ISSUES IMPACTING CONTINUOUS PULSE OXIMETRY MONITORING AND WIRELESS CLINICIAN NOTIFICATION SYSTEM AFTER SURGERY

EVALUATION OF ISSUES IMPACTING WIRELESS CLINICIAN NOTIFICATION SYSTEM IN A RANDOMIZED CONTROL TRIAL INVOLVING POSTOPERATIVE VITAL SIGNS MONITORING AND CONTINUOUS PULSE OXIMETRY

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A Thesis Submitted to the School of Graduate Studies in Partial Fulfillment of the Requirements for the Degree Master in eHealth

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TITLE: Evaluation of issues impacting wireless clinician notification system in a randomized control trial involving postoperative vital signs monitoring and continuous pulse oximetry

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LAY ABSTRACT

The VIGILANCE study was a randomized controlled trial assessing the impact of continuous vital signs monitoring with alerts to nurses on the incidence of postoperative complications in surgical ward patients. This thesis identified and evaluated issues with implementation of wireless monitoring systems in the hospital. During VIGILANCE study issues affecting the intervention implementation were documented on case report forms, alarm event forms, and nursing questionnaires. Data related to these issues were explored using the Clinical Adoption Framework. Identified issues included nursing workflow changes, patient withdrawal, wireless network connectivity, false alarms, monitor malfunction, probe issues, and wireless network standards. The issues affected 'access' through decreased ability of nurses to make complete use of the monitors; 'care quality' of the intervention through decreased effectiveness; and 'productivity' by interfering in the care coordination. Future studies should aim to include front-line nurses, appropriate wireless network, and comfortable cableless devices in their planning.

ABSTRACT

Background

The VItal siGns monItoring with continuous puLse oximetry And wireless cliNiCian notification aftEr surgery (VIGILANCE) study was a randomized controlled trial designed to assess the impact of continuous vital sign monitoring with alerts to nursing staff on the incidence of postoperative complications in surgical ward patients. Multiple factors interfered with the eHealth intervention implementation and conduct of the VIGILANCE study. Through examination of these challenges, the overall aim of this thesis was to help foster an understanding of the difficulties related to eHealth intervention implementation. The specific objectives were to identify issues related to implementation of intervention system of the VIGILANCE study, and to evaluate the influence of these issues on intervention adoption.

Methods

During the VIGILANCE study, issues affecting the implementation of the intervention were documented on case report forms, alarm event forms, and a nursing feedback questionnaire. In this thesis, the issues were identified and evaluated using the Clinical Adoption Framework.

Results

The key issues identified include nursing workflow changes, patient withdrawal, wireless network connectivity, false alarms, monitor malfunction, probe issues, and wireless network standards. These issues affected the service, system and information quality. As a result, these issues impacted 'access' through decreased ability of nurses to make complete use of the monitors; 'care quality' of the trial intervention through decreased effectiveness; and 'productivity' through interference in the coordination of care, and thus decreased clinical adoption of the monitoring system.

Conclusion

Patient monitoring with eHealth technology in surgical wards has the potential to improve patient outcomes. However, proper planning that includes engagement of front-line nurses, installation of appropriate wireless network infrastructure, and use of comfortable cableless devices are required to maximize the potential of continuous monitoring.

Keywords: Continuous pulse oximetry; wireless notification; issues; evaluation of issues; clinical adoption framework; remote monitoring; postoperative monitoring; false alarm; WLAN.

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ABBREVIATIONS

CA	Clinical adoption
CPOX	Continuous pulse oximetry
ECG	Electrocardiography
HR	Heart Rate
HITS	Health information technology services
ICU	Intensive care unit
IEEE	Institute of Electrical and Electronics Engineers
ISM	Industrial, scientific, and medical
LOS	Length of stay
PR	Pulse rate
QoS	Quality of service
REDCap	Research Electronic Data Capture
RCT	Randomized controlled trial
RR	Respiratory Rate
SpO_2	Oxygen saturation
Temp	Temperature
VIGILANCE	VItal siGns monItoring with continuous puLse oximetry And wireless cliNiCian notification aftEr surgery
WLAN	Wireless local area network

DECLARATION OF ACADEMIC ACHIEVEMENT

This is a sandwich thesis that includes three chapters and is based on a core project that is detailed in chapter 2, which has been prepared for publication in a peer-reviewed journal. The following are the contributions made by me, Prathiba Harsha towards this thesis: conceptualization, protocol writing, data extraction, data verification, data analysis, designing the figures and writing the manuscript and its submission. The co-authors named in chapter 2 contributed towards acquiring and managing patient data and preparing the manuscript for publication.

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CHAPTER ONE: INTRODUCTION

1. Introduction

With increasing population and life expectancy, there has been an increase in the number of surgeries and nearly 313 million surgeries are performed worldwide every year (Weiser et al., 2015). Subsequently, the number of patients having perioperative complications such as myocardial infarction, stroke, cardiac arrest, infection and bleeding has increased. Another postoperative complication is respiratory depression. Among these postoperative complications, nearly half of them can be prevented with appropriate postoperative care (Weiser et al., 2008).

With an increasing number of surgeries, there is increased pressure on the hospitals for early discharge and patient turnover, especially in the surgical wards. This has increased the demand and workload on the care providers. One of the measures taken to relieve this pressure and improve healthcare services is using information and technology solutions during the perioperative period. eHealth interventions are being used in various forms in hospitals and monitoring systems are one of them.

Vital signs monitoring is routine on all wards of a hospital. Depending on the critical nature of the patient and the type of surgery they had, there is

increased monitoring to detect deterioration and prevent complications. Although tremendous improvements have been made in the field of patient monitoring, adoption of continuous monitoring technologies in complex health environments have been slow and challenging. Most of the research to date on patient monitoring solutions report on the patient outcomes in the context of deployments of these technologies. The challenges associated with implementation and adoption are less well studied in comparison. For future eHealth technology implementation and adoption, it is essential to report on the barriers and challenges encountered during research studies with eHealth intervention. Thus, we evaluated the challenges and issues encountered during a randomized controlled trial which had monitoring with continuous pulse oximetry as an intervention.

2. Literature Review

Following a review of studies of all designs, written in English using the databases (Medline, PubMed, Embase, Google Scholar and Web of science), studies which reported on eHealth solution and implementation were selected. The combination of keywords and database headings were used to find the published articles related to (1) respiratory depression (2) monitoring in surgical wards (3) eHealth monitoring solutions (4) key components of the monitoring solutions and (5) issues and challenges with implementation of eHealth intervention. The reference lists of the key articles were also searched. A

combination of following search terms was included: *postoperative, respiratory, depression, arrest, pulse oximetry, continuous, monitoring, ward, wireless, eHealth, implementation, evaluation, framework, issues, barriers.*

2.1 Postoperative respiratory depression. Postoperative respiratory complications like respiratory arrests is one of the complications that occur in patients who are monitored infrequently (Hodari, Tsiouris, Eichenhorn, Horst, & Rubinfeld, 2013; Sun et al., 2015). Decreased oxygen saturation (SpO_2) indicating respiratory depression can lead to respiratory arrest. Perioperatively, with the use of opioids for pain management, patients are prone to respiratory depression (Lam et al., 2017). Moreover, patients with sleep apnea are at a higher risk for respiratory depression during the first three days postoperatively (Lee et al., 2015). Patients without sleep apnea also have higher apnea-hypopnea index postoperatively, predisposing them to respiratory depression (Chung, Liao, Yegneswaran, Shapiro, & Kang, 2014). Undetected and or untreated respiratory depression can lead to brain injury, myocardial ischemia, other cardiorespiratory morbidities and mortality (Sun et al., 2015).

2.2 Monitoring in surgical wards. Patient monitoring to detect any deterioration is expected in on surgical wards. But in the post-surgical wards, patients are monitored only every four to six hours or often only once during a shift depending on the workload of the nurses' and nurse to patient ratio (Hands et al., 2013; McGain et al., 2008). Vital sign monitoring during the night is irregular

and inconsistent (Hands et al., 2013). Patients prone to respiratory depression such as sleep apnea patients are currently monitored in stepdown units and intensive care units (ICU), leading to a shortage of beds in these units and preventing their use for other high-risk patients. Because of the low nurse to patient ratios, patients on wards are not monitored more frequently (Paul et al., 2019). Hence the infrequent monitoring on surgical wards, opioids use, and higher apnea-hypopnea index can predispose patients postoperatively to code blues, ICU transfers and resuscitations. Early recognition is required to prevent complications of respiratory depression (Lam et al., 2017; Paul et al., 2019).

2.3. eHealth solutions to address the clinical problem. Black et al., (2011) categorized the diverse eHealth solutions through conceptual mapping into the solutions that, (1) enable data storage, (2) management and transmission, (3) facilitate clinical decision support, and (4) further remote monitoring (Black et al., 2011). Perioperative informatics including continuous remote monitoring is performed to facilitate recovery and early discharge (Freundlich & Ehrenfeld, 2018; M. H. McGillion et al., 2018).

Various models have been tried with regards to using technological solutions in patient monitoring perioperatively. Substantial development in the field is the migration towards wireless technology, evolution of biosensors, capturing multiple physiological parameters, increasing use of mobile, Bluetooth, and RFID technology and facilitating early hospital discharge by providing

support through remote patient monitoring at home (M. H. McGillion et al., 2018; Nangalia, Prytherch, & Smith, 2010; Vegesna, Tran, Angelaccio, & Arcona, 2017). To monitor vital signs such as heart rate (HR), respiratory rate (RR), non-invasive blood pressure, Temperature (Temp), including oxygen saturation (SpO_2) various solutions have been tried in the perioperative settings. The monitoring solutions can either alert through bedside 'alarm' or send 'notification' to the health care provider of any changes in patient's condition that might require them to take actions to treat or prevent an adverse event (AAMI, 2011). When the alarms are generated by invalid readings from patients, monitoring system or the patient-device interface—they are called 'false alarms' (AAMI, n.d., 2011).

The studies which had vital sign continuous monitoring interventions in general surgical wards were included. Literature search showed 23 primary studies with a continuous monitoring solution in hospital out of which 18 were in general surgical wards as illustrated in Figure 1. Two systematic reviews systematically reviewed the effectiveness of continuous monitoring in general wards (Cardona-Morrell, Prgomet, Turner, Nicholson, & Hillman, 2016; Downey, Chapman, Randell, Brown, & Jayne, 2018).

