[59]. Experience based design has been used in a feasibility study to explore ways for patients to speak up in primary care[60]. Patients identified polypharmacy as a key threat to their safety.

Limitations and challenges of this study

Given that the rate of failed innovation or improvement interventions in the health service is high and that many are planned in desk-top exercises we believe that we have developed an

engaging framework that allows teams to validate ideas in a structured manner with limited resources.

Patient representatives for our workshops were not selected in a representative fashion. Given the exploratory character of the our study and its resulting limited sample size we refrained from measuring activation[61] of participants or comparable systems of measurement. In the absence of comparative metric for design processes we can only state feasibility but are unable to qualify or quantify the differential impact of our co-design methodology.

Implications for clinical practice: Wicked problems

It is generally acknowledged that for a novel idea to become an innovation it needs to be feasible, viable and desirable[62]. Our co-design method, while challenging at times, has many benefits including grounding the intervention in the real-world experiences of patients and healthcare teams. This might be of particular relevance in addressing 'wicked' or 'complex' problems that defy linear approaches[63]. The chosen scenarios were 'Wicked Problems'[64]: are a: "class of social system problems which are ill-formulated, were the information is confusing, where there are many clients and decision makers with conflicting values, and where the ramifications in the whole system are thoroughly confusing."[65]. 'Complex' and 'Wicked' would seem to be barriers to other forms of design where the synchronous way of reviewing problems and solutions from multiple view-points at the same time would seem particularly pertinent.

Implications for research

It is generally acknowledged that for a novel idea to become an innovation it needs to be feasible, viable and desirable[62]. Participatory Design provides a way to include stakeholders in designing solutions development and delivery of service improvement: Evaluation of the design process based on clinical impact is needed to compare output in relation to the design inputs and in comparison, to other ways to change services.

CONCLUSIONS

Designing for complex problems might benefit from the use of multiple perspectives. The design of interventions that allow those affected to own/control/deliver them would seem key for addressing patient safety problems. The BASE prototypolgy has the potential to facilitate future iterative developments of prototypes and allow the measurement of impact on

behaviour of patients, carers and health-care professionals. Co-design has great potential as a methodology for engaging patients to help understand and redesign health systems and for enhancing patient outcomes even in acute care.

REFERENCES

1. Farrugia G, Plutowski RW. Innovation Lessons From the COVID-19 Pandemic. *Mayo Clin Proc*. 2020;95(8):1574-1577. doi:10.1016/j.mayocp.2020.05.024
2. Innovate UK. *Design in Innovation Strategy 2020-2024*. London; 2020.
3. Bradley P, Willson A, Buss P, et al. *Achieving Prudent Healthcare in NHS Wales*.; 2014.
4. Rix A, Marrin K, Lewis P, Jones R, Shorrocks O. Prudent health care and patient activation An appraisal prepared for the Planned Care Programme Acknowledgements Acknowledgements are due to of the Planned Care Programme for their support and patience, and to Mike Spencer (1000 Lives) and Ruth Dineen (Co-production Wales) for their advice on Patient Experience and Co- production respectively. 2015.
5. Clarke D, Jones F, Harris R, Robert G. What outcomes are associated with developing and implementing coproduced interventions in acute healthcare settings? A rapid evidence synthesis. *BMJ Open*. 2017;7. doi:10.1136/bmjopen-2016-014650
6. Nesta. People powered health co production catalogue. 2012:89.
7. Gallagher M, Wales H, Dineen R, Wales C-P. Seeing is Believing: Co-production Case Studies from Wales (version 06 - 12 January 2016). 2012.
8. National Voices. Realising the value: how should we think about value in health and care? 2015;(September):20.
9. Batalden M, Batalden P, Margolis P, et al. Coproduction of healthcare service. *BMJ Qual Saf*. 2015;(pii: bmjqs-2015-004315.).
10. Alsem MW, van Meeteren KM, Verhoef M, et al. Co-creation of a digital tool for the empowerment of parents of children with physical disabilities. *Res Involv Engagem*. 2017;3(1). doi:10.1186/s40900-017-0079-6
11. Davies N, Mathew R, Wilcock J, et al. A co-design process developing heuristics for practitioners providing end of life care for people with dementia. *BMC Palliat Care*. 2016;15(1):68. doi:10.1186/s12904-016-0146-z
12. Bringing User Experience to Healthcare Improvement: The Concepts, Methods and Practices of Experience-Based Design: Amazon.co.uk: Bate, Paul, Robert, Glenn: 8601200768732: Books. https://www.amazon.co.uk/Bringing-User-Experience-Healthcare-Improvement/dp/1846191769. Accessed June 22, 2020.
13. Joseph-Williams N, Lloyd A, Edwards A, et al. Implementing shared decision making in the NHS: lessons from the MAGIC programme. *BMJ*. 2017;357:j1744.

doi:10.1136/bmj.j1744

14. Melnick ER, Probst MA, Schoenfeld E, et al. Development and Testing of Shared Decision Making Interventions for Use in Emergency Care: A Research Agenda. *Acad Emerg Med*. 2016;23(12):1346-1353. doi:10.1111/acem.13045
15. Flynn D, Knoedler MA, Hess EP, et al. Engaging patients in health care decisions in the emergency department through shared decision-making: A systematic review. *Acad Emerg Med*. 2012;19(8):959-967. doi:10.1111/j.1553-2712.2012.01414.x
16. Simpson N, Milnes S, Steinfort D. Don't forget shared decision-making in the COVID-19 crisis. *Intern Med J*. 2020;50(6):761-763. doi:10.1111/imj.14862
17. Contreras CM, Metzger GA, Beane JD, Dedhia PH, Ejaz A, Pawlik TM. Telemedicine: Patient-Provider Clinical Engagement During the COVID-19 Pandemic and Beyond. *J Gastrointest Surg*. 2020. doi:10.1007/s11605-020-04623-5
18. Stevens DP, Marshall BC. A decade of healthcare improvement in cystic fibrosis: Lessons for other chronic diseases. *BMJ Qual Saf*. 2014;23(SUPPL1):i1-i2. doi:10.1136/bmjqs-2014-002871
19. Crandall W, Kappelman MD, Colletti RB, et al. ImproveCareNow: The development of a pediatric inflammatory bowel disease improvement network. *Inflamm Bowel Dis*. 2011;17(1):450-457. doi:10.1002/ibd.21394
20. Berry SK, Siegel CA, Melmed GY. Quality Improvement Initiatives in Inflammatory Bowel Disease. *Curr Gastroenterol Rep*. 2017;19(8). doi:10.1007/s11894-017-0581-x
21. Piper D, Iedema R, Gray J, Verma R, Holmes L, Manning N. Utilizing experience-based co-design to improve the experience of patients accessing emergency departments in New South Wales public hospitals: An evaluation study. *Heal Serv Manag Res*. 2012;25(4):162-172. doi:10.1177/0951484812474247
22. Bowen S, McSeveny K, Lockley E, Wolstenholme D, Cobb M, Dearden A. How was it for you? Experiences of participatory design in the UK health service. *CoDesign*. 2013;9(4):230-246. doi:10.1080/15710882.2013.846384
23. Schenkel S. Promoting patient safety and preventing medical error in emergency departments. *Acad Emerg Med*. 2000;7(11):1204-1222. doi:10.1111/j.1553-2712.2000.tb00466.x
24. Hogan H, Healey F, Neale G, Thomson R, Vincent C, Black N. Preventable deaths due to problems in care in English acute hospitals : a retrospective case record review study. 2012;(July). doi:10.1136/bmjqs-2012-001159
25. Vennik FD, Van De Bovenkamp HM, Putters K, Grit KJ. Co-production in healthcare:

rhetoric and practice. *Int Rev Adm Sci*. 2016;82(1):150-168. doi:10.1177/0020852315570553

26. Parkinson JA, Eccles KE, Goodman A. Positive impact by design: The Wales Centre for Behaviour Change. *J Posit Psychol*. 2014;9(6):517-522. doi:10.1080/17439760.2014.936965
27. Tricco AC, Antony J, Zarin W, et al. A scoping review of rapid review methods. *BMC Med*. 2015;13(1):1-15. doi:10.1186/S12916-015-0465-6/TABLES/6
28. Design Scenarios - Communicating the Small Steps in the User Experience | Interaction Design Foundation. https://www.interaction-design.org/literature/article/design-scenarios-communicating-the-small-steps-in-the-user-experience. Accessed July 13, 2018.
29. Rasoulifar R, Thomann G, Villeneuve F. Scenarios and the design process in medical application. *CIRP Des Conf Compet Des*. 2009;6.
30. Carroll JM. Five reasons for scenario-based design. *Interact Comput*. 2000;13(1):43-60. doi:10.1016/S0953-5438(00)00023-0
31. Reeder B, Demiris G. Building the PHARAOH framework using scenario-based design: A set of pandemic decision-making scenarios for continuity of operations in a large municipal public health agency. *J Med Syst*. 2010;34(4):735-739. doi:10.1007/s10916-009-9288-3
32. Valaitis R, Longaphy J, Ploeg J, et al. Health TAPESTRY: Co-designing interprofessional primary care programs for older adults using the persona-scenario method. *BMC Fam Pract*. 2019;20(1):1-11. doi:10.1186/s12875-019-1013-9
33. Institute of Medicine (US) and National Academy of Engineering (US) Roundtable on Value & Science-Driven Health Care. Healthcare System Complexities, Impediments, and Failures. In: *Engineering a Learning Healthcare System: A Look at the Future*. National Academies Press (US); 2011.
34. Ou L, Chen J, Assareh H, Hollis SJ, Hillman K, Flabouris A. Trends and Variations in the Rates of Hospital Complications , Failure-to-Rescue and 30-Day Mortality in Surgical Patients in New South Wales , Australia , 2002-2009. 2014;9(5):2002-2009. doi:10.1371/journal.pone.0096164
35. Taenzer AH, Pyke JB, McGrath SP. A review of current and emerging approaches to address failure-to-rescue. *Anesthesiology*. 2011;115(2):421-431.
36. Seys D, Wu AW, Van Gerven E, et al. Health Care Professionals as Second Victims After Adverse Events : A Systematic Review. *Eval Health Prof*. 2012;36(2):135-162.

37. Johnson JK, Farnan JM, Barach P, et al. Searching for the missing pieces between the hospital and primary care: mapping the patient process during care transitions. *BMJ Qual Saf*. 2012;21 Suppl 1(Suppl 1):i97-105. doi:10.1136/bmjqs-2012-001215
38. Johnson JK, Barach P, Vernooij-Dassen M, HANDOVER Research Collaborative. Conducting a multicentre and multinational qualitative study on patient transitions. *BMJ Qual Saf*. 2012;21 Suppl 1(Suppl 1):i22-8. doi:10.1136/bmjqs-2012-001197
39. O'Donnell D, Ní Shé É, McCarthy M, et al. Enabling public, patient and practitioner involvement in co-designing frailty pathways in the acute care setting. *BMC Health Serv Res*. 2019;19(1). doi:10.1186/S12913-019-4626-8
40. Hospital A, Chan RJ, Green T, et al. Use and reporting of experience-based codesign studies in the healthcare setting: a systematic review. doi:10.1136/bmjqs-2019-009570
41. McKinney A, Fitzsimons D, Blackwood B, White M, McGaughey J. Co-design of a patient and family-initiated escalation of care intervention to detect and refer patient deterioration: Research protocol. *J Adv Nurs*. 2020;76(7):1803-1811. doi:10.1111/jan.14365
42. Strickland W, Pirret A, Takerei S. Patient and/or family activated rapid response service: Patients' perceptions of deterioration and need for a service. *Intensive Crit care Nurs*. 2019;51:20-26. doi:10.1016/J.ICCN.2018.11.007
43. Newell K, Corrigan C, Punshon G, Leary A. Severe asthma: emergency care patient driven solutions. *Int J Health Care Qual Assur*. 2017;30(7):628-637. doi:10.1108/IJHCQA-09-2016-0127
44. Noble A, Nevitt S, Holmes E, et al. Seizure first aid training for people with epilepsy attending emergency departments and their significant others: the SAFE intervention and feasibility RCT. *Heal Serv Deliv Res*. 2020;8(39):1-190. doi:10.3310/HSDR08390
45. Blackwell RW née, Lowton K, Robert G, Grudzen C, Grocott P. Using Experience-based Co-design with older patients, their families and staff to improve palliative care experiences in the Emergency Department: A reflective critique on the process and outcomes. *Int J Nurs Stud*. 2017;68:83-94. doi:10.1016/j.ijnurstu.2017.01.002
46. Subbe CP, Tomos H, Jones GM, Barach P. Express check-in: developing a personal health record for patients admitted to hospital with medical emergencies: a mixed-method feasibility study. *Int J Qual Heal care J Int Soc Qual Heal Care*. 2021;33(3). doi:10.1093/INTQHC/MZAB121
47. Blackwell RW née, Lowton K, Robert G, Grudzen C, Grocott P. Using Experience-based Co-design with older patients, their families and staff to improve palliative care

experiences in the Emergency Department: A reflective critique on the process and outcomes. *Int J Nurs Stud*. 2017;68:83-94. doi:10.1016/J.IJNURSTU.2017.01.002

48. Piper D, Iedema R, Gray J, Verma R, Holmes L, Manning N. Utilizing experience-based co-design to improve the experience of patients accessing emergency departments in New South Wales public hospitals: An evaluation study. *Heal Serv Manag Res*. 2012;25(4):162-172. doi:10.1177/0951484812474247
49. *Time to Act - Severe Sepsis: Rapid Diagnosis and Treatment Saves Lives*. London ; 2013.
50. Ham C (Ed), Berwick D (Ed). *Organising Care at the NHS Front Line: Who Is Responsible?* London; 2017.
51. Johnson JK, Haskell HW, Barach PR. *Foundations for Core Competencies Case Studies in Patient Safety*. Burlington, MA 01803: Jones & Bartlett Learning; 2016.
52. Diamond D. The Impact of Applying Design Thinking. 2020.
53. Share and engage with the Design Sprint Community. https://designsprintkit.withgoogle.com/methodology/phase3-sketch/crazy-8s. Accessed May 17, 2020.
54. Jones H V, Smith H, Cooksley T, et al. Checklists for Complications During Systemic Cancer Treatment Shared by Patients, Friends, and Health Care Professionals: Prospective Interventional Cohort Study. *JMIR mHealth uHealth*. 2020;8(9):e19225. doi:10.2196/19225
55. Subbe CP, Tomos H, Jones GM, Barach P. Express check-in: Developing a personal health record for patients admitted to hospital with medical emergencies: A mixed-method feasibility study. *Int J Qual Heal Care*. 2021;33(3). doi:10.1093/INTQHC/MZAB121
56. Donabedian A. The Quality of Care How Can It Be Assessed? *JAMA* . 1988;260:1743-1748.
57. Gooberman-Hill R, Jinks C, Bouças SB, et al. Designing a placebo device: Involving service users in clinical trial design. *Heal Expect*. 2013;16(4):100-110. doi:10.1111/hex.12043
58. Armstrong N, Herbert G, Aveling EL, Dixon-Woods M, Martin G. Optimizing patient involvement in quality improvement. *Heal Expect*. 2013;16(3). doi:10.1111/hex.12039
59. Lawton R, O'Hara JK, Sheard L, et al. Can patient involvement improve patient safety? A cluster randomised control trial of the Patient Reporting and Action for a Safe Environment (PRASE) intervention. *BMJ Qual Saf*. 2017;26(8):622-631.

doi:10.1136/bmjqs-2016-005570

60. Knowles S, Hays R, Senra H, et al. Empowering people to help speak up about safety in primary care: Using codesign to involve patients and professionals in developing new interventions for patients with multimorbidity. *Heal Expect*. 2018;21(2):539-548. doi:10.1111/hex.12648
61. Hibbard J, Gilburt H. *Supporting People to Manage Their Health: An Introduction to Patient Activation*.; 2014.
62. How to Prototype a New Business – IDEO U. https://www.ideou.com/blogs/inspiration/how-to-prototype-a-new-business. Accessed June 22, 2020.
63. Peters BG. What is so wicked about wicked problems? A conceptual analysis and a research program OPEN ACCESS. *Policy Soc*. 2017;36(3):385-396. doi:10.1080/14494035.2017.1361633
64. Buchanan R. *Wicked Problems in Design Thinking*. Vol 8.; 1992.
65. Rittel, H.W.J. WMM. Rittel, Horst W. J., Dilemmas in a General Theory of Planning , Policy Sciences, 4:2 (1973:June) p.155. *Policy*. 1973;2:155.

APPENDIX: literature search terms used (sample)

- ((emergency[Title/Abstract]) OR (deterioration[Title/Abstract])) AND ("co-design" OR "co-produce" OR "co-creation" OR "co-create" OR "co- production") – 82 screened – 7 included

- (emergency care[MeSH Terms]) AND (co-production OR co-design OR co-creation) – 20 screened – 1 duplicate

- (critical care[MeSH Terms]) AND (co-production OR co-design OR co-creation) - 10 screened – 1 duplicate

- ("Emergency Treatment"[Mesh]) AND "User-Centered Design"[Mesh]) – No reference

- (Emergency) AND "User-Centered Design"[Mesh] – 13 screened - none included

- (emergency) AND (co-production [Ti] OR co-design [Ti] OR co-creation[Ti]) AND hospital – 23 screened – none included

- (acute [ti/abstract]) AND ("co-design" [ti] OR "co-produce" [ti] OR "co-creation" [ti] OR "co-create" [ti] OR "co- production"[ti]) – 21 screened – 1 duplicate

4.6 Paper 6: Checklists for Complications During Systemic Cancer Treatment Shared by Patients, Friends and Health Care Professionals: Prospective Interventional Cohort Study

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ABSTRACT

Background: Advances in cancer management have been associated with an increased incidence of emergency presentations with disease- or treatment-related complications.

Objective: This study aimed to measure the ability of patients and members of their social network to complete checklists for complications of systemic treatment for cancer and examine the impact on patient-centered and health-economic outcomes.

Methods: A prospective interventional cohort study was performed to assess the impact of a smartphone app used by patients undergoing systemic cancer therapy and members of their network to monitor for common complications. The app was used by patients, a nominated "safety buddy," and acute oncology services. The control group was comprised of patients from the same institution. Measures were based on process (completion of checklists over 60 days), patient experience outcomes (Hospital Anxiety and Depression Scale and the General version of the Functional Assessment of Cancer Therapy at baseline, one month, and two months) and health-economic outcomes (usage of appointments in primary care and elective and unscheduled hospital admissions).

Results: At the conclusion of the study, 50 patients had completed 2882 checklists, and their 50 "safety buddies" had completed 318 checklists. Near daily usage was maintained over the 60-day study period. When compared to a cohort of 50 patients with matching disease profiles from the same institution, patients in the intervention group had comparable changes in Hospital Anxiety and Depression Scale and General version of the Functional Assessment of Cancer Therapy. Patients in the Intervention Group required a third (32 vs 97 nights) of the hospital days with overnight stay compared to patients in the Control Group, though the difference was not significant. The question, "I feel safer with the checklist," received a mean score of 4.27 (SD 0.87) on a Likert scale (1-5) for patients and 4.55 (SD 0.65) for family and friends.

Conclusion: Patients undergoing treatment for cancer and their close contacts can complete checklists for common complications of systemic treatments and take an active role in systems supporting their own safety. A larger sample size will be needed to assess the impact on clinical outcomes and health economics.

INTRODUCTION

Advances in cancer management continue to improve patient outcomes but are also associated with an increase in emergency presentations with disease- or treatment-related complications [1]. The challenges of acute oncology presentations have led to an interest in developing optimal care models and support systems for meeting patients' needs [2]. Cancer patients seeking emergency care generally have longer lengths of stay, higher admission rates, and higher mortality than non-cancer patients [3].

Individualized management of acute cancer presentations is important to ensure services can mirror routine cancer care [4]. There is an increasing number of acute cancer presentations that can be risk-assessed for care in an outpatient ambulatory setting utilizing technology to support clinicians and patients. Complications of cancer and its treatments are predictable (fever, diarrhea, skin reactions, and drug-specific effects) and, in part, preventable.

Patients, friends, family, and other carers are often able to identify deviations from a patient's normal status as a first step to facilitate calls for help. Peer support has been used in other settings to improve clinical care and safety, allowing families and friends to look after vulnerable patients, including those discharged after a stroke [5]. Mobile health apps for patients with cancer have the potential to track deterioration [6], support education, and recovery [7-9].

Modular redundancy is the duplication of critical components of a system to increase the reliability of performance in the design of technology [10] or clinical services [11]. Checklists allow redundancy by allowing multiple users to verify safety and are widely used in health care [12-15]. The United Kingdom Oncology Nursing Society (UKONS) has developed checklists for symptom-driven telephone triage [16].

