DITO Project

eChain of Prevention

A Translational Clinical Informatics approach to deteriorating patient care

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1 Foreword

The authors of this document and first deteriorating patient workshop team would like to dedicate this document to Master Aaron McCarter and his brave family for their help in sharing his story to shape developments in the care of seriously ill patients.

I would also like to thank my wife (Helen), family and those who have been in my corner, unconditionally, for the first part of a journey to transform development of safety critical information systems with open standards.

To all those for which an integrated chain of prevention has been too late, this work is the beginning of a movement for the integration of deteriorating patient care across specialty silos and business systems with open standards.

Dr Sandy Davey

2 A standardised approach to knowledge transfer

2.1 Aim

The overall project aim is to establish a standardised approach to knowledge transfer for digital transformation of rescue systems of care throughout the healthcare industry. In contrast to current proprietary approaches the project will be led by a collaborative consortium of NHS trusts and industry partners. This work is enabled by a substantial grant from Innovate UK and will utilise extensive patient and public engagement to transform care of deteriorating patients by enabling more effective and lower cost digital systems to better support professionals in delivery of care. The community will use an open approach, support scale and spread of a standardised electronic Chain of Prevention (eCoP). It is intended that each organisation making use of the approach outlined in this publication will provide feedback to support continuous improvement and evolve the digital transformation projects for deteriorating patients. This will help the system for digital transformation take as much of an active learning approach to improving the design and deployment of technology as the organisations do in providing care.

This publication aims to provide a description of, rationale for and guidance on the use of Translational Clinical Informatics methodology for development and deployment of electronic health record technology to improve deteriorating patient care.

2.2 Why this approach with digital health technology for deteriorating patients?

Deteriorating patient care is a public health problem for which the development of interoperable and integrated digital solutions has been lacking. Structure and processes of care for deteriorating patients are ubiquitous, they could and should be standardised. This has not been the case at a national level. From personal experience and literature review organisations have found integration of similar systems, with overlapping clinical function technically challenging and expensive. Furthermore, projects that have been successful locally will not necessarily be suitable for scale or spread without significant local customisation. By curating a common understanding of the structure and processes of care for deteriorating patients and the processing of information by end users it is possible to create a national standard for development and deployment of electronic health record technology to support care of deteriorating patients. This approach allows a more organised approach to one of the biggest clinical and socio-technical challenges in 21st century medicine, the digitisation of health records (1)

2.3 Scale of the problem: NCEPOD, NMR & NPfIT

Over the last century healthcare has evolved dramatically. Both the number and complexity of patients requiring hospital admission has increased significantly. With advances in clinical practice the range and severity of conditions that are survivable with acute care has kept pace with these changing demographics. Cardiac arrest, both in and out of hospital, has received intensive national attention and efforts to treat patients in the last fifty years. In more recent years focus of the acute care community has shifted from an emphasis on treatment of, to the prevention of cardiac arrest (2). Despite the evolution of acute care systems (3) failure to recognise and respond to deterioration is persistent problem. Repeated confidential enquiries (4-10), national audits and observational studies (11 - 19) report a significant proportion of patients still experience suboptimal care prior to a wide range of adverse clinical outcomes (ACOs) or serious adverse events (SAIs) in addition to cardiac arrest. These outcomes include unplanned ICU admission, emergency surgery, acute kidney injury and in patient death. Most recently, the National Mortality Review programme and the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) thirty years of learning report highlighted failure to rescue is a serious and persistent problem (20, 21). With around sixteen million emergency admissions to acute trusts each year in NHS England (22) even a small fraction of potentially avoidable adverse clinical outcomes is an enormous problem. As the population continues to expand and emergency admissions continue to increase, deteriorating patient care is a serious public health problem that requires high reliability approach to care.