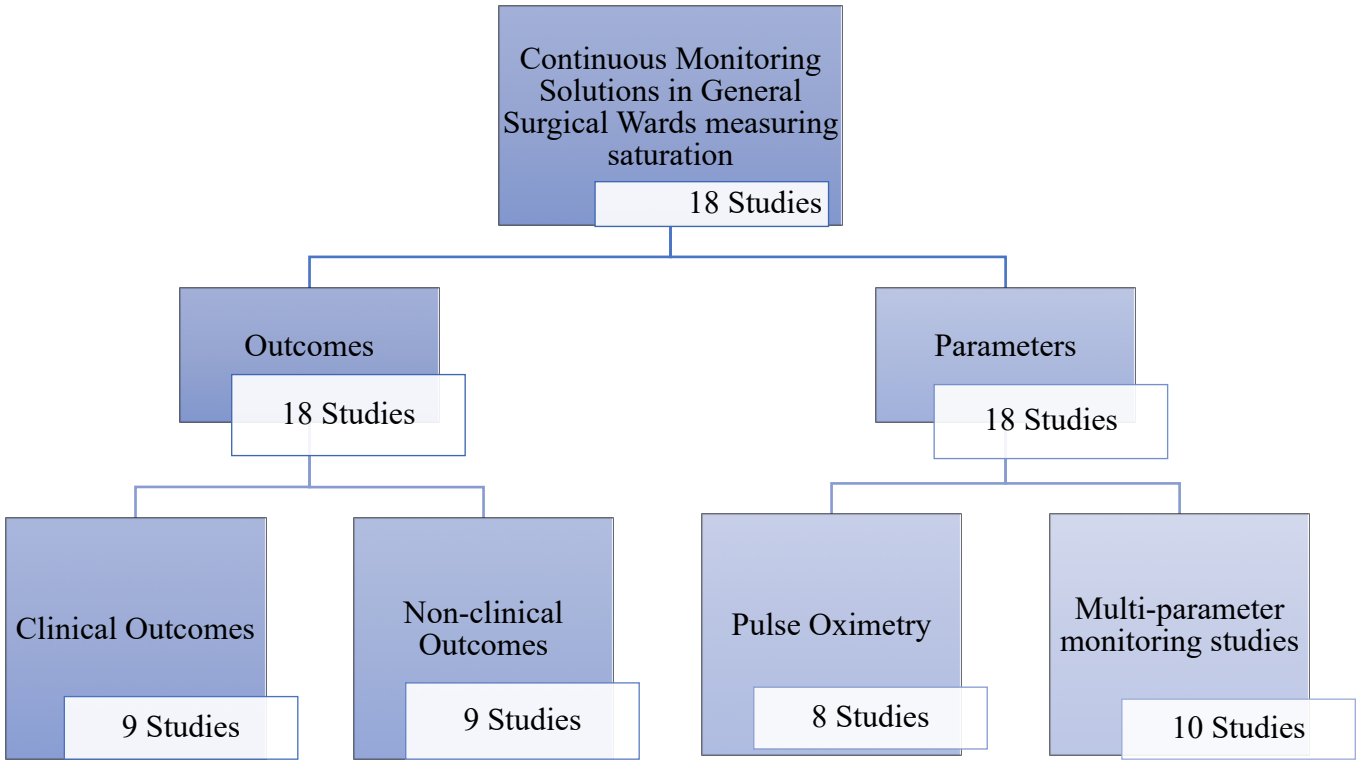

Figure 1. Results of Literature Search for Studies with Continuous Monitoring Solutions as Intervention in General Surgical Wards

The characteristics of continuous monitoring studies are summarized in the Table 1. Out of the 18 studies, nine studies had *clinical* patient outcomes as their primary and/or secondary outcomes (Brown, Terrence, Vasquez, Bates, & Zimlichman, 2014; Duus et al., 2018; Kisner, Wilhelm, Messerli, Zünd, & Genoni, 2009; Ochroch et al., 2006; Paul et al., 2019; Sun et al., 2015; Taenzer, Pyke, Mcgrath, & Blike, 2010; Watkinson et al., 2006; Wong, Tsui, Yung, Chan, & Cheng, 2004) and nine studies had *non-clinical* outcomes as their primary outcomes (Gazarian, 2014; Gross, Dahl, & Nielsen, 2011; Jeskey et al., 2011; Prgomet et al., 2016; Slight et al., 2014; Taenzer, Pyke, Herrick, Dodds, & McGrath, 2014; Voepel-Lewis et al., 2013; Watkins, Whisman, & Booker, 2016; Weenk et al., 2017).

Eight of the 18 primary studies features continuous pulse oximetry only or SpO_2 and HR in combination as shown in Table 1 (Kisner et al., 2009; Ochroch et al., 2006; Paul et al., 2019; Sun et al., 2015; Taenzer et al., 2010, 2014; Voepel-Lewis et al., 2013; Wong et al., 2004). Ten of the 18 primary studies had intervention solution measuring more vital signs than SpO_2 and HR (Brown et al., 2014; Duus et al., 2018; Gazarian, 2014; Gross et al., 2011; Jeskey et al., 2011; Prgomet et al., 2016; Slight et al., 2014; Watkins et al., 2016; Watkinson et al., 2006; Weenk et al., 2017). A summary of available literature for studies with continuous monitoring solutions as intervention in general surgical wards is

illustrated in Figure 1. The clinical outcomes assessed by these studies are illustrated in Table 2 and non-clinical outcomes are in Table 3.

Table 1

Characteristics of Continuous Monitoring Intervention Studies in General Surgical Wards

Authors, Year, Country	**Monitoring System**	**Parameters**	**Population**	**Design**
Brown et al., 2014, USA	EarlySense system, Earlysense Inc., Waltham, Mass	HR, RR	Medical and surgical patients	Controlled, retrospective-prospective study
Duus et al., 2017, Denmark	Isansys Lifetouch, Isansys Lifecare, Oxforshire, United Kingdom; Nonin WristOx 3150, Nonin Medical inc., Minnesota, USA	HR, RR, Single lead ECG, SpO2	Abdominal Surgery patients age ≥65 years, elective major abdominal cancer surgery with an estimated duration >2 hours, and preoperative sinus rhythm	Observational Study

Table 1

Characteristics of Continuous Monitoring Intervention Studies in General Surgical Wards

Authors, Year, Country	**Monitoring System**	**Parameters**	**Population**	**Design**
Gazarian, 2014, USA	ECG monitoring	ECG, SpO2	Medical and surgical ward nurses	Prospective, descriptive, observational study.
Gross et al., 2011, USA	Audio/video telepresence system - eICU, VISICU Philips Healthcare; critical care bedside monitor - IntelliVue MP5, Philips Healthcare; Telemetry system - IntelliVue Telemetry System, Philips Healthcare	ECG, SpO2, RR	Subacute medical and surgical floor patients	Retrospective Observational Study

Table 1

Characteristics of Continuous Monitoring Intervention Studies in General Surgical Wards

Authors, Year, Country	**Monitoring System**	**Parameters**	**Population**	**Design**
Jeskey, et al., 2011, USA	Wireless physiological monitor	HR, RR, BP, SpO2	Nurses on acute post-surgical units	Exploratory action feedback research Study
Kisner et al., 2009, Switzerland	Auricall pulse oximetry; Oxygen therapy for patients with SpO2 < 90%	HR, SpO2	Cardiac surgery patients	Controlled, retrospective-prospective study
Ochroch et al., 2006, USA	Nellcor Puritan-Bennett's N-3000 with Oxinet II CPOX	SpO2	Cardiothoracic surgery patients	Non-blinded RCT
Paul et al., 2019, Canada	Wireless respiratory monitoring system - Covidien, Dublin, Ireland	SpO2, HR	Mixed surgical ward patients	Non-blinded parallel RCT Pilot

Table 1

Characteristics of Continuous Monitoring Intervention Studies in General Surgical Wards

Authors, Year, Country	**Monitoring System**	**Parameters**	**Population**	**Design**
Prgomet et al., 2016, Australia	ViSi Mobile monitors - Sotera Wireless, California	HR, RR, BP, SpO2, ECG, Temp	Respiratory and neurosurgery nursing staff and two doctors.	Mixed method study comprising structured surveys, in-depth interviews and device trial
Slight et al., 2014, USA	EarlySense motion-sensing under-mattress device	HR, RR	Medical and surgical patients	Analysis
Sun et al., 2015, USA, Canada	Nellcor OxiMax N-600x - Covidien, Dublin, Ireland	SpO2	Non-cardiac surgery patients of >45 years	Prospective blinded observational study
Taenzer et al., 2010, USA	Patient surveillance system - Masimo's Patient SafetyNet	SpO2, HR	Surgery patients	A Before-and-After Concurrence Study

Table 1

Characteristics of Continuous Monitoring Intervention Studies in General Surgical Wards

Authors, Year, Country	**Monitoring System**	**Parameters**	**Population**	**Design**
Taenzer et al., 2014, USA	Patient surveillance system - Masimo's Patient SafetyNet	SpO2, HR	Medical and surgical patients	Prospective observational study
Voepel-Lewis et al., 2013, USA	CPOX with paging notification system	SpO2	Ortho-surgical patients with patient-controlled analgesia	Prospective observational study
Watkins et al., 2015, USA	Sotera Wireless continuous monitoring system	HR, RR, BP, SpO2	Medical and surgical ward nurses	Prospective observational study based on surveys
Watkinson et al., 2006, UK	Propaq portable multiparameter monitors - Welch Allyn, NY, USA	HR, RR, BP, SpO2, ECG, Temp	Medical and surgical patients	Non-blinded RCT

Table 1

Characteristics of Continuous Monitoring Intervention Studies in General Surgical Wards

Authors, Year, Country	**Monitoring System**	**Parameters**	**Population**	**Design**
Weenk, 2017, Netherlands	ViSi Mobile - Sotera Wireless and HealthPatch - Vital Connect	HR, RR, BP, SpO2, 3-5 lead ECG, Temp	Medical and surgical patients	Pilot feasibility study
Wong et al., 2004, China	Oxypleth ginger probe pulse oximeter	SpO2	Fracture patients with surgeries	Prospective observational study