Patients are competent to carry out surveillance and management of chronic conditions, as demonstrated by people with diabetes checking their blood sugars, people with asthma monitoring their peak flows, and people with heart failure recording their weight. Patients

admitted to the hospital as medical emergencies can assist in the recording of key safety-critical information [17]. Information about cancer improves compliance, especially if it is tailored to individual needs and context-specific [4].

The study aimed to test the feasibility of a smartphone-based checklist that allows redundant access to safety-critical processes for patients, members of their immediate social network, and health care professionals to stimulate patients and carers to seek medical assistance when necessary while providing reassurance when appropriate.

METHODS

Study Design

The trial was designed as a prospective interventional cohort study.

Participants

Oncology patients attending outpatient clinics at the Ysbyty Gwynedd, North Wales, were invited to take part in the study. Patients were eligible if they had a known malignancy and were receiving treatment for cancer, including chemotherapy, radiotherapy, immunotherapy, or best supportive care. Patients were eligible for enrollment during the entirety of their treatment course.

Patients were excluded from the trial if they were receiving end of life care or lacked a smartphone to access the app. There were 50 app licenses available for the trial, and 100 patients were recruited. Patients who did not want to use the smartphone app and patients recruited after all the licenses had been distributed were recruited into a control group to provide indicative data on service usage in patients not using the app.

All participants, including controls, gave written informed consent.

Smartphone App

The content of the app was co-produced in four focus group events. Focus groups consisted of 15 patient representatives, clinicians, and health-service researchers. Checklists were based on the UKONS 24-hour triage tool [16], the UKONS Oncology/Hematology risk assessment tool for Primary Healthcare Professionals [18], and a symptom assessment tool included in the Cancer Research UK Patient treatment record adapted from the UKONS 24-Hour Triage Tool [19]. UKONS tools classify symptoms and signs according to risk and urgency into

green, amber, and red with linked actions for escalation from generic advice (green) to encouragement to seek a routine appointment or an urgent assessment (amber or red) (Figure 1).

Figure 1: Sample screenshots of checklist items. Item 2 (breathlessness or chest pain) is linked to a red escalation, item 7 (urine problems) is linked to amber escalation.

Clinicians, patients, and researchers devised a hierarchy of safety-relevant symptoms in two iterations. Items were summarized in nine screens, and item rankings were decided by consensus. Checks were presented in order of priority, starting with the most urgent and life-threatening symptoms.

The system allows the addition of disease- or treatment-specific checks in the content management system. For this study, only a generic checklist was activated. Prototypes were tested against typical case studies. Symptoms that were “red flags” generated a recommendation to the patient to seek medical care. The app sent text reminders to patients once a day to complete the checklist.

Each patient was asked to invite one family member or friend to be their “Safety buddy.” Safety buddies also downloaded the checklist app to their smartphone. Safety buddies received push notifications if the patient did not complete the checklist within an agreed timeframe or if patients reported potentially serious symptoms (equivalent to red fields in the

UKONS checklist): “You might want to call your friend/family member.” Safety buddies were then asked to complete the checklist on their phone with the patient (Figure 2).

Figure 2: Workflow of the application

A dashboard for the acute oncology team showed notifications and alerts that could be annotated by clinicians. Nurse specialists reviewed the reported symptoms once daily via an online dashboard and followed up with patients if the symptoms required further attention.

Use of the App

Patients were enrolled for 60 days. Patients and the friend or family member were encouraged to access the app to record symptoms at least once daily. It was emphasized to patients that nursing staff would not be monitoring the app constantly and, therefore, the onus was on them to seek medical care if urged to do so by the app. App users received a call after a week to check for technical difficulties in app usage.

Outcome Measures

The Hospital Anxiety and Depression Scale (HADS) [20] and the General version of the Functional Assessment of Cancer Therapy (FACT-G) [21] were completed at baseline, one month, and two months.

Health-economic outcomes consisted of the usage of appointments in primary care and elective and unscheduled hospital admissions.

Patient Feedback

Patients and carers were able to provide feedback within the application. They were asked to use a Likert scale with gradings from 1 (strongly disagree) to 5 (strongly agree).

Project Governance

The study was conducted according to the principles of the World Medical Association’s Declaration of Helsinki 2013 [23]. A study board supervised the development, testing, and evaluation. The group met every three months to issue interim reports and to review risk logs and possible adverse events. Ethics approval was granted (REC reference: 18/WA/0213).

RESULTS

Recruitment

Patients were recruited from January 24, 2019, to September 17, 2019. Of the 197 patients approached, 100 agreed to participate—50 in the control group and 50 in the intervention group. Of the 100 participants, 56 were female. Groups were matched for gender, type of cancer, and performance status, but patients in the control group were older (mean 59, SD 13 years vs mean 68 SD 13 years; *P*<.001) (Table 1).

Table 1. Participants, co-morbidities, cancer type, performance status, and treatment.

(p-values for chi-square test)

Item		Intervention	Control	*P* value
Age, years, mean (SD)		59 (13)	68 (13)	*P*<.001
Gender female, n (%)		27 (54)	29 (58)	p=0.687
Co-morbidities, n				
	Diabetes	2	8	
	Chronic obstructive pulmonary disease	4	5	
	Ischemic heart disease	1	5	
Cancer type, n (%)				p=0.354
	Breast	12 (24)	11 (22)	
	Bowel	13 (26)	9 (18)	
	Lung	6 (12)	15 (30)	
	Kidney	3 (6)	2 (4)	
	Rectal	3 (6)	2 (3)	
	Pancreatic	1 (2)	3 (6)	
	Prostate	2 (4)	2 (4)	
	Esophagus	2 (4)	2 (4)	
	Testicular	3 (6)	0	
	Ovarian	1 (2)	2 (4)	
	Rectal	3 (6)	0	
	Endometrial	2 (4)	0	
	Gastric	1 (2)	0	

	Leiomyosarcoma	0	1 (2)	
	Mesothelioma	0	1 (2)	
Performance status, n				p=0.308
	0	20	16	
	1	22	21	
	2	5	9	
	3	0	2	
Treatment, n				p=0.669
	Chemotherapy	45	45	
	Radio- and chemotherapy	3	2	
	Surgery and chemotherapy	1	1	
	Surgery	0	1	
	Best supportive care	1	1	

Checklist Utilization

Checklists were used 2882 times by the 50 patients in the intervention group, a median of 62 times per patient with the number of uses ranging from 13 to 102 times over the study period. App use resulted in no alert being generated on 2715 occasions, indicating no or no significant symptoms. On 167 (5.8%) occasions, actions were advised. There were 130 green alerts, 28 amber alerts, and 9 red alerts.

Usage by patients was 284 times in the first week, 347 times in the second week, and 228 times in the ninth week of participation.

Of the 50 nominated friends and family members, 31 used the checklists in the app to support their patient partner for a total of 318 times. Usage generated no alert on 267 occasions; in 28 instances, contact of a health care professional was advised. There were 18 amber alerts, 9 red, and 1 major alert.

Friends and family members used the app 77 times in the first week, 67 times in the second week, and 16 times in the ninth week.

Symptoms flagged by the checklists were, in order of frequency, exhaustion (102), nausea (23), fever (14), chest pain (13), sore mouth (13), diarrhea (11), pain (8), constipation (5), skin and eye complaints (4), pins and needles (3), mental health issues (2), visual disturbances (1), and urinary symptoms (1).

Logs completed by the acute oncology team indicated 23 patient calls in response to checklist items. Calls covered a broad range of topics, including technical advice (2 calls), reassurance (8 calls), and advice to admit (4 calls).

Clinical Outcomes

Patients in the intervention group had 19 scheduled inpatient days, 40 unscheduled days in the hospital, and 32 unscheduled days in the hospital involving overnight stays. Patients in the control group had 2 scheduled inpatient days, 108 unscheduled days in the hospital, and 97 unscheduled days in the hospital involving overnight stays. There were 40 patients in the intervention group and 38 patients in the control group who spent no unscheduled time in the hospital. Patients in the intervention group required a third as many hospital days with overnight stay in comparison to the control group.

Patients and primary care practices requested information about appointments in primary care. In the first week after enrollment, patients in the intervention group saw their general practitioner 10 times, and patients from the control group 3 times. In the subsequent 3 weeks, patients from the intervention group saw a general practitioner 20 times, and patients in the control group saw a general practitioner 14 times. In the second month, patients from the intervention group saw a general practitioner 30 times, and patients from the control group had 15 visits.

Anxiety and Depression

Patient experience was captured by standardized questionnaires and informal feedback from inside the application. A HADS score of 11 or more indicates clinically significant anxiety or depression. At baseline, the average HADS score was 7.9 (SD 7.2) in the control group and 10.2 (SD 6.1) in the intervention group (Figure 3). HADS scores of 11 or greater were observed in 14 patients in the control group and 26 patients in the intervention group. After one month, participants with a HADS score >11 had declined to 13 in the control group and 20 in the intervention group. At two months, 11 control patients and 18 intervention patients fulfilled the same criteria.

Values for the FACT-G were not significantly different at baseline, one month, or two months. Over the full duration of the study, 6 patients in the control group and 10 patients in the intervention group improved by more than 10% over their baseline (Figure 4-6).

Figure 3: Hospital Anxiety & Depression Scale mean at baseline, one month, and at the end of the study period.

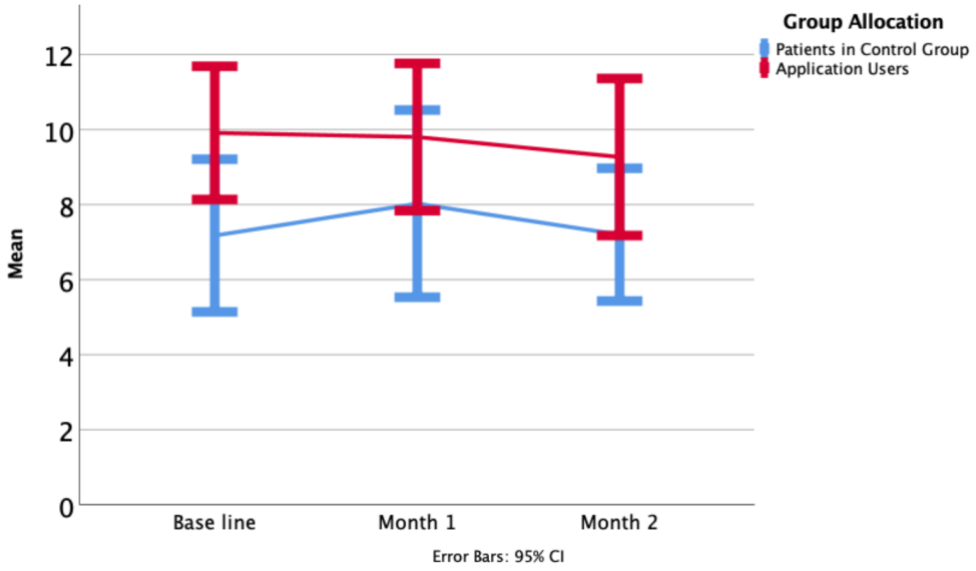


Figure 4: General version of the Functional Assessment of Cancer Therapy (FACT-G) overall means at baseline, one month, and at the end of the study period.

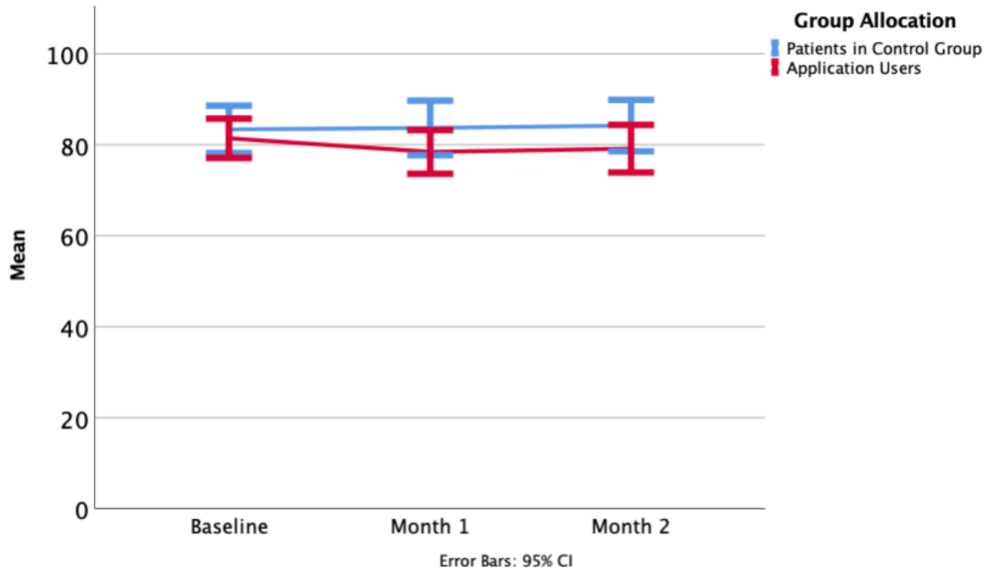


Figure 5: General version of the Functional Assessment of Cancer Therapy (FACT-G) Social and Family wellbeing subscore means at baseline, one month, and at the end of the study period.

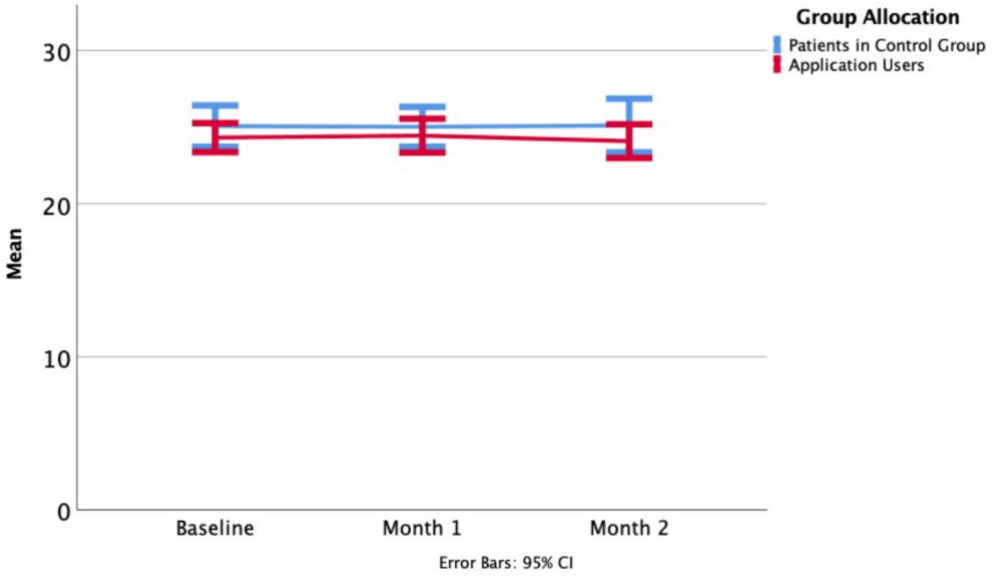
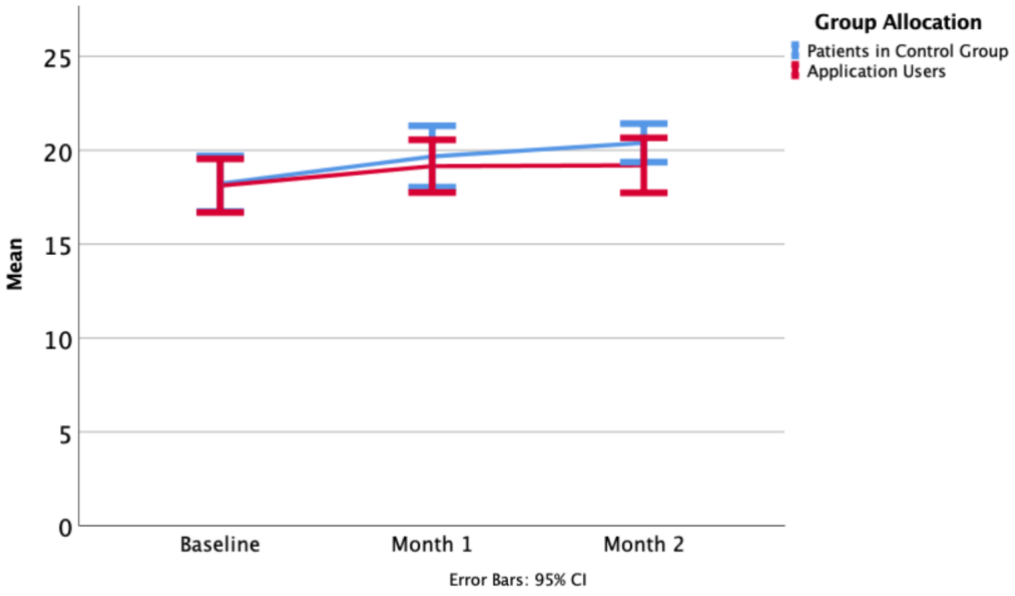


Figure 6: General version of the Functional Assessment of Cancer Therapy (FACT-G) Emotional wellbeing subscore means at baseline, one month, and at the end of the study period.



Feedback From Patients, Friends, and Families

Structured feedback was submitted from within the application by 48 patients and 25 family members and friends (Table 2). Mean ratings on a Likert scale with values from 1 (strongly disagree) to 5 (strongly agree) to the question "I feel safer with the checklist" was 4.27 (SD 0.87) for patients and 4.55 (SD 0.65) for family members and friends. The question "The link to a health care professional is helpful" yielded mean ratings of 4.61 (SD 0.74) for patients and 4.75 (SD 1.35) for family members and friends.

Table 2: Structured feedback using Likert scales with values from 1 (strongly disagree) to 5 (strongly agree).

	Patients (all)	Family and friends (all)	Patients:		
			First assessment	Last assessment	Delta
The information in the app is helpful (mean)	4.32	4.2	4.07	4.45	0.38
The link to a friend or relative is helpful (mean)	4.48	4.41	4.42	4.27	–0.15
The link to a health care professional is helpful (mean)	4.61	4.75	4.55	4.66	0.11
I feel safer with the checklist (mean)	4.27	4.55	4.17	4.41	0.24

DISCUSSION

With the KeepMeSafe application, patients and their families and friends were able to use a smartphone app to work through a list of common complications of cancer and systemic therapies. We demonstrated the feasibility of assistance by members of the patients' social network at times when patients felt unable to complete the checklist themselves. To our

knowledge, this is the first time that patients and members of their social network have been deployed as redundant parts of a safety system.

Patients were only able to participate if they owned a smartphone. This limitation might exclude some patients, but the percentage of people actively using smartphones in the UK in 2019 was 82.9%, the highest in the world [22]. The limited size of our study and the fact that the intervention and control groups were not randomized or matched means that the study does not allow conclusions about clinical outcomes, effectiveness, or efficiency.

Patients experience higher levels of anxiety and depression than the general population [23] though consistent with other contemporaneous cohorts of people who have cancer in the UK [24].

In a review of the literature of clinical trials involving mobile health apps, we found 17 studies of between 12 and 2352 patients [25]. Smartphone apps or internet portals primarily collected data on clinical symptoms or activity data with some improvement in patient-reported outcome measures. The authors found limited evidence for effects on mortality or cancer-related morbidity, including complications and health-economic outcomes. Many studies did not report on app usage. Only a few studies have reported improvements in quality of life [26,27]. App for monitoring pain and linked to the ability to escalate to a clinician might lead to improved symptom control [28]. Recruitment rates of 50% in our study are comparable to other trials in this field [29].

We collected data of indicative health-service usage by reporting days spent in the hospital and appointments with primary care physicians. We observed trends towards increased usage of primary care appointments and decreased usage of hospital days for unscheduled admissions in the younger intervention group.

App usage was high and comparable with other high-quality applications [30]. Patients and their buddies reported satisfaction with the information in the app and its links to health care staff and reported feeling safer with the application. It is difficult to say that patients felt more empowered to reach out to health care staff (or that the app encouraged them to do so), given that the majority of contacts were initiated by nursing staff. At least eight of these contacts received telephone advice, however, and it might be inferred that having easy access to health care staff in this way reduced the burden on primary care services.

Limitations identified in the literature review were addressed by measuring app usage and validated clinical outcome measures and surrogates for health economic measures, albeit in a non-randomized single-center study. Many mobile health apps are designed for single diseases [31-33] or use generic metrics such as physical activity [34], with only a few applications reporting patient outcomes [35]. By using a content management system as the underlying architecture, we enabled agile, modular development for future expansion to rarer complications, tailoring to different cancers, individualized treatment regimes, and patient preferences. While this study was limited in scope to proof-of-concept, it has generated the methodology for larger trials powered to demonstrate improvements in patient-centric outcomes.

The study demonstrates that patients and those close to them can take an active part in a redundant safety system. Technology can facilitate laypersons to undertake some of the safety-critical screening functions that are normally undertaken by nurses based on the UKONS clinical checklists.

