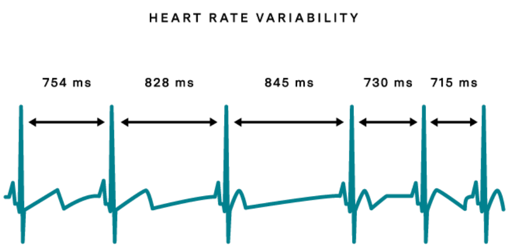
Continuous Physiological Data Storage – The new standard for patient surveillance

Submitted by Randall Bardwell

Monitoring a patient in the ICU is a challenge given the real-time nature of physiological signals. Most high-acuity patient monitors will save 24/48/72 hours of "full-disclosure data" which typically includes all of the live waveforms, trend data, alarms, and discrete parameter data. The data from the distal patient monitor is typically interfaced to a central station/server, which is then stored in a SQL/SQLess database and linked via UDP and TCP/IP to inbound and outbound servers for HL7, FHiR, LIS, etc. This is where granular data is kept for searching alarm records and limited data mining. Storing parameter data, even genetic markers can be stored in a SQL or SQL-less environment. Storing waveforms, however, of any type, be it ECG, EEG, SPO2, respiratory, etc. are more difficult, because they are continuous, and to some degree, need to look attractive to the clinician who is reviewing them. Waveforms are important not only for clinician review but also to be able to "feed" clinical AI algorithms with quality data to be able to ascertain cardiology wave-shape classification and to be able to "see" fiducial points (markers) on the ECG QRS complex.



For instance, one of the most popular clinical predictive analytics algorithms looks at heart-rate variability (HRV) and converts to a positive predictor of sepsis[1]. The algorithm was first commercialized by Dr. Randall Moorman as the "CoMet" protocol[2] to prognosticate sepsis development in pediatric patients. Apple watches use a similar, but more specious algorithm in the Apple watch to prognosticate atrial fibrillation from heart-rate variability. To determine HRV, you only need to know where the R wave is in the QRS complex and measure the delta between consistent R-waves. It is a measurement over forty years old and was developed on the first retrospective Holter Systems. Even a Fitbit can generate HRV, but is not as accurate as having your own R-wave detection and conversion algorithm generated by a composite beat with a dedicated analog front-end (AFE) and appropriate filtering to filter out artifact as well as aberrant beats before applying an eight or 16 beat sliding scale for the actual heart rate digit measurement.

Most clinical people are familiar with a 12-lead ECG/EKG which is ten seconds long. An ambulatory ECG, or Holter recording can be 24/48/72 hours long. On the other hand, continuous patient monitoring stores every second of every waveform, parameter, and alarm events. It was first brought onto the market in 2005 by Excel Medical.

The Science: Excel Medical "Bedmaster" product was the first to fill the void in providing not just alarms strips, and high and low heart-rate and parameter excursions. Originally, ten years ago, you needed a niche "black-box" product to be able to store and export continuous physiological data and alarms, to be able to play back and forth like a video tape recorder. In fact, the "BedMaster" product (a name chosen by an engineer if there ever was one :), was the first product to be able to export waveforms, a task easier said than done. To understand the market drivers, you have to first go back in time to when the export of continuous patient data was impossible.

History: Forty years ago at a small but influential company in Milwaukee, Wisconsin USA, called Marquette Electronics, a man by the name of Dr. Richard Crane invented a data transfer format for propagating ICU patient data over a network. Richard Crane, PhD, was the VP of engineering at Marquette Medical Systems. The year was 1985, and GE had just acquired the patient monitoring line from GE Medical Systems which included what was the predecessor to the GE Solar line of high-acuity patient monitors, which were only recently discontinued after thirty years on the market.

Dr. Crane invented a UDP data packet technology that would allow the transfer of up to eight waveforms that generally was assigned to three ECG channels, for posterior, lateral, and anterior lead coverage, i.e., (II, aVF, V5) as well as SPO2, respiratory and invasive blood pressure waveforms. The "Unity Network" protocol, as it was very successfully marketed, also carried all of the parameter and alarm data. Given the low sampling rate of physiological waveforms (1Khz for ECG, 150 Hz for pressures), it did not take a great deal of network fortitude to export up to 200 patients at a time on a conventional HP DL360 server. Over time, both GE and Philips launched their own high-speed continuous data feed. GE's interface is called Carescape and Philips interface is the PiiC iX.

