Journal of Electrocardiology 86 (2024) 153777

Contents lists available at ScienceDirect

Journal of Electrocardiology

journal homepage: www.jecgonline.com

Technical article: Overview of hospital-based data capture systems that acquire continuous ECG and physiologic data

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ARTICLE INFO

Keywords:
Data capture system
Physiologic monitoring
ECG monitoring
Technical aspects of research
Data collection
Intensive care unit
Research methods

ABSTRACT

Data capture systems that acquire continuous hospital-based electrocardiographic (ECG) and physiologic (vital signs) data can foster robust research (i.e., large sample sizes from consecutive patients). However, the application of these systems and the data generated are complex and requires careful human oversight to ensure that accurate and high quality data are procured. This technical article will describe two different data capture systems created by our research group designed to examine false alarms associated with alarm fatigue in nurses. The following aspects regarding these data capture systems will be discussed: (1) history of development; (2) summary of advantages, challenges, and important considerations; (3) their use in research; (4) their use in clinical care; and (5) future developments.

Introduction and Brief Summary

Hospital-based data capture systems that acquire continuous electrocardiographic (ECG) and physiologic (vital signs) data can be used in both research and clinical care. In the case of research, data are captured in the background, analyzed retrospectively for research purposes, and therefore, do not interrupt clinical care. In the case of clinical care, data capture systems can be used for quality assurance projects and/or patient safety evaluation (i.e., following an untoward/sentinel patient event). This technical article will describe two different hospital-based ECG/physiologic (vital signs) data capture systems created by our research group. The following aspects of using data capture systems will be discussed: (1) history of development; (2) summary of advantages, challenges, and important considerations; (3) their use in research; (4) their use in clinical care; and (5) future developments.

History of Development

System 1: Our ECG/physiologic data capture system was established in 2013 and was in place until 2019 [1]. This system was designed specifically for research purposes by the bedside monitoring manufacturer whose devices were used in our intensive care unit (CareScape Bx50 Gateway System, GE Healthcare, Milwaukee, WI); thus, this system was not a commercial product. A closed network system captured data via a gateway system from all of the bedside monitors ($n = 77$ beds) in the adult intensive care units (ICUs) (Fig. 1). Three adult ICU types were included: cardiac (16 beds), medical/surgical (32 beds), and neurological (29 beds). Continuous waveform and numeric data streamed to a secure server in our research lab via a third-party hardware device (BedMaster, Excel Medical Electronics, Inc., Jupiter, FL). The following data were captured from the bedside ICU monitors (Solar 8000i bedside monitor, version 5.4 software, GE Healthcare, Milwaukee, WI): (1) all available waveforms (e.g., ECG [seven channels], arterial blood pressure (BP), central venous pressure, intracranial pressure, thoracic impedance respiration and plethysmogram); (2) numeric vital signs (e.g., heart rate, BP non-invasive and invasive, Sp02 and respiratory rate); (3) alarm settings (i.e., crisis, warning or advisory, and message/technical); (4) audible and inaudible alarms; and (5) alarm adjustments made by nurses (e.g., parameter threshold, alarm settings). It should be noted that nurses cannot make adjustments to asystole, ventricular fibrillation or ventricular tachycardia alarms. The ECG sampling rate was 240 Hz. Because data were collected in the context of

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https://doi.org/10.1016/j.jelectrocard.2024.153777
Received 17 May 2024; Received in revised form 16 July 2024; Accepted 8 August 2024
Available online 10 August 2024

research, human subject approval was established. The hospital's Institutional Review Board approved the research protocol (12–09723) with waiver of patient consent because bedside monitoring was standard of care and we examined the data retrospectively. A major strength of this data capture system was that data were collected from consecutive ICU patients reducing selection bias.