Real-time response to alerts would require 24/7 cover of staff who are familiar with diseases and treatment modalities. Scale-up of usage, including utilization for follow-up of patients with cancer, would require limited investment into the soft-ware platform but reliable investment into the teams that support cancer services locally and nationally.

This application may be a useful tool in aiding patients to access early and appropriate acute cancer care. It may also have a role in supporting ambulatory outpatient management of presentations suitable for this model of care.

Future research will have to tease out the effect size in multiple settings. The number of friends and family members forming a safety network for patients may be relevant for the effect-size; several safety partners might support patients better than just a single partner.

Ways to strengthen ownership and activation of patients in future versions of the application might include incentives for usage or link to continuous monitoring with wearable sensors to supplement patient-reported symptoms with quantitative measures of risk [36].

The hypothesis of the checklist application that remains to be tested in larger trials is that usage of electronic checklists tailored to the needs of patients with cancer will improve reliability and timeliness of engagement with their multi-disciplinary team.

We hope to affect patients with cancer positively by first facilitating safer care: complications are, in large part, predictable. Checklists allow patients to be actively involved in the prevention of adverse events. Modular redundancy of safety-critical processes is a key mechanism to provide safe and stable systems in other industries [10]. The usage of checklists by multiple partners should ultimately lead to a testable reduction in preventable adverse outcomes. Lastly, we believe in the value of greater autonomy of patients through participation. Access to safety-critical information in a personalized and context-specific way is key for patient activation [37]. We fully expect that this will also improve resilience to acute complications [38].

CONCLUSIONS

We co-produced a checklist application for smartphones with cancer patients, their friends, and families and demonstrated proof of concept as a networked and scalable safety intervention.

It is feasible to enable patients undergoing treatment for cancer to contribute to their own safety in recognizing complications of cancer and their therapy. To assess the impact on clinical outcomes requires larger randomized trials but utilizing such applications may form a key aspect of future acute cancer care.

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Conflict of Interest

The study was funded by an iGrant from TENOVUS UK. The corresponding author (CPS) was funded in part by an Improvement Science Fellowship from The Health Foundation.

Abbreviations

FACT-G: General version of the Functional Assessment of Cancer Therapy

UKONS: United Kingdom Oncology Nursing Society

REFERENCES

1. Navani V. How has acute oncology improved care for patients? Curr Oncol 2014 Jun;21(3):147-149 [FREE Full text] [CrossRef] [Medline]
2. Cooksley T, Rice T. Emergency oncology: development, current position and future direction in the USA and UK. Support Care Cancer 2017 Jan;25(1):3-7. [CrossRef] [Medline]
3. Cooksley T, Kitlowski E, Haji-Michael P. Effectiveness of Modified Early Warning Score in predicting outcomes in oncology patients. QJM 2012 Nov 01;105(11):1083-1088 [FREE Full text] [CrossRef] [Medline]
4. Hibbard J, Helen G. Supporting people to manage their health: an introduction to patient activation. In: The King's Fund. London: The King's Fund; 2014.
5. Rogerson L, Burr J, Tyson S. The feasibility and acceptability of smart home technology using the Howz system for people with stroke. Disabil Rehabil Assist Technol 2020 Feb;15(2):148-152. [CrossRef] [Medline]
6. Theile G, Klaas V, Tröster G, Guckenberger M. mHealth Technologies for Palliative Care Patients at the Interface of In-Patient to Outpatient Care: Protocol of Feasibility Study Aiming to Early Predict Deterioration of Patient's Health Status. JMIR Res Protoc 2017 Aug 16;6(8):e142 [FREE Full text] [CrossRef] [Medline]
7. Geng Y, Myneni S. Patient Engagement in Cancer Survivorship Care through mHealth: A Consumer-centered Review of Existing Mobile Applications. In: AMIA Annu Symp Proc. Patient Engagement in Cancer Survivorship Care through mHealth: A Consumer-centered Review of Existing Mobile Applications. AMIA . Annu Symp proceedings AMIA Symp. 2015; 2015 Presented at: AMIA 2015 Annual Symposium; Nov. 14-18; San Francisco p. 580-588.
8. Davis SW, Oakley-Girvan I. mHealth Education Applications Along the Cancer Continuum. J Cancer Educ 2015 Jun;30(2):388-394 [FREE Full text] [CrossRef] [Medline]
9. Nasi G, Cucciniello M, Guerrazzi C. The role of mobile technologies in health care processes: the case of cancer supportive care. J Med Internet Res 2015 Feb 12;17(2):e26 [FREE Full text] [CrossRef] [Medline]

10. Wakerly J. Microcomputer reliability improvement using triple-modular redundancy. New York; 1976 Jun Presented at: Proceedings of the IEEE; 1976; New York p. 889-895 URL: https://apps.dtic.mil/dtic/tr/fulltext/u2/a042246.pdf [CrossRef]
11. Subbe CP, Duller B, Bellomo R. Effect of an automated notification system for deteriorating ward patients on clinical outcomes. Crit Care 2017 Mar 14;21(1):52 [FREE Full text] [CrossRef] [Medline]
12. Daniels R, Nutbeam T, McNamara G, Galvin C. The sepsis six and the severe sepsis resuscitation bundle: a prospective observational cohort study. Emerg Med J 2011 Jun;28(6):507-512. [CrossRef] [Medline]
13. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AHS, Dellinger EP, Safe Surgery Saves Lives Study Group. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 2009 Jan 29;360(5):491-499. [CrossRef] [Medline]
14. Arriaga AF, Bader AM, Wong JM, Lipsitz SR, Berry WR, Ziewacz JE, et al. Simulation-based trial of surgical-crisis checklists. N Engl J Med 2013 Jan 17;368(3):246-253. [CrossRef] [Medline]
15. Subbe CP, Kellett J, Barach P, Chaloner C, Cleaver H, Cooksley T, Crisis Checklist Collaborative. Crisis checklists for in-hospital emergencies: expert consensus, simulation testing and recommendations for a template determined by a multi-institutional and multi-disciplinary learning collaborative. BMC Health Serv Res 2017 May 08;17(1):334 [FREE Full text] [CrossRef] [Medline]
16. Oncology/Haematology 24 Hour Triage Rapid Assessment and Access Toolkit. https://www.ukons.org/site/assets/files/1134/oncology_haematology_24_hour_triage.pdf. London: UKONS; 2016. URL: https://www.ukons.org/site/assets/files/1134/oncology_haematology_24_hour_triage.pdf [accessed 2020-09-05]
17. Subbe C. Driving safety and signposting risk - Report to the SHINE programme of the Health Foundation. Bangor. The Health Foundation. London: The Health Foundation; 2015. URL: https://www.health.org.uk/sites/default/files/Betsi%20Cadwaladr%20final%20report_website%20version.pdf [accessed 2020-09-05]

18. United Kingdom Oncology Nursing Society. Oncology/Haematology Treatment Toxicity Risk Assessment Tool For Primary Healthcare Professionals. London. London: UKONS; 2017. URL: https://www.macmillan.org.uk/_images/oncology-treatment-toxicity-risk-assesment-tool_tcm9-317392.pdf [accessed 2020-09-05]
19. Your Cancer Treatment Record. London: Cancer Research UK; 2018. URL: https://publications.cancerresearchuk.org/publication/your-cancer-treatment-record [accessed 2020-09-05]
20. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983 Jun;67(6):361-370. [CrossRef] [Medline]
21. Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, et al. The Functional Assessment of Cancer Therapy scale: development and validation of the general measure. J Clin Oncol 1993 Mar;11(3):570-579. [CrossRef] [Medline]
22. Breeman S, Cotton S, Fielding S, Jones GT. Normative data for the Hospital Anxiety and Depression Scale. Qual Life Res 2015 Feb;24(2):391-398. [CrossRef] [Medline]
23. Global Mobile Market Report 2019 - Light Version. Newzoo.com.: newzoo; 2019. URL: https://resources.newzoo.com/hubfs/Reports/2019_Free_Global_Mobile_Market_Report.pdf [accessed 2020-09-05]
24. Lindner OC, McCabe MG, Boele F, Mayes A, Talmi D, Radford J, et al. Discussing factors associated with quality of life in cancer follow-up appointments: a preliminary test of a pragmatic model for clinical practice. Clin Rehabil 2019 Apr;33(4):762-772. [CrossRef] [Medline]
25. Osborn J, Ajakaiye A, Cooksley T, Subbe CP. Do mHealth applications improve clinical outcomes of patients with cancer? A critical appraisal of the peer-reviewed literature. Support Care Cancer 2020 Mar;28(3):1469-1479 [FREE Full text] [CrossRef] [Medline]
26. Rincon E, Monteiro-Guerra F, Rivera-Romero O, Dorronzoro-Zubiete E, Sanchez-Bocanegra CL, Gabarron E. Mobile Phone Apps for Quality of Life and Well-Being Assessment in Breast and Prostate Cancer Patients: Systematic Review. JMIR Mhealth Uhealth 2017 Dec 04;5(12):e187 [FREE Full text] [CrossRef] [Medline]
27. Fjell M, Langius-Eklöf A, Nilsson M, Wengström Y, Sundberg K. Reduced symptom burden with the support of an interactive app during neoadjuvant chemotherapy for

breast cancer - A randomized controlled trial. Breast 2020 Jun;51:85-93 [FREE Full text] [CrossRef] [Medline]

28. Zheng C, Chen X, Weng L, Guo L, Xu H, Lin M, et al. Benefits of Mobile Apps for Cancer Pain Management: Systematic Review. JMIR Mhealth Uhealth 2020 Jan 23;8(1):e17055 [FREE Full text] [CrossRef] [Medline]
29. Gustavell T, Sundberg K, Langius-Eklöf A. Using an Interactive App for Symptom Reporting and Management Following Pancreatic Cancer Surgery to Facilitate Person-Centered Care: Descriptive Study. JMIR Mhealth Uhealth 2020 Jun 17;8(6):e17855 [FREE Full text] [CrossRef] [Medline]
30. Langius-Eklöf A, Christiansen M, Lindström V, Blomberg K, Hälleberg Nyman M, Wengström Y, et al. Adherence to Report and Patient Perception of an Interactive App for Managing Symptoms During Radiotherapy for Prostate Cancer: Descriptive Study of Logged and Interview Data. JMIR Cancer 2017 Oct 31;3(2):e18 [FREE Full text] [CrossRef] [Medline]
31. Denis F, Viger L, Charron A, Voog E, Dupuis O, Pointreau Y, et al. Detection of lung cancer relapse using self-reported symptoms transmitted via an internet web-application: pilot study of the sentinel follow-up. Support Care Cancer 2014 Jun;22(6):1467-1473. [CrossRef] [Medline]
32. Rosen KD, Paniagua SM, Kazanis W, Jones S, Potter JS. Quality of life among women diagnosed with breast Cancer: A randomized waitlist controlled trial of commercially available mobile app-delivered mindfulness training. Psychooncology 2018 Aug;27(8):2023-2030. [CrossRef] [Medline]
33. Golsteijn RHJ, Bolman C, Volders E, Peels DA, de Vries H, Lechner L. Short-term efficacy of a computer-tailored physical activity intervention for prostate and colorectal cancer patients and survivors: a randomized controlled trial. Int J Behav Nutr Phys Act 2018 Oct 30;15(1):106 [FREE Full text] [CrossRef] [Medline]
34. Kanera IM, Willems RA, Bolman CAW, Mesters I, Verboon P, Lechner L. Long-term effects of a web-based cancer aftercare intervention on moderate physical activity and vegetable consumption among early cancer survivors: a randomized controlled trial. Int J Behav Nutr Phys Act 2017 Feb 10;14(1):19 [FREE Full text] [CrossRef] [Medline]

35. Warrington L, Absolom K, Conner M, Kellar I, Clayton B, Ayres M, et al. Electronic Systems for Patients to Report and Manage Side Effects of Cancer Treatment: Systematic Review. J Med Internet Res 2019 Jan 24;21(1):e10875 [FREE Full text] [CrossRef] [Medline]
36. Liao Y, Thompson C, Peterson S, Mandrola J, Beg MS. The Future of Wearable Technologies and Remote Monitoring in Health Care. Am Soc Clin Oncol Educ Book 2019 Jan;39:115-121 [FREE Full text] [CrossRef] [Medline]
37. Prey JE, Woollen J, Wilcox L, Sackeim AD, Hripcsak G, Bakken S, et al. Patient engagement in the inpatient setting: a systematic review. J Am Med Inform Assoc 2014;21(4):742-750. [CrossRef] [Medline]
38. Bradley-Roberts E, Subbe C. Role of Psychological Resilience on Health-Outcomes in Hospitalized Patients with Acute Illness: A Scoping Review. Acute Med 2017;16(1):10-15. [Medline]

4.7 Paper 7: Express Check-In: Developing a Personal Health Record for Patients Admitted to Hospital with Medical Emergencies – A Mixed Method Feasibility Study

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Authors

Christian P Subbe, DM, FRCP PGCert Medical Education, Ysbyty Gwynedd, Bangor and Senior Clinical Lecturer, School of Medical Sciences, Bangor University, Bangor LL57 2DG, UK; c.subbe@bangor.ac.uk

Hawys Tomos, Helen Hamlyn Centre for Design at the Royal College of Art - Howie St, Battersea, London SW11 4AY; hawys.tomos@network.rca.ac.uk

Gwenlli Mai Jones, Cardiff University & Ysbyty Gwynedd, Bangor, Penrhosgarnedd, Bangor LL57 2PW, gwenllimai@hotmail.co.uk, jonesgm14@cardiff.ac.uk

Paul Barach, Clinical Professor; Children's Hospital of Michigan, Wayne State University School of Medicine, 3901 Beaubien Blvd, Detroit, MI 48201, USA; pbarach@gmail.com

ABSTRACT

Background

Patient participation is increasingly recognized as a key component in the redesign of health care processes and is advocated as a means to improve patient safety. We explored the usage of participatory engagement in patient-created and co-designed medical records for emergency admission to hospital.

Methods

Design: Prospective iterative development and feasibility testing of personal health records.

Setting: An Acute Medical Unit in a University affiliated hospital.

Participants: Patients admitted to hospital for medical emergencies.

Interventions: We used a design-led development of personal health record prototypes and feasibility testing of records completed by patients during the process of emergency admission. 'Express-check-in' records contained items of social history, screening questions for sepsis and acute kidney injury, in addition to the patients' ideas, concerns and expectations.

Main outcomes measures: The outcome metrics focused on feasibility and a selection of quality-domains: Effectiveness of recording relevant history, time-efficiency of documentation process, patient centredness of resulting records, staff and patient feedback. The incidence of sepsis and acute kidney injury were used as surrogate measures for assessing the safety impact.

Results

The medical record prototypes were developed in an iterative fashion and tested with 100 patients in which 39 patients were 70 or older, and 25 patients were classified as

clinically frail. 96% of the data items were completed by patients with no or minimal help from healthcare professionals. The completeness of these patient records was superior to that of the corresponding medical records in that they contained deeply held beliefs and fears, whereas concerns and expectations recorded by patients were only mirrored in a small proportion of the formal clinical records. The sepsis self-screening tool identified 68% of patients requiring treatment with antibiotics. The intervention was feasible independent of the level of formal education and effective in frail and elderly patients with support from family and staff. The prototyped records were well received and felt to be practical by patients and staff. The staff indicated that reading the patients' documentation led to significant changes in their clinical management.

Conclusions

Medical record accessibility to patients during hospital care contributes to the co-management of personal health care and might add critical information over and above the records compiled by healthcare professionals.

Keywords

Emergency admission, personal health record, co-production, patient-centred

INTRODUCTION

Policy makers have expressed the belief that health care needs to shift from a model where the patient is seen as a passive spectator in his or her own healing process, to a participatory model in which Personal Health Records (PHRs) could empower patients while making health care professionals more aware of the underlying patients safety risks(1).

The admission process to hospital is a key, anxiety provoking moment in the patient's journey and a focus of intense training for medical and nursing trainees. Documentation is exclusively done by healthcare staff and comes at a measurable expense of working time(2).

PHRs promote meaningful engagement and might improve key aspects of care (3). PHRs have been used in primary care and long-term disease management but evidence for hospital usage remains limited and knowledge about the safety impact of PHRs is largely confined to medication safety(4). Previous work by our group demonstrated that patients are able to participate in their own safety management in acute care settings even while admitted for emergency treatment in hospital(5).

We report the results from the Express-Check-in patient engagement project aimed at developing and testing novel documentation formats to support patient contribution to their own health records during emergency hospital admissions. In particular we aimed to

1. determine the feasibility of patients contributing to their health records in this setting.
2. measure patient satisfaction, and
3. record the healthcare worker's impressions on the value of patient contributions to the work of health care workers.

METHODS

Study Design and Settings

We conducted a prospective mixed-method study in the Acute Medical Unit (AMU) of a university-affiliated District General Hospital in Wales, UK. AMUs receive patients with medical emergencies who are referred to hospital either directly from General Practitioners or after self-presentation to the Emergency Department to establish an underlying condition, initiate treatment where required and monitor patient progress. Severity of illness of attending patients is variable with 5 to 10% suffering from a potentially life-threatening condition (6,7). The study AMU consisted of an assessment area with 5 trolleys, an ambulatory care area with 3 trolleys and a bedded area with 23 beds.

Participants

Inclusion criteria: Adult patients aged 18 years or older referred to the AMU for assessment due to a medical emergency from General Practice. Patients who were critically ill as indicated by a value of the National Early Warning Score (NEWS) of more than 6 and patients receiving end-of-life care were excluded.

Development of the intervention

Prototype Development

The Personal Health Record prototype was developed and tested through an iterative design process involving ethnographic observations and a series of workshops over a 12-months period (Figure 1).

a. *A residential two-day workshop* was held at the Pontio Innovation Lab(8) at Bangor University in 2018. The workshop was facilitated by a team trained improvement science and human-centred design. The workshop included equal participation from clinicians and patient representatives. The workshop identified transfer of information

between patients and clinicians as a uniquely problematic design challenge and suggested potential interventions including a personal health 'passport' containing safety-critical information. The proceedings from the workshop have been submitted for publication elsewhere (under review and available upon request).

b. *Ethnographic observations* (9,10) were conducted over a five day period in March 2019 and focused on patients' experiences in the AMU. Four researchers (MD, BE, BJ, BS) used predominantly a 'fly-on-the-wall' technique'(11) by passively observing patients and staff. Direct observation discerned that communication between patients and clinical teams tended to commonly be a one-way process ("talking at the patient") or task-based ("your test is at 10:00"). In the presence of medical staff very few patients were seen to ask questions or talk about things that worried them. The observers noted that patients spent extensive time waiting and preparing to be seen by their medical team and that this period of time constituted a potential opportunity for patients to actively contribute to their care by documenting their concerns and questions. Confirmative interviews were conducted with patients, doctors and nurses. The observations and reflections were collated daily in a semi-structured debriefing with one of the authors (CPS).

c. *Development of prototype:* This information was utilised during rapid-design workshops, facilitated by faculty trained in human-centred design (HT) to ideate and develop concepts.

d. Concepts were prototyped by the team and subsequently iterated and pilot tested on a group of patients.

e. The improved proto-type was used for the feasibility testing.

f. The final iteration of the Personal Health Record was implemented into clinical practice (Appendix 1).

The Intervention

The study intervention was informed by recommendations about data fields of UK clinical records from the Royal College of Physicians Health informatics Unit(12). The product was cross-referenced with data items collected from existing clinical documentation and good practice for consultation including with questions about the patient's condition, social history, ideas about the nature of their admission, concerns about their health and hospital stay and expectations(13). The social history was identified as an area of high importance for care planning(14).

Items related to sepsis and acute kidney injury were included as surrogates for potential safety impact: The sepsis screening questions were developed in a previous study(15) as indicative of sepsis: *'Do you think you have an infection?*' and '*In the past week, have you experienced any fever, chills or abnormal sweating?'.* A coloured and numbered chart based on the NHS Wales KidneySafeBracelet (5) (Figure 2) was used to identify potential acute kidney injury: numbers 1 to 3 correspond to more dilute urine and numbers 4 to 6 represent more concentrated urine. The number 7 is red, indicating haematuria. Data items readily available from other sources were excluded (previous medical history from primary care record, medication history from electronic record, vital signs from care records).

Feasibility testing of the intervention

A convenience sample of patients presenting to the AMU during office hours was recruited. The patient participants were screened after an initial assessment by a triaging nurse. The patients were given information sheets about the study and all study subjects gave written consent. The patients filled out their study records, and these were filed with their clinical records. The patient participants were followed up in the hospital on the day after

recruitment for interventions related to sepsis (antibiotic prescription) and acute kidney injury (intravenous fluid prescription).

