FDA AI/ML White Paper

FDA asked: “In what ways can a manufacturer demonstrate transparency about AI/ML-SaMD algorithms ...?”


We propose that state and context information are necessary to provide transparency for AI/ML-SaMD algorithms
Transparency, Safety, and Clinical Context

• As we have demonstrated in our research on interoperable systems, robust meta-data may be essential for safe and effective real-time decision support and AI/ML systems.

• Clinicians use clinical context and device state to interpret erroneous and missing data in complex real-world systems. (Examples to follow)

• Digitally capturing the requisite context and state to replace humans-in-the-loop is challenging due to limitations of existing technology.
Capturing Essential Information to Achieve Safe Interoperability

Sandy Weinger, PhD, Michael B. Jaffe, PhD, Tracy Ransch, CCE, and Julian M. Goldman, MD

In this article, we describe the role of "clinical information" to assure the safety of interoperable systems, as well as the system's ability to deliver the requisite clinical functionality to improve care. Descriptions are methods and metrics for capturing the electronic health record, workflow, hazards, and device interactions in the clinical environment. Key user (clinical and technical) needs and system requirements can be derived from the information, thereby improving the communication to clinicians to medical device and information technology system developers. This methodology is intended to assist the care healthcare system, including researchers, standards developers, regulators, and manufacturers, by providing clinical definition to support requirements in the systems engineering process, particularly those focusing on the development of integrated Clinical Endpoints described in standard ASTM F2750. Our focus is on integrating and documenting "relevant" actions, interchanges and monitoring interactions. A simplified approach to the use of the system using a documentation tool called medical device interface data model and integrating language standards related to health systems and product usability, data exchange, data models, data sharing, clinical decision support, and interoperability. Portions of the analysis of a clinical care models for a "patient-centered analytics safety framework" and presented to illustrate the value of this method. Collecting better clinical adverse events data, which is relevant, and information and proposed solutions can help to identify opportunities to improve current data capture and interoperability and support a learning health system to improve healthcare delivery. Developing and analyzing clinical scenarios are the first steps in creating solutions to address patient safety problems and realize clinical innovation. A Web-based research tool for implementing a means of acquiring and managing this information, the Clinical Scenario Repository (MDM Program), is described. (Anesth Analg 2017;124:83-94.)

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Foreseeable Causes of Missing and Spurious data (in EHR/EMR)

Missed bradycardia in EHR

Text from clinician: “Just brady to 30, went into junctional escape with reverse p”

Minimum rate in EHR ~ 45

No evidence of HR=30 in EHR (Green dots represent HR values)

Missing low SpO₂ in EHR

Monitor reveals low SpO₂ “84%” at 2:07

SpO₂ 84% at 2:07

No evidence of SpO₂ = 84% in EHR (Blue ticks representing SpO₂ values)

Falsely low SpO₂ data in EHR

Spuriously low SpO₂ in EHR caused by NIBP cuff inflation

Return of Pulse Ox Plethysmogram

The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems
Which $O_2$ saturation value will be used by the AI/ML algorithm?

Lab data showing the effect of Pulse Oximeter Averaging Time Setting on Measured SpO$_2$ Value

Experiment: Simulator is set to create transient desaturation from 99% -> 70% -> 99%

Pulse Ox is set to 16 sec averaging time

Pulse Ox is set to 2 sec averaging time

Only the device set to 2 sec averaging time accurately tracks and display the nadir saturation of 70%. Example demonstrates importance of averaging time metadata to interpret clinical data.

Data time-stamp errors:
Source of time reference and methods of time correction/synchronization (if performed) should be disclosed for AI/ML transparency.

Blood-gas machine clock is incorrect at 12:06

The incorrect lab measurement time is stored in lab system.

We documented medical device clock-time errors exceeding many years!

Correct time was 12:10

EMR time stamp error

Blood gas analyzer in OR

Data from JM Goldman MD / MGH
Summary

Manufacturers should:

1) Be fully aware of the impact of current medical device interoperability gaps on obtaining contextually rich data sets for AI/ML algorithms.

2) Disclose the clinical context and state of devices used to generate AI/ML data sets to enhance the safe application of the resultant algorithms.