Table 2

Continuous Monitoring Studies Reporting Clinical Outcomes

Authors, Year, Country	**Mortality**	**Cardiac arrest**	**ICU transfer**	**Naloxone administration**	**Hypoxemia**	**Other clinical events**
Brown et al., 2014, USA			✓			✓
Duus, 2017, Denmark					✓	✓
Kisner et al., 2009, Switzerland						✓
Ochroch et al., 2006, USA			✓			
Paul et al., 2019, Canada		✓		✓	✓	
Sun 2015, 2015, USA, Canada					✓	
Taenzer et al., 2010, USA			✓			✓

Table 2

Continuous Monitoring Studies Reporting Clinical Outcomes

Authors, Year, Country	**Mortality**	**Cardiac arrest**	**ICU transfer**	**Naloxone administration**	**Hypoxemia**	**Other clinical events**
Watkinson et al., 2006, UK	✓	✓	✓			
Wong, 2004, China					✓	

Table 3

Continuous Monitoring Studies Reporting Non-Clinical Outcomes

Authors, Year, Country	Alarms	Feedback	Issues	Implementation	Other
Gazarian, 2014, USA	✓	✓	✓		
Gross, 2011, USA	✓		✓		
Jeskey, 2011, USA		✓		✓	
Paul et al., 2019, Canada					✓Tolerance
Prgomet, 2016, Australia		✓			
Slight, 2014, USA					✓Return of investment
Taenzer et al., 2014, USA					✓Accuracy of data
Voepel-Lewis et al., 2013, USA	✓		✓		
Watkins et al., 2015, USA		✓			
Weenk, 2017, Netherlands		✓	✓		✓Measurement differences

2.3.1. Pulse Oximetry monitoring solutions. As discussed, one of the most common critical care patient monitoring solutions is pulse oximetry (Jubran, 2015)**.** Literature search showed that eight continuous pulse oximetry (CPOX) intervention studies in general surgical wards investigated clinical outcomes and seven studies assessed nonclinical outcomes.

Kisner et al., (2009) used Auricall® continuous pulse oximetry (CPOX) to monitor HR and SpO_2 in cardiac surgery patients in general wards, followed by oxygen therapy to hypoxic patients. This controlled retrospective-prospective study showed decreased incidence of atrial fibrillation in the monitored group (18%) of patients compared to the patients with standard monitoring (28%) (Kisner et al., 2009). In another retrospective-prospective study, CPOX with the wireless pager notification system (Patient SafetyNet, Masimo, Irvine, CA) was used in orthopedic surgery patients (Taenzer et al., 2010). The study results indicated decreased ICU transfers and rescue events in the continuously monitored patients. Ochroch et al., (2006) also used CPOX (Nellcor Puritan-Bennett's N-3000 with Oxinet II system) in cardiothoracic surgery patients in a randomized controlled trial (RCT). The study found that there was no reduction in the ICU transfer rate or mortality with CPOX monitoring on general wards (Ochroch et al., 2006).

In a prospective observational blinded study, Sun et al., (2015) used CPOX (Nellcor OxiMax N-600x, Covidien, Dublin, Ireland) to assess the hypoxemic episodes in non-cardiac surgical patients. This observational study (n=1500) captured CPOX data on 833 included patients. Hypoxemic episodes were defined as $SpO_2 < 90\%$ and these were found in 37% of the monitoring data from the patients compared to only 5% recorded by the nurses indicating low documentation of hypoxemic events in patient records. In the same cohort, 21% had prolonged hypoxemia (10 minutes/hour) indicating that hypoxemia events are common in surgical patients

(Sun et al., 2015). In another prospective observational study with CPOX (Oxypleth ginger probe pulse oximeter), in postoperative fracture repair patients, Wong et al., (2004) also found that hypoxemic events were common and suggested for CPOX monitoring in fracture-repair surgery patients (Wong et al., 2004).

In a prospective observational study, Taezner et al., (2014), assessed the accuracy of the manually charted data compared to the readings from the CPOX (Patient SafetyNet, Masimo, Irvine, CA). They found that the SpO_2 values manually charted by the nurses were higher by 6.5% (Confidence interval 4.0% - 9.0%) compared to the CPOX readings around the same time (Taenzer et al., 2014). Voepel-Lewis et al., (2013) in their prospective observational study with CPOX with paging notification system in orthopedic surgical patients assessed the alarm burden, response times and alarm relevance (Voepel-Lewis et al., 2013). In 26% of the clinically significant events, the alarm notifications were not sent via the hospital paging system and hence missed by the nurses and this highlighted the problem with paging burden with the hospital system. Out of the 710 notifications, 46% (n=329) were because of monitor artifact accounting for false notifications (Voepel-Lewis et al., 2013).

Lam et al., (2017) systematically reviewed literature evidence on adult patients, who were monitored with CPOX and/or capnography in their systematic review and meta-analysis. Although there were few studies trending towards decreased ICU transfer, there is lack of evidence on CPOX monitoring decreasing rescue team visits and mortality (Lam et al., 2017).

2.3.2. Multi-parameter monitoring solutions. Technological improvements and evolution of bio-sensors has facilitated continuous monitoring of vital signs in recent years. Watkinson et al., (2006) in their non-blinded RCT used a multiparameter monitor (Propaq portable multiparameter monitors by Welch Allyn, NY, USA) in medical and surgical patients to

assess cardiac arrest, mortality along with other complications and found that there was no difference in adverse events and mortality between the intervention arm and the standard arm (Watkinson et al., 2006). But in a recent observational study (Duus et al., 2018), hypoxia, tachycardia along with other events were detected more in the continuously monitored patients (using Isansys Lifetouch, Isansys Lifecare, Oxforshire, United Kingdom; Nonin WristOx 3150, Nonin Medical inc., Minnesota, USA). There was no difference in the detection of bradycardia, tachypnea and bradypnea observed between those monitored continuously verses those monitored intermittently (Duus et al., 2018).

Continuous monitoring intervention studies have also made attempts to assess the impacts of alarms in the general wards. In a retrospective observational study to assess the alarm frequency generated by electrocardiography (ECG), SpO_2 and RR (using a critical care bedside monitor by Intellivue MP5, and a bidirectional WMTS telemetry system by IntelliVue Telemetry System, Philips Healthcare), Gross et al (2011) found that a few number of patients had higher number of alarms contributing to alarm overload. This shows that there is a need for customization of the alarm threshold depending on the patient conditions (Gross et al., 2011).

2.4. Continuous monitoring system in hospital environment. The new growth of disruptive continuous monitoring technologies in the healthcare industry has been challenging to adopt in the complex, traditional hospital environment as it is challenging to evaluate its impact on workflow and hospital process (Coye & Kell, 2006). There are various factors which influence technology adoption in the hospital, such as, the critical nature of the clinical problem the technology is addressing, policies, culture towards adoption in that clinical setting and the perception of the benefits of this technology by the various stakeholders (Atun, 2012).

Jeskey et al., (2011) in their exploratory action-feedback study with nursing feedback explored the real-life implication of implementing continuous monitoring in their surgical wards through narrative feedback from the nurses (Jeskey et al., 2011). Understanding the change in workflow, the stakeholders affected, measures required for change management, and plan for managing the newly available device data were identified as important measures for better clinical adoption (CA) prior implementing an RCT with technology in the busy surgical wards (Jeskey et al., 2011).

In a prospective, descriptive, observational study, Gazarian et al., (2014) observed nurses' response to continuous monitoring of ECG and oxygen saturation. They identified gaps in practices related to alarms and concluded that managing alarms in the hospital wards was complex as it involved patient assessment, consulting the physician and collaboration with team members. The study also found that the false alarms and monitor beeps impact nurses' workflow (Gazarian, 2014).

In a prospective observational study (Watkins et al., 2016), surveys were applied to nursing staff (n=24) in general surgical and medical wards to understand the impact of continuous monitoring system (Sotera wireless monitoring system). The survey findings showed that 92% of the nurses agreed with the alert and alarm frequency and the average alarm rate was 10.8 alarms per patient per day (Watkins et al., 2016).

Slight et al., (2014) in their return of investment analysis of using continuous monitoring solution (EarlySense motion-sensing under-mattress device) in general medical and surgical wards identified highly positive return on investment in their five-year model assessing length of stay (LOS) and treatment of pressure ulcers.

Prgomet et al., (2016) used a wireless continuous monitoring device (ViSi mobile monitors, Sotera Wireless, California) in their mixed method study to understand the perceptions, concerns and benefits of the nurses and the doctors (Prgomet et al., 2016). Comfortable devices, clear interdisciplinary communication plan on the use of the device with detailed training on using, application, interpretation of device data along with providing support through champions on the wards was identified as key requirements prior implementation of the devices (Prgomet et al., 2016). Weenk et al., (2017) in their feasibility study also used ViSi mobile wireless device (ViSi mobile by Sotera Wireless and HealthPatch by Vital Connect) and investigated measurement differences, connectivity issues, user feedback along with feasibility outcomes. Although the devices were well received by the patients, the connectivity issues led to increased frequency and duration of artifacts (Weenk et al., 2017).

Ross et al., (2016) in their systematic review identified various factors influencing the implementation of eHealth technologies in different healthcare settings (Ross, Stevenson, Lau, & Murray, 2016). The authors recommend selecting the technology after assessing the fit of the individual eHealth technology to the existing environment, its complexity and cost. During implementation planning, leadership, champions, incentives, policies and standards should be taken into consideration. Understanding the knowledge, beliefs and other attributes of the involved stakeholders, providing them support during all phases of implementation followed by evaluating the implementation were considered to be the facilitators for the adoption of technology (Ross et al., 2016).

2.5. Continuous monitoring system studies in Canada. There were only two studies with continuous monitoring solution in general surgical wards from Canada (Paul et al., 2019; Sun et al., 2015). Both studies happened at Juravinski Hospital, Hamilton Health Sciences,

Hamilton, Canada. Currently, a multicenter RCT, with multiparameter continuous monitoring intervention, by McGillion et al., (2016) is underway and Hamilton General Hospital, Hamilton, Canada is one of the study sites (M. McGillion et al., 2016). The monitoring systems used in the included studies shows that none of them are from Canada indicating no technologies were available in Canada to support continuous monitoring at the pre-market evaluation stage, i.e., technology readiness level.

