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Characterising clinically integrated remote sensing and digital alerting tools for the assessment of health status in community and hospital care

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BSc (hons) MBChB (hons)

2022

Submitted in part fulfilment of the requirements for the degree of

Doctor of Philosophy in Medicine of the University of London

and the Diploma of Imperial College, 2022

"Technology is an extension of the human body" *Marshall McLuhan*

Acknowledgements

Firstly, I would like to thank my parents, who have encouraged me to pursue my own path in order to gain knowledge. Without their guidance throughout the years, I would not have the drive to be ambitious and pursue this PhD.

My greatest achievements, to come from my time of undertaking a PhD, have been the birth of my two children. Despite the sleepless nights, the opportunity to see both kids grow has been priceless. For this, and all the unwavering support given to me by my wife, I dedicate this thesis to Emese, Musa, and Asiyah.

I would also like to thank my supervisors for their endless support; Dr Meera Joshi, who laid the foundations of the work that I have attempted to build upon, in the hope that I have done the initial work justice. Dr Sadia Khan who facilitated the entire trial over at West Middlesex Hospital, and whom without this work would not have been possible. Dr Hutan Ashrafian, for his continuous and exaggerated words of encouragement during times of need and, lastly, Lord the Professor Ara Darzi who enabled this innovative work to take place.

I would like to express my gratitude to the wonderful research nurses, Dr Arti Sharma and Miss Antonia Koutsoukou, from the National Institute for Health Research (NIHR) clinical research network. Without them, recruitment and data collection would not have been possible.

A special thank you also to the charitable donations from CW+ for funding and supporting this work. Lastly, to my fellow clinical research fellows and friends (Viknesh Sounderajah, Amish Acharya, and Kyle Lam) thank you for facilitating much of my work and listening to my habitual complaining.

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Abstract

Remote monitoring and digital alerting tools have gained momentum in their popularity, owing to both recent technological advances and the COVID-19 pandemic, facilitating a more digitised workflow. Continuous remote monitoring of vital signs, using wearable sensors, provide additional datapoints which may result in earlier detection of deterioration and treatment; therefore, improving clinical outcomes.

A system was chosen based on previous validation and usability research, this was a wearable sensor which measured axillary temperature, heart and respiratory rates every 2 minutes. Upon breeching tailorable thresholds, alerts were sent to healthcare professionals requesting acknowledgement with the subsequent clinical action recorded.

The implementation of this system was tested in two parallel streams. Firstly, in community settings through repositioned hotels; the system was used to assess a proof-of-concept model of healthcare delivery for individuals requiring mandatory isolation for COVID-19. In total, 10 vital alerts were generated across 4 participants, resulting in telephone contact, reassurance, or adjustment of the sensor. Secondly, in an acute secondary care surgical setting, there were no significant differences in planned and unplanned intensive care admissions, hospital length of stay, or 28-day mortality.

Mixed-methods analyses of barriers and facilitators for implementation of remote monitoring and digital alerting tools within complex health organisations was conducted. Technological acceptance and key evaluation measures were mapped to system use (human), user satisfaction (human), environment (organisation), structure (organisation), information and service quality (technology), and system quality (technology).

Remote sensing and digital alerting tools can enhance healthcare delivery and workflows. This thesis delivers key recommendations to push healthcare systems into a digitally enabled era which can improve patient safety, targeting the failure to recognise and escalate phenomenon of clinically deteriorating patients.

Statement of Originality

I certify that, to the best of my knowledge, the contents of this thesis are my own work. This thesis has not been submitted for any other degree elsewhere. The intellectual content of this thesis is a result of my own work and all the assistance received have been acknowledged.

Copyright Statement

Publications Arising from the Thesis and Related Work

1. **Iqbal FM**, Lam K, Joshi M, Khan S, Ashrafian H, Darzi A. Clinical outcomes of digital sensor alerting systems in remote monitoring: a systematic review and meta-analysis. NPJ Digit Med. 2021 Jan 8;4(1):7. doi: 10.1038/s41746-020-00378-0. PMID: 33420338

2. **Iqbal FM**, Joshi M, Davies G, Khan S, Ashrafian H, Darzi A. Design of the pilot, proof of concept REMOTE-COVID trial: remote monitoring use in suspected cases of COVID-19 (SARS-CoV-2). Pilot Feasibility Stud. 2021 Mar 5;7(1):62. doi: 10.1186/s40814-021-00804-4. PMID: 33673868.

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Selected Presentations Arising from the Thesis

1. **Iqbal FM**, Joshi M, Khan S, Davies G, Ashrafian H, Darzi A (2020). REmote MOni-Toring usE in suspected cases of COVID-19 (SARS-CoV 2): the REMOTE-COVID trial. Pilot, proof of concept?
   Oral presentation at: *Research, Innovation and Quality Improvement 2020, Chelsea & Westminster NHS trust.*

2. **Iqbal FM**, Joshi M, Khan S, Davies G, Ashrafian H, Darzi A (2020). The pilot, proof of concept REMOTE-COVID trial: remote monitoring in suspected cases of COVID-19 (SARS-CoV 2)
   Virtual webinar delivered to: *Institute of Global Health Innovation Forum.*

3. **Iqbal FM**, Joshi M, Khan S, Davies G, Ashrafian H, Darzi A (2020). Insight into mental health of individuals undergoing mandatory isolation
   Oral presentation at: *Research, Innovation and Quality Improvement 2020, Chelsea & Westminster NHS trust.*

4. **Iqbal FM**, Joshi M, Khan S, Davies G, Ashrafian H, Darzi A (2020). Clinical outcomes of digital sensor alerting systems in remote monitoring: a systematic review and meta-analysis.

   Oral presentation at: *Research, Innovation and Quality Improvement 2020, Chelsea & Westminster NHS trust.*

5. Koutsoukou A, Joshi M, Khan S, **Iqbal FM**, et al (2019). The Affect of Body Mass Index on Wearable Sensor Data Availability

   Poster presentation at: *NIHR CRN Chelsea & Westminster NHS trust.*

List of Abbreviations

ACP	American College of Physicians
AF	Alert fatigue
AI	Artificial intelligence
ASA	American Society of Anaesthesiologists
BAME	Black Asian Minority Ethnic
BP	Blood Pressure
CE	European Conformity
CI	confidence interval
ECG	Electrocardiography
EHR	Electronic Health Record
EQUATOR	Enhancing Quality and Transparency of Health Research
EWS	Early Warning Score
FDA	Food and Drug Administration
GP	General Practitioner
HMIC	Health Management Information Consortium
HOT-fit	human, organisation, and technology
HR	Heart Rate
ICO	Information Commissioner's Office
IP	impedance pneumography
IRR	Incidence rate ratio
IT	Information Technology
ITU	Intensive Treatment Unit
LOS	Length of Stay
MHRA	Medicines and Healthcare products Regulatory Agency
NEWS 2	National Early Warning Score 2
NHS	National Health Service
NICE	The National Institute for Health and Clinical Excellence
OR	Odds ratio
PDSA	Plan, Do, Study, Act

PHE	Public Health England
PSM	Propensity score matching
RCGP	Royal College of General Practitioners
RCP	Royal College of Physicians
RCT	Randomised Controlled Trial
RR	Respiratory Rate
SARS-CoV 2	Severe acute respiratory syndrome coronavirus 2
SMH	Society of Hospital Medicine
SUS	system usability scale
TAM	Technology Acceptance Model
UI	User Interface
UK	United Kingdom
USA	United States of America
UX	User Experience
WHO	World Health Organisation
WMD	weighted mean difference

1. Introduction

1.1 Vital Signs

1.1.1 Origin of The Early Warning Score (EWS)

As the end of the 20th century approached, research began to indicate the growing incidence of adverse events and unnecessary deaths in hospital patients. The findings of the landmark Harvard Medical Practice Study highlighted that a substantial proportion of injuries and adverse events to hospital patients were the result of substandard care rather than disease processes.[4] This led to slight or short-term disabilities, but on occasion permanent damage which contributed to their death. However, this was not a state related phenomenon, rather a global one with comparable retrospective and prospective reviews reporting similar rates elsewhere in the United States of America (USA) and Australia; in the United Kingdom (UK), approximately 11% of patients experienced an adverse event.[5–9]

In 1991, Early Warning Score (EWS) were first proposed as a solution to act as a clinical prediction model based upon measured vital signs.[10] Initially, this included Heart Rate (HR), systolic blood pressures, Respiratory Rate (RR), temperature, and use of the AVPU (alert, voice, pain, unresponsive) scale. The model is purposed to identify the likelihood of deterioration of hospital patients; EWS trigger a warning so that care can be escalated upon signs of deterioration. In 1991, a modified EWS was introduced to selectively tailor to surgical patients with the components aggregated to yield a score to facilitate subsequent action (e.g., facilitate transfer to a critical care facility).[11] Following on from this the Audit Commission, in 1999, reported that the efficacy of critical care services varied substantially between hospitals and recommended the use of EWS as a means of standardisation.[12]

1.1.2 National Early Warning Score 2 (NEWS 2)

Fast forwarding to today, through further refinements, the Royal College of Physicians (RCP) have endorsed the use of the National Early Warning Score 2 (NEWS 2) score to be adopted across the UK, which has become mandated as a standard of care by The National Institute for Health and Clinical Excellence (NICE).[1, 13], For patients on general (non-intensive wards),

it is recommend that vital signs are recorded every 12h as a minimum; each vital parameter routinely measured in clinical practice (HR, RR, temperature, Blood Pressure (BP), oxygen saturations (& supplemental oxygen), and level of consciousness) and individually scored according to severity. This is aggregated for a total NEWS 2 score (Figure 1.1) which dictate subsequent action in a protocolised manner. Observations are performed every 4-6 hours for those with a NEWS 2 of 1-4, hourly for a NEWS 2 of 5-7, and continuously for patients with a NEWS 2 of 7 or more (Figure 1.2). For acutely unwell patients, an increased frequency of monitoring is required. However, due to staffing issues, relative resource scarcity, and perceived nursing beliefs have meant that real world compliance to these recommended timings can be low.[14, 15]

Physiological parameter	Score 3	2	1	0	1	2	3
Respiration rate (per minute)	≤8		9–11	12–20		21–24	≥25
SpO_2 Scale 1 (%)	≤91	92–93	94–95	≥96			
SpO_2 Scale 2 (%)	≤83	84–85	86–87	88–92 ≥93 on air	93–94 on oxygen	95–96 on oxygen	≥97 on oxygen
Air or oxygen?		Oxygen		Air			
Systolic blood pressure (mmHg)	≤90	91–100	101–110	111–219			≥220
Pulse (per minute)	≤40		41–50	51–90	91–110	111–130	≥131
Consciousness				Alert			CVPU
Temperature (°C)	≤35.0		35.1–36.0	36.1–38.0	38.1–39.0	≥39.1	

Figure 1.1: NEWS 2 scoring system adapted from [1]

1.1.3 Measuring vital parameters

These EWS are centred around the notion of early identification and intervention of inpatients at high risk of deterioration through the detection of prodromal alterations in vital signs (i.e., raised RR or reduced blood pressure). Indeed, these changes have been shown to precede adverse clinical events.[16–23] An adverse event can be defined as an unintended injury as a result of delayed or incorrect medical management that exposed the patient to an increased risk of death or measurable disability.[24]

A range of devices are available and vary across the National Health Service (NHS); most commonly, the DINAMAP CARESCAPE™ V100 Vital Signs Monitor and the Welch Allyn CONNEX® Spot Monitor are used.[25, 26] Typically, these are performed by healthcare assistants

NEW score	Frequency of monitoring	Clinical response
0	Minimum 12 hourly	• Continue routine NEWS monitoring
Total 1–4	Minimum 4–6 hourly	• Inform registered nurse, who must assess the patient • Registered nurse decides whether increased frequency of monitoring and/or escalation of care is required
3 in single parameter	Minimum 1 hourly	• Registered nurse to inform medical team caring for the patient, who will review and decide whether escalation of care is necessary
Total 5 or more Urgent response threshold	Minimum 1 hourly	• Registered nurse to immediately inform the medical team caring for the patient • Registered nurse to request urgent assessment by a clinician or team with core competencies in the care of acutely ill patients • Provide clinical care in an environment with monitoring facilities
Total 7 or more Emergency response threshold	Continuous monitoring of vital signs	• Registered nurse to immediately inform the medical team caring for the patient – this should be at least at specialist registrar level • Emergency assessment by a team with critical care competencies, including practitioner(s) with advanced airway management skills • Consider transfer of care to a level 2 or 3 clinical care facility, ie higher-dependency unit or ICU • Clinical care in an environment with monitoring facilities

Figure 1.2: Clinical response to the NEWS 2 thresholds adapted from [1]

and either transcribed onto paper-based NEWS 2 charts with scores manually calculated or more recently, automatically calculated after integration with electronic health records. Moreover, as the devices used for observation measurement typically do not measure RR, manual recording of RRs are notoriously inaccurate with sub-optimal inter-rater variability.[27, 28] This process remains time-consuming and presents a significant opportunity cost and undue clinical risk in an area that could undergo further automation.

1.1.4 Limitations of EWS

Since their implementation, EWS have reported to have good predictive value for intensive care transfer, 30-day mortality, intensive care mortality, and cardiac arrest with cross-specialty application; improved communication between health care workers; and international relevance with adoptions of EWS occurring in high and low income developing countries.[29]

However, EWS research is riddled with complexity with the existing literature hinting at methodological flaws for assessing their efficacy, particularly in relation to other areas of clinical prediction modelling.[30, 31] One reason for this is the volume of data produced as a result of multiple vital sign measurements throughout an individual's hospital stay with the most

efficacious way of analysing such data remaining unclear. Secondly, chosen outcome measures and time horizons (e.g., admission to intensive care within 24h or throughout duration of stay) have created heterogeneity within the EWS literature.[32]

Therefore, these variations during development and validation of models could prohibit real-world generalisability and applicability. One systematic review reported inadequate handing of statistical issues (including sample size and regression errors), model calibration with external validation, and significant risk of bias across EWS literature.[32]

Furthermore, the practicalities of using paper-based NEWS 2 charts, still employed in certain institutions, are error-prone. Inadequate monitoring frequency and NEWS 2 calculations; transcription errors from the observation machine; misplacement of paper-based charts; and illegibility of paper-based charts have all been reported.[33–35] Though, one critical limitation is the intermittent nature of reporting vital signs reliant upon EWS protocols which has potential for allowing acute episodes of deterioration to be missed.[29] These limitations can constitute the failure-to-rescue phenomenon, which can negatively impact clinical outcomes.[36]

1.1.5 The role of rapid response systems

Rapid response systems have been established because of evidence of failure to rescue, which led to serious adverse events.[37] The aim of this system was to improve the safety of hospital patients (based on non-intensive wards) who were deteriorating.[24]

Successful management of a deteriorating patient is dependent on the act of two key closed-loop models (Fig. 1.3). The first, afferent limb, involves assessment and monitoring of vital parameters (protocolised through NEWS 2). Once deteriorating has been recognised and the appropriate prescribed action undertake, the second efferent limb takes effect. This can involve a rapid response team to engage and determine if further escalation (to intensive care) is appropriate or administer alternative intervention to help stabilise.

This adds to the complexity of measuring 'crude' outcome measures (e.g., hospital length of stay, mortality) and attributing improvement to EWS alone. Partly because the recognition and management of deteriorating patients consists of successful execution, alongside longitudinal refinements in local practices, of the rapid response system.

Since the implementation of rapid response systems, their effectiveness has been questioned.

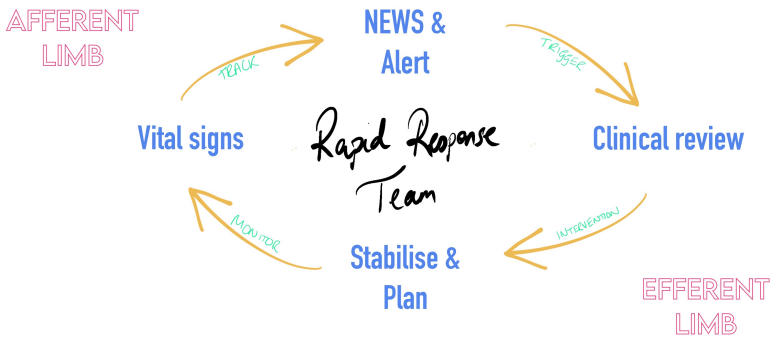

Figure 1.3: Rapid response system: a culmination of two closed-loop models

They were introduced following five single-centre before and after comparisons with further randomised trials reporting no benefit.[38] Furthermore, meta-analyses have supported the need for further research to explore potential benefits; to date, little evidence can support demonstrable effect in improving outcomes.[39, 40]

As a result, failure to rescue events continue to be prevalent with significant associated morbidity and mortality.[13, 38, 41–44] Collectively, there is robust evidence that the current provision of care requires improvements and optimisation.[45–47] Given that most serious adverse events are preceded by prodromal changes in vital signs in hospital wards; in most cases, there should be sufficient time to deliver an appropriate intervention to prevent a serious adverse event from occurring.[41, 48] Therefore, further efforts are needed in line with the digitisation storm to refine or revolutionise existing rapid response systems.

1.2 Global Burden of Disease

1.2.1 Demand for healthcare

The growth in life expectancy of survival into old age is a tribute to one of humanity's major accomplishments.[49] This global improvement can be attributed to advancements in healthcare delivery, personal and environmental hygiene. In the UK alone, doubling of the proportion of the population aged 65 years and older from 7% to 14% was accomplished in 46 years, 68 years in the USA , and more rapidly in just 26 years in China.[50]

As a result, population ageing is a potent driver for increases in disease burden, particularly for age-related disorders (e.g., dementia, stroke, diabetes); it is also these disorders that carry the greatest contribution towards burden owing to their chronic nature, often resulting in unnec-

essary hospitalisations.[49, 51] One study reported that avoidable hospitalisation increased by a factor of 1.35 for each additional chronic condition and 1.55 for each additional body system affected.[52] In 2015, it was estimated that approximately 54% of adults over 65 years of age had at least two long-term health conditions; by 2035, over 2.5 million adults of the same age group will live with four or more long-term conditions.[53] With this trajectory, the current healthcare system will be unsuitable for serving the needs of the population.

In conjunction, complexity and breadth of healthcare has increased through advances in minimally invasive surgery and specialised interventions. As developments continue to be made, further complexity with augmented reality integration, big data analytics, and machine learning approaches will continue to incorporate into existing practice.[54] However, the rising demands of healthcare with greater intricacies to navigate remain an existing phenomena; in order to cope previously, the NHS has undergone restructuring of hospital trusts and reorganisation of service provision through centralisation of care. This involves a 'hub' hospital which acts to deliver specialist care with 'spoke' hospitals arranging referrals and dealing with more general cases.[55]

1.2.2 The strain on the current system

It is debated whether centralisation of care has improved clinical outcomes with the increasing fragmentation of clinical care between multiple providers.[56] In 2019-20, there were 17.2 million admissions recorded, a 15.5% increase over the past decade. In the same year, there were approximately 25 million emergency department presentations, a rise of 17% since the previous decade.[57, 58] Although the COVID-19 pandemic initially reduced the burden with fewer emergency attendances, a rebound phenomenon is currently being witnessed with the resumption of full services.[59][60] Consequently, coupled with the burden of 'catch-up' service provision and delayed presentations due to temporary re-modelling, a greater load is expected upon the NHS.

With the continued burden and complexity of the ageing population, the surge of resource demand heightened by the COVID-19 pandemic, and the already financially constrained NHS, there is a pressing need for policy makers to devise novel strategies to cope and deliver a service fit for the needs of the population.

1.2.3 The digitisation storm

The Topol Review (2019) was commissioned to inform successful integration of innovative technologies within the NHS.[61] Digitisation through the introduction of electronic health records, clinical decision support systems, and electronic prescribing have been taking place within the NHS, a result largely attributed to the £12.8 billion investment in a National Program for Information Technology.[62] These e-health initiatives have been justified upon the grounds of addressing the lack of uniformity across different hospitals in differing quality and safety of healthcare provision; reducing overall efficiencies with an improvement in costs.[63] However, the implementation and adoption of these tools have seldom been smooth, a result of hospitals being constituted as large complex systems; a lack of integration frameworks being developed; and poorly devised adoption strategies potentially resulting in minimal value creation, frustration and unincentivised workflow changes.[64, 65]

Despite this, there was evidence that favoured the role of remote monitoring and digital technologies in healthcare delivery, offering a new pathway that safely supported clinical needs and has potential to offer greater convenience.[66–68] However, the literature remains primitive with poor quality heterogenous designs. With the onset of the pandemic and restructuring of healthcare delivery, the importance of technology enabled health transformation was emphasised with greater reliance and rapid initiation of operating remote monitoring and wearable solutions.[69, 70] Therefore, as digitisation and acceptance of e-health rapidly continues to accelerate, there is a pressing need to explore the role of remote sensing solutions in primary and secondary care settings and the influence on clinical care.

1.3 Wearable Sensing Systems

1.3.1 Medical devices and continuous monitoring

A solution to improving early recognition of clinical deterioration may be through maximising the potential offered through wearable technologies. This industry has been expanding exponentially over the last few years.[65] Unobtrusive wearable sensors, registered as medical devices, can offer real time continuous multi-parameter monitoring of vital signs, which would revolutionise current practice of intermittent vital sign monitoring undertaken according to the NEWS 2 protocol. The collection of additional data points is hypothesised to allow for earlier

recognition of deterioration and reduce the time constraints for healthcare personnel, allowing for enhance and more efficient delivery of clinical care.[71]

A diverse array of wearable sensors have been described in the literature, including clothing monitors, patches, watches, chest-straps, and arm-band monitors which are available to record vital parameters.[72, 73] Each capable of measuring differing vital signs with some including accelerometer and other biometric data. Newer iterations offer greater movement and less restrictions than current monitoring and can free up healthcare staff to perform alternate tasks; moreover, they offer potential for integration of machine learning integration to offer a predictive component.[72]

Whilst many sensors are targeted at consumers, for use in healthcare settings, regulatory requirements dictate obtainment of European Conformity (CE) and/or Food and Drug Administration (FDA) approvals. In the UK, this would permit registration with the Medicines and Healthcare products Regulatory Agency (MHRA) for clinical use. With this process becoming more streamlined and improvements in wireless capabilities, internal algorithmic processing, battery life, and alerting capabilities to support clinical decision, increasing interest in their application of remote monitoring has been occurring.

1.3.2 The role of digital alerts

Digital alerting mechanisms act as a clinical decision support tool by requesting appropriate action following detection of clinical deterioration. Sensor data are often sent to a central monitoring unit or mobile device through a secure server; some manufacturers additionally run internal algorithms to reject distorted or poor quality data, improving reliability.[74] Alerts are subsequently generated when pre-established thresholds for vital parameters, often tailorable, are breached. Current alerting mechanisms include alert transmission to a mobile device; automated emails generated to a healthcare professional; video consultations; interactive voice responses; or web-based consultations.[74–76]

Alerts can be conveyed to a broad number of allied healthcare professionals, including nurses, pharmacists, physicians, counsellors, and physicians but also to patients.[77] One study for digital alerting in patients with sepsis demonstrated significantly reduced hospital and intensive care length of stay with alerting mechanisms.[72] However, these findings were noted mainly through observational designs and could be confounded by the use of rapid response teams,

improving the afferent limb and not relying on digital alerting alone. The literature remains devoid of high-quality studies with regards to optimal alerting mechanisms including the best suited recipient to act upon the alert, the frequency of alerting, and monitoring schedules.

1.4 Early Research

The accuracy of wearable sensors, though measures of limits of agreement, have been validated through several studies. Comparisons with routine nursing measurements, bedside monitors, and other sensors have all been reported.[78] In general, accuracy has been acceptable with small errors in mean difference, particularly when compared with intensive care unit-grade monitoring system.[79] However, inaccuracies when compared with manual nursing observations have also been described, the latter being notoriously unreliable as previously described.[80] Another study reported that not all vital parameters can be measured accurately by sensors, with RR suffering the greatest variability.[81] Given that changes in RR often precede changes in other vital parameters and is a predictor for serious adverse events, the accurate measurement of this metric is paramount.[16, 28]

However, a digit bias, when comparing nursing measurements of RR is a well reported phenomenon.[80, 82, 83] This refers to the prevalence of RRs of 16, 18, and 20.[84] Therefore, comparisons against observations recorded by nursing staff may not be appropriate.

Mixed methods and qualitative studies of patients have reported high levels of acceptance, comfort, safety, and deemed as the favourable.[85–87] Yet, patients have expressed the importance of over-reliance on numbers with concerns of devices displacing contact with clinical staff.[85, 88, 89] Evaluations by healthcare staff have been more mixed with concerns expressing increased workloads, excessive capture of data which may not be clinically meaningful, and alert fatigue.[87–89]

Studies reporting impact of clinical outcomes are primitive. A case series highlighted the potential of remote sensing through earlier recognition of deterioration in patients, including identification of sepsis, fever, and paroxysmal atrial fibrillation.[74] However, a randomised pilot study reported no differences between clinical outcomes (evidence of sepsis, hospital length of stay, and readmission) when using wearable sensors; this trial suffered from imbalanced arms.[75] Another pilot study reported significant response to alert times following recognition

of deterioration but similarly demonstrated feasibility of wearable sensors and digital alerting systems in acute settings.[90]

To date, there remains a paucity of adequately powered trials, with balanced control arms, that describe implementation of remote sensing systems and their potential influence on clinical outcomes appropriately.

1.5 Thesis Aims

The underlying hypothesis of this thesis is that digital alerting, through remote sensing systems, can be deployed in community and secondary care settings to improve healthcare delivery to patients and improve workflows for healthcare staff.

More specifically:

- To appraise the existing literature of studies measuring outcomes relating to digital alerting systems on remote monitoring solutions through a systematic review and meta-analysis (Chapter 2).
- To undertake a 'proof-of-concept', feasibility study of remote sensing systems for remote healthcare delivery in a repositioned hotel, in response to the first wave of the COVID-19 pandemic (Chapter 3).
- To describe barriers and facilitators for healthcare staff in order to understand the perceptions of the remote monitoring hotel model and gather patient perceptions of receiving remote sensing (Chapter 3).
- To design a real world, pragmatically designed clinical trial testing the effects of remote sensing and digital alerting in acute surgical patients on patient outcomes (i.e., mortality, length of stay, intensive care admissions) within secondary care on non-intensive wards (Chapter 4).
- To identify key factors that map to a validated health systems framework integrating human, organisational, and technological factors from key stakeholders influencing successful widespread implementation in the National Health Service (NHS); therefore, enabling the proposition of a road map for future implementation of remote sensing solutions (Chapter 5).

