

Use of in situ simulation and human factors engineering to assess and improve emergency department clinical systems for timely telemetry-based detection of life-threatening arrhythmias

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ABSTRACT

Background and objectives Medical simulation and human factors engineering (HFE) may help investigate and improve clinical telemetry systems. Investigators sought to (1) determine the baseline performance characteristics of an Emergency Department (ED) telemetry system implementation at detecting simulated arrhythmias and (2) improve system performance through HFE-based intervention.

Methods The prospective study was conducted in a regional referral ED over three 2-week periods from 2010 to 2012. Subjects were clinical providers working at the time of unannounced simulation sessions. Three-minute episodes of sinus bradycardia (SB) and of ventricular tachycardia (VT) were simulated. An experimental HFE-based multi-element intervention was developed to (1) improve system accessibility, (2) increase system relevance and utility for ED clinical practice and (3) establish organisational processes for system maintenance and user base cultivation. The primary outcome variable was overall simulated arrhythmia detection. Pre-intervention system characterisation, post-intervention end-user feedback and real-world correlates of system performance were secondary outcome measures.

Results Baseline HFE assessment revealed limited accessibility, suboptimal usability, poor utility and general neglect of the telemetry system; one simulated VT episode (5%) was detected during 20 pre-intervention sessions.

Systems testing during intervention implementation recorded detection of 4 out of 10 arrhythmia simulations ($p=0.03$). Twenty post-intervention sessions revealed more VT detections (8 of 10) than SB detections (3 of 10) for a 55% overall simulated arrhythmia detection rate ($p=0.001$).

Conclusions Experimental investigations helped reveal and mitigate weaknesses in an ED clinical telemetry system implementation. In situ simulation and HFE methodologies can facilitate the assessment and abatement of patient safety hazards in healthcare environments.

INTRODUCTION

Central and distributed telemetry systems to monitor and display patient vital signs and cardiac rhythms are widely installed in a variety of healthcare environments. Notwithstanding arrhythmia recognition software, ST segment analysis algorithms and other enabling features, these telemetry systems depend on proper configuration, deployment, use and maintenance in order to effectively alert providers to critical changes in patient status. Furthermore, the functionality of telemetry systems can be impaired by the clinical demands and workflow characteristics of specialised acute care settings such as Emergency Departments (ED).

ED telemetry applications have been assessed in select patient cohorts (eg, low-risk chest pain observation unit admissions,¹⁻⁴ ED patients in transit⁵⁻⁷); however the performance and value of cardiac telemetry and vital signs monitoring for the general, undifferentiated ED population as a whole remains unexamined. Coincident with recent media and regulatory body attention on monitoring-related patient safety,⁸⁻¹³ investigators hypothesised that medical simulation methodologies and human factors engineering (HFE) could be applied to (1) the objective assessment of ED clinical systems performance with respect to detection of life-threatening cardiac arrhythmias and (2) the experimental development and implementation of practical solutions for identified deficiencies in telemetry system functions. This manuscript reports results from the Accessible Real-time clinical Guidance through Updated Signals (ARGUS) programme, intended to apply on-site simulation and HFE investigation to the clinical ED systems tasked with detecting cardiac arrhythmias.

METHODS

Setting and sample

The study was conducted in two 16-bed units of the adult ED for an academic regional referral hospital (719 beds; annual ED census 103 000 adult visits). Each of the two ED care units featured the StarView telemetry system (Philips Healthcare, Andover, Massachusetts, USA), bedside patient monitors in all treatment rooms (excepting one room on one unit), one centrally-located telemetry display station without dedicated monitoring staff, and one pair of hallway telemetry displays (see online data supplements 1 and 2). The remaining urgent care and behavioural care areas did not feature telemetry monitoring; resuscitation bays and chest pain observation units were excluded from study due to continuous bedside nurse presence for patient monitoring. Personnel from the institution's simulation centre and departments of biomedical engineering and emergency medicine developed and implemented the programme.

The study subject pool included all on-duty clinical personnel (eg, physicians, nurses, technicians, students, ancillary personnel) working in the ED during unannounced study sessions who could be expected to respond to patients exhibiting life-threatening cardiac arrhythmias or vital sign aberrancies. As a study examining the clinical performance of established processes and response systems (ie, not individual responders) during routine ED care, informed consent was not obtained from subjects; confidentiality was maintained, and individual identifiers were not collected. Patients in the live ED environment were not involved. The research protocol was approved by the Institutional Review Board of the study site.

Simulation protocol development and baseline telemetry system performance assessment

On the basis of the American Heart Association recommendation for detection and treatment of non-perfusing ventricular fibrillation/ventricular tachycardia within 3 min of onset, investigators chose a 180-s window for simulation of arrhythmias. Sinus bradycardia at a rate of 20 bpm and ventricular tachycardia at 150 bpm were selected for simulation due to their presumed impact and relevance to ED patient care and safety. A PS/97 (BAPCO, defunct) biomedical equipment testing simulator was configured to generate the appropriate cardiac monitor ECG telemetry signals. An arrhythmia simulation session study tool was developed for observation and recording of system performance data (see online data supplement 3), for example, time between initiation and detection of simulated arrhythmia, detection method (ie, central telemetry display, hallway telemetry display, or bedside monitor (either in-room or broadcast across CareGroup, a broadcasting feature to relay alarms across designated monitors)). Upon finalisation of simulation protocol and checklist (see online data supplement 4), study sessions were scheduled for dates and times that were selected with a random number generator, compatible with research assistant availability and within specified study periods. (Although of potential interest for investigation of the effect of nighttime-associated factors that impact ED clinical operations, study sessions between 23:00 and 7:00 were not able to be conducted due to research personnel scheduling restrictions).