Study of the Intervention

We conducted iterative testing of the intervention during two, four-week periods in March/April and May/June 2019. The results of the intervention were compared to the documentation in clinical records by healthcare professionals. No formal sample size calculation or assessment of bias were undertaken.

Measurement

The intervention was assessed using validated metrics of quality(16) including effectiveness, efficiency, patient satisfaction and staff satisfaction, and defined as follows:

i. **Effectiveness of the intervention:** '*Are patients able to complete the records?'* For the purpose of the study, the patients were assessed at time of their presentation. Relatives, friends, formal or informal carers with the patient were permitted to assist patients in completing their medical records. Additionally the response to patient reported indicators of sepsis and acute kidney injury was reviewed.

ii. **Efficiency**: The duration of time required to complete the record was measured in a convenience sample of the patients recruited.

iii. **Patient-centredness**: Patient documented their ideas, concerns and expectations in relation to the care episode. Clinical records by medical staff including the documentation of the admitting doctor and the first encounter with the admitting consultant were screened manually for any evidence that ideas, concerns and expectations of patients were referenced and addressed during the subsequent clinical encounters.

iv. **Patient satisfaction**: The feedback from patients was collected within 24 hours of completion of the record using five tailored statements related to the experience of

completing records, a comparison to past experience of the admission process and views on future preferences. The replies were graded with 5-point Likert scales ranging from 'strongly agree' to 'strongly disagree.' (Appendix 2)

v. **Staff satisfaction**: Feedback from staff was collected through a bespoke survey on the acceptability and usability of the patient record (Appendix 3). The staff were interviewed within 24 hours of completion of the record and asked to rate the unique value of the patient documentation on a scale from 1 to 10 and to confirm their awareness of patient concerns. The staff feedback forms were linked to specific patient participant numbers in order to assess potential association with patient characteristics.

Data Analysis

Qualitative and quantitative data were collected and analysed. The differences between groups were assessed using independent T-testing for normally distributed variables and Mann-Whitney U tests were used for non-normally distributed variables. Chi-square or Fisher's exact test were used for the categorical variables. Analyses were performed using SPSS software (SPSS version 22.0, IBM, Armonk, NY, USA). P-values of less than 0.05 were as regarded as significant.

Sub-group analysis were performed in order to understand the variation within the data: The patient-participants were characterized by age, gender, level of formal educational, frailty using the Clinical Frailty Scale(17), severity of acute illness using the National Early Warning Score (NEWS) (18) and whether they presented alone in order to understand the contextual elements that might contribute to the success, failure and cost of their care.

The Completeness of data was calculated as a percentage of data entry fields completed by patient participants. The accuracy of data was evaluated through a close comparison with nursing and medical records.

The qualitative data was used to inform our deeper understanding about patient and staff communication, acceptance of the intervention, and any feedback about the medical record design and effectiveness but was not formally analysed.

Ethical considerations

The ethics approval was granted for this study by the Research Ethics Committee, Bangor [18/WA/0110]. None of the authors reported conflicts of interest in relation to the study.

The reporting followed the revised Standards for Quality Improvement Reporting Excellence (Squire 2.0)(19).

RESULTS

Recruitment

A total of 162 patients were screened and 100 patients were included for further analysis during two two-week periods in 2019. Of the patients screened 27 were excluded based on criteria stated above, and 30 declined due to feeling unwell, tiredness, concern of not understanding the questions, inability to write due to hand pain, inability to see the questions due to poor eyesight or lack of interest; 5 patients were lost to follow-up.

Participants

The characteristics of the patient population are summarized (Table 1). Thirty-nine patients were 70 years old or older, 25 patients were classified as frail and 33 patients needed assistance from a partner or family member to complete the questionnaire. Of the 25 patients who were classified as frail, 18 had limited formal education ($p<0.000$), 10 required help with a walking aid ($p<0.000$) and 20 (80%) received help completing the questionnaire.

Measures of Quality

i. Effectiveness

The completeness of record documentation for social history and warning signs for acute kidney injury and sepsis were assessed.

Social history: The rate of completion for data items of the social history by patients was 96% (SD 6%) and all but 5 patients completed more than 90%. Completion rate was not affected by the level of frailty, severity of illness or educational status (Chi-Square test n.s.). The rate of completion by admitting doctors was 59% (SD 23%) and was much lower than patient record completions (Wilcoxon Signed Ranks-test ($p<0.000$)).

Screening for sepsis and Acute Kidney Injury: 96 patients completed the sepsis self-screen questionnaire. 31 patients received antibiotics. Each affirmative answer to the two screening questions was scored with one point: A high proportion of patients who subsequently received antibiotics scored two points on the self-screen i.e. 21 of 25 (84%) who scored two, 7 of 22 (32%) who scored one and 2 of 49 (4%) who scored zero points (Chi-Square test $p<000$). A score of two points identified 68% of patients requiring treatment with antibiotic. No differences were noted in the number of patients receiving intravenous fluids. Ninety-four patients completed the Acute Kidney Injury self-screening question: The 28 patients with concentrated urine (4 or above on a scale from 0 to 9) were more likely to receive intravenous fluid (12 patients, $p<0.005$) but not more likely to be diagnosed with Acute Kidney Injury (4 patients, $p=.83$) than those patients with more dilute urine.

ii. Efficiency

The time required to complete the records was measured in a sample of 53 patients. The completion took a mean of 7 minutes (standard deviation 3.5 minutes). There was no

differences in the times taken between patients who were frail and those who were not frail (p=.92) and between patients who received help and those who completed the questionnaire on their own (p=.48).

iii. Patient centredness

Seventy-five patients documented ideas about their health condition, 72 recorded concerns and 85 specified expectations they wanted met (Table 2: sample quotations). Of ideas expressed by patients, 65% matched those documented by doctors as part of their differential-diagnosis. In only 12 of the 75 patients, were the documented patient concerns explicitly addressed subsequently in the medical or nursing records.

iv. Patient Satisfaction

A total of 41 feedback-cards were collected from patients, 14 of these patients were frail. To the question '*I enjoyed writing in my hospital notes'* 38 (93%) agreed or strongly agreed. 28 patients (68%) agreed or strongly agreed that they would like to contribute more to their hospital documentation. When asked to compare their experience to their experience of a previous hospitalization, where applicable, 23 patients (64%) preferred to contribute to their documents. Preferences were unrelated to degree of frailty (p=.217; Chi-square test).

Patients commented on the level of effort required to complete the record: "*That was easy enough", "It gives me something to do whilst I wait".* Patients appreciated the opportunity to document their views but were worried about adverse consequences of omitting important features:

"If I'm being honest, I like the idea, and thank you for inviting us to help, but I get forgetful. I'm scared that I'll forget to write important medical information. I don't know what's important to write down and what's not".

v. Staff Satisfaction

Twenty-four staff feedback forms were collected: 10 from nurses, 10 from doctors, three from senior medical students and one by another member of the clinical team. Eleven cards (46%) related to frail patients: Twenty staff (83%) rated the value of patient documentation for their work 6 or higher on the 10-point rating scale. The rating was unrelated to professional group. Staff were only partially aware or totally unaware of concerns of 9/11 (82%) frail patients and 3/13 (23%) of non-frail patients. The staff indicated that reading the patient's documentation led to a significant change in their clinical management (8 patients) or partial change in patient management (10 patients). Medical staff commented that "*this makes patients more engaged*". Another doctor stated that "*I would be more likely to look in this rather than the nursing notes, because I can never find anything in the nursing notes!"*.

DISCUSSION

Statement of principal findings

We demonstrated that records can be competently completed by a significant proportion of patients even in emergency settings, including frail patients when supported by carers assisting them, and that these add significant value to clinical decision making as assessed by physicians and nurses. Completion rates for the social history were higher for patients than for clinicians. The use of patient generated medical records was related to several dimensions of quality: it was time-efficient for patients and patients and staff widely praised the study records acceptability.

Strength and limitations

Our study has significant limitations: First, the present study has the inherent challenges of being conducted in a single centre. From the experience of the authors of

working in over 30 hospitals on four continents if would appear that the processes that we observed might still be representative of the ways that patients are assessed on admission to hospital in many settings both in the United Kingdom and further afield. Our iterative approach could hence be applied in comparable settings. Second, patients with serious physiological instability and those receiving end of -life-care were excluded because of concerns about the validity of the consent process in this patient population. It is possible that a proportion of these excluded patients and/or their carers might have been able to contribute to their care. Third, it is perceivable that paper documentation might have been more suitable for our comparatively elderly patient cohort who might have struggled with digital technology(20). Integration of patient generated records into an existing documentation system or indeed an electronic health record was not tested in this study but was in a subsequent study(21). Finally, we did not formally assess the cost of implementing our intervention.

Interpretation within the context of the wider literature

The discrepancy between ideas, concerns and expectations voiced by patients and the lack of their documentation in clinical records is concerning. While a patient-centric approach is advocated in training guidelines and by policy makers, it is not consistent with the way healthcare systems including medical documentation systems are set up. Key patient social information, which can impact patient's needs, is all too often as documented in our study, unidentified, undocumented and overlooked by clinicians (22,23).

Several studies have compared the completeness of the history obtained by patient-completed documentation as compared with healthcare professional entries into medical notes in primary care(24), orthopaedic surgery outpatients(25), emergency medicine(26) and surgical emergency admissions presenting with a single symptom (abdominal pain)(27). Hershey(24) and Boissonnault(25) found that less complex and closed questions improved

completion rates and accuracy of patient-completed documents. Renggli(26) and Saravanan(27) reported, similar findings to our study, in which patients completed their relevant items at a much higher rate of completion then that completed by their healthcare professionals.

Implications for policy, practice and research

The cost of documentation in clinical care is determined by the cost of the recording system(28) and the time for data entry and retrieval as well as changes to work-efficiency by having access to the right information in the right place at the right time(29). Documentation consumes a quarter of the working time of nurses and doctors (2) and constitutes up to 40% of working time required for the admission of new patients(2,30): Implementing self-documentation by patients represents a major opportunity for redesign of clinical workflows and could serve the dual purpose of reducing workload of health care staff, whilst promoting better patient engagement and safety. The establishment of Express-check-in and Express-check-out facilities in hotels and airports served as inspiration for this project and is reflected in its name. We appreciate that the effects of transferring tasks from staff to patients might affect their relationship and work satisfaction of staff and this requires further research.

Conclusions

Personal Health Records are increasingly used in primary care and chronic disease programs. A comparable approach appears achievable and inevitable for documentation during emergency hospital admission. We demonstrated the feasibility, efficiency and efficacy of a patient-delivered record and its potential to contribute to patient-centred hospital documentation. The evidence for impact on clinical outcomes will require larger studies. We demonstrated improved completeness of records even in patients who were frail, elderly, or had limited formal education.

Further investigation is required to measure the impact of the approach on safety outcomes and formal measures of work-flow and health economics as part of an integrated health record systems study.

Contributorship

CPS and PB conceived the concept for this study. HT, GJ, MD, BE, BJ and BS developed the intervention around principles of human centred design, GJ, MD, BE, BJ and BS collected the data and undertook the primary analysis. CPS and PB wrote the initial manuscript and undertook further analysis. All authors contributed to further versions of the manuscript and approved the final version.

Ethics and other permissions

The ethics approval was granted for this study by the Research Ethics Committee, Bangor [18/WA/0110].

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Conflict of interests

None of the authors reports any conflict of interest in relation to this manuscript.

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Data availability statement

The data underlying this article cannot be shared publicly due to reasons of the privacy of individuals that participated in the study. The data will be shared on reasonable request to the corresponding author.

REFERENCES

1. Emanuel EJ, Emanuel LL. Four Models of the Physician-Patient Relationship. JAMA J Am Med Assoc. 1992 Apr 22;267(16):2221–6.

2. Sabin J, Khan W, Subbe CP, Franklin M, Abulela I, Khan A, et al. 'The time it takes... How doctors spend their time admitting a patient during the acute medical take. Clin Med (Northfield Il). 2016 Aug 1;16(4):320–4.

3. Wyatt J, Sathanandam S, Rastall P, Hoogewerf J, Wooldridge D. Personal health record (PHR) - landscape review | RCP London. 2016.

4. Kelly MM, Coller RJ, Hoonakker PLT. Inpatient portals for hospitalized patients and caregivers: A systematic review. Vol. 13, Journal of Hospital Medicine. Society of hospital medicine; 2018. p. 405–12.

5. Use of traffic icons to guide the behaviour of health care staff, patients and carers at the bedside | The Health Foundation [Internet]. [cited 2021 Jun 4]. Available from: https://www.health.org.uk/improvement-projects/use-of-traffic-icons-to-guide-the-behaviour-of-health-care-staff-patients-and

6. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Heal Care. 2008 Jun 1;17(3):216–23.

7. Holland M, Subbe C, Atkin C, Knight T, Cooksley T, Lasserson D. Society for Acute Medicine Benchmarking Audit 2019 (SAMBA19): Trends in Acute Medical Care. Acute Med. 2020;19(4):209–19.

8. About Pontio Innovation | Bangor University [Internet]. [cited 2021 Feb 26]. Available from: https://www.bangor.ac.uk/about/pontio-innovation

9. Launer J. Patients as ethnographers. Vol. 93, Postgraduate Medical Journal. BMJ Publishing Group; 2017. p. 371–2.

10. Daker-White G, Hays R, McSharry J, Giles S, Cheraghi-Sohi S, Rhodes P, et al. Blame the patient, blame the doctor or blame the system? A meta-synthesis of qualitative studies of patient safety in primary care. PLoS One. 2015;10(8):1–42.

11. Fly on the Wall in User Research | Think Design [Internet]. [cited 2021 Jun 3]. Available from: https://think.design/user-design-research/fly-on-the-wall/

12. Carpenter I, Ram MB, Croft GP, Williams JG. Medical records and record-keeping standards. Vol. 7, Clinical Medicine, Journal of the Royal College of Physicians of London. Royal College of Physicians; 2007. p. 328–31.

13. Matthys J, Elwyn G, Van Nuland M, Van Maele G, De Sutter A, De Meyere M, et al. Patients' ideas, concerns, and expectations (ICE) in general practice: Impact on prescribing. Br J Gen Pract. 2009 Jan;59(558):29–36.

14. Behforouz HL, Drain PK, Rhatigan JJ. Rethinking the social history. N Engl J Med. 2014 Oct 2;371(14):1277–9.

15. Willis S, Rual E, Subbe CP. Express Self Check-In for patients with Sepsis. In: 14th International Conference on Medical Emergency Teams and Rapid Response Systems. Manchester; 2018.

16. IOM. Crossing the Quality Chasm: A New Health System for the 21st Century - Institute of Medicine. Institute of Medicine. 2001.

17. Rockwood K, Song X, MacKnight C, Bergman H, Hogan DB, McDowell I, et al. A global clinical measure of fitness and frailty in elderly people. CMAJ. 2005;173(5):489–95.

18. Jones M. NEWSDIG: The national early warning score development and implementation group. Vol. 12, Clinical Medicine, Journal of the Royal College of Physicians of London. 2012. p. 501–3.

19. Ogrinc G, Davies L, Goodman D, Batalden P, Davidoff F, Stevens D. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): Revised publication guidelines from a detailed consensus process. BMJ Qual Saf. 2016 Dec 1;25(12):986–92.

20. Alvarez-Galvez J, Salinas-Perez JA, Montagni I, Salvador-Carulla L. The persistence of digital divides in the use of health information: a comparative study in 28 European countries. Int J Public Health. 2020 Apr 1;65(3):325–33.

21. Subbe CP, Pearson N, Wischhusen S, Hibbs R, Wright S, Xenou M. Scenario-based design for a hospital setting: An exploratory study of opportunities and barriers for personal health records usage. Futur Healthc J. 2020 Jun 15;7(2):125–30.

22. Srivastava R. Complicated lives - Taking the social history. Vol. 365, New England Journal of Medicine. Massachussetts Medical Society; 2011. p. 587–9.

23. Daly C, Callanan I, Butler M. Safety comes first: Are doctors attentive enough to their initial clinical assessment notes? Ir Med J. 2013 Dec;106(10):316–8.

24. Hershey CO, Grant BJB. Controlled trial of a patient-completed history questionnaire: Effects on quality of documentation and patient and physician satisfaction. Am J Med Qual. 2002 Jul;17(4):126–33.

25. Boissonnault W, Badke M. Collecting Health History Information: The Accuracy of a Patient Self-administered Questionnaire in an Orthopedic Outpatient Setting. Phy

Ther. 2005 Jun;85(6):531–43.

26. Renggli JF, Eken C, Siegrist V, Ortega RN, Nickel C, Rosin C, et al. Usability of a Web-based Software Tool for History Taking in the Emergency Department. Acute Med. 2020;19(3):131–7.

27. Saravanan B, Muhammad R, Geach R, Jenkinson LR. Comparison of the history obtained by patient-completed questionnaires with doctors' standard notes for patients with acute abdominal pain. Postgrad Med J. 2009;85(1010):634–6.

28. Menachemi N, Brooks RG. Reviewing the benefits and costs of electronic health records and associated patient safety technologies. Vol. 30, Journal of Medical Systems. J Med Syst; 2006. p. 159–68.

29. NHS Improvement. Resources to support the safe adoption of the revised National Early Warning Score (NEWS2). 2018.

30. Sabin J, Subbe CP, Vaughan L, Dowdle R. Safety in numbers: Lack of evidence to indicate the number of physicians needed to provide safe acute medical care. Clin Med J R Coll Physicians London. 2014;14(5):462–7.

Table 1: Characteristics of Patient Participants (n=100)

Category	**Median / N**
Age (years)	Median age 60 years (IQR 40-70)
Gender	53 female, 47 male
Frailty as measured by the Clinical Frailty Scale (CFS)	Median CFS 3 (‘managing well’) (IQR 2-5)
Use of a walking aid or help required with walking	16 patients
Educational status General Certificate of Secondary Education or equivalent A-levels or equivalent No educational qualification	 41 patients 55 patients 4 patients
National Early Warning Score on admission	Median score 1 (IQR 0-2)

IQR: Interquartile range

Table 2: Quotes from the Patient Recorded Documentation

I. **Do have any ideas about what's causing your current symptoms? If so, what are they?**
"Bleed in gut. Black stools." *(Medical diagnosis: Upper gastro-intestinal bleed)*
"Self-inflicted stupidity - drugs." (Medical diagnosis: Groin abscess after drug injection)
"Fluid on the lung or chest infection." (Medical diagnosis: Community acquired pneumonia with pleural effusion)
II. What are your worries or fears currently (if any)?
"To end my life in peace without too much pain."
"That I'll be in a wheelchair forever."
"Taking blood or anything needle-related."
"I've been suffering with panic attacks since the number of infections I get is increasing".
III. Is there anything specifically you were expecting or hoping the hospital staff could do for your during this visit?
"To get mobile again and enjoy life to the full."
"Allocated to a more permanent ward, not moved around."
"Reassurance and help with pain."

Figure 1: A conceptual framework/flow chart provides a visual representation of the iterative development process of the personal health record prototype for usage by patients admitted with medical emergencies. The prototypes were developed during an innovation lab (a) in 2018. Ethnographic observations in March 2019 led to modifications of the prototype with further changes during subsequent Plan-Do-Study-Act (PDSA) cycles, a four-stage rapid cycle improvement model used for improving a process or carrying out change in March/April 2019. Clinical testing (e) was undertaken in April, May and June 2019.