2. The impact of digital alerting systems on remote monitoring solutions in healthcare: a meta-analysis

Part of this chapter has been published as:

> **Iqbal FM**, Lam K, Joshi M, Khan S, Ashrafian H, Darzi A. Clinical outcomes of digital sensor alerting systems in remote monitoring: a systematic review and meta-analysis. NPJ Digit Med. 2021 Jan 8;4(1):7

2.1 Introduction

The advancement of healthcare delivery has developed an ageing population, placing a burden upon healthcare services that has never been greater.[91] In order to cope with the rising demand of service delivery, and continue to develop healthcare provision, novel strategies need to be tested and implemented.[49]

The initial concept of telemedicine was coined in 1879, with an article in the Lancet reporting the use of telephone consults to reduce unnecessary office visits; the first use of hospital-based telemedicine was reported to be in the late 1950s in psychiatric institutions.[92] With further innovation, telemedicine has become a greater umbrella term incorporating concepts of digital health, e-health, m-health, and remote monitoring, amongst others.[93, 94] The emergence of digital health, a poorly defined entity, is a result of the rapid rate of progression of these technologies. One advantage of digital health and remote monitoring is the potential for suitable individuals to stay at home rather than in expensive hospital facilities by means of non-invasive digital technologies (e.g., wearable sensors). These can collect biometric data, support health provider assessment, and aide clinical decision making.[95]

Although randomised trials have exhibited the potential for remote monitoring in reducing in-hospital visits, time required for patient follow-up, and hospital costs in individuals fitted with cardiovascular implantable electronic devices,[96–98] the work has suffered from significant limitations with deprived data capture; poor description of implementation strategies, particularly in healthcare structures differing to the National Health Service (NHS); and the absence of demonstrating long-term benefits.

The fundamentals of clinical care involve routine monitoring of vital signs. These consist of Heart Rate (HR), Respiratory Rate (RR), Blood Pressure (BP), temperature, and oxygen saturations, and are considered an important aide in detecting clinical deterioration, as prodromal changes may long precede an adverse event.[19, 20]

Within the National Health Service (NHS), outside of critical care settings, routine intermittent monitoring of these is undertaken, in accordance with early warning scores (i.e., National Early Warning Score 2 (NEWS 2)). This protocolised response, endorsed by The Royal College of Physicians, grades a severity score to individual vital sign parameter which, when combined for an overall score, indicates further management and appropriate escalation.[1] Therefore, observations are performed every 4-6 hours for those with a score of 1-4, hourly for a score of 5-7, and continuously for patients with a NEWS 2 score of 7 or more. For acutely unwell individuals, an increased frequency of monitoring is recommended.[1] Since the introduction of this protocolised approach, clinical outcomes have been improved and its implementation has shown good predictive value.[29] However, a severe limitation of this intermittent approach leads to the potential for acute deterioration in between measurements to be missed.[29] Further issues, such as insufficient frequency of monitoring and miscalculation of NEWS 2 scores; transcription errors from observation machines; misplacement of paper-based charts have also been reported.[33–35]

With the miniaturisation of wearable sensors, they offer to be powerful diagnostic tools for continuously monitoring such biometric data remotely, proposing a non-invasive and ambulatory opportunity alongside partnered software products to generate alerts at the onset of deterioration. The culmination of additional data points offers the prospective of early recognition to advance the timeliness of care delivery and improvement of health-related outcomes.[99] This extends the possibility of allowing continuous remote monitoring not only on non-intensive wards within secondary care but also outside of secondary care, promising to be a potential solution to the highlighted issues.

Digital alerting mechanisms, through partnered software, allow for appropriate action following recognition of clinical deterioration. Current reported mechanisms used in remote monitoring include alert transmission to a mobile device; automated email alerts sent to healthcare professionals; video consultations; interactive voice responses; or web-based consultations.[76] These alerts can be sent to a variety of healthcare professionals with nurses, pharmacists, physicians,

counsellors, and physicians all being utilised, but can also be sent to patients.[77] There remains a lack of consensus regarding the optimal alerting system; factors that influence uptake of digital solutions by healthcare staff and patients; the prompt and appropriate response to alerts; and the cohort of individuals most appropriate as a target for such systems.

One study reported the outcomes for community based remote monitoring in individuals suffering with chronic diseases (e.g., hypertension, obesity, and heart failure), however the included studies were heterogenous, low quality, and underpowered.[77] Moreover, the meta-analyses described obesity related intervention outcomes (i.e., body mass index, weight, waist circumference, body fat percentage, systolic blood pressure, and diastolic blood pressure) and were not focussed on service utilitarian outcomes. Furthermore, the evaluation of digital alerts following the identification of abnormal parameters was not the main focus of this study. This focal phase, through appropriate intervention, has potential to influence outcomes. The rapid evolution of digital products has warranted an updated systematic review targeting the description of digital alerting mechanisms across wider medical and surgical cohorts to draw generalisable lessons and directions for future research.

2.2 Aims

The aims of this chapter, therefore, were:

1. To identify the current breadth of evidence evaluating digital alerting systems used in remote monitoring and describe the associated health-related findings through a systematic review and meta-analysis.

2. To appraise the quality of existing evidence with respect to digital alerting systems and remote monitoring.

3. To describe the different digital alerting mechanisms reported in the literature.

4. To identify gaps in the literature and focus on future directions of research.

2.3 Methods

2.3.1 Design

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines.[100] The review was registered prospectively at the International Prospective Register of Systematic Reviews (PROSPERO ID: CRD42020171457).

2.3.2 Search Strategy and databases

A systematic search, with the assistance of expert librarian support, was performed through Ovid in Medline, EMBASE, Global health, Health Management Information Consortium (HMIC), and PsycINFO databases without language restriction. The appropriate MeSH terms and free text all field search was performed and combined with appropriate Boolean operators for "home", "monitoring", "remote sensing", "self-monitor*", "self-track*", "remote monitor*", "home monitor*", "biosensing techniques", "wireless technology", "telemedicine", "monitoring, physiologic", "monitoring, ambulatory", "home care services", "ehealth", "mhealth", "telehealth", "digital", "mobile", "social networking", "internet", "smartphone", "cell phone", "wearable electronic devices", "internet", "electronic alert*", "alert*", "messag*", "text messaging", "inform", "communicat*", "communication", "patient reported outcome measures", "outcome and process assessment", "outcome", "treatment outcome", "outcome assessment", "fatal outcome", "adverse outcome pathways", "patient outcome assessment", "morbidity", "mortality", "length of stay", "patient admission". Further studies not captured by the search were identified through bibliometric cross-referencing.

All identified studies were uploaded to Covidence, a Cochrane supported systematic review package tool.[101] Initial screening was conducted by one investigator and verified by a second to determine if the eligibility criteria were met. Discrepancies were discussed and resolved by consensus. Studies meeting the inclusion criteria underwent full-text screening.

2.3.3 Study selection criteria

Studies published relating to the primary and secondary outcomes listed below were included. Included study participants were adults (aged 18 years or over) discharged home with a digital alerting system (i.e., wearable sensor, non-invasive wireless technology, telemedicine, or remote monitoring). The last search was performed in October 2019.

Abstracts, conference articles, opinion pieces, editorials, case studies, reviews, and meta-analyses were excluded from the final review. Studies with inadequate published data relating to the primary and secondary outcome measures were additionally excluded.

2.3.4 Data extraction and outcome measures

All included study characteristics and outcome measures were extracted by one investigator (FI) and verified by a second (KL). All full text reports of studies identified as potentially eligible after title and abstract review were obtained for further review.

The primary outcome measure was hospitalisation and inpatient visits. Secondary outcome measures include mortality, hospital Length of Stay (LOS), emergency department visits, and outpatient visits.

2.3.5 Quality assessment (risk of bias)

Randomised Controlled Trial (RCT) were methodologically graded with the Jadad Scale.[102] This score range from 0-5; scores <3 were considered low quality and scores ≥ 3 were considered high quality. The risk of bias Cochrane tool was used to assess internal validity; this assesses: i) randomisation sequence allocation; ii) allocation concealment; iii) blinding; iv) completeness of outcome data; and v) selective outcome reporting, classifying studies into low, high or unclear risk of bias.[103]

Non-randomised trials were assessed using the Newcastle-Ottawa scale.[104] It comprises 3 variables: i) patient selection; iii) comparability of study groups; and iii) assessment of outcomes. Scores range from 0-9, scores ≤ 3 were considered low quality, between 4-6 moderate quality, and >7 high quality. Quality assessment was assessed by one reviewer and validated by a second.

2.3.6 Data Analysis

A meta-analysis of means, hazard ratio, and means of proportion were performed using Stata (v15.1. StataCorp LCC, TX). Variables were converted into a common metric where appropriate (e.g., days for time), and a percentage change for outcomes between control and intervention arms were calculated where possible. Hospitalisation and inpatient admissions were grouped as one variable.

Continuous variables were compared through weighted mean difference (WMD) with 95% confidence interval (CI). Where only the median was reported, it was substituted for mean. Where range was reported, it was converted to standard deviation through division of four; an assumption of normal distribution was made for this to occur. Forest plots were generated for all included studies.

Pooled effect sizes were calculated using a random effects model due to the likely presence of between-study variance and estimated using the DerSimonian and Laird method.[105] Heterogeneity was assessed with the I^2 statistic. A value less than 30% was considered as low heterogeneity, between 30-60% moderate, and over 60% as high.

2.4 Results

2.4.1 Study characteristics

A total of 2417 citations were retrieved through literature searches. Two articles were additionally found through bibliographic cross-referencing. Full text review was performed for 128 articles with 33 meeting the inclusion criteria for analysis, of which, 21 were randomised controlled trials with the remaining prospective or retrospective studies. Of the 33 included studies, 26 allowed for either a weighted means, pooled hazard ratio, or proportional meta-analysis.

All pooled studies were prospective with the majority being randomised trials. However, most studies included were low in quality (Table 2.1) with only having follow-up periods beyond 12 months.[106, 107] The characteristics of included studies and a PRISMA flow diagram are depicted in Table 2.1 and Figure 2.1, respectively.

Table 2.1: Characteristics of included studies with Jadad & Newcastle-Ottawa scores

Author	Year	Journal	Design	N	Follow-up	Score
Baker et al.[108]	2013	*J Am Geriat Soc*	Retrospective	3534	2 years	High
Basch et al.[109]	2016	*J Clin Oncol*	RCT	766	6 months for quality of life; 12 months for mortality	Low*
Bekelman et al.[110]	2015	*JAMA Intern Med*	RCT	384	12 months	Low*
Biddiss et al.[111]	2009	*J Telemed Telecare*	Prospective	45	18 (5) months (average, SD)	Moderate
Bohm et al.[106]	2016	*Eur Heart J*	RCT	1002	18 months	Low*
Calvo et al.[112]	2014	*Respir Med*	Cluster RCT	59	7 months	Low*
Chen et al.[113]	2013	*J Med Internet Res*	Prospective	141	6 months before and after	Moderate
Del Hoyo et al.[114]	2018	*J Med Internet Res*	RCT	63	24 weeks	Low*
Denis et al.[115]	2019	*Support Care Cancer*	Prospective	41	3 weeks	Moderate
Godleski et al.[116]	2012	*J Telemed Telecare*	Prospective	76	6 months before and after	Moderate
Heidbuchel et al.[117]	2015	*Eur Heart J*	RCT	303	24 ($\pm$2) months	Low*
Kotooka et al.[107]	2018	*Heart Vessels*	RCT	181	15 (0-31) months (mean, range)	Low*
Lee et al.[118]	2019	*Ann Surg*	RCT	100	90 days	Low*
Lewis et al.[119]	2010	*COPD*	RCT	40	26 weeks telemonitoring + 26 weeks without (total 52 weeks)	Low*
Licskai et al.[120]	2013	*Can Respir J*	Prospective	22	3 months before and after	Moderate
Luthje et al.[121]	2015	*Europace*	RCT	176	15 months	Low*
Martin-Lesende et al.[122]	2017	*Eur J Gen Pract*	Prospective	28	12 months before and after	Moderate

Continued on next page

Author	Year	Journal	Design	N	Follow-up	Score
McElroy et al.[123]	2016	*J Surg Res*	Prospective	443	30 days	Moderate
Mousa et al.[124]	2019	*Ann Vasc Surg*	RCT	30	30 days	Low*
Oeff et al.[125]	2005	*Herzschrittmacherther Elektrophysiol*	Prospective	24	12 months before and after	Moderate
Pedone et al.[126]	2015	*J Am Geriat Soc*	RCT	90	6 months	Low*
Pinnock et al.[127]	2013	*BMJ*	RCT	256	12 months	Low*
Pinto et al.[128]	2010	*J Neurol Neurosurg Psychiatry*	RCT	39	3 years	Low*
Ringbaek et al.[129]	2015	*Int J Chron Obstruct Pulmon Dis*	RCT	281	6 months	Low*
Santini et al.[130]	2009	*J Interv Card Electr*	Prospective	67	11 (6-20) months (median, range)	Moderate
Scherr et al.[131]	2009	*J Med Internet Res*	RCT	108	6 months	Low*
Seto et al.[132]	2012	*J Med Internet Res*	RCT	100	6 months	Low*
Sink et al.[133]	2018	*J Telemed Telecare*	RCT	168	8 months	High*
Smeets et al.[134]	2017	*J Med Internet Res*	Prospective	282	34 months (mean)	High
Steventon et al.[135]	2012	*BMJ*	Cluster RCT	3154	12 months	Low*
Steventon et al.[136]	2016	*BMJ Open*	Retrospective	1432	10.4 months (average)	High
Vianello et al.[137]	2016	*BMC Pulm Med*	RCT	334	12 months	Low*
Yount et al.[138]	2014	*J Pain Symptom Manage*	RCT	253	12 weeks	Low*

* Jadad score

RCT: randomised controlled trial

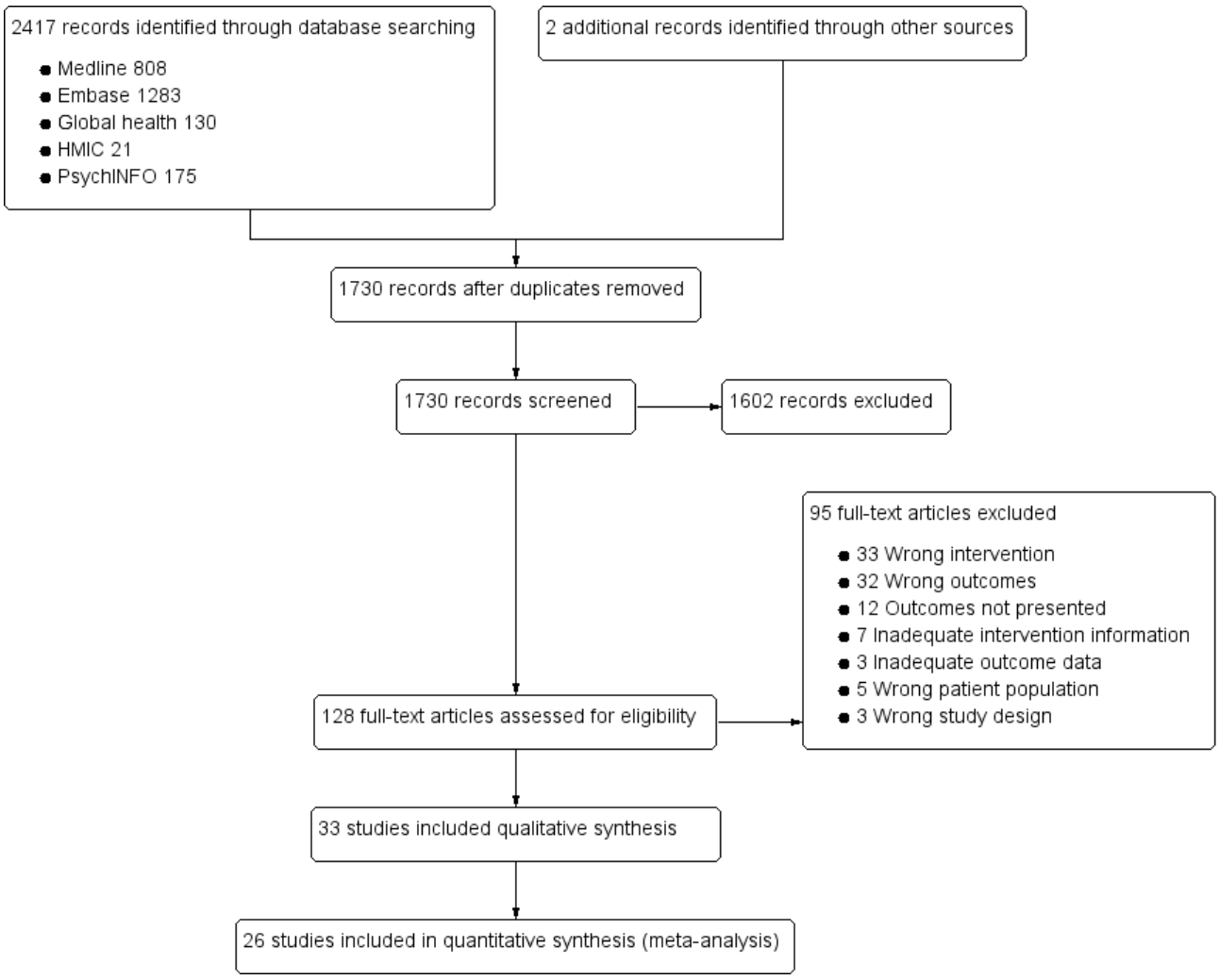

Figure 2.1: PRISMA flow diagram

2.4.2 Hospitalisation and inpatient admissions

Six studies demonstrated a mean decrease in hospitalisation/inpatient admissions of 9.6% (95% CI 4.9–14.3%, $I^2 = 96.4\%$, Figure 2.2) favouring digital alerting systems. However, pooled WMD reported no change in hospitalisation from six studies (WMD 0.061; 95% CI -0.197–0.318, $I^2 = 78\%$).[113, 117, 122, 129, 132, 138] Pooled HRs for all-cause hospitalisation similarly demonstrated no significant difference (HR 0.916; 95% CI 0.781–1.074, $I^2 = 0\%$).[106, 107]

Six additional studies, reporting on cardiovascular related hospitalisation, saw no benefit from digital alerting (mean decrease 10.1%; 95% CI -24.9–4.7%, $I^2 = 95.6\%$ and pooled HRs 0.907; 95% CI 0.757–1.088, $I^2 = 2.4\%$).[106, 121, 126, 131, 134]

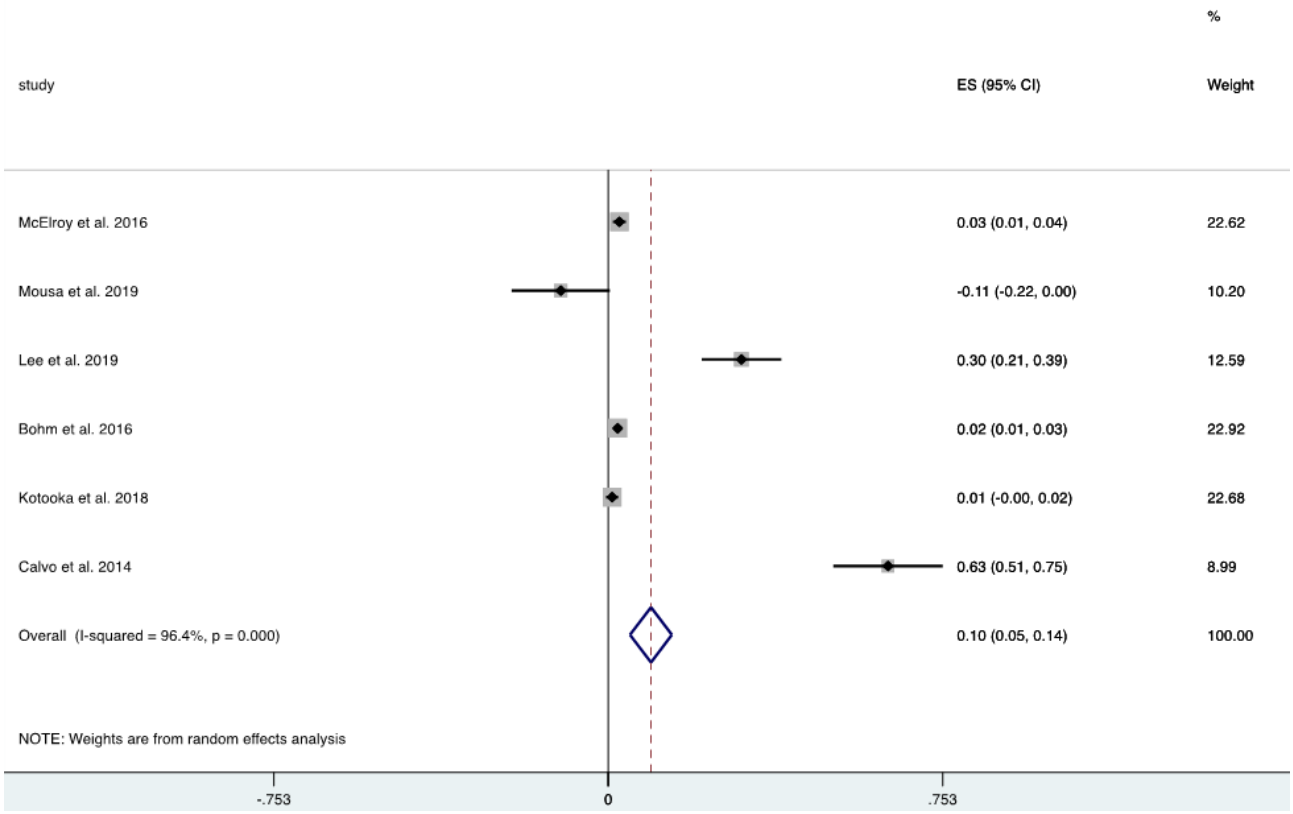

Figure 2.2: Forest plot for hospitalisation

2.4.3 Mortality

A total of 16 studies reported on this outcome measure. Twelve studies demonstrated a 3% mean decrease in all-cause mortality from digital alerting systems (95% CI 2–3%, Figure 2.3), however this was significantly heterogenous ($I^2 = 94.4\%$). Moreover, pooled HRs of five studies reported no change in all-cause mortality (HR 0.89; 95% CI 0.79–1.01, $I^2 = 30.3\%$).[106, 108, 113, 134, 136]

There was no relationship between cardiovascular mortality and digital alerting from a subgroup cardiovascular cohort (mean decrease 0.9%, 95% CI -0.6–2.4%, $I^2 = 25.7\%$).[106, 131]

2.4.4 Length of stay

Ten studies were included; digital alerting reduced hospital LOS by a mean difference of 1.043 days (95% CI 0.028–2.058 days, p<0.001, $I^2 = 95.5\%$, Figure 2.4).[113, 117, 119, 122, 123, 127, 129, 131, 132, 137]

A sub-cohort of chronic obstructive pulmonary disease (COPD) cases found no benefit of digital

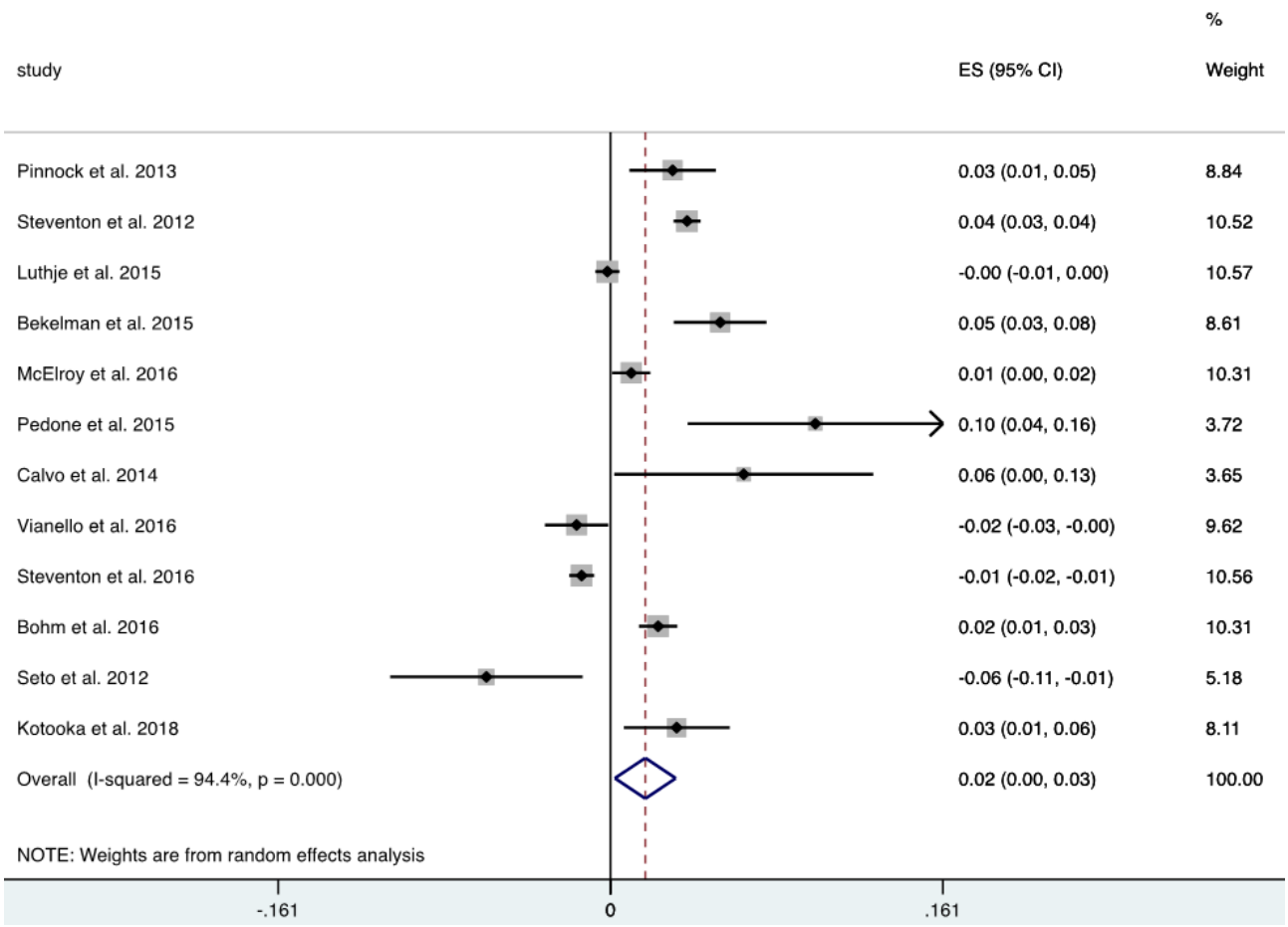

Figure 2.3: Forest plot for mortality

alerting with respect to LOS (mean difference 0.919 days; 95% CI -1.878–3.717 days, p=0.213, $I^2 = 35.3\%$).[127, 129, 137]

2.4.5 Emergency department visits

Eight studies were included; there was no benefit of digital alerting (mean difference 0.025; 95% CI -0.032–0.082, $I^2 = 51.8\%$).[113, 119, 121, 122, 129, 132, 135, 138]

2.4.6 Outpatient and office visits

The five included studies demonstrated no benefit of digital alerting (mean difference 0.223 days; 95% CI -0.412–0.858, $I^2 = 95.7\%$).[113, 119, 129, 132, 135]

Sub-group data from Ringbaek et al. (respiratory and non-respiratory) and Lewis et al. (primary care chest and non-chest related visits) were combined for this analysis.