Twenty *pre-intervention* arrhythmia simulation sessions were conducted to determine baseline ED system performance. After clearance with the ED clinical manager and determination of the absence of study exclusion criteria (eg, surge/disaster conditions, programme personnel on active clinical duty) prior to each scheduled session, investigators temporarily marked an unoccupied ED treatment room as 'occupied' on the computerised physician order entry tracking system. An investigator connected the simulator to the in-room bedside monitor to generate an ECG tracing of a study arrhythmia, which was simulated and displayed for 180 s. When available, a second investigator confirmed arrhythmia display on the ED telemetry system, observed for arrhythmia detection by ED personnel and interrupted any potential study-prompted clinical activity that could impact live patients or departmental operations. The simulated arrhythmia was recorded as being detected if and when any ED clinical provider either (1) responded in person to the ED treatment room housing the arrhythmia generator or (2) appropriately interacted with any telemetry system station in response to the arrhythmia or resultant alarm. The first two subjects responding to each arrhythmia simulation received gift certificates as study incentive. No debriefing was completed except for a brief explanation of study protocol.

Development of HFE knowledgebase, determination of telemetry system repair and revision specifications, and implementation of experimental intervention

Study investigators employed a selective, phased HFE approach (consistent with those advocated by experts^{14–20}) to study and improve the existing ED telemetry system implementation. A focused knowledgebase to define pre-intervention system state and HFE objectives was compiled from multiple sources and methods, starting with a literature review, hardware inventory (for type and mechanism of damage and loss), functions diagnostic (eg, device up-time, configuration, communications, networking), real-time clinical use observation and end-user Web survey for needs analysis (querying staff on system knowledge, use and customisation preferences). Findings from the initial assessment activities indicated that the telemetry system (as originally installed in 2005) featured limited accessibility, suboptimal usability, poor utility and general neglect by its anticipated user base. Hardware exhibited signs of moderate physical damage as well as a lack of maintenance, for example, two of the four system-hosting PCs did not boot up; connector pins on ECG cable connectors were bent and precluded signal transmission; keyboard and mouse interfaces were inaccessible or missing. Real-time observation revealed that the central telemetry stations and their alarms were consistently ignored by clinical staff; non-clinical personnel stationed in proximity to the central displays were observed to intermittently mute alarms without reviewing or reporting them. Fifty-three per cent of 18 attending physicians (33% of practice group) and 26% of 21 nurses (approximately 10% of active ED nursing staff) who responded to pre-intervention Web surveys reported that the telemetry system did not impact their clinical practice. Physicians and nurses who indicated definite impact on their clinical practice reported an average of 2 ± 2 (median 1) and 4 ± 4 (2) such instances, respectively, in the 5-year period since system deployment at the study site.

Informal discussions with small user groups comprising registered nurse (RN's), medical doctor (MD's) and ED technicians during shift-change assembly and impromptu on-shift meetings contributed to a better understanding of the relevant hardware, task, process, user, organisational and environmental factors and issues. Institutional expert input and guidance were obtained through discussions with ED clinical practice and administrative leadership councils as well as 5S (seiri (sort), seiton (straighten), seiso (systematic cleaning), seiketsu (standardize), and shitsuke (sustain)), patient safety and simulation workgroups. Given the low incidence of true positive live patient alarm events, direct observation methods were focused on the baseline arrhythmia simulation sessions to generate snapshot task analysis data (and work environment conditions data). RN charting activities

were separately observed and web surveyed to characterise relevant workflow needs for optimal application of downstream HFE interventions.

The knowledgebase was then used to determine specifications for ED telemetry system repair and revision within the constraints of fixed monitoring hardware (ie, sensor capabilities), detection software (algorithms) and software usability characteristics (display gestalt, information clustering, alarm message format, content mapping (both cognitive and geographic)). Target specifications for system intervention were defined in select HFE categories (with implementation methods) through a modified Delphi process involving investigators and ED stakeholders: improved alarm audibility (hardware repair and repositioning) and visibility (central display relocation; distributed large-screen display installation at high-impact/high-traffic locations), alarm parameter matching to end-user needs (adjustment of vital sign thresholds and arrhythmia triggers for high-priority 'red' alarms; CareGroup monitor pairing) and interface disambiguation (touchpad-based input). Discussions were held iteratively with institutional biomedical engineers, the device manufacturer and end-users to verify the feasibility, processes and value of the repair and revision specifications. Mechanisms for the necessary extension of physical infrastructure, routine system maintenance, personnel orientation and equipment in-servicing (with feedback opportunities) were arranged to address environmental and organisational deficiencies in the existing system.

HFE specifications, methods and mechanisms were integrated to establish an overall system revision design. This resulted in the programme's experimental multi-element intervention, specifically engineered to deliver (1) improved system *accessibility*, (2) increased system *relevance* with enhanced signal:noise ratio and system *utility* for real-world ED practice and (3) organisational processes for system *sustainment* with a stable user base (see table 1 for details). The intervention was implemented incrementally over 17 months at the study site after completion of baseline simulation-based system performance assessment.

Interim and post-intervention telemetry system performance assessment

An interim analysis was planned and conducted during the intervention phase for system safety monitoring, ongoing assessment for revision of study intervention and to serve as an additional prompt for end-user familiarisation and utilisation of the system (through the intentional co-option of an anticipated Hawthorne effect). Ten *interim* arrhythmia simulation sessions were completed 3 months into the study.

