Evaluation of a CE Approved Ambulatory Patient Monitoring Device in a General Medical Ward


Abstract — An evaluation of a newly CE approved bedside monitoring device used in a general hospital ward is presented. This evaluation has shown that it is feasible to use the system within this environment to provide medical staff with supplementary information on patient health, at more frequent intervals than traditional monitoring methods. The physiological data recorded by the body worn device is wirelessly transmitted to a patient management system for storage and display. Good correlation between heart rate values recorded by hospital staff and those recorded by the automated Vitalsens VS100 system was observed. The system has highlighted clinical information that routine observations alone did not readily identify. This can provide clinicians with a better view of the overall health status of the patient. Such medical issues include those witnessed in this study, namely paroxysmal AF, ectopic beats, increasing heart rates recorded prior to a hypoglycaemic event, general high and low heart rate trends and various instances where clinically relevant ECG data has been captured.

I. INTRODUCTION

Rapid medical developments of the 20th century have enabled people in the 21st century to have a greater life expectancy. Technology is constantly offering more efficient ways to meet the needs of the current healthcare system. An aging world population dictates that healthcare systems have to treat an increasing number of patients with various states of chronic illnesses [1]. Technology can be implemented to address the increased workload on clinical staff and hospital systems. One such area of application is the undertaking of routine medical observations. Recent miniaturisation and commercial viability of wireless monitors for in-patients offers the potential to reduce this labour-intensive practice and release staff to partake in other important strategic areas of nursing practice.

Such labour saving devices aim to offer a robust method of gathering patient observations compared to the paper-based chart approach. They promise to offer savings on costs accrued due to patient care, reduce medical errors, increase resource utilization and allow clinicians to prioritize patient care to improve clinical outcomes and time to discharge [2]. A number of products have arrived on the market in recent times with the goal of meeting the needs of modern hospital ward healthcare [3]-[5]. Some of the devices have been designed to facilitate further development of wearable wireless medical sensor applications, whereas others are primarily sold as commercial monitoring systems.

This paper reports on the completion of the first phase of an ongoing clinical evaluation of a wireless patient monitor in a busy modern hospital ward. The system was used on a range of chronically ill patients to periodically record lead II electrocardiograms (ECG), heart rate and skin temperature.

Publication of this work at this time is significant as it serves to highlight the current progress in the clinical implementation of smart devices in patient monitoring. It also communicates the promotion of the technology required for both the current and impending needs of patient management and care, since tomorrow’s world is rapidly becoming today’s reality.

II. DEVICE UNDER EVALUATION

The device under evaluation is the recently CE approved Vitalsens VS100 patient monitor from Intelesens Ltd. (Northern Ireland), who have developed a range of innovative electrode components and vital signs monitoring systems [6].

Figure 1: Vitalsens device and sensor

The product combines disposable electrodes, offering reduced motion artifact for high quality vital sign collection [7], with a reusable, miniaturized clip-on body-worn device for non-invasive vital signs monitoring. The devices are complemented with a web based tool (Canberra) developed by Intelesens Ltd. Canberra assists clinicians by providing an interface for the management of Intelesens devices and the patients being monitored using these devices. All patient data and medical trends can be viewed via a web browser. With further development and implementation into the hospital’s current network setup, Canberra and the Vitalsens VS100 systems have the potential to facilitate organized and responsive patient monitoring in a ward environment.

A. Current approach on NHS wards

The established NHS (UK) procedure is that ward nursing staff perform routine patient observations (Obs), which are fundamental to the care and treatment of in-patients and to
the response of medical staff. The regularity of these observations is dictated by the patient’s medical status, although in general the normal frequency is every four hours. Patient information recorded during a routine Obs round includes responsiveness, respiratory rate, heart rate (HR), blood pressure (BP), core temperature, urine output and blood oxygen levels (SpO₂).

During this evaluation, data was recorded by nursing staff using a portable bedside monitor and entered into an Electronic Care Record (ECR). This system uses a simple algorithm to assign each patient with a Modified Early Warning Score (MEWS) [8] relating to their current health status. Should the patient move outside of the accepted ‘safe’ thresholds for any of the parameters mentioned above, they will be given a higher MEWS score and medical staff can be alerted if required. This approach aims to provide medical staff with an earlier indication of which patients are at risk of deteriorating.

