

» BIOSIGN: DESIGN OF NEW TECHNOLOGY FOR MONITORING ACUTELY ILL PATIENTS

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The first and most important criterion to consider when designing new medical technology is whether or not it will fulfil an *unmet* clinical need. BioSign is a new system, designed by Professor Tarassenko and his research group in the Department of Engineering Science, which addresses the *unmet* needs of the acutely ill hospital patient who suddenly deteriorates.

Every day, patients die unnecessarily in hospitals. In the UK, the National Patient Safety Agency (NPSA) reported this summer that the most important action which could be taken to improve patient safety was “to identify patients who are deteriorating and act early.” Similarly, in the US, the Institute of Health Improvement (IHI) recently made the deployment of teams able to respond to patient deterioration the main priority in its 100,000 Lives campaign. There is increasing evidence

that early detection of patient deterioration, followed by appropriate action, not only reduces preventable deaths but also reduces the numbers of heart attacks or unscheduled admissions to intensive care. Reports in the literature suggest that failure to respond to patient deterioration promptly and appropriately leads to increased morbidity and mortality, increased requirement for intensive care and elevated costs.

In today's hospitals, NHS patients are stratified according to their needs, from Level 0 to Level 3:

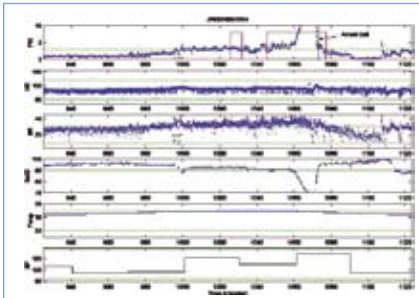
- **Level 0:** Patients whose needs can be met through *normal ward care* in an acute hospital.
- **Level 1:** Patients at risk of their condition deteriorating, or those recently relocated from higher levels of care, whose needs can be met on an acute ward with

additional advice and support from the critical care team.

- **Level 2:** Patients requiring more detailed observation or intervention including support for a single failing organ system or post-operative care and those ‘stepping down’ from higher levels of care.
- **Level 3:** (Intensive Care Unit – ICU) Patients requiring advanced respiratory support alone or basic respiratory support together with support of at least 2 organ systems. This level includes all complex patients requiring support for multi-organ failure.

The trend of keeping patients out of hospital if at all possible will accelerate, and so, in future, patients who do come into hospital will be much sicker than in the past. They will therefore be more likely to have adverse events, and will require more vigilance.

Why is patient deterioration so often missed? All level 2 patients (high-dependency unit, step-down unit or coronary care unit) and some level 1 patients (upper end of general ward) are continuously monitored but they are only observed by the nursing staff every few hours. Patient monitors on a ward generate hundreds of false alerts every day (86 out of every 100, according to an MIT study) and so their alarms are mostly ignored by the nursing staff. BioSign is the first system to eliminate the problem of false alerts and provide reliable, early warning of patient deterioration through its unique, patented technology for signal integration (also known as data fusion). After an original development trial in Oxford, BioSign has recently demonstrated its clinical



200 minute BioSign monitoring prior to a cardiac arrest call. Heart Rate and Blood Pressure remain normal throughout the period. Temperature gradually increases. More significantly, the Breathing Rate increases rapidly, indicating shallow breathing. This increase, together with dip in oxygen saturation (SaO_2), first triggers the BioSign alert 50 minutes before the arrest call.



BioSign display at the time of an alert: the five parameters are the respiratory rate (RR), the blood pressure (BP), the oxygen saturation level (SpO_2), the heart rate (HR) and the skin temperature (temp). The pie chart indicates that the most abnormal parameter is the respiratory rate (in yellow), followed by the heart rate (in grey).

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effectiveness in a step-down unit and high-dependency unit in two major clinical trials in the US.

BioSign provides early warning of patient deterioration from the five standard vital signs (heart rate, respiration rate, body temperature, oxygen saturation and blood pressure), which it fuses into an index of patient status: the BioSign Index (BSI). The data fusion model is a probabilistic model of normality in five dimensions, previously learnt from the vital sign data acquired from a representative sample of high-risk adult patients. The model of normality stored in BioSign is used to evaluate the probability that the vital sign parameters acquired from the patient being monitored can be considered to be normal, with respect to those in the training data set. An alert is generated whenever the vital sign parameters are abnormal enough to be outside the 'envelope of normality' and cause the BSI, whose value increases with abnormality, to cross the alerting threshold.

In Phase I of a 1,000-patient trial recently completed in a 24-bed step-down unit (SDU) at the University of Pittsburgh

Medical Center in the US, BioSign was used purely for data collection, and the data fusion algorithm was evaluated retrospectively to investigate whether the BSI could predict the intervention of the UPMC Medical Emergency Team (MET).

During the 8 weeks of Phase 1 (corresponding to 332 patient admissions and 18,000 hours of monitoring), MET activation occurred on 10 occasions (4 respiratory, 2 cardiac, 1 mixed respiratory + cardiac, and 3 other [1 chest pain, 2 acute mental status change]). All 7 MET events of respiratory and/or cardiac cause were detected by BioSign in advance. The mean advanced detection time prior to MET activation was 6.33 hours, demonstrating that data fusion can provide early warning of patient deterioration. During the same 8-week period, there were only 1.6 false alerts per 100 hours of monitoring, i.e. a false alert rate of 0.38 per patient per day.

During Phase III of the same trial, BioSign was used to manage the SDU patients and to trigger the intervention of the Medical Emergency Team.

The number of critical events indicating serious physiological deterioration fell to 0.197 per 100 hours during this phase (BioSign driven patient management), in comparison to Phase I (data collection only) when it was 0.608 per 100 hours, i.e. a greater than 3:1 reduction as a result of the clinical staff intervening early in response to BioSign alerts.

BioSign has the potential to change the way that healthcare for acutely ill patients is delivered in hospitals. The assignment of patients to the "optimal level of care" on a real-time basis using data fusion will lead to lower costs (shorter lengths of stay in hospital, fewer unscheduled admissions to ICU) and improved patient outcomes (fewer adverse events such as cardiac arrests or unexpected deaths).

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