Upon implementation of all major elements of the study intervention, a set of 20 *post-intervention* arrhythmia simulation sessions was completed; the study protocol for these observations was adjusted to monitor for

Table 1 Experimental multi-element HFE intervention

System feature	Specific deficiencies identified in baseline system implementation	Experimental intervention implemented	HFE basis for intervention
Physical/human-machine HFE (system hardware+accessibility)			
Alarm system hardware (alarm audibility)	Alarm speakers muted or non-functional	<ul style="list-style-type: none"> • Repositioning of speakers to distributed telemetry display locations • Adjustment of alarm volumes for audible, less obtrusive notification 	<ul style="list-style-type: none"> • Hardware assessment • Real-time observation • Simulation observation • End-user Web survey and discussions
Alarm system hardware (alarm visibility)	Telemetry displays located in peripheral areas (eg, hallways, spaces for ED interpreting services)	<ul style="list-style-type: none"> • Repositioning of central telemetry displays to physician stations • Installation of distributed telemetry large-screen displays at nurse stations (with reduced emphasis/reliance solely on audible alarms) 	<ul style="list-style-type: none"> • Hardware assessment • Real-time observation • Simulation observation • End-user Web survey and discussions
System input interface	Traditional keyboard and mouse input devices missing, also suboptimal for limited workspace	<ul style="list-style-type: none"> • Placement of touchpad input devices at physician station telemetry displays and at nursing stations for intuitive interaction 	<ul style="list-style-type: none"> • Hardware assessment • Usability assessment • End-user discussions
Cognitive/Human-Software HFE (System Informational Relevance+Utility)			
Clinical relevance	Poor signal:noise ratio, with excessive false alarms (anticipatory and immediate) ²¹ resulting in 'alarm fatigue'	<ul style="list-style-type: none"> • Alarm parameter adjustment to reduce false alarms, ie, <ul style="list-style-type: none"> – 'Red' alarms only for: <ul style="list-style-type: none"> – Asystole >4 s – Bradycardia <40 bpm – Tachycardia >130 bpm – (VF) or (VT)>100 bpm – 'Yellow' alarms for: <ul style="list-style-type: none"> – NSVT – R-on-T PVC – SVT >180 bpm – Ventricular rhythm >14 PVCs • Additional vital sign alarms: <ul style="list-style-type: none"> – SBP >200 mm Hg – SBP <90 mm Hg – SpO₂ <89% – Removal of all RR alarms (eg, apnoea) • Two-room CareGroup pairing 	<ul style="list-style-type: none"> • Real-time observation • End-user Web survey and iterative discussions for participatory design • Institutional expert input +guidance with modified Delphi process
General utility	Low yield of system access for clinical providers	<ul style="list-style-type: none"> • System integration into nurse charting informational workflow 	<ul style="list-style-type: none"> • End-user Web survey, discussions • RN observations
Organisational/human-organisation HFE (system maintenance+user base)			
System maintenance	System PC components in disrepair (disconnected, physically distressed and/or non-booting PC's)	<ul style="list-style-type: none"> • Repositioning and updating of system PC components in separate, secluded spaces • Coordination of institutional infra-structure for routine maintenance 	<ul style="list-style-type: none"> • Hardware assessment • Institutional expert input • 5S principles (sort, straighten, sweep, standardise, sustain)
User awareness	Widespread knowledge deficit of system presence, availability and features	<ul style="list-style-type: none"> • Announcement of study conduct and intervention at ED personnel meetings • Study simulation sessions 	<ul style="list-style-type: none"> • Real-time observation • Simulation observation • End-user Web survey and discussions
User familiarity	Widespread knowledge deficit of system operation	<ul style="list-style-type: none"> • Group in-servicing and on-shift in-servicing of ED personnel 	<ul style="list-style-type: none"> • Real-time observation • End-user discussions

ED, emergency department; HFE, human factors engineering; NSVT, non-sustained ventricular tachycardia; PVC, premature ventricular contraction; RR, respiratory rate; SBP, systolic blood pressure; SpO₂, oxygen saturation (pulse oximetry); SVT, supraventricular tachycardia; VF, ventricular fibrillation; VT, ventricular tachycardia.

simulated arrhythmia detection at the newly-installed nursing station distributed telemetry displays.

Accession and compilation of real-world correlates of telemetry system performance

Live environment alarm log records of all telemetry-monitored beds in the two study ED care units were reviewed daily during the 2-week post-intervention study phase for true positive and false positive

ventricular tachycardia red alarms (ventricular rate > 100 bpm for >5 s) and bradycardia red alarms (ventricular rate <40 bpm); patient identifiers and details of their management, disposition and outcomes were not accessed. Unsolicited anecdotal provider reports of system utility to study investigators were collected over the duration of the study.

An informal survey was conducted for up to 100 end-users to gauge the matching of post-intervention

system functions with user needs; suggestions and feedback for future improvements were also collected. In order to reformulate and highlight the HFE-modified telemetry system as a new, enabling technology, respondents were additionally asked to indicate where they perceived it to fit on a 'hype cycle' framework (see online data supplement 5).²²

Data analysis

Descriptive analyses were performed on arrhythmia simulation characteristics (eg, time of day, numbers of patients in live ED, arrhythmia type simulated) for the pre-intervention, interim and post-intervention sessions. Each dataset was examined with two-tailed Fisher's exact tests and Wilcoxon rank-sum tests for the proportion of simulated arrhythmias detected, mean time until arrhythmia detection, clinical role of detector/responder, method of arrhythmia detection and proportion of detected arrhythmias that were correctly identified.

RESULTS

Simulated arrhythmia detection performance data

Twenty pre-intervention, 10 interim and 20 post-intervention arrhythmia simulation sessions were conducted over three separate 2-week periods during the 19 months between October 2010 and April 2012 (see figure 1A,B). Equal numbers of sinus bradycardia and ventricular tachycardia arrhythmias were simulated at randomly pre-selected dates and times (as allowed by study site clinical conditions) across day and evening workshifts on all days of the week; research assistant scheduling precluded overnight shift study sessions. Sessions were split evenly across the two study ED urgent care areas; room locations used were a convenience sample based on departmental clinical activity. Two study sessions were aborted due to protocol violations (data excluded from analysis) and rescheduled.

During pre-intervention sessions, none of the 10 simulated sinus bradycardia episodes were detected; a physician detected 1 of 10 simulated ventricular tachycardia episodes at 70 s through an arrhythmia alarm broadcast across a four-room CareGroup. Overall baseline system performance was 5% detection of simulated arrhythmias.

The 10 interim sessions recorded one sinus bradycardia arrhythmia detection out of five episodes (20%; $p=0.50$ for Fisher's exact test in comparison with baseline performance) at 80 s and three ventricular tachycardia arrhythmia detections out of five episodes (60%; $p=0.29$) at 78 ± 54 s, for an overall detection rate of 40% ($p=0.03$).

