mHealth Applications in Medical Devices
How can mobile health enhance patient experience and reduce the cost of patient treatment?

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mHealth in Medical Devices

- mHealth Summit 2010: mHealth defined as “the delivery of healthcare services via mobile communication devices”

- mHealth Summit 2014: mHealth covers “mobile, wireless, digital, wearable, telehealth, gaming, connected health, consumer engagement…..”

- This focus of this talk is the application of mHealth to Medical Devices for wearable, wireless, patient monitoring

- The case study is the SensiumVitals system, which proactively notifies clinicians of patient deterioration between routine ‘obs rounds’, prompting early intervention:
  - improved patient safety
  - lower treatment costs
  - promoting clinical efficiency
UK Company: Two Divisions Share Technology & Expertise

Core skills / common technologies

- Wireless communications
- Hardware & software expertise
- RF capability
- Sensor technology
- Apps & cloud-based services
Over 20 Million Radio Modules Sold

Proven, Reliable, Wireless Connectivity
SensiumVitals - Disruptive Patient Monitoring Technology

Current Systems

Patient tethered to the monitor

Vital signs primarily taken during routine observation rounds every 4-8 hours.

SensiumVitals System

Monitor worn by the patient

Vital signs taken every 2 minutes
The Deteriorating Patient – Why?

Careful observation and appropriate action can save lives

Deterioration in acutely unwell patients can happen quickly and have catastrophic effects, so observations must be recognised as a fundamental rather than basic task.

Sepsis

For every hour’s delay in the treatment of Sepsis, the patients risk of death increases by 7.6%  

It’s estimated that 33% of bed days are taken up by patients with Sepsis in the UK  

The average cost of treating a patient with Sepsis is £10,000  

60% of deaths, cardiac arrests and unplanned ICU admissions were preceded by abnormal physiology  

11% of patient deaths reported to the NRLS were as a result of deterioration not detected or acted upon  

Action taken in the early stages can prevent deterioration progressing to cardiac arrest  

“There are always times of being short-staffed so then it’s about prioritising workload and taking obs appropriately. Some patients with delayed discharge are having regular obs when there’s really no need for that and other patients who need it aren’t getting it done.”  

[Senior nurse]
The Deteriorating Patient - What

**Pyrexia (>37.5°C)**
- Possible Causes:
  - Infection – 50% of pyrexia cases
  - High ambient temp
  - Drugs
  - Stroke
  - Myocardial infarction

**Tachypnoea (>20 Br/m)**
- Possible Causes:
  - Asthma
  - Pulmonary Embolism
  - Pneumonia
  - Acute respiratory distress syndrome
  - Anaphylaxis
  - Heart failure
  - Shock

**Tachycardia (>100 bpm)**
- Possible Causes:
  - Heart failure
  - Pulmonary embolism
  - Pneumonia
  - Acute respiratory distress syndrome
  - Anaphylaxis
  - Shock
  - Thyrotoxicosis

**Bradycardia (<60 bpm)**
- Possible Causes:
  - Myocardial infarction
  - Hypothermia
  - Hypoxia
  - Hypothyroidism
  - Hypovolaemia
  - Raised intracranial pressure

**Sepsis**
- Starts with Systemic Inflammatory Response Syndrome (SIRS) 2 or more of:
  - Temp >38c or <36c
  - Heart Rate >90bpm
  - Resp Rate >20brpm
- Plus known/suspected infection
## The Deteriorating Patient – Who & Where

<table>
<thead>
<tr>
<th>General Medical</th>
<th>Post Surgical</th>
<th>A&amp;E</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Step down from ICU / Higher acuity areas</td>
<td>• In-patient surgery - elective</td>
<td>• Patients awaiting formal medical review</td>
</tr>
<tr>
<td>• Potential for patients to readmit to CC</td>
<td>• In-patient surgery – emergency</td>
<td>• Waiting for results or further treatment</td>
</tr>
<tr>
<td>• Work closely with clinical outreach teams</td>
<td>• Complications after surgery:</td>
<td>• Waiting for an in-patient bed</td>
</tr>
<tr>
<td></td>
<td>• Haemorrhage</td>
<td>• Patient deteriorates while waiting</td>
</tr>
<tr>
<td></td>
<td>• Cardiovascular</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Infection/sepsis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Respiratory depression</td>
<td></td>
</tr>
</tbody>
</table>

### Neutropenic Patients
- Cancer/Chemotherapy
- Autoimmune Diseases
- Drug regimes
- Patient group more susceptible to infection
- Important to get antibiotics on board asap

### Elderly Care
- Increased co-morbidities
- Patient group can deteriorate quickly
- Atypical presentation more likely e.g.
  - no chest pain with MI
  - no cough with chest infection
- Less likely to raise awareness of feeling unwell
SensiumVitals® Features