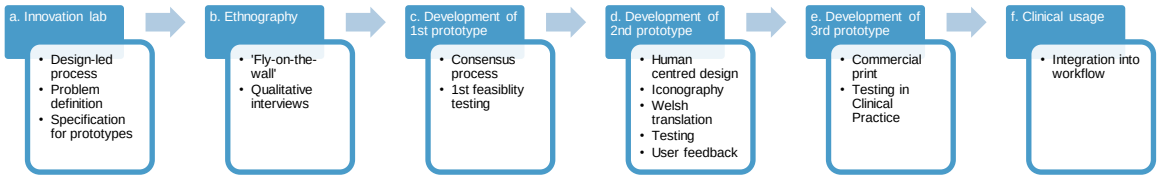


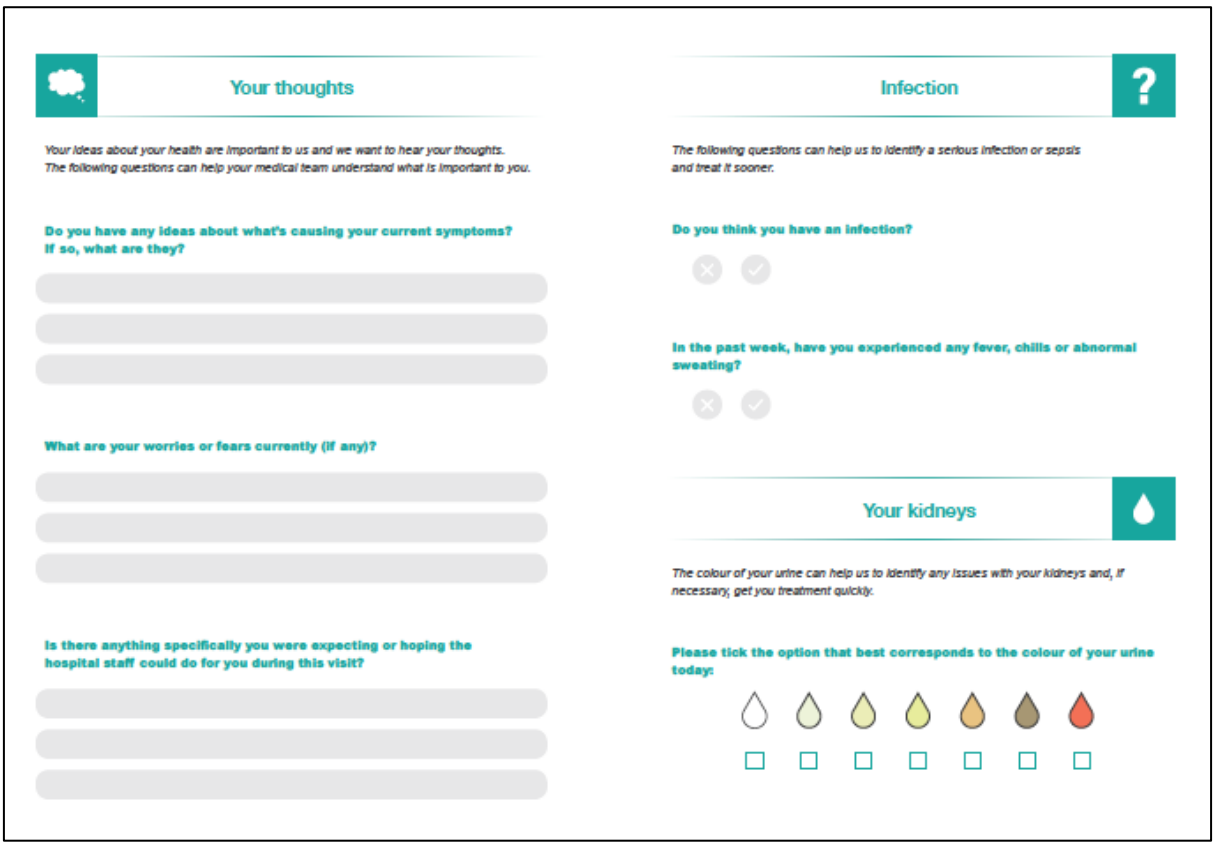
Figure 2

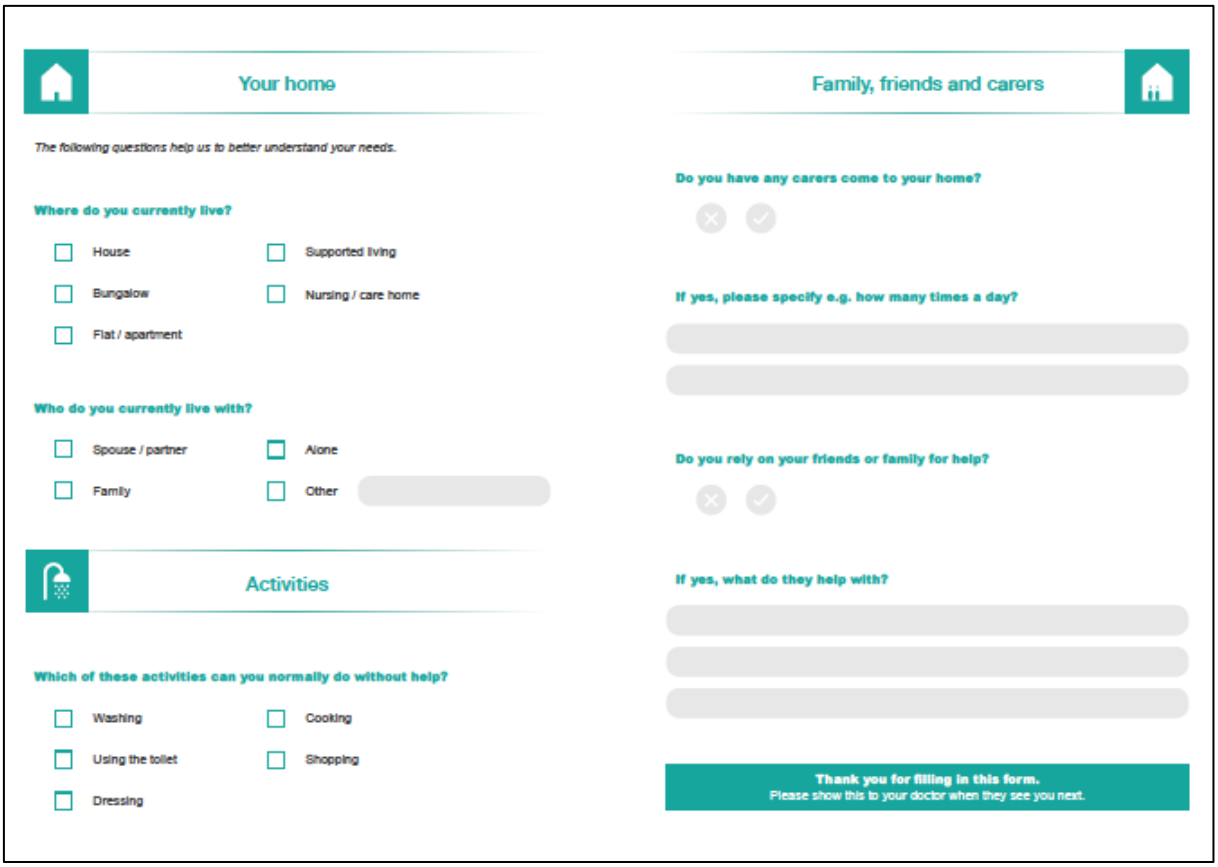
KidneySafeBracelet: patients are requested to inform their clinical team of the colour of their urine as compared to the colours on the bracelet. Bracelets are single patient-use only .

Supplementary material

APPENDIX 1

Sample pages from the EXPRESS-Check-in document. The original is A4 sized. The document was developed in iterative cycles. The sample if from the final version and shows the lay-out and key topics. The use of icons structured the content, and a large font was chosen to help visually impaired patients.





Your home

The following questions help us to better understand your needs.

Where do you currently live?

- ☐ House
- ☐ Bungalow
- ☐ Flat / apartment
- ☐ Supported living
- ☐ Nursing / care home

Who do you currently live with?

- ☐ Spouse / partner
- ☐ Family
- ☐ Alone
- ☐ Other

Activities

Which of these activities can you normally do without help?

- ☐ Washing
- ☐ Using the toilet
- ☐ Dressing
- ☐ Cooking
- ☐ Shopping

Family, friends and carers

Do you have any carers come to your home?

If yes, please specify e.g. how many times a day?

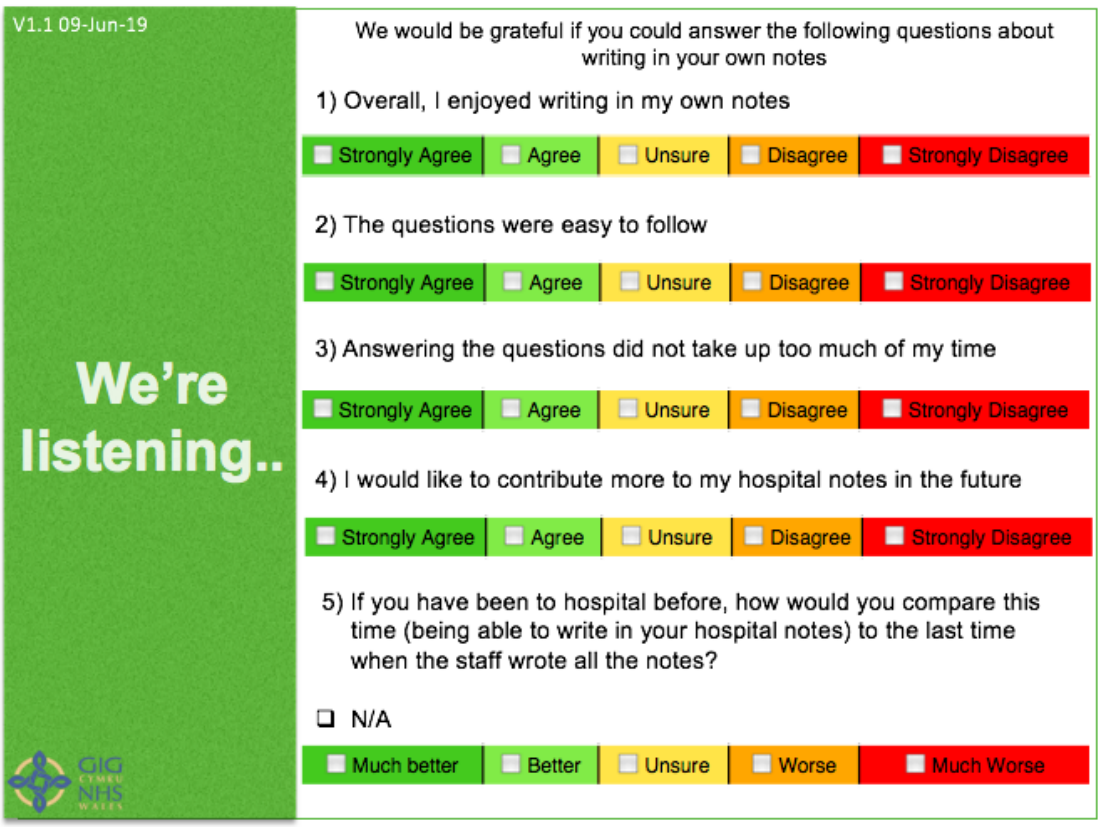
Do you rely on your friends or family for help?

If yes, what do they help with?

Thank you for filling in this form.
Please show this to your doctor when they see you next.

APPENDIX 2

Patient feedback questionnaire. The questionnaire was handed to a sample of patients subsequently to completing their records



V1.1 09-Jun-19

We're listening..

We would be grateful if you could answer the following questions about writing in your own notes

1) Overall, I enjoyed writing in my own notes

☐ Strongly Agree ☐ Agree ☐ Unsure ☐ Disagree ☐ Strongly Disagree

2) The questions were easy to follow

☐ Strongly Agree ☐ Agree ☐ Unsure ☐ Disagree ☐ Strongly Disagree

3) Answering the questions did not take up too much of my time

☐ Strongly Agree ☐ Agree ☐ Unsure ☐ Disagree ☐ Strongly Disagree

4) I would like to contribute more to my hospital notes in the future

☐ Strongly Agree ☐ Agree ☐ Unsure ☐ Disagree ☐ Strongly Disagree

5) If you have been to hospital before, how would you compare this time (being able to write in your hospital notes) to the last time when the staff wrote all the notes?

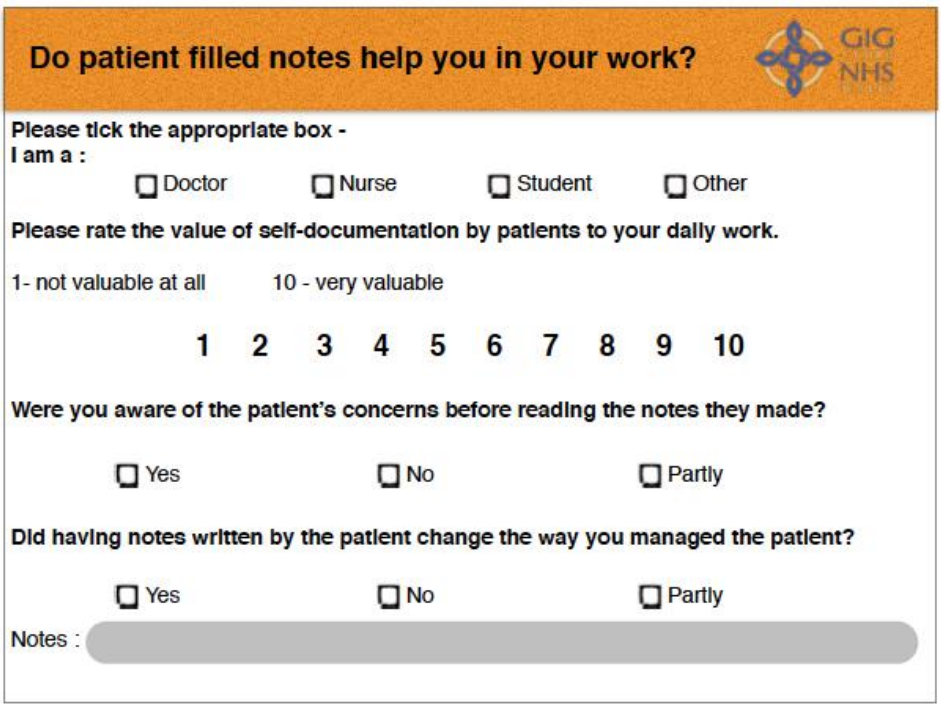
☐ N/A

☐ Much better ☐ Better ☐ Unsure ☐ Worse ☐ Much Worse

GIG CYMRU NHS WALES

APPENDIX 3

Staff feedback survey. The survey was disseminated to staff including doctors and nurses after admission of a patient who had completed a personal health record.



Do patient filled notes help you in your work?

GIG NHS

Please tick the appropriate box -
I am a :

☐ Doctor ☐ Nurse ☐ Student ☐ Other

Please rate the value of self-documentation by patients to your daily work.

1- not valuable at all 10 - very valuable

1 2 3 4 5 6 7 8 9 10

Were you aware of the patient's concerns before reading the notes they made?

☐ Yes ☐ No ☐ Partly

Did having notes written by the patient change the way you managed the patient?

☐ Yes ☐ No ☐ Partly

Notes :

5. Summary of submitted work

In this chapter I will summarize the work that forms part of the submission and outline the key learnings.

5.1. Digital Healthcare as an enabler of patients' safety: Scoping reviews

Electronic platforms are a key enabler of scalable interventions to facilitate safer care. To understand the electronic landscape, I conducted the following literature reviews:

(i) Safety Electronic health records

Zegers and colleagues have created a framework for interventions to reduce adverse events in hospital (Zegers *et al.*, 2016). By undertaking a systematic review of systematic reviews, they identified 14 themes in hospital safety. Their published search algorithm was applied to studies examining the implementation of Electronic Health Records (EHRs) (Subbe, Tellier and Barach, 2021). Given that EHRs are multi-million-pound investments it is surprising how few observational or interventional studies have been published by health service researchers or indeed EHR companies. The few identified studies showed clear benefit through a reduction of prescribing errors. Other possible effects were not examined. The literature search was supplemented by a targeted search using names of leading brands of EHRs, showing again no convincing evidence that the investment into EHRs translates into measurable changes in patient outcomes. The absence of evidence for effectiveness is not necessarily an absence of effectiveness. It would however be unusual that companies would hold back data on improved outcomes if they would be available.

The published scoping review of electronic records was supplemented by two further reviews of the literature not included in this submission: an unpublished search of the literature on Personal Health Records (PHRs) and a published review of use of wearable sensors in urgent and emergency care: PHR are a specific application of EHRs which can be used in hospital or at home. I discovered limited evidence that safety impact had been measured for patients admitted to hospital. My findings were mirrored in a

contemporaneous published review of the same topic (Kelly, Coller and Hoonakker, 2018).

Deterioration of patients in hospital is often predicted by changes in vital signs (Subbe *et al.*, 2001). Many patients now own smart-watches or other devices that are able to measure vital signs at home. I led a scoping review of the literature on use of wearables in urgent and emergency care. Despite the recent explosion in the number of wearable sensors in the consumer and medical market I found little evidence that data from devices has been used to improve safety of patients in the community or during assessments in urgent and emergency care (Hamza *et al.*, 2021).

(ii) Patients suffering with cancer are a subgroup of patients that might be worth of special attention a case-study for the examination of safety incidents: Patients receive powerful treatments with chemotherapy, radiotherapy, immune-therapy or other treatments which have well described side effects that occur at often predictable times after treatment. I therefore led a critical appraisal of mHealth applications with a specific view of effects on a range of clinical outcomes including adverse events (Osborn *et al.*, 2020). The review found that mHealth applications did focus predominantly on education and wellbeing of patients with limited evidence for design of trials that would impact on dimensions of the tipple aim (*The IHI Triple Aim | IHI - Institute for Healthcare Improvement*, no date) such as morbidity or mortality patient satisfaction or health economic metrics.

5.2. Co-design of safety interventions for sick patients in acute and emergency care

Co-design and co-production include methods that allows patients and staff to participate in the creation of services. There is convincing evidence that co-production can lead to better services and patient outcomes at a lower cost for the care of patient groups and that shared decision making between patients and clinicians improves outcomes for individual patients. In acute care co-production and shared decision making can be challenging as patients can be sick, delirious, or comatose and have only limited capability of collaborating in their own care and safety of care.

I explored the use of Personal Health Records with a stakeholder group of health service researchers, information technology specialists, clinicians and patient

representatives hosted by the Health Informatics Unit of the Royal College of Physicians (Subbe, Øvretveit, *et al.*, 2019). Mixed groups of participants reviewed a sample of clinical case studies and collated barriers and facilitators for implementation and impact of PHRs. While there was consensus that Personal Health Records offered opportunities for patients and families to be involved in care processes, patient representatives were concerned that differences in health and digital literacy could lead to further disadvantages for patient groups who already face challenges.

Scenario based design (Rosson *et al.*, 2002) observes behaviours and interactions, with objects or people, in typical scenarios to inform the design of healthcare interventions. In order to gain more direct insights into the potential of PHRs to support safer care we conducted an observational study in a simulated hospital environment (Subbe *et al.*, 2020). We asked patients with different capabilities, including older people with frailty, to use a commercially available PHR. Direct observation revealed significant challenges in the application and highlighted limitations for the application of PHRs in hospital in general, and for time-sensitive safety applications in particular.

Together with the Team from 'Pontio Innovation' I then coordinated two workshops to design safety interventions for patients in an acute care hospital environment. The structure of the workshops followed an epistemological method of prototypology that has been developed at Bangor University: The BASE-methodology (Goodman, Pierce and Owen, 2013; Parkinson, Eccles and Goodman, 2014). The methodology assumes that knowledge about a design challenge is distributed between those who experience a service as patients or clinicians, those who have knowledge of the **B**usiness sense, the **A**esthetic, the underlying **S**cience and the practicalities of **E**ngineering. By creating agile groups with participants from each of these backgrounds the methodology is uniquely able to discover and define design challenges and develop and deploy solutions. I described the methodology for the first time in its application in emergency care (Subbe, Goodman and Barach, 2022).

We undertook two workshops: The first workshop examined the challenge of deteriorating patients in hospital and identified patient-held checklists as a viable intervention. For practical reasons this intervention was subsequently tested outside of hospital with patients undergoing treatment for cancer (Jones *et al.*, 2020). Patients who receive treatment for cancer have highly predictable side-effects during a definable time

window following treatment (often within two weeks). This made testing of the principle of patient-held checklists viable with a smaller patient sample. The second workshop examined the transfer of information between patients presenting as emergencies and secondary care providers on admission to hospital. The recommended intervention was a patient-generated and held personal health record containing safety critical information (Subbe *et al*., 2021).

The prototypes from both workshops were subsequently tested in interventional trials (see below).

5.3. Interventional studies

The co-produced prototypes from the workshops were subsequently further developed with patients and healthcare professionals and tested in intervention trials:

(i) Patient-held checklists

The 'Keep-Me-Safe' mHealth application is a checklist of side-effects for patients undergoing systemic treatments for cancer based on a commonly used checklists for health care professionals (Jones *et al.*, 2020). The application was tested for 60 days by 50 patients and their net-worked friend or family member ('safety-buddy'). The application was persistently used for the study period and feedback from users was very positive. The feasibility study was not powered to show clinical impact. but no adverse events were observed. The use of peer support between lay people in a social network as an intervention for improving safety is novel: we all look for help if we are poorly and those who are close to use are uniquely placed to support. Using Michie's behaviour change wheel (Michie, van Stralen and West, 2011) the use of peer support brings together capability, opportunity and motivation to detect and escalate the care of deteriorating patients in and outside of hospital. We have previously described the use of modular redundancy (Subbe, Duller and Bellomo, 2017) as a safety principle: In modular redundant systems safety critical tasks are carried by a number of parts or partners. This means that failure or error of an individual does not automatically results in catastrophic consequences as other individuals hold the same knowledge and are able to intervene. The principle of modular redundancy is integral to high reliability industries but rare in patient safety and has to my knowledge never been described with a patient or relative as part of a redundant system. The application in a digital intervention is therefore scalable. A multi-centre study is now required to test whether the principle of patient held

checklists improves clinical care and patient satisfaction. In the same vein further research is required to identify the optimal number of ‘safety-buddies’ for individual patients and the impact of close friendship or kinship on reliability of the process.