The system's overall simulated arrhythmia detection rate during post-intervention sessions was 55% ($p=0.001$). Three of 10 simulated sinus bradycardia episodes (30% at 152 ± 23 s; not significant (NS) for Fisher's exact test in comparison with baseline

performance) and 8 of 10 simulated ventricular tachycardia episodes (80% at 55 ± 49 s; $p<0.01$; relative risk 2.67, CI (0.98 to 7.22) with respect to sinus bradycardia) were detected (see table 2). Time of day, weekday versus weekend, ED census (total, in-room, waiting) and provider:patient ratios did not exhibit significant correlation with simulated arrhythmia detection in any programme phase. Time to simulated arrhythmia detection did not change across study phases.

Real-world correlation data

Alarm log record review of the live telemetry system for study ED care units after intervention revealed frequent false positive alarms for ventricular tachycardia (124 false out of 127 logged; positive predictive value 0.02) and bradycardia (8 false out of 17 logged; positive predictive value 0.53). Investigators received recurring reports of distinctive instances of system impact on patient management and clinical care (eg, patient admission to higher-acuity setting based on telemetry-based detection of malignant arrhythmia) at a rate of approximately one report every few months (see table 3). Sixteen of 28 respondents to the post-intervention HFE survey perceived the telemetry system as either starting or already helping to empower clinical providers during patient care duties; 11 additional respondents considered the system as having the potential to improve patient care (see online data supplement 5).

DISCUSSION

Consistent and timely detection of immediately life-threatening conditions, along with expeditious response, is essential in acute care settings. Yet the deterioration of patients from clinical stability into respiratory failure, hypoperfusive states and malignant cardiac arrhythmias may be subtle, rapid, paroxysmal or otherwise unpredictable in such environments.²³ As a mechanism to assist busy clinical staff in meeting this challenge, ED telemetry systems offer real-time, automated remote monitoring of their patients. Yet implemented telemetry systems are often unable to meet complex real-world functional demands and fail to overcome complications arising from innate technological limitations. Notwithstanding scientific and medical advances, telemetry systems can exhibit poor network signal:noise characteristics²⁴⁻²⁶—critical alarms may be overly sensitive and predominantly false, yet significant events may not be sufficiently highlighted; the alarm framework may not even be able to accommodate operational information demands.²⁷ Additional inadequacies may lie in the design of alarms and biomedical interfaces, software algorithms, monitoring utilisation criteria, and a myriad of complex confounding factors (eg, patient movement, ambient noise, provider workload and staffing patterns). With most of these issues beyond their control and ability to correct, frontline clinical end-users may fully disengage from interacting with telemetry systems. Of concern, poor design and functionality in

Program and Study Session Characteristics

Program Phase	Pre-Intervention Phase	Intervention Implementation [Interim] Phase	Post-Intervention Phase
Program HFE Elements	Literature review Hardware inventory + functions diagnostic; real-time clinical use observations, and informal usergroup discussions Physician + nursing group Web survey Physician station + interface display physician + nursing group discussion Alarm parameter adjustment Physician group in-servicing	Ongoing telemetry system maintenance Ongoing real-time clinical use observations, informal usergroup discussions, participatory design + institutional expert input / guidance Nursing group large-screen display Web survey Nursing group in-servicing Nursing group in-servicing	Nursing group in-servicing Nursing station large-screen display + interface installation nursing station large-group supplemental feedback period
Year	2010	2011	2012
Month	Sep. Oct. Nov. Dec.	Jan. Feb. Mar. Apr. May Jun. Jul. Aug. Sep. Oct. Nov. Dec.	Jan. Feb. Mar. Apr. May
Session date	9/29/2010 Tue 9/29/2010 Wed 9/30/2010 Thu 10/1/2010 Fri 10/2/2010 Sat 10/3/2010 Sun 10/4/2010 Mon 10/5/2010 Tue 10/6/2010 Wed 10/7/2010 Thu 10/8/2010 Fri 10/9/2010 Sat 10/10/2010 Sun 10/11/2010 Mon 10/12/2010 Tue	12/12/2010 Sun 12/13/2010 Mon 12/14/2010 Tue 12/15/2010 Wed 12/16/2010 Thu 12/17/2010 Fri 12/18/2010 Sat 12/19/2010 Sun 12/20/2010 Mon 12/21/2010 Tue 12/22/2010 Wed 12/23/2010 Thu 12/24/2010 Fri	4/2/2012 Mon 4/3/2012 Tue 4/4/2012 Wed 4/5/2012 Thu 4/6/2012 Fri 4/7/2012 Sat 4/8/2012 Sun 4/9/2012 Mon 4/10/2012 Tue 4/11/2012 Wed 4/12/2012 Thu 4/13/2012 Fri 4/14/2012 Sat 4/15/2012 Sun

Live ED Care Environment Telemetry Ventricular Tachycardia Red Alarm Records [ventricular rate >100bpm for >5 seconds]

True positive alarms	not recorded	True positive alarms	not recorded	True positive alarms	not recorded
False positive alarms	not recorded	False positive alarms	not recorded	False positive alarms	not recorded
Positive predictive value	not applicable	Positive predictive value	not applicable	Positive predictive value	not applicable

ED Care Environment Simulated Ventricular Tachycardia Telemetry Red Alarms [ventricular rate 150 bpm for 180 seconds]

Live ED Care Environment Telemetry Extreme Bradycardia Red Alarm Records [ventricular rate <40 bpm]

True positive alarms	not recorded	True positive alarms	not recorded	True positive alarms	not recorded
False positive alarms <td>not recorded</td> <td>False positive alarms <td>not recorded</td> <td>False positive alarms <td>not recorded</td> </td></td>	not recorded	False positive alarms <td>not recorded</td> <td>False positive alarms <td>not recorded</td> </td>	not recorded	False positive alarms <td>not recorded</td>	not recorded
Positive predictive value	not applicable	Positive predictive value	not applicable	Positive predictive value	not applicable

