Towards the improvement of patients’ safety with continuous wireless monitoring: Pilot at Saint John’s Health Center

Introduction

Currently, the majority of patients in hospital have measurements of vital signs taken manually at six to eight hour intervals. This relatively infrequent monitoring means that deterioration in patient conditions may go undetected for hours, leading to serious consequences including further treatment, re-admittance to intensive care units, or even death [1]. Different clinical studies showed that there were physiological signs of deterioration and/or at least one life-threatening event in considerable numbers of patients just a few hours before being urgently admitted into intensive care units [2,3].

Early warning scoring (EWS) systems have currently been implemented in some hospitals to attempt to alert/notify the onset of adverse physiological events: enabling medical teams to act faster and deliver adequate care to patients before the occurrence of severe complications. Although there is evidence about the potential benefits of using EWS systems [10], they are limited by the frequency with which vital signs can be practically and affordably measured by clinical staff.

Sensium Vitals

SensiumVitals™ is a wireless, wearable, FDA (510k) cleared medical device, with smart sensor interface and transceiver, aimed at the general wards of hospitals. This ultra-low power, small device is a disposable thin patch attached to patients under their clothing using conventional ECG pre-gelled electrodes.

This patch runs a number of embedded algorithms that allow continuous monitoring of patients’ vital signs (heart-rate, respiration rate & temperature) with a high degree of accuracy. SensiumVitals® wirelessly communicates this physiological information to doctors and nurses via the hospital IT system, allowing patients to ambulate freely within the hospital confinements whilst still being continuously monitored (figures 2 and 3).
As part of the hospital procedures to evaluate patients in the general ward, clinicians and nurses can set up alerts that can be sent to pagers/handheld devices and mobile phones to warn them of adverse physiological events suggesting patients’ decline. Thus, this system enables caregivers to prioritise patients based on their condition and intervene earlier in the case of deterioration. SensiumVitals® has a battery life of five days, covering the average length of a general ward stay in the hospital. The entire device is easily removed from the patient and disposed of at the time of discharge.

Saint John’s Health Center

In 2010, Saint John’s Health Center opened its doors to a state-of-the-art replacement hospital built from the patient’s perspective. Saint John’s provides the community with easy access to internationally acclaimed, academic–level medical care and the latest medical technology in a homelike environment – without having to navigate the labyrinth of a typical, large academic medical center. For example, Saint John’s Emergency Department (ED) was designed with input from local paramedics, physicians, nurses, hospital staff and others to make it more efficient and comfortable. The new ED is located directly below the Operating Rooms and Cardiac Catheterization Laboratory, adjacent to the Imaging Center and near the Diagnostic Center, so patients needing X-rays, ultrasounds, lab work or electrocardiograms are only a hallway away. To further make navigating the hospital easier, Saint John’s has combined its multiple oncology centers into a single site and moved all its inpatient beds, with the exception of the Women’s Health Department, into the Chan Soon–Shiong Center for Life Sciences (CSS).

The two buildings that make up Saint John’s – the Howard Keck Diagnostic Center and CSS – have 266 beds. The personnel comprise around 1,600 employees, 500 of which are nurses in addition to nearly 1,000 physicians on its medical staff roster. While there are more than 5,000 community hospitals in the U.S., only a handful of them can boast the academic–level care provided by Saint John’s. The Health Center’s strong community–based services combine with its internationally recognized programs to create an environment where patients can feel at ease knowing they will be taken care of physically, emotionally and spiritually.

As a cutting-edge technology hospital, Saint John’s is aware of the positive impact that wireless monitoring technology may have on the early detection of patients’ deterioration. This aspect together with the high quality of its facilities and staff made this health center the ideal choice for conducting our first SensiumVitals® pilot.
The pilot was carried out in the general ward. One hundred and sixty eight patients of different ages (mean 69.3 ± SD 19.8 year-old) and presenting with different characteristics/conditions participated in the pilot. The clinical staff involved in the pilot included the Director of Medical Surgery, Registered Nurses (RNs), Certified Nursing Assistants (CNAs), and IT Personnel.

In the current workflow at Saint John’s Heath Center, nurses (RNs and CNAs) monitor vital signs. Temperature, heart rate, blood pressure and SPO2 are monitored using conventional monitors, whereas respiration rate is recorded manually. The frequency of monitoring is established by the doctors and range between 4 to 8 hours for hospitalised patients.

Clinical Pilot

Methods

The nurses participating in the pilot were trained by super-users (i.e. RNs fully trained in SensiumVitals®): covering aspects such as the application/removal of the patch and monitoring of vital signs on the computer system. Initially, they set the alerts limits based on nursing parameters in accordance with the hospital policy.

RNs were given higher access to set the limits for patients with specific baseline vital signs that may have otherwise been outside the general pre-set (default) limits. Based on their experience, they readjust the limits in accordance to several factors such as patient’s age, gender, present condition, medical history and previous vital signs, when available.