(ii) Patient-generated and held personal health record

A patient-generated and held personal health record (Subbe *et al.*, 2021) to facilitate safe admission to hospital for those with medical emergencies was tested in 50 patients: the overwhelming majority of patients were able to use the paper version of the passport and recording of patients’ ideas, concerns and expectations in relation to hospital admission was consistently better documented by patients (and in some cases by their accompanying relatives) then in clinical records of their healthcare professionals. Patients were also able to self-identify surrogate markers for severe infection requiring prescription of antibiotics by their clinician.

6. Appraisal of findings

In this chapter I will discuss the implications of the submitted publications and reflect on the learnings in the light of broader literature in patient safety.

6.1. Expected and unexpected findings

The research represented in this manuscript started with the assumption that a broader role for patients is possible in most settings where health is delivered, including in emergency settings and during acute illness. Patient representatives were highly engaged in focus groups and while planning the interventional studies. Patients participating in the feasibility studies were willing to complete detailed questionnaires about their disease on admission to hospital and patients with cancer who used the checklist application did not want to abandon the application after the end of the trial. All this is positive and encouraging for the development of processes and artefacts in acute care that give patients a stronger voice and potentially more control.

The co-design framework that I explored in two workshops was well received by participants seemed to result in viable prototypes. Design thinking (Stickdorn *et al.*, 2018) is the accepted industry standard for innovation. There is no good reason why it shouldn't apply to healthcare. Traditional methods relying on user feedback or focus groups often result in interventions that don't live up to the expectations of those initiating them (Lyle and Pope, 2019, O'Hara, *et al*., 2017). The adaptation of the BASE methodology integrated patients into the epistemological stakeholder groups thereby allowing the assessments of problems, and subsequently solutions from multiple perspectives simultaneously with a level of reality-check that might not be possible when groups of patients (or other stakeholder groups) are interviewed in isolation. For the development of clinical prototypes an expansion of the BASE methodology by my collaborators (Goodman, Pierce and Owen, 2013; Parkinson, Eccles and Goodman, 2014) an adaption to include the unique knowledge of patients to P-BASE would therefore seem sensible.

Involvement of patients does not always yield results: patients who were asked to contribute to daily reviews in one of my other studies did not take up the opportunities to take greater control of their own care: We developed patient-held checklists for ward-rounds that could capture safety critical interventions in several Plan-Do-Study-Act

cycles with groups of patients. These remained highly person dependent and did failed to gain traction with patients or healthcare professionals (Lewis *et al.*, 2022).

My experience reflected that of other authors in the same setting (Redley et al 2019). While innovative interaction with patients in outpatient clinics, and contributions at the threshold to hospitals, report successes, implementing interventions in inpatient settings is significantly more challenging. One study from Australia found that shared decision making was rarely observed during ward rounds (Redley *et al.*, 2019). The authors highlighted opportunities to support patient capability and clinician led opportunity but also stressed that they observed different patient preferences and behaviours. The authors describe these as 'active control preference', 'shared control preference' and 'low control preference'. Passive control preference has also been observed in studies of patients with cancer (Cohen *et al.*, 2008). Neither studies measured health literacy or activation and this might be a relevant omission: technical language used by clinicians in secondary care might serious limit the ability of patients to connect.

The role-transformation between the engaged, enabled, activated patient and the passive receiving patient might happen close to the hospital door. Whether this observation is robust and consistent requires further exploration: A setting where a patient is lying in a bed and a healthcare professional sitting or standing might create a strong frame to shape beliefs and behaviours.

Digital health was a theme in several of my included papers. Patient held information seems to be under-utilised in electronic health records and mHealth applications: Despite the colossal investment into 'big-tech' in hospital my reviews found that the clinical impact that is reported in the peer reviewed literature is negligible. On the other hand, our low-budget prototype smartphone application with checklists for patients with cancer and those close to them was well loved. The setting (community / outpatient vs inpatient) might affect engagement. The 'small-tech' app in the pocket might convey a feeling of control and autonomy that is difficult to replicate in a large 'industrial' hospital setting. The idea that big institutions might discourage patient engagement and perpetuate care inequalities has been explored by Goffman (Goffman, 2017). His concept of the 'Total Institution' relates to the perception of impersonal care by staff, with a 'failure to maintain' emotional contact with patients and lack 'face work' that assures patient and fosters commitment (Hope *et al.*, 2022). The relationship with staff become hence a key ingredient of any intervention, the social glue that holds things together.

The importance of patients' relationships with healthcare staff is something that my fellowship only explored to a degree. On the other hand, the enabling of care through relations to relatives and friends played a role in one of the studies and some of the observations would support a focus on the patients' social network as the core of future interventions: The smartphone checklist-application used a 'safety buddy' and adherence was high for 60 days, well in excess of usually reported adherence with wearables or digital interventions. And even elderly patients were able to complete documentation systems at the hospital front door if supported by relatives. This 'scaffolding' by patients and relatives has been explored as a mechanism for increased resilience of healthcare systems (O'Hara, Aase and Waring, 2019). As O'Hara and co-workers state: by adding engagement at different levels of care patients and relatives might 'dampen performance variability particularly where variability may have a disproportionate impact on desired outcomes' (2019, p3): When given the opportunity patients will use their capability and motivation to find work-arounds that deliver safer, better care.

These findings link to observations about the impact of initiatives that use informal groups and sociable community activities (Milligan *et al.*, 2013; Wilson and Cordier, 2013; Foster, Munoz and Leslie, 2018; Sport Wales, Street Games and Social Prescribing Youth Network, 2021) to affect healthy behaviours: 'Men's Sheds' and other interventions of 'social prescribing' add mutual support of people with similar life-challenges, break social isolation and allow peer support and sharing of solutions with no or minimal input from healthcare professionals. It remains to be seen how those principles can be further scaled to impact on measurable changes in safe delivery of care.

In my interventional studies I used informal networks to support patients explicitly (in creating 'safety buddies' for checklists) and implicitly (by allowing relatives to assist patients with patient-generated and held records on admission to hospital). Families are thought to often the default for support of patients, but their interest might not always be aligned with patients and especially in Western or urban societies availability of family support might be limited. Understanding the impact of the quality and strength of a social relationship of safety behaviours will require further exploration.

6.2. Limitations and challenges

The set-up of the Improvement Science fellowship allowed me considerable freedom of methods and connections to global patient safety experts who generously supported the

work with their advice and presence at key events such as focus groups and workshops with patients.

My work followed an accepted framework for the design of novel services and solutions. The ‘double diamond’ has been widely used for the design of public services but has been less applied in the context of the National Health Service (NHS). Experience based design (Donetto, Tsianakas and Robert, 2014) is the only other method that seems to have been used in published studies in emergency care, but the framework of using short videos as the main intervention seemed too limited for the intent to develop actual innovative prototypes for better care.

The lack of a mature EHR in my own health board limited deeper insights into the specific challenges of patients to make themselves heard in this new digital environment. While EHRs are now used in over 80% of NHS organisations that level of sophistication and integration still varies widely. My study designing an mHealth application (Jones *et al.*, 2020) provided important insights into the specific safety challenges of smart devices and compensated partially for a more digital environment for the research.

Prototypes were tested with patients in several clinical settings. All patients were patients receiving health care in North Wales. North Wales has limited ethnic diversity but is bilingual with stark social gradients, thus providing examples for challenges through cultural diversity. The learnings from this population might be usefully complemented by insights from a broader patient population, including insights into the effects of gender, ethnicity, health literacy and digital literacy.

My interventional studies included small patient populations, studied for up to two months. Impact of the proposed interventions if delivered at scale or longitudinal effects on organizational culture and patient activation are unknown.

The findings outlined in this submission build on existing insights: While I didn’t use formal frameworks on human factors such as SEIPS my manuscripts describe environments, tasks, processes and outcomes. Application of SafetyY II’s FRAM model might have added further depth to the insights from the feasibility studies and allowed to understand limitations for implementation and scaling: I used process mapping and story-boards in the workshop to understanding timing of safety processes and explored inputs

and resource utilisation in the interventional studies. Outputs were however limited in their time horizon and to patient centred outcomes, and preconditions were only incompletely described through characterisation of the patient population and clinical areas. A more in-depth understanding of health and digital literacy (see below) and controls immanent in the hospital environment would aid the understanding of patient delivered interventions.

6.3. The perspective of patients and families on patient safety

My research found evidence for a broader scope of patient participation in their own safety. In both interventional studies family members were assisting with the delivery through acting as 'safety buddies' and supporting the completion of the patient-delivered and held records. This close relationship between patients and family members might require further exploration to understand its potential for the delivery of clinical safety. The perspective of patients and those close to them on patient safety could be explored through a number of lenses: child-parent, patient-family, etc.

The parent-child relationship is the prime example of a relationship supporting care. Patients and their families form a unique bond. Parents support their children while at home or admitted to hospital. Adult children care for their parents. There are differences in the degree of support depending on culture and gender: In broad terms Mediterranean and Asian cultures might foster closer bonds of responsibility than Northern European families. Daughters often end up shouldering the bulk of care responsibility if compared to the engagement of sons (Grigoryeva, 2014).

Families are facilitators of quality and safety of care: The supportive relationships between family members are therefore a natural social network. Its impact on the quality and safety of care delivered has been examined in a number of settings. Families are a valuable resource in the care of hospitalised patients (Bélanger, Desmartis and Coulombe, 2018) and contribute even to care of relatives admitted to Critical Care Units (Hetland *et al.*, 2017) and in this setting might provide reassurance and familiarity and hence take a role in the prevention of delirium (Rosa *et al.*, 2018). Family members are a

particular source of safety for patients with dementia (Yin, Lin and Chen, 2023). During the pandemic their absence led to real concerns about patient safety (Correia *et al.*, 2022).

When considering the effects on patient safety then safety culture and family participation in care are closely related (Burlakov *et al.*, 2021): Family members' satisfaction is higher where ward teams show a commitment to quality and safety. Family care givers can see themselves as part of the care team (Schaepe and Ewers, 2018) and feel that they can play an active role in improving the safety of care by prevention of errors (Yen *et al.*, 2020).

While support of a family member might be perceived as a burden by those supporting my studies found little evidence for this in a within the boundaries of the testing of specific safety related tasks.

6.4. Health literacy as a co-factor for patient safety

My research found encouraging patient engagement in the use of checklists and patient-generated health records but I am unsure whether patients who contributed were representative of the overall population with regards to their digital or health literacy. The potential mediating role of health literacy in patient safety is probably under-researched. Personal Health literacy is defined as the "cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health" (*Health promotion glossary*, no date) or "the degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others." (Centre for Disease Control, 2020). There are multiple tools (Haun *et al.*, 2014), that can measure a broad range of constructs of health literacy including 'basic reading and writing skills, disease-specific knowledge and practical skills' or 'social health literacy competence and the ability to interpret and critically assess health information' (Urstad *et al.*, 2022). All these are likely to matter when it comes to using patient understanding of constructs of health, written text and iconography, or active contribution to health records.

It has been reported that in the United Kingdom 7 million adult citizens have the reading age of a primary school chid and 2 in 5 adults might not be able to understand

written health care information (Health Education England, no date). Health literacy might hence be a pivotal factor in more democratic and patient enabled models of care.

The importance of health literacy is well known from the nursing literature (Ross, 2007). From a patient point of view limited health literacy of parents has impact on safety of hospitalised children (Glick *et al.*, 2019) throughout the patient journey during admission, inpatient stay and discharge process. Health literacy affects the safety of surgical operations (Elgin, 2018): patients need to understand potential complications and required behaviours that enable safe care. For the often young patients with Cystic Fibrosis better health literacy is associated with metrics of quality and safety such as the number of outpatient visits, days in hospital and quality of life (Jackson *et al.*, 2020).

There is limited evidence from interventional studies targeting health literacy: An application with interactive risk calculators, motivational messages and the tracking of lifestyle goals for cardio-vascular health led to improvements in physical activity and health literacy but not other outcomes (Redfern *et al.*, 2014, 2020). Few studies have explicitly focused on communication of patient safety risks (Kim *et al.*, 2020). This is echoed in the literature on personal health records: Allowing patients access to electronic health records improved some measures of quality of care, including medication adherence in a systematic review with meta-analysis. But: only four of the identified studies used any metric of health literacy and even those focused mostly on the construct of 'learning' by patients (Neves *et al.*, 2020). More often than not research into patient held records focuses on frequency of 'usage' and only few studies have addressed the quality of patient interaction and impact of this newly available information on decision making of patients and healthcare professionals (Fraccaro *et al.*, 2018).

Usage of technology and health literacy are linked: Health literacy and internet access have a strong association (Estacio, Whittle and Protheroe, 2019) and health literacy is positively correlated with the use of digital applications such as activity trackers, patient portals, fitness and nutrition applications (Mackert *et al.*, 2016). Throughout Europe health literacy and digital access differ according to gender, age group and health needs with the poorest digital access found in groups of men over the age of 45 with no chronic health issues (Alvarez-Galvez *et al.*, 2020). Increasing use of digital applications might therefore be a useful target for interventions aimed at increasing health literacy. In vulnerable populations a number of interventions have been tested to increase usage of

digital portals: Using the SEIPS framework interventions focusing on engagement of individuals (P or 'person' in SEIPS, see below) had the strongest evidence base (Grossman *et al.*, 2019).

Health inequalities might result from limited access to digital technology and poor understanding of health-related issues. Those with greatest needs of healthcare might have hence the least access to digital technology and the lowest health literacy (Menendez *et al.*, 2021). The digital divide of usage of the Internet and access to health-related information is greatest for those who are elderly and have low health literacy (Levy, Janke and Langa, 2015). There is a lag in internet usage for health purposes in those 65 years or older(Sarkar *et al.*, 2010) and specifically in those elderly patient with no formal education on low incomes (Estacio, Whittle and Protheroe, 2019). Digital solutions might be less deployed in rural communities with poor infrastructure (DeMonte, DeMonte and Thorn, 2015) with an additional challenge through the fact that much research in underserved populations is undertaken in urban areas (Chesser *et al.*, 2015).

My work did not formal explore literacy in the participants of the two interventional studies. Educational status was recorded for patients taking part in the Express-check-in (Subbe *et al.*, 2021) but not for the study on digital Check-lists (Jones *et al.*, 2020). Patients might not want to disclose difficulties with literacy (Easton, Entwistle and Williams, 2013): for this reason interventions need to take into account low literacy while facilitating disclosure. To use digital interventions some health and digital literacy might be an essential requirement for patients to participate though some content can be conveyed through non-verbal content such as video clips or icons. At the same time digital interventions allow to track usage of an intervention as a surrogate of understanding.

Future work in this field does therefore need to include metrics of health literacy and social deprivation to gauge feasibility, scalability and equitable access to healthcare in the digital age.

6.5. Implications for clinical care based on programme theory

My work included in this submission adds to the body of evidence that demonstrates that patients, far from being passive observers in the delivery of safer care, can take an active role, even in acute care. The programme theory for this work was based on my previously published framework for patient safety based on the 'chain of survival' (Subbe, C. P., 2013) where safety depends on recording of safety critical information, recognition of abnormalities, reporting of abnormalities to those who can respond and a repeated feedback look. The work presented in this thesis adds encouraging detail to the role of patients in this chain:

Patients can **record** safety critical information such as allergies, past-medical history or checklists for side-effects of cancer care. Patients can measure vital signs such as blood pressure, heart rate or oxygen saturations, pathology results such as blood sugar, or levels of anticoagulants, and track body weight in heart failure. In our study with patients undergoing treatment for cancer recording included commonly noted side effects of treatments (Jones *et al.*, 2020).

Importantly patients can **recognize** their deteriorating health status based on subjective wellbeing or interpretation of measures obtained in their home. In our study, there were examples of patients and 'safety buddies' calling the helpline as suggested by the checklist mHealth application (Jones *et al.*, 2020).

Patients can **report** abnormal findings and escalate care through family members (Jones *et al.*, 2020; Subbe *et al.*, 2021) or healthcare professionals. This is part of everyday clinical care through appointments in primary care, self-presentation in Emergency Departments, or ultimately by alerting Rapid Response Teams through systems such as Call-4-Concern (Bucknall *et al.*, 2021).

Patients can **respond** to abnormalities in their health status by initiating treatment with steroids and antibiotics in COPD, increasing the dose of inhalers in asthma or altering treatments regimes in inflammatory bowel disease. While all of these treatments

would have previously been initiated after a review by a healthcare professional (usually a doctor) it is now accepted that patients can safely initiate these treatments, and this provides safe and possibly safer care than a reliance on the availability and judgement of a healthcare professional.

In this submission I have shown that patients can record key priorities of hospital care such as ideas, concerns and expectations (Subbe *et al.*, 2021b). They can further record side-effects of cancer therapy, recognise the abnormalities and using a digital application report those side effects to responders (H. V Jones *et al.*, 2020).

My midlevel theory was based on the behaviour change model by Michie et al (Michie, van Stralen and West, 2011). This hypothesised that lack of capability and opportunity might deprive patients of valuable chances to improve the safety of their care. My studies enabled the physical opportunity of documenting warning signs and care priorities in checklists and clinical records and through an inbuilt model of risk assessment with the UKONS escalation algorithm. The paper that developed this contribution to theory was however only published after the submission of this manuscript (Subbe *et al.*, 2024).

Healthcare is a complex adaptive system. Safety in healthcare relies often on inter-connected chains of actions by different members of a multi-professional team. The reliability of a single chain of actions can be calculated mathematically but is often most vulnerable through the existence of a 'weakest' link. At a system design level reliability of processes can be improved by reducing the number of steps required or by reducing the reliance on handoffs and multiple interfaces (Lee, *et al.,* 2016). By allowing a single actor, i.e. a healthcare professional or patient to complete a series of actions or indeed the complete chain of actions might therefore reduce vulnerability and increase reliability of safety critical actions.

To counteract the unpredictable behaviour of complex system high reliable industries can also deploy the principle of modular redundancy (Lyons and Vanderkul, 1962). We have previously shown that redundancy of safety critical steps can be adapted for monitoring solutions in healthcare with significant reduction in mortality, cardiac arrests, overall adverse events and improved outcomes for those requiring intensive care (Bannard-Smith and Subbe, 2015; Subbe, Duller and Bellomo, 2017). It seems clear from

the findings of this fellowship that patients could provide some of the needed redundancy in healthcare to establish more resilient and reliable systems. The simple actions required are (at least in theory) scalable through electronic health records and connected health care applications. With the greater engagement of service users, the ‘meaningful use’ of electronic health records might finally achieve the as yet unfulfilled ambition of greater patient safety (Trout *et al.*, 2022).

There is a question over what might bring more consistent entry of patient-reported experience or outcomes into records. The patient wellness scale (Albutt, O’Hara, *et al.*, 2020; Albutt, O’Hara, *et al.*, 2020) is a tool with two questions around changes to wellbeing. This and others simple tools that can be used as part of routine workflow might lend themselves to broader implementation.

7. Conclusions and recommendations for future research

The work that I present in this submission demonstrates my contributions to theory, methodology and practice of acute care with a focus on safety outcomes for patients.

My contributions to the theory of acute care include the extension of two theoretical frameworks to patient safety: the COMB-model from behaviour psychology and modular redundancy from high reliability industries.

My contribution to methodology consists of the application of design thinking to the development of solution focused research programmes and clinical prototypes and a novel method for co-design using the P-BASE framework.

My contributions to practice include an expansion of knowledge about Electronic Health records through review of the literature and through direct observation as a well as the development and implementation of novel analogue and digital prototypes for health records into clinical care. Prototypes were tested with patients in North Wales. Studies of prototypes were designed to demonstrate feasibility of the concepts but were underpowered to show safety benefits at the level of patients, teams, or organisations.

My findings could support the creation of more resilient safety systems.
Future research could assess the impact on health equity and the influence of health literacy.

The key learnings from this work should inform future clinical research (recommendations 1-3) and policy (recommendations 4 & 5)

Contribution 1: Behaviour change models: Patients in acute care have capability to be involved in their safety if opportunities are provided

Capability, opportunity and motivation are necessary elements for behaviour change interventions (Michie, van Stralen and West, 2011). The principles are universal and as such applicable to patient safety. Assuming motivation of healthcare professionals and patients to deliver and receive safe healthcare, it is clear that capability and opportunity are often constrained by shortage of time or social opportunity through organisational culture. Health technology might offer patients the capability to contribute to safer care

by making use of their intimate knowledge of their own health (capability) and abundance of time while being present at the place of interest (opportunity).

