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# Implementing Real-Time Clinical Decision Support Applications on OpenICE: A Case Study Using the National Early Warning System Algorithm

David Arney, Yi Zhang, Julian M. Goldman
MD PnP Program, Massachusetts General Hospital
*Cambridge, MA 02139*
{darney, yzhang134, jmgoldman}@mgh.harvard.edu

Barbara Dumas
Qualitypark US
*Newton, MA 02465*
barbara.dumas@qualitypark.us

***Abstract*—This paper presents the design and implementation of a software application, called MEWS, that implements the Royal College of Physician's National Early Warning (scoring) System on the OpenICE interoperable platform. The MEWS app, as a real-time clinical decision support (RT-CDS) application, does not require the use of an Electronic Health Record System to support its operation. Instead, it is able to receive patient vital sign measurements from any patient physiological monitoring device connected to OpenICE, irrespective of the device manufacturer. Based on the received vital signs, MEWS calculates an overall score indicating the monitored patient's current status and is intended to direct clinicians to patients showing signs of deteriorating conditions and hence needing immediate intervention.**

**The implementation and deployment of the MEWS app on OpenICE presents a preliminary step to understand the challenge of establishing (data) interface protocols to enable medical device interoperability generally, and for RT-CDS applications in particular, and to establish requirements for bridging the gap of current industrial standardization activities in addressing this challenge.**

***Index Terms*—Interoperable medical system, data interface, real-time clinical decision.**

## I. Introduction

Interoperable medical systems (IMSs) constitute a special class of medical cyber physical systems (CPSs), in which medical devices (sensors and actuators), medical software applications (apps), and other supporting equipment are coordinated to fulfill a shared medical purpose (typically defined by certain medical apps). To achieve interoperability, devices, apps, [1] and equipment in an IMS exchange information (contextual, clinical or operational) with each other, and make use of such information to provide safer and more effective patient care [1].

However, the innovation and adoption of IMSs have fallen far behind expectations and healthcare needs, partly due to the fact that most medical devices currently on the market have not been designed to interoperate: these devices either lack communication capabilities or utilize proprietary communication protocols that are only supported by devices from the same manufacturers. These approaches do not provide the comprehensive capabilities necessary for safe device integration, data communication, and medical device control for the care of a single high-acuity patient.

To overcome this hurdle, it is crucial for the healthcare industry to establish ecosystems, in which 1) stakeholders share standardized terminologies for specifying medical device meta-models and data interfaces, which not only allow vendors to unambiguously specify the information expected to transmit across the boundary of their products, but also support others to correctly interpret and utilize such information; 2) stakeholders are clear about their responsibility in assuring the conformance of their products to the specifications [2].

Some example industrial ecosystems, such as ORnet [3] and ICE Alliance [4], have been organized to allow manufacturers to collaborate in building shared, reusable assets (including device meta-models, data interfaces, and shared interoperability architectures) that support rapid system development approaches aligned with a particular architecture.

Given that the existing ecosystems are loosely organized, much work needs to be done to further improve the cooperation of manufacturers and standardize data exchange of interoperable devices and equipment.

In particular, medical device manufacturers need to provide sufficient disclosure of the data transmitted across the boundary of their products. Such disclosure should include information regarding the format and semantics of input and output data, as well as the expected quality of such data. The device might also need to include its operational status as part of its output to allow other components in the system to ascertain what mode the device is in and whether particular operations are enabled.

Disclosing device output data in a standardized way provides other manufacturers and system integrators enough information about the device to be able to tell whether it is compatible with a particular intended use. An interoperable

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[1] It is possible that a software application, either standalone or running on an interoperable platform, is a medical device, as known as Software as Medical Device (SAMD).

infrastructure must, in addition to providing quality network services to transmit information within an interoperable system, monitor the availability, quality and compatibility of exchanged information to enable adequate performance for the intended clinical use. Emerging medical device interoperability standards, such as AAMI/UL 2800-1 [5], call for standardized disclosure and sharing of device data, but details of implementation are outside of the scope of these standards.