III. Evaluation Methods

The key aims of the evaluation of the Vitalsens system were to assess:

- The **reliability** of the device
- The **accuracy** of the physiological measurements
- The **feasibility** of streaming observational data at pre-definable intervals to an electronic care record
- The **robustness** of this type of approach to gathering patient vital signs / observations compared to the paper-based bed-end chart approach
- The **acceptability** to nursing staff and patients
- The **effectiveness** of the technology and the **usefulness** to medical staff
- The **potential impact** this technology could have on improving patient care and outcomes.

The proof-of-concept evaluation was carried out to a predefined protocol. Suitable patients admitted to a four-bedded bay in one of the general medical wards of the Ulster Hospital took part in the evaluation. Each patient being monitored was assigned a device and the relevant patient information was recorded using the Canberra system. Medical staff then applied an electrode to the patient and connected a device in order to begin monitoring. Devices were configured to transmit 10 seconds of ECG data, as well as heart rate and skin temperature readings every 30 minutes to a small Bluetooth-enabled netbook located at the top of the ward. In addition to this, nursing staff were asked to press the Obs Button during routine rounds in order to send this data outside of the configured times. This data was later compared with the standard bedside observations recorded and entered into the ECR by hospital staff.

The clinical characteristics of the patient population that took part in the evaluation were in-patients staying in a general medical ward. All of the patients participating were female, with the exception of one male who stayed in the normally all-female bay for a short time. The next phase of the evaluation will include a more even number of male and female patients due to the inclusion of an additional all-male bay. Patients had a mean age of 64 years with ages ranging from 23 to 94 years. Primary diagnoses of the patients varied but were largely chronic heart, chest and kidney disease.

IV. Results/Discussions

In four weeks of testing, twenty patients were monitored with 2000 hours of monitoring being undertaken. Six of the twenty patients were monitored continuously for over one week, with three being monitored for more than ten days. One representative patient (‘Patient 15’) has been selected as an example to illustrate system performance. General comments about the results from other patients are provided in the main study findings.

A. Results from ‘Patient 15’

Patient 15 was a 94 year old female who had been diagnosed with hypothyroidism, ischaemic heart disease and atrial fibrillation. The patient was monitored using the Vitalsens system for 7 days and 18 hours. Table 1 outlines the routine observations entered into the ECR by medical staff and those recorded and transmitted by the Vitalsens system. Figure 2 shows the comparison between pulse rate (recorded by nursing staff using a pulse oximeter) and heart rate calculated from the ECG signal recorded by the Vitalsens system when the Obs button was pressed. Figure 3 shows core temperature (recorded by nursing staff using an ear thermometer) and skin surface temperature recorded by a small thermistor in the electrode patch.

Analysis of the data revealed that the mean percentage error of the heart rate captured using the Vitalsens system compared with clinical observations is -11.2% with an average difference of -5.9 bpm. The mean percentage error for core and skin temperature is 3.9% with an average difference of 1.5° C. While the exact correlation between skin and core temperature is not firmly established, such offsets corroborate with [9]. It is recognised that skin temperature is not a widely used parameter in patient health status assessment; however it is believed that the method of skin temperature measurement used by the Vitalsens system may compensate for this. The electrode structure (including adhesive foam) behaves as an insulating layer and, when applied to the skin, encapsulates the temperature measurement site in a microclimate, insulated from the effects of changes in the immediate adjacent environment. This provides a buffer between the sensor and the surrounding environment which might otherwise affect temperature readings at the skin surface. The graph shown in Figure 3 provides a comparison between measured skin and core temperatures for one patient. In order to ascertain whether a strong enough correlation between these temperatures exists, the readings taken for the whole patient population will need to be considered to provide a wider overview. The Vitalsens system has the added benefit of

95
measuring heart rate and temperature at 8 times the frequency than standard observations allow, hence offering more representative biomedical data to clinicians.

Table 1

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ECG data was also measured and transmitted along with heart rate and temperature. Figure 4 shows a typical ECG recording from the Vitalsens system displaying a good example of atrial fibrillation recorded from Patient 15.

B. Results from other patients

With respect to the data recorded from the other patients that took part in the study, each patient was monitored for four days on average. In general, the system had considerable clinical impact during the four week evaluation. The use of the Vitalsens System highlighted that one patient was experiencing paroxysmal atrial fibrillation (AF) which then led to a change in the patient’s treatment and care management. This arrhythmia was only identified using the Vitalsens System and not from the routine Obs data entered into the ECR. Ectopic beats were detected on a few patients; for one patient frequent ventricular ectopic beats took place the day before they required haemodialysis. High heart rates were transmitted to the Canberra website in a patient having a hypoglycaemic event prior to ward staff detecting and confirming hypoglycaemia. While the nursing staff reacted to this in a timely and appropriate manner, it could be assumed that implementing the Vitalsens system into a monitoring environment such as this, could result in staff having a better overview of changes in patient conditions much sooner than with current monitoring practices.