Digital transformation is widely accepted as one of the ways in which care providers can keep pace with the challenge of providing high reliability care in an ageing NHS. Despite numerous potential benefits, the NHS has been notoriously slow to support adoption of health information technology. This latent digital inertia has been further magnified by the highly flawed and failed National Programme for IT (NPfIT) (1, 23). In the wake of NPfIT digital transformation attempts have continued with both tier one vendors offering enterprise solutions to a small number of trusts with large funds for capital expenditure and smaller standalone systems for specific clinical processes. This developed into a best of breed approach to achieving a single integrated national EHR. From a deteriorating patient perspective a number of systems that address operational problems such as patient flow, electronic observations and task planning began to spread in acute trusts. Over the last five years a number of papers on a range of topics relevant to deteriorating patients have been published with headline results of saving lives. Focus of these papers range from automation of early warning scores (24-28), acute kidney injury alerts (29) to sepsis alerts and machine learning algorithms (30, 31) to predict ACOs. Despite the implicit potential of standalone digital record technology to improve patient outcomes, the broader clinical community remains disappointed with its impact. There remains a number of barriers to adoption, some are clinical (use, usability etc.) some are technical and some are transformational (scale of change to practices is difficult to roll out without huge amounts of leadership support) and some of the issues lie with interoperability (and all of the sub-context surrounding that). Review of the recent evidence reveals a number of problems with conflict of interests, methodological limitations and fixation of magic bullet solutions for a complex but ubiquitous socio-technical problem.

Three broad challenges have been identified as critical to the success of EHR technology (32, 23). Usability, interoperability and resistance to process of care transformation have been identified a critical contributors to the widespread failure of EHR technology to achieve its expected potential impact on patient outcomes. Although the paper highlighting this problem was published in 2013 the themes are persistent as is highlighted by the establishment of organisations such as Interopen and NHSX.

Whilst there are examples of localised successes published in the popular media there is a real problem with scalability, spread and cost. Recent evidence highlights the magnitude of investment required to achieve performance gains. Although process adherence and patient satisfaction improved organisational efficiency did not. This was attributed to the large cost associated with EHR implementation. This publication refers to a seven year period in which over $30bn was invested in North America (33). Whilst, at a high level, deteriorating patient care is a very uniform process, digital transformation is not. Not every organisation can afford the capital expenditure for an enterprise wide EHR implementation from a tier one vendor with sufficient digital maturity to deliver a multifunctional rapid response system of care. This means each of the several hundred acute trusts and commissioning groups and many thousand GP practices in NHS England are looking to procure solutions at local level in settings with very different levels of digital maturity. This wide range of digital maturity means that feature and workflow expansion required for an effective deteriorating patient system is delivered in heterogeneous organisational contexts with various levels of digital processes and systems (Figure 1). Furthermore, without a standardised and robust approach to development and deployment of digital tools for deteriorating patients there is significant potential to waste a large amount of money, bit by bit, on small stand-alone solutions that are not poorly integrated. The problem of integration and having an active efferent limb is further highlighted by the move of many recent eObs vendors to partner with or become bigger EHR providers.

Figure 1. Delivering electronic transformation of deteriorating patient care in heterogeneous settings

<table>
<tr><th colspan="7">EHR Full / Part.... Digital improvement / implementation project</th></tr>
<tr><td>Business systems</td><td>RIMS</td><td>LIMS</td><td>ePMA</td><td>Notes</td><td>eObs</td><td>PAS</td></tr>
<tr><td>Specialities</td><td>Medical</td><td>Surgical</td><td>Nursing</td><td>AHP</td><td>BMS</td><td>Other</td></tr>
<tr><td>Setting</td><td>Acute</td><td>Elective</td><td>Primary</td><td>Out-pt</td><td>ED</td><td>Other</td></tr>
<tr><td colspan="7">Feature & Workflow Development / expansion</td></tr>
<tr><td colspan="3">Business systems</td><td colspan="2">Specialities</td><td colspan="2">PAS</td></tr>
<tr><td colspan="7">Information architecture</td></tr>
<tr><td colspan="7">Post deployment features & workflow extension £££££</td></tr>
<tr><td colspan="7">Outcomes after unscheduled care</td></tr>
</table>

Figure 2.1: Figure 1. Delivering electronic transformation of deteriorating patient care in heterogeneous settings