The paper describes the implementation of a MEWS (Modified national Early Warning System) as an interoperable, open-source real-time clinical decision support (RT-CDS) app on the OpenICE platform [6], which serves as a case study to allow us to investigate the potential limitations of existing clinical terminologies, such as IEC 11073-10101 [7], in capturing essential information needed for enabling medical device interoperability in clinical settings such as acute patient care. Lessons learned from this work might also lay down the foundation of requirements to improve existing clinical terminologies related to the identification and standardization of clinical information, so as to ensure safe and effective medical device interactions.

The rest of the paper is organized as follows: section II provides brief background information of MEWS and OpenICE; details of designing and testing the MEWS app are described in section III; lessons learned from implementing the MEWS app are summarized in section IV; and section V concludes the paper.

## II. Background

**MEWS**. RT-CDS apps could facilitate improvement of patient care through capabilities such as automatically presenting applicable clinical practice guidelines, hosting physiologic closed loop control algorithms, delivering sensitive and specific clinical alarms, and recording all data in a clinical "black box" recorder. [2] Automating assessment algorithms like MEWS allows for patients to be assessed more frequently than caregivers can do manually, and connecting the algorithm to a continuous data source like OpenICE, where data is typically reported once per second, allows catching transient changes.

Rapid transient changes in vital signs may indicate patient decompensation and the onset of more serious problems. When algorithms like MEWS operate on data from EMRs or manually collected data, they receive updates at frequencies ranging from once per 15 minutes to once every four hours. Consequently, many changes in vital signs, for example transient drops in oxygen saturation, are not seen by the MEWS algorithm.

The MEWS method was first proposed by the Royal College of Physicians (UK) in 1997 under the name of NEWS (National Early Warning Score system) [8] and later updated [9] in 2017, with the goal of driving the "step change" required in the assessment and response to acute illness. A score is allocated to each of six physiological parameters – namely respiration rate, oxygen saturation, temperature, systolic blood pressure, heart rate, and AVPU – where the magnitude of the score reflecting how far the parameters vary from the norm. Patients with low scores can continue to be monitored normally, those with elevating or high scores should be attended to appropriately. Many clinical studies have demonstrated that the MEWS method enables early detection of patient physiological deterioration, and hence is beneficial for improving clinical outcome for the patients [10], [11].

[2]A standard for the ICE data recorder is under development by the AAMI Interoperability Working Group.

TABLE I
Scoring Respiratory Rate in NEWS

| Respiratory Rate | Score |
|---|---|
| $\leq 8$ | $+3$ |
| 9 - 11 | $+1$ |
| 12 - 20 | 0 |
| 23 - 24 | $+2$ |
| $\geq 25$ | $+3$ |

MEWS can use physiological measurements already recorded in routine practice and often reported using devices that raise alarms when a single vital sign crosses a parameter but it is clear that such alarms may be raised too late. Scoring vital signs helps to quantify patient status reporting that a patient is in imminent danger of deteriorating.

Table I shows the respiratory rate scoring algorithm in MEWS, where patients with a normal respiratory rate between 12 and 20 add zero to their score. Patients with very high or low respiratory rates add up to three points. NEWS includes similar algorithms for other vital signs, and all of the scores are summed to give the final patient score.

The MEWS algorithm provides a well-vetted use case including descriptions of sensor data, algorithms, and preferably, a means to easily customize parameters for a specific patient.

**OpenICE**. OpenICE is an open-source research platform instantiating the Integrated Clinical Environment interoperable architecture defined in the AAMI 2700-1 standard [12] (formally ASTM F2761). Implemented on top of the DDS (Data Distribution Service) communication infrastructure, OpenICE provides a clinical ecosystem to support the connection and interaction of medical devices and clinical apps for a wide range of clinical research. It includes built-in supervisor and network controller apps to coordinate the connected devices, apps, and equipment, as well as an array of simulated devices (i.e., apps simulating the behavior of devices commonly seen in hospital settings) to support rapid prototyping and evaluation of interoperable solutions. Notably, the development of OpenICE has been driven by example applications and use cases including x-ray machine and ventilator synchronization, safety interlocks for patient-controlled analgesia, and interoperable alarms for cardiac surgery.