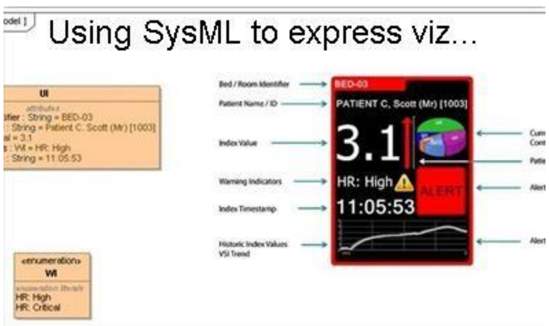
Today's continuous patient monitoring market

"Continuous patient surveillance" as it is called became a popular topic after a company called OBS Medical created the Visensia Safety Index[3] - is a clinical predictive algorithm (not AI or ML based, BTW) that has an amazing 86% positive predictive score for being able to tell you is a patient is going to "code" or fail with a six-hour predictive window.

Clinical predictive analytics protocols of course, are nothing new. The Multi-Warning or MEWS[4], as well as the peds variant, the Pediatric Early Warning Score[5] has been in use for years with manual data input for decades. Cerner started selling the Rothman Index[6] a decade ago, with its automatically-captured measurements including parsed nursing notes, so the concept of natural language processing or Spark NLP in healthcare[7] has been around for a while as well.

Unfortunately, the market for enterprise-wide clinical predictive AI hasn't ended up as being as transformed as are the clinical imaging platforms, in terms of market success, as interfaces for discrete physiological signals are more difficult to subject to AI, as you must first normalize them and clean up the data prior to digitization. In the hospital ICU model, that is the role of the patient monitor. This is always a case of "you get what you pay for", as you can't expect a Fitbit to be able to provide as accurate of heart rate variability data in an ambulatory environment with zero patient preparation. The analogue front-end of a patient monitor can use DSP or digital technology to filter raw signals which at least require a second microprocessor core to provide co-processing functions for digital filtering. Multi-lead monitors have more data and more computer resources as well. So enterprise systems provide obviously cleaner data for use in analytics.

The future of physiological clinical prediction algorithms



Visualizations: One of the most important jobs of the clinical algorithm visualization methodologies is the ability to communicate that information to the clinician in an intuitive manner. While there are many books on the subject of data visualization, creating viz's for clinical AI visualization require more fore thought with regard to relevance or contribution index as the OBS Medical example to the left shows with their pie chart.

Methods of conveying clinical predictive algorithms: The example to the left also shows that same OBS Medical algorithm visualization expressed in terms of SysML. Indeed one of the greatest problems of clinical predictive analytics in enterprise settings is their cost which is a function of their narrow scope. By employing container technologies in the cloud such as Kubernetes, the same clinical data platform (WAVE[10]) can be used to monitor various feeds to provide multiple feeds for a graph-database[11] data-lake environment. The entire algorithm, parameter feed, visualization object and feed can be represented in SysML thus providing algorithm portability.

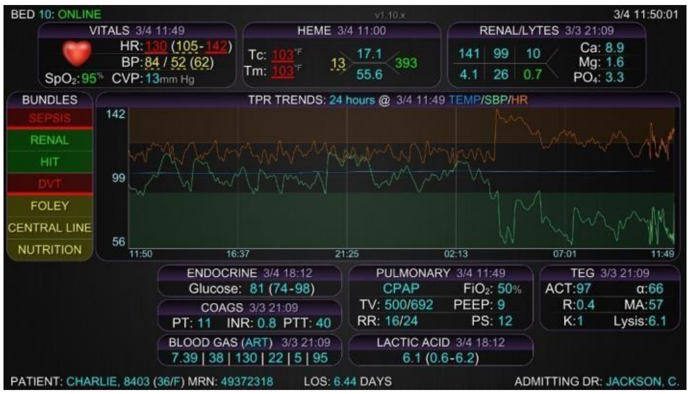
Intuitive Interfaces: Unscrambl.ai has a new intuitive AI interface called Qbo that allows your clinical predictive system to respond to human-like textual or voice queries. The cloud or edge interface can take the algorithm-derived visualizations and broadcast those to wearable devices or patient monitors.