When one or more of the patient’s vital signs exceeded the limits set in the system, notifications were generated. Such notifications sent alert messages to a pager carried by either the charge nurses or the super-users. Once the pager notification was received, the carrier of the pager called the RN to let her know that she needed to check her patient as well as the computer system to acknowledge the alert. Depending on the alert and the patient’s status, the RN or CNA would take a corroborating set of vital signs with the standard vital signs monitor used on the unit to ascertain the validity of the alert.

Super-users also logged these alerts and corroborated vital signs during the course of the pilot to aid the adjustment of pre-set parameters and alert frequencies, and hence to reduce the number of invalid/nuisance alerts (which may occur as a result of different factors such as inappropriate initial/default alerts limits, motion artefacts affecting the respiration signal, or in the case of temperature when the patient raises the arm and exposes the sensor to the environment) whilst maintaining the rate of valid alerts.

Once a patient was admitted in the ward, their assigned RN’s and CNA’s first assessed if they were eligible to wear the patch or not. In accordance to the pilot’s guidelines, patients excluded from the pilot were those:

- Presenting with allergies to ECG electrodes and/or medical graded tape.
- With pacemakers or implanted defibrillators.
- Under 18 years old.
- Presenting with an open wound at the patch’s attachment site.
Currently on telemetry

When eligibility was confirmed, patients were approached and given information regarding SensiumVitals® and the pilot. After a brief introduction and the information leaflet had been given to the patients, they were asked if they would like to be participants in the pilot. If they were in agreement, the nurse or the assistant applied the patch and added the patient to the system.

Patients were encouraged to ask questions and make comments for the duration of their stay. At the time of discharge, patients were removed from the computer system and the patch removed and disposed of in the waste bin.

Outcome measures and data analysis.

In order to establish initial conclusions about the overall performance/effectiveness of the system and other aspects such as practicality and clinical acceptance, a number of outcome measures were adopted.

First, the rate of alarms per patient per day was calculated, and its range used to identify the best and worst case scenario in the light of the maximum acceptable number of alarms before impinging the effectiveness of the system due to fatigue/desensitization. Second, we quantified the per cent of patients that gained benefit from the system by receiving opportune and rapid intervention. The latter was supplemented with a brief description of a number of cases where the system emitted notifications/alarms. Furthermore, the per cent of alarms raised by each physiological parameter was calculated.

Another important aspect considered in this pilot was the satisfaction and acceptability of the system by clinicians, nurses and patients. Therefore, qualitative instruments such as questionnaires and informal interviews were applied to gather the perceptions/feedback and key facts about the system.

Results and discussion

Notifications

It is well known that notifications that can be easily distinguished increases patient safety. However, too many nuisance/false notifications may overwhelm the clinical staff so that they become fatigued. This ‘cry-wolf’ effect causes desensitization that may lead the clinical staff to ignore some genuine notifications warning about a serious life-threatening event [5, 6]. When analysing the super-users logs it was found that, after optimising the system settings, 52.6% (20 out of 38 per month) of the notifications helped to detect deterioration, allowing timely response by nurses. A review of publications and accredited reports about others’ clinical experience with different products showed that the number of false notifications can be high, reaching up to 90% or more in some studies [5-9]. Thus, this result was deemed as satisfactory.

Users’ perceptions and feedback

All the registered nurses who were part of the pilot were surveyed during the first and second month of the pilot in order to gather their perceptions and
feedback about the use of SensiumVitals® as a method for continuous patient surveillance.

Preliminary questions targeted aspects such as ease of application/use, clinical relevance of vital signs values observed, and potential benefits of using the system. The questionnaire was applied twice during the course of the pilot – before and after the optimization of both the system and alerts limits configuration.

Figures 4 and 5 illustrate the responses of the nurses to the questionnaire. From the graphs it became evident that indicators of clinical acceptance, better performance and benefit of using the system notably increased after the optimisation period. These indicators also revealed how the level of satisfaction using the system increased as the nurses learnt to use the system and got used to it – to the point that the phrase “patching up the patient” became popular across the clinical staff operating in Saint John’s general ward.

Finally, the responses from the survey not only suggest that continuous monitoring using SensiumVitals® was considered useful (figure 6), but also that the system really helped by generating true early warnings of adverse events leading to patient deterioration. In terms of valid alerts, this reaffirms the satisfactory results described above in the notifications section of this document.

Further feedback from the nurses revealed that in some cases the system provided additional benefit to a number of patients unable to talk and others presenting with conditions such as stroke, myocardial infarction, gastrointestinal bleeding, influenza, and fever and urinary tract infections amongst others.

Case studies

There were a number of cases that illustrated how patients benefited from using the digital patch, as they received timely intervention soon after notifications were generated and delivered to the clinical staff by the SensiumVitals® surveillance system.