2.6. Conclusion. Although there is limited evidence, five out of eight studies found that continuous monitoring solutions in general surgical wards can improve clinical outcomes. Alarm burden, false alarms, complex alarm management, missed notifications, need for customization of alarm threshold, connectivity issues and monitor artifacts were some of the issues reported by few of the studies. But there is lack of evidence of impact of these issues on clinical adoption of the system by various stakeholders. Literature examining factors impacting continuous monitoring systems in complex hospital infrastructure is limited. Identifying the issues and evaluation of its impact on the continuous monitoring system would be useful to better facilitate implementation of monitoring systems in hospitals.

3. The Research Setting

3.1. The VIGILANCE Study. The VItal siGns monItoring with continuous puLse oximetry And wireless cliNiCian notification aftEr surgery (VIGILANCE) study was a RCT conducted to assess the impact of CPOX monitoring with alerts to nurses on the incidence of respiratory resuscitations with naloxone, code blues and intensive care unit transfers in a cohort of post-surgical patients in a general surgical ward setting represented a timely opportunity for the anesthesia service at the Hamilton Health Sciences to work toward reducing the rate of postoperative respiratory complications (Paul et al., 2019). This study was completed in two

surgical wards of the Juravinski Hospital in Hamilton. Hamilton Integrated Research Ethics Board approval was granted for consent waiver as all the patients transferred to the surgical wards were eligible for the study (ClinicalTrials.gov, Registration number - NCT02907255). Patients were randomized either to standard care or intervention arms. Standard arm patients received routine monitoring with the nurses measuring vital signs every 4-6 hours. Intervention arm patients received standard monitoring along with continuous monitoring with CPOX (Paul et al., 2019). This study was one of the two continuous monitoring system studies in Canada (Table 1). Examining and understanding the CA of the monitoring system will help future eHealth implementation studies.

3.2. Evaluation of issues impacting the VIGILANCE study

3.2.1. Need for evaluation. During the conduct of the VIGILANCE, the study team faced several issues and challenges. In particular, there were challenges associated with introducing continuous monitoring systems into the complex hospital infrastructure during the conduct of other continuous monitoring studies (Jeskey et al., 2011; Prgomet et al., 2016).

Catwell and Sheikh (2009), in their article, argued the importance of evaluating the eHealth intervention during all stages of implementation for successful adoption and prevention of future implementation failures (Catwell & Sheikh, 2009). Reflecting and evaluating the eHealth implementation studies at all stages including post-implementation helps in relaying the benefits and challenges to the clinical staff and help improve their perception on the overall benefits of eHealth technology and adoption (Catwell & Sheikh, 2009; Ross et al., 2016).

3.2.2. Clinical adoption framework for evaluation. Lau and Kuziemsky (2016) in their handbook provide an evidence-based approach for evaluation of eHealth technologies. These Canadian authors also provide use cases and examples of studies, including eHealth studies

conducted in Canada and where their various evaluation methods are used (Lau & Kuziemsky, 2016). To evaluate the clinical adoption of technology by clinicians, the authors provide a conceptual framework called the clinical adoption (CA) framework (Lau & Kuziemsky, 2016, pp. 55–74). To guide this evaluation report, conceptually, the CA framework was used to examine the uptake of monitoring technology by clinicians during the VIGILANCE study. The CA framework provides a multilevel view of various factors impacting the CA of eHealth intervention (Lau & Kuziemsky, 2016). The three levels and the dimensions included under them are as follow:

1) Macro level: healthcare standards, legislation, policy and governance, funding and incentive, societal, political and economic trends
2) Meso level: people, organization and implementation
3) Micro level: health information technology quality, usage quality and net benefits

The overarching premise of the framework is that for successful CA of technology all the factors at the various levels of the CA framework need to be managed efficiently. Lower the quality of technology, as defined by decreased functionality, performance, security, content, availability and responsiveness, there is associated decreased usage, user satisfaction and acceptance by the stakeholders and overall decreased net benefits. As this framework included measures that allowed us to understand multi-level factors in the eHealth intervention environment−it was used as a guide to identify issues and organize our findings.

4. Thesis objective and outline

The general objective of this thesis is to understand the various barriers related to eHealth intervention implementation and provide recommendations to prevent future implementation failures. The specific objectives of this evaluation report is to: (1) identify issues related to the

deployment of the eHealth intervention system of the VIGILANCE study, and (2) evaluate the influence of these issues on intervention adoption.

This thesis is in "sandwich" format, consisting of:

- Chapter 1 is the introduction chapter. The background on the clinical problem of respiratory depression and infrequent monitoring in the surgical wards, the technology solutions that have been tried to address this problem and the need for evaluating the challenges associated with eHealth intervention is described in this introductory chapter.
- Chapter 2 is an evaluation report of issues impacting continuous monitoring and wireless notification system of the VIGILANCE intervention. The CA framework was used to organize the results. Lessons learned from the evaluation along with recommendations to address the various issues are also provided.
- Chapter 3 is the conclusion chapter. The various issues identified, the results of the evaluation report, and the implications on research, policy and practice along with future directions are summarized in this chapter.

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CHAPTER 2

Issues Impacting Continuous Pulse Oximetry Monitoring and Wireless Clinical Notification System After Surgery

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ABSTRACT

Background: Research has shown that introducing eHealth patient monitoring interventions can improve healthcare efficiency and clinical outcomes. VIGILANCE (The **V**Ital si**G**ns mon**I**toring with continuous pu**L**se oximetry **A**nd wireless cli**N**i**C**al notification aft**E**r surgery) was a randomized controlled trial (n=2049) designed to assess the impact of continuous vital sign monitoring with alerts to nursing staff on the incidence of respiratory resuscitations with naloxone, code blues, and intensive care unit transfers in a cohort of post-surgical patients in a ward setting. This report identifies and evaluates key issues and challenges associated with introducing wireless monitoring systems into complex hospital infrastructure during the VIGILANCE eHealth intervention implementation. Potential solutions and suggestions for future implementation research are presented.

Methods: During the VIGILANCE study, issues affecting the implementation of the eHealth intervention were documented on case report forms, alarm event forms, and a nursing user feedback questionnaire. These data were collated by the research and nursing personnel and submitted to the research coordinator. In this evaluation report, the clinical adoption framework was used as a guide to organize the identified issues and evaluate their impact.

Results: Using the clinical adoption framework, we identified issues within the framework dimensions of 'people', 'organization' and 'implementation' at the meso level, as well as standards and funding issues at the macro level. Key issues included: nursing workflow changes, patient withdrawal, wireless network connectivity, false alarms, monitor malfunction, probe issues, and wireless network standards. At the micro level, these issues affected the quality of the service in terms of support provided, the quality of the information yielded by the monitors, and the functionality, reliability and performance of the monitoring system. As a result, these issues

impacted ‘access’ through decreased ability of nurses to make complete use of the monitors; ‘care quality’ of the trial intervention through decreased effectiveness; and ‘productivity’ through interference in the coordination of care, and thus decreased clinical adoption of the monitoring system.

Conclusion: Patient monitoring with eHealth technology in surgical wards has the potential to improve patient outcomes. However, proper planning that includes engagement of front-line nurses, installation of appropriate wireless network infrastructure, and use of comfortable cableless devices are required to maximize the potential of eHealth monitoring.

Keywords: Continuous pulse oximetry; wireless notification; issues; evaluation of issues; clinical adoption framework; remote monitoring; postoperative monitoring; false alarm; WLAN.

INTRODUCTION

Background

Although technological adoption in the hospital environment is slow compared to other fields, there has been a recent increase in digital health solutions proposed for healthcare issues as technologies improve [1]. With increased workload demands on healthcare providers, hospitals have turned to technological solutions to improve efficiency and safety of patient care [2]. Patient assessment in a typical post-surgical ward happens only once every four to six hours or, at times, just once during day shifts, and irregularly at night [3–5]. This infrequent monitoring, combined with the need for opioids and sedatives, and the risk of respiratory depression may predispose patients postoperatively to more frequent cardiorespiratory arrests (i.e., code blues), intensive care unit (ICU) transfers and need for resuscitation [6–8]. Early detection is the key to preventing complications [9]. Pulse oximetry, capnography, and wireless remote automated monitoring with clinician notification systems are some of the methods that are being used to support safe patient care in the face of declining clinical staff complements [9–11].

The **V**Ital si**G**ns mon**I**toring with continuous pu**L**se oximetry **A**nd wireless cli**N**i**C**al notification aft**E**r surgery (VIGILANCE) study examined the impact of continuous pulse oximetry (CPOX) on the incidence of postoperative respiratory complications [8]. VIGILANCE was an unblinded randomized controlled trial (RCT), targeting non-cardiac post-surgical patients (n=2049) at the Juravinski Hospital, Hamilton, Canada. All trial patients with an anticipated length of stay of at least 24 hours were scheduled to stay on one of two surgical wards (E4 and F4), and were randomized to either the standard (n=1019) or the intervention arms (n=1030). The standard arm participants received routine monitoring including assessments every four hours by nurses. The intervention arm patients received continuous monitoring of blood oxygen saturation (SpO_2) and

pulse rate (PR) using a wireless respiratory monitoring system (Nellcor Oxinet III system, Covidien, Dublin, Ireland) in addition to standard monitoring [8,12].

VIGILANCE Setting and Structure of Intervention and Network

The monitoring system within the intervention arm allowed for bedside monitoring and wireless pager notification of clinical staff when the alarm threshold was exceeded. Alarms were set at a threshold of $SpO_2 < 90\%$ and PR of ≤ 50 or ≥ 130 per minute, to set a balance between safety and false alarms [8]. The network structure of the monitoring system was comprised of probe, pulse oximeter unit, transmitter, an optional monitor stand, access points, wireless network, switch, central station, pager transmitter, and pagers as shown in the Figure (Figure 1) [12,13].

