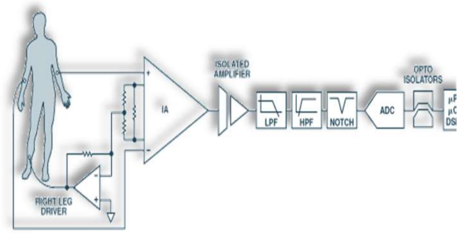
Clinical Predictive/Surveillance Scores: Past, Present, and Future

The world has embraced consumer clinical devices for some time now - the Apple watch being the latest example of consumer fascination with technology-based self-diagnostic tools. The advent of the Analog Devices AD620 low-noise, high-gain operational amplifier thirty years ago meant it was now possible to build very small amplifiers well-suited for physiological applications, such as ECG, EMG, and EEG, with just a handful of components. It wasn't long until simplistic single-lead ECG devices flooded the market with various incarnations of this hardware, except now it has been updated to include some simplistic measurement tools and filtering. It wasn't long until someone figured out that you could couple the ECG to Bluetooth and the consumer ECG industry was born. But ECG capture specifications are not all created alike, and in the hospital an ECG/EKG means a 12-lead. A single-lead ECG leaves lot of data on the table.



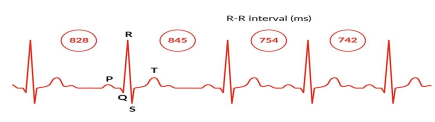
The ubiquitous AD620 ECG schematic

Early predicative algorithms for medicine included the Early Warning Score (EWS) with its many permutations that were an early attempt to view multiple parameters to identify patterns in five par. Next the Rothman Index added the concept of searching structured parameter data along with non-structured nursing notes which at one time was considered the new frontier of clinical data mining.

Small snippet of XML file showing signed-integer representation of waveforms and man-readable data.

In 2005, after leaving Marquette Electronics (now GE Medical), Dr. Richard Crane, (retired) wrote a small piece of software for GE Unity patient monitoring network. , small piece of software that would open up the live UDP packets and extract data including waveforms, which is converted to XML. The GE Carescape connects to the patient monitoring network, converting up to 200 patient beds into 2-second streaming XML in a protocol called high-speed data interface (HSDI). It should be noted that each of the bedside monitors requires its own streaming license (~$1K). Philips has a nearly identical system called PIIC six that outputs a similar system that outputs an XML file (as exampled on the right).

R-R Interval



The advantage this provides is the ability to import waveforms in a signed-integer format. ECG waveforms especially provide a great deal of promise for discovery. Heart Rate Variability (HRV) computation is easy to accomplish, as it has been analyzed for approximately 40 years in 24-hour ambulatory monitoring (Holter" monitoring). To determine heart rate variability, first identify the tallest peak on the QRS complex, which is typically the R-wave; measure the time between beats to find the R-R interval. To get a high-resolution HRV report, one may use open-source software such as Kubios. From there, one may use a separate AI algorithm to help identify episodes of atrial fibrillation. Those who have studied the Apple watch AFib algorithm, such as this cardiologist, say that it is fairly accurate in older subjects but that the positive predictive value of the Apple watch AFib drops to approximately 40% for individuals under the age of fifty. This product has set the entry-level consumer health device expectations and price-point as well as the acceptance of algorithm-interpreted clinical data.

Kubios HRV Report

Thus far, everything previously discussed could be filed under "heart-rate variability and sepsis-into-AFib detection" category of predictive analytics, which makes up the majority of today's FDA-cleared analytics on the market. Beyond HRV, the concept of incorporating other clinical parameters has been implemented successfully at OBS Medical where their "Visensia Safety Index" boasts an 85% positive predictive value for identifying patient deterioration which, for an in-patient, translates to whether a patient will "code" or needs to be resuscitated. The interesting story behind the Visensia Safety Index is that their algorithm came out of an Oxford University study of failure analysis modes in the Rolls-Royce jet engines. OBS Medical translated the algorithm into one that can process five vital sign parameters as inputs. The algorithm uses ECG only for R-wave-triggered heart rate variability and also incorporates other parameters including SPO2, NIBP, and body temperature.