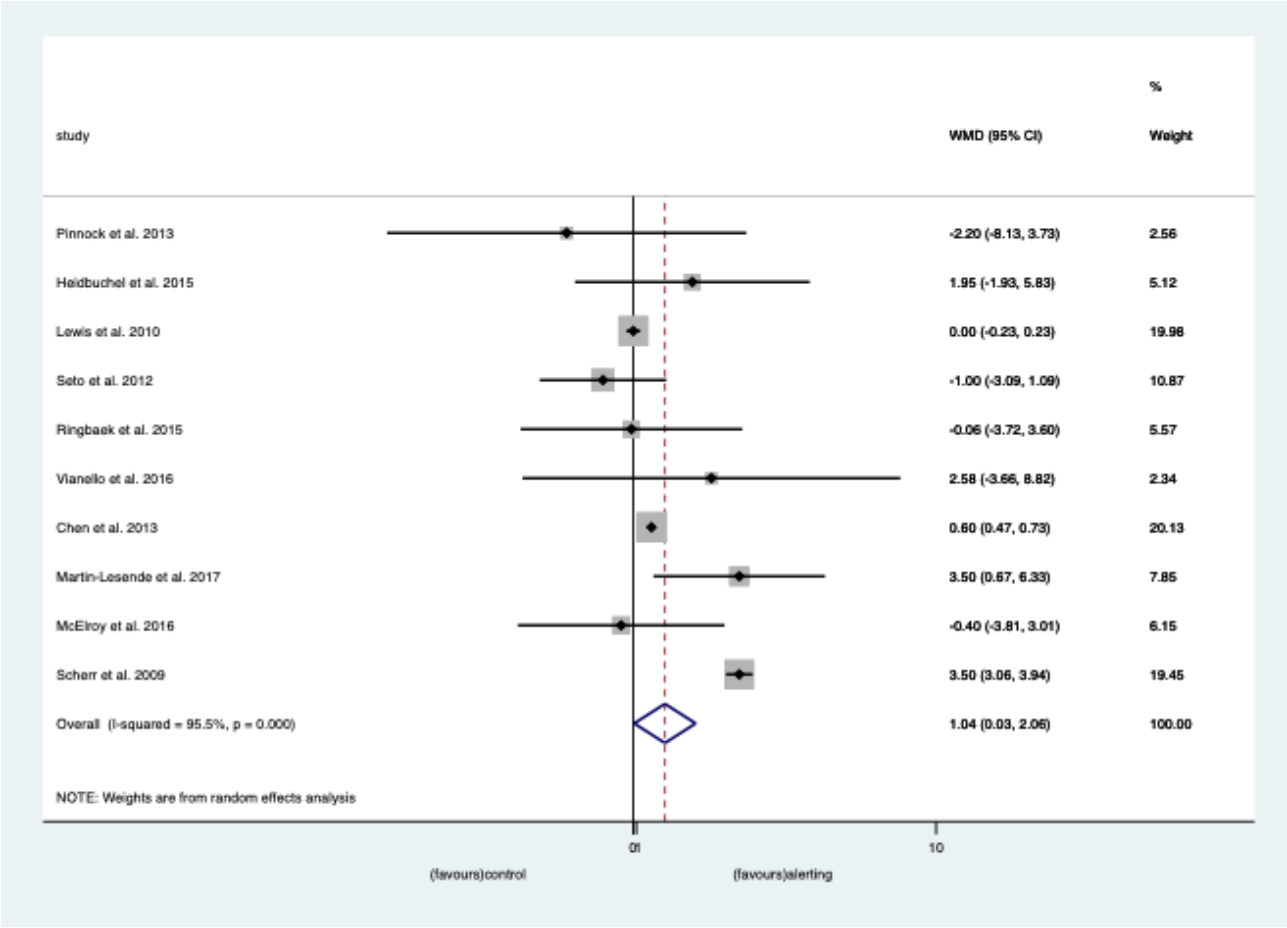

Figure 2.4: Forest plot for length of stay

Similarly, no statistically significant benefit of alerting was noted from three additional studies.[114, 124, 135]

Sub-group analysis of a respiratory cohort demonstrated a mean difference of 1.346 days (95% CI 0.102–2.598, $I^2 = 93.8\%$).[126, 129]

2.4.7 Risk of bias assessment

The risk of bias for included randomised trials is presented in Figure 2.5. Overall, seven studies were deemed to be at low risk, 10 studies had some concerns, and the remaining were judged as high risk of bias.

Allocation was random across all 20 studies with 15 adequately stating the method used for generating random sequence.[106, 107, 109, 110, 112, 114, 118, 119, 124, 127, 129, 132, 133, 137, 138] Vianello et al. utilised a dedicated algorithm to check for imbalances for baseline variables with clear randomisation sequence methods detailed.[137] However, concealment measures were

Figure 2.5: Risk of Bias assessment

not mentioned, resulting in a judgement of 'some concerns' for risk of bias for randomisation. Three additional studies were given the same judgement due to lack of concealment descriptions.[109, 117, 138] Ringbaek et al. clearly described their method for randomisation but information on concealment was not given and baseline demographic differences were noted between groups; as such, randomisation was judged to be at high risk of bias.[129] Similarly, randomisation for Scherr et al. was deemed to be at high risk of bias.[131]

Sink et al. blinded participants with digital alerts not forwarded to healthcare providers in the control arm.[133] This, a result of their automated telephone intervention collecting self-reported symptom data rather than continuous physiological parameter recording through wear-

able sensors or smart devices, as utilised by the other trials, made participant blinding possible. A low risk of bias was, therefore, judged.

The risk of attrition bias was deemed low across all included studies with missing numbers clearly reported and deemed to not have impacted the overall results. There was mostly a complete follow-up of all participants.

Insufficient information was provided to assess whether other important risk of biases exists in 4 studies so were judged as some concerns.[106, 126, 129, 137] Basch et al. clustered groups into computer experienced and computer in-experienced but numbers across various arms were unequal for selected outcome measures. Therefore, a judgement of high risk of bias was given.[109] Comparably, Scherr et al. performed multiple analyses with both intention-to-treat and per-protocol. Only the latter revealed significant results favouring their telemonitoring system.[131]

2.4.8 Alerting mechanisms and response to alerts

The alerting mechanisms reported in the literature have been summarised in Table 2.2. Mechanisms included text messaging, email notifications, alerts on telemonitoring hubs/web-based platforms, as well as trialling audible alerts sent to study participants rather than healthcare professionals.

Table 2.2: Study Characteristics of Alerting Mechanisms and Responses

Study	Cohort	Data collected	Digital alerting mechanism	Response to alerts	Control
Baker et al.[108]	HF; COPD; DM	Vital signs; symptom questionnaire; mental health questionnaire;	Health Buddy electronic device with 4 buttons to collect data and uploaded to a web portal which risk stratifies responses.	Care manager review: specifics not mentioned.	Retrospectively matched
Basch et al.[109]	Oncology	Self-reported symptoms	Self-reporting through web-based interface (STAR). E-mail alerts triggered when a symptom worsened by 2 points or reached an absolute grade 3.	Nurses performed interventions: 1) telephone counselling, 2) medication changes, 3) Emergency/hospital referral)	Usual clinic visits with clinicians to discuss symptoms.
Bekelman et al.[110]	HF	BP; HR; weight; self-reported symptoms; mood	Daily telemonitoring using home-based equipment. The telemonitoring system assigned a risk to each response on the system.	Medium-risk indicators were reviewed by nurses for further action. All high-risk indicators were acted on by contacting the patient for assessment.	Usual care
Biddiss et al.[111]	HF	BP; HR; weight; quality of life questionnaire; symptom questionnaire	Biometrics entered daily into the 'Doc@home' health monitor. The data were transmitted at night through telephone. Alerts generated if pre-established thresholds crossed.	Monitoring practitioners contacted patient for further assessment.	-
Bohm et al.[106]	HF	Intrathoracic fluid status monitoring	OptiVol fluid index alert, changes in thoracic impedance resulting from accumulation of intrathoracic fluid generated a text message alert to responsible physician.	Data were reviewed remotely, and the patient contacted within 2 working days by phone to evaluate and take appropriate measures	Usual care without telemonitoring.
Calvo et al.[112]	COPD	Oxygen saturation; HR; BP; spirometry; peak expiratory flow	Daily monitoring of biometrics transferred through Tele-Modem™ to clinical monitoring team. A red alert was generated if pre-established thresholds were breeched in MPM™ call centre system.	A nurse contacted the patient to verify the alert. Following this, the alert was escalated to a Pneumologist. Actions include: 1) telephone advice, 2) home visits, 3) emergency department visits	Usual care

Continued on next page

Study	Cohort	Data collected	Digital alerting mechanism	Response to alerts	Control
Chen et al.[113]	Coronary heart disease; HF; arrythmia; angina; syncope; DM	BP; HR; ECG; oxygen saturations; blood glucose	Real-time transmission of biometrics to health record clouds under synchronous surveillance by the Telehealth Centre. Alerting mechanism not specified.	Nurse case managers contacted the patient when abnormal data transmitted with advice ascertained from a cardiologist.	Pre-implementation
Del Hoyo et al.[114]	Inflammatory bowel disease	Weight; vital signs; quality of life	NOMHAD web-based home platform used. Electronic communication could take place between healthcare provider and users. Individualised alerts were generated for abnormal values.	After receiving an alert, the specialised medical staff, recommended action plans: 1) medication adjustment, 2) telephone calls, 3) in-person visits	Usual care in accordance with local and national guidelines.
Denis et al.[115]	Oncology	Temperature; symptom questionnaire	Bioconnect web application allowing daily biometric transmission. If algorithmic thresholds triggered, automatic email notifications were sent to the physician	Medical team called the patient for assessment. Actions include: 1) quick planned hospitalisation (bypass ED), 2) stay at home and blood test taken, 3) antibiotic administration	-
Godleski et al.[116]	Mental health	Symptom behaviour questionnaire; substance abuse questionnaire	Health Buddy electronic messaging device used to answer questions daily by pressing large buttons on front of device. Nurse practitioner reviewed transmitted data and contacted the patient by telephone for concerning responses.	Actions included: 1) telephone assessment, 2) medication adjustment, 3) inpatient visit, 4) emergency department visit	Pre-implementation
Heidbuchel et al.[117]	CIED	CIED metrics	Continuous, automatic remote monitoring with frequency of data analysis and the response to alerts left to the investigator's discretion.	Alerts resulting in: 1) hospital admissions, 2) internal discussions, 3) phone calls, 4) visits to physician, 5) web-review	Usual care (in office regular visits)
Kotooka et al.[107]	HF	Weight; BP; HR; body composition	Karada Karte™ telemonitoring system which transmitted data daily to the central web server via the internet. If pre-established parameter thresholds exceeded, monitoring nurses would notify the physician	Physician actions included: 1) telephone guidance, 2) medication changes, 3) warning threshold adjustment, 4) hospital admission	Usual care (in accordance with the 2010 Japanese Circulation Society Guidelines)

Continued on next page

Study	Cohort	Data collected	Digital alerting mechanism	Response to alerts	Control
Lee et al.[118]	Transplant (liver)	Temperature; BP; blood glucose; weight; symptom questionnaire; medication use.	Tablet with bluetooth devices transmitted data daily to central web server via the internet. Different alerting algorithms trialled.	Alerts responded by the nurse care coordinator and escalated to care provider. Treatment or clinic visit initiated if appropriate.	Usual care: log vital signs daily for 90 days. Instructions provided for deterioration
Lewis et al.[119]	COPD	Temperature; oxygen saturations; HR; symptom questionnaire	Telemonitoring hub (Docobo™) transmitting biometrics to a web-based system (doc@HOME). An alerting e-mail was sent to the community team if pre-established thresholds were exceeded.	The chronic disease management team called patients on receipt of this alerting e-mail for further assessment during working hours (Mondays - Fridays, 9 am - 5 pm)	Usual care
Licskai et al.[120]	Asthma	Symptom questionnaire; peak expiratory flow; medication use.	The server analysed biophysical inputs daily. E-mail alerts were sent for moderate and high-risk days; and asthma control assessment displayed as green, yellow or red zone with the corresponding asthma management advice.	Asthma control assessment displayed as green yellow or red zone and gave appropriate asthma management advice.	Pre-implementation
Luthje et al.[121]	HF with CIED	Bioimpedance measurements from CIED	OptiVol fluid index alert, impedance value taken daily and compared with a roving reference value - built into the CIED.	Phone assessment with alerting patient was conducted. If signs of clinical decompensation, admit to hospital, if no signs of decompensation, adjust diuretic medication.	Usual care
Martin-Lesende et al.[122]	HF; chronic lung disease	BP; oxygen saturations; HR; RR; weight; symptom questionnaire	Daily self-monitoring of parameters sent using smartphones to a specific Web-platform. When pre-established threshold values were crossed, red or yellow alerts were triggered.	Not specified	Pre-implementation
McElroy et al.[123]	Cardiac surgery	Oxygen saturation; HR; BP; weight; symptom questionnaire; ambulation data; adherence to medication	Abnormal biometrics, concerning survey responses, missed digital check-ins registered through a digital health kit triggered an automated notification to the healthcare team.	Actions include: 1) video chat/phone call, 2) medication adjustment, 3) education, 4) referral to nurse practitioner/doctor/emergency department.	Discharge education booklet; medication education cards; interactive vital signs and weight log; phone call within 48h of discharge and every 4-5 days for 30 days.

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Study	Cohort	Data collected	Digital alerting mechanism	Response to alerts	Control
Mousa et al.[124]	Peripheral arterial disease (with groin incision)	Temperature; weight; BP; oxygen saturation; symptom questionnaire; surgical site pictures	Sensor metrics were uploaded to tablets with the Enform® application, syncing to a web-portal. Alerts were generated for values that exceeded pre-established thresholds.	Experienced nurses contacted patients by phone or used the app-integrated messaging for assessment following concerning alerts.	Usual care
Oeff et al.[125]	HF	Weight; BP; HR/rhythm; RR; oxygen saturations; symptom questionnaire	Daily telemonitoring transmission of biometrics. Alerts were generated when individualised limits were exceeded.	Actions include: 1) discussion with doctor; 2) medication adjustment; 3) planned hospital admission	Pre-implementation
Pedone et al.[126]	HF	BP; oxygen saturations; weight; HR	Geriatricians evaluated the data daily once transmitted through the telemonitoring kit. Alerts were generated if data exceeded an individualised prespecified range and were displayed on the monitoring system.	Actions taken: 1) scheduled office appointments, 2) acute care ward review	Usual care
Pinnock et al.[127]	COPD	Oxygen saturation; daily symptom questionnaire (dyspnoea, sputum purulence/volume, cough, wheeze, fever)	Algorithms, based on the symptom score, alerted the clinical monitoring team through secure internet connection, using a touch screen telemonitoring kit (Lothian), if daily readings had not been submitted daily or a certain score obtained.	Action include: 1) initiating patient contact. 2) home visit, 3) commencing rescue treatment, 4) immediate admission.	Usual care without telemonitoring
Pinto et al.[128]	Amyotrophic lateral sclerosis with respiratory failure on NIV	NIV data (IPAP, expiratory positive air pressure; inspiratory/expiratory ratio; backup rate; ventilation sensitivities; rise time	Data transmission with a modem through TCP/IP protocol occurred. All data that were SD±1 of the mean values of unpublished pilot data generated alerts.	A message was sent to the physician who could decide on possible setting changes, schedule an office visit or phone call, or conduct a real time communication.	Management of NIV settings were performed through regular visits
Ringbaek et al.[129]	COPD	Spirometer; oxygen saturations; weight; self-reporting symptoms (dyspnoea, sputum colour/volume/purulence)	Data were transmitted daily to a call centre through telemonitoring equipment: categorised and prioritised with alerts generated if values were alarming.	Contact initiated by the respiratory nurse during working days (Monday – Friday, 9am to 3pm).	Usual care

Continued on next page

Study	Cohort	Data collected	Digital alerting mechanism	Response to alerts	Control
Santini et al.[130]	HF; arrythmias	Patient activity; HR variability; intra-thoracic impedance	Daily transmission through CareLink with an audible alarm to alert the patient when a programmable threshold is crossed.	If the patient was alerted or felt worse, to contact the responsible physician who request additional device transmissions, unscheduled visits or emergency room admissions.	-
Scherr et al.[131]	HF	BP; HR; weight; medication use	Data transmitted using a mobile telemonitoring kit (Zope) daily. Values outside individually adjustable borders resulted in an email/text alert.	Physicians contacted the patient directly via the mobile phone to confirm the parameters and adjust medication.	Usual care without telemonitoring
Seto et al.[132]	HF	Weight; BP; ECG; symptom questionnaires	Daily transmission of biometrics to a mobile phone, then transferred to a data repository. If pre-established thresholds crossed, email alerts sent to a cardiologist.	Dependent on cardiologist. Actions include retaking measurements, changing medication, attending emergency department or calling 911.	Usual care: visiting clinic between once every 2 weeks to once every 3-6 months.
Sink et al.[133]	COPD	Self-reported symptoms	Daily automated messages/calls daily from a central server to communicate disease-specific biometric data on ExpCOPD. The designed message algorithms use Bayesian branching logic to generate alerts to text, email, pager, or phone.	Following an alert, the medical resident contacted the patient for assessment and/or initiated appropriate intervention.	Received the same daily automated message without alerts.
Smeets et al.[134]	HF with CIED	Bioimpedance measurements from CIED	Daily alert transmissions generated when predefined alarm thresholds were crossed. OptiVol and CorVue algorithms for bioimpedance alerts generation.	Phone contact initiated by a nurse. Subsequent protocolised action was taken in consultation with a HF specialist.	CIED without bioimpedance alerts generated.
Steventon et al.[135]	COPD; HF	Oxygen saturations; blood glucose; weight; symptom questionnaires	Readings taken at the same time each day for up to five days per week, symptom questions and educational messages.	Monitoring centres (with specialist nurses matrons), used protocolised responses.	Usual care
Steventon et al.[136]	COPD; HF; DM	Weight; oxygen saturation; BP; temperature; blood glucose; peak-flow; coagulation; 1-lead ECG	Readings taken and automatically transmitted to a triage centre through 'mymedic' telemonitoring hub.	If set thresholds were exceeded, patients were contacted; escalation to a physician for further plan was initiated.	Usual care

Continued on next page

Study	Cohort	Data collected	Digital alerting mechanism	Response to alerts	Control
Vianello et al.[137]	COPD	HR; oxygen saturation	Alternate day recording of observations through a telemonitoring kit. Alerts generated when individualised pre-established thresholds crossed.	A pulmonary specialist called the patient for assessment during normal working hours (Monday – Friday, 0800-1600). Actions include: 1. Modify medication, 2. Home visit by district nurse, 3. Set up an office appointment, 4. Escalate a visit to the Emergency Department.	Usual care without telemonitoring
Yount et al.[138]	Advanced lung cancer	Symptom questionnaire	Weekly calls placed using telephone based interactive voice response system for symptom monitoring, responses entered using the telephone keypad.	Responses meeting a pre-defined threshold for a symptom generated an e-mail to the site nurse. Patients contacted for assessment.	Symptoms monitored weekly but no automated delivery

RCT: randomised controlled trial; COPD: chronic obstructive pulmonary disease; HF: heart failure; DM: diabetes mellitus; CIED: cardiac implantable electronic device; NIV: non-invasive ventilation; HR: heart rate; BP: blood pressure; RR: respiratory rate; STAR: Symptom Tracking and Reporting.

2.5 Discussion

2.5.1 Principal findings

This body of work provides evidence for reductions in hospitalisation and inpatient admissions through digital alerting mechanisms in remote monitoring. It should, however, be noted that included studies were significantly heterogenous and of poor quality; consequently, results should be interpreted cautiously. Nevertheless, it may infer that digital alerting mechanisms for remote monitoring solutions could provide benefit across a wide assortment of patient cohorts. Pooling of mean differences did not reproduce this finding but the included studies for the latter analysis consisted of longer follow-up periods, containing more individuals suffering with chronic medical conditions (e.g., COPD, heart failure) compared to the former, which incorporated acute surgical cohorts with shorter follow-up periods; indeed, the differing population groups and follow-up periods may explain these findings.[113, 117, 122, 129, 132, 138]

It has been reported that avoidable hospitalisation increases by a factor of 1.35 for each additional chronic condition and 1.55 for each additional body system affected.[52, 139] Consequently, a chronic disease burden – prevalent amongst the ageing population – increases the susceptibility to repeated hospitalisations and, whilst digitisation may revolutionise healthcare delivery, a more multi-faceted approach should be optimised for scalable improvement. Factors relating to hospital departments (e.g., seniority of clinician reviewing, busyness of department, community service delivery) and external factors (e.g., patient education and activation, behavioural insights towards digitisation, social support available) are likely to significantly contribute and may impact widespread deployment of novel digital technologies.[140]

Hospital length of stay was shortened with the use of digital alerting. The earlier recognition of deterioration can act as a point of review and initiating treatment may explain this; a recent systematic review concluded that digital alerts similarly reduced hospital length of stay in sepsis by 1.3 days.[66] Although it should be noted that comorbidities, polypharmacy, health literacy, and severity of initial presentation are just some confounding variables that additionally influence length of stay.[141–143] Nevertheless, this review adds further support to the literature favouring digital alerting mechanisms in remote monitoring across medical and surgical cohorts.

A small reduction in all-cause mortality from digital alerting systems was noted. This relation-

ship was not reproduced from pooled hazard ratios which may be explained by the difference of study qualities included in the analyses. Only 3 studies included were high quality; Of which, significant weighting was given to a 2013 study by Baker et al. utilising the Health Buddy telemonitoring platform which has since become obsolete.[108, 130, 134] Early iterations of digital alerting and telemonitoring platforms may suffer significant pitfalls, preventing successful use, but also health management changes over time, and these could explain the described relationships.

Visits to the emergency departments demonstrated no benefit of digital alerting mechanisms from pooled mean differences. Earlier recognition of deterioration should prevent presentation to emergency departments and inpatient hospitalisations with non-urgent reviews scheduled for outpatient visits. Despite this, there was no change in overall outpatient or clinic visits. However, respiratory sub-group data did demonstrate a reduction in outpatient visits though the analysis was a culmination of only two studies. Further randomised trials for specific medical cohorts and conditions may address the benefit of digital alerting in affecting outpatient visits. Additionally, research capturing scheduled and unscheduled presentations to hospital, including emergency department visits, outpatient visits, and hospitalisations would be vital in addressing whether workloads can be altered across these departments alongside the description of how well digital systems have been optimised in the emergency department setting.

2.5.2 Limitations

Despite the significance of the outcomes assessed, our analysis had limitations based on the variety of methodologies used and overall study quality, with the majority scoring low. One of the challenges of this review was the relatively broad study into the effectiveness of digital alerting on clinical outcomes. Whilst this allowed us to examine the similarities across various alerting mechanisms, it created significant heterogeneity. The justification of which was to determine effectiveness of alerting tools pragmatically across various cohorts, determining their overall efficacy as a tool to assist clinical decision making. Nevertheless, this limitation, largely a result of the paucity of high-quality literature, is to be acknowledged.

The paucity in high quality, robust, literature limits the conclusions drawn in our review. The included non-randomised trials, due to their observational nature, are prone to selection biases, particularly pre-post implementation designs which can be theoretically confounded by longi-

tudinal changes in healthcare provision. Moreover, integrated feedback loops and responses to alerts are likely to feed into the Hawthorne effect,[144] an additional source of bias of human behaviour created in response to the awareness of being observed. Lastly, the literature search was conducted before the emergence of the COVID-19 pandemic which has undoubtedly accelerated the adoption and research of digital technologies whilst likely altering perceived healthcare and patient perceptions favourably towards their use.[145, 146] A repeated search may generate a new body of evidence with outcomes more in favour of digital alerts. Nonetheless, a great number of variables allowing for comprehensive characterisation of the digital alerting literature has been conducted which, to the authors' knowledge, has not been undertaken previously.

2.5.3 Areas for further research

Further research to answer several important questions is required. Firstly, the optimal frequency of alerting; a range of remote monitoring schedules were utilised for data collection, including continuous,[117] daily,[107, 116, 118, 120–134] only during office working hours (Monday-Friday),[119, 135, 137] and weekly.[138] Indeed, given the diverse methodology in the literature, response time variation would be expected with potential for missing early signs of acute deterioration. Studies with less intense monitoring schedules may be suited for a cohort of individuals less prone to acute deterioration, regardless, a 'window of opportunity' presents itself for missing clinical deterioration in less frequent schedules. Second, which team members to be alerted and what nature of alert to be utilised. Alerts were frequently generated when pre-established thresholds, often tailorable, were breeched or for concerning responses to symptom questionnaires resulting in web platform-based notifications, email alerts, telephone calls, texts, or pagers sent to members of a healthcare team (Table 2.2). In contrast, Santini et al. used audible alarms to alert patients when thresholds were breeched, empowering individuals to contact their responsible physician for further assessment.[130] It is unlikely that one type of alert will be suitable for all individuals but further work identifying the most rapidly acknowledged and actionable alerts is required, including the exploration of alerts sent to individuals alongside healthcare professionals.

Although mixed-methods and qualitative experiences of healthcare staff have revealed potential clinical value of wearable sensors in providing individualised patient monitoring, aiding clinical decision making, and increasing efficiency in prioritising patients,[89] and the use of these technologies are well perceived by patients with enhanced feelings of safety and comfort,[85, 86, 147]

this study has highlighted that there is a noticeable omission from the published literature detailing human factor engineering evaluations and clear description of implementation strategies. Notably, how sensing systems integrate into an existing workflow and healthcare perceptions to any potential change in workflow. The importance of human factor analysis has been supported through guidance published by the MHRA and insights through heuristic review and summative evaluations should target understanding potential delays in response to those receiving alerts; negative (ethical and legal) implications of unactioned alerts, ensuring that if alerts do fail to recognise deterioration, they do not pose unnecessary risk to patients.[148] Lastly, a systematic human factors evaluation into potential workflow alterations with appropriate resource allocation is required to understand if the clinical outcomes reported in this study are repeatable and scalable, going beyond the limited device-specific barriers and facilitators reported in existing literature.