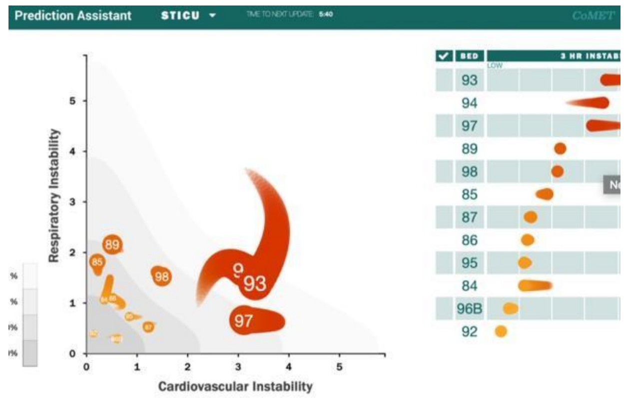
New Transport Protocol: Part of the Bionet project is to also design a secure, extensible physiological transfer protocol to replace the existing HSDI protocol and the not-ready-for-prime time yet IHE real-time waveform protocol.

New Visualization Technology: Using Unity 3D and other streaming 3D platforms for visualization will provide the ability to display large amounts of data for specific conditions using 3D and Augmented Reality to view a patient's viz and any associated trends and records. Similar to what Decisio health is doing from a display perspective.

APPENDIX:

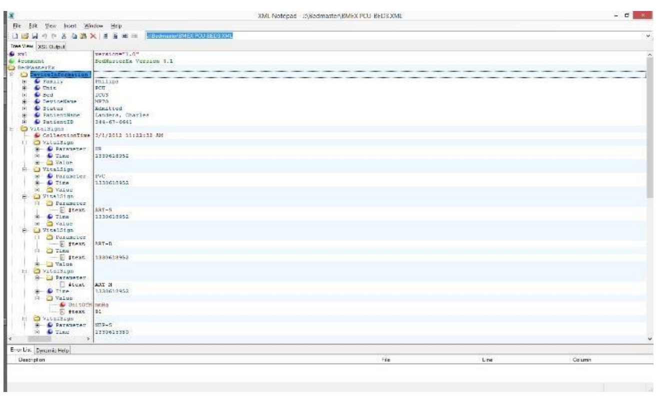
1. Decisio Health DRG specific data display (left) and CoMet Score (right):





The concept is to display specifically the relevant, salient, important clinician chosen data **2.**

Example: HSDI XML file screen grab:



waveforms are stored as signed integers in q2 second snippets.

The data is converted to high-speed XML which both Philips and GE call "HSDI" for high-speed digital interface data which is typically aimed at an AWS ingestion engine with Kinesis to break down the HSDI data to heart-rate variability (HRV) for the tired, but effective [HRV algorithm]() for sepsis determination algorithms and the HRV to atrial fibrillation correlation algorithm, such as the one that the Apple Watch employs. The problem with HSDI data is that it is XML, and is neither secure nor lightweight, so is always passed via an edge-server in an anonymized format to fulfill HIPAA compliance.

Appendix:

1. HRV to Afib correlation algorithm (link)
2. Dr. Randall Mooreman CoMet Protocol (link)
3. OBS Medical The Visensia Safety Index (link)
4. Modified Early Warning System (MEWS) (link)

5. Pediatric Early Warning Score (PEWS) (link)
6. Rothman Index (link)
7. Natural Language Processing for Healthcare (link)
8. Kubios HRV algorithm – www.kubios.com
9. Unscrambl.ai Qbo intuitive interface (link)
10. WAVE – Excel Medical (now ~~Hillrom~~, Baxter)1st FDA 510K cleared platform for clinical predictive analytics (link)
11. Graph Database (link)
12. Decisio Health (link)