System development and deployment on a mix of different paper and digital systems means that each implementation must draw clinical information from an already established range of different or replace a paper process. It can be appreciated from figure one that while each business or speciality system and setting deals with a discrete use case the underlying clinical information is essentially identical from a conceptual perspective. Unfortunately, the clinical information recorded on paper or stored electronically is highly mismatched. So when it comes to integrating this information more horizontally, the new system must reinvent a large fraction of clinical information that already exists in each system but is not computationally identical. As this happens at a local level and drives revenue, vendors are eager to customise to local needs and engage with clinicians. Such proprietary packaging of medical knowledge with local customisation is the main cause of poor semantic interoperability. Limited interoperability causes vendor lock in that stalls iteration and feature roadmap development with large upfront costs that could have been avoided. This economic burden directly drives the second factor contributing relative failure of EHR to effect improvements in patient care at a national level. Problems with usability are also highlighted by emerging concerns about EHR contribution to physician burnout in America. Usability in the acute setting is a complex challenge as clinicians have to contend with low technology to user ratios, busy wards and the need to access, analyse and author clinical information at or near the bedside. Process change is essential if digital transformation is to improve outcomes for patients that deteriorate in hospital. There are established organisational barriers that limit horizontal team working across settings and specialties. Electronic observations as a solution to suboptimal deteriorating patient care is a prime example of this. Improved Early Warning Score accuracy and automation still requires ability to action alerts. Irrespective of c-Statistic there will inevitably be an unavoidable increase in clinical workload from optimising recognition of patient deterioration. Failure to adjust people & process to optimise workflow around enhanced detection and escalation of care will neutralise the benefits of enhancing afferent limb performance in the new system of care.

In summary, there is a real population need for digital transformation of deteriorating patient care. Digital transformation offers potential to achieve a high reliability approach to recognition and rescue of patient deterioration. However, efforts up to this point have not been robust and reproducible from a clinical or cost effectiveness perspective. Systems for deteriorating patient care are both ubiquitous and standardisable. By taking a universal approach to development and deployment of deteriorating patient systems key stakeholders will address factors contributing to the relative failure of EHR technology to help deliver the triple aim up to this point. The next sections outline how improvement science supports system scoping for a translational clinical informatics approach to developing and deploying useful and usable systems with robust and reproducible process, outcome and balancing measures.

2.4 Health IT: an improvement science & high reliability perspective

Developing technology for deployment in complex systems requires a rigorous understanding of the care pathways, social context and digital landscape within an organisation. A single focus on mapping a workflow fails to capture the complexity in which the application will be deployed. Typical informatics discovery or business process mapping tools tend to focus on small aspects of a complicated system. Building related elements separately without a shared understanding of the bigger picture creates barriers to horizontal integration of digital solutions at a later point. While some patients may come to hospital under single speciality and receive mono-speciality care along a specific workflow, this is not usually the case. The patient journey cuts horizontally across multiple specialties and silos within the organisation. While semantic and pure technical interoperability of discrete systems is well recognised, horizontal interoperability along the patient journey and within the healthcare system is not. This can be considered as a socio-technical interoperability problem. As digital maturity increases or new technology evolves integration of separate systems around the patient journey that were developed with a specific process in mind becomes a much bigger problem. Combining an improvement science approach to understanding the system with conventional approaches allows the community to curate deeper and socio-technical insights that form the basis for digital transformation of deteriorating patient care. The open standards community believes considering socio-technical interoperability early in the design phase improves future proofing in a rapidly expanding field. Both Donabedian (33) and high reliability system models (34) of care are particularly important to understanding the structure and process of care. The NASSS framework provides critical contextual insight into the interactions of a proposed technology and its physical and social environment (35).

From a Donabedian perspective patient outcomes are determined by structure and process of care (33). High reliability considerations view structure and processes from those with a separate functions of routine or planned and rescue systems of care. The focus is split between minimising error by getting care right first time and resolving error or rescuing the system when an error occurs (34). In the healthcare setting routine and rescue systems are not thought of as completely distinct elements. Structure & process for rescue systems of care are well defined and discussed in more detail below. Most clinicians will be familiar with these concepts as the getting it right, first time (GIRFT) initiative and rapid response systems (RRS). High reliability systems are also characterised by an open and active learning culture. This must be incorporated into plans for digital transformation of deteriorating patient care. Given the link to ACOs it is especially important that such digital tools support an objective framework for both critical appraisal of ACO antecedents and celebration of the ACOs avoided by the team. The role of learning is acknowledged below with a description of the chain of prevention.