OBS Medical Visensia Safety Index

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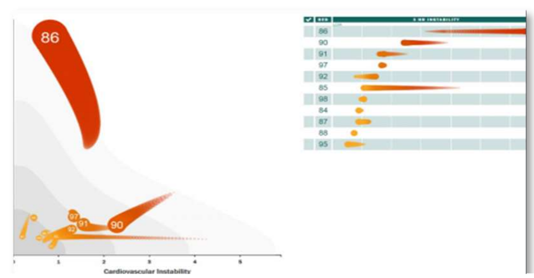
There are six generations of clinical predictive clinical algorithms:

- Algorithms that analyze electrocardiographic rhythm and morphology data to feed into non-AI or non-ML algorithms such as ECG self-interpretation programs.
- Early MEWS/PEWS/EWS (Early Warning Score) were attempts at looking for clues in the data.
- Rothman Score parsed nursing notes for unstructured data in conjunction with vital signs.
- Heart rate variability into AFib detection algorithm for sepsis or general patient deterioration on a high-acuity/inpatient basis.
- OBS Medical multivariate predictive algorithm using ECG (for HR only) , SPO2, temperature, and NIBP.
- Waveform variability based algorithms including Dr. Andrew Seely's WAVE protocol that analyzes variability in the expired CO2 respiratory waveform patterns to determine if a patient will pass spontaneous breathing trials which are required to be weaned from a ventilator.
- AI/ML-based algorithm employ wave-shape analysis of the ECG QRS morphology (waveform structure) ECG measurements rather than simplistic heart rate calculated from R-wave only. These AI measurements (such as ST segment amplitude and slope) can be used to create algorithms to predict heart attacks.

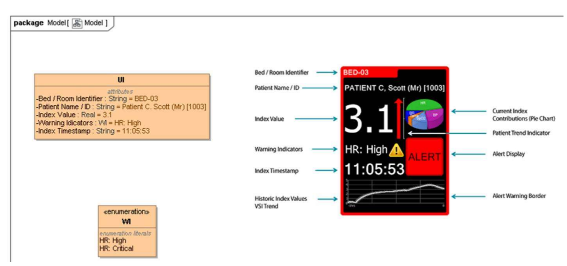
The current state of the art in cardiology AI is still advancing and is limited to single-lead AFib prediction such as the algorithm created by Cardiologs in conjunction with Apple for the Apple watch which performs the AFib algorithm using Edge AI.



CoMet Score

Visualization: One of the difficult aspects of creating an algorithm is to concurrently design what needs to be an instantly discernable visualization object, preferably with some values and reasoning statements. These visualizations will often need to go beyond the custom capabilities of most BI programs such as Power BI and offer the ability to create a dynamic 3D objects such as the CoMet score, created by Dr. Randall Mooreman. The CoMet score is a sepsis prediction tool for the NICU.

Object-Oriented Algorithms: One of the difficulties in using predictive surveillance algorithms is that there are many of them. The patient monitoring system must be programmed to out to a specific, singular instance of an algorithm at a particular port and IP address. One way to encapsulate both the algorithm and the visualization object is Unified Mark-Up Language. UML provides a method of sharing these algorithms and visualization objections together, allowing them to be shared via a community.



Current dynamic clinical data transport protocols include:

MFER ISO/TS 11073-92001 – Used by Nihon Kohden in their PM data export systems, otherwise no commercial users.
MQTT – Message Queing Telemetry Transport. More of an IoT transport protocol, but secure.
"X73" or ISO 11073 Use is non-existent probably due to lack of real-time waveform support.
XMPP – Extensible Messaging and presence protocol: "pub/sub"
XML – The current method de rigueur. Of high-speed data interfacing (HSDI)

The current project at hand is to create all of the above:

1. A headless miniaturized patient monitor to capture diagnostic-quality data and stream to the cloud as well as to an app.
2. A new algorithm to make use of special parameters that PICSI can provide in an ambulatory setting for general surveillance.
3. A new transport protocol for high-speed medical IoT data: secure, lightweight, cool acronym (kidding)
4. A new visualization object to coincide with the algorithm.
5. A new use of UML to store both the algorithm and the visualization object making them portable.

The mission is to capture the data parameters and waveforms from the device store them in SQLite with the other parameters such as SPO2, NIBP received from BT, encapsulate in a continuous-feed protocol sent securely to the cloud where they are processed into reports and a visualization object that can be sent back to the device/user.