ED Care Environment Simulated Sinus Bradycardia Telemetry Red Alarms [ventricular rate 20 bpm for 180 seconds]

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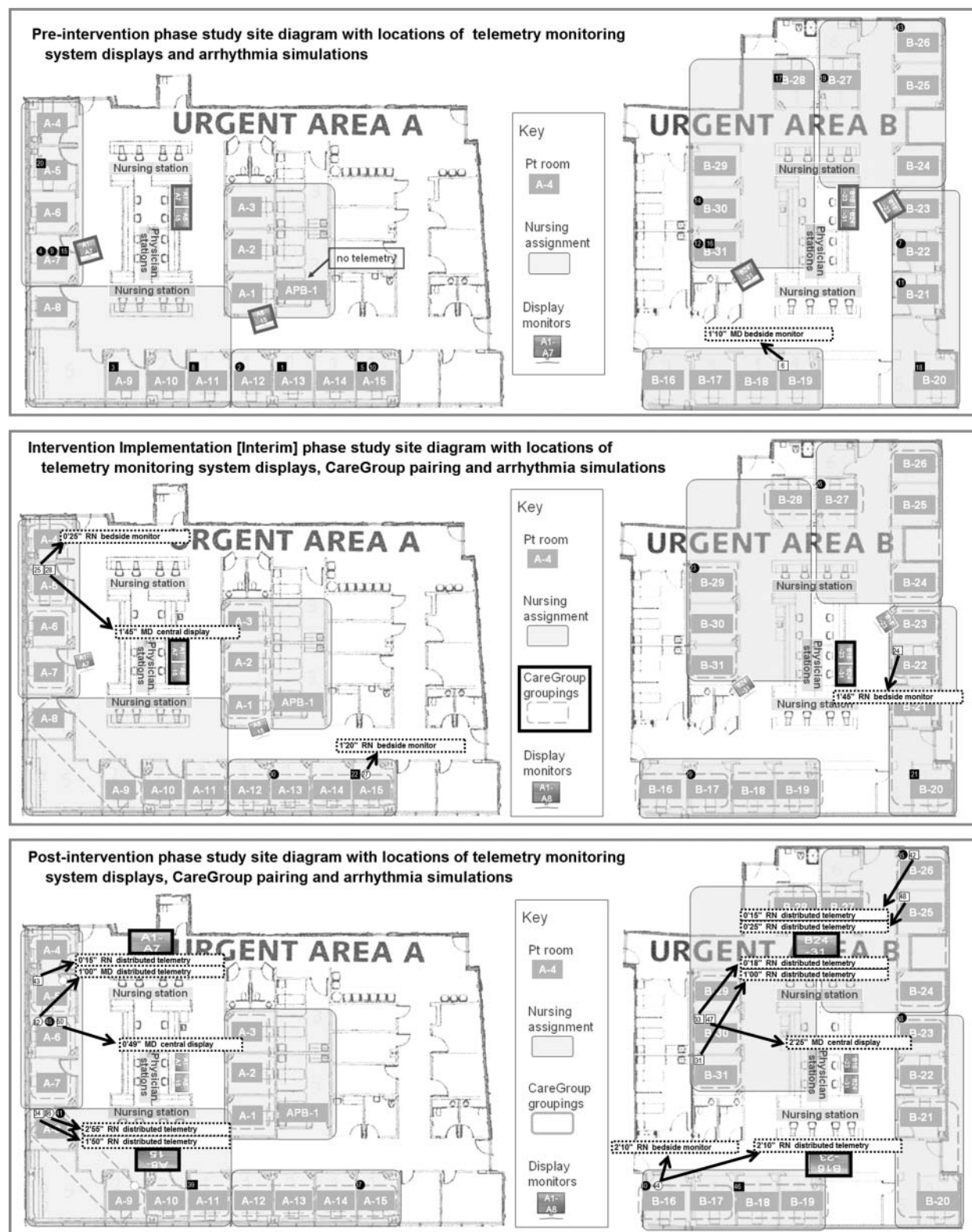


Figure 1b Composite images of ARGUS study site, study interventions, study session characteristics [locational and arrhythmia] and data collected. The top, middle, and bottom panels illustrate pre-intervention (baseline state), intervention implementation [interim] (after physician station telemetry display re-positioning and modifications, alarm parameter adjustment, physician in-servicing) and post-intervention phases (after nursing staff in-servicing, nurse station distributed telemetry large-screen display and interface installation) layouts, respectively - interventions are highlighted with . Patient care space locations where arrhythmias were simulated are indicated by markers; simulated arrhythmias detected during study have callouts indicating time until detection (minutes ['] seconds ["]), detector's clinical role, and detection method.

Table 2 Simulated arrhythmia detection data and analysis

Programme phase	Simulated arrhythmia					Sinus bradycardia					Ventricular tachycardia+sinus bradycardia				
	Ventricular tachycardia					Ventricular tachycardia					Ventricular tachycardia				
	Non-detection	Detection	Sensitivity, % (n)*	pt		Non-detection	Detection	Sensitivity, % (n)*	pt		Non-detection	Detection	Sensitivity, % (n)*	pt	
Pre-intervention (N _{pre} =20)	9	1	10 (10)	0.077		10	0	0 (10)	0.333		19	1	5 (20)	0.031	
Intervention Implementation (Interim) (N _{int} =10)	2	3	60 (5)			4	1	20 (5)			6	4	40 (10)		
Post-intervention (N _{post} =20)	2	8	80 (10)		0.006	7	3	30 (10)	0.210		9	11	55 (20)	0.001	

*Study sessions only assessed for simulated arrhythmia detection, that is, there were no 'non-event' sessions to elicit true negative alarms and false positive alarms for system specificity analysis.
†2-Tailed Fisher's exact test, $\alpha=0.05$.

these types of systems have been found to precipitate medical 'noise pollution',^{28–31} 'cry wolf effect',^{32–34} or 'alarm fatigue',^{35 36} and unintended consequences, even patient harm.^{37 38}

Due to ongoing concerns regarding the utility and safety of an existing ED telemetry monitoring system, study investigators conducted the Accessible Real-time clinical Guidance through Updated Signals research programme with the systematic application of HFE methods and in situ medical simulation. Unlike previous reviews of arrhythmia telemetry, primarily set in inpatient cardiac units,^{39–51} the current study protocol and intervention addressed an ED-care setting designated for patient populations presenting with the full spectrum of illness and injury severity. Objective exploration of the telemetry system in these general purpose ED areas revealed unaddressed weaknesses, unrecognised faults and unfulfilled potential. In confirmation of anecdotal reports, the study found substantial evidence of debilitating system dysfunction resulting from suboptimal configuration, deployment and maintenance—a worrisome demonstration of the misapplication of sophisticated healthcare-enabling technologies.