As suggested above, routine systems of care are predetermined workflows or clinical pathways organised around a specific specialty, disease or clinical problem. Acute myocardial infarction, emergency laparotomy and severe sepsis pathways are good examples. These systems operate well when the condition frequently presents in an overt and readily identifiable way. However, many patients either do not have a clear diagnostic label or deteriorate while receiving a routine pathway of care.

Rescue systems of care are designed to recognise evolving or established life threatening organ dysfunction that precedes adverse clinical outcomes such as death, cardiac arrest or unplanned critical care admission. In some cases, such as acute kidney injury, the organ dysfunction is the target condition and antecedents are more than clinical signs on examination. Rescue systems of care are ubiquitous and cross cutting systems that have been described in many ways. As this project overall aim is to improve reduce of deteriorating patients, anatomy of rescue care is described in more detail below.

Use of the NASSS (35) framework for eCOP will be explored as the project progresses. It is likely there will be additional information added based on learning from later development and deployment work.

2.5 Summary

- Appreciate the system from a Donabedian & high reliability perspective - i.e. the patient journey not a silo or speciality workflow or setting
- Sociotechnical interoperability of systems silos is improved when they are designed with the overarching view of SPO rescue systems.
- Application NASSS framework will be tested.

3 Anatomy of rescue care: Rapid Response Systems & Chain of Prevention

In 2006 the first international consensus conference on medical emergency teams defined four elements of rapid response systems (RRS). This was to unify the emerging concepts of rapid response teams, critical care outreach and medical emergency teams. Conceptually, front line elements of rapid response systems were described in terms of linear afferent and efferent limbs for recognition and rescue of deteriorating patients, respectively (3). Overarching governance and case review elements were also described. More recent work used the cardiac arrest chain of survival concept to present RRS components as separate links in a chain of prevention (COP) that includes education, monitoring, recognition, call for help and response (2).

In reality RRS span multiple structural, electronic, paper and human elements that do not always form a neat feedback loop or linear chain within a golden final six hours prior to an ACO. Clinical professionals involved in rapid response systems of care varies considerably. Some organisations have specific medical emergency teams or patient at risk teams while other areas use critical care outreach teams to support recognition and rescue of deteriorating patients. Furthermore, patient populations served are very heterogeneous as RRS / COP span all specialties and settings in healthcare.

For purposes of standardising digital transformation of deteriorating patient care while maximising interoperability this work utilises the chain of prevention concept. Despite their simplicity both RRS & COP are useful concepts to describe a complex system. Both are generally based around a vital sign generated early warning score (EWS) trigger with escalation protocol and ABCDE based assessment for recognition and response from a professional with a level of clinical competency that matches acuity of the physiological trigger. One of the key areas not well addressed in either of the descriptions above is the role of communication and handover within and between teams over time. Patient deterioration often progresses in a way that cuts across shifts, specialities and even physical settings or sites. Communication within and between teams is an essential element of a RRS or COP. This is illustrated below with a modification to the chain of prevention proposed by Smith (2). Version 2.0 of the Chain of Prevention contains a communication ring that emphasises the flow and evolution of clinical information is as important as the call for help in an established crisis.

Figure 3.1: eChain of Prevention Version 2

3.1 Summary

- Active learning system - celebrates & critically identifies & incorporates best practice

4 Problems with deteriorating patient care - why does it (still) go wrong?

Design of digital health technology must consider underlying causes of system failure. With deteriorating patient care system failure has catastrophic consequences. Finding recurrent themes in complex systems that can fail in an almost infinite number of ways is difficult. By examining ACOs through a chain of prevention lens it is possible to localise where the weak links are and examine why they fail. With over 30 years of NCEPOD reports, Observational studies and case record review programmes several themes have been highlighted. At a system level there are many problems not directly amenable to digital transformation. Acute care is provided by consultant supervision of trainees for a high volume of patients in time constrained setting. Furthermore the complexity of patient acute illness and underlying comorbidity is increasing. Not only are clinicians operating in time constrained settings they are operating at or near and sometimes over capacity. The system factors contributing to ACOs can be summarised as high volume, high velocity care for complex patients at or over capacity. At a process of care level there are multiple opportunities to improve care that are amenable to digital transformation. Problems have been described with both monitoring and response links while there are many problems with a lack of learning from ACOs. Monitoring with early warning scores is an obvious process that can be improved. But it must also be remembered that for many health care professionals the EWS also serves as their recognition tool. The NEWS2 iteration into an ABCDE format highlights the shift toward use of vital signs as a recognition tool. From a recognition and response perspective problems with deteriorating patient care can be condensed into:

1. Content of clinical assessment
2. Cognition - bias and error
3. Contingency plans
4. Communication within and between teams

Content of clinical assessment: incomplete ABCDE note & NEWS chart is a common finding in chart review of patients that experience adverse clinical outcomes. This means assessment of patient condition or risk of adverse event is incomplete. Much work has focused on NEWS. More recent publications highlight the problem with ABCDE assessment and actions by junior members of the team.

Cognitive bias and error frequently contribute to delays in recognition & response to evolving or established serious / critical illness (37 - 44). It has not received much attention from RRS perspective and the impact is often diluted by latent but accidental recovery processes. This leads to a degree of redundancy and intrinsic dissonance in the system toward causality over contribution & latent threat.

Contingency plans are often inadequate and fail to take into account patient personalised risk

Communication between and within teams in space and time is a serious challenge. The goal is to achieve common grounding / mutual understanding between agents but a low signal to noise ratio and other factors pervert the high fidelity flow and evolution of clinical information (45).

Active learning is also an essential component of high reliability care. Digital COP projects should consider integration of national mortality review and human factors frameworks to facilitate optimal organisational learning (16 - 18, 46).

4.1 Role of family or carers in Chain of prevention v2.0

While rescue care processes traditionally focus on clinical team performance there is evidence that family or carer involvement is not only beneficial but essential for high reliability care. Often family members or carers of patients that suffer an adverse clinical outcome describe an uneasy and persistent visceral sensation that something is not quite right despite reassurance that is often (unintentionally) obstructive. Evidence from recent work on nurses worry (47) suggests that family or carers recognise signs of evolving or established organ dysfunction from serious illness but are unable to express (or be heard) in a way or with vocabulary that matches the assessment construct used by professionals. There are some questions around family initiated escalation of care

1. Are family and carers competent to escalate / communicate concern
2. How do they escalate / communicate concerns?
3. Who escalate / communicate concerns to?
4. What if there appears to be persistent obstruction / avoidance in face of failure to improve?

There is no doubt that digital transformation could enhance family or carer activation of RRS/COP. Unless this aspect is designed at an early phase clinical performance and interoperability will be difficult to build at a later stage.

4.2 Processing information - an alternative paradigm for digital health technology

There is a poorly expressed distinction between providing information for process of care or clinical workflows and processing information by an end user to make decisions about care. The former is an attractive option for decision makers and an easier target for vendors than the latter. Optimising processing information is not solely about user interface and experience. There are various ways in which processing information at a single or multi-patient level can be enhanced. Maximising processing of information should be recognised as a critical function of all digital health technology let alone something as safety critical as eCOP. Health care professionals process information in four main ways in the conduct of care:

1. A1: Access
2. A2: Analysis
3. A3: Authoring
4. A4: Actioning

A1: Access to information is a core element of care. Defining who & what is important in the care pathway for deteriorating patients.

A2: Analysis of information from multiple sources in a time efficient and cognitive ergonomic format is the key to usability and utility.

A3: Authoring forms an essential part of care management and communication within and between teams. As discussed in more detail below, there are considerations around how records support cognitive synthesis and information hierarchy has a strong influence on UI real estate and the process of common grounding.

A4: Actioning instructions and appreciation of process state is an important part of care management and communication. Critical processes often end up omitted because of problems in process state management.

Although clinicians process information in four main ways as outlined above, understanding the purpose for processing information by an end user is helpful in the user interface and features design of any digital health technology. Health care professionals process information for care or communication we events. Both care and communication events require information processing for synthesis, state process monitoring and sharing information for common grounding (45). Although purpose of clinical information processing is very similar, the user interface and features requirements can be considerably different.