2.6 Conclusion

In conclusion, this chapter provides evidence that digital alerts used in remote monitoring can reduce hospital length of stay, mortality, and may reduce hospitalisations. Digital technologies continue to innovate and have the capacity to change current healthcare provision. There is need not only for large, robust, multi-centre, randomised trials studying digital alerting mechanisms in a varied cohort of individuals but also for description of implementation strategies. Trials should seek to cycle different alerting protocols to understand optimal alerting to guide future widespread implementation not only within secondary and tertiary care settings but, importantly, in community settings, as implementation of new technologies within home settings has potential to truly revolutionise healthcare delivery.

3. Remote monitoring and wearable sensors in hotels, a response to the COVID-19 pandemic: the proof-of-concept, REMOTE-COVID trial

Part of this chapter has been published as:

Iqbal FM, Joshi M, Davies G, Khan S, Ashrafian H, Darzi A. Design of the pilot, proof of concept REMOTE-COVID trial: remote monitoring use in suspected cases of COVID-19 (SARS-CoV-2). Pilot Feasibility Stud. 2021 Mar 5;7(1):62

Iqbal FM, Joshi M, Davies G, Khan S, Ashrafian H, Darzi A. The pilot, proof of concept REMOTE-COVID trial: remote monitoring use in suspected cases of COVID-19 (SARS-CoV 2). BMC Public Health. 2021 Apr 1;21(1):638

3.1 Introduction

On 11 March 2020, the global case load of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV 2) (COVID-19) had increased drastically and the World Health Organisation (WHO) characterised SARS-CoV 2 (COVID-19) as a pandemic.[149] This focussed global efforts to reduce the healthcare burden placed upon local health systems, in order to minimise the over-stretching of existing limited resources with clear repercussions for patient safety.[150] Therefore, to mitigate viral spread, the British Government introduced various public health measures to help tackle the rapidly rising rates of transmission. Initially, Public Health England (PHE) recommended that a period of mandatory isolation was required for individuals who were deemed as high risk; namely reserved for travellers entering the United Kingdom (UK) suspected of harbouring SARS-CoV-2 having travelled or transited through high-risk countries.[150]

With the healthcare system struggling to cope with the mismatch of bed space availability, rising caseload, and a reduced workforce – a result of the rapid viral spread within secondary care – novel digital strategies could be deployed to assist in managing the caseload remotely in suitable cases. Within secondary care, detection of clinical deterioration is aided through intermittent monitoring of vital sign data;[20] often trends can inform the likelihood of clinical

deterioration.[19, 20] With innovations in wearable sensors and associated software harbouring alerting mechanisms, continuous remote monitoring solutions have become an attractive, viable solution to support clinical decision making for healthcare professionals and allow unwell individuals to receive care outside of expensive hospital facilities during times of crisis.[95, 151–154]

As PHE enforced mandatory isolation on travellers entering the UK, hotels situated near airports have potential to be isolation hubs; with appropriate infrastructural and healthcare support, they can deliver healthcare outside of hospitals and remotely monitor vital signs. Those recognised as deteriorating could then be transferred to hospitals for treatment. This model has potential to reduce the strain on secondary care.

Although delivery of healthcare in repositioned hotels is theoretically possible through continuous remote monitoring, it has yet to be studied; given the global pandemic and fear of future waves at the time, assessing the viability of this model was justified.

3.2 Aims

The aims of this chapter, therefore, were:

1. To describe and evaluate a model of healthcare delivery outside of hospital settings during the first wave of the pandemic.
2. To provide proof-of-concept of continuous remote monitoring in a repositioned hotel, acting as an extension to a healthcare trust for individuals suspected of COVID-19 using a wearable sensor system.
3. To determine the feasibility of implementing this model, with a focus on wearability, data usability, and safety.

3.3 Methods

3.3.1 Study design

This was a pragmatically designed, observational, feasibility study, developed in accordance with recommendations from the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.[155]

All participants provided informed consent. Ethical approval was granted by the London – Queen's Square Research Ethics Committee (IRAS: 281757). The work was performed in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki. Patient data was anonymised ensuring privacy. Storage and handling of personal data complied with the General Data Protection Regulation.

3.3.2 Study participants and setting

This study was conducted in two hotels located near London airports from May to June 2020. Individuals arriving at London airports having departed from or transited through high-risk countries or healthcare staff who were suspected of having COVID-19 and unable to isolate safely at home (a result of lodging with vulnerable people, for example), were recruited into hotels for isolation, and were eligible for the study. Individuals with a pacemaker, skin reaction to the wearable patch, or consent withdrawal were excluded.

The duration of isolation varied, in accordance with changing government guidelines – particularly during the first wave of the pandemic, swab results, and symptomatology. These individuals were assessed by healthcare professionals, underwent a polymerase chain reaction swab if necessary, and were fitted with a wearable patch before being securely transferred to their rooms; they were followed for the duration of their stay.

3.3.3 Implementation strategy, wearable sensors, and alerts

As part of the response to the first wave of the pandemic, the government had re-prioritised healthcare staff whilst postponing elective and community-based services.[156] A central monitoring hub was established to monitor the recorded parameters by the NHS healthcare staff from a local Trust. The hub consisted of a site manager, porters, security staff, nurses, ambulance services, professional cleaners, access to a 24h General Practitioner (GP), and hotel staff. The purpose of this model was not to provide care at the level of a hospital, but rather to act as a monitoring centre to detect deterioration, escalating appropriate cases to secondary care, thereby reducing the resource burden.

A disposable, lightweight, waterproof, wearable wireless 'patch' (SensiumVitals™, The Surgical Company) attached to a participant's chest with two adhesive Electrocardiography (ECG) electrodes. This was chosen after extensive product evaluation.[72] It records axillary temperature,

heart and RRs every two minutes. This provided continuous remote monitoring for the lifespan of the internal battery (5 days).

Data were then transmitted to the central monitoring hub, viewable through a secured web-browser (or a mobile phone device), through radiofrequency and dedicated intranet hotspots (bridges) installed in hotel rooms (Figure 3.1). Bridges were 'plug-and-play', requiring minimal technical literacy (Figure 3.2). Each bridge was able to cover more than one room; however, in order to account for potential connectivity losses or data attrition, a contingency setup was built into the installation ensuring all rooms would be covered by an additional bridge.

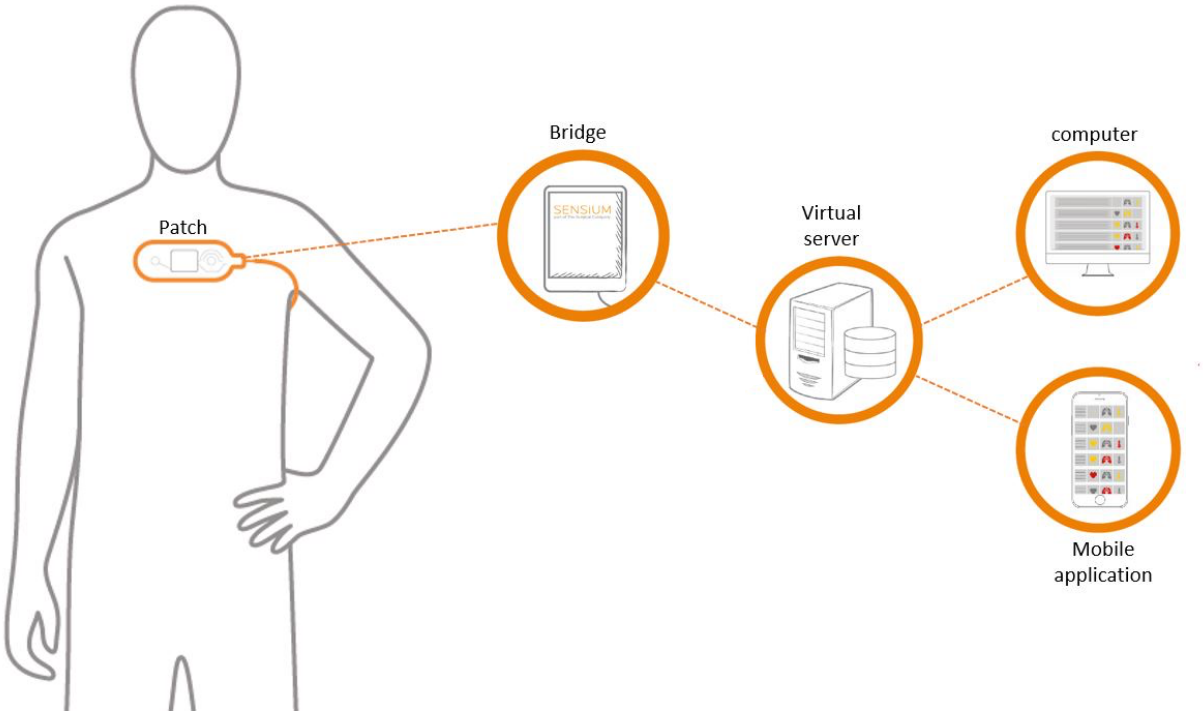
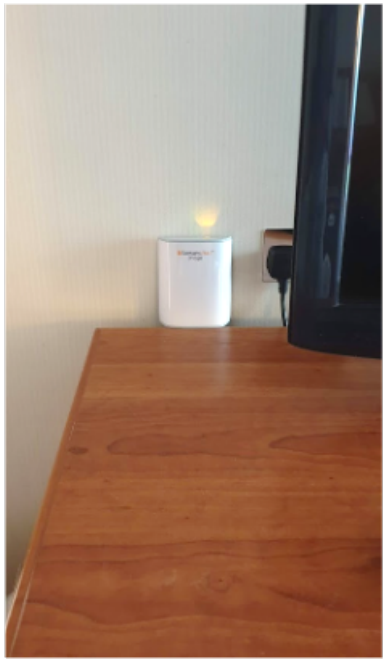


Figure 3.1: SensiumVitals™ monitoring system; permission granted to use image by SensiumVitals™

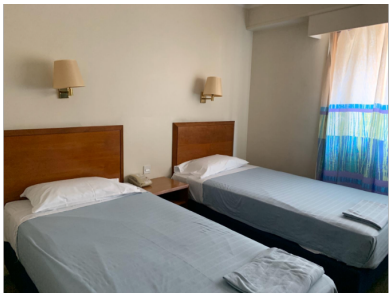
RR was recorded using principles of impedance pneumography (IP)and HR through R-R intervals measured through single-lead ECG.[157] In the axilla, a temperature-sensitive resistor was positioned. Raw physiological signals underwent digital filtering and a digital making stage through embedded algorithms within the sensor to ensure noisy or irregular signals were excluded, thereby undergoing a quality assurance check in order to reduce false alerts.[157] The sensor records in 2 minute cycles in a sequential manner, firstly recording HR, then RR, and lastly temperature (Figure 3.3).

All alerts were viewed by dedicated trained nursing staff placed at the hotel, providing on-site

(a) Sensium Bridge plugged in



(b) Sensium Bridge plugged in



(c) Layout of hotel room

Figure 3.2: Installation of bridges and layout of hotel rooms

24 hour cover. Alert transmissions were generated when predefined alarm thresholds for vital parameters were crossed and were based on red or amber NEWS 2 thresholds.[153] However, these could be individually tailored, if required.

Recorded data by SensiumVitals™ system was stored on a created secured hotel network and was accessable only by research personnel. The hotel was acting an extension to a local healthcare trust; therefore, the SensiumVitals™ system inherited hospital procedures and data backup policies, ensuring data access and servers were secured.

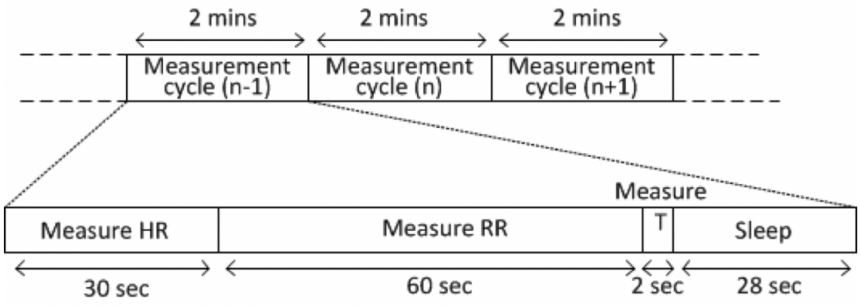


Figure 3.3: SensiumVitals™ sequential vital sign recording cycle; permission to use image granted by SensiumVitals™

3.3.4 Intervention protocol for alerts

All incoming alerts were deemed to be of potential clinical relevance and resulted in a phone contact between the interpreting nurse and the participant; each hotel room had installed landlines. This allowed for additional question seeking at the discretion of the health care worker to gain insight. Potential outcomes included administration of analgesia, general education and anxiety management, virtual GP review, or escalation to the hospital. These actions were protocol driven and were under evaluation to ensure their appropriateness.

3.3.5 Outcome measures and progression criteria

As a proof-of-concept study, outcomes were primarily focussed on feasibility although exploratory clinical outcomes were also assessed.

Feasibility outcomes

1. Rate of participation
    (a) Using the confidence interval approach,[158] for a minimum sample size of 10 individuals, we estimate a rate of participation of 90% with a 95% confidence interval of +/- 18%.
2. Alert generation following recognition of an abnormal vital sign (e.g., raised temperature).
    (a) We aimed for a minimum of 5 vital alerts to be generated to demonstrate feasibility.
3. Number of adverse events relating to the sensor system (e.g., skin reaction to sensor preventing trial continuation)

Exploratory clinical outcomes

1. The total number of alerts, proportion of actioned alerts, and resultant actions (i.e., phone consultation, virtual general practitioner review, transfer to hospital) were measured.
2. Acceptability and usability of the SensiumVitals™ system by healthcare staff and participants.

3.3.6 Statistical analysis

Descriptive statistics were used to describe baseline characteristics, alerting frequencies, and events.

Acceptability and usability of the SensiumVitals™ system by participants and healthcare staff was evaluated through a mixed methods approach, consisting of semi-structured interviews and questionnaires. For participants, these were completed at the end of their isolation; for healthcare staff, they were conducted once familiarity with the system was established.[153] The questionnaires consisted of five-point Likert scale responses (strongly disagree to strongly agree), with elements adapted from the validated system usability scale (SUS) (Figure 3.5 and 3.6).[159] Semi-structured interviews, conducted using prepared topic guides (Appendix A), were recorded, anonymised, and transcribed verbatim before entered in to NVivo 12 for analysis. Topics covered included comfort, understanding, safety, and repeated use; these were based on previously published literature.[85, 147, 160]

Frequency distributions for Likert scale responses were generated. Interview transcripts were analysed using Braun and Clarke's thematic analysis.[161] This involved the independent review of transcript by two researchers, evaluating for common attitudes and experiences between participants. Emergent themes were subsequently coded; data were systematically reviewed to ensure the identified themes were suitable. Facilitators and barriers were determined from healthcare staff.[162, 163]

3.3.7 Power considerations

As a proof-of-concept study, initiated at the onset of an unknown viral pandemic with a poorly established progression; this study aimed to appraise the feasibility for hotel remote sensing. There was a paucity in the literature to support power calculations. However, a confidence interval approach, as outlined above was conducted; as a result, a minimum sample size of 10 was intended for.

3.4 Results

3.4.1 Study population

A total of 14 participants were enrolled into the study after excluding one participant (stating anxiety as a reason), and participant flow is demonstrated in Figure 3.4 . Baseline demographics are displayed in Table 3.1. The mean length of stay at the hotel was 3.1 (SD: 1.8) days.

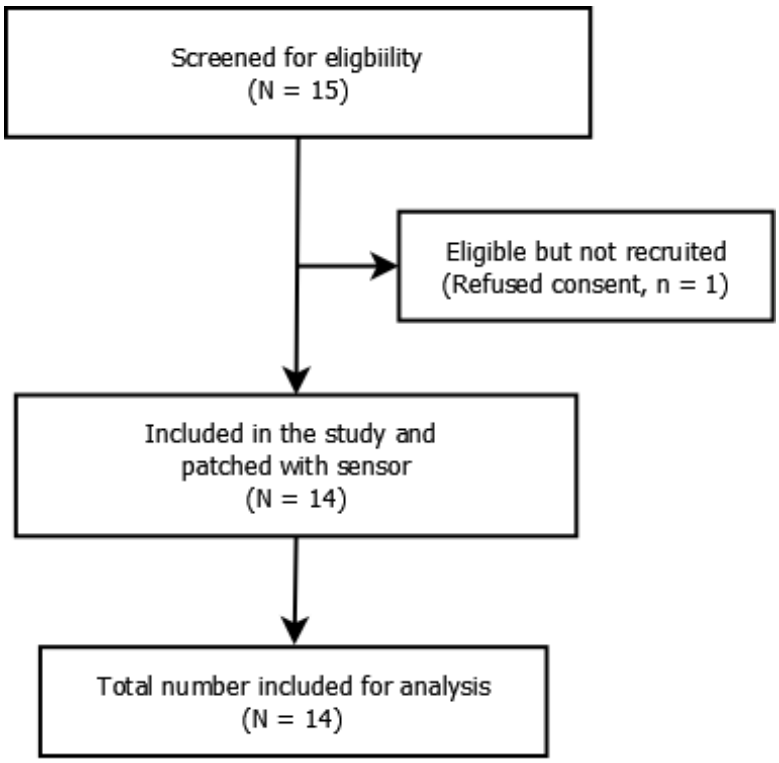


Figure 3.4: Participant flow diagram

Table 3.1: Baseline Characteristics

Characteristics (N=14)	**N (%)**
Age (years), mean (SD)	34.9 (11.0)
Male	7 (50)
Female	7 (50)
Caucasian	7 (50)
Black Asian Minority Ethnic (BAME)	7 (50)
SARS-CoV 2 swab positive	3 (21.4)
Co-morbidity:	
None	6 (42.9)
Asthma	3 (21.4)
Cardiovascular (e.g., hypertension)	2 (14.3)
Neurological (e.g., migraine, seizures)	2 (14.3)
Anxiety/depression	2 (14.3)

3.4.2 Clinical events

A total of 10 vital alerts were generated across four individuals (Table 3.2). There were two unactioned alerts (for abnormal RR) which expired. None of the recruited individuals required hospitalisation or virtual GP review. Two individuals developed a skin reaction to the adhesive (tape or ECG electrodes) but continued to participate in the study and treatment was not required. There were no dropouts.

Table 3.2: Clinical events following alerts

Events	Alert	Management
10 vital alerts in 4 patients	Abnormal temperature reading (1 episode)	Anti-pyretic (paracetamol) administered following telephone consultation (1 episode)
	Abnormal respiratory rate reading (9 episodes)	No action taken following telephone review (6 episodes)
		Electrodes reapplied (1 episode)

3.4.3 Device performance for data availability

When recorded values failed to meet the internal quality assurance check of the sensor or failed to accurately record the value (i.e., movement artefact; incorrect sensor application; battery depletion; device failure) then a '-1' value was computed.

In this study, a total of 16844 datapoints were generated for each recorded variable. For HR 35.4% of datapoints were given a '-1' value and were missing, 59.4% for RR, and 24.2% for temperature readings.

3.4.4 Healthcare and participant perceptions

Participant perceptions

Nine participants (out of 14) responded to questionnaires and four (out of 14) participated in semi-structured interviews. Overall, guests perceived the sensor to be comfortable, felt safer with its use, and would wear the sensor again; it was perceived to be uncomplicated. Frequency distributions of participant responses are displayed in Figure 3.5.

Three main themes materialised from the interviews: i) functionality; ii) comfort and usability; and iii) sense of security.

Functionality

Overall, participants were aware of the purpose of monitoring with the miniaturisation of the

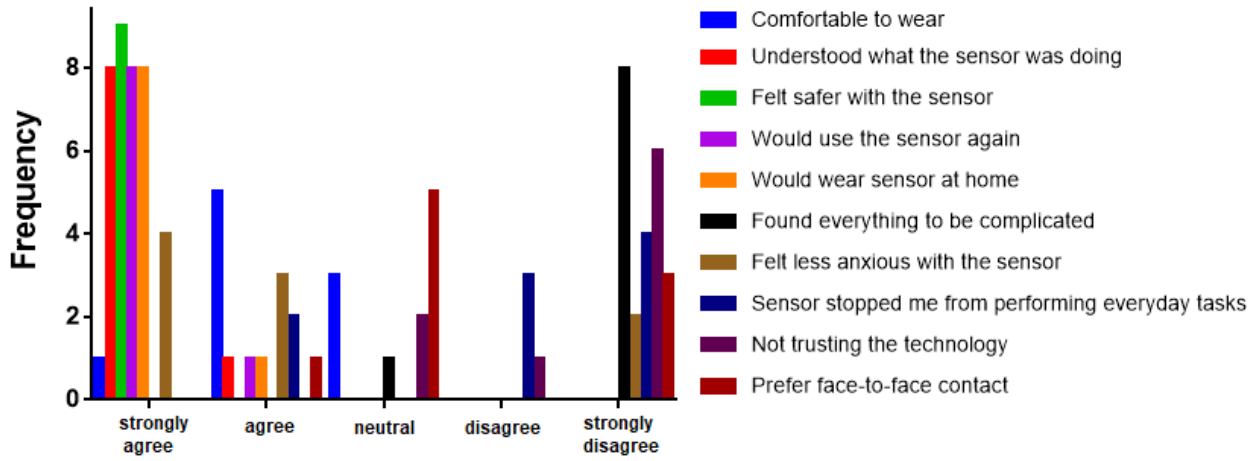


Figure 3.5: Frequency distribution of participant questionnaire responses

sensor reported to be appealing.

> "...monitor you remotely from the [central monitoring] station... something that's an alteration or a shift [in your vital signs], [the nurses] can then contact us and see how we're feeling and if it matches [the vital sign readings]...you can't really see [the sensor through] the clothes. It's quite small...you can't see it" (guest 1)

> "it was not heavy at all." (guest 2)

One obvious advantage was the reduction in viral exposure to healthcare staff and this was reflected by participants.

> "you can have limited contact to patients, especially if the patient is infectious. I'd say that you can monitor the patient [without] having frequent contact... so it's good." (guest 2)

Comfort and usability

Most guests reported the sensor as comfortable to wear in the questionnaire. However, it may require a short instance to become accustomed to the sensor.

> "it's not really that uncomfortable...I got used to it over time. It's just about adjusting to it the first time I wore it." (guest 2)

Guests reported mixed experiences on the practicalities of wearing the sensor with their daily activities.

"I tended not to sleep on my side as I thought it might come off. It wasn't particularly restrictive [otherwise]. (guest 3)

"when I shower I'm always very cautious to wash around it." (guest 1)

"I think the tape [to fasten the temperature wire] was a little bit [inconvenient] but not the actual wire" (guest 3)

"At first it was difficult to adjust [to]. It was like it felt a bit tight, I mean the tape on my underarm was a bit tight... also I did wonder the probe to lose contact with my skin, because I wanted the monitoring to be precise. And so I was always worried about losing contact with the probe on my skin... over time it was comfortable... I got used to it over time... washing or sleeping wasn't a problem" (guest 4)

"I took it off [before] I had my shower... I would have probably been a bit reluctant to shower in it." (guest 3)

Sense of security

Participants felt reassured and comforted by the knowledge that they were receiving continuous monitoring remotely.

"I felt, to be honest, probably a bit more comfortable that somebody's keeping an eye on things... things can deteriorate quickly." (guest 3)

"I feel secure and I felt safe being there, being monitored" (guest 2)

"It felt good. It gave me a little bit more of a sense of being monitored and cared for." (guest 4)

None of the guests felt the sensor was intrusive.

"it's not too intrusive of what my activities are" (guest 1)

3.4.5 Healthcare staff perceptions

A total of six staff members responded to the questionnaire and participated in semi-structured interviews.

The hotel model of healthcare provision was perceived with mixed feedback amongst nursing staff. However, most staff felt that the technology was trustworthy, unburdensome, and im-

proved the level of care delivered from the remote sensing technology. Frequency distributions for healthcare staff are shown in Figure 3.6.

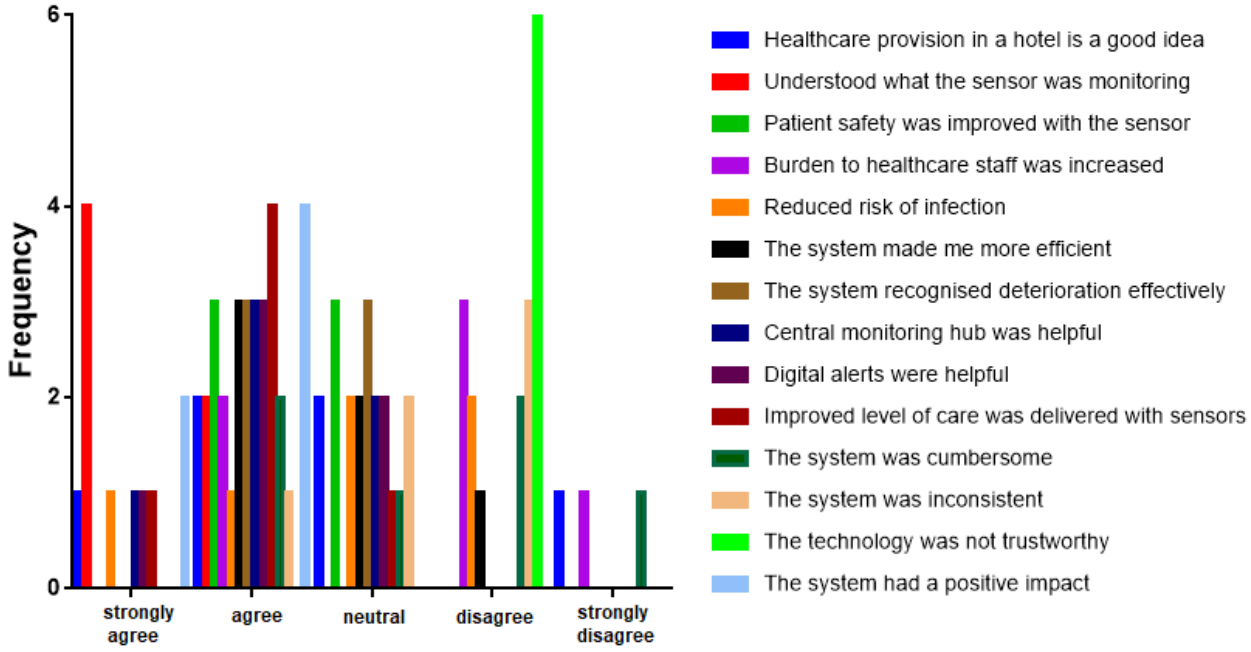


Figure 3.6: Frequency distribution of healthcare staff questionnaire responses

Two main themes emerged from the interviews which were sub-categorised into facilitators and barriers: i) factors relating to the sensor and ii) perceived usefulness.