In response to the identification of these shortcomings, investigators modified and 're-booted' the study site's telemetry monitoring system and existing clinical infrastructure in a recursive and data-driven manner for effective early warning and detection of severe arrhythmias. This was congruent with prior investigations,^{52 53} but with provision for the unique characteristics of ED-practice settings, an emphasis on proactive probing to actively use-test the system,^{54 55} and minimisation of work-disruptive changes in provider responsibilities. Efforts to engage and familiarise ED staff with telemetry system functions also focused on end-user participation in system revision discussions, equipment in-service sessions, and embedding of system use into routine clinical workflow, for example, placement of prominent data-mirroring displays in clear view of nurse workstations for convenient assistance with chart documentation. Experimental data demonstrated how these concrete, real-world utility and usability measures improved system functionality to alleviate alarm fatigue; translational impact at the bedside was also noted through feedback and informal reports. Conversely, a composite analysis of the study site's arrhythmia simulation detection performance (ie, for 'true positive' alarms in response to simulated arrhythmia events) and of the live environment telemetry system log records (for 'true' and 'false' positivities of logged alarms based on retrospective review) still reveals poor overall sensitivity and low positive predictive values, respectively, for significant arrhythmias.

As a clinical informational adjunct, the study site telemetry system is now being used for routine clinical care; studies are planned to assess ongoing operational performance, both simulated and live. As the system is

Table 3 Study site emergency department provider reports of live environment arrhythmias detected through telemetry system and impact on patient disposition

Program phase	Date	Patient presentation	Live arrhythmia detected on telemetry*	Method of arrhythmia detection; detector	Impact of telemetry information on patient disposition
Pre-intervention	No reports or data recorded				
Intervention Implementation (Interim)	November 2010	Elderly patient with constipation	Rapid AFib (150–170 bpm, SBP 90 mm Hg)	Central telemetry display; physician	Transfer to critical care ED area; admission location not recorded
	January 2011	Not recorded	Rapid AFib	Central telemetry display; physician	Transfer to critical care ED area; admission location not recorded
	May 2011	Not recorded	Sinus pause	Central telemetry display; physician	Transfer to critical care ED area; admission location not recorded
		Young patient with chest pain (prior to evaluation by physicians)	NSVT	Central telemetry display; physician	Transfer to critical care ED area; admission to intermediate cardiac care unit
	June 2011	Syncope	VT	Central telemetry display; physician	Transfer to critical care ED area; admission to medical floor with telemetry
	August 2011	Not recorded	SB (30 bpm)	Central telemetry display; physician	Transfer to critical care ED area; admission to intermediate cardiac care unit
Post-intervention	March 2012	Elderly patient with weakness and dyspnoea	VT	Distributed telemetry display; physician	Transfer to critical care ED area; admission to intermediate cardiac care unit
	April 2012	Not recorded	Rapid AFib	Distributed telemetry display; nurse	Not recorded
	April 2012	Elderly patient with syncope	Sinus pause (>30 s)	Central telemetry display; physician	Transfer to critical care ED area; admission to medical floor with telemetry

*Arrhythmias detected by study investigators not included in table data. Unless shown, rate, duration and other parameter data were not reported.

AFib, atrial fibrillation; bpm, beats per minute; ED, emergency department; NSVT, non-sustained ventricular tachycardia; SB, sinus bradycardia; SBP, systolic blood pressure; VT, ventricular tachycardia.

unlikely to ensure faultless detection of all significant monitor alarms, measures to further improve and supplement its functions are being considered at the organisational level, for example, dedicated telemetry monitoring staff,^{56 57} revision of practice guidelines,^{58 59} computerised physician order entry-prompted reduction of unnecessary monitoring and clinical trigger systems.^{60 61} Next-generation sensors^{38–41} and intelligent monitor display interfaces,^{66–69} signal filtering^{28 70} and multivariate analyses that aggregate discrete physiological parameter datastreams,⁷¹ may help address some of the bedside factors that impact the monitoring and management of increasingly complex and sick patient populations.^{72 73}

Distinct from the incremental revisions and upgrading of existing patient monitor and telemetry equipment, innovative systems approaches will be necessary to overcome the persistent challenges involved in effectively detecting, localising and conveying critical patient information as an accurate alarm to appropriate clinical personnel with a minimum of unnecessary disturbance. Potential research and development efforts may feature the integration of smart monitoring instruments, locative devices and intelligent

software agents into a provider-embedding, networked and informatics-mediated clinical information space. Akin to evolving ‘augmented reality’ applications, this approach could use commercially available components such as securable, movement-tolerant sensors with wireless connectivity (eg, for fitness monitoring), radiofrequency locator badges, directional visual alert/sound focusing devices, and ‘push’ messaging agents for accurate and selective provider notification. This ‘need-to-know’ data delivery model would bypass, reduce and de-emphasize ambient noise through clear and discrete alarm signals that self-navigate to, and disturb, only specified end-users. Investigators are preparing for collaborative investigations that build on these concepts to better understand the limitations and potential associated with the use of patient-monitoring telemetry systems.

Limitations

Simulation session numbers were limited by the need to minimise disruptions to patient care and departmental operations; the effect of not having simulated arrhythmia detection data for night shifts on overall telemetry system performance assessment is unknown.