## III. Implementing MEWS on OpenICE

Monitoring patients, particularly critically ill patients, requires intelligently integrating information about the patient's changing condition and taking into account the complexities inherent in reaching consensus between a multitude of

caregivers on treatment plans and goals that may shift and evolve over time. Creating an RT-CDS application that supports caregivers without providing redundant or clinically non-actionable alerts is difficult. The MEWS application presented in this paper does not attempt to solve this problem. Instead, it is intended as an aid to caregivers to indicate patients who may be in need of additional monitoring.

Due to its simplistic nature, the MEWS algorithm can be implemented with pencil and paper at the bedside as part of regular charting (in fact, many previous research efforts have been focusing on implementing and improving the original NEWS algorithms such as [13]). Building it instead as a software application in the interoperable OpenICE environment allows the algorithm to update more quickly and preferably automatically – it can calculate the score as quickly as vital signs arrive, often once per second – and frees caregivers from the necessity of doing the calculation manually. Automating the calculation also introduces the possibility of implementing more complicated algorithms and incorporating more measurements, though this also adds the risk of losing the elegant simplicity and usability of the NEWS algorithm.

### *A. MEWS Implementation*

Monitoring applications, such as MEWS, use data from patient monitors to create alerts, notifications, and even clinical alarms not available from existing devices. In some cases, no single device has all the necessary information to implement such an application. In others, device manufacturers are unwilling or unable to implement novel algorithms on existing medical devices because of the technical and regulatory challenges of updating device software.

Both of these challenges are true for MEWS: standalone patient monitors often do not have all of the necessary patient information, and device manufacturers are reluctant to build the algorithm into their products. This necessitated implementing the algorithm as a stand-alone application. Given the capability of OpenICE in connecting various patient monitoring and therapeutic devices (such as ventilators), building the MEWS algorithm on the OpenICE platform allows us to leverage our library of existing device interfaces to speed up its development. We believe that implementing the MEWS concept on OpenICE can not only provide a basis for monitoring stabilized casualties, but also enable an assessment of the medical device interfaces, platform interoperability, and application functionality to support more clinically complex RT-CDS algorithms, such as those for autonomous medical care.

In clinical practice it is likely that multiple patient monitoring devices are used to measure the same patient vital signs at the same time. For example, heart rate could come from an EKG, pulse oximeter, or invasive blood pressure sensor. Each of these devices has its own measurement technology (e.g. ECG uses cardiac electrical activity whereas pulse oximetry uses pulsatile blood flow to calculate heart rate or pulse rate), signal processing algorithms, and potential modes. This results in that the values and even the meaning of measurements from one device might be different than those from the other. Unfortunately, there is not yet consensus among clinicians on how to generalize the interpretation of cases where multiple sources disagree (although these can be interpreted in the context of a specific clinical and monitoring state). The current implementation of the MEWS app supports the user to select one source for scoring when multiple sources of the same vital sign are available. We leave it to future work to equip MEWS with more intelligent algorithms that calculate more accurate patient condition scores from disagreeing patient measurements.

We implemented the MEWS application on the OpenICE research platform that communicates with connected medical device components and apps to interact in real time. A score was assigned to each of five physiological parameters (respiration rate, oxygen saturation, temperature, systolic blood pressure, and heart rate) as recommended by the Royal College of Physicians (UK). The original definition of MEWS also includes urine output as a monitored vital sign. In the absence of a connected urometer, we chose to omit this metric from our implementation. Urine output could be measured and entered manually into the MEWS application and this could be added to the application in the future.

The magnitude of the risk score reflects how far the parameters vary from the norm. Our current implementation of MEWS, as shown in Figure 1,[3] combines the essential functionality of MEWS, creating a single numeric score, with a graphical display of recent patient history. Individual vital signs can be added or removed from the display dynamically and sources of each vital sign are shown as the devices are available on the OpenICE network. For example, Figure 1 illustrates the (trending of) SpO_2, Heart Rate, and Respiration Rate measurements received . Each of these vital signs has one or more devices providing readings.

Built on the OpenICE platform, the MEWS app can work with any patient monitor or other source of vital signs supported by OpenICE without any modifications. It is also able to use the platform to supply sources of vital signs: it does not need to track connected devices, negotiate communications, or handle unexpected connection and disconnection of devices; this is all managed by the OpenICE platform.