Factors relating to the sensor

Facilitators

Overall, healthcare nurses favoured the dimensions of the sensor and the simplicity of the system.

> "It was quite compact, quite small. Easy to apply" (nurse 6)

> "portability... the individual patients/guests are not restricted in their movements... [the system] was quite intuitive and quite easy" (nurse 2)

> "person doesn't seem to know they're wearing it, so that's good" (nurse 3)

> "I'm quite surprised actually that they could carry on with the routine activities, even shower with it, without having to remove it and reapply it which I thought was fantastic.... I think the guests liked it too. I know one guy who came, a young gentleman, he was really glad that we were monitoring him" (nurse 6)

Barriers

Adhesive tapes and electrodes were noted to have varying efficacy amongst different guests, affecting overall signal quality. This required repeated fastening and replacement in some cases.

> "we had one person who the electrodes kept popping off so that might be something [that needs] improving." (nurse 2)

> "I think a weakness was the temperature probe." (nurse 4)

> "There are one or two guests that the readings were not coming out as we would have liked. And it could be because they were moving very fast or they have removed [the sensor] from its position." (nurse 5)

Perceived usefulness

Facilitators

The system was perceived as providing a clinical insight by healthcare staff whilst reducing viral exposure.

> "I think for our group of patients it's been really good. Because they're behind a closed door it has given us an opening to see what else is going on" (nurse 3)

> "It's quite beneficial. It saves time and if the machine is accurate and that it will trigger any intervention if necessary and I think it's a good thing." (nurse 5)

> "gave me additional reassurance that we knew exactly what was going on" (nurse 6)

> "easier to sort of escalate if people needed further treatment quickly" (nurse 1)

> "I think staff exposure [to coronavirus] was reduced" (nurse 6)

> "it gives them [nurses] time to be able to do other things with them." (nurse 3)

Barriers

Nurses reported the need for trained staff to action alerts and, for some individuals, may be a source of anxiety.

> "that is a safety issue, people need to know how to use things properly, how to escalate the information it's providing them with properly because to not use it

puts the patient at risk." (nurse 2)

"You still need sort of trained staff to understand what it all means so you wouldn't be able to run it here with a healthcare assistant or with no nurses, you'd need to have a healthcare professional that was experienced here." (nurse 1)

"there may be some patients where mental health may be the dominant thing that you're trying to treat... wearing this patch may feed into a paranoia or a confusion or something like that." (nurse 2)

3.5 Discussion

3.5.1 Principal findings

This chapter has demonstrated a rapid model that was successfully deployed at the very onset of the pandemic, describing implementation considerations, demonstrating feasibility and proof-of-concept. Hotels were repositioned and fitted with remote sensing technologies, no longer open to the public. This model of staffing the hotel with healthcare staff and security resulted in a novel health space. Alerts were generated upon abnormal vital parameters which aided with clinical decision making locally. Moreover, a broad overview of participant and healthcare perceptions on wearable sensors and alerting mechanisms was delivered; an addition to the existing literature which has primarily explored the use of patient attitudes of sensors within secondary care settings. Given the rapid change in healthcare delivery, fuelled by the pandemic, and the implementation of remote sensing solutions in our model, this work has laid a foundation for wearable sensors and digital alerting mechanisms which will continue to develop and be implemented in current healthcare setups.[85, 164]

Within our cohort, only a small proportion of generated alerts required clinical action. There were no individuals that required escalation either for virtual GP review or hospitalisation. Given the small sample size and short duration of stay at the hotels, the potential benefits of remote monitoring and digital alerts could be under appreciated. Moreover, the recruited cohort had few co-morbidities and were young; therefore, served a low potential for severe illness requiring a higher level of care (i.e., hospitalisation). However, given the observed clinical events and lack of dropouts, the exploratory nature of this work has proven feasibility.

The SensiumVitals™ system has been evaluated on non-intensive medical and surgical wards previously but did not find any discernible improvement with respect to clinical outcomes from remote vital sign monitoring.[75, 147] However, this initial work failed to describe the implementation timeframes and suffered from imbalanced arms across the two trial arms.[75] Nonetheless, the studies did demonstrate feasibility of such systems in hospital settings. Barriers and facilitators, identified through semi-structured interviews, have highlighted the importance of design, comfort, and safety for patients. Moreover, both healthcare staff and patients favoured the belief of continuous vital sign monitoring in general wards.[147] It should be noted that many of the patients interviewed were admitted for malignant disease which is likely to influence qualitative perceptions. Moreover, the clinical value of these systems differs greatly in secondary care to community settings and their perceived value is likely to have undergone change as a result of the pandemic. Our trial identified additional perceptions in remote sensing environments focussing outside of secondary care settings, captured at a pivotal point during the pandemic.

3.5.2 Limitations

Despite the strengths of this study with rapid implementation at the onset of the pandemic, a time of uncertainty and delivering healthcare in a hotel, the design presents inherent limitations. To maximise capacity at the sites, a pragmatic, observational design was favoured with randomisation not deemed suitable. Furthermore, government restrictions were constantly reviewed with regular changes occurring for air travel and isolation guidelines; this significantly altered our sample size and participant length of stay.

Additionally, the inclusion of healthcare staff who wore the sensor, who were inherently familiar with vital signs and clinical observations may bias the description of favourable experiences. However, such individuals are also likely to carry greater expectations owing to their familiarity. As such, their presence is unlikely to affect the demonstration of proof-of-concept. Device specific outcomes, such as the wavering effectiveness of adhesive tapes and electrodes, lack generalisability when compared to other available sensors but provide a broad insight into design considerations.

3.5.3 Future directions for research

Further work should seek to develop implementation strategies and better understand escalation protocols for use of remote sensing within the community. The application of this technology could be invaluable in nursing homes which could similarly identify appropriate cases for escalation or provide trend vital sign data for virtual GP review, aiding clinical decision making. Furthermore, this model of delivering care should be tested at a larger scale, as rapid implementation during crisis has been proven to be possible, in particular understanding the drivers which can transform hotel in to health spaces.

Before the outbreak of the COVID-19 pandemic, global societies, such as the American College of Physicians (ACP), the Society of Hospital Medicine (SMH), the Royal College of Physicians (RCP), and the Royal College of General Practitioners (RCGP) all promoted the use of high-value care.[165–167] This directive indicates careful resource allocation whilst delivering the best possible care. With the scarcity of resources, exacerbated during times of crisis, our model can envisage potential future adoptions.

3.6 Conclusion

In conclusion, this trial demonstrated feasibility of remote sensing systems to assist with healthcare delivery outside of a secondary care setting; furthermore, healthcare staff and participants experiences were perceived positively. The future of wearable technologies with continuous remote monitoring have potential to pair with artificial intelligence, incorporating predictive algorithms and facilitating enhancement in healthcare delivery in not only secondary care but also in remote and community settings. Further work should explore the effect of remote sensing and its impact on clinical outcomes, particularly given the evolving model of healthcare delivery, accelerated by the pandemic.

4. The implementation and outcomes of wearable sensors, alerting systems, and continuous remote monitoring in secondary care

Part of this chapter has been published as:

> **Iqbal FM**, Joshi M, Khan S, Ashrafian H, Darzi A. Implementation of Wearable Sensors and Digital Alerting Systems in Secondary Care: Protocol for a Real-World Prospective Study Evaluating Clinical Outcomes. JMIR Res Protoc. 2021 May 4;10(5):e26240. doi: 10.2196/26240. PMID: 33944790
>
> **Iqbal FM**, Joshi M, Fox R, Koutsoukou T, Sharma A, Wright M, Khan S, Ashrafian H, Darzi A. Outcomes of Vital Sign Monitoring of an Acute Surgical Cohort With Wearable Sensors and Digital Alerting Systems: A Pragmatically Designed Cohort Study and Propensity-Matched Analysis. Front Bioeng Biotechnol. 2022 Jun 27;10:895973. doi: 10.3389/fbioe.2022.895973. PMID: 35832414.

4.1 Introduction

Within secondary care, routine but intermittent monitoring of Heart Rate (HR), Respiratory Rate (RR), temperature, Blood Pressure (BP), oxygen saturations (& supplemental oxygen), and levels of consciousness, is conducted for individuals admitted to non-intensive (general) hospital wards. In order to standardise the delivery of clinical care nationally, early warning scores (i.e., National Early Warning Score 2 (NEWS 2)) are endorsed through professional bodies (e.g., The Royal College of Physicians) to protocolise the monitoring regularity which incorporate and score each vital parameter according to severity. These can be combined detailing an overall score which dictate appropriate action.[1]

The premise of monitoring vital signs and implementing early warning scores is based around the principle that clinical deterioration can be detected through prodromal changes (e.g., worsening tachypnoea or reducing blood pressure); with appropriate early intervention this may prevent an adverse event.[16–23] This, therefore, is considered a central component in delivering effec-

tive clinical care and their implementation has shown good predictive value on deterioration, positively influencing clinical outcomes.[29]

However, clinical deterioration can still be unnoticed resulting in late referrals to critical care units; worsened morbidity, and mortality.[13, 41–43, 168, 169] This, in part, is a consequence of the limitations of EWS, notably their intermittent nature, which can allow for acute deteriorations in between the routinely scheduled observations to be missed.[29] Furthermore, inadequate monitoring frequencies and NEWS 2 calculations; transcribing errors from observation machines; misplacement of paper-based charts (still used in some trusts) have all been reported.[33–35]

Given the continued advancements, discreteness, and small footprint of wearable sensors, they propose an attractive solution with a small footprint for remote near real-time continuous vital sign monitoring. With the generation of additional data points autonomously, there is potential for earlier recognition of deterioration with an improved and more efficient workflow for healthcare staff.[71] Alerting mechanisms prompt and request additional action from healthcare staff on central monitoring hubs or mobile devices, having been generated once pre-established, but customisable, thresholds for vital parameters are breached. This, if successful, can positively influence clinical outcomes with long term potential for the application of machine learning approaches to predict deterioration rather than relying on protocol-driven intermittent traditional based measurements.[78]

One study supported the use of digital alerting and remote monitoring systems in cases of sepsis to reduce hospital and intensive care length of stay,[66] however the included studies within this review were predominantly of low-quality suffering with various bias. Another study reported that there was a paucity in the literature with regards to the efficacy of wearable continuous monitoring on clinical outcomes.[170] Furthermore, an additional study reported no conclusive evidence to favour continuous monitoring outside of intensive care settings.[171] However, substantial design heterogeneity, cohort selection bias, and lack of controls have limited the generalisability as well as significant conclusions. Moreover, the real-world applicability of digital interventions is rarely reported, a crucial element for identifying issues during implementation which, in turn, would influence the success of a digital solution.

Reported experiences of nursing staff, based in secondary care, state the potential functional value of wearable sensors in supporting individualised patient monitoring, aiding clinical deci-

sion making, and increasing efficiency in prioritising patients, particularly during busier shifts. However, they favour the introduction of a selection process to adapt to an individual's need as not all patients require continuous monitoring.[89]

As of now, studies have been preliminary, with a focus on acceptability, feasibility, reliability, and user experiences of wearable sensor based continuous monitoring.[75, 79, 147, 170, 172] There is a need for a description of real-world incorporation of digital alerts into remote monitoring within secondary care, to determine its true efficacy.

4.2 Aims

The aims of this chapter, therefore, were:

1. To undertake a pragmatically designed trial to evaluate remote monitoring and alerting systems in secondary care.
2. To assess the clinical outcomes following implementation of wearable sensors and digital alerts.
3. To describe the implementation strategy and highlight key issues for future research.

4.3 Methods

4.3.1 Study design

This was a pragmatically designed, single-centre, pre-post implementation study conducted on the acute surgical unit at our institution (West Middlesex University Hospital) and developed in accordance with recommendations from the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.[155]

The setup of this department involved reviewing acute surgical presentations referred from primary care or the emergency department. This included acute abdominal pain caused by a selection of pathologies (e.g., bowel obstruction, appendicitis, cholecystitis, diverticulitis) but also acute bleeding symptoms (e.g., haematuria, rectal bleeding) and was staffed by a rotating on-call system of healthcare professionals. Indeed, this cohort represented potential to rapidly deteriorate where the utilisation of digital alerts may be impactful. Considerations were given

to a medical cohort, however, the rapid rate of patient transfer to other long stay wards risked a high degree of data attrition; given the financial and logistical needs to engineer wards for digital alerting systems in hospitals, a decision was made, in conjunction with key stakeholders, to trial the acute surgical unit.[173]

The pre-implementation phase (September 2017 to May 2019) involved using the SensiumVitals™ system in combination with usual care. However, healthcare staff were unable to view the sensor data and digital alerts were not generated. Usual care, in our institution, involved intermittent monitoring of vital signs in accordance with the NEWS 2 protocol. This thesis represents a continuation of the work previously set out. Therefore, the pre-implementation data, which served as a control, was primarily conducted by Joshi et al.[174]

In the post-implementation phase (May 2019 to March 2020), alerting systems following recognition of abnormal parameters was activated. These alerts were transmitted to mobile devices and central monitoring hubs, with alert acknowledgement required from healthcare staff.

All participants provided informed consent. Ethical approval for this study was granted by the Yorkshire & The Humber - Leeds East Research Ethics Committee (reference: 17/YH/0296; IRAS: 222979) and this trial was performed in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki. Patient data were anonymised to ensure privacy. Storage and handling of personal data complied with the General Data Protection Regulation.

4.3.2 Stakeholder engagement and implementation strategy

Before commencing the project, several stakeholders were engaged to ensure successful implementation. This included obtaining permission from the Estates and Information Technology departments. As a result, bridges were installed by the hospital Estates department, ensuring adherence to local policies, and allowing for communication and recording of vital parameters between the wearable sensors to both the central monitoring hubs and the provided mobile devices.[173]

Previous deployment of a different digital solution (a smartphone app), developed by a large industry partner, in a different hospital network attracted significant media and public attention. This followed from an investigation undertaken by the Information Commissioner's Office (ICO) because of the nature of data processing between the Trust and the industry partner.[175–177] In our initiative, having learnt from these well publicised breaches, associated sensor software

was integrated with the hospital admissions data system, this allowed for consenting participants to be added to the sensor system digitally. All data were stored and retained on hospital networks, alleviating data security concerns.

Senior clinicians, nursing staff, and senior ward sisters were informed of the project through engagement meetings to assist with recruitment and gain understanding of the study aims. Healthcare staff were trained directly to use the system with regular formal and informal feedback sessions to ascertain areas of User Experience (UX) and User Interface (UI) improvements, which were fed back to SensiumVitals™; ad-hoc refreshers were given throughout the duration of the study.

4.3.3 Wearable sensor and alerting thresholds

A disposable, lightweight, waterproof, wearable 'patch' (SensiumVitals™, The Surgical Company) was attached to a participant's chest with two adhesive ECG electrodes, recording HR, RR and axillary temperature every two minutes, as previously described in this thesis. These data and any subsequent generated alerts were viewable and actionable through a secured web-browser or mobile devices provided to healthcare staff (Figure 4.1). Previously, barriers relating to healthcare professionals using their own mobile devices, in a 'bring your own device (BYOD)' model, to view patient records on a personal device were deemed problematic with concerns regarding privacy and security.[178] Therefore, to alleviate these apprehensions, healthcare professionals were provided with mobile devices, avoiding a BYOD model.

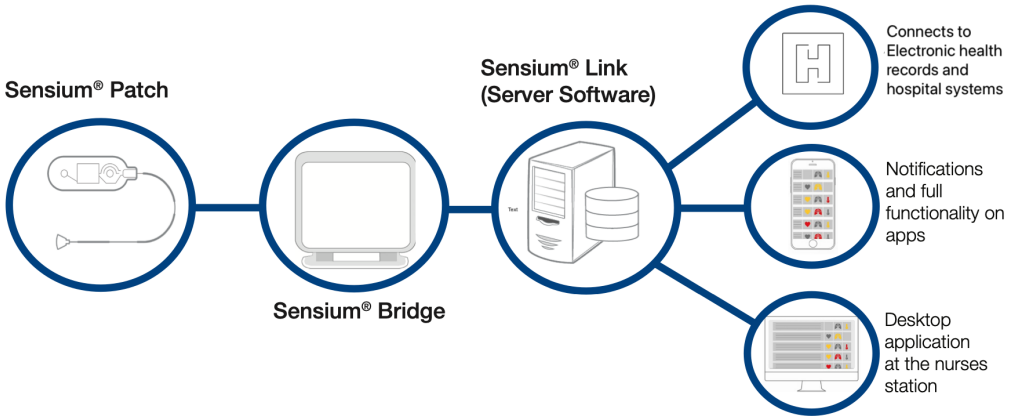


Figure 4.1: Overview of the SensiumVitals™ system deployed in secondary care; permission to use image granted from SensiumVitals™

Captured data by the sensor was processed with patented embedded algorithms which prevented

reporting of noisy or irregular signals to reduce false alerts. This was a two-stage process, firstly there was an initial digital filtering stage where unwanted artefacts were removed from recorded signals (i.e., from external sources or through muscular electrical activity); a second decision-making stage followed which ensured that the recorded signal met a succession of rules and empirically derived thresholds. This allowed the final value to be recorded and interpreted by the end user and certified that a quality assurance check was undertaken.[157, 172]

Alerts were generated when pre-established thresholds were breeched for 10 consecutive minutes for measured vital signs. A ten-minute window was based on (unpublished) internal pilot testing data which tested periods ranging from 6-18 minutes. Ten minutes was chosen to balance the risk of alert fatigue to healthcare staff against the potential usefulness of alerts. These thresholds were individually tailorable but were initially programmed to trigger, in accordance with red (HR over 131 beats per minute, RR over 25 breaths per minute) and yellow (temperature of 38.1 degrees Celsius) NEWS 2 cut-offs.[1]

Ensuing actions taken by healthcare staff were recorded, including: repeating a full set of observations; reviewing the clinical status of the participant; escalating for a review from a senior member of the healthcare team; re-adjusting the electrodes for improved data capture; initiating further treatment or following a protocol (e.g., sepsis 6); or taking no further action.[179] The decision to act upon the alert remained at the clinical acumen of the healthcare professional who received the alert.

4.3.4 Eligibility criteria

Adults (aged over 18 years) admitted to the acute surgical unit and able to understand the participant information sheet were eligible for inclusion. Individuals with cardiac implantable electronic devices; a skin reaction to the wearable sensor or its components; an open chest wound; or those who withdrew consent were excluded from the study.

4.3.5 Outcome measures

Measurable outcomes included hospital length of stay, intensive care use (planned or unplanned), and 28-day mortality. Outcomes were obtained from case note review, SensiumVitals™ data, and electronic health records. Additionally, the availability of data recorded from the sensor was measured.

4.3.6 Statistical analysis

All values are expressed as median (range) or number (%). Categorical variables were compared using the chi-squared or Fisher's exact test, dependent on the observations available. Non-parametric data were analysed using the Wilcoxon Rank Sum test. Odds ratio and incidence rate ratios were calculated for recorded outcome measures.

Propensity score matching (PSM) was used to estimate the effect of digital alerting on clinical outcomes accounting for confounding by the included covariates. Balanced cohorts were created using 1:1 'optimal' PSM logistic regression model.[180] Included covariates were age, sex, ethnicity, American Society of Anaesthesiologists (ASA) grade, presenting NEWS 2 score, and comorbidities as per the Charlson Index.[181]

Balance diagnostics were conducted using standardised mean differences, with a value of <0.1 indicating good balance; love plots were generated to depict balance.[180] Data analysis was performed in RStudio version 3.6.3 (R Studio, Boston, MA, USA) with ggplot2, Matchit, gtsummary packages.[180, 182, 183] A P value of <0.05 was deemed as statistically significant.

4.3.7 Power considerations

The lack of surrounding data for the primary outcome measure prevented formal power calculations. However, based on a previous study, sample sizes between 325-625 were estimated to be appropriate; thought the results of the recruited 226 participants were not significant.[75] Therefore, we targeted a minimum of 600 individuals to be recruited.

As a result of the unforeseen COVID-19 pandemic and, subsequent restructuring of the acute surgical unit, this trial concluded prematurely, limiting our original planned sample size.

4.4 Results

4.4.1 Baseline demographics and balanced cohort assembly

The 1:1 matching method matched the post-implementation group (n = 141) with the same number of subjects from the pre-implementation group (n = 141) with the remaining unmatched samples dropped (n = 138, Figure 4.2). After matching, only ethnicity: Minority Ethnic and admission type (i.e., elective or emergency) remained imbalanced. However, this difference was

not deemed meaningful because of the low number of participants across these variables, and the overall improvement in other ethnicity categories.

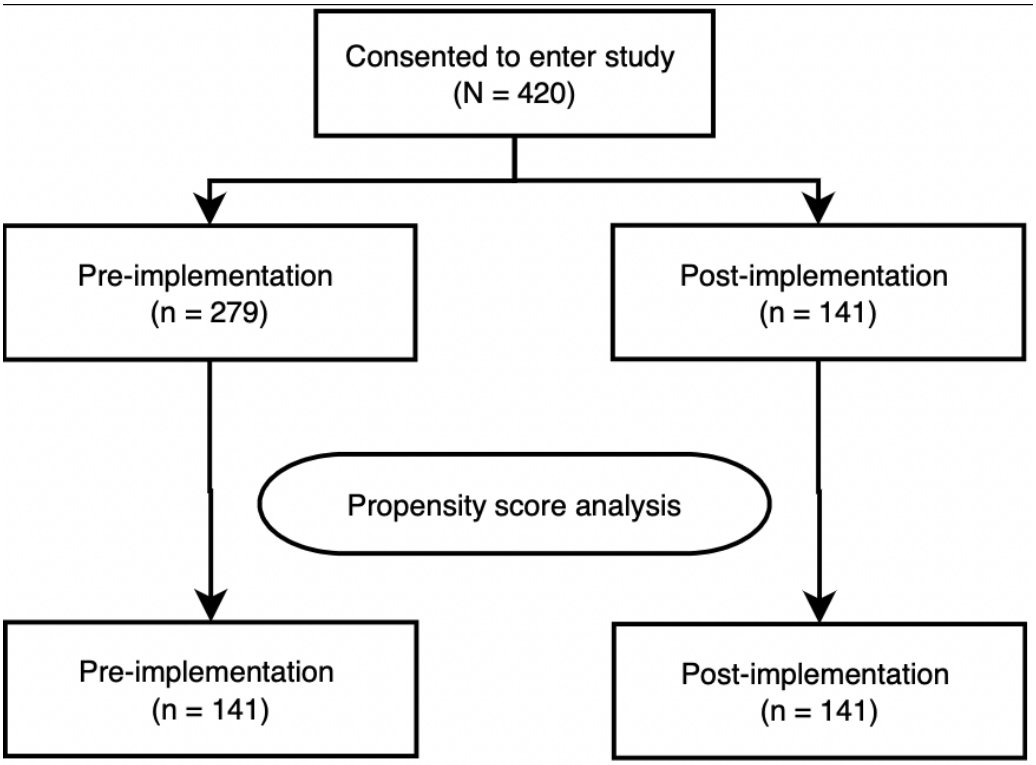


Figure 4.2: Participant flow diagram

Baseline demographics of the unmatched and matched cohorts are presented in Table 4.1. The standardised mean differences of all covariates are displayed as a love plot in Figure 4.3. The median age of the entire cohort was 52 (range: 18-95) years and the median duration of wearing the sensor was 1.3 (interquartile range: 0.7-2.0) days.

Table 4.1: Baseline demographics before and after propensity score matching.

Characteristic	Before Propensity Score Matching				After Propensity Score Matching			
	N	**Pre-implementation**, N=279[1]	**Post-implementation**, N=141[1]	**p-value**[2]	**N**	**Pre-implementation**, N=141[1]	**Post-implementation**, N=141[1]	**p-value**[2]
Age	420	51 (35 – 66)	55 (36 – 73)	0.061	282	51 (39 – 71)	55 (36 – 73)	0.54
Sex	420			0.14	282			0.55
F		154 (55)	67 (48)			72 (51)	67 (48)	
M		125 (45)	74 (52)			69 (49)	74 (52)	
Ethnicity	420			0.008	282			0.71
Black African		11 (3.9)	6 (4.3)			5 (3.5)	6 (4.3)	
Black Carribean		2 (0.7)	1 (0.7)			0 (0)	1 (0.7)	
Caucasian		193 (69)	87 (62)			92 (65)	87 (62)	
East Asian		5 (1.8)	0 (0)					
Middle Eastern		9 (3.2)	0 (0)					
Minority ethnic		5 (1.8)	9 (6.4)			5 (3.5)	9 (6.4)	
South Asian		54 (19)	38 (27)			39 (28)	38 (27)	
BMI	276	27 (23 – 31)	28 (25 – 31)	0.63	177	27 (23 – 32)	28 (25 – 31)	0.83
ASA	420			0.51	282			0.24
1		61 (22)	30 (21)			28 (20)	30 (21)	
2		161 (58)	83 (59)			84 (60)	83 (59)	
3		47 (17)	19 (13)			26 (18)	19 (13)	
4		10 (3.6)	9 (6.4)			3 (2.1)	9 (6.4)	
Charlson Comorbidity index	420	1.00 (0.00 – 3.00)	1.00 (0.00 – 3.00)	0.27	282	1 (0 – 3)	1 (0 – 3)	0.65
Presenting NEWS severity	420			0.12	282			0.91
zero		120 (43)	64 (45)			62 (44)	64 (45)	
low		145 (52)	71 (50)			74 (52)	71 (50)	
medium		6 (2.2)	6 (4.3)			5 (3.5)	6 (4.3)	
high		8 (2.9)	0 (0)			0 (0)	0 (0)	
Admissions	420			0.001	282			0.006
elective		2 (0.7)	10 (7.1)			1 (0.7)	10 (7.1)	
emergency		277 (99)	131 (93)			140 (99)	131 (93)	

[1] Median (IQR); n (%)

[2] Wilcoxon rank sum test; Pearson's Chi-squared test; Fisher's exact test

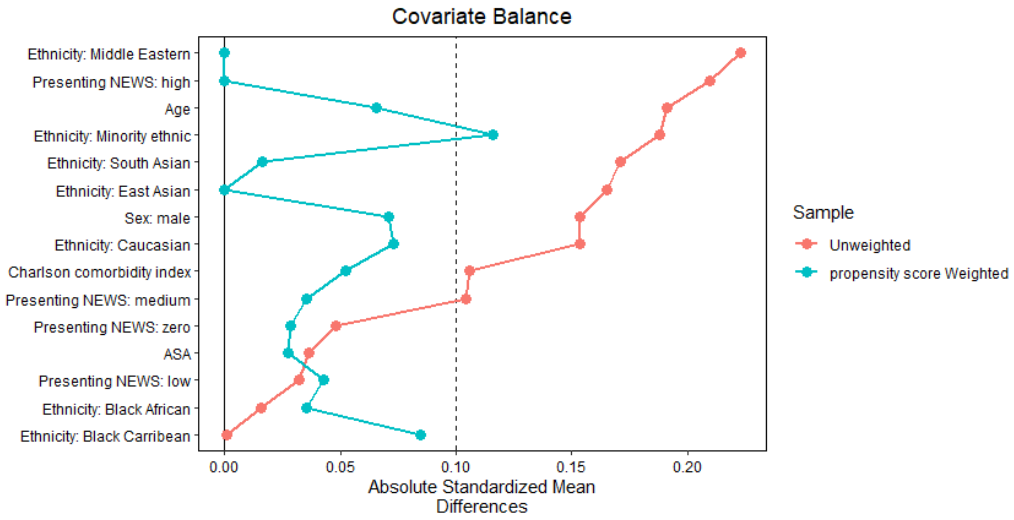


Figure 4.3: Love plot depicting covariate balance with standardized mean differences following propensity score matching.