While system 1 allowed us the ability to acquire an extremely robust dataset, several challenges existed. First, the data were often not well organized, which we determined was related to the third-party hardware device used to store and stream the data (system described above). For example, the ECG/physiologic data for an individual patient was frequently broken down into multiple and numerous segments, in some case of very short duration. To overcome this challenge, our group developed an algorithm to first merge all the patient's data from the multiple segments, and second to reorganize the data into 24-h time blocks using a midnight-to-midnight timeframe. This standardization made it much easier to analyze both individual and cohorts of patients. Second, the data were converted into a suitable public domain format using a loss-less compression architecture capable of achieving a compression rate of approximately 4:1. Using this approach, a compressed 24-h file with both waveform and numeric data was approximately 100 MB and one month of data was compressed to approximately 125GB. This approach fostered analyses, data sharing, and allowed for testing and processing by new algorithms developed by our group.

System 2: In 2019, our hospital purchased new bedside ECG/physiologic monitors from a different monitoring manufacturer (Philips IntelliVue, MX800, A08 M.04.00, Philips Healthcare, Amsterdam, the Netherlands). The hospital also purchased the manufacturer's commercially available data capture system (Data Warehouse Connect, Philips Healthcare, Cambridge, Massachusetts). The ECG/physiologic data flow is shown in Fig. 2**.** For this system, data are archived on the manufacturer's enterprise-level server. The stored data are proprietary to the manufacturer and require vendor specific software applications to interpret the data. In our case, we developed a data extraction process to transfer the data onto separate secure research servers in our laboratory in a CSV format for off-line analysis. Similar to the process described for system 1, patient level files in 24-h blocks using a midnight to midnight time period. System 2, similar to system 1 (described above), captured data in the adult ICUs (now 93 beds) and we expanded our data collection to step-down/telemetry units ($n = 229$ beds). Similar data are captured: (1) all available waveforms (e.g., ECG [seven channels], arterial blood pressure (BP), central venous pressure, intracranial pressure, thoracic impedance respiration and plethysmogram); (2) numeric vital signs (e.g., heart rate, BP non-invasive and invasive, Sp02 and respiratory rate); (3) alarm settings (i.e., red, yellow and inoperative/technical); (4) audible and inaudible alarms; and (5) alarm adjustments made by nurses (e.g., parameter threshold, alarm settings). Similar to system 1, nurses cannot make adjustments to asystole, ventricular fibrillation or ventricular tachycardia alarms.

System 2, a commercial product, included features and functions not available with system 1, which is not surprising since system 1 was designed specifically for research purposes. Unlike system 1, system 2 is designed to acquire continuous data in an individual patient as they move among beds (new bed within the same unit) and different clinical units (move to/from ICU to step-down/telemetry unit). One can only take advantage of this feature if the same manufacturer's devices are used throughout the hospital, which can vary by hospital. The sampling rate of this system is 500 samples per second at 0.05–150 Hz bandwidth. A 24-h file with diagnostic quality ECG waveforms, numerics, and alarms placed on the SQL database is 750 MB/patient/day.

Summary of Both Systems

Having experience with two distinct data capture systems has been enlightening. Below is a summary of our experiences that describe advantages, challenges, and important considerations. First, data capture systems must conform to institutional policies that apply to the use and storage of private health information. Collaborating with the institution's information technology department when the system is established and on an ongoing basis to ensure compliance is important. While the data capture is done automatically, we had a few instances with system 1 when data capture had been interrupted. To solve this, we assigned a research team member to evaluate the system weekly to ensure data capture was maintained. System 2 does not appear to have this issue but human oversight to verify this weekly is still part of our process. Weekly backup of data is also performed at this verification stage.