- Wearable, wireless, continuous monitoring for general ward patients
  - heart rate, respiratory rate, axillary temperature
  - patient worn monitor patch
  - low cost, single patient use to avoid cross infection risk
  - FDA cleared & CE Marked

- Ultra low power device, near real-time vitals every 2 minutes, 5 day battery life
- Lightest, most unobtrusive patient monitor on market
- Clinical evidence for efficacy and cost effectiveness
The SensiumVitals System

- **SensiumVitals Bridge**
  - Connects to ADT & EMR System

- **SensiumVitals Patch**
  - Wireless Monitoring Application Screen
  - Notifications sent to handheld devices

- **MG Virtual Server**
  - Controls bridges
  - Tracks patches
  - No patient names

- **MAS Virtual Server**
  - Links patient ID to patch
  - Notifications via email / SMS
  - User interface (using https)
  - Connects to ADT & EMR System

**System Details**
- Connects to ADT & EMR System
- Wireless Monitoring Application Screen
- Notifications sent to handheld devices
## Patient Summary Screen

<table>
<thead>
<tr>
<th>Patch</th>
<th>Room-Bed</th>
<th>Patient by Name</th>
<th>Heart Rate</th>
<th>Blood Pressure</th>
<th>Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>1220 - 2</td>
<td></td>
<td>Beaudry, Serge</td>
<td>90</td>
<td>16</td>
<td>38.0</td>
</tr>
<tr>
<td>1219 - 2</td>
<td></td>
<td>Deschamps, Christian</td>
<td>98</td>
<td>17</td>
<td>36.7</td>
</tr>
<tr>
<td>1505 - 1</td>
<td></td>
<td>Gauthier, Emily R</td>
<td>77</td>
<td>14</td>
<td>36.0</td>
</tr>
<tr>
<td>1209 - 2</td>
<td></td>
<td>Lagacé, Jean-Francois</td>
<td>87</td>
<td>16</td>
<td>36.8</td>
</tr>
</tbody>
</table>
What makes SensiumVitals special?

**Measurement**

- Designed for ambulatory context
- Reliable - can reject false / spurious data, therefore fewer false alerts
- Clinical grade accuracy
  - HR very robust and accurate +/- 2 bpm
  - Temperature +/-0.2°C
  - Respiration +/- 2 Brp/m

**Connectivity**

- SensiumVitals has roaming and ultra low low power
  - roaming not enabled by BTLE
  - low power not enabled by Wi-Fi
- Connection to EMR and ADT with quick and easy bar code association

**Sensors**

- Smallest lightest patch (15g)
- Longest battery life (5 days)
- Accurate
- Uses off-the-shelf pre-gelled electrodes, rather than a fully adhesive patch
- SensiumVitals is the only player (in discreet wearables) with axillary temperature sensor
The SensiumVitals Ultra-Low Power Patch

- Weight 15g
- 5 day battery life
- 3 hours of data storage
- Uses standard ECG electrodes
- Wireless range – 10m LOS
- Showerproof (IP54)
- Disposable
- Transmits HR, RR & T every 2 mins
How we measure Vital Signs

Temperature, heart rate (HR) and respiration rate (RR) are measured and calculated in sequence, and then transmitted together at the end of every 2 minute slot.

Heart Rate
- SensiumVitals acts as a single ECG lead with 2 ECG electrodes placed on the upper torso.
- Average heart rate is calculated on the SensiumVitals® patch from a 30s strip

Respiration
- Respiration is measured by a method called impedance pneumography
- Impedance pneumography is good for monitoring sedentary respiration (patients who are not very active).
  If the patient is moving or talking the system may not display a respiration value.

Temperature
- Axilla temperature is measured using a sensor placed under the arm. Axilla temperature is accepted by most clinicians.
Challenges of Ambulatory Monitoring

• The average values of HR, RR and temperature must be calculated from the raw ECG, IP and thermistor measurements.

• For ‘clean’ signals e.g. patient simulator or resting patients, the algorithmic processing required is quite straightforward.

• Real life situations can result in corrupted signals which need to be recognised by the algorithms so as not to give spurious results.

• Signal corruptions can result from various means including mains interference, motion artefact (ambulatory patients), leads off, or incorrect electrode application.
Motion Artefact - ECG

![ECG preprocessing](image)

- **High-pass**
- **Low-pass**
- **Osea output**
Irregular Signal - Respiration

With Mobile Phone: Good Agreement

With Mobile Phone: Rejected RR

Good Signal

Poor Signal
Confidence Indicator

- The aim of the CI is to indicate whether the value reported from the algorithm is a reliable value (i.e. ‘good’ signal).

- If the CI indicates that the value is NOT reliable, an ‘invalid signal’ flag is raised and no value is reported.
Ambulatory algorithms – using “Confidence Indicators”

Input signal → Signal Conditioning → Physiological Event Detection

Noisy and/or Irregular Signal?