My experimental studies evidenced that co-produced safety interventions are feasible even in acute and emergency care and that patient-owned safety critical information has the potential to leverage knowledge of those for whom outcomes of care matter most. Although patient preferences vary, I found that about half of the patients requiring acute care are willing and able to engage with interventions that might improve the safety of their own care. In the context of the COM-B behaviour change model this insight should help to enable the development of further interventions to improve safety.

Agency for patients can be extended to those close to a patient: friends and families. This evidence is in line with learning about peer support from behavioural psychology but had not been previously expanded to and exploited for the purpose of improved patient safety.

Recommendation 1: Complex patient safety systems might be more robust if capability and opportunity for patients can be strengthened and seen as a resource in a wider clinical team. Opportunities for scalable patient centred care during hospital stay need to be explored proactively to support equitable care across the patient journey in line with evidence from chronic disease programmes. Established tools from design thinking and behaviour psychology should be used to enable greater choice for patients to control and impact their care. The effects on equality and diversity, accountability and governance need to be explored further.

Contribution 2: Patients can be active parts of systems with modular redundancy

The findings from my research demonstrated that some tools for safe patient care that are usually deployed by health care professionals can be translated, adapted, and used by patients and those close to them. The essential principle of modular redundancy for the architecture of safety critical systems can hence be expanded to include patients and their social networks in analogue or digital form. Sharing of information within social networks of those ‘who care’ is almost certainly a viable alternative to professional supervision for some conditions.

Recommendation 2: The optimum size and shape of a ‘social’ network aimed to support safety of care that uses modular redundancy is unclear and opportunities and barriers for implementation will need further research. Innovators might want to focus initially on

translating systems used by health care professionals for use by the wider public while taking into account the effects of health and digital literacy on interventions.

Contribution 3: Co-design based on epistemology

My work identified a dearth of evidence for coproduction and codesign methods in acute care. By expanding the existing BASE model to include patients as a key source of knowledge about care I was able to develop prototypes for interventions at pace. P-BASE is a viable new way of co-design for clinical applications.

Recommendation 3: The methodology demonstrated in this submission can be easily applied to new areas of clinical care but has primarily been tested a micro-system level. It would hence require further studies to explore use at meso- or macro-level.

Contribution 4: Design thinking as a method of research

The body of this submission is based on the Double-Diamond methodology. This methodology is widely used for the development of artefacts or services. My work demonstrates the suitability for the development of prototypes or indeed a whole programme of research. As traditional models of research design thinking uses deep understanding of context and users to create interventions. Unlike traditional models of research interventions are built to be 'broken' at early stages of development. This allows a degree of agility that might be particularly advantageous where environments are complex and during times of fast changes.

Recommendation 4: Exposure to design thinking is spreading in healthcare but might require adoption by government funders to develop full impact.

Contribution 5: Patient safety & digital health: Plenty of talk – (nearly) no data

While there is a lot of rhetoric about co-production of health and patient ownership of digital records, I found extremely limited evidence in the published literature that this challenge has been taken up at scale by either healthcare organisations or indeed technology companies for the part of healthcare where data matters for life and death decisions in the way that it does in acute and emergency care.

Healthcare policy emphasises the importance of co-production, shared decision making and access of patients to their records but neither the development of services nor health-service research have kept track. Many digital start-ups and indeed larger

companies emphasise their commitment to patient engagement but there is sobering little evidence in materials that are in the public domain that this translates into measurable patient safety benefits of their products.

The absence of effective, transparent, and authoritative metrics for providers of 'co-produced' services and digital healthcare suppliers is a gap that hinders development, implementation, and evaluation of innovative patient-centred models of care. Given that purchasers of healthcare records are often closely aligned with government bodies or indeed publicly funded it would appear that a lack of adequate policy might be a co-factor enabling the current landscape of digital health.

Recommendation 5: This work identifies the need for an authoritative assessment-framework of digital health records that is in line with the assessments required for other medical interventions and assists health care providers and funders to maximise clinical return on investment. This will require collaboration of professional bodies and policy makers.

8. Declarations of Authorship

Scoping reviews

Subbe, C. P., Tellier, G. and Barach, P. (2021) 'Impact of electronic health records on predefined safety outcomes in patients admitted to hospital: A scoping review', *BMJ Open*. BMJ Publishing Group, 11(1). doi: 10.1136/BMJOPEN-2020-047446.

> I wrote the protocol and undertook 80% of the analysis. I wrote the first draft of the manuscript.

Osborn, J. *et al.* (2020) 'Do mHealth applications improve clinical outcomes of patients with cancer? A critical appraisal of the peer-reviewed literature', *Supportive Care in Cancer*. Springer, 28(3), pp. 1469–1479. doi: 10.1007/s00520-019-04945-4.

> I wrote the protocol, I undertook the final analysis and wrote the first draft of the manuscript.

Manuscripts on co-production

Subbe, C. P., Øvretveit, J., *et al.* (2019) 'Digital Technology: Opportunities and barriers for usage of personal health records in hospital – report from a -workshop of the Health Informatics Unit at the Royal -College of Physicians', *Future Healthcare Journal*. Royal College of Physicians, 6(1), pp. 52–56. doi: 10.7861/FUTUREHOSP.6-1-52.

> I organised and chaired the workshop and wrote the first draft of the manuscript.

Subbe, C. P. *et al.* (2020a) 'Scenario-based design for a hospital setting: An exploratory study of opportunities and barriers for personal health records usage', *Future Healthcare Journal*. Royal College of Physicians, 7(2), pp. 125–130. doi: 10.7861/FHJ.2019-0061.

> I wrote the protocol, organised and led the testing, and wrote the first draft of the manuscript.

Subbe, C. P., Goodman, A. and Barach, P. (2022) 'Co-design of interventions to improve acute care in hospital: A rapid review of the literature and application of the BASE methodology, a novel system for the design of patient centered service prototypes', *Acute medicine*. NLM (Medline), 21(4), pp. 182–189. doi: 10.52964/AMJA.0922.

> I organised and chaired the workshops, I wrote the first draft of the manuscript.

Interventional studies

Jones, H. V. *et al.* (2020a) ‘Checklists for complications during systemic cancer treatment shared by patients, friends, and health care professionals: Prospective interventional cohort study’, *JMIR mHealth and uHealth*. JMIR Publications Inc., 8(9). doi: 10.2196/19225.

I wrote the protocol, hosted workshops with patients, undertook the bulk of the anlysis and wrote the frist draft of the manuscript.

Subbe, C. P. *et al.* (2021a) ‘Express check-in: Developing a personal health record for patients admitted to hospital with medical emergencies: A mixed-method feasibility study’, *International Journal for Quality in Health Care*. Oxford University Press, 33(3). doi: 10.1093/INTQHC/MZAB121.

I wrote the protocol, I undertook part of the analysis, I wrote the first draft of the manuscript.

9. Appendix: Other Outputs

Output from the work has been disseminated in academic journals and through posters and oral presentations at Academic Conferences including

- Society for Acute Medicine (Harrogate 2019)
- International Symposium on Human Factors and Ergonomics in Health Care (Chicago 2019)
- International Society for Rapid Response Systems (Manchester 2018; Singapore 2019)
- International Forum for Quality & Safety (Amsterdam 2018; Glasgow 2019)
- THIS Space (Cambridge 2020)
- Patient Safety Congress (Manchester 2022)
- Annual Patient Powered Safety Conference (Bangor, 2019-23)
- A report for the Bevan Commission (Patient Powered Safety: Reducing harm through co-production with patients 2019)
- An online blog (https://www.base-lab-health.org/blog)

10. Bibliography

Albutt, A., O'Hara, J., *et al.* (2020) 'Can Routinely Collected, Patient-Reported Wellness Predict National Early Warning Scores? A Multilevel Modeling Approach', *J Patient Saf*.

Albutt, A., O'Hara, J., *et al.* (2020) 'Involving patients in recognising clinical deterioration in hospital using the Patient Wellness Questionnaire: A mixed-methods study', *Journal of Research in Nursing*. SAGE Publications Ltd, 25(1), pp. 68–86. doi: 10.1177/1744987119867744.

Allen, D. (2014) *The invisible work of nurses : hospitals, organisation and healthcare*. Routledge Advances in Health and Social Policy .

Alvarez-Galvez, J. *et al.* (2020) 'The persistence of digital divides in the use of health information: a comparative study in 28 European countries', *International Journal of Public Health*. Springer, 65(3), pp. 325–333. doi: 10.1007/s00038-020-01363-w.

Bannard-Smith, J. and Subbe, C. P. (2015) 'Critical illness on general floors: Reliability plus redundancy equals resilience?', *Critical Care Medicine*. Lippincott Williams and Wilkins, 43(7), pp. 1541–1542. doi: 10.1097/CCM.0000000000001049.

Barry MJ, E.-L. S. (2012) 'Shared decision making—the pinnacle of patient-centered care.', *N Engl J Med Engl J Med*, 366, pp. 780–1.

Batalden, M. *et al.* (2015) 'Coproduction of healthcare service.', *BMJ Qual Saf*, 136(pii: bmjqs-2015-004315.), pp. 1–3. doi: 10.1136/bmjqs-2014-003673.

Bélanger, L., Desmartis, M. and Coulombe, M. (2018) 'Barriers and facilitators to family participation in the care of their hospitalized loved ones', *Patient Experience Journal*. The Beryl Institute, 5(1), pp. 56–65. doi: 10.35680/2372-0247.1250.

Bell, S. K. *et al.* (2015) 'Partnering with patients for safety: The opennotes patient reporting tool', *Journal of General Internal Medicine*, 30, p. S220. Available at: http://www.embase.com/search/results?subaction=viewrecord&from=export&id=L71877824.

Bell, S. K. *et al.* (2016) 'When doctors share visit notes with patients: a study of patient and doctor perceptions of documentation errors, safety opportunities and the patient–doctor relationship', *BMJ Quality & Safety*, (May), p. bmjqs-2015-004697. doi: 10.1136/bmjqs-2015-004697.

Braithwaite, J., Wears, R. L. and Hollnagel, E. (2015) ‘Resilient health care: Turning patient safety on its head’, *International Journal for Quality in Health Care*. doi: 10.1093/intqhc/mzv063.

Bucknall, T. *et al.* (2021) ‘When patients (and families) raise the alarm: Patient and family activated rapid response as a safety strategy for hospitals’, *Future Healthcare Journal*. Royal College of Physicians, 8(3), pp. e609–e612. doi: 10.7861/FHJ.2021-0134.

Burlakov, N. *et al.* (2021) ‘The Association Between Quality and Safety Climate of a Hospital Ward, Family Members’ Empowerment, and Satisfaction With Provided Care’, *Journal of Nursing Scholarship*. John Wiley and Sons Inc, 53(6), pp. 727–736. doi: 10.1111/jnu.12682.

Carayon, P. *et al.* (2006) ‘Work system design for patient safety: The SEIPS model’, *Quality and Safety in Health Care*. doi: 10.1136/qshc.2005.015842.

Carayon, P. *et al.* (2011) ‘Work system barriers and facilitators to family engagement in rounds in a pediatric hospital’, *Healthcare Systems Ergonomics and Patient Safety 2011*, pp. 81–85.

Carayon, P. *et al.* (2020) ‘SEIPS 3.0: Human-Centered Design of the Patient Journey for Patient Safety HHS Public Access’, *Appl Ergon*, 84, p. 103033. doi: 10.1016/j.apergo.2019.103033.

Centre for Disease Control (no date) *What Is Health Literacy?* Available at: https://www.cdc.gov/healthliteracy/learn/index.html (Accessed: 10 April 2023).

Chesser, A. *et al.* (2015) ‘Navigating the digital divide: Literacy in underserved populations in the United States’, *Informatics for Health and Social Care*. Taylor and Francis Ltd, 41(1), pp. 1–19. doi: 10.3109/17538157.2014.948171.

Cohen, E. *et al.* (2008) ‘Pain beliefs and pain management of oncology patients’, *Cancer nursing*. Cancer Nurs, 31(2). doi: 10.1097/01.NCC.0000305693.67131.7D.

Correia, T. S. P. *et al.* (2022) ‘Safety and Family-Centered Care during Restriction of Hospital Visits due to COVID-19: The Experience of Family Members.’, *Journal of personalized medicine*. MDPI, 12(10). doi: 10.3390/jpm12101546.

Coulter, A. *et al.* (2016) ‘At the heart of health Realising the value of people and communities Report’, (March), p. 55.

Coulter, A. and Mearns, B. (2015) ‘Patient engagement and health information technology : supporting high need , high cost patients’, pp. 1–16.

Davies, U. and Wilson, K. (2015) *Design Methods for Developing Services*. London. Available at: https://www.designcouncil.org.uk/sites/default/files/asset/document/DesignCouncil_Design methods for developing services.pdf (Accessed: 10 August 2019).

Delbanco, T. *et al.* (2010) ‘Open notes: Doctors and patients signing on’, *Annals of Internal Medicine*, pp. 121–125.

DeMonte, C. M., DeMonte, W. D. and Thorn, B. E. (2015) ‘Future implications of eHealth interventions for chronic pain management in underserved populations’, *Pain management*, 5(3), pp. 207–214. doi: 10.2217/PMT.15.9.

Department of Health (2015) *NHS Constitution for England*, *The NHS Constitution establishes the principles and values of the NHS in England*. doi: 26 March 2013.

Donetto, S., Tsianakas, V. and Robert, G. (2014) ‘Using Experience-based Co-design (EBCD) to improve the quality of healthcare: mapping where we are now and establishing future directions’. Available at: https://www.kcl.ac.uk/nursing/research/nnru/publications/reports/ebcd-where-are-we-now-report.pdf (Accessed: 17 November 2017).

Easton, P., Entwistle, V. A. and Williams, B. (2013) ‘How the stigma of low literacy can impair patient-professional spoken interactions and affect health: Insights from a qualitative investigation’, *BMC Health Services Research*, 13(1), pp. 1–12. doi: 10.1186/1472-6963-13-319.

Elgin, C. (2018) ‘The importance of understanding health literacyforperioperativepatientsafety’, *AORN Journal*. Wiley-Blackwell, 107(1), pp. 126–130. doi: 10.1002/aorn.12008.

Ellins, J. and Coulte, A. (2005) ‘How engaged are people in their health care? Findings of a national telephone survey’, *Findings of a national telephone*, (November), pp. 1–50. Available at: http://www.collaborationhealthcare.com/7-11-11Patient-Activation-Survey.pdf.

Elliott, J. (2016) ‘Safety I and safety II: the past and future of safety management.’, *Ergonomics*. Ashgate Publishing Ltd, 59(6), pp. 859–60. doi: 10.1080/00140139.2015.1093290.

Estacio, E. V., Whittle, R. and Protheroe, J. (2019) ‘The digital divide: Examining socio-demographic factors associated with health literacy, access and use of internet to seek health information’, *Journal of Health Psychology*. SAGE Publications Ltd, 24(12), pp. 1668–1675. doi: 10.1177/1359105317695429.

Fiks, A. G. *et al.* (2015) ‘Parent-Reported Outcomes of a Shared Decision-Making Portal in Asthma: A Practice-Based RCT’, *Pediatrics*, 135(4), pp. e965–e973. doi: 10.1542/peds.2014-3167.

Foster, E. J., Munoz, S. A. and Leslie, S. J. (2018) ‘The personal and community impact of a Scottish Men’s Shed’, *Health & Social Care in the Community*. John Wiley & Sons, Ltd, 26(4), pp. 527–537. doi: 10.1111/HSC.12560.

Foy, R. *et al.* (2011) ‘The role of theory in research to develop and evaluate the implementation of patient safety practices’, *BMJ Quality & Safety*. BMJ Publishing Group Ltd, 20(5), pp. 453–459. doi: 10.1136/BMJQS.2010.047993.

Fraccaro, P. *et al.* (2018) ‘The influence of patient portals on users’ decision making is insufficiently investigated: A systematic methodological review’, *International journal of medical informatics*. Int J Med Inform, 111, pp. 100–111. doi: 10.1016/J.IJMEDINF.2017.12.028.

Frampton, S. B., Guastello, S. and Lepore, M. (2013) ‘Compassion as the foundation of patient-centered care: the importance of compassion in action.’, *Journal of comparative effectiveness research*, 2(5), pp. 443–55. Available at: http://www.ncbi.nlm.nih.gov/pubmed/24236742.

Glick, A. F. *et al.* (2019) ‘Health Literacy in the Inpatient Setting: Implications for Patient Care and Patient Safety’, *Pediatric Clinics of North America*. W.B. Saunders, 66(4), pp. 805–826. doi: 10.1016/j.pcl.2019.03.007.

Goffman, E. (2017) ‘Asylums: Essays on the social situation of mental patients and other inmates’, *Asylums: Essays on the Social Situation of Mental Patients and Other Inmates*. Taylor and Francis, pp. 1–386. doi: 10.4324/9781351327763/ASYLUMS-ERVING-GOFFMAN.

Goodman, A., Pierce, I. and Owen, L. (2013) ‘12 flowers, 4 schools and a blooming contention! Enterprise by Design and the MUD(BASE) prototypology.’, in *IEEC*. Sheffield, UK.

Gorman, R. K., Wellbeloved-Stone, C. A. and Valdez, R. S. (2018) ‘Uncovering the

invisible patient work system through a case study of breast cancer self-management'. doi: 10.1080/00140139.2018.1503339.

Grigoryeva, A. (2014) 'Daughters provide as much elderly parent care as they can, sons do as little as possible', in *Science Daily*. American Sociological Association (ASA). Available at: https://www.asanet.org/daughters-provide-much-elderly-parent-care-they-can-sons-do-little-possible/ (Accessed: 6 May 2023).

Grossman, L. V *et al.* (2019) 'Interventions to increase patient portal use in vulnerable populations: A systematic review', *Journal of the American Medical Informatics Association*, pp. 855–870. doi: 10.1093/jamia/ocz023.

Hamza, M. *et al.* (2021) 'Can vital signs recorded in patients' homes aid decision making in emergency care? A Scoping Review', *Resuscitation plus*. Resusc Plus, 6, p. 100116. doi: 10.1016/J.RESPLU.2021.100116.

Haun, J. N. *et al.* (2014) 'Health Literacy Measurement: An Inventory and Descriptive Summary of 51 Instruments', *Journal of Health Communication*, 19, pp. 302–333. doi: 10.1080/10810730.2014.936571.

Hayes, C. W., Batalden, P. B. and Goldmann, D. (2014) 'A "work smarter, not harder" approach to improving healthcare quality.', *BMJ quality & safety*, (January), pp. 1–3. doi: 10.1136/bmjqs-2014-003673.

Health Education England (no date) *Improving health literacy*. Available at: https://www.hee.nhs.uk/our-work/knowledge-library-services/improving-health-literacy (Accessed: 10 April 2023).

Health promotion glossary (no date). Available at: https://www.who.int/publications/i/item/WHO-HPR-HEP-98.1 (Accessed: 10 April 2023).

Henriksen, K., Joseph, A. and Zayas-Cabán, T. (2009) 'The human factors of home health care: A conceptual model for examining safety and quality concerns', *Journal of Patient Safety*, 5(4), pp. 229–236. doi: 10.1097/PTS.0b013e3181bd1c2a.

Hetland, B. *et al.* (2017) 'Factors Influencing Active Family Engagement in Care Among Critical Care Nurses', *AACN advanced critical care*. NIH Public Access, 28(2), p. 160. doi: 10.4037/AACNACC2017118.

Hodges, L. R. and Larrañaga, M. D. (2021) 'Emergency management as a complex adaptive system', *Journal of Business Continuity and Emergency Planning*, 14(4), pp. 354–368. Available at: https://pubmed.ncbi.nlm.nih.gov/33962703/ (Accessed: 20

August 2023).

Hogan, H. *et al.* (2012) 'Preventable deaths due to problems in care in English acute hospitals: a retrospective case record review study', *BMJ Quality & Safety*, 21(9), pp. 737–745.

Holden, R. J. *et al.* (2013) 'SEIPS 2.0: a human factors framework for studying and improving the work of healthcare professionals and patients', *Ergonomics*. Taylor & Francis, pp. 1669–1686. doi: 10.1080/00140139.2013.838643.

Holden, R. J. and Carayon, P. (2021) 'SEIPS 101 and seven simple SEIPS tools', *BMJ Quality and Safety*, 30(11), pp. 901–910. doi: 10.1136/bmjqs-2020-012538.

Holden, R. J., Cornet, V. P. and Valdez, R. S. (2020) 'Patient ergonomics: 10-year mapping review of patient-centered human factors', *Applied Ergonomics*. Elsevier Ltd, 82(October 2019), p. 102972. doi: 10.1016/j.apergo.2019.102972.

Holden, R. J. and Mickelson, R. S. (2013) 'Performance barriers among elderly chronic heart failure patients: An application of patient-engaged human factors and ergonomics', *Proceedings of the Human Factors and Ergonomics Society*, pp. 758–762. doi: 10.1177/1541931213571166.

