ABSTRACT
A clinical study in a Northern Ireland hospital and clinic explored the potential clinical value of continuous Intelesens Surveillance Monitoring of patient vital signs in step-down and general wards. Patients who took part in the study were invited to describe their experiences of using the monitoring system, which includes the wireless AINGEAL device that attaches to a patch applied to the body. Among patients responding to a questionnaire, 95 percent or more found the system comfortable to wear and unobtrusive, easily tolerated removal of the patch, and said they would prefer to wear the device on a future hospital visit over not having continuous monitoring.

BACKGROUND
Patients discharged from the ICU to lower-acuity care areas can remain vulnerable to adverse events, yet typically are under periodic observation by nurses rather than monitored continuously. With reduced monitoring outside the ICU environment in step-down and general wards, sentinel events are frequently undetected, leading to complications that possibly could have been avoided. For example, there is clear evidence that changing vital signs and a period of deterioration can occur six to eight hours before a cardiopulmonary arrest. This situation can be improved by appropriate vital signs monitoring that is well accepted by patients and caregivers. Such technology enables patient vital signs information to be accurately and consistently measured, recorded, and relayed to front-line staff frequently enough to allow deteriorating patients to be identified earlier and cared for appropriately. A continuous monitoring solution can only be effective if it fits easily into clinicians’ workflow and is comfortable and readily accepted by patients.

STUDY PROCEDURE
A clinical study at the Ulster Hospital in Dundonald (South Eastern Health and Social Care Trust) and the Ulster Independent Clinic in Belfast, both in Northern Ireland, aimed to evaluate the relationship between respiratory rate and oxygen saturation in a diverse adult population in the hospital setting. Patients were continuously monitored using an Intelesens Surveillance Monitoring device and a wrist-worn pulse oximeter for up to three days during their hospital stay. Data were reviewed retrospectively, and analysis was applied to define the relationship between respiratory rate and pulse oximetry. As an addition to the study, patient feedback on device comfort, wearability and acceptability was collected. This case study looks at how Intelesens Surveillance Monitoring was received by patients that took part.

MONITORING TECHNOLOGY
The Intelesens Surveillance Monitoring solution provides health professionals with relevant and timely indicators of patients’ health. A comfortable and unobtrusive body worn monitor intelligently measures ECG and heart rate, respiration waveform and rate, and skin temperature. This information is sent via Wi-Fi to an intuitive central station platform. Clinicians can see at a glance current and previous health status, view trending information, and be alerted immediately to breaches in predefined limits for heart rate, respiration rate, skin temperature and SpO₂. (SpO₂ can be integrated with the system as an option). The limits can be tailored to suit each patient. Key cardiac arrhythmia detection algorithms are also used to notify healthcare personnel of ventricular fibrillation and asystole events.

PATIENT POPULATION
The study included 73 patients (41 male and 32 female) ages 25 to 89 years, with a median age of 65 years. Patients’ Body Mass Index (BMI) was derived and recorded if this information was available in their medical notes. Figure 2 shows the how BMI was distributed across the study population.

PATIENT EXPERIENCE
Sixty-seven of the 73 patients returned questionnaires at the end of monitoring. Patients were first asked how acceptable the system was to wear throughout their hospital stay. Ninety-seven per cent of patients found the device and electrode to be comfortable,
and found patch removal acceptable. Ninety-five per cent found the system to be discreet and ninety-nine per cent would wear the system again during a future hospital visit. Patients were asked specifically about skin irritation from the electrode patch during and after wear. No issues were presented relating to skin irritation during the study; the electrodes were very well tolerated.

97% of patients found the system **comfortable** to wear

95% found the system to be **Unobtrusive**

97% reported **acceptance of patch removal**

99% would wear the system

### Acceptability of AINGEAL Device & Electrode

<table>
<thead>
<tr>
<th>Acceptability</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Acceptable</td>
<td>50</td>
</tr>
<tr>
<td>Not an issue</td>
<td>20</td>
</tr>
<tr>
<td>Very Unacceptable</td>
<td>10</td>
</tr>
</tbody>
</table>

### Skin Irritation During & After Wear

<table>
<thead>
<tr>
<th>Skin Irritation</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>During wear</td>
<td>60</td>
</tr>
<tr>
<td>After removal</td>
<td>10</td>
</tr>
</tbody>
</table>

### What did patients value most about Surveillance Monitoring?

- Comfortable 29%
- No wires attached 16%
- Feeling of security 31%
- Small size 19%
- Other 5%

Patients were asked what they believed to be the most positive aspect of the Intelesens Surveillance Monitoring system. Most patients valued the feeling of security that they could be continuously monitored throughout their stay in hospital. They also rated very highly the comfort and convenience of not having to be attached to wires.

To investigate where potential improvements could be made to the system, patients were asked what they liked least about the system.