OpenICE includes device interfaces for many devices commonly seen in hospital settings. These device interfaces communicate with medical devices using the devices' proprietary communication protocols. After receiving data from medical devices, these device interfaces translate the representation of the received data from the devices' proprietary encoding into the IEC 11073-10101 terminology set, and retransmit it using the OMG's DDS (Distributed Data Service) middleware [14]. App developers who use the same standardized terminology are able to receive data from the devices without having to know the details of each device's proprietary protocol and data representation.

[3] All data illustrated in Figure 1 was received from a Philips MX800 patient monitor.

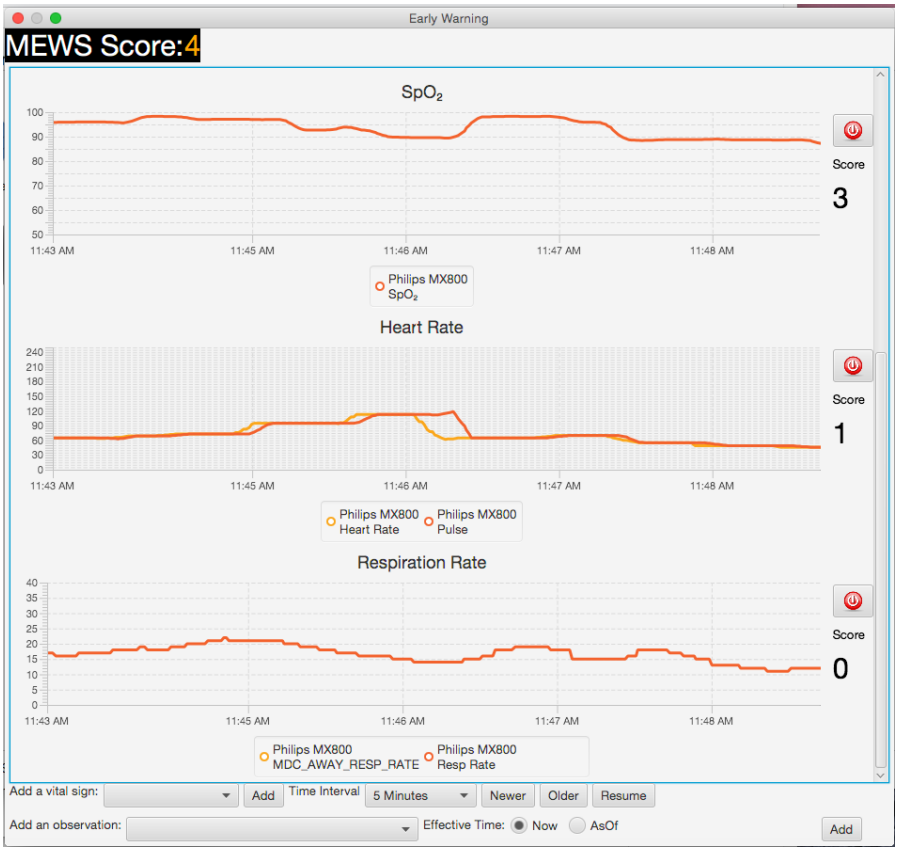


Fig. 1. MEWS Implementation on OpenICE.

Figure 1 shows two sources of Heart Rate from the MX800 patient monitor: one from the EKG sensor and the other from the pulse oximeter. Divergence between these two sources is clearly visible at times when the values are changing rapidly. This is primarily due to the different averaging times for these two sources. The MEWS app graphs recent values for these vital signs over a time interval that is configured with a drop down box. Another drop down box allows adding additional vital sign graphs. The numeric MEWS score is displayed at the top of the screen, and each vital sign row indicates the amount contributed to the total MEWS score by that vital sign. In this example, the total score of four is the sum of three points from the low oxygen saturation measurement and one point from the low heart rate.