In this section we present three of these cases:

Case 1:

A 28 year old male was admitted on the 10/30/12 with complaints of abdominal pain, nausea, vomiting, and diarrhoea. The patient had a medical history of shoulder melanoma with excision 3–4 years ago, otherwise healthy per history and physical. Patient was patched with SensiumVitals® at 10:00 am during the same day of admission. At approximately 11:13 pm, the patient showed signs of tachycardia which increase throughout the night from 95 beats per minute (bpm) up to 127 bpm at 02:18 am on 10/31/12 (figure 7). The alerts emitted by the system warranted a call to the rapid response team. Thereby, the patient was transferred to the intensive care unit, and then underwent surgery with a resultant diagnosis of perforated proximal stomach.

Case 2:

An 87 year old male with history of metastatic cancer and recently treated with chemotherapy was admitted in the general ward on 10/11/12. The patient was diagnosed with hypotension and multifocal pneumonia at the time of...
admission. The following morning the SensiumVitals patch was applied on the patient, which reported a low temperature of 94.1 °F at 9:59 am. Later in the afternoon (at 01:43 pm) the SensiumVitals® reported that the temperature increased to 100.0 °F. During immediate observation it was noticed that the patient was shivering, and consequently the RN was notified. At 02:07 pm the SensiumVitals® alerted that temperature had further increased to 101.3 °F. At that point the patient was given with Tylenol and intravenous antibiotics. Around 4:00 pm it was observed that the temperature values were back to normal (figure 8).

Case 3:

A 97 year old female was admitted on 11/09/12 with failure to thrive, dehydration, loss of appetite, urinary tract infection and hypernatremia. The digital patch was applied to this patient the same day at 09:00 am. At 3:24 pm a high HR (169 bpm) alert was generated and then confirmed manually (i.e. by taking the pulse) at 3:25 pm. The system also alerted on high respiration rates reaching up to 29 brpm (see figure 9). Consequently, the doctor in charge was notified and an electrocardiogram (EKG) was ordered. At 4:07 pm the MD notified that the EKG results revealed atrial fibrillation with rapid ventricular response. Consequently, the patient received treatment (i.e. Digoxin), and was scheduled for manual check of vital signs every 8 hours.

Three days after, at 08:58 am, the patient generated another alert, but this time for low HR (42 bpm). Her doctor was notified and the Digoxin was discontinued. Finally the patient was referred to Cardiology Consultation.
Figure 4. Feedback from nurses using SensiumVitals® before system optimization.

Figure 5. Feedback from nurses using SensiumVitals® after system optimization.

Figure 6. Feedback from nurses about usefulness of having continuous monitoring using SensiumVitals®. The Bar plot shows the levels of agreement in this statement before and after optimising the system.
Figure 7. Surveillance plot for case study 1. Note that this example reflects the patient HR status at different intervals/times/days during his stay in the general ward. Note that HR values outside the limits (areas shaded in red) were alerted/notified by the SensiumVitals® system from onset at 10/30/2012 11:13 PM, and reached up to 127 bpm at 2:18 AM of the following day; triggering the rapid response of the clinicians and subsequent patient transference to ICU and delivery of the right treatment/intervention.

Figure 8. Surveillance plot for case study 2. In this example the plot shows the patient’s temperature status at different intervals/times during the following day after being admitted in the general ward. Note that low and high temperature values outside the limits (areas shaded in dark blue and red respectively) were alerted/notified by the SensiumVitals® system. The high temperatures reached up to 101.7 °F, but shortly decreased after the patient was given with Tylenol and intravenous antibiotics.

Figure 9. Surveillance plot for case study 3. This example shows the patient’s respiratory trends at different times since the patch was applied. High respiratory rates (area shaded in red) were notified by the Sensium vitals system on 11/09/2012 from 3:24 pm. After medical intervention, respiratory rates decreased to values below the alerts limits and improved during the following day.
Conclusions

The preliminary experience at Saint John’s Health Centre has demonstrated that Sensiumvitals® system is a valuable tool to support the clinical staff in continuous healthcare monitoring and early warning detection of adverse physiological events of patients hospitalised in the general ward.

The results obtained from quantification of the number of useful alerts, perceptions of the nurses and case studies showed the perceived value of the system and acceptance in the clinical practice.

In summary, some key benefits of Sensiumvitals® revealed during this pilot experience are as follows:

- SensiumVitals® enables early detection of deterioration – patients at risk can be treated sooner / improves patient safety.
- The digital patch is lightweight unobtrusive wireless patch is comfortable to wear and enables patients to be ambulatory – improves patient recovery.
- The system integrates well with existing clinical workflows and will be useful for generating automated patient early warning scores.

Further information

For further information about SensiumVitals® and/or the pilot, please contact us at info@toumaz.com.

References