The application of simulation to generate select telemetry readings and elicit system-level responses may have suffered from unrecognised limitations that limit the ability to generalise study findings to live clinical settings. Simulations were constrained by ethical issues that would have arisen from fully re-creating the healthcare 'footprint' of an actual patient (ie, registration forms, chart work, electronic medical record, bed occupancy, clinical care activities) in a high-occupancy ED. As live environment alarm record data prior to intervention were not obtained, the programme's impact on real-world arrhythmia detection and on causal factors that originally resulted in ED telemetry system underperformance could not be precisely determined. Underlying process issues that pertain to patient entry into the ED-care environment and onto telemetry monitoring systems were not addressed in this study.

CONCLUSIONS

Experimental investigation with arrhythmia simulations helped reveal and mitigate weaknesses in an acute care patient monitor telemetry system implementation. Data-driven, participatory HFE with in situ simulation-based assessment methodologies can be applied to the examination and abatement of patient safety hazards in acute care healthcare settings.

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Contributors All authors contributed substantially to the programme, study and manuscript and are qualified for authorship as specified by ICJME criteria: (1a)

Substantial contributions to conception and design: LK, RP, RMB, FJG, EG, JEM, BO, DCP, NAS, GDJ. (1b) Acquisition of data: LK, RP, FGG, GAP, NMT, RSA, KSB, JD, RMB, DCP, DH. (1c) Analysis and interpretation of data: LK, RP, RMB, FJG, EG, JEM, BO, DCP, NAS, DH, GDJ. (2) Drafting the article or revising it critically for important intellectual content: All authors. (3) Final approval of the version to be published: All authors. LK had full access to all of the data in the study and takes responsibility for the integrity of the data, the accuracy of the data analysis and the manuscript as a whole; no additional data are available.

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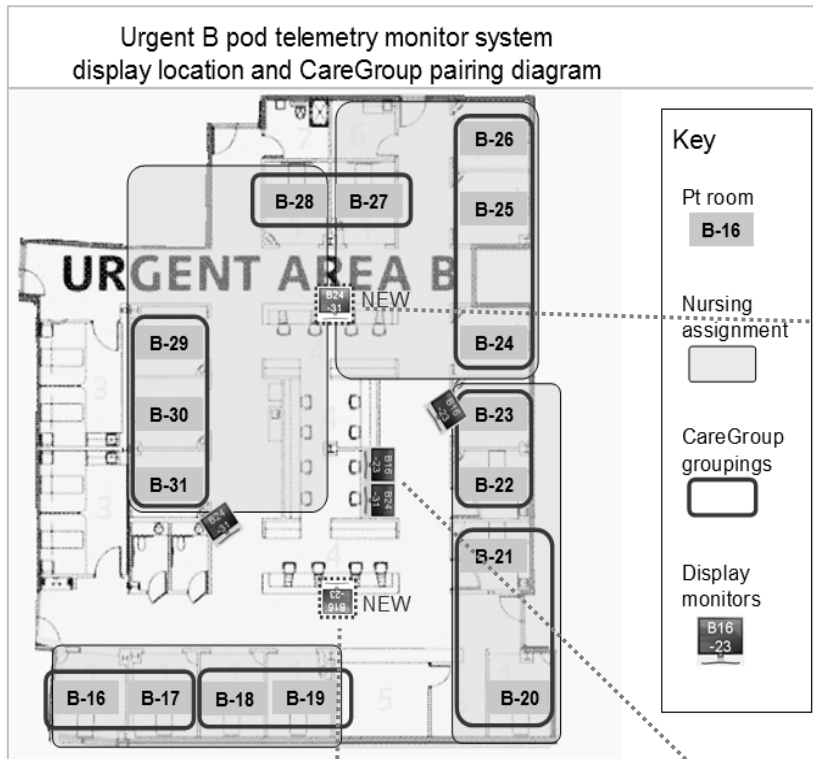
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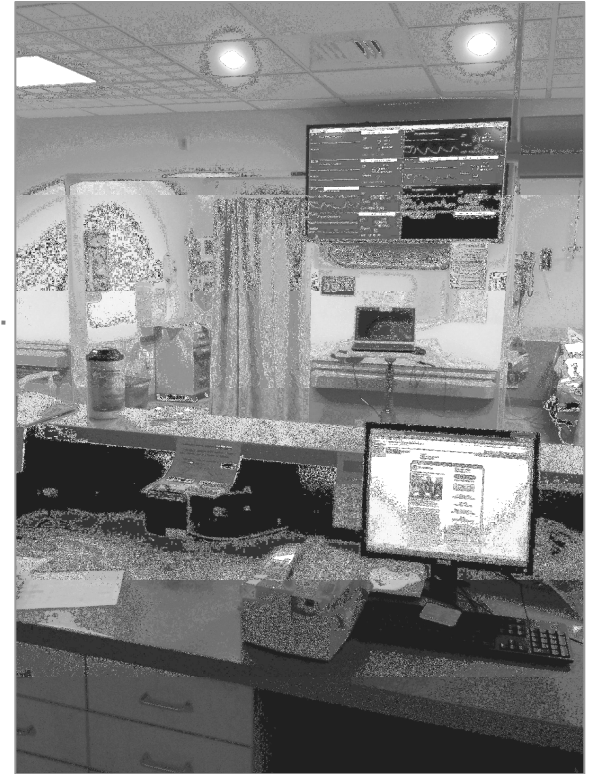
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Online Data Supplement 2: ARGUS Program Diagram for Details of Urgent B Pod Physician [Central] and Nursing [Distributed] Telemetry Display / Station Interventions.



Floor map of Urgent B care area.



Post-intervention image of Urgent B care area northside nursing station featuring newly installed distributed telemetry large-screen display and interface.



Post-intervention image of Urgent B care area southside nursing station featuring newly installed telemetry distributed large-screen display and interface.



Post-intervention image of Urgent B care area physician station featuring repositioned central telemetry displays and touchpad interfaces.