4.4.2 Response to alerts and clinical outcomes

Overall, 78 alerts were generated for 46 participants. Of which, 58 alerts (33 participants) were actioned. Nursing staff acknowledged generated alerts through a designated mobile application on provided devices, a detailed breakdown of responses by abnormal vital parameter has been tabulated for actioned alerts (Table 4.2).

Table 4.2: Action taken following abnormal vital sign alert.

Action Taken	**Heart Rate**	**Respiratory Rate**	**Temperature**	**N**
Full set of observations repeated	2 (3.4%)	12 (21%)	5 (8.6%)	19 (33%)
Initiated Sepsis Pathway	1 (1.7%)	0 (0%)	4 (6.9%)	5 (8.6%)
No Action Taken	4 (6.9%)	8 (14%)	1 (1.7%)	13 (22%)
Participant clinically well after review	0 (0%)	10 (17%)	0 (0%)	10 (17%)
Reapplied Electrodes	1 (1.7%)	6 (10%)	1 (1.7%)	8 (14%)
Refer to Senior clinician	1 (1.7%)	0 (0%)	2 (3.4%)	3 (5.2%)
N, n (%)	9 (16%)	36 (62%)	13 (22%)	58 (100%)

Members of the research team met weekly with ward managers and senior nurses to monitor the workflow change and feedback previous alerting acknowledgement times as well as gather barriers to change. Briefly, however, themes relating to inappropriate resources (i.e., poor staffing levels and sudden unincentivized workflow changes) were noted. Furthermore, regular training sessions for the nursing staff to encourage use of mobile devices in responding to digital alerts was provided.

The median alert acknowledgement time was 111 (range: 1-2146) minutes. The sizeable varia-

tion in alert acknowledgement time has been plotted in Figure 4.4.

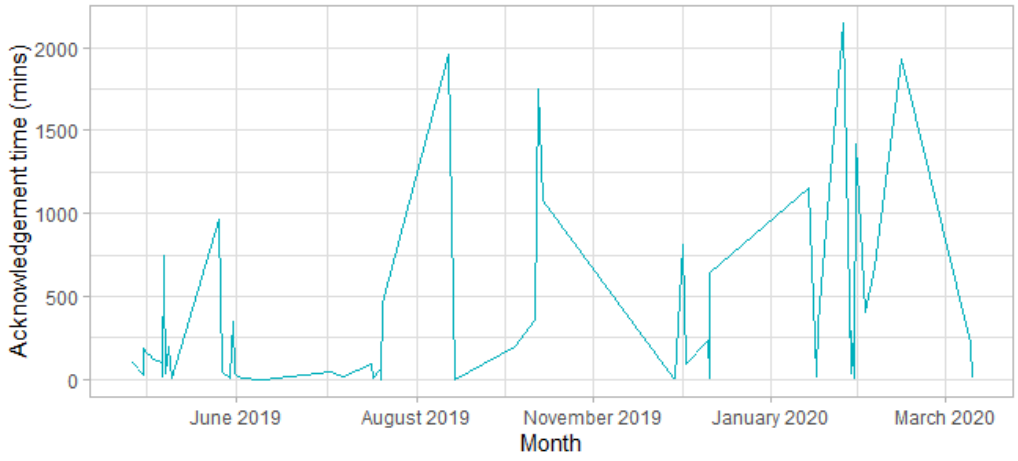


Figure 4.4: Time series displaying the alert acknowledgement time by healthcare staff.

Clinical events have been summarised in Table 4.3. Overall, planned (Odds ratio (OR): 0.49; 95% CI 0.02-5.20) and unplanned (OR: 0.49; 95% CI 0.02-5.20) intensive care admissions, 28-day mortality (OR 0.99; 95% CI 0.04-25.3), and length of stay (incidence rate ratio: 1.03; 95% CI 0.92-1.14) were similar across both cohorts, following propensity score matching.

Table 4.3: Summary of outcome measures before & after Propensity score matching (PSM)

Outcome	Before propensity score matching				After propensity score matching			
	OR (95% CI)	p-value	IRR (95% CI)	p-value	OR (95% CI)	p-value	IRR (95% CI)	p-value
ITU admissions (planned)	0.33 (0.02-1.93)	0.30			0.49 (0.02-5.20)	0.57		
ITU admissions (unplanned)	0.39 (0.02-2.47)	0.40			0.49 (0.02-5.20)	0.57		
28D mortality	0.99 (0.05-10.5)	0.99			0.99 (0.04-25.3)	0.99		
Length of stay			1.04 (0.95 to 1.13)	0.44			1.03 (0.92-1.14)	0.63

4.4.3 Device performance for data availability

When recorded values failed to meet the internal quality assurance check of the sensor or failed to accurately record the value (i.e., movement artefact; incorrect sensor application; battery depletion; device failure) then a '-1' value was computed.

In this study, a total of 696577 datapoints were generated for each recorded variable. For HR 31.7% of datapoints were given a '-1' value and were missing, 58.6% for RR, and 20.2% for temperature readings. Moreover, the maximum duration the sensor monitored HR, RR, and temperature was 5182, 628, and 2346 minutes, respectively.

4.5 Discussion

4.5.1 Principal findings

This study did not report any favourable benefits to wearable sensors and alerting systems in our cohort across the chosen outcome measures (i.e., hospital LOS, mortality, and Intensive Treatment Unit (ITU) admissions). This contrasts with the meta-analysis conducted in Chapter 2, which reported that digital alerting reduced hospital LOS.[184] However, a multitude of factors should be considered to explain these differences. Firstly, most of the constituent studies included in the meta-analysis were of low quality; moreover, the considerable variation in time taken to respond to an alert by healthcare staff, rapid turnover of participants resulting in the short duration of sensor use, and the premature conclusion of our trial may additionally explain our findings.

Within this study, healthcare staff favourably perceived the wearable sensor solution with potential improvements for patient safety and reduced staff burden, despite no previous experience with telemetry or digital solutions.[160] However, this opposes our findings of prolonged response times. This is likely to be multifactorial including changing culture of adopting innovation; inadequate resources (both time and available training) for healthcare professionals; winter-bed pressures; but, particularly in this study, the perceived usefulness by healthcare professionals and the impact of sensing technology in its current state was deemed as unincentivized additional labour given rota shortages and absence of permanent staff.[160] Of note, missing data values from the sensor were common, particularly for RR, which may have impacted the perceived usefulness of a device and subsequent engagement from healthcare staff. However, given that observations were performed continuously, even with the missing values, data availability was greater than when following usual care indicated by the NEWS 2 protocol.

In addition, alerts generated for abnormal RR were common in our cohort, yet none of the participants required escalation for senior review and were deemed well. This false alarm phenomenon has been reported elsewhere and is a recognised limitation of IP as a technique utilised by the sensor to measure RR.[80, 157] Similarly, this may affect the perceived usefulness of sensing systems, contributing to disengagement from healthcare staff and prolonged response times, as noted in our study. Machine learning approaches have the potential to improve artefact detection;[185] further work is required to determine if the implementation of

classification models, convolutional neural networks, or heuristic algorithms within wearable sensors can improve the accuracy of RR readings. Conversely, alerts for abnormal HR and temperature resulted in senior review and initiation of further treatment but the proportion of meaningful actions taken were low, suggesting that further optimisation for parameter thresholds was required and warrants further exploration. Despite this, wearable sensors were well perceived by the participants, with enhanced feelings of patient safety, comfort, and centralised monitoring,[86] in keeping with the literature.[85, 147]

An array of human and organisation factors have historically contributed to difficulty in implementing digital technologies. Parallels can be drawn from when Electronic Health Record (EHR) were introduced and implemented. Although global evidence has demonstrated the improved record quality, increased administrative efficiency, and enhanced quality of care (such as reduced medication errors and higher guideline adherence) with EHR use,[186–188] implementation across complex hospital systems in the UK has been challenging.[64]

A physician's perception of uncertainty, a component of complexity science, was linked to poor EHR use across a diverse range of medical specialties.[189] Changes to workflow, time constraints, and lack of user involvement are major barriers to successful implementation.[187] To draw parallels, although sensors are increasingly able to measure multiple vital signs, not all parameters can be recorded by all sensor systems and some parameters remain intermittent (i.e., BP). As a result, there remains a reliance on multiple modalities to ensure early warning score calculations, a requirement instituted from hospitals. This can be a source of frustration for healthcare staff and for patients requiring multiple modalities of monitoring, reducing overall healthcare efficiency.

One study reported the experience of alert fatigue for healthcare staff; the burdensome nature to carry additional devices; and inadequate training for nursing staff to interpret continuous data as barriers to successful adoption of digital alerting.[147] These factors are likely to have contributed towards the substantial variation in alert acknowledgement by healthcare staff noted in this trial. Introduction of health policies and legislation, in conjunction with apt resources, may be a meaningful way to facilitate workflow change. The passage of the Health Information Technology for Economic and Clinical Health Act in 2009 and the Meaningful Use policy, helped overcome the previously stagnant adoption of EHR.[190–192]

4.5.2 Limitations

Although this pragmatic design has highlighted key issues with real-world applicability, it presents inherent limitations. Firstly, PSM was used to adjust for several important variables, however there may be missing additional relevant variables that may affect outcomes. Secondly, the lack of randomisation meant that causal relationships could not be established. Furthermore, with clinical research, a change in workflow cannot be mandated resulting in an unincentivized workflow change to healthcare staff, a limitation in effectively testing the efficacy of digital alerting systems in the real world. The fast turnover of the acute surgical unit, in hindsight, likely contributed to the short length of stay and duration of sensor limiting the inference of our outcome measures and risking attrition bias. The pandemic has accelerated the adoption of digital technologies and altered perceptions favourably towards their adoption;[145, 146] as this trial concluded prematurely, at the onset of COVID-19, our work may be perceived differently if it were repeated in the current climate. The early conclusion of this work has likely resulted in the underpowering of our trial. Lastly, digital literacy, human and system factors (e.g., staffing) play a significant contributory role in successful adoption of novel digital solutions and were not fully examined in this trial.

4.5.3 Areas for further research

Future research should seek to include information system evaluation frameworks that test implementation attributes, strategies, and organisational aspects during piloting of digital solutions, particularly as the pandemic has altered attitudes towards digitisation.[145, 146] Indeed, sensors and alerting systems have been met favourably when used for remote monitoring of individuals suspected of COVID-19.[154] Furthermore, refinements to wearable sensors are required to offer monitoring of all vital parameters alongside refinements in parameter thresholds for which alerts are generated, which may aid workflow improvement and adoption. Further work should test a variety of alerting mechanisms that are actionable by multiple healthcare professionals of differing seniority to optimise implementation.

Our work has highlighted the need to consider organisational, system, and human factors when implementing novel digital solutions and designing trials. For optimal integration, we recommend the involvement of healthcare staff during trial design when changes to workflows are expected with consideration of mandated changes; PDSA cycles for model of improvement

may be a useful tool in such settings, allowing for regular evaluations.[193] Testing novel digital solutions through the quality improvement measures may be a more effective means of testing their real-world efficacy. Furthermore, we recommend ensuring adequate training (and re-training) is provided with the introduction of new technologies and that a variety of healthcare professionals are included in an area of the hospital with longer inpatient stay. This trial may have been perceived differently if junior doctors were responsible for acknowledging clinical alerts.

4.6 Conclusion

In conclusion, this trial implemented wearable sensors and alerting systems in secondary care. For successful implementation and optimisation of novel systems, human and organisational factors should be tested in conjunction of digital solution deployment, where further work should be conducted. This could unlock the true potential for remote monitoring digital solutions in improving overall efficiency of healthcare delivery and impacting clinical outcomes. Predictive modelling could truly revolutionise hospital based medicine, through AI-based algorithms to predict deterioration and initiate early treatment, hospital bed pressures may become a thing of the past.

5. Barriers and facilitators of key stakeholders influencing successful digital implementation of remote monitoring solutions: a mixed-methods analysis

Part of this chapter has been published as:

> **Iqbal FM**, Joshi M, Khan S, Wright M, Ashrafian H, Darzi A Key Stakeholder Barriers and Facilitators to Implementing Remote Monitoring Technologies: Protocol for a Mixed Methods Analysis. JMIR Res Protoc. 2022 Jul 21;11(7):e38437. doi: 10.2196/38437. PMID: 35862185.

5.1 Introduction

Since the onset of the COVID-19 pandemic, adoption and implementation of novel healthcare pathways have globally accelerated. A key change has been transitioning beyond the traditional face-to-face model of healthcare delivery with the incorporation of novel remote monitoring solutions.[194, 195] They offer a significant advantage in moderating viral exposure risk to healthcare staff, reducing community spread, and delivering quality healthcare remotely for exposed or infected individuals.[196, 197]

The integration of telemedicine and remote monitoring into medical practice is expected to expand by appropriately permitting selected individuals to continue living at home rather than admitting them into secondary care; this very premise is the foundation of virtual wards.[198] With the recent improvements made to wearable technology, they can support health provider assessment and clinical decision making through collected biometric data both in secondary care and in the community.[95, 199–202]

However, successful implementation of digital technologies across complex hospital systems is seldom a smooth process.[64, 203, 204] One study, implemented wearable sensors and alerting systems within secondary care, reported no improvements in clinical outcomes to patients.[173, 205] The aim was to use wearable sensors to provide continuous remote monitoring to patients admitted to acute (non-intensive) wards and alert healthcare staff upon recognition of deteri-

oration. Interestingly, although the digital solution was able to pick up clinical deterioration in vital signs and alert healthcare staff, responding to the alert was met with significant delay. This was in spite of healthcare staff reporting favourable perceptions of digital solutions with potential improvements for patient safety and reduced staff burden.[160] Therefore, there is a need to further explore implementation issues.

Patients have reported high levels of acceptance, comfort, safety, and deemed such digital tools favourably.[85, 86, 170] The main concerns, from a patient perspective, surround potential over-reliance on numbers with diminishing contact from clinical staff.[85, 89, 147] Healthcare staff perceptions, however, have been more mixed with concerns expressing changing and increasing workloads, uncertainty surrounding the clinical meaningfulness of captured data, and alert fatigue.[89, 147, 170] Although mixed-methods exploration of these two key stakeholder groups have been well documented, understanding how to integrate remote monitoring digital tools within the NHS requires furthers examination of cultural and management issues within the healthcare organisation, an area where evidence is missing.

Within the United Kingdom (UK), large health informatics programmes and widespread digital transformations are delivered by NHS Digital, a non-departmental public body.[206, 207] To support digitisation, NHS England have formed a framework, consisting of three ambitions: digitally ready, mature, and data enabled services.[208] In line with this, NHS England have supported for the development and use of virtual wards, further indicating the 'digital push'.[198] Therefore, for policy-makers, is it only through understanding barriers and facilitators of key organisational members that provision of digitally enabled care and smooth deployment can be driven. A framework to evaluate the notion of fit between human, organisation, and technology (HOT-fit) has been proposed.[2] This provides a foundation to report on factors, focussing on the alignment between and compatibility of these three domains.

5.2 Aims

The aims of this chapter, therefore, were:

1. To evaluate key stakeholder perspectives when implementing remote monitoring solutions in the National Health Service (NHS), identifying factors that could affect successful execution and adoption, using the HOT-fit framework.

2. To propose a road map for implementing wearable solutions within secondary care.

5.3 Methods

5.3.1 Study design

A mixed methods approach was implemented consisting of semi-structured interviews and questionnaires.[209] This was developed in accordance with recommendations from the Standards for Reporting Qualitative Research (SRQR) guidelines, where appropriate.[210] The semi-structured interviews were conducted with high level stakeholders from industry, academia, and healthcare providers who have played an instrumental role with prior experience of implementing digital solutions. Additionally, a validated questionnaire was undertaken to ascertain the perceived technological acceptance of new remote monitoring systems. Questionnaires were sent out electronically at the beginning of December 2021. Non-responders were sent two follow-up email reminders.

To ensure appropriate recruitment from all key stakeholders, a key informant strategy was followed for purposive recruitment.[211, 212] Individuals were identified through their notable work with implementation of remote monitoring solutions in healthcare; authors of impactful research in the literature; major digital technology companies; technicians involved with digital tool infrastructure development; and experts recommended by peers. This represented a variety of groups including academics, clinicians, allied healthcare professionals, and Google Health who had experience with implementing digital solutions with the NHS.

5.3.2 Ethical approval

All recruited participants provided informed consent. Ethical approval for this study was obtained by Imperial College London's Science Engineering Technology Research Ethics Committee (reference: 20IC6331) and was conducted in accordance with Good Clinical Practice guidelines and the Declaration of Helsinki. Storage and handling of personal data complied with the General Data Protection Regulation.

5.3.3 Questionnaires

An adapted version of the Technology Acceptance Model (TAM) questionnaire was used (Figure 5.3); this validated questionnaire has shown acceptably high Cronbach alpha values.[213] The proposed theoretical framework (Information Technology Acceptance) is shown in Figure 5.1. It has been adapted from Chau and Hu,[214] comprising individual context, technological context, and organisational context. Further adaptations from Gagnon et al. with the inclusion of theories of interpersonal behaviour and reasoned action, building on the Technology acceptance Model proposed by Davis have been included.[213–217] As such, individual context consists of compatibility (factors that affect acceptance of a new technology) and attitude (a perception of the individual to adopt a technology); technological context consists of perceived usefulness and perceived ease of use of technologies. Lastly, organisation context consists of facilitators and subjective norm; the latter can be described as social (an individual's perception to a behaviour) or descriptive (behaviour of others).

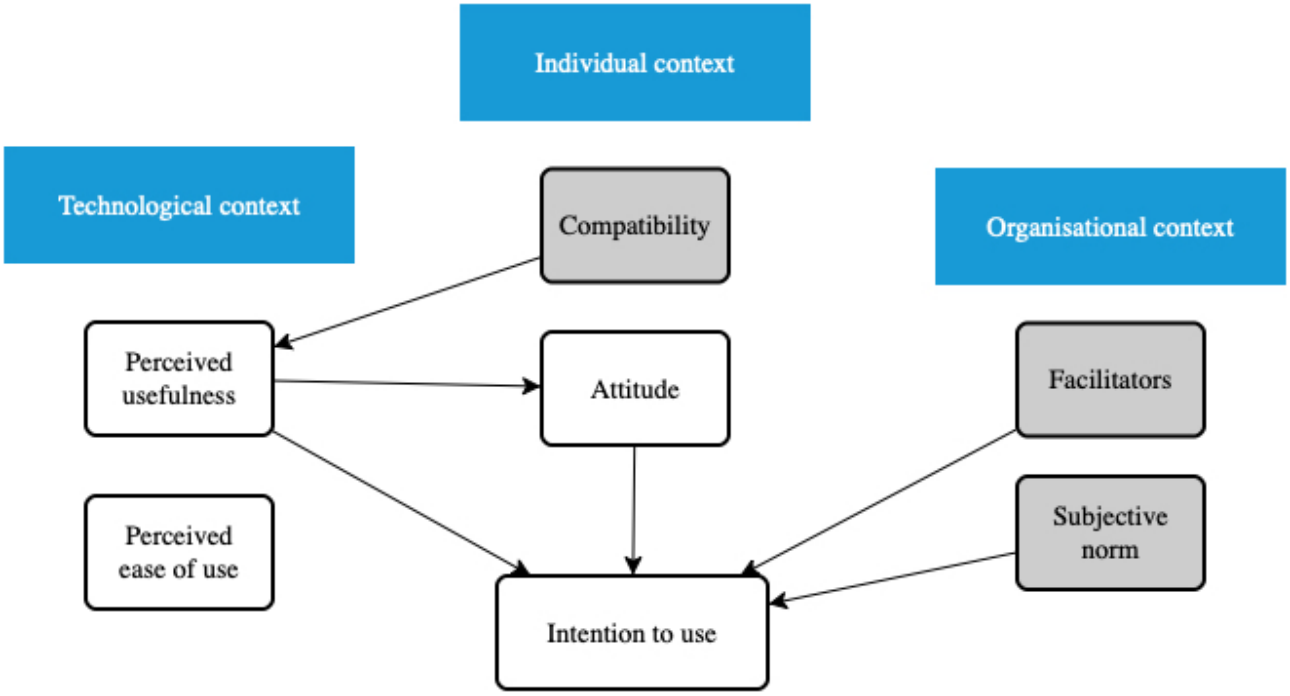


Figure 5.1: Theoretical framework for the modified Technology Acceptance Model (TAM) questionnaire

5.3.4 Semi-structured interviews

All participants were invited to part in semi-structured interviews conducted by the lead researchers. A structured topic guide was created (Appendix B) following a literature review that

drew heavily from a model proposed by Simblett et al. and by the HOT-fit framework.[2, 218]

Data collection was an iterative process; emerging recurring concepts were incorporated into the interview guide for further exploration with remaining participants. Interviews were recorded, anonymised, and transcribed verbatim before being entered into NVivo 12 for analysis.

5.3.5 HOT-fit framework

In 1992, a model to evaluate information system quality was developed and was named the 'DeLone and McLean Information System Success Model (ISSM)'. This identified six dimensions to determine information system quality: 1) system quality; 2) information quality; 3) use; 4) user satisfaction; 5) individual impact; and 6) organisational impact.[219]

Separately, a model for IT-organisational fit had been developed (MIT90s) which described the success is deploying IT in organisations was dependent on: 1) external environment; 2) organisational strategy; 3) individual and roles; 4) organisation structure; 4) technology; and 6) management processes.[220]

In 2006, Yusof et al. developed a framework which merged these models together, identifying dimensions that can be mapped onto and used as a reference model for evaluating the performance, effectiveness, and impact of health systems.[2, 221] A fit between human, organisational, and technological factors is required to ensure successful implementation and has been highlighted in Figure 5.2. Since its inception, this framework has been used to evaluate EHR implementation.[222]

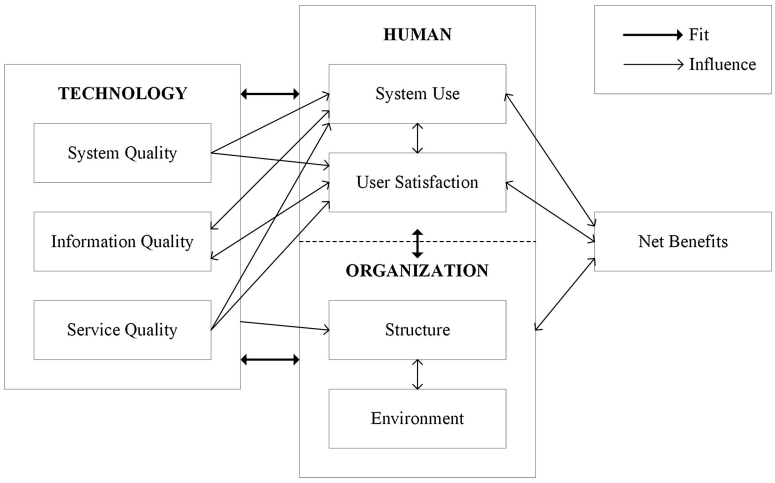


Figure 5.2: The human, organisation, and technology (HOT-fit) framework adapted from Yusof et al.[2]

5.3.6 Data analysis

Frequency distributions were generated for the 7-point Likert scale responses of the modified TAM questionnaire using R studio with the 'Likert' package.[223]

Transcribed interviews were analysed using a broadly deductive approach,[161] with the topic guide adapted, as previously described.[218] This formed the basis for the initial predefined coding framework and was undertaken by two independent researchers to determine barriers and facilitators.[161] An iterative process of coding and data indexing occurred, ensuring key aspects were not missed from the predefined coding framework. Subsequent emerging themes were summarised and mapped to the evaluation measures corresponding to each dimension of the HOT-fit framework.[2] The results were discussed until consensus was reached.

5.4 Results

5.4.1 TAM questionnaire

A total of 11 participants responded (response rate: 50%) to the questionnaire and has been represented in a Likert plot (Figure 5.3). Overall, the technology surrounding remote monitoring and virtual wards were well perceived by the questioned stakeholders; facilitating the care of patients and that these pathways, initially introduced during the pandemic, are likely to change long-term healthcare provision. However, some concerns regarding the existing infrastructure to support their use alongside whether this technology will improve efficiency was noted. Of note, there was uncertainty regarding if most patients would welcome virtual wards or remote monitoring.