ECG traces recorded from a patient with a history of chronic heart failure tied in well with expected ECG characteristics. High and low heart rate patterns and trends were easily identified and noted by the supervising Consultant, along with T wave inversion and other clinically relevant ECG characteristics. One patient was moved to the renal unit for haemodialysis and was absent from the ward for approximately four hours. The device was not removed from the patient and on return to the ward, the device transmitted the four events that had been stored to device memory while the system was out of range. This patient was essentially being monitored during the first two hours of their haemodialysis treatment, despite being at the other side of the hospital site. Before the evaluation commenced, the medical staff were advised to remove any chest hair from male patients that might interfere with the adhesion of the patch electrode to the skin. However, even with little or no skin preparation, the electrode provided excellent ECG signal quality during monitoring.
Overall, the Vitalsens system was successful in recording and transmitting physiological information that correlated well with the standard observations made by nursing staff (Table 1). Feedback from medical staff using the system was positive at this stage of the evaluation. The Canberra system required minimal input from nursing staff and their roles centred on administering the Vitalsens System at the patient’s bedside, ensuring electrode ‘health’, checking that fully charged devices are used and pressing the Obs button during observation rounds. This level of involvement was acceptable to the nursing staff using the system.

The Consultant on the ward held an active role in the initial application of electrodes and system setup for the first patients. He was also involved in the use of the Canberra website throughout the evaluation once patient suitability had been assessed. The Consultant commented positively on the high quality ECG waveforms transmitted and the wealth of additional information that these would provide in a clinical setting. The majority of patients quickly forgot they were wearing the system, even after one week of monitoring.

A. Future development

Phase 2 will extend monitoring to two bays in the hospital ward and will be capable of monitoring 10-12 patients simultaneously. This will then expand in Phase 3, when all patients in the ward will be monitored by the system (depending on patient suitability and consent) using WiFi enabled devices allowing the system to be integrated into the hospital’s current network architecture. The WiFi module to be implemented for Phase 3 is currently being trialled using Intelesens’ wireless respiration monitor. However, the current Vitalsens system can also be used in environments that incorporate Bluetooth access points if they are available. Other modifications to the system include increasing the memory capacity to facilitate longer out of range monitoring and allowing data to be retained by the device after switch off. The Canberra website is also undergoing development to provide staff with more information regarding device battery levels and leads off alerts, along with a more refined layout which should make the interface more user-friendly.

Future clinical trials will focus on providing more consistency and validity of temperature data. This can include ensuring that medical staff record core temperatures from patients using the same ear on each occasion, or ensuring that the same tympanic thermometers are used for each patient. With this information, an assessment can be made on whether skin temperature can be seen as a reliable and useful indicator of patient health status.

It is anticipated that additional physiological monitoring can be integrated into this application. This includes respiration and pulse oximetry monitoring, and use of on-board accelerometer information. There is potential for ECG algorithms developed by Intelesens to be incorporated into the system to alert staff of suspected incidences of bradyarrhythmia, ventricular tachycardia and atrial fibrillation. These select algorithms (along with others used for intelligent detection of several key arrhythmias) currently form the basis of another Intelesens wireless monitoring system [10].

V. CONCLUSIONS

This evaluation has shown that the Vitalsens VS100 system has potential to provide clinical staff with additional patient information at more frequent intervals than current practices and resources allow. The investigators are satisfied that the key aims of the evaluation have been well met. Evaluation in a live environment has provided invaluable insight into how the system can be further optimised.

The system displayed good correlation with heart rate values taken by nurses, with the added value of reduced motion artifact ECG data that is easily interpretable. The system under evaluation has demonstrated its genuine potential to be used as a clinical tool to assist clinical decision-making on hospital wards. Importantly, it picked up abnormalities which the general observations may have missed, such as paroxysmal AF, ectopic beats, increasing heart rate preceding a hypoglycaemic event, high and low heart trends, and T wave inversion. The detection of these medical problems on a small group of volunteers will now allow the researchers to focus on customised development for such a ward, thus allowing for improved smart devices. Indeed, this work serves to pave the way to full realization of automated bedside patient monitoring as a standard in efficient vital signs recording, resulting in an effective system that can bring real benefits to patients and even improve patient care and safety while in hospital.

ACKNOWLEDGMENT

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REFERENCES