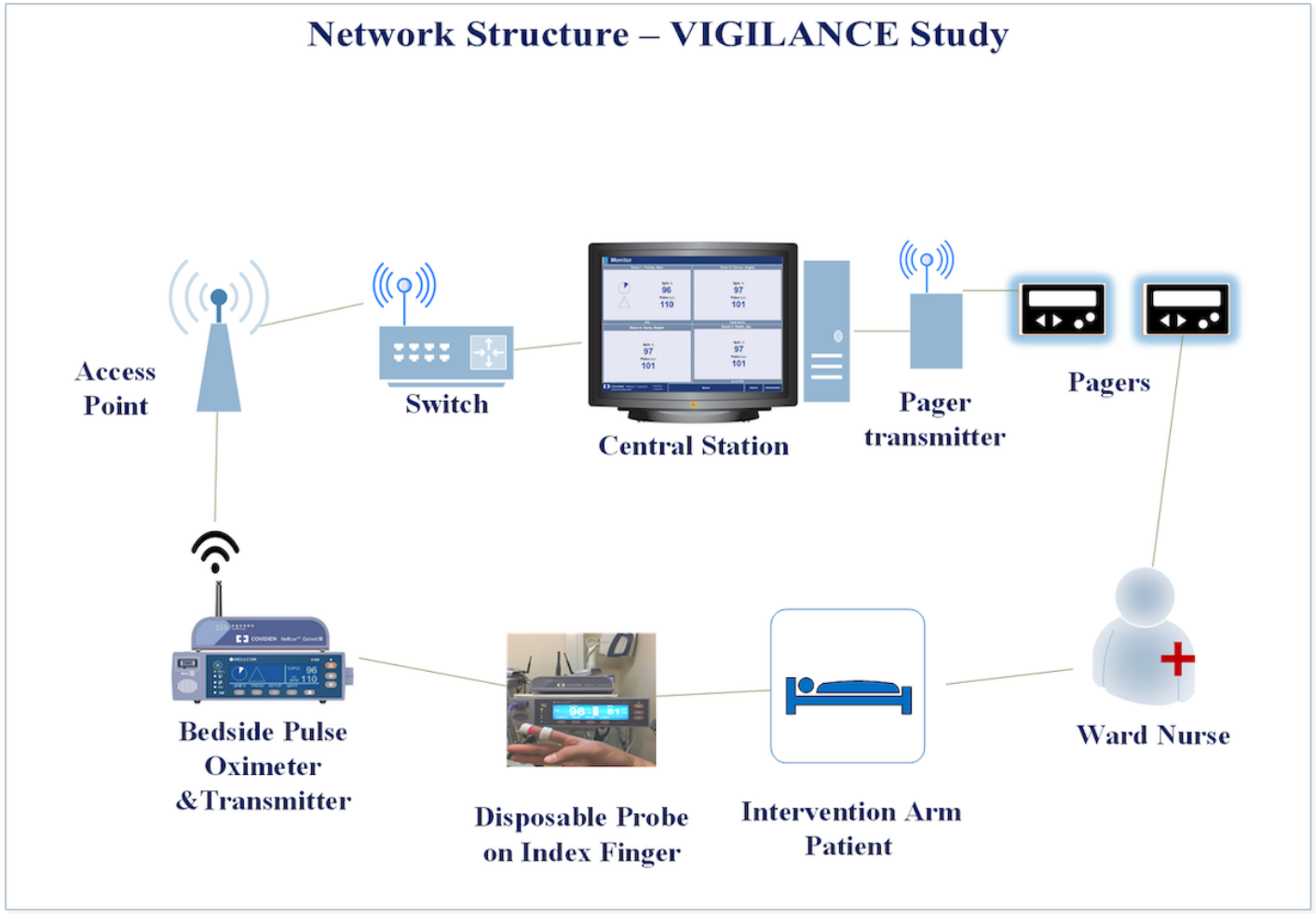

Figure 1: Network Structure of the monitoring system of the VIGILANCE Study.

The oximetry probe on the patient's finger was connected to the bedside CPOX monitor through a cable. The CPOX monitor sent patient data through a wired port to the transmitter. The transmitter converted the data into Ethernet data and wirelessly sent it to the central station via access points. The hospital wireless network structure was made up of the Institute of Electrical and Electronics Engineers (IEEE) standards 802.11a and 802.11g. The IEEE 802.11a standard provided up to 54 Mbps in a 5 GHz band, whereas IEEE 802.11g used 2.4 GHz band [14]. During the installation of the Wireless Local Area Network (WLAN), the Health Information Technology Services (HITS) staff had installed the access points after assessing the wireless connectivity, size of the rooms, and structure of the wards [15]. As shown in the Figure (Figure 2), there were seven access points forming a WLAN on the E4 surgical wards and as Figure 3 illustrates, there were six access points on the F4 ward (Figure 3).

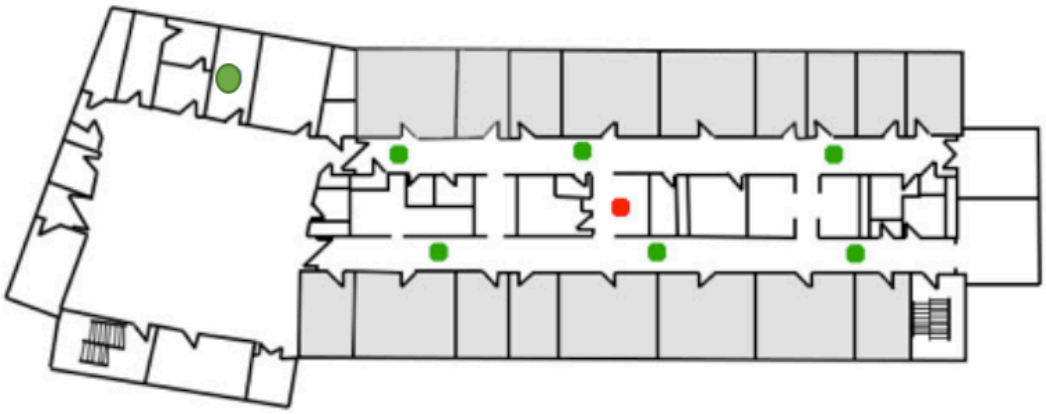

Figure 2: Access points in E4. Legend: green – access points in E4 ward, red – central station, grey rooms – indicate patient rooms, unfilled/white rooms – other rooms or spaces.

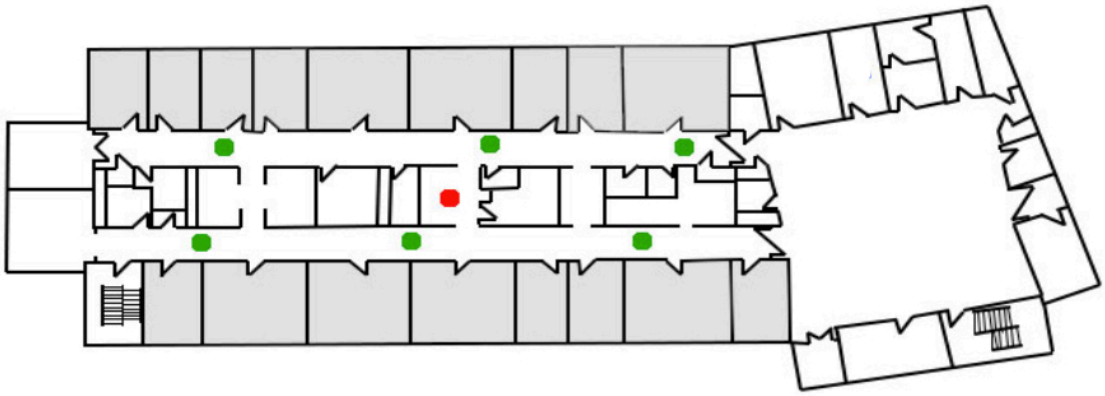

Figure 3: Access points in F4. Legend: green – access points in F4 ward, red – central station, grey rooms – indicate patient rooms, unfilled/white rooms – other rooms.

Information from the access points was wirelessly sent to the hospital's internet routers or switch, which were connected to the central station on their respective wards. The patient data including the patient name, SpO_2 (%), and PR (bpm) along with alarm details were displayed to the healthcare personnel at their respective central station. The central station served as the application server and had the Oxinet III software that was required to read the information from the CPOX [12].

Need for Evaluation of Issues and Objectives

The VIGILANCE study represented a timely opportunity for the anesthesia service at our institution to work toward reducing the rate of postoperative respiratory complications [8]. At the time, clinical trials research on eHealth patient monitoring was a burgeoning field, with little prior experience to draw upon— the challenges associated with introducing digital health systems into the complex hospital infrastructure were not well studied or appreciated [2,16]. Based on our experience, we found that multiple factors interfered with the implementation and

conduct of the VIGILANCE study. The purpose of this report was to engage in a reactive analysis by reflecting on the challenges faced by the VIGILANCE research team during the project implementation, followed by identification and evaluation of issues to facilitate future improvements [17]. Through examination of the issues and challenges we faced, our overall aim was to help foster understanding of the difficulties related to eHealth implementation and prevent future implementation challenges [2]. In so doing, our specific objectives were: (1) to identify issues related to deployment of the eHealth intervention system of the VIGILANCE study, and (2) to evaluate the influence of these issues on intervention adoption.

METHODS

Design and Conceptual Framework

The presentation of findings in this evaluation report has been guided by Lau et al.'s Clinical Adoption (CA) framework [18,19]. The CA framework is an extension of the benefits evaluation framework by Canada Health Infoway, designed to lend guidance to understanding factors influencing eHealth intervention adoption in healthcare organizations at macro, meso, and micro levels [18–20]. The overall rationale behind this framework is that for the successful clinical adoption of technology, the various factors in the framework need to be managed efficiently [18,19].

For this evaluation, selective constructs were used depending on the issues identified and the context of the project [19,21]. The people, organization, and implementation issues at the meso level were identified [19]. The healthcare standards and funding constructs were included at the macro level [19]. At the micro level, system, information, and service quality, use, and net benefits in terms of care quality, access, and productivity were evaluated [19].

Data Source

During the conduct of the VIGILANCE study, some of the issues that affected the eHealth intervention arm were documented in the case report forms, alarm event form, and nursing user feedback questionnaire.

The VIGILANCE study case report forms included items pertaining to patients' deviation from the assigned intervention, the evidence of the type of monitoring received, and the reasons for patient withdrawal of the study intervention. These data were captured through the Research Electronic Data Capture (REDCap) system [22].

An alarm event form was used to capture details of alarms and the nursing response to these. Nurses who were assigned to intervention patients completed these forms when patients had any 'true' or 'false' alarms, and documented the associated symptoms, along with measures taken to address the alarms. Once the patient was discharged, these alarm event forms were deposited in the study storage box and collected by the research nurse, de-identified, scanned and saved in the study folder in Dropbox [23]. Forms that were not deposited were scanned along with the patient chart into the Sovera hospital health record storage system [24].