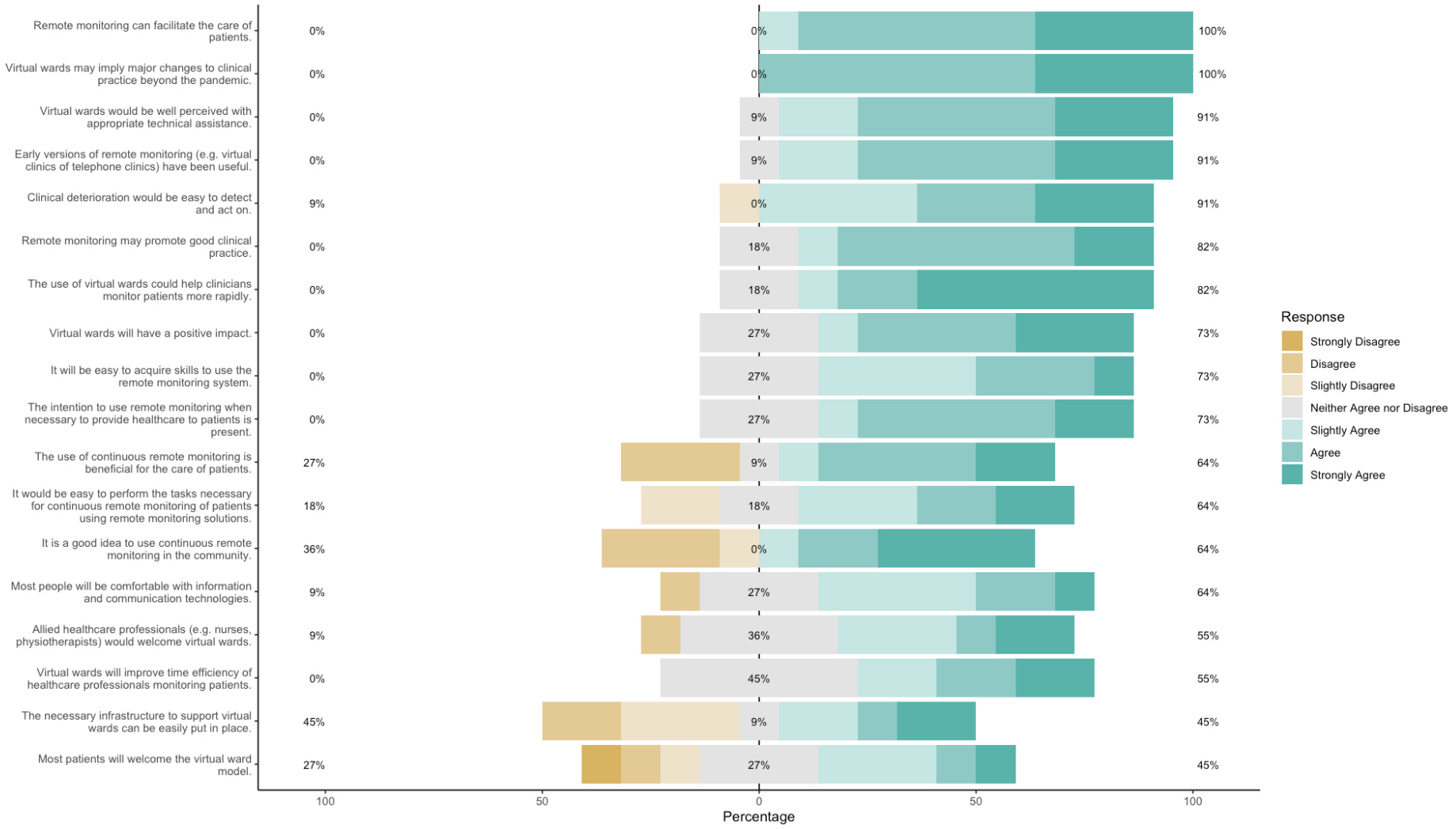


Figure 5.3: Likert plot displaying the responses to the modified Technology Acceptance Model (TAM) questionnaire

Table 5.1: Demographics of included participants

Group	Role 1	Role 2	Role 3	Role 4	Role 5	Role 6	Role 7
Healthcare Trusts	Director of Strategy, Research and Innovation	Chief Clinical Information Officer and Caldicott Guardian	Digital Quality Improvement Lead	Project Manager	Chief Information Officer	Systems, Integration Interoperability Architect	Lead Nurse for remote monitoring
Academics	Clinical Lecturer	Clinical Lecturer	Chief Scientific Advisor				
Google Health	Clinical Lead	Clinical Specialist	Product Manager	Implementation Specialist	Implementation Manager	Program Manager	
Other	Programme Director: Innovation of health	Managing Director: Digital Health					

5.4.2 Semi-structured interviews

A total of 22 participants were approached, of which 18 (response rate: 81.8%) participated in the semi-structured interviews (Table 5.1). An overview of the factors, by dimension, that respondents felt were responsible for contributing towards implementation has been summarised in Table 5.2.

Table 5.2: An overview of evaluation measures reported

Dimension	Evaluation Measure	Factor
System use	Expectation and beliefs	+Improved efficiency +appropriate selection of end users suitable for digital tool
	Training, knowledge and expertise	-lack of trouble-shooting support +engage with new starters
	Motivation	-large data burden -post-COVID fatigue of staff +finding local champions
User satisfaction		+develop relationships for feedback -previous negative experiences with no feedback of benefit
Environment		-overburdened NHS system
Structure	Clinical process	+clear strategic framework and partnership
Information and service quality		-poor interoperability -poor user interface/user engagement
System quality	Perceived ease of use Perceived usefulness	-failure to provide added value

System use

Expectations and beliefs

The prospect of introducing novel remote monitoring technologies was felt to facilitate implementation through improved efficiency, particularly since the implementation of electronic health records has improved data availability and clarity.

> "with the implementation [and] introduction of electronic health records where the data that's available is so granular. And in addition to new technologies that are coming. I think that you can do a lot more, remotely or virtually, and it does make things a lot more efficient. . . ." (participant 15)

> "from a patient perspective, we don't want to one size fits all approach. We need to be clear about how we personalize this and how it's relevant and meaningful." (participant 17)

Training, knowledge, and expertise

Problems with troubleshooting and training available were reported, reducing the likelihood of successful implementation due to a lack of support available.

> "We've had problems when trying to use the remote monitoring, it came up with an error and then I have to try and sort that out, you know? It's just things like that that make extra work." (participant 16)

> "I know that the nurses have struggled a huge amount with remote monitoring, and I expected that... because there's a lot of upskilling." (participant 18)

However, engaging with early with healthcare workers and getting their involvement was shown to improve implementation of remote monitoring solutions.

> "[we received] better engagement by tying the implementation with the new starters in the role and the changeover of junior doctors, because it was a new product to offer to new junior doctors." (participant 3)

Motivation

It was felt that motivation to engage with technologies would be impacted through the excessive availability of data, acting as a deterrent.

> "we need to be mindful about the data burdens, not just for patients but for staff because this kind of remote technology follows you around. You basically could work 24/7 365 of the year." (participant 17)

In addition, following the pandemic, many healthcare workers are fatigued and unmotivated to engage in change, acting as a barrier to successful remote technology implementation.

> "... post-COVID the workforce has been decimated, been exhausted and is fatigued. It's not the only problem though, because you know as well as I do that the NHS has run this model of where it's good will. We've never had infrastructure that we needed to do stuff and we still get a huge amount done. So it's not the only driver at the moment. It's more noticeable because of where people's heads are at

and obviously where their physical levels and mental levels of exhaustion are..." (participant 17)

However, respondents also noted that finding a few motivated individuals to champion change at a local level can help implementation.

"I asked them to self-nominate three of them who were interested in helping [implement]. So they led and supported the [technology]...." (participant 18)

User satisfaction

Respondents reported that previous experience with digital tools tied into user satisfaction. Feedback to end users demonstrating meaningful impact was deemed important for engagement and successful implementation.

"where staff or patients, for example, have been involved in projects before that they haven't had any feedback from, haven't seen any meaningful outcome from... they're like, well, why would I want to get engaged with this? That's a lot of energy and effort from me and I won't see any benefit." (participant 17)

"... develop relationships, so between, if you like, supplier and developer and clinical staff so you've got these rapid cycles of feedback and learning." (participant 1)

Environment

Respondents reported that previous hinderance to effective implementation has been because of an over-burdened system unable to give the appropriate attention to integrating a digital solution within the NHS.

"NHS is overburdened and so that level of diligence... wasn't there until it had to be, until things became mission critical... that comes down to a bandwidth problem...." (participant 10)

Similarly, under-resourcing was noted to be a barrier, particularly during early stages where issues would arise.

"more resource to get [things] kick started [is usually needed]... because we had to go through all the teething problems ourselves which created extra work for us." (participant 16)

> "we've got very limited resources, that they're very thinly spread across all of the IT projects that require integration and interoperability... just the sheer volume of work that the Trust has heaped on us over the last three or four years is the bigger constraining factor." (participant 4)

Lastly, organisational culture supporting digitisation was a commonly reported theme with some institutions more readily accepting of innovation over others.

> "organisational culture can be both the barrier and facilitator. We know that there are some organisations that are much more ready and able to adopt innovation. I think from an organisational perspective, competing priorities are a huge issue....If your IT is majorly engaged in doing something else, for example an EHR implementation, its ability to support remote monitoring and other technologies is really poor." (participant 17)

Structure

Respondents also commented on the need for a clear process through developing a strategic partnership and framework would facilitate implementation and should be planned before roll-out.

> "strategic framework is crucial on things....What does a strategic partnership look like? What is the direction that we want to jointly head in? What do we want to achieve together, and what are the different components to get there...." (participant 1)

> "Making [the product vision and road map] clear as early on and getting that input right at the beginning of any kind of feature development. So that there is expectation alignment on what is being developed whether the minimal viable product meets the use cases that it needs to, and that there's a partnership in prioritizing these features and when they're delivered. As opposed to just showing a feature set a few weeks before it gets deployed... I think that initial understanding of the vision... and getting that clinical engagement as early on helps to set the path going forward." (participant 12)

Information and service quality

Respondents noted the need for digital tools to be interoperable and usable, as poorly designed digital tools would be a barrier, hindering an overly strained NHS system.

> "the challenges are IT and interoperability... you don't want 20 bits of data...from 20 apps that don't work, so that's the usability and the accessibility and the staffing of these models because traditionally they basically get added onto someone's day job. But that day person's already overwhelmed." (participant 17)

System quality

Respondents highlighted that for a digital tool to be successfully implemented, it needed to provide added value with perceived usefulness and ease of use being crucial.

> "[What] was the added value in [this digital app]? All it did was render some of the information that we already had in a limited manner, back in the mobile device." (participant 8)

> "usability, the accessibility, and the staffing of these models [are really poor] because traditionally they basically get added onto someone's day job.... The data element [is also] really poor, so you get a lot of enthusiasts doing a lot of projects. But if you then say where's your evidence that makes any difference to anything meaningful that matters to patients and staff, they can't produce that. I think the digital health tech industry has been really slow at that." (participant 17)

Furthermore, it was believed that the best way to implement a digital tool (e.g., remote monitoring solutions) was through rapid quality improvement cycles following the PDSA technique, focussing on targeting user experience issues.

> "...believe the technology suffered from very poor clinical and user engagement. So I know [technological companies] will tell us they've had loads of user engagement, but actually most patients wouldn't say that, they'd say well, why is it like this? No, why is nobody been engaged in the design for this?" (participant 17)

> "...trying to give clinical input into feasibility, usability, implementation in terms of the design of how we were going to implement stuff, so...[a] genuine PDSA type approach to implementation, and I was quite involved in some of the thinking

about spread and how do you get this utilised across different parts of the Trust. . . ” (participant 1)

5.5 Discussion

5.5.1 Principal findings

This study explored barriers and facilitators for implementing digital tools, in particular remote monitoring solutions, within the NHS alongside the acceptance of such technology using the modified TAM questionnaire. Using the HOT-fit framework, a systematic examination of human, organisation, and technological factors were categorised allowing for a multiple angled approach to a multifaceted problem. Therefore, key barriers and facilitators could be mapped onto 6 dimensions which incorporated aspects for digitisation: system use (human), user satisfaction (human), environment (organisation), structure (organisation), information and service quality (technology), and system quality (technology).[2]

With regards to system use, the importance of improving workflow efficiency; having appropriate trouble-shooting support available for staff; finding local champions to help integration within the clinical workforce; and positively engaging with healthcare staff were highlighted as facilitators. To support this, young staff have been deemed the most likely to engage and benefit most from a new workflow.[221, 224–226] This, in part, may be explained by more adept digital literacy skills and technical proficiencies associated with junior members.[227] Within the literature, concise and tailored education surrounding implementation have been promoted as important facilitators.[228]

Key barriers relating to system use and environment included poor training and the burden of data, particularly with continuous remote monitoring of vital sign. This data may not always be clinically meaningful or because of poor resourcing, may not be acknowledged appropriately, generating additional work for existing staff which are already overburdened.[75, 205] Previously, this unincentivized workflow change constituted poor response times to alerts generated through alerting systems in an acute surgical ward.[205] In this current study, 36% of respondents of the modified TAM questionnaire were unsure whether allied healthcare professionals would welcome virtual wards (Figure 5.3). One study highlighted that these workers, in particular nurses and clinicians, were the most important gatekeeps for remote monitoring

solutions.[229] Therefore, engagement of these groups and fostering positive relationships delivering regular feedback would enhance user satisfaction; allow user interface and engagement issues to be proactively tackled; and, subsequently, success of implementation.

Concerning system quality, perceived usefulness and ease of use were deemed as important facilitators for successful implementation. Within the literature, intuitive and user-friendly systems have confirmed this with easier acceptance.[221, 225] The modified TAM questionnaire similarly confirmed this in our cohort, particularly through questions concerning acquiring new skills and impact, emphasising that remote monitoring technology could be readily accepted.

5.5.2 Limitations

This study included key stakeholders belonging to a broad selection of groups (academics, industry, healthcare) in order to create a broad understanding of factors that influence implementation of remote monitoring solutions within the NHS. Given that previous studies have focussed on end-user testing, this study sought to provide a top-down view to give better understanding of considerations that could influence widespread implementation.[86, 160]

However, in doing so, our interpretations have some limitations. Firstly, the broad heterogenous sample of key stakeholders included may identify issues that are generalisable but the non-probabilistic sampling may have resulted in a selection bias. Despite this, the use of semi-structured interviews yield pertinent considerations for pragmatic implementation in hospital settings. In addition, differences between various hospitals and departments, which may have different attitudes towards digital technologies, were not explored in this study. A final limitation relates to the missing dimensions of the HOT-fit framework, such as government sector. Data on politics, localisation, competition of wearable sensors, and external communication were not ascertained.

5.5.3 Further research and recommendations

Although our cohort displayed that there was overall acceptance of remote monitoring technology (Figure 5.3), there remains a deficiency with respect to successful implementation. This was noted most recently in one study where the median time to acknowledge an alert from healthcare staff was 111 (range: 1–2146) minutes despite early recognition of deterioration from remote sensing.[205] Therefore, further research should incorporate human factors and

behaviour evaluation when implementing remote monitoring solutions with the NHS; moreover, utilising implementation frameworks such as HOT-fit should be undertaken to ensure multiple angles have been carefully considered.

In order to propose a road map, key stakeholders should formulate a clear strategic framework to guide implementation and include early involvement of end users. This early fostering of relationships can provide rapid feedback (regarding strategy of implementation, user interface, or user experience issues) and engage staff; feedback could be acted upon through PDSA cycles allowing for progressive improvement.[193]

Furthermore, industries and digital health start-ups, hoping to develop remote monitoring solutions, should engage with key stakeholders to target a product that would be deemed as providing meaningful value with an appealing user interface to maximise success with end-users; implementation should not be a forced top-down operation but should respect the autonomy of end users in the system who ultimately influence outcomes.

Lastly, infrastructural support should be in place before implementation, with appropriate resourcing in place to maximise information technology integration with involvement from technical support staff, further resourcing and staffing will likely improve the prioritisation of digital roll-outs.

5.6 Conclusion

In conclusion, implementation of remote monitoring solutions with the NHS remains a complex challenge. The results of this study have highlighted key stakeholder perceptions which could influence successful integration. Through the proposed recommendations, there is potential for future remote sensing solutions to be more successfully integration within our healthcare practice, resulting in more novel pathways expanding beyond virtual wards.

6. Conclusions

6.1 General Discussion

This thesis has explored the potential for remote sensing tools with respect to continuous vital sign monitoring through novel wearable sensors, specifically digital alerting systems used in non-intensive secondary care wards and community settings. At each opportunity, workflows for healthcare staff (Figure 6.3), clinical outcomes, and key barriers and facilitators enabling their uptake have been identified. The measurement of vital signs, within secondary care, has remained primitive both from a technological and system perspective, requiring the physical presence of healthcare staff to record vital signs intermittently through various means. This thesis explored the potential of digitising this process, representing potential for enhanced remote monitoring not only in secondary care but also in community settings.

This presented body of work has built upon the foundations laid out previously;[174] which included critical appraisal of the literature identifying available medical grade sensors that focussed on multi-parameter vital sign monitoring;[72] the exploration of reliability, feasibility, usability (through real world testing), and potential benefits of integrating remote sensing solutions within secondary care.[86, 90, 160] Through this, and additional market scoping, the SensiumVitals™ system was selected as the wearable sensor of choice. This disposable, lightweight, waterproof sensor, with a battery life of 5 days was selected based on its inconspicuous profile; internal quality assurance algorithms to disregard poor quality data; a well-established relationship with the company allowing for UX and UI changes; and lastly, the greatest volume of published literature evaluating its reliability and feasibility.[75, 79, 80, 147, 172] It is able to measure HR, RR, and core temperature continuously. As vital parameters breeched pre-established thresholds, established in accordance with the NEWS 2 protocol,[1] digital alerts were transmitted to healthcare staff in the form of a push notification on a provided mobile device and/or a flashing web notification through a secured portal, requiring acknowledgement.

As the COVID-19 pandemic stretched the already constrained NHS resources further, this thesis has focussed on how remote monitoring technologies have the potential to improve patient outcomes and create an alternative, more efficient workflow for healthcare staff with less physical

reliance. In keeping with the Topol review and the ambitions described by NHS England to support digitisation,[61, 198] this thesis describes integration issues that need to be tackled in order to support implementation of remote monitoring and alerting solutions. This will allow for more robust testing to determine whether this technology has potential for long term impact.

6.2 Main Findings and Review of Thesis Aims

In the introduction to this thesis, the principal aim underpinning this work was to determine if digital alerting, through remote sensing systems, could be deployed in community and secondary care settings. In doing so, improve healthcare delivery, workflows, and provide value to patients and/or healthcare staff. To interrogate this aim, each of the following chapter summaries have focussed on a particular component of digital alerting and remote sensing.

6.2.1 Clinical outcomes of digital alerting and remote monitoring

The introduction of this thesis underlined the importance of vital sign monitoring as prodromal changes precede adverse events. Consequently, through effective rapid response systems (involving appropriate detection and intervention; Figure 1.3) clinical outcomes may be improved for patients. Building upon this, Chapter 2 systematically appraised the existing evidence of remote monitoring; identified digital mechanisms which alerted healthcare professionals or patients (Figure 6.1), following recognition of deterioration; and depicted the subsequent clinical outcomes. This highlighted the potential value to both healthcare staff and patients available from remote sensing technologies. The limitations of the current literature helped shaped the future chapters of this thesis, in particular: alerting strategies; barriers and facilitators for adoption noted by healthcare staff; feedback from patients regarding the experience of novel telehealth solutions; and the need for detailed description of implementation strategies.

Multiple modalities for alerting have been reported with differing schedules, ranging from continuous daily, and weekly. This broad scheduling variation suggests that differing cohorts (e.g., acute surgical versus chronic medical) may benefit from differing protocols and that the literature surrounding optimal alerting protocols is immature. Moreover, the optimal recipient of alerts has yet to be established as pharmacists, healthcare professionals, and patients have all been reported as appropriate targets. Therefore, there is a pressing need to establish a strategic

framework which incorporates an optimal alerting regime, targeted at a specific cohort with a chosen recipient, before introducing remote sensing into a local system. This, through multiple cycles of rapid evaluation, may allow for clinical benefit.

Although some benefit to reducing hospital length of stay (mean reduction of 1.04 days) and mortality (mean reduction of 3%) were described; cautious interpretation is required, as the literature was largely heterogenous with the majority of constituting studies considered low quality.[184] However, this meta-analysis carved the foundation for this thesis by identifying the potential clinical value through digital alerting and remote sensing.

Figure 6.1: Alerting mechanisms following recognition of clinical deterioration

6.2.2 Proof-of-concept testing of remote sensing in hotels

In Chapter 3, feasibility and proof-of-concept were successfully examined through remote delivery of healthcare, in a hotel, for suspected cases of COVID-19 during the first wave of the COVID-19 pandemic. This was facilitated through engineering a hotel with remote monitoring solutions; additionally, an understanding of barriers and facilitators to novel community-based monitoring was undertaken through a mixed methods analysis for healthcare staff and recruited individuals. This method offers an opportunity for technological companies to draw from end-user preferences and continue to refine a digital product. As this trial received UK Chief Medical Officer approval, it generated interest for policy makers to draw from the experiences

of implementing a novel model for community based remote monitoring. The lessons from initiating our rapid pathway to service the government's needs of mandatory isolation, in order to avoid overburdening hospital systems, were later expanded through home pulse oximetry through NHS England and NHS Improvement, demonstrating the long-term impact.[70] As we move beyond the height of the COVID-19 pandemic, novel remote monitoring pathways are expected to increase, allowing for further community based management of diseases.[230–232]

In the first wave of the pandemic, protection of healthcare staff and reducing potential for viral transmission were considered essential to preserve the workforce. Prior to this study, individuals were receiving limited monitoring during their mandatory isolation period locked in a hotel room, despite the 24h staffing by various members belonging to the healthcare team (e.g., nurses, paramedics). Given that the rate and severity of deterioration of SARS-CoV 2 were unknown at this stage, the lack of monitoring raised potential for rapid acute deterioration to be missed. Upon installing 'plug-and-play bridges' to allow data transmission from the wearable sensor to a secured laptop and mobile device, continuous vital sign monitoring was enabled for individuals suspected of COVID-19 and isolating in a hotel room with limited contact. Therefore, the inclusion of continuous monitoring of HR, RR, and temperature through the SensiumVitals™ patch provided an aide for clinical decision making, through alerting of worsening parameters, should there be a need to escalate appropriate cases to acute secondary care.

Feasibility was deemed based on i) alerts successfully generated following a sustained 10-minute period of abnormal vital signs being recorded; this window was established based on previous experience which depicted the smallest monitoring window with the least amount of data loss, when comparing sensor data to ward observations.[174] More recently, this window has been further validated after evaluation of various adaptive threshold-based alarm strategies.[3] These alerts could be acted upon by the clinical staff present at the hotel; ii) the rate of participation which exceeded what was calculated according to the confidence interval approach; iii) the low incidence of adverse events relating to the sensor system. Previously, discontinuation with this sensor has been reported due to discomfort,[75] however there were no dropouts, serious adverse events relating to the sensor or discontinued cases from our cohort, although some discomfort was also reported.

The qualitative component of the study reported three key themes from the semi-structured

interviews for recruited participants: i) functionality of remote monitoring in a small sensor without risking the threat of viral transmission; ii) varying levels of comfort and practicalities, particularly when showering, although this settled after a short accustoming period; and iii) a sense of security from being monitored remotely.[154] These findings were in keeping with the published literature although 2 further themes have been identified: i) the importance of nursing contact and ii) reliability of the technology with regards to data security and system failure.[85] The importance of nursing contact, while still relatable, predates the COVID era and shifting paradigm of remote solutions.[233, 234] In addition, as technologies continue to update their architecture, system stability is likely to improve.

Healthcare perceptions delineated through the validated system usability scale (SUS) and semi-structured interviews were perceived with more uncertainty. Overall, two key themes were identified: i) the miniturisation of the sensor was appealing, however certain constituent components (e.g., adhesive pads) resulting in frustration due to poor contact and subsequent poor signal recordings; ii) the perceived usefulness of the system through continuous remote monitoring and reducing viral exposure. However, reservations regarding the training available; safety of using a new system with complete technological reliance; and fear of inappropriate expectations following deployment of this technology (e.g., expecting ICU level of care outside of intensive settings) were noted.

This model, rapidly developed in response to the surge in SARS-CoV 2 cases, has demonstrated that healthcare delivery available outside of traditional medical facilities is achievable. It is paramount to carefully select a pre-defined selection criteria of individuals suitable for care outside of acute settings and support appropriate training of healthcare staff to become comfortable with remote sensing technologies. To our knowledge, this remains the first study to establish remote sensing in a hotel; a model that helped inform NHS Digital's 'COVID oximetry @home', allowing appropriately triaged patients to avoid hospital admission using pulse oximetry remote monitoring to reduce healthcare service burden.[70, 235]

6.2.3 Clinical outcomes of remote sensing systems in acute secondary care

Chapter 4 of this thesis explored the integration of remote sensing solutions in a pragmatically designed pre-post implementation trial based in an acute surgical unit to determine if clinical

outcomes (i.e., hospital length of stay, mortality, or intensive care admissions) could be improved when compared against usual care (intermittent vital sign monitoring guided by NEWS 2).

An identical alarm strategy was arranged, as described in the previous chapter, based on a sustained 10-minute interval of abnormal vital signs. Upon breaching the vital parameter thresholds, alerts were sent to nursing staff on provided mobile devices requiring acknowledgment for the subsequent action taken (Table 4.2). Through a 1:1 'optimal' PSM logistic regression model, there were no statistically significant differences in critical care admission (planned or unplanned), hospital length of stay, or 28-day mortality between the two groups. To minimise confounding bias from expectant longitudinal changes in workflows and protocols of the historical pre-implementation group, a PSM design was opted for.[236] Of particular significance in our results was the sizeable variation in responding to alerts (range: 1–2,146 minutes, Figure 4.4).[205] Despite recurrent efforts made with engaging key stakeholders to champion the project and implement within local policies, the response time to alerts suggested that various challenges have yet to be adequately addressed.

In this study, alerts for abnormal respiratory rates were common; despite this, none of the participants required escalation for senior review and were deemed well. This false alarm phenomenon can contribute to Alert fatigue (AF) and is also a recognised limitation of impedance pneumography (IP) utilised as a method for measuring RR in many wearable sensors.[80, 157] The principle of IP relies on Ohm's law; by transmitting alternating electrical currents (iK) measured through skin ECG electrodes, changes in thoracic impedance (measured as voltage, V) can be detected over a 60 second duration to estimate RR (Figure 6.2).[237–239] However, signal interruptions due to movement artefact or poor electrode contact frequently occur, resulting in measurement errors and impeding true clinical decision making.[239, 240]

AF is defined as desensitisation to safety alerts resulting in ignored or unactioned alerts.[241] It is increasingly recognised as an unintended consequence to computerisation and its effect towards patient safety is being progressively studied.[242] The Joint Commission and the Society for Critical Care Medicine asked accredited hospitals to make alarm management a top safety priority, leading to a 2016 National Patient Safety Goal to address the safety concerns of AF.[243, 244]

Furthermore, although generated alerts for abnormal heart rate and temperature resulted in senior review, the proportion of subsequent meaningful actions was low. This likely affected the

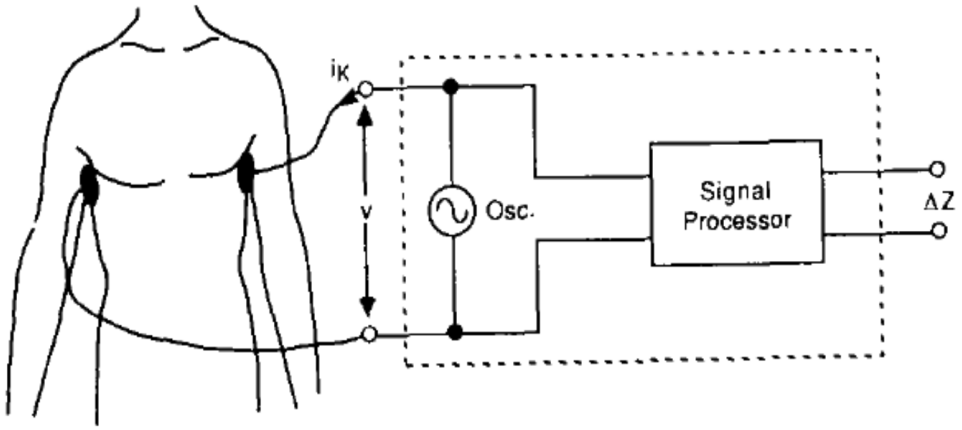


Figure 6.2: Pictorial representation of IP; image reproduced with permission from SensiumVitals™ (iK: electrical current; Z: resistance; V: voltage)

perceived usefulness of remote sensing systems, contributing to disengagement from healthcare staff and prolonged response times. Indeed, further exploration of parameter thresholds is still required to improved clinical value and reduce alert fatigue.