An important advantage of a data capture system is that data are

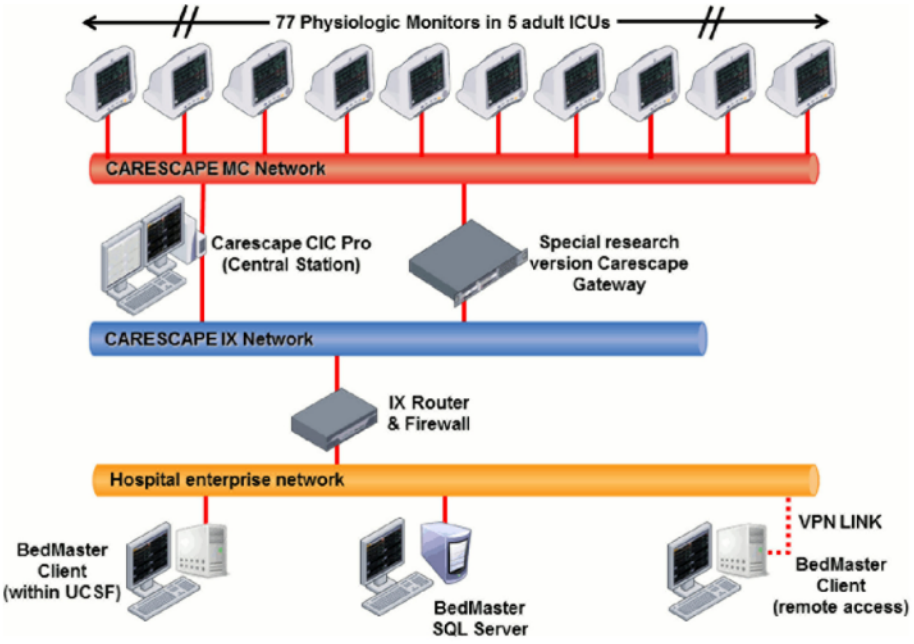

Fig. 1. Illustrates the System 1 infrastructure used to capture continuous electrocardiograph (ECG) and physiologic data from intensive care unit bedside monitors [1].

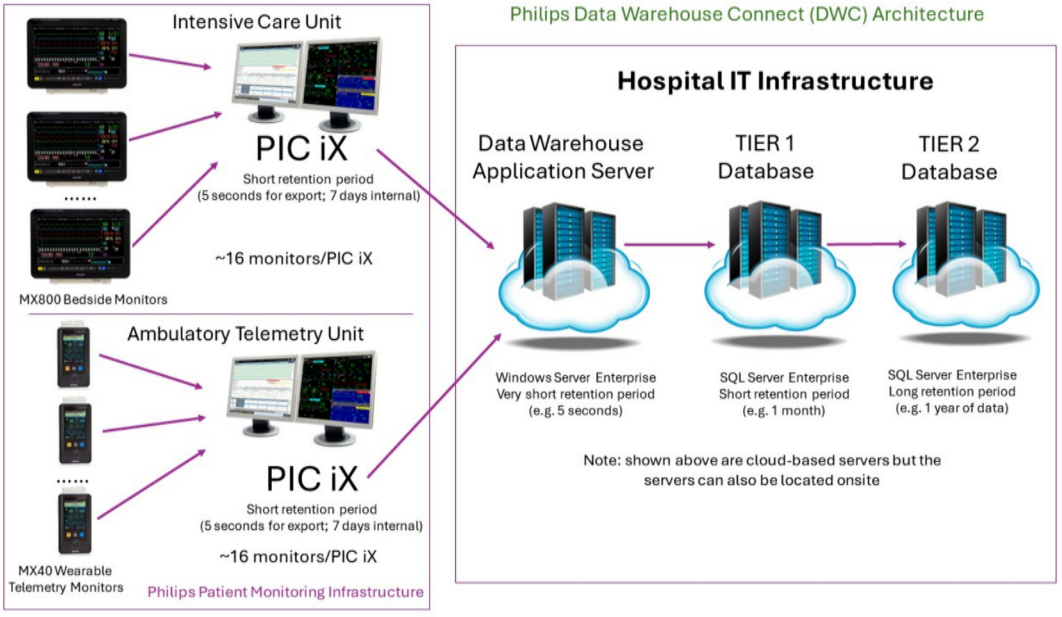

Fig. 2. Illustrates the System 2 infrastructure used to capture continuous electrocardiograph (ECG) and physiologic data from intensive care unit bedside monitors and ambulatory telemetry unit monitors.

acquired in consecutive patients, which substantially reduces selection bias in the context of research. In addition, because the data are acquired in the background, clinical care is not interrupted. However, there are important considerations. First, the accuracy of the ECG data may be compromised if lead placement is inaccurate, which is common in clinical practice. Second, the context of a patient's clinical course, symptoms, care decisions etc. must be obtained from the electronic health record (EHR), which is time consuming and may not be documented.