Hollnagel, E., Wears, R. L. and Braithwaite, J. (2015) *From Safety-I to Safety-II: A White Paper*. Available at: https://www.england.nhs.uk/signuptosafety/wp-content/uploads/sites/16/2015/10/safety-1-safety-2-whte-papr.pdf (Accessed: 1 July 2019).

Hollnagel, E. and Woods, D. D. (1983) 'Cognitive Systems Engineering: New wine in new bottles', *International Journal of Man-Machine Studies*. Academic Press, 18(6), pp. 583–600. doi: 10.1016/S0020-7373(83)80034-0.

Hoonhout, L. H. F. *et al.* (2009) 'Direct medical costs of adverse events in Dutch hospitals.', *BMC health services research*, 9, p. 27. doi: 10.1186/1472-6963-9-27.

Hope, J. *et al.* (2022) '"I'll put up with things for a long time before I need to call anybody": Face work, the Total Institution and the perpetuation of care inequalities', *Sociology of Health and Illness*, 44(2), pp. 469–487. doi: 10.1111/1467-9566.13435.

IDEO (2020) *IDEO Design Thinking*, *IDEO*. Available at: https://designthinking.ideo.com/.

Jackson, A. D. *et al.* (2020) 'Associations between health literacy and patient outcomes

in adolescents and young adults with cystic fibrosis', *European journal of public health*. Eur J Public Health, 30(1), pp. 112–118. doi: 10.1093/EURPUB/CKZ148.

Jones, H. V. *et al.* (2020) 'Checklists for complications during systemic cancer treatment shared by patients, friends, and health care professionals: Prospective interventional cohort study', *JMIR mHealth and uHealth*. JMIR Publications Inc., 8(9).

Keller, S. C. *et al.* (2019) 'Hazards from physical attributes of the home environment among patients on outpatient parenteral antimicrobial therapy', *American journal of infection control*. Am J Infect Control, 47(4), pp. 425–430. doi: 10.1016/J.AJIC.2018.09.020.

Kelly, M. M., Coller, R. J. and Hoonakker, P. L. T. (2018) 'Inpatient portals for hospitalized patients and caregivers: A systematic review', *Journal of Hospital Medicine*. Society of hospital medicine, pp. 405–412. doi: 10.12788/jhm.2894.

Kim, Y. S. *et al.* (2020) 'How to improve patient safety literacy?', *International Journal of Environmental Research and Public Health*. MDPI AG, 17(19), pp. 1–12. doi: 10.3390/ijerph17197308.

Ko, H. *et al.* (2010) 'Patient-held medical records for patients with chronic disease: a systematic review.', *Quality & safety in health care*, 19(5), p. e41. doi: 10.1136/qshc.2009.037531.

Kohn, L. T., Corrigan, J. M. and Molla, S. (2000) *To Err Is Human*, *Medicine*. doi: 10.1017/S095026880100509X.

Kurtz, C. F. and Snowden, D. J. (2003) 'The new dynamics of strategy: Sense-making in a complex and complicated world', *IBM Systems Journal*. doi: 10.1147/sj.423.0462.

Lawton, R. *et al.* (2015) 'Can staff and patient perspectives on hospital safety predict harm-free care? An analysis of staff and patient survey data and routinely collected outcomes', *BMJ Quality & Safety*, 24(6), pp. 369–376. doi: 10.1136/bmjqs-2014-003691.

Lawton, R. *et al.* (2017) 'Can patient involvement improve patient safety? A cluster randomised control trial of the Patient Reporting and Action for a Safe Environment (PRASE) intervention', *BMJ Quality and Safety*. BMJ Publishing Group, 26(8), pp. 622–631. doi: 10.1136/bmjqs-2016-005570.

Leveille, S. G. *et al.* (2012) 'Evaluating the impact of patients' online access to doctors' visit notes: designing and executing the OpenNotes project.', *BMC medical informatics and decision making*, 12, p. 32. Available at:

http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=3351950&tool=pmcentrez&rendertype=abstract.

Levy, H., Janke, A. T. and Langa, K. M. (2015) 'Health Literacy and the Digital Divide Among Older Americans', *Journal of General Internal Medicine*. Springer New York LLC, 30(3), pp. 284–289. doi: 10.1007/S11606-014-3069-5.

Lewis, S. *et al.* (2022) 'How to Hospital: Barriers to developing a patient "Hospital Survival Guide" to support information transfer during ward-rounds on the patient journey from admission to hospital to discharge', *BMJ Open Quality*. BMJ Publishing Group, 11(1). doi: 10.1136/BMJOQ-2021-001556.

Loeffler E, Power G, Bovaird T, Hine-Hughes F, E. (ed.) (2013) *Co-production of health and wellbeing in Scotland.* Brimingham: UK: Governance International.

Lyons, R. E. and Vanderkul, W. (1962) 'The Use of Triple-Modular Redundancy to Improve Computer Reliability', *IBM Journal* , 6(2), pp. 200–209. Available at: https://pdfs.semanticscholar.org/7edb/887ed7f15203eccb614095af001ea74bcfb6.pdf (Accessed: 27 April 2019).

Mackert, M. *et al.* (2016) 'Health literacy and health information technology adoption: The potential for a new digital divide', *Journal of Medical Internet Research*. JMIR Publications Inc., 18(10). doi: 10.2196/JMIR.6349.

MacNab, M. *et al.* (2015) 'Oximetry-supported self-management for chronic obstructive pulmonary disease: mixed method feasibility pilot project', *BMC health services research*. BMC Health Serv Res, 15(1). doi: 10.1186/S12913-015-1135-2.

Malec, J. F. *et al.* (2007) 'The Mayo High Performance Teamwork Scale : Reliability and Validity for Evaluating Key Crew Resource Management Skills', 2(1), pp. 4–10.

Mansukhani, R. (2015) 'Listen Doctor, the Patient Just Might Be Right.', *JAMA internal medicine*, 175(9), pp. 1442-1443.

McNab, D. *et al.* (2016) 'Understanding patient safety performance and educational needs using the "Safety-II" approach for complex systems', *Education for Primary Care*. Radcliffe Publishing Ltd, 27(6), pp. 443–450. doi: 10.1080/14739879.2016.1246068.

Menendez, M. E. *et al.* (2021) 'The Telehealth Paradox in the Neediest Patients', *Journal of the National Medical Association*. National Medical Association, 113(3), pp. 351–352. doi: 10.1016/J.JNMA.2020.09.144.

Michie, S., van Stralen, M. M. and West, R. (2011) 'The behaviour change wheel: A new method for characterising and designing behaviour change interventions', *Implementation Science*, 6(1). doi: 10.1186/1748-5908-6-42.

Milligan, C. *et al.* (2013) *Men's Sheds and other gendered interventions for older men: improving health and wellbeing through social activity A systematic review and scoping of the evidence base A report for the Liverpool-Lancaster Collaborative (LiLaC) and Age UK School for Public Health Research*.

Moehlenbrink, C., Wies, M. and Jipp, M. (2011) 'Monitoring principles in aviation and the importance of operator redundancy', in *Conference Proceedings - IEEE International Conference on Systems, Man and Cybernetics*, pp. 2828–2835.

Neves, A. L. *et al.* (2020) 'Impact of providing patients access to electronic health records on quality and safety of care: a systematic review and meta-analysis', *BMJ quality & safety*. BMJ Qual Saf, 29(12), pp. 1019–1032. doi: 10.1136/BMJQS-2019-010581.

Norman, D. A. (2013) *The Design of Everyday Things*, *Human Factors and Ergonomics in Manufacturing*. doi: 10.1002/hfm.20127.

O'Hara, J. K., Aase, K. and Waring, J. (2019) 'Scaffolding our systems? Patients and families € reaching in' as a source of healthcare resilience.', *BMJ Quality and Safety*, 28(1), pp. 3–6. doi: 10.1136/bmjqs-2018-008216.

O'Hara, J. K., Baxter, R. and Hardicre, N. (2020) '"Handing over to the patient": A FRAM analysis of transitional care combining multiple stakeholder perspectives', *Applied Ergonomics*. Elsevier Ltd, 85. doi: 10.1016/J.APERGO.2020.103060.

O'Malley, H. and Arksey, L. (2005) 'Scoping studies: towards a methodological framework', *International Journal of Social Research Methodology*, 8(1), pp. 19–32.

Odell, M., Gerber, K. and Gager, M. (2010) 'Call 4 Concern: patient and relative activated critical care outreach', *British Journal of Nursing*, 19(22), pp. 1390–1395.

Offner, P. J., Heit, J. and Roberts, R. (2007) 'Implementation of a rapid response team decreases cardiac arrest outside of the intensive care unit', *Journal of Trauma*, 62(5), pp. 1223–1228. Available at: http://www.ncbi.nlm.nih.gov/pubmed/17495728.

Osborn, J. *et al.* (2020) 'Do mHealth applications improve clinical outcomes of patients with cancer? A critical appraisal of the peer-reviewed literature', *Supportive Care in Cancer*. Springer, 28(3), pp. 1469–1479. doi: 10.1007/s00520-019-04945-4.

Parkinson, J. A., Eccles, K. E. and Goodman, A. (2014) 'Positive impact by design: The Wales Centre for Behaviour Change', *Journal of Positive Psychology*. Routledge, 9(6), pp. 517–522. doi: 10.1080/17439760.2014.936965.

Pham, H. and Galyean, W. J. (1992) 'Reliability analysis of nuclear fail-safe redundancy', *Reliability Engineering and System Safety*, 37(2), pp. 109–112.

Phelps, G. and Barach, P. (2014) 'Why has the safety and quality movement been slow to improve care?', *International journal of clinical practice*. WILEY-BLACKWELL, 111 RIVER ST, HOBOKEN 07030-5774, NJ USA, 68(8), pp. 932–5. Available at: http://apps.webofknowledge.com.librweb.laurentian.ca/full_record.do?product=WOS&search_mode=CitingArticles&qid=9&SID=1BXmOeJYrpejITftuXv&page=1&doc=1.

Ralston, J. D. *et al.* (2014) 'Home blood pressure monitoring, secure electronic messaging and medication intensification for improving hypertension control: a mediation analysis', *Applied clinical informatics*. Appl Clin Inform, 5(1), pp. 232–248. doi: 10.4338/ACI-2013-10-RA-0079.

Rapp, K. and Stroup, C. (2016) 'How Can Organizations Adopt and Measure Design Thinking Process?', *Cornell University ILR School*, (Fall). Available at: http://digitalcommons.ilr.cornell.edu/student/138.

Redfern, J. *et al.* (2014) 'A randomised controlled trial of a consumer-focused e-health strategy for cardiovascular risk management in primary care: The Consumer Navigation of Electronic Cardiovascular Tools (CONNECT) study protocol', *BMJ Open*, 4(2). doi: 10.1136/bmjopen-2013-004523.

Redfern, J. *et al.* (2020) 'A digital health intervention for cardiovascular disease management in primary care (CONNECT) randomized controlled trial', *NPJ digital medicine*. NPJ Digit Med, 3(1). doi: 10.1038/S41746-020-00325-Z.

Redley, B. *et al.* (2019) 'Patient participation in inpatient ward rounds on acute inpatient medical wards: A descriptive study', *BMJ Quality and Safety*. BMJ Publishing Group, 28(1), pp. 15–23. doi: 10.1136/bmjqs-2017-007292.

Rosa, R. G. *et al.* (2018) 'Study protocol to assess the effectiveness and safety of a flexible family visitation model for delirium prevention in adult intensive care units: A cluster-randomised, crossover trial (The ICU Visits Study)', *BMJ Open*. BMJ Publishing Group, 8(4). doi: 10.1136/bmjopen-2017-021193.

Ross, J. (2007) 'Health Literacy and Its Influence on Patient Safety', *Journal of*

Perianesthesia Nursing, 22(3), pp. 220–222. doi: 10.1016/j.jopan.2007.03.005.

Rosson, M. B. *et al.* (2002) 'Scenario-Based Design in: The Human-Computer Interaction Handbook: Fundamentals, Evolving Technologies and Emerging Applications', in. Lawrence Erlbaum Associates, pp. 1032–1050.

Sarkar, U. *et al.* (2010) 'The literacy divide: health literacy and the use of an internet-based patient portal in an integrated health system-results from the diabetes study of northern California (DISTANCE)', *Journal of health communication*. J Health Commun, 15 Suppl 2(Suppl 2), pp. 183–196. doi: 10.1080/10810730.2010.499988.

Sathanandam, S., Rastall, P. and Hoogewerf, J. (2016) *Personal health record (PHR) landscape review Final report*.

Schaepe, C. and Ewers, M. (2018) '"I see myself as part of the team" - family caregivers' contribution to safety in advanced home care.', *BMC nursing*. BioMed Central Ltd., 17(1), p. 40. doi: 10.1186/s12912-018-0308-9.

Schraagen, J. M. *et al.* (2010) 'Assessing and improving teamwork in cardiac surgery Assessing and improving teamwork in cardiac surgery', pp. 1–6. doi: 10.1136/qshc.2009.040105.

Seys, D. *et al.* (2012) 'Health Care Professionals as Second Victims After Adverse Events : A Systematic Review', *Evaluation & the Health Professions*, 36(2), pp. 135–162.

Snowden, D. (2010) *The Cynefin Framework*, *CognitiveEdge*.

Sport Wales, Street Games and Social Prescribing Youth Network (2021) 'Wales Youth Social Prescribing, Sport and Physical Activity', (March). Available at: https://www.england.nhs.uk/personalisedcare/social-prescribing/.

Steinmo, S. H. *et al.* (2016) 'Bridging the gap between pragmatic intervention design and theory: using behavioural science tools to modify an existing quality improvement programme to implement "Sepsis Six".', *Implementation science : IS*, 11(1), p. 14. doi: 10.1186/s13012-016-0376-8.

Stickdorn, M. *et al.* (2018) *This is service design doing : applying service design thinking in the real world : a practitioner's handbook*.

Subbe, C. P., W. J. (2013) 'Failure to rescue: using rapid response systems to improve care of the deteriorating patient in hospital.', *AVMA Medical & Legal Journal*, 19(1), pp. 6–11. Available at: http://cri.sagepub.com/content/19/1/6.

Subbe, C. P. *et al.* (2001) ‘Validation of a modified early warning score in medical admissions’, *QJM - Monthly Journal of the Association of Physicians*. Oxford University Press, 94(10), pp. 521–526. doi: 10.1093/QJMED/94.10.521.

Subbe, C. P., Øvretveit, J., *et al.* (2019) ‘Digital Technology: Opportunities and barriers for usage of personal health records in hospital – report from a -workshop of the Health Informatics Unit at the Royal -College of Physicians’, *Future Healthcare Journal*. Royal College of Physicians, 6(1), pp. 52–56. doi: 10.7861/FUTUREHOSP.6-1-52.

Subbe, C. P. *et al.* (2020) ‘Scenario-based design for a hospital setting: An exploratory study of opportunities and barriers for personal health records usage’, *Future Healthcare Journal*. Royal College of Physicians, 7(2), pp. 125–130. doi: 10.7861/FHJ.2019-0061.

Subbe, C. P. *et al.* (2021) ‘Express check-in: Developing a personal health record for patients admitted to hospital with medical emergencies: A mixed-method feasibility study’, *International Journal for Quality in Health Care*. Int J Qual Health Care, 33(3). doi: 10.1093/intqhc/mzab121.

Subbe, C. P. *et al.* (2024) ‘Martha’s rule: applying a behaviour change framework to understand the potential of complementary roles of clinicians and patients in improving safety of patients deteriorating in hospital’, *British Journal of Hospital Medicine*. MA Healthcare Ltd, 85(2). doi: 10.12968/HMED.2023.0422/ASSET/IMAGES/LARGE/HMED.2023.0422_F02.JPEG.

Subbe, C. P., Duller, B. and Bellomo, R. (2017) ‘Effect of an automated notification system for deteriorating ward patients on clinical outcomes’, *Critical Care*, 21(1). doi: 10.1186/s13054-017-1635-z.

Subbe, C. P., Goodman, A. and Barach, P. (2022) ‘Co-design of interventions to improve acute care in hospital: A rapid review of the literature and application of the BASE methodology, a novel system for the design of patient centered service prototypes’, *Acute medicine*. NLM (Medline), 21(4), pp. 182–189. doi: 10.52964/AMJA.0922.

Subbe, C. P., Tellier, G. and Barach, P. (2021) ‘Impact of electronic health records on predefined safety outcomes in patients admitted to hospital: A scoping review’, *BMJ Open*. BMJ Publishing Group, 11(1). doi: 10.1136/BMJOPEN-2020-047446.

Subbe, C. P. and Welch, J. R. (2013) ‘Failure to rescue: Using rapid response systems to improve care of the deteriorating patient in hospital’, *Clinical Risk*, 19(1), pp. 6–11. doi: 10.1177/1356262213486451.

The IHI Triple Aim | IHI - Institute for Healthcare Improvement (no date). Available at: http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx (Accessed: 30 August 2020).

Toffler A. (1980) 'The third wave: the classic study of tomorrow.', in. New York: Bantam.

Trout, K. E. *et al.* (2022) 'The Impact of Meaningful Use and Electronic Health Records on Hospital Patient Safety', *International journal of environmental research and public health*. Int J Environ Res Public Health, 19(19). doi: 10.3390/IJERPH191912525.

Unruh, K. T. and Pratt, W. (2007) 'Patients as actors: The patient's role in detecting, preventing, and recovering from medical errors', *International Journal of Medical Informatics*, 76, pp. S236–S244. doi: 10.1016/j.ijmedinf.2006.05.021.

Unruh, K. T. and Pratt, W. (2008) 'The Invisible Work of Being a Patient and Implications for Health Care: "[the doctor is] my business partner in the most important business in my life, staying alive" Motivation: Why Study Patient Work?', *Conf Proc Ethnogr Prax Ind Conf*, (1), pp. 40–50. doi: 10.1111/j.

Urstad, K. H. *et al.* (2022) 'Definitions and measurement of health literacy in health and medicine research: a systematic review', *BMJ Open*. British Medical Journal Publishing Group, 12(2), p. e056294. doi: 10.1136/BMJOPEN-2021-056294.

Valdez, R. S. and Holden, R. J. (2016) 'Health Care Human Factors/Ergonomics Fieldwork in Home and Community Settings', *Ergonomics in Design*. SAGE Publications Inc., 24(4), pp. 4–9. doi: 10.1177/1064804615622111.

Vincent, C., Neale, G. and Woloshynowych, M. (2001) 'Adverse events in British hospitals: preliminary retrospective record review.', *BMJ (Clinical research ed.)*, 322(7285), pp. 517–519.

Walker, P. P. *et al.* (2018) 'Telemonitoring in Chronic Obstructive Pulmonary Disease (CHROMED). A Randomized Clinical Trial.', *American journal of respiratory and critical care medicine*. United States, 198(5), pp. 620–628. doi: 10.1164/rccm.201712-2404OC.

Ward, J. K. and Armitage, G. (no date) 'Can patients report patient safety incidents in a hospital setting? A systematic review'. doi: 10.1136/bmjqs-2011-000213.

Werner, N. E. *et al.* (2021) 'Human factors/ergonomics work system analysis of patient work: state of the science and future directions', *International Journal for Quality in Health Care*, (S1), pp. 60–71. doi: 10.1093/intqhc/mzaa099.

Wilson, N. J. and Cordier, R. (2013) ‘A narrative review of Men’s Sheds literature: reducing social isolation and promoting men’s health and well-being’, *Health & Social Care in the Community*. John Wiley & Sons, Ltd, 21(5), pp. 451–463. doi: 10.1111/hsc.12019.

Yardley, S. *et al.* (2022) ‘Which human factors design issues are influencing system performance in out-of-hours community palliative care? Integration of realist approaches with an established systems analysis framework to develop mid-range programme theory’, *BMJ Open*, 12(1), pp. 1–15. doi: 10.1136/bmjopen-2020-048045.

Yen, P. Y. *et al.* (2020) ‘Development and Validation of WeCares, a Survey Instrument to Assess Hospitalized Patients’ and Family Members’ “Willingness to Engage in Your Care and Safety”’, *Joint Commission Journal on Quality and Patient Safety*. Joint Commission Resources, Inc., 46(10), pp. 565–572. doi: 10.1016/j.jcjq.2020.07.002.

Yin, G., Lin, S. and Chen, L. (2023) ‘Risk factors associated with home care safety for older people with dementia: family caregivers’ perspectives’, *BMC geriatrics*. NLM (Medline), 23(1), p. 224. doi: 10.1186/s12877-023-03893-3.

Zegers, M. *et al.* (2016) ‘Evidence-based interventions to reduce adverse events in hospitals: a systematic review of systematic reviews’, *BMJ Open*, 6(9), p. e012555. doi: 10.1136/bmjopen-2016-012555.