1. Clinical Care encounters
    a. Synthesis & State process
        - Diagnosis & dysfunction
        - Tests & treatment
    b. Shared understanding / Common Grounding
        - Patient & family or carer understanding of
2. Communication for handoff
    c. Synthesis & State process

- New issues escalated / challenged

d. Shared understanding / Common Grounding

- MDT & shift changes

Both the above purposes must deal with presentation of, and interaction with, large volume and variety of complex information to an end user. There will also be an inherent structure and hierarchy that affects how the information should be presented and interacted with. Further consideration must be given to the variety of professionals processing the information for these two broad and very different purposes. This leads to consideration of rules for context based presentation and features that support interaction with the clinical information.

4.3 What does it do? A mechanism of action perspective on Health IT

One of the most noticeable problems during discovery for digital health projects is that discussion often switches between content and features without explicit awareness of the distinction and dependency of either. This leads to difficulty in scoping and costly post deployment features expansion. There is also a significant impact on usability as clinical expectations for advanced functions to facilitate authoring, analysis or action go unmet. Building on the information processing perspective it is important to appreciate feature or function development f

Having a shared understanding of the basic mechanisms of action for digital health technology will support more effective clinical engagement between health care professionals and application architects. There are four broad mechanisms by which digital health technology can support processing of clinical information by healthcare professionals.

1. TM1: Task management & automation / alerting
2. TM2: Telemedicine / remote consulting
3. DM1: Decision / cognitive support.
4. DM2: Data mining / science & AI

TM1: Task management & automation / alerting - is one of the lower hanging fruit in digital transformation but the underlying need to curate and contextualise clinical information for a particular end user is a difficult challenge. The flow and evolution of information must be grounded with multiple actors in every patient's story at both low and high levels of granularity.

TM2: Telemedicine / remote consulting - bringing the clinical expertise to many patients electronically instead of physically has a clear advantage.

DM1: Decision / cognitive support is already provided with paper records. Using clinical noting templates to minimise diagnostic error is a long-standing practice. Digital records have potential to support cognition in a much more dynamic way. Usability and distinction between primary and secondary use data is critical to avoid excessive data collection burden during the clinical encounter. Clinical noting is a medium for the integration and synthesis information critical to diagnosis and treatment. Cognitive support could be regarded as passive decision support. Active Decision support is an important feature but requires clear information model and local engagement for process triggers and action agreement.

DM2: Data mining / science & AI. Advanced analytics are promising but, at the time of writing, have not yet penetrated front line digital health technology. There are also ethical considerations around fair use of special category data for research and development of a product that will be sold back to the data subject in a way that could impact on their right to access health care. Personalised risk prediction and hand over are promising areas to explore application of these functions.

4.4 Translational Clinical Informatics: A Code to Clinical Practice Approach

In the first section the relative failure of traditional digital transformation projects was highlighted. Using the eChain of Prevention as an example, an alternative paradigm for development and deployment of digital health technology is discussed in this section. Given similarities with pharmaceutical research and development methods, this paradigm is discussed as a translational clinical informatics model. Translational Clinical Informatics combines an improvement science methods with iterative design and use of high fidelity simulation for both development and deployment in complex adaptive systems such as RRS.

4.5 Scoping system "structure, function & pathology" for Health IT

Using a high reliability lens to appreciate existence of routine and rescue systems of care as a framework to understand the overarching structure and process that can be improved for better outcomes. Rescue care structure and elements of the chain of prevention span a number of clinical processes that are considered discrete with traditional informatics approaches. Functionally, each link in the chain of prevention can be considered from a processing information perspective. Both care and communication events are encompassed with the chain of prevention and each has specific functional considerations. Pathology of adverse clinical outcomes in terms of system failure are well appreciated. Pharmacology or digital health technology mechanism of action approach allows developers to target weak links in the chain of prevention.

Figure 2. Structure & function approach to digital health technology design

4.6 Building a Minimum Viable Prototype (not product!)

Following exploration and development of a robust understanding of the system as outlined above, design of a minimum viable prototype (MVP) for iterative preclinical development is the next step. Clinical and technical requirements specification of an eChain of Prevention MVP must cover a set of minimum features for an afferent and efferent element application and map potential links with various EHR Systems to maximise future development as digital maturity increases.