Online Data Supplement 3: ARGUS Study Tool.

ARGUS Study Tool

Session date: ____/____/ 2010 / 2011 / 2012

Session time: : :

Session ED census: Active patients in all ED treatment rooms: _____

Patients in all ED waiting areas: _____

Arrhythmia type: Sinus bradycardia Ventricular tachycardia

Simulation location (area / room): Urgent A _____ Urgent B _____

Time of arrhythmia initiation: ____:____:____

Time of arrhythmia detection: ____:____:____

Arrhythmia first responder role:

CNA / ED technician

Physician

Nurse

Other: _____

Method of detection:

Central telemetry display

Distributed telemetry display

Bedside monitor

Other: _____

Correct recognition of simulated arrhythmia: Yes _____ No _____

Online Data Supplement 4: ARGUS Study Protocol.

Pre-simulation:

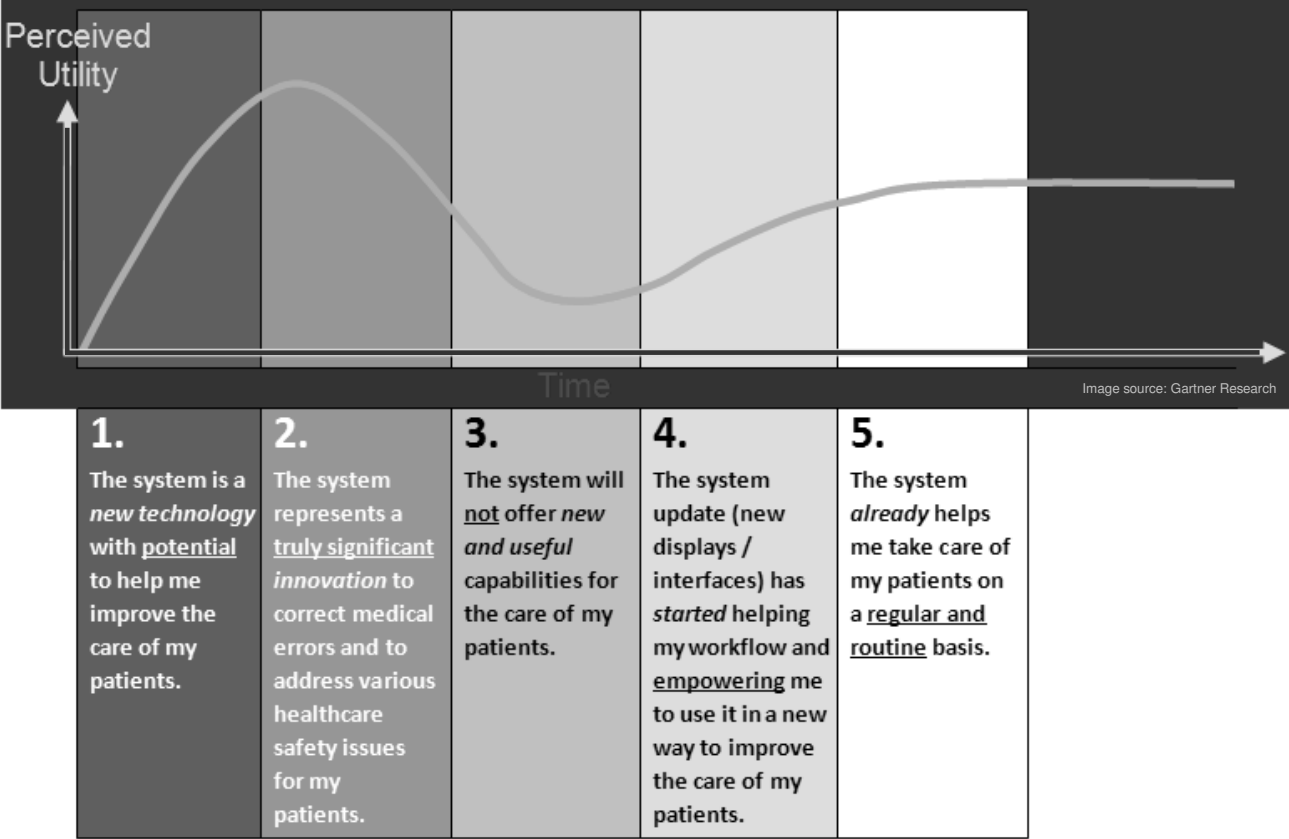
- Discuss study session clearance with the on-duty ED clinical manager
- Determine the absence of exclusion criteria for study conduct
(e.g., surge / disaster conditions, program personnel on active clinical duty)
- Identify an unoccupied ED Urgent A / B pod treatment room and mark off as “occupied” on MedHost CPOE tracking system
- Connect simulator to in-room bedside monitor

Simulation:

Investigator 1 (bedside monitor):	Investigator 2 (central + distributed telemetry stations)
<ul style="list-style-type: none">□ <i>Generate</i> study arrhythmia monitor tracing as per randomization chart□ <i>Start</i> stopwatch when arrhythmia displays on bedside monitor□ <i>Observe</i> at bedside□ <i>Record</i> first responder(s) and time of arrival at bedside□ <i>Distribute</i> gift cards to first 2 respondents□ <i>Terminate</i> arrhythmia at 180 seconds if no responders□ <i>Disconnect</i> simulator	<ul style="list-style-type: none">n/a□ <i>Start</i> stopwatch when arrhythmia displays at central telemetry station□ <i>Observe</i> at central telemetry station□ <i>Record</i> first responder(s) and time of recognition of arrhythmia□ <i>Distribute</i> gift cards to first 2 respondentsn/a□ <i>Delete</i> simulated arrhythmia record from telemetry system log

Online Data Supplement 5: Gartner "Hype Cycle" Framework for Post-intervention End-user Survey and Responses.

Please drop in your feedback + suggestion stub to indicate your agreement with one of the following five assessments of the new telemetry monitor system displays / interfaces.



3	8	1	10	6	Number of responses (total 28) indicating agreement with each "Hype Cycle" assessment
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