### *B. Assessment of MEWS*

We have performed preliminary testing to assess the functionality of the MEWS app and its compatibility with OpenICE as well as various patient monitoring devices in our MD PnP lab's "virtual hospital testbed" (http://mdpnp.mgh.harvard.edu/our-lab/). The testing proceeded in two steps:

1) The first set of test cases were executed to evaluate the compatibility of MEWS with OpenICE and patient monitoring devices (physical or simulated) connected to OpenICE.
2) The second set of test cases were executed to verify that the MEWS app is able to calculate correct patient scores based on the received patient measurements per [9].

It should be noted that the assessment of usability and clinical effectiveness of the MEWS app is beyond the scope of this paper and hence left to future work.

**1. Compatibility Testing**

In the first set of tests, the MEWS app was tested to see whether it could correctly receive patient vital signs from patient monitoring devices connected to OpenICE, regardless of which communication protocols were used by these devices. For this purpose, patient vital signs displayed on the user interface of MEWS were compared to those displayed on the patient monitoring devices for consistency, so as to confirm that MEWS correctly receives and interprets the received data.

We have evaluated the compatibility of MEWS with three bedside patient monitoring devices: Philips Healthcare's IntelliVue MP70 [4], Philips Healthcare's MX 800 monitors [5], and GE healthcare's Solar 8000M/i monitor [6].

[4]https://pacificmedicalsupply.com/philips-intellivue-mp70-patient-monitor/.
[5]https://www.usa.philips.com/healthcare/product/HC865240/intellivue-mx800-bedside-patient-monitor.
[6]http://www3.gehealthcare.com/~/media/downloads/us/services/equipment%20services/support-center/daylight-savings-time/patient-monitoring/monitors/gehc-service-manual_solar-8000m-i-patient-monitor-v5-2008.pdf.

A set of simulated devices (i.e., apps) built in OpenICE to generate various simulated patient vital signs, such as *ElectroCardioGram*, *Invasive Blood Pressure*, and *Multiparameter Monitor*, were also used to test MEWS' compatibility. Details of these simulated devices can be found at www.openice.info.

During the tests, Fluke Biomedical's ProSim 8 patient simulator [7] was used to generate patient physiological conditions for physical patient monitoring devices, while the *Simulation Control* app built in OpenICE was used to configure the values (ranges and peaks) of patient vital signs reported by the simulated devices.

All tests performed at this step demonstrated that the MEWS app displayed patient vitals in consistent with those reported by the patient monitoring devices.

**2. Feature Testing**

At this step, a set of patient monitoring data segments (each for 30 minute episode of patient monitoring in different simulated clinical scenarios) previously recorded were loaded to OpenICE and played back to MEWS for scoring. Notably, each data segment is essentially a mixture of data streams recorded from each device involved in the clinical scenario, which are time synchronized based on the OpenICE's reference clock.

Manual review was performed in the feature testing to examine whether MEWS was able to calculate correct scores, including scores for each vital sign and the overall score, for any data point in these data segments.

The feature testing indicates that MEWS calculated correct scores per [9] for any data point in the replayed data segments. Figure 2 illustrates a screenshot of MEWS during one of the feature tests, where the lower part of the MEWS displayed the charting of the replayed patient vital signs, with the corresponding vital sign scores displayed to the right of each chart, and the overall patient score displayed on top.

One challenge of implementing a scoring system on an interoperable platform is managing multiple sources of a single vital sign. It is not uncommon for a single patient monitor to display different values for the same core physiological function when it is measured using different technologies. Pulse rate from a pulse oximeter and heart rate from an EKG both give an indication of how fast the patient's heart is beating, but often show different numeric values even for a healthy patient and would be expected to be different when the patient experiences an acute decompensating illness, such as pulseless electrical activity (PEA). In this implementation, we examine all of the available sources for a vital sign and use whichever source gives the worst (highest) score. This means that our implementation may tend to have higher rates of false positives, for instance, when a pulse oximeter is double-counting the pulse rate (reporting 160 when the real rate is 80), but also a lower rate of false negatives (it will score based on a low pulse rate from the pulse oximeter even if there is a normal-range EKG heart rate during PEA). Different

[7]https://www.flukebiomedical.com/products/biomedical-test-equipment/patient-monitor-simulators/prosim-8-vital-signs-patient-simulator.