Yes → Classification Stage

No → Vital sign value & statistics of noise and regularity

“INVALID” Reading

Report Vital Sign Value
### Sensium Algorithms – summary table

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Range</th>
<th>Accuracy</th>
<th>Precision</th>
<th>Robustness</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR</td>
<td>30-200 bpm</td>
<td>± 2 bpm – with artificial and real data</td>
<td>1 bpm</td>
<td>&gt; 99% success rate reporting valid HRs.</td>
</tr>
<tr>
<td>RR</td>
<td>5-60 brpm</td>
<td>± 2 brpm with artificial data and less than ± 4 brpm with real resting data</td>
<td>1 brpm</td>
<td>&gt; 90% success rate reporting valid RRs from ambulatory (motion) and resting data.</td>
</tr>
<tr>
<td>Temp</td>
<td>32 - 44 ºC</td>
<td>± 0.2 ºC</td>
<td>0.1 ºC</td>
<td>Rejection of abrupt temperature changes that are not physiological in nature</td>
</tr>
</tbody>
</table>

HR and RR algorithms were evaluated with more than 1000 episodes of artificial and real physiological signals from patients and healthy volunteers.
Clinical Trials: Accuracy

• Objective
  – Evaluation of the accuracy and performance of the patch against a widely-used monitoring device (Philips MP30)

• Location
  – St. Mary’s Hospital (part of Imperial College NHS Trust)

• Patient Demography
  – Post-operative patients (20)
  – Challenging Clinical Conditions (41)

HEART RATE:
Mean difference -1.1 ±3.9 BPM with confidence interval of 95%

RESPIRATORY:
Mean difference 0.206 ±3.14 BPM with confidence interval of 95%
Patient Trials: Clinical efficacy and health economic evidence

Clinical benefits

• 168 patient study at Saint John's, Santa Monica
• Condition of 12% of monitored patients deteriorated between routine observation rounds, and were captured by SensiumVitals®
• Proved the need for SensiumVitals® on general med/surg wards for earlier patient treatment & improved outcomes

Health economic benefits

• “There is strong, unambiguous evidence that SENSIMUMVITALS™ System is cost effective” Dr S. Eapen, Analysis Group Inc, Boston
• Patient length of in-hospital stay was reduced by an average of 4 days, with overall treatment saving of over $5,500 per patient ($9,000 & 6 days per patient for a subset)
• Potential for total savings of around $200,000 annually per ward
• Deployment across NHS could save over £1 billion

*Health economic study by Analysis Group Inc, matched monitored patients to a control group of 18,279 patients, by diagnosis and age, sourced from OptimumCare & Medicare databases.
• 28 year old male presented with abdominal pain, diarrhoea and vomiting – admitted & patched at 10am

• Later that day at 11.13pm patient demonstrates tachycardia rising from 95bpm to 127bpm at 02.18am

• The system notifications & ability to track the rising trend enabled a rapid response team to be deployed

• The patient was transferred to ICU & underwent surgery for a perforated proximal stomach
• 87 year old male patient admitted who has recently undergone chemotherapy

• Diagnosed with hypotension & pneumonia on admission

• The patch initially recorded a low temperature, but later sent a notification that the temperature had increased to 100 degrees F. When checked the patient was shivering.

• As the temperature continued to rise to 101.3 degrees F the system sent another notification, he was prescribed IV Antibiotics & Tylenol

• 2 hours later the patients temperature could be seen to reduce
97 year old female admitted with dehydration, UTI, loss of appetite and hypernatremia

Patch applied at 9am, at 3.25pm high respiration rates were detected, up to 29 brpm and notifications sent. The system also detected a high heart rate spike of 169 bpm

The doctor in charge ordered an EKG for further analysis, this revealed atrial fibrillation with rapid ventricular response

The patient was prescribed Digoxin & referred for further cardiology consultation
SensiumVitals System Benefits

**For the Clinician**
- Real time, early detection & warning of patient deterioration with trend
- Provides information where you need it - at the nurse station or web enabled device
- Integrates with existing workflow without customisation

**For the Hospital**
- Improved patient outcomes - improved patient satisfaction
- Reduced length of stay (bed days) and treatment cost
- Quick and easy to install, paperless connection to the hospital’s ADT and EMR

**For the Patient**
- Comfortable, lightweight, non-intrusive, wearable patch
- Reassurance of continuous monitoring, 24/7 throughout the patient stay
- Total freedom of movement
References

1. Nursing Times Deteriorating Patient Supplement

2. NHS, National Patient Safety Agency (November 2007) Recognising & responding appropriately to early signs of deterioration in hospitalised patients

3. Patient Safety First, Prevent Harm from Deterioration (2008)