Nursing user feedback surveys were also administered to ward nurses after completion of the VIGILANCE study and will be reported in a separate study. Any other issues related to VIGILANCE pulse oximeter, wireless network connectivity or nursing workflow, as experienced by the ward staff and the research personnel, were reported to the study coordinator on an ongoing basis.

Data Analysis

Data analysis involved identification of issues from the data sources, categorization of these issues under the meso and macro level of the CA framework, and evaluation of the impact of

these on the micro level constructs of the CA framework by reflecting on the VIGILANCE study happenings during discussions within the study team [17,19]. The problems identified at the meso level were described under people, organization, and implementation categories and those identified at the macro level were described under standards and funding category [19]. The impact of these issues on the micro level factors of the CA framework was described under quality, usage, and net impact category [19].

The identified issues were quantified and are presented using descriptive statistics generated through REDCap along with counts and percentages for these issues.

RESULTS

This evaluation report used the CA framework to organize multiple issues that impacted the VIGILANCE intervention. Findings from this evaluation are summarized in the Figure (Figure 4) [18,19]. A detailed analysis of the constructs of the CA framework is included in Multimedia Appendix 1

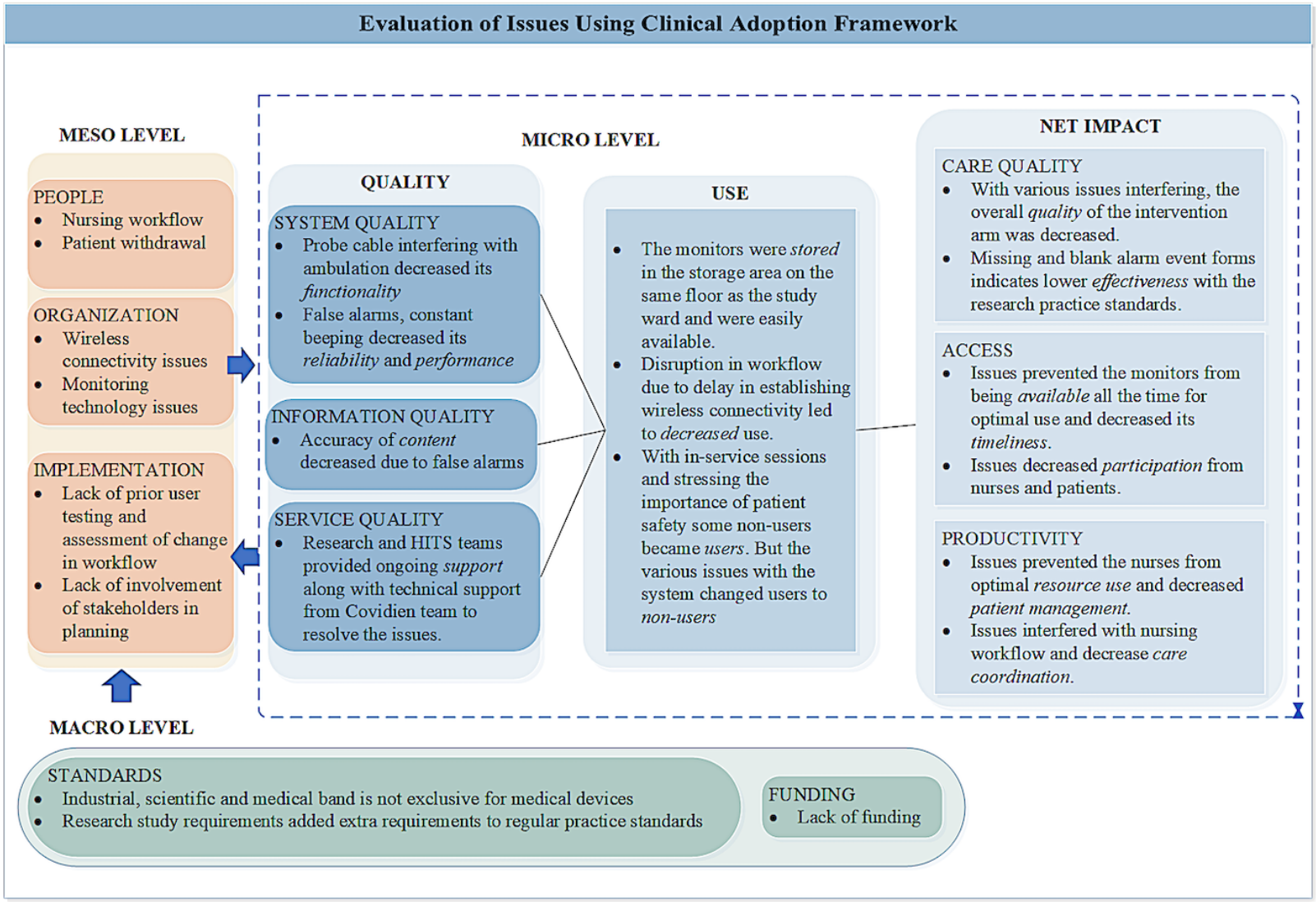

Figure 4: Evaluation of issues using clinical adoption framework [18,19].

People

This includes issues encountered by the key stakeholders – nurses and patients.

1. Nursing workflow: Process changes related to the VIGILANCE study protocols resulted in changes to nursing workflows on the study wards. Upon receiving a newly transferred study subject, the nurse assigned to the study patient had to: (1) determine whether the patient was randomized to the standard care or the intervention arm; (2) connect the patient to the monitor; (3) carry the pager; (4) respond to any alarm notifications; and (5) enter the alarm information on the study form. Nursing staff compliance with the study was assessed using the alarm event forms. Among the scanned alarm event forms from the intervention arm, 2.33% (24/1030) were blank without any entry by the nurses and nearly 22.91% (236/1030) of the forms could not be found indicating decreased compliance with the research practice standards despite multiple in-service sessions. Troubleshooting issues took their time away from actual clinical work.
2. Patient withdrawal: After starting on the monitoring, 10.68% (110/1030) withdrew from the CPOX monitoring. Out of 110 individuals, 74 did not provide any reason for withdrawal and the remaining 36 patients provided a total of 44 different reasons. The reasons in the comment section captured various other causes for patient withdrawal. These reasons were categorized and presented in Table (Table 1).

Table 1: Reasons for patient withdrawal from continuous monitoring

Reason	**Number of patients (%)[a]** **N =110**
No reason provided for withdrawal from monitoring	74 (67.27)
Probe cable	10 (9.07)
Too many false alarms	6 (5.4)
Uncomfortable probe	6 (5.4)
Restriction in ambulation	4 (3.6)
Noise / beeps	4 (3.6)
Confusion / anxiety	3 (2.7)
Monitor malfunction	3 (2.7)
Sleep disturbance	2 (2.7)
Allergic to Velcro	1 (0.9)
Carpal tunnel	1 (0.9)

[a]Percentage calculated will add up to more than 100% as patients reported more than one reason for withdrawal

Organization issues

This includes challenges associated with the wireless network connectivity and the monitoring technology.

1. Wireless network connectivity: Research personnel and HITS staff reported that the fundamental structure of the wireless network had the greatest negative impact on VIGILANCE study implementation. The central station failed to display the data being recorded by the oximeters because of a failure in connection at some point in the long cascade of communication Figure (Figure 1). The hospital had upgraded to a newer wireless structure just before the use of these monitors and a firmware was installed by Covidien to connect to this newer wireless network. This was thought to have caused the connectivity issue initially. Once the monitor lost wireless connectivity, the network connection required reauthentication for security purpose, but the firmware did not support this function optimally. In the hospitals that did not require reauthentication, the firmware was not required for the monitors to connect to the network. This prevented the bedside monitor from connecting promptly to the central monitor and led to nurses taking prolonged time in some cases and in other cases failing to connect the monitor. Although the access points were installed to create a WLAN, the monitors in the rooms farther from the central station had more difficulty in connecting to the WLAN. The CPOX monitors in both E4 and F4 would alternate between the wireless channels, 1, 6, or 11, by default and were later set permanently to only channel 6 resulting in somewhat better stability. Along with unsupported wireless adapter firmware inside the monitor, other medical devices that were connected to WLAN increased the traffic and caused interference. Interference from non-medical devices such as microwaves, and other wireless devices was thought to be another cause for the wireless CPOX failing to connect to WLAN [25].

2. Monitoring technology issues: Out of 1030, 369 patients reported at least one monitoring-related issue and in total 380 issues were identified. The list of monitoring technology issues for which quantitative data were available is presented below in the Table (Table 2).

Table 2: Monitoring technology issues

Issue	**Number of patients[a] (%) N=369**
At least one false alarm	318 (86.17)
Monitor malfunction	36 (9.75)
Stopped using monitor due to probe or probe cable	16 (4.33)
Stopped using monitor due to false alarms	6 (1.62)
Stopped using monitor due to constant beeping or noise	4 (1.08)

[a]Percentage calculated will add up to more than 100% as patients reported more than one monitoring technology issue

If the SpO_2 was >90% and if the patient was not bradycardic or tachycardic, the alarm was considered to be false. Among the intervention patients, 30.87% (318/1030) had at least one episode of false alarm. The most common reason for false alarms was movement of the probe. These false alarms resulted in notifications sent to the nurses, with the nurses going back to the patient room to examine the patient leading to disruption in their workflow and alarm fatigue.

Failure of the bedside CPOX monitor to connect or respond was considered as monitor malfunction. Malfunction constituted for 9.75% (36/369) of the monitoring technology issues and led to these patients receiving standard monitoring.

Constant beeping or noise from a monitor occurred when it was unable to connect to an access point. This issue led to 1.08% (4/369) of the patients with monitoring technology issues to discontinue use of the monitor.

An uncomfortable probe or the probe cable resulted in 4.33% (16/369) of the patients withdrawing from the wireless monitoring system.

The research personnel and the nurses reported that the bedside monitor was too large for patient rooms. The dimensions were 8.4 cm × 26.4 cm × 17.3 cm [13]. Although the monitor itself was not that big, the broad base of the monitor stand, along with the intravenous stand and a chair in the cramped patient cubicle, made the nurses feel as if the monitors were bulky.