Another challenge of note was that the ECG/physiologic data were not automatically paired with EHR data, which is important when analyses require patient level data (i.e., demographics, clinical history, medications, clinical outcomes etc.). To address this, we added a Data Scientist to our team and developed a process to link both data types (ECG/physiologic with EHR). The key variables required to link the data were the patient's medical record number (MRN) and dates/times of admission or monitoring which can be obtained from the hospital's admission/discharge/transfer (ADT) system. Once the data are procured using this process a second validation was performed to ensure that the correct EHR data had been acquired. As a first step, a structured query language (SQL) script was developed to procure a random sample of 20 ICU patients. The validation process was performed by both the Data Scientist, who has an understanding of common issues with EHR data extraction, and the study's Principal Investigator because they understand the context of the ICU setting. Data validation ensured the following: (1) the correct ICU admission was selected; (2) the SQL script correctly captured the variables of interest; and (3) the dataset was complete (i.e., no missing data). Then, the Data Scientist and the PI independently performed visual validation by having both the SQL file (i.e., Excel file) and the EHR open at the same time. The following steps were used to validate the EHR data with the 20 ICU patients selected: (1) verification of the MRN with the correct admission and discharge dates/times; (2) verification that the row data (i.e., patient) matched what was in the EHR (i.e., demographics, clinical history, medications, etc.); (4) verification that column data were correct (e.g., SQL script asked for age and sex and these are listed); and (5) identify that there are no missing data. Once the above steps were performed in the EHR system, the ECG/physiologic data were examined to ensure that the patient's MRN and the dates/times of the ICU admission matched. This validation process ensured that any subsequent data procurement using the developed SQL script was consistent (reliable) and valid (i.e., once correct data does not inadvertently become incorrect). Once the SQL script was validated, it was dated and the version noted for use in subsequent data extractions. The above validation process was done when a new data pull was performed to ensure that the EHR data labels had not changed and/or that new data labels were added, which is not uncommon in EHR systems.

The above validation process helped us uncover some important issues worth noting. First, an incorrect MRN could be entered by the nurse when the patient was admitted. Second, because a patient had to be manually discharged from the monitor by the nurse, a patient may not have been discharged from the bedside monitor when transferred from the ICU to the step-down/telemetry unit (improved condition requiring a lower level of care), to another bed within an ICU, or a different ICU type, which could merge the prior patient's data with a newly admitted patient's data. We found that 7% of the ICU patients were moved to a different ICU bed within the same ICU to accommodate nurse staffing or the acuity level of a patient, or were moved to a different ICU type based on the patients diagnosis. An example of the latter might occur in a patient initially admitted with a suspected neurological diagnosis but was later found to have a cardiac problem. Patient transitions (bed and unit) were reduced with system 2 because this system is designed to acquire continuous data as a patient moves to different beds (within the same unit) and clinical units (to/from ICU and step-down/telemetry unit). Third, monitoring was not paused when the patient was temporarily disconnected (i.e., off the unit for surgery or a test, bathing, etc.) and can result in false alarms. Importantly, these issues can be identified and resolved using the EHR linkage process described above. For example, alarms generated when monitoring had not been paused (e.g., left ICU for surgery) were identified from dates and times and deleted.

Costs associated with establishing each system varied. System 1 was installed for research purposes with costs covered by a research grant established between the university and the monitoring manufacturer. System 2 was purchased by our hospital when they introduced new bedside monitors into the adult ICUs (licensed/bed; ~$1400/bed). However, we incurred costs to purchase servers to store research data in our laboratory (outside of the hospital's system), which was ~$12,000/server (includes computer, disk drives, expanded memory. Etc.). In addition, for research grants we budget for costs associated with de-

identification and data storage, which are ~$25,000/year. Personnel costs are also added to maintain our system. A cost analysis prior to establishing a data capture system is an important aspect and varies by setting and the purpose of their use.