Perceptions obtained from a broad range of healthcare staff involved with this study reported six key themes: i) problems with existing monitoring; ii) potential for improved patient safety and earlier identification of unwell patients; iii) improved care for patients; iv) integration of technology was required to improve healthcare; and v) potential to improve workflow for staff. However, fear of technological displacement resulting in healthcare job losses was also noted.[160] Despite the positive response reported by staff, lengthy response times indicate that adoption of technologies that require new workflows are seldom straightforward. Possible contributors include changing culture of adopting innovation; inadequate resourcing, training, and troubleshooting available; inadequate staffing to designate appropriate time towards new solutions; and perceived usefulness of the technology acting in conjunction with the unincentivized additional labour to adopt a new workflow.

To add further support for using sensors, feedback from patients has been positive with enhanced feelings of patient safety; the perception of reducing workload for busy clinical staff; and the majority of patients feeling that the sensor was comfortable to wear.[86]

Within the published literature, studies have largely evaluated validation of feasibility outcomes.[170] This chapter represents a pragmatic real world assessment of alerting systems and remote monitoring solutions within the NHS. Although our results did not demonstrate any difference in

clinical outcomes, we identified that key human, organisational, and technological factors need to be incorporated to future studies to fully understand the potential of remote monitoring solutions and target an improvement of alert response times. This work marks the first detailed description, to our knowledge, of the implementation strategy utilised; necessary stakeholder engagement; and evaluation of outcomes, with appropriately balanced cohorts, alongside pinpointing key areas for future research.

6.2.4 Barriers and facilitators of key stakeholders influencing adoption of remote sensing technologies

Having identified healthcare and patient perceptions, a systematic examination using a mixed-methods approach consisting of semi-structured interviews, mapped to a validated reference model (human, organisation, and technology (HOT-fit)) and a Technology Acceptance Model (TAM) questionnaire was undertaken in order to better guide future attempts at implementation. Chapter 5, therefore, appraised the barriers and facilitators, using a multifaceted approach, towards deployment of remote sensing within the NHS.

The need for a road map to guide future implementation of remote monitoring solutions within the NHS was highlighted through Chapter 5, a paucity in the current literature. It emphasised the need of a clear strategic framework, with early involvement of all key stakeholders, including end-users. This should be done in an environment that fosters positive relationships, allowing for regular feedback to be obtained and acted upon. Additionally, collaboration from industry partners should aim to be problem solvers to extinguish a system or clinical issue, thereby maximising potential for successful deployment. Lastly, appropriate resourcing of all staff (clinical and technical) should be sought.

This chapter identified a neglected area in the literature despite the influence of health informatics in technological adoption within complex health systems such as the NHS. To our knowledge, this is the first broad undertaking of using intricate framework dimensions to describe remote monitoring integration within health information systems. Evaluating and understanding the constituents of these domains for future trial designs will likely increase the overall success of digital rollouts which will allow for future clinical trials to better display potential benefits of novel digital solutions.

6.3 Implications of Conducted Research

The intention of this thesis was to generate an evidence base for remote sensing solutions and determine if they could provide tangible benefit for patients and healthcare staff. Remote monitoring pathways serve to either escalate cases of deterioration early to avoid transfer to critical care or to avoid unnecessary hospital admissions. Based upon these ideologies and since the inception of the work carried out here, virtual wards have been established which use pulse oximetry to monitor oxygen levels and identify cases of silent hypoxia in COVID-19.[245] Given the changing paradigm in how remote monitoring solutions are perceived with greater acceptance and growing adoption,[145, 146] important lessons can be ascertained.

Within this thesis, the first trial to formally evaluate outcome measures from remote sensing systems with balanced cohorts was undertaken, stretching beyond feasibility and usability work. Although the focus of this was in surgical patients, remote sensing has cross-specialty applications, with further evaluations beginning to unfold in oncology, respiratory, and gastroenterology specialties, to name a few.[246, 247, 247] Moreover, this thesis was the first to establish a novel hotel-based model using remote sensing. This work set the foundation to further expand community based monitoring, as in the instance of 'COVID oximetry @home'.

Policy makers should incorporate human factors and behaviour evaluations when changing workflows through the introduction of remote monitoring pathways. This will allow a better understanding of financial and technical requirements for successful adoption, in particular targeting issues for delayed response times upon alert generation, as displayed in this work. There should be a collaboration between all key stakeholders (patients, healthcare professionals, policy makers, and industry). Moreover, appropriate allocation of resources both in terms of staffing but also dedicated teaching and troubleshooting for healthcare staff should be available, ensuring that variations in digital literacy are accounted for to create a digitally enabled workforce. NHS England have pledged £200 million of funding with a further contribution of £250 million in 2023/4.[248] It is imperative these funds are allocated to deal with the highlighted issues.

Overall, engaged and activated patients perceive the use of this technology favourably and accept this integration as a natural advancement. However, questions concerning patients with less digital confidence or health engagement exist. In addition, from a healthcare provider perspective, the NHS has emphasised the need for a digital workforce,[249] healthcare staff

who are less technologically abled may engage less with future technologies which may impact health outcomes.[250]

Throughout this thesis, a close working relationship with SensiumVitals™ was maintained, which allowed for a mutually beneficial partnership. They offered training and troubleshooting to healthcare professionals to improve proficiency with the technologies. Acting upon feedback obtained from end-users will increase the likelihood of engaging with remote monitoring solutions. However, noticeably this was slower than anticipated. One example involves the web portal displaying alerts which was based on legacy software (Internet Explorer); this has been phased out by the trust in way for web browsers capable of supporting the newer markup (HTML 5) language. Unfortunately, the company were delayed in updating their own web portal for this to be implemented in the timeframe of our trial.

Lastly, this thesis demonstrated that despite early engagement with healthcare staff, these professionals have autonomy to act outside of an orchestrated digital rollout. Further understanding of the factors responsible for this are required.

6.4 Limitations of the Thesis

Although many of the limitations of the research have been presented within this thesis already, there remain important general considerations which require discussion.

6.4.1 Alert strategies and thresholds

Many of the alerts generated within this thesis did not result in meaningful clinical action. In Chapter 4, none of the alerts generated for RR required senior review. Similarly, alerts for HR and temperature rarely resulted in clinically meaningful actions (Table 4.2). Alerts were generated when pre-established thresholds were breeched for 10 consecutive minutes. These thresholds were based on red (HR over 131 beats per minute, RR over 25 breaths per minute) and yellow (temperature of 38.1°C) NEWS 2 cut-offs. From previous testing, alerts for low observations were turned off due to their high false positive rate. This was reinforced in another study with the false discovery rate reported to be 52% during the daytime and 68% during the night.[3] Indeed, further optimisation of alerting strategies may improve the proportion of meaningful alerts.

The accuracy of measured RRs from the SensiumVitals™ sensor has been conflicting. Limits of agreements have been wide although many studies have also validated their acceptability with variations of less than 2 breaths per minute compared with nursing measurements.[80, 172, 174] However, given that none of the RR alerts resulted in meaningful action, this can frustrate healthcare staff and reduce willingness to engage with remote monitoring technologies. IP is heavily susceptible to movement artefact which can generate erroneous signals.[251] Therefore, abnormal RR alerts could indicate a more mobile, well patient which can contribute to the disengagement of clinician staff relying on such systems to generate alerts for clinically deteriorating patients. This is of particular importance given that changes in RR are often the first warning sign of clinical deterioration. Machine learning approaches to improve artefact detection are currently being studied to determine if the accuracy of respiratory rate readings can be improved.[185]

Six alternative alert strategies for the SensiumVitals™ system have been simulated to determine if this occurrence could be improved. Firstly, threshold individualisation for patients using the cumulative density function based off the previous 24h of available vital sign data; thresholds are adjusted according to calculated percentiles to create personalised thresholds. Secondly, elevating the upper thresholds of alerting for post-operative patients for the first four days after surgery to account for the surgical stress response. Thirdly, increasing the annunciation delay for the number of successive abnormal measurements. Additionally, elevating the HR and RR thresholds during the daytime by a fixed percentage. Next, reducing the night-time reduction of lower HR and RR thresholds; and lastly, a slope based alarm system where the slope of the linear regression line calculated over a past time interval exceeds a threshold.[3] The performance of these have been summarised in Table 6.1.

Table 6.1: Performance of various alerting strategies, adapted from van Rossum et al.[3]

Alarm strategy	**Justification**	**AEs with true positive alarms (%)**	**False detection rate (% of alarms classified as false positive)**	**Total alarm rate (alarms/patient/day)**
Original		61	59	0.49
Threshold individualisation	Tailoring thresholds individually	78	83	1.81
Post-op elevation of upper thresholds	Account for surgical stress response	56	45	0.42
Increase annunciation delay interval	Optimise alerting strategy	50	50	0.25
Day-time elevation of upper HR/RR thresholds	Compensate for increased day physical activity	50	66	0.35
Night-time reduction of lower HR/RR thresholds	Compensate for low HR/RR at night	61	55	0.45
Slope-based alarms	Assess vital signs based on time trends	78	94	3.47

The various strategies have potential to reduce the total alarm rate, however minimal improvement in overall alarm performance was noted.[3] Indeed, further research on combining various strategies are still required to reduce the false detection rate, the burden of alert fatigue, and overall clinical meaningfulness.

6.4.2 Alert fatigue

Several healthcare technologies (i.e., smart infusion pumps, and clinical decision support systems in EHR) produce an auditory/visual warning to warn clinical staff of unsafe situations. However, this can be overwhelming when such high prevalence of alerting exists. An observational study conducted in intensive care environments measured an average of 45.5 alarms per patient per hour.[252] Another study reported that electronic prescriptions generated alerts for 3-6% of all orders, resulting in several warnings throughout the day for ordering clinicians, the majority of which were overridden.[241] In an alert saturated system, additional alerts with large false detection rates from remote sensing systems may further contribute to alert fatigue. As a result, engagement and perceived usefulness of such systems diminish. This adds further rationalisation for the prolonged response times reported in this thesis.

6.4.3 Data Availability

In Chapter 3 and 4, the data availability for the SensiumVitals™ system were reported. Signals that failed to meet the internal quality assurance check from imbedded algorithms or from poor electrode contact were not reported. The proportion of vital parameters rejected were similar across both studies (Table 6.2). As described previously, RR readings were readily rejected, a limitation of IP.

Temperature was measured through a probe secured using adhesive to the axilla. Poor positioning or displacement can result in distorted or rejected data. Therefore, attaching this sensor requires precision to ensure adequate signal quality. Furthermore, more mobile patients or those with extreme body habitus may not have optimal placement. This precise placement and potential displacement remain limitations for the sensor.

Table 6.2: Proportion of vital parameters not reported from the SensiumVitals™ patch

Chapter 3: Remote-COVID (Total datapoints, n=16844)			**Chapter 4: Secondary care (Total datapoints, n=696577)**		
HR	RR	Temperature	HR	RR	Temperature
5965 (35.4%)	10004 (59.4%)	4069 (24.2%)	220525 (31.7%)	408336 (58.6%)	140634 (20.2%)

6.4.4 Digital literacy

Digital literacy and technological proficiency of healthcare staff were not examined in this thesis which may influence the uptake of novel digital technologies. The Department of Health and Social Care have endorsed rapid expansion of technology use, including remote monitoring and virtual wards, to help tackle hospital pressures.[253] This 'digital revolution' requires appropriate digital assessment, training and education of healthcare staff to ensure inclusive uptake.

6.4.5 Technological transition

During the commencement of the work laid out in Chapter 4, the institution relied upon paper-based documentation. However, a transition to EHR were later rolled out. This took priority over the research conducted which meant that the Information Technology team responsible for the smooth operation of the recorded data streams from the sensor were otherwise occupied to assist with trouble shooting. This resource deprivation meant that subsequent software updates for SensiumVitals™, issues with the bridges, and Wi-Fi connections took longer to solve and affected participant recruitment.

6.4.6 Sample size

The number of participants in this study who generated alerts for deterioration were low. Therefore, the conducted studies were underpowered to detect significant differences for clinical outcomes. Further appropriately powered randomised trials have been suggested to help combat this; with the work conducted in this study, power calculations may now be more readily performed to guide future sample sizes.

6.4.7 Validity

The work in this thesis tested one remote sensing system in a single ward of a hospital institution. If participants left the ward, recording of vital parameters would result in data loss unless they returned within 3 hours. Although steps were taken to mitigate this, the reality of a fast-turnover acute surgical ward meant that some loss was unavoidable. Greater resource and funding are required for suitable scalability testing. The additional testing in a hotel, in part, raises the generalisability.

Although the testing of SensiumVitals™ has generated important general considerations, other sensors may impart different learning. However, few alternative sensors had the willingness to collaborate with academic partners or had proposed remote sensing technology with deprived efficacy.

6.5 Future Directions of Research

As advancements in remote sensing technology continue to transpire, the ability for non-invasive continuous remote monitoring and alerting to be used in hospital settings and in people's homes can become a convincing reality.

Inspiration from the Point-of-Care Key Evidence Tool (POCKET) was undertaken to categorise future directions.[254] This multi-dimensional evaluation checklist was designed through a Delphi process to guide evaluation for point of care tests and can be adapted for remote sensing technologies.

Technical Improvements

Improvements to data availability need to be made, in particular, increasing the functionality of the sensors by incorporating more vital signs (e.g., blood pressure). Moreover, including additional metrics such as accelerometers for fall detection; and targeting battery life improvements and charging capabilities can improve the overall functionality of wearable sensors.

Future wearables should attempt to improve the portability of devices with smaller footprints, particularly for the elderly as heavy sensors may be a deterrent but also to expand their use for younger population groups in the future.

For home-related sensing, systems must be made accessible as consumers may be unwilling or unable to afford access to remote healthcare technology. Furthermore, installation and maintenance of devices should be minimal, allowing for greater accessibility for people of varying technological literacies. As global digital health literacy will steadily increase over time, incorporation of remote sensing with other 'internet of things' appliances can be undertaken, allowing an ecosystem of health delivery. Recently, Tesla's self-driving vehicle aided the transport to hospital of a person diagnosed with a pulmonary embolism;[255] there is potential to incorporate remote vital sign monitoring, predict the need for clinical assistance, and support healthcare delivery in the future through integration with other 'internet of things' devices.

Clinical Pathways

The current and future potential clinical pathways have been depicted in Figure 6.3. This highlights the potential of remote monitoring in earlier detection of deterioration (both in a home setting and in secondary care), resulting in alert generation and subsequent clinical review and prompt treatment. Patients could be referred into virtual ward pathways either from hospitals, emergency departments, or from GPs. Therefore, receiving remote monitoring at home. Ultimately, this may have the potential to improve outcomes and reduce hospital burden, as early intervention may result in admission avoidance.

Through pre-emptive medicine, whereby clinical deterioration can be predicted, novel pathways for various patient cohorts can be established. For example, predictive modelling through remote monitoring of chronic heart failure patients who are likely to decompensate can receive appropriate medical intervention, following alerts, to avoid decompensation and hospital admissions. This could be expanded to variety of different medical and post-operative cohorts. A wearable, internet-enabled ECG patch was able to remotely calculate serum potassium levels with an error between 5–8%.[256] This has very clear implications for remote management and drug titration of renal and cardiac patients to avoid hospital admissions.

Through COVID-19, virtual wards have already been established, with further refinements to the implementation process, pathways may continue to change current healthcare approaches. Future work should look to evaluate the advantages and disadvantages of introducing new pathways for patients and healthcare staff.

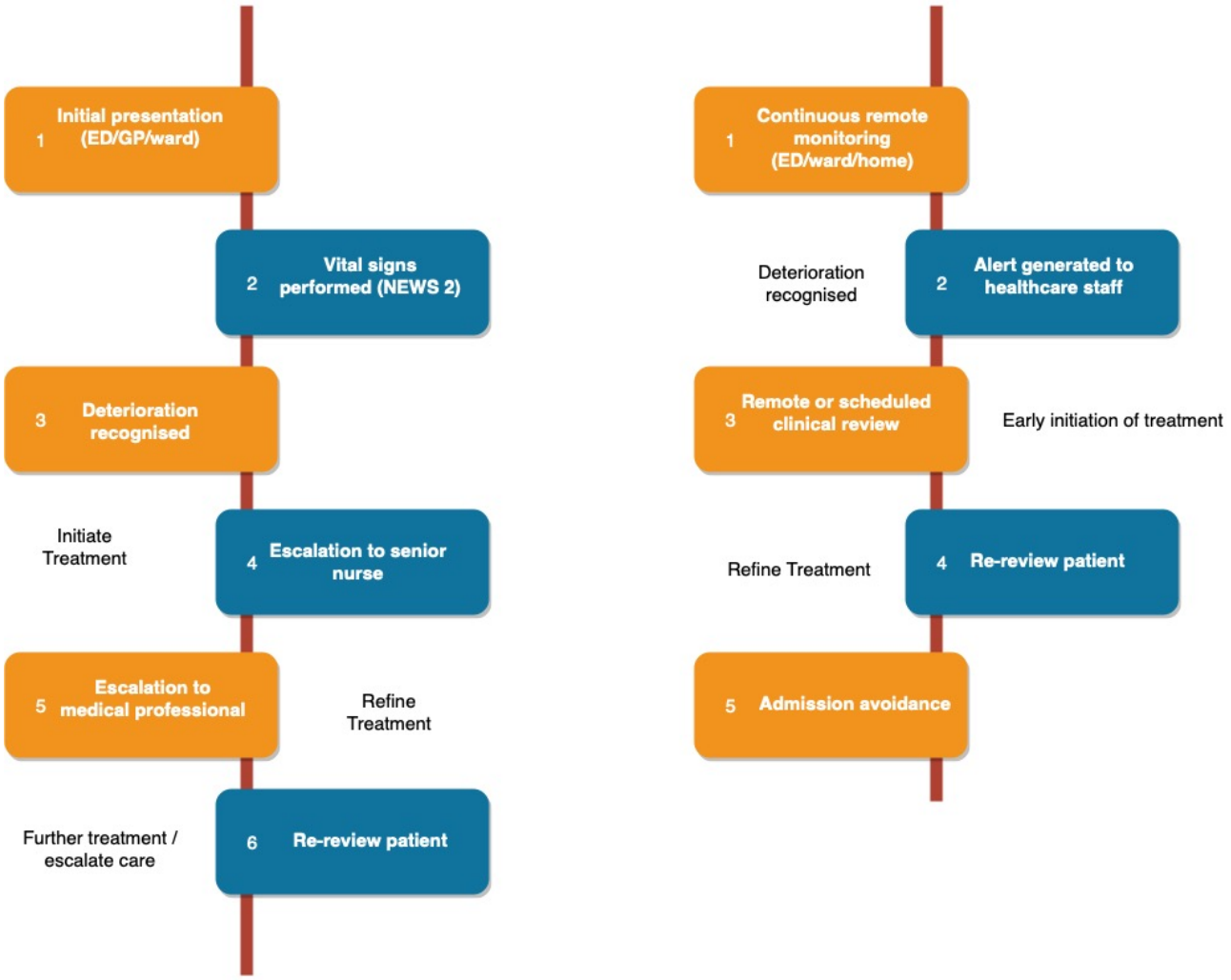


Figure 6.3: Current clinical pathway (left) and the potential for a new clinical pathway (right)

Stakeholders

The need for further stakeholder analysis is paramount. Although the use of HOT-fit was critical in highlighting barriers and facilitators, further work including the incorporation of governing bodies, members belonging to NICE are required. This can facilitate guideline production for remote monitoring and digital alerting tools.

The importance of interoperability, data availability and cybersecurity has become more apparent. Governing bodies should develop remote sensing international standards, interoperability, and legal provisions to protect healthcare professionals and end-users. The commercialisation of healthcare can create conflicts of interest with respect to selling healthcare data for non-healthcare needs. One example of this was with the well-publicised investigation of the data sharing agreement with Google DeepMind and one NHS trust.[175] Provisions to tackle this should be written into legislation to preserve data protection. Questions concerning the

overall quality of care compared with in-person visits, ease of access to data, degree of patient activation; availability of services; regulatory and legal protections; contract handling by different vendor providers are all obstacles that require careful consideration and further understanding.[257] Future research should focus on understanding each of these key components.

Economic Evaluation

There is a paucity in the literature describing cost effectiveness and cost utility analyses. One study reported potential cost utility savings with sensor use;[258] however, the model was based on findings that were not replicated in this thesis, in particular the reduction in hospital length of stay through the SensiumVitals™ sensor.

Future research for economic evaluations need to factor in: cost of sensor, consumables, and costs before and after implementing a new pathway. Additionally, an economic analysis with quality adjusted life years (QALY) and an incremental cost effectiveness ratio (ICER) should be undertaken if clinical outcome improvement has been demonstrated.

Device Performance

Over the coming years, as virtual wards continue to get deployed, an opportunity to develop machine learning algorithms from the rich available data will be present and can be stored in big data analytic units. Two key advantages from this come to mind, the first is the capability of improving the accuracy of RR readings through enhanced artefact detection through classification models, convolutional neural networks, and heuristic algorithms.[185] The second is to develop prediction models for those at risk of deterioration and can include wider data, such as blood results.[259, 260] However, for this to occur, data need to be homogenised, processed, and stored in a means that offers value, representing a challenge in itself.[261]

This could be made possible through maximising the potential of integrated care systems in establishing infrastructure to support collaborative working and integration in centralised servers, housing patient data.[262]

A study in 2022 highlighted the need for an evidence standards framework for Artificial intelligence (AI)-enabled digital technologies;[263] efforts should be made to improve the transparency and merit of AI-based evidence, to enhance the overall quality of patient care by minimising

bias in AI datasets. One example of this is the development of STARD-AI, as part of the Enhancing Quality and Transparency of Health Research (EQUATOR) initiative, that will specifically focus on the reporting of AI diagnostic accuracy studies [264].

Usability and Training

Efforts to standardise the implementation of remote monitoring systems needs to be made; this can be done through the development of standard operating protocols and allow systemised training for healthcare staff. As a result, subsequent trials conducted on usability will be more meaningful in identifying which features result in improved outcomes. This will also tackle the fear of fragmentation as companies look to dominate the market share in this expanding field.

Parallels can be drawn from the fragmentation of EHR in the UK which result in communicative breakdowns and impact patient safety; moreover, the IT infrastructures within the NHS are outdated and have previously been affected by malware.[265, 266] These issues need to be addressed to improve patient safety and enhance the potential of remote sensing solutions.

6.5.1 Recommendations

As such, the following recommendations for future research are listed:

1. Evaluate optimal alerting strategies; it is likely various strategies will be required for differing medical and surgical specialities.
2. Develop advanced machine learning algorithms to improve identification of actionable alerts.
3. Identify appropriate data management systems and ensure appropriate standards are followed to minimise bias in data.
4. As an evidence standards framework is produced for AI enabled digital technologies, new datasets should follow this to better train remote sensing algorithms.
5. Evaluate the empowerment of patients to become participants of their own healthcare and take ownership to deal with certain alerts and obtain appropriate clinician support, if required.
6. Integrate remote sensing within existing infrastructure and integrated care systems.

7. Increase the capability of measuring more vital sign parameters and other biometrics, generating real-time data across multiple organ systems and disease processes for a complete and timely assessment of patient status.
8. Determine the cost-benefit and cost-effectiveness of remote sensing systems.
9. Undertake interoperability assessments to highlight future areas of concern.
10. Evaluate commercial obligatory end-user agreements to appreciate degree of privacy and data control.

6.6 Conclusions

As the NHS enters a challenging era, remote sensing and digital alerting tools present an opportunity to improve healthcare delivery and enhance workflows for healthcare staff. Remote sensing has the potential to be part of the solution in the response to recovering from the pandemic.

This thesis has highlighted current limitations and future directions required to adequately assess their full potential. Going forward, there is true potential in home based remote sensing allowing individuals to avoid hospital admissions. This has the power to shift the NHS into a digitally enabled era less reliant on physical hospitals.

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A. Remote-COVID interview topic guide

A.1 Healthcare Staff

Experience in healthcare

Role in Healthcare

1. What are the good points about the wearable patch?
2. How do you think that the wearable patch can affect guest safety for hotel guests?
    (a) Please explain in what way
    (b) Can you give specific examples of this?
    (c) Patient deterioration?
3. How do you think that the wearable patch can affect the care of patients with COVID19?
    (a) Please explain in what way
    (b) Can you give specific examples of this?
    (c) Escalation of care?
4. How was your training to use the wearable patch?
    (a) Was this adequate?
    (b) Anything you would change?
    (c) Did you have support if you had problems?
    (d) Where did the support come from?
5. Were there any barriers or facilitators to wearable patch use?
6. Were there any problems with the new technology?
7. If you could improve the wearable patch what would you change?
    (a) any design features?

(b) Attachment on patients?

A.2 Participants

Age

Gender

Any previous experience with a sensor?

1. Did you understand what the patch you were wearing was used for?
   (a) Detection of becoming unwell?
2. How do you feel about being monitored with the patch?
3. Did you understand what the patch you were wearing was used for?
   (a) Peace of mind?
   (b) Invasion of privacy?
4. How comfortable was the patch to wear?
   (a) how was the form factor?
5. Were there any problems wearing the patch?
6. If you could change this patch in some way how would you change it to make it better?
7. Would you consider wearing this patch or a similar patch at home, and why?

B. Chapter 5: Interview topic guide

1. What is your current role?
2. How long have you been in this role?
3. What do you understand by remote monitoring?
4. What do you understand by virtual ward?
5. Would you use remote monitoring or virtual ward interchangeably?
6. What are you attitudes towards remote monitoring?
    (a) Is it a distraction?
    (b) Is it another initiative that you feel will pass in due course
7. Do you have any experience where this has been used?
    (a) If so, where was it used?
8. What are the barriers of implementing remote monitoring or virtual wards?
9. What are the facilitators of implementing remote monitoring or virtual wards?
10. What are the major factors that lead to adoption and usage?
    (a) What human factors?
    (b) What technology factors?
    (c) What organisational factors?
11. What implementation strategies are required for successful adoption of digital technologies?
12. What cost issues do you anticipate?