Implementation issues

The pulse oximeter and central monitor connectivity to WLAN testing was done, and the channels were adjusted according to the connectivity after the study initiation. Prior to study initiation, training and in-service sessions with the continuous monitoring system were held to train the ward nurses. Research nurses visited the ward on a daily basis to provide support and to collect the study forms. To reduce the incidence of false notifications due to transient events, notification was only sent to the nurses after 30 seconds of the event, with a delay of 15 seconds set for both of the pager notification and the bedside monitor [8]. Prior to the study commencement, the research ethics board application required all the involved hospital areas including the nursing managers of the study wards to assess the study requirements and comment back to the originator. This did not require prior testing of the devices or assessment of the

change in workflow. The ward nurses and HITS team were not part of the study design or planning. The feedback from the nurses was sought after the study was completed. This led to difficulty managing change with the nursing workflow and delay in detecting connectivity issues.

Standards and funding issues

The frequency that is internationally followed for the Industrial, Scientific and Medical band (ISM) is between 2.4 and 2.5 GHz, and this is not exclusive for medical devices and hence the issue of interference [10]. Congestion caused by multiple medical and non-medical devices (eg, microwaves, non-hospital devices such as mobile phones) trying to connect to the WLAN, resulted in connectivity issues [25]. Research study requirements changed the workflow for the nurses and added extra requirements to their regular practice standards. There was a lack of 'funding' to involve front-line nurses as part of the study team to lead the project on the wards.

Quality, use and net impact

An evaluation of impact of the meso and macro level issues on the constructs of the micro level is included in Multimedia Appendix 1 and summarized in Figure (Figure 4). The key meso and macro level issues identified during the VIGILANCE study impacted system, information, and service quality at the micro level that led to: (1) decreased use; (2) suboptimal system access; (3) decreased care coordination; and (4) decreased effectiveness and efficiency of the system. The wireless connectivity issues and monitor malfunction affected the 'access' through decreased ability of the nurses to make complete use of the monitors; patient withdrawal, change in nursing workflow, false alarms, wireless connectivity, and probe issues affected the 'care quality' of the trial intervention through decreased effectiveness; and 'productivity' by interference with care

coordination. Thus, the decreased quality of the eHealth solution led to decreased clinical adoption by stakeholders.

DISCUSSION

This evaluation report examining the key challenges impacting the implementation of the VIGILANCE trial identified multiple issues in people, organization, implementation, standards, and funding dimensions of the CA framework [19]. Key issues included nursing workflow changes, patient withdrawal, wireless network connectivity, false alarms, monitor malfunction, probe issues, and wireless network standards. These issues led to decreased net benefits and thus decreased clinical adoption of the monitoring system.

Comparison with Prior Work

Ross et al.'s [2] systematic review discussed factors that influenced eHealth systems in clinical environments. Factors such as the ability of eHealth interventions to adapt to the local environment, system functionality, implementation climate, stakeholder engagement, and stakeholder knowledge and beliefs are consistent with the issues that were identified in this study [2].

Soomro and Cavalcanti [14] in their article studied the challenges and opportunities associated with WLAN in hospital environments. The 802.11a and 802.11g wireless network standards, which operate on the distributed coordinated function, work on the random-access mechanism where multiple analog and digital signals are combined and transmitted randomly [14]. When there is an overlap of these signals, the channels will retry randomly to transmit after some time and there might be the loss of real-time data [14]. To address this lack in Quality of Service (QoS) support, some of the proposed solutions include: (1) extensions such as 802.11e that can provide priority QoS-based access depending on the type of signal (voice, video, best-effort,

background traffic) and parameter-based QoS (allots channel time to each station); (2) guaranteed QoS for distinctive traffics; (3) differentiated services architecture based on traffic and QoS guarantees; and (4) integrated networks with WLAN and wireless personal area networks [14,26]. Some additional factors that affected WLAN connectivity include coexistent interference from other devices operating in the same ISM band, different configuration requirements for various devices, and the increasing use of mobile devices [14,27]. With the increasing use of mobile and wireless technology in healthcare, hospitals must update their infrastructure accordingly [27]. Wireless medical device manufacturers must ensure that devices can coexist with other devices prior to their approval for pre-market submission according to the current guidelines by Food and Drug Administration in the United States [28]. Standards for coexistence and to test coexistence of the wireless medical devices are currently being developed [28,29]. International groups and the Continua Health Alliance have been formed and are collaborating to standardize medical devices and transmission of data [10,30].

Literature has shown that having a comprehensive approach that involves the stakeholders during the planning of any eHealth implementation yields better results with increased buy-in, improved workflow, and acceptance of the system [2,31]. In the eHealth projects, issues with change management have led to project failures and omission to test the system prior to implementing is one of the main reasons [32,33]. User testing before implementation ensures that the system works according to plan and facilitates user buy-in with the digital intervention [32,34]. Champions have been identified in the literature as crucial components of eHealth intervention implementation [2,31]. Therefore, involving users in planning the workflow and testing, and engagement of front-line nurses who could act as champions of the wireless system monitoring

would have facilitated VIGILANCE team to identify any system issues, streamline the workflow, and engage the nurses more efficiently.

False alarms and constant beeping led to patients withdrawing from the continuous monitoring system and also interfered with the nursing workflow. 'Alarm fatigue' is a major concern in the hospital environment with the increasing use of monitoring technology in the hospitals; desensitization of the healthcare providers due to constant exposure to alarms, beeps, and other noises can put the patient's safety at risk [4,35]. False alarms from the CPOX due to the motion has been a significant concern over the years [36]. A cableless oximetry probe is a potential solution to remove hindrances to patient ambulation after surgery [34]. With the recent improvement in motion-resistant technology and algorithms, manufacturers are now using new techniques to address this issue [37].

Lau et al. used the CA framework to evaluate impact of electronic medical record post-implementation in an ambulatory care clinic [19,21]. Various evaluation studies including systematic reviews have used this framework to understand technology adoption in different clinical settings [19,38,39]. The CA framework offered a multilevel, interrelated view of the various issues impacting the VIGILANCE intervention implementation. An underlying premise is that the lower the quality of technology, as defined by decreased functionality, performance, security, content, availability, and responsiveness, there is associated decreased usage, user satisfaction, and acceptance by the stakeholders and overall decreased net benefits [19].

Limitations

A key limitation of this report is that the need to evaluate the impact of factors that might have affected the VIGILANCE study was conceived post study design and hence we do not have event numbers for all the issues. As this report looked at issues impacting just a single

intervention, they might not be generalizable to other eHealth interventions. Future evaluations could include formal evaluation throughout different phases of the project to enhance eHealth intervention implementation and stakeholder management.

Lessons Learned

The findings from this study support the significance of giving importance to not only health outcomes but also to evaluating the process and 'people' aspects of eHealth research projects to overcome challenges and to optimize the use of eHealth intervention. In a hospital setting, it is essential for the originators of eHealth research projects to ensure that the stakeholders such as nurses, other health care providers, and information and technology staff are consulted in planning and implementing the intervention, establishing the workflow, and testing the intervention in the already-existing hospital infrastructure. Identifying champions among the involved stakeholders and having them as leaders of a research project is crucial for better stakeholder engagement and successful eHealth project completion. Medical device manufacturers are encouraged to consider alarm fatigue while providing configuration and display features for the devices. The lessons learned from this study can help future eHealth research implementation projects. Key issues and potential solutions are summarized in Table (Table 3).

Table 3: Key issues and potential solutions for eHealth research projects

Issues	**Potential solutions**
Issues with stakeholder engagement and change management	Involve key stakeholders in planning, establishing workflows, and user testing. Project originators should identify champions and involve them to lead the projects from front-line.
Monitoring technology issues	Usability testing in the actual hospital environment prior to project implementation.
Wireless connectivity	Test for interference and connectivity in the actual environment prior to procuring wireless medical devices.
False alarms	Medical device manufacturers are encouraged to consider alarm fatigue while providing configuration and display features.

Conclusion

Lau et al.'s CA framework was a useful tool for categorizing and understanding the impact of issues that influenced the deployment of the intervention in the VIGILANCE study. The wireless network in the hospital was demonstrated to be a critical enabler for eHealth interventions. Devices should be chosen based on the available bandwidth and the ability of the device to coexist with other connected devices. Alarm fatigue should be considered while configuring medical devices. Managing change, establishing workflows, usability testing, and engaging stakeholders are key factors in deploying new digital health solutions aimed at improving the process of care and ultimately patient outcomes. The complexities surrounding the

implementation of digital interventions should be taken into consideration along with the clinical outcomes while planning eHealth research studies.

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Contributions

1. PH has contributed toward conceptualization, protocol writing, data collection, data analysis, and writing first draft of this manuscript along with assisting data extraction and data verification of the VIGILANCE study.
2. JP is the principal investigator of the VIGILANCE study and has contributed toward conceptualization, study methodology, interpretation of the data, supervision, and manuscript writing.
3. MC is a co-investigator of VIGILANCE study and created the VIGILANCE study database using REDCap, collected data, trained data collectors, and reviewed this manuscript.

4. NB is a co-investigator of VIGILANCE study, assisted with the study management, and reviewed this manuscript.
5. AT managed the randomization, data collection, created study documents, coordinated the VIGILANCE study team members, contributed toward the interpretation of the results, and has reviewed this manuscript.
6. AC was one of the research nurses who made daily rounds on the study wards and assisted with training the ward nurses and troubleshooting any issues with the wireless monitoring system. AC contributed toward the interpretation of the results and has reviewed this manuscript.
7. DB was one of the research nurses who made daily rounds on the study wards and assisted with training the ward nurses and troubleshooting any issues with the wireless monitoring system. DB contributed toward the interpretation of the results and has reviewed this manuscript.
8. ZS was one of the research assistants who assisted with troubleshooting any issues with the wireless monitoring system and contributed toward the identification of issues. ZS contributed toward the interpretation of the results and has reviewed this manuscript.
9. TV is the biostatistician who performed the data analysis for VIGILANCE study and reviewed this manuscript.
10. JW is the biomedical system administrator who assisted with configuring the monitors to the wireless network, troubleshooting any issues with monitor and wireless network. JW contributed toward the interpretation of results and has reviewed this manuscript.
11. MM contributed toward supervision, interpretation of the results and has reviewed this manuscript.

12. LT contributed toward study conceptualization, manuscript writing, study methodology, interpretation of data, and supervision.