Outcomes following Unscheduled Care			
Consider PATIENT Journey & elements of high reliability care			
Routine: GIRFT		Rescue: RRS	
Information architecture (Archetype / FHIR / PRSB mapping) – what is the necessary clinical content?			
Elements	Composition	Templates	Other classes
Information processing considerations for front end – what does end user do with the info?			
Access	Analysis	Authoring	Action
Front end features with iteration & innovation – what does application do to support end user?			
Task management –planning & alerting	Telemedicine	Data mining / science	Decision / cognitive Support
Pre-deployment features workflow & development for operationally viable tool			
Deployment with high fidelity simulation as training as service improvement project			
EHR Full / Part.... Digital improvement / implementation project			

Figure 4.1: Figure 2. Structure & function approach to digital health technology design

4.6.1 Clinical requirements

- Task Management / navigation
- Event Schedule classes (1S & 2US)
- Task-Patient-Device process
- ISBAR framework / template for dynamic situation & background
- Transcription / transfer of clinical action / assessment
- IBSAR framework / template for recommendations: Analysis & Task planning
- Event audit & edit
- Master Physiology Event Timeline

EHR systems eCOP may need to link with.

- General dependencies - enterprise wide systems e.g. PAS / MPI / Spine / Enhanced Prescribing Database
- Education - incident reporting & review tools
- Monitoring - observations & telemonitoring
- Recognition - ABCDE clinical noting
- Communication - hand off systems
- Response - CPOE Systems

Developing an operationally viable product (OVP) by testing and iteratively developing the MVP is the final step before deployment. The use of high fidelity simulation to support this process is discussed below.

4.7 High Fidelity Simulation

Many clinicians and other health care professionals recount their early encounters with mission critical digital health tech as on the job training. Yet airline pilots receive many hours training and redundant live flight time when becoming familiar with new flight controls. High fidelity simulation has potential for dual benefit to both development and deployment phases of new digital health technology. From a development perspective, one of the main problems with DHT is the potential for a golden goose effect. Traditional design test build deploy cycle has proven costly with post procurement "critical" feature development that was overlooked early in the project. Recent evidence highlights that it has taken $30bn in America for EHR suppliers to begin deployment of systems that have adequate usability. On the job familiarisation with complicated software is not a safe or effective way to deploy even a small standalone system. By extending the use of high fidelity simulation into deployment phase there are additional benefits to staff, from an organisational learning perspective. Learning how to use new tools in a range of clinical scenarios optimises understanding of the clinical system or problem that is being used for the simulation.

4.8 Iterative development of operationally viable prototype before procurement

Even with the most fastidiously developed clinical specifications, further insight into the structure and functions of eCOP will be gained with high fidelity simulation based preclinical testing. With sufficient spread of clinical scenarios it is possible to saturate how the tool would be used by most people most of the time. Using traditional DBTD leaves a much bigger gap for implementation that is usually filled with a large number of requests for customisation. (48 - 51)

4.9 Deployment for continuous improvement and change management

Using high fidelity simulation for deployment is not just good change management, it has a potentially very useful unintended benefit on care of deteriorating patients. As highlighted above the change management process effectively becomes a complex multifaceted intervention that supports core knowledge and competency development beyond use of technology. Wright Singh Meeks (52, 53)

4.10 Outcomes based accountability: measuring utility, usability & use-affinity

There are a variety of measures that can be used and misused in the evaluation of digital health technology. As already highlighted above, both the clinical problem and solution are not amenable to a traditional evidence based medicine approach. By combining an improvement science, Donabedian and information systems approach it is possible and more robust to use a suite of measures in evaluating the impact of a digital health technology (54, 55). The measures available are listed by complexity, below.

- **Counting**: Accuracy & adherence of afferent & efferent limb processes. Should include balancing measures around workload and alarm fatigue.