Fig. 2. A Snapshot of MEWS Interface During Feature Testing.

choices for managing multiple sources of vital signs may be valid in different environments, and there is much room for development of more sophisticated device management algorithms that take into account common device failure modes.

## IV. Discussion

Standards to support correct and seamless exchange of operational, contextual, and clinical information within IMSs is a key enabler of medical device interoperability. It provides clear guidelines for manufacturers to establish and disclose comprehensive interoperability specifications for their products that prescribe the products' capabilities and behavior related to interoperability, such as expected interactions through interoperable interfaces, device data/meta-data models, and data communication protocols. It should be noted that the development of clinical and operational data standards for IMSs should be driven by the clinical scenarios to be accomplished by these systems, as well as the level of interoperability that each entity intends to achieve [15].

It is only with clear interoperability specifications for each entity within an IMS can the system integrator make objective determination on: 1) all entities are suitable for the system's intended medical use; 2) all necessary resources and risk controls have been provided for each entity in the system to ensure its correct operation; and 3) system-level risks, due to the integration of entities within the system, have been identified and mitigated.

We rely upon the IEEE 11073-10101 clinical terminology [7] set in OpenICE to provide a standard set of terms (in other words, data elements) for communicating patient vital signs to the MEWS app and for the MEWS app to interpret the received vital signs. The IEEE 11073-10101 terminology, however, is still evolving and lacks the necessary level of richness to fully describe the metadata around vital signs. For example, it does not include clinical terms for the

averaging time of $SpO_2$ values measured by pulse oximeters, which is important to assess whether the $SpO_2$ values are appropriate for detecting potentially rapid oxygen desaturation in the patient in certain clinical settings. [8]

An incomplete clinical terminology might either prevent necessary data elements from being exchanged among entities within an IMS, or make it difficult for manufacturers to map the output of their devices to standardized terms due to a lack of semantic details (e.g., often only the name of the term or a terse description is available), which in turn could lead to misunderstanding and inappropriate use of device output data.

We acknowledge that it is a never-ending task to build and maintain a clinical terminology rich enough to support medical device interoperability for all possible clinical scenarios. However, all stakeholders in the ecosystem should share the responsibility of identifying and defining data terms necessary for different clinical scenarios. Device manufacturers can aid this effort by providing mappings from their terms to standards, by participating in standardization efforts, and by better documenting terms in their manuals.

Many industrial and academic efforts have been dedicated to bridging the gap between existing industrial efforts and clinical terminologies needed for medical device interoperability. One noteworthy effort is Medical Device Interface Data Sheet (MDIDS) [18], which proposes a clinical scenario driven approach to derive and formalize the information needed to exchange in the clinical environment to support device interaction, ensure correct clinical workflow, and mitigate potential system hazards.

In addition to standard-driven development and disclosure of interoperability specifications, it is also critical to establish a coordinated process among stakeholders across the ecosystem to better clarify the roles and responsibilities of assuring safety, effectiveness, and quality of devices and equipment to be used in IMSs. For example, manufacturers of interoperable medical devices need to conduct testing to demonstrate that these devices behave per their interoperability specifications. System developers of an IMS, on the other hand, should perform qualification and integration testing to ensure appropriate components being correctly integrated, and conduct system-level verification and validation to confirm the system functions safely and as expected. Notably, the UL/AAMI 2800 standard establishes the first exemplar coordinated lifecycle process for stakeholders in the IMS ecosystems [5].

## V. Conclusions and Future Work

The MEWS application provides a useful, vetted RT-CDS application to develop methods that can be used to evaluate the performance of connected medical device and RT-CDS apps on other ICE platforms. We are continuing to evaluate using scoring systems from MEWS to identify devices, signals, integration and performance requirements as a basis for informing testing and evaluation of interoperable system components. The device testing and evaluation methods will generalize to other applications besides MEWS.

[8]The appropriate averaging time for $SpO_2$ measurement depends on clinical context, for example excessive averaging time can obscure the depth of desaturation and associated reductions in airflow (RAF) in sleep studies [16], while longer averaging time is beneficial to overcome the poor signal-noise ratio in $SpO_2$ due to patient motion and poor perfusion [17].

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