CONFLICTS OF INTERESTS

None declared

ABBREVIATIONS

1. ICU – intensive care unit
2. VIGILANCE - **V**Ital si**G**ns mon**I**toring with continuous pu**L**se oximetry **A**nd wireless cli**N**i**C**al notification aft**E**r surgery
3. CPOX – continuous pulse oximetry
4. SpO_2 – oxygen saturation
5. PR – pulse rate
6. IEEE – Institute of Electrical and Electronics Engineers
7. WLAN – wireless local area network
8. HITS – health information technology services
9. CA – clinical adoption
10. REDCap – Research Electronic Data Capture
11. ISM – industrial, scientific, and medical
12. QoS – quality of service

Multimedia Appendix 1: [Evaluation of impact of issues on the measures of the clinical adaption framework]

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SUPPLEMENTAL MATERIAL

Multimedia Appendix 1: Evaluation of impact of issues on the measures of the clinical adoption framework [19]

Levels	**Dimension**	**Category**	**Evaluation of measures**
Meso	People	Stakeholders, their expectations, roles and responsibilities	Nursing issues – the research study requirements, connectivity issues and false alarms led to changes in the nurses' workflow. Patient issues – false alarms, probe cable, uncomfortable probe and other issues led to patients withdrawing from continuous monitoring.
	Organization	Infrastructure, technology structure	Wireless network connectivity – interference with other medical and non-medical devices led to connectivity issues. Monitoring technology issues – impacted micro level factors negatively.
	Implementation	Project	Daily visit by the research nurse to the study wards to troubleshoot and support the nurses improved the nursing engagement as the

			study progressed. But front-line nurses and hospital information and technology services staff were not involved in planning and as part of the study leadership team.
Macro	Standards	Technology standards, Practice standards	Wireless medical devices interact at the same ISM band as that of microwaves and other non-hospital wireless devices such as mobiles; this increases traffic and causes interference. Research study requirements changed the workflow for the nurses and added extra requirements to their regular practice standards.
	Funding	Remunerations	There was a lack of funding to involve front-line nurses as part of the study team.
Micro	System Quality	Functionality – Ease of use, features	Probe cable prevented the device from being completely wireless; this also interfered with patient ambulation.

			Wireless connectivity issues made it difficult for nurses to connect the devices. The monitor size and its bulkiness made it inconvenient for the patients and nurses in the already cramped patient's cubicles.
		Performance – Accessibility, reliability, response time	The constant beeping and false alarms affected the nurses from trusting the system and its reliability. The prolonged time the monitors took to connect to the wireless network and failing to connect impacted its response time.
	Information Quality	Content – Accuracy, completeness, comprehension	The false alarms affected the accuracy of the alerts the nurses were receiving at the central station. The missing alarm event forms indicate that the information was not completely used, and the instructions were not followed. The blank alarm event forms

			might suggest that the nurses might not have comprehended the information correctly.
		Availability – Timeliness, consistency	Although the alarms were received promptly by the nurses, the constant beeping and false alarms made it inconsistent. This led to nurses ignoring the beeping and contributed toward alarm fatigue.
	Service Quality	Responsiveness – Ongoing support, training	The research team and the HITS team provided ongoing support and tried to resolve the issues. The Covidien technical support team also provided support to address the issues. But, even with updates and installation of custom firmware, the monitors ran into wireless connectivity issues.
	Use	Use behavior pattern – Type, location and flexibility of actual usage	The monitors were stored in the storage area on the same floor as the study ward and were easily available for the nurses. The

			central monitor was conveniently located in the nursing station. As connecting the monitors to the patients and establishing the wireless connection took a long time, there was disruption to the nurses' workflow leading to decreased use of these monitors.
		Intention to use – Reasons for non-users who became users	With the research team doing in-services and stressing on the importance of patient safety, more nurses started using the system. The nursing staff who saw the real potential of the use of the monitoring system in detecting respiratory depression also became users. But the various issues with the system changed some users to non-users.
	Care Quality	Patient safety – Preventable adverse events	The purpose of the CPOX was to record and notify the nurses if the patient had abnormal readings. With various issues interfering, the intervention patients did not

			receive complete monitoring that they were assigned. The research data entry took time away from patient care for the nurses.
		Appropriateness and effectiveness – Adherence and compliance with practice standards	The missing and blank alarm event forms indicates that not everyone was compliant with the research practice standards.
	Access	Ability to access service – Availability, timeliness	The wireless connectivity issues prevented the monitors from being available all the time and decreased its timeliness.
		User participation – Patient and nurse participation	The missing and blank alarm event forms indicate that the monitoring system was not used optimally. Among the patients who received the intervention, 10.4% of them withdrew from continuous monitoring after starting it due to various reasons.

	Productivity	Efficiency – Provider resource use, improved patient management	With the nursing staff running into issues with the monitoring system regularly, there was no optimum use of the monitoring system, and hence all the intervention patients did not receive the monitoring entirely as planned. This led to the decreased efficiency of the system.
		Care coordination – Care provision, continuity of care across continuum	The issues prevented the nurses from providing continuous care.

CHAPTER 3: CONCLUSION AND FUTURE CONSIDERATIONS

This chapter summarises the results of the thesis, and also highlights lessons learned and key implications in practice, policy and research.

1. Summary

The summary of the evaluation of issues impacting continuous pulse oximetry monitoring and wireless clinical notification system after surgery is provided in the Text box 1.

Text box 1. *Summary of the evaluation of issues impacting continuous pulse oximetry monitoring and wireless clinical notification system after surgery*

What is the problem addressed in this thesis?

Deployment of continuous monitoring devices are increasing in hospital settings, especially in surgical wards with the objective of improving patient monitoring to prevent complications and assist healthcare providers in their patient care. But adoption of these solutions is slow and there is lack of reporting of associated challenges and barriers.

Why the evaluation of "Issues Impacting Continuous Pulse Oximetry Monitoring and Wireless Clinical Notification System After Surgery" was performed?

A comprehensive review of literature has shown mixed results with regards to adoption of eHealth solutions in hospitals and arguments have been made to consider evaluation of eHealth interventions during all stages of the implementation to understand the challenges and factors that impact eHealth interventions.

What was done and what were the results?

The clinical adoption framework was used as a guide to identify and present the issues that impacted the VIGILANCE study intervention. Issues were identified through data review and reflecting on the issues through team discussions. The issues identified were nursing workflow changes, patient withdrawal, wireless network connectivity, false alarms, monitor malfunction, probe issues, and wireless network standards. These issues decreased the effectiveness of the eHealth intervention and decreased clinical adoption of the monitoring system in the hospital.

2. Lessons learned

Based on the results from the evaluation report, we learned the significance of assessing implementation process and stakeholder perceptions along with clinical outcomes in eHealth intervention research studies conducted in healthcare settings to overcome challenges and to optimize the use of eHealth intervention. The results also showed the need for workflow assessment and device testing in the actual environment, prior to launching the technology live and involving all key stakeholders in this process. Medical device manufacturers are encouraged to consider alarm fatigue while providing configuration and display features for the devices.

The lessons learned from this study can help future eHealth research implementation projects.

3. Implications on research, policy and practice.

The literature review demonstrates a lack of continuous monitoring research studies in general hospital wards. A survey of evidence shows that there is lack of reporting of issues associated with eHealth implementation. We recommend that more research involving patient monitoring solutions in hospitals are required and these studies should consider assessing not only clinical outcomes, but also non-clinical outcomes, such as, stakeholder perceptions, implementation process evaluation and evaluation of technology adoption. Lessons learned and recommendations from the evaluation report can be generalized to implementation of continuous monitoring studies and may represent better clinical adoption of the system and change management. With increasing medical devices using wireless network, policy makers are faced with the challenge to regulate these devices prior to their usage in clinical environment. The wireless network standards and coexistence of wireless devices within the same wireless network

is a major challenge which was reported in the evaluation report. These issues highlight the need for supporting policies to address this concern.

4. Future considerations

Future eHealth intervention studies should consider several strategies prior to implementation. During the planning stage, key stakeholders should be involved to assess the changes to the workflow and workload and plan for the necessary measures to address these changes (Granja, Janssen, & Johansen, 2018; Pandi-Perumal et al., 2015; Ross et al., 2016). Involving them in the planning of the project along with the user testing of the eHealth intervention will help in identifying the required changes to the workflow and if there are any technical issues in the clinical environment such as wireless interference and connectivity issues (M. McGillion et al., 2016). McGillion et al., prior to their multi-centre randomized controlled trial (RCT) with continuous monitoring system in surgical wards, performed a user-testing study involving ward nurses (n=26) and patients (n=11), to optimize the required workflows. The feedback provided during testing helped the study team to address training and change management, as well as to undertake measures to improve end-user experiences (M. McGillion et al., 2016; Ouellette et al., 2018).

The project originators should ensure that alarm configuration can be modified as required by the stakeholders (Winters et al., 2018). Prior user testing will also show if the eHealth intervention is a good 'fit' for the involved stakeholders (Gagnon et al., 2012; Muhammad & Mohammed Albejaidi, 2017). Project originators should identify champions and involve them to lead the projects from front-line (Gagnon et al., 2012; Ross et al., 2016). Wireless sensors and cableless probes are suggested to promote patient ambulation, remote

monitoring and eventually decrease the workload on the nurses (Majumder, Mondal, & Deen, 2017; M. McGillion et al., 2016).

Governmental and non-profit organizations are taking measures to address wireless connectivity issues, interference and loss of critical monitoring data due to connectivity issues (Continua Health Alliance, n.d.; FDA, 2013). Project originators need to consider these standards before selecting the device. For the device manufacturers, it is crucial to demonstrate that a wireless medical device can co-exist with other wireless devices for approval from the Food and Drug Administration (FDA, 2013).

For successful adoption of wireless devices in the hospitals, the hospital administration should consider upgrading the wireless network structure and adding the required extensions to provide the appropriate Quality of Service (QoS) support depending on the necessity. For example, depending on the type of signal that needs to use the wireless network and its priority level, i.e., analog or digital, voice or video, the newer extensions such as 802.11e can provide priority based access to the channels in the wireless local area network (Alavikia, Khadivi, & Hashemi, 2012; Soomro & Cavalcanti, 2007).

In conclusion, patient monitoring with eHealth technology in surgical wards has the potential to improve patient outcomes. However, proper planning that includes engagement of front-line nurses, installation of appropriate wireless infrastructure, and the use of comfortable wireless devices are required to maximize the potential of eHealth monitoring.

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