- **Timing**: Score to door time, Trigger time or duration and frequency
- **Outcomes**: MAELOR, 3rd Consensus conference on Medical emergency teams, CUMSUM charts for predicted mortality
- **Quality of care**: Use of structured judgment review methods helps standardise review of care when explicit measures are not available.
- **Quality of information system**: User acceptance testing, Delone & McLean, NICE digital health technology evidence framework.
- **Cost effectiveness**: NICE DHT evidence framework

The overall method in which impact is measured is also important. Before and after designs have significant methodological disadvantages. Use of stepped wedge design methods in deployment has been reported and is a pragmatic way to balance the constraints of complex systems with the need for more robust evidence of effectiveness (56, 57)

As the project proceeds more detail on measures used and results generated will be added.

4.11 Summary

- Appropriate panel of measures for continuous improvement should include a variety of process and outcome measures.

5 Conclusion

Understanding the structure and process of care and problems within the system supports enhanced design of digital health technology for deteriorating patients. Using an iterative improvement science based approach from code to clinical practice maximises the utility, usability and user-affinity predeployment. This will optimise the clinical and cost benefit of digital health technology deployed in a live healthcare setting for seriously ill patients.

6 Appendix 1: Scoping workshop facilitator guide

6.0.1 Suggested outcomes for an eChain of prevention (eCOP) v2.0 workshop

- Formalise a shared understanding of Rapid Response Systems and Chain of Prevention concepts as safety critical systems in preventing adverse clinical outcomes.
- Consider chain of prevention failure from an information processing perspective.
- Appreciate how generic functions of eHealth technology can support information processing to remediate failures in deteriorating patient care with an eChain of prevention.
- Describe the use of high fidelity simulation for both iterative preclinical development and deployment to ensure innovation that is useful, usable and used.

6.0.2 eCOP v2.0 Workshop Agenda & Details

Scoping for an eChain of prevention [Outline]
0900 - 0930 Registration, introductions & outline for common grounding 0930 - 1015 **Deteriorating patients: lessons from NCEPOD, NMR & NPfIT** 1015 - 1045 **Overview of eChain of Prevention & Translational Clinical Informatics Approach** 1045 - 1100 Instructions to group for workshop participation 1100 - 1130 Tea / Coffee 1130 - 1230 **First Solution Requirement group discussion - Process mapping the chain** 1230 - 1330 Lunch 1330 - 1500 **Second Solution Requirement group discussion - Structure, function & features** 1500 - 1530 Tea / Coffee 1530 - 1700 **Features roadmap discussion**

6.0.3 Guidance on conducting eCOPv2.0 TCI workshop & description of deliverables

Introduction - What is it and why are we using it? An overview of the holistic approach (add diagram from your presentation). eChain of Prevention with details of what is described above.

Steps to follow during workshops;

1. Structure, Process & Outcome
    a. Consideration of problems with Deteriorating Care
    b. Definition of adverse clinical outcomes
    c. Structure of the chain of prevention & RRS
    d. Process & macro (minimum) workflow
2. Consideration of RRS / COP from an Information Processing mapped to 4As & 4 main mechanisms of action
3. Scoping ISBAR - NEWS tool
    e. Content scoping for work on gap analysis in UK Clinical Models
    f. Function, features & charts - UX/UI
4. Discuss role of High Fidelity Simulation in development and deployment

Process Map: Monitoring - Communication - Response chains of eCOP v2.0

Observation (Low, Medium, High), this is equally applicable to apply this approach for RESET, any acute care EHR technology. See separate diagram.

TCI scoping template: ISBAR-NEWS

Structure / Content				Function / features								
Section	Element	Data	End-user information Processing notes	Mechanisms of Action / features notes	A1	A2	A3	A4	TM1	TM2	DM1	DM2
ID (Patient / Professional)												

Situation	Participant	
Background	Presenting	
	PM/D/PHx	
	Progress	
Assessment / Action -	All NEWS Vitals	
NEWS		
	RR	
	SpO2 (Def)	
	SpO2 (Alt)	
	FiO2	
	HR	
	SBP	
	DBP	
	ACVPU	
	TEMP	
	NEWS	

Recommendations Assessment/

Grade/ Date/ Timing/|||||||| ||Intervention|A-E Class T/T Class|||||||| ||Monitoring|NEWS Other||||||||

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