The majority of patients found nothing at all negative about the AINGEAL device and electrode. When asked this question, almost 10 percent of patients noted that patch removal was the least pleasant aspect. Generally however, as indicated in the previous question, patch removal was well tolerated. A few patients saw being aware of the device if they moved to lie on their left side as being negative. Some patients noted occasional mild itching at the electrode site but did not consider this to be an inconvenience. Electrode wear was well tolerated; patients reported no issues in response to specific questions on irritation.
and did not report irritation during daily visits by investigative staff.

Patients were asked if they would want to wear the AINGEAL device during any future hospital visits. Almost three-quarters of patients would want to be monitored; one-quarter had no particular preference.

**Acceptance of wearing again.**

One patient stated a preference not to wear the device again. This patient’s electrode lost adhesion during the night due to excessive perspiration.

Patients were invited to provide any additional comments relating to the device or the study. Very positive feedback was provided relating to their experiences with the AINGEAL device and electrode. Examples are provided in the table below.

<table>
<thead>
<tr>
<th>Wearing this was absolutely no problem. Respondent 5.</th>
</tr>
</thead>
<tbody>
<tr>
<td>I found the AINGEAL device easy to wear with little discomfort, even when sleeping. Respondent 8.</td>
</tr>
<tr>
<td>The AINGEAL monitor and patch were comfortable to wear. Respondent 15.</td>
</tr>
<tr>
<td>I forgot about the device while I was wearing it. It was uncomfortable when I lay on my left side, but comfortable when lying on my back. Respondent 40.</td>
</tr>
<tr>
<td>This didn’t bother me at all. Respondent 41.</td>
</tr>
<tr>
<td>The AINGEAL device was fine. I never noticed it. Respondent 44.</td>
</tr>
<tr>
<td>The patches are fine as they don’t get in the way. Respondent 73.</td>
</tr>
</tbody>
</table>

**CLINICAL OPINION**

The principal investigators of the clinical study commented on the system following retrospective review of the data recorded and the clinical cases that presented.

Dr Roy Harper, Principal Investigator, Ulster Hospital

“I have been fortunate to be involved in evaluating the AINGEAL device within a busy acute medical ward at the Ulster Hospital in Dundonald, Northern Ireland. To require in-hospital care you need to be really ill and traditional vital signs monitoring within a typical ward environment is no longer adequate to ensure optimal patient care. We need to up our game and Intelesens Surveillance Monitoring does this in a robust, reliable, effective and discreet manner. It is easily worn by patients and, while promoting mobility the device monitors key vital signs and feeds them to a central database for alerting and viewing. It is clear from our evaluations that Intelesens Surveillance Monitoring presents a clearer and much more comprehensive picture of an individual patient’s clinical status, so we can identify more problems and identify them sooner when therapeutic interventions are more likely to be effective. I can’t wait until this type of pervasive ambulant in-hospital monitoring is the norm.”

Dr Kieran Fitzpatrick, Principal Investigator, Ulster Independent Clinic

“Having seen the AINGEAL device used in clinical practice, I think there is a bright future for this solution. It is simple to use and was effective in picking up those early signs which would indicate when things are starting to go wrong with a patient. That is where a good monitor scores. It allows the clinical team to spot a patient who is starting to ‘go off’, alerting the team who can then step in to sort out the problem before the patient deteriorates.”

**DESIGN ENHANCEMENTS**

Following the study the AINGEAL device underwent iterative design reviews and enhancements to enhance patient and clinician experience and allow the solution to be practically used on a larger scale. Enhancements included more robust casing, better visual indications, a completely removable battery with a multiple-bay charging solution and the implementation of an advanced setup mode for service and biomedical users. Subsequent evaluation of the new version of the device confirmed that the changes did not impact on the patient experience. Feedback obtained from 71...
patients monitored in three different care areas provided the following responses:

- 99% found the system comfortable
- 92% found patch removal acceptable
- 96% reported no irritation during wear
- 98% reported no irritation after wear
- 96% found the system unobtrusive
- 97% would wear the system again

**CONCLUSION**

The patient feedback collected during the clinical study has provided excellent insight into patient acceptance of the AINGEAL device, electrode and overall Intelesens Surveillance Monitoring solution. Patients tolerated all aspects of the system well, reporting high levels of acceptance of earlier and current versions of the technology. Retrospective review of vital signs data in context of the patient cases that presented provided clinicians with insight into how the system would be used in the clinical setting. The benefits that Intelesens Surveillance Monitoring can bring to patients and to their caregivers were highlighted.

“I think this would improve efficiency and provide less costly healthcare.”
Respondent 55

“This is a good compact shape. It is a brilliant idea to monitor vital signs continuously. Congratulations if they are going to use these devices in our hospitals.”
Respondent 54

“I didn’t notice that I was wearing the AINGEAL once it was applied. AINGEAL is very worthwhile. Now the nurse doesn’t have to come in every 5 seconds to check up.”
Respondent 72

“I didn’t even feel AINGEAL on. One patch was itchy occasionally. This was a worthwhile exercise – there were no negatives. I felt no discomfort at all.”
Respondent 42

“This is a very feasible idea. I think it would sell well.”
Respondent 33
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