We also learned that caution should be used when analyzing the data "as is." Arrhythmia alarms, as one example, are often false positive [1–3]. There is also the possibility of missing true events. In both instances, human annotation may be required. A specific example of why and how annotation is useful in the context of research is provided below.

Lastly, considerations associated with data sharing both within and outside of an institution are important. Aspects to consider include: (1) a data de-identification (and re-identification) process; (2) formatting the data in a suitable public domain format; (3) file size; (4) definitions of data variables; (5) method of sharing (public platform, secure server etc.); and (5) knowledge of institutional and Federal policies related to data sharing. These processes require both expertise and funding and need be accounted for.

Description of How a Data Capture System can be Used for Research

Our research group has used data from the above described systems for several research projects primarily focused on understanding alarms generated during bedside ICU monitoring that can contribute to alarm fatigue in nurses and other clinical staff [1,4–8]. While this problem primarily affects nurses, patient safety is compromised because true events can be missed [1,4,5,7–10]. The seminal work, entitled the University of California San Francisco (UCSF) Alarm study conducted in 2013, examined all of the alarms (audible and inaudible) generated from bedside ICU monitors during a one-month study period in 461 consecutive ICU patients [1]. A total of 2,558,760 unique alarms were generated: 1,154,201 (45%) arrhythmia; 612,927 (24%) parameter (i.e., too high, too low); and 791,632 (31%) technical (i.e., ECG leads off, artifact, line/probe disconnect). There were 381,560 audible alarms that resulted in an audible alarm burden rate of 187/bed/day. Of the 1,154,201 arrhythmia alarm types, the vast majority were for premature ventricular complexes (n = 854,901; 74%). Six arrhythmia alarm types (n = 12,671) that were configured as audible alarms, thus clinically important, were annotated as true or false and included: asystole, ventricular fibrillation, ventricular tachycardia, accelerated ventricular rhythm, pause and ventricular bradycardia. Of 12,671 annotated ECG arrhythmia alarms, 90% were false positive. This study in consecutive ICU patients, represents the largest study to date and clearly illustrated the magnitude of this problem. Our group has published a number of subsequent studies that have built on this work ranging from patient factors associated with true and false arrhythmia alarms [3,10–12], signal quality as a source of false arrhythmia alarms [1,13], specific ECG factors associated with false arrhythmia alarms [1,3,10,14], alarm adjustments made by nurses [15,16], actionable versus non-actionable arrhythmia alarms [12,17–21], the frequency of thoracic impedance respiration alarms [11] and premature ventricular complex alarms [18,20,21].

Most recently, our group used our database to test a new ventricular tachycardia (VT) algorithm created by our group in 5320 consecutive ICU patients with 572,574 h of monitoring (19 months) [2]. We focused specifically on VT because of the lethal arrhythmia types (asystole, ventricular fibrillation, VT), VT is the most frequent alarm and has the highest rate of false positive alarms (90%) [1,17,22–24]. After processing the data with our new VT algorithm, the VT alerts generated from our new algorithm (n = 25,325) were annotated as true or false by five clinical experts. This rich annotated database, acquired from modern-day bedside monitors using a variety of waveforms (e.g., seven ECG channels, arterial blood pressure, and SpO2) is now available as a Medical Device Development Tool, via the Food & Drug Administration for use by monitoring manufacturers and other researchers to develop and test new VT algorithms [25].

Clinical Role

While data from our ECG/physiologic data capture system has been used primarily for research purposes, our group has collaborated with our hospital on several projects designed to guide clinical alarm management strategies [26]. For example, our group participated on the UCSF Medical Center's Clinical Alarms Management (CALM) Committee. This committee was charged with developing a strategic plan to meet The Joint Commission's, National Patient Safety Goal specific to hospital-based alarm management (NPSG.006.01.01; Use Alarms Safely) [7]. Our data were used to help the hospital develop an alarm "inventory" to better understand default settings and the frequency and types of alarms generated from bedside ICU monitors. The alarm inventory was used to develop an alarm device "risk assessment score." The risk assessment score was used to determine the following for each alarm type: potential for harm if not monitored; clinical oversight required; current clinical oversight process; and the frequency of use per patient during hospitalization. Based on our data, changes were made to default settings for arrhythmias (turn off accelerated ventricular rhythm alarms; defined as a wide QRS rhythm <100 beats/min) and Sp02 settings (widen high and low parameter settings). This work lead to updates to our hospital's policies and procedures for alarm management and were used to make recommendations for educational initiatives for clinical staff and monitor watcher staff.

Another way in which our research group collaborated with our hospital was when new ECG/physiologic monitors were purchased for all of the adult ICUs. Prior to installation, a member of our research team was invited to participate on the ECG/Physiologic Monitoring Integration Committee. This group was charged with recommending optimal default settings for the bedside monitors. Both our data and published works from our group were used to guide the proposed default alarm settings. As one example, we recommended that all types of premature ventricular complex (PVC) alarms (seven available types) be set to an inaudible setting. Rather, we recommended that PVCs/h be displayed on the bedside monitor but not alarm. This recommendation was based on a published study that found PVC alarms (six types available) were extremely common. In 446 ICU patients, there were 797,072 PVC alarms during 45,271 h of ECG monitoring, or 17.6 PVC alarms/h [20]. Isolated PVCs were the most frequent (n = 646,665; 81.13%) and R-on-T type were the least frequent type (n = 2321; 0.29%). In a subsequent study, we found that in adjusted logistic regression models, none of the six PVC types were associated with VT [19]. Not only was our alarm data valuable (sheer number of PVC alarms), but our published work that examined patient outcomes was used to support this recomendation.

Future Developments

Our experience with two different data capture systems used for research, has allowed us to appreciate the nuances, both positive and negative, of each type of system. We observed an increase in the ease of use and sophistication from system 1 to system 2, which reflects advancements made to data capture systems (newer hardware/software) and the incorporation of feedback from end users. At present, our group is only able to perform retrospective data analysis, which means prospective real-time testing of novel algorithms (like the VT algorithm created by our group) is not currently possible. Future systems that have capability to identify life-threatening arrhythmias in real- or near real-time would open up the possibility to conduct meaningful clinical trials. Lastly, at present the ECG/physiologic data are not automatically combined with the EHR data. An application that could perform this merge of ECG and EHR data would be another important advancement to understand the impact of arrhythmias on patient outcomes.

Conclusions

The use of data capture systems for the acquisition of continuous hospital-based ECG and physiologic data promotes robust research (i.e., large sample sizes from consecutive patients). This article highlights their value in alarm fatigue research, how the data can be used to guide alarm settings in clinical care and how the data can be used to test novel algorithms to improve detection of lethal arrhythmias. However, working with these systems is complex and requires careful human oversight to ensure that both accurate, high quality data, and clinically meaningful data are used in these applications.

Author statements

- the work described has not been published previously except in the form of a preprint, an abstract, a published lecture, academic thesis or registered report.
- the article is not under consideration for publication elsewhere.
- the article's publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out.
- if accepted, the article will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

All authors have made substantial contributions to all of the following:

1. The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
2. Drafting the article or revising it critically for important intellectual content.
3. Final approval of the version to be submitted.

All authors are accountable for all aspects of the work to ensure that the questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Funding

This work was supported by the National Institutes of Health (grant R01HL167975; Pelter PI); and the UCSF Center for Biosignal Research.

CRediT authorship contribution statement

Michele M. Pelter: Writing – original draft, Conceptualization. **Priya A. Prasad:** Writing – review & editing, Methodology, Conceptualization. **David W. Mortara:** Writing – review & editing, Resources, Funding acquisition, Data curation, Conceptualization. **Fabio Badilini:** Writing – review & editing, Software, Data curation, Conceptualization.

Declaration of competing interest

